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ULTRASONIC CAVITATION TECHNOLOGY IN OBSTETRICS AND GYNECOLOGY

Guidelines for doctors





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The guidelines are devoted to the use of low-frequency ultrasound in combination with various antiseptics and drugs in the prevention and treatment of pelvic inflammatory diseases. The authors evaluated the effectiveness of the method in various clinical situations: infectious and inflammatory diseases of the vagina and cervix, acute and chronic endometritis, preparation for gynecological surgeries, as well as prevention and treatment of postpartum diseases (endometritis, perineal ulcers, etc.). The guidelines describe the methods of using the ultrasonic surgery cavitational device «FOTEK» in outpatient and inpatient bases. The guidelines are written for practicing obstetrician-gynecologists, interns, clinical residents. It is recommended for doctors training courses.

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LIST OF ABBREVIATIONS

A2M — alpha-2-macroglobulin
ART — ancillary reproductive technology
CE — chronic endometritis
CFU — colony-forming units
CIN — cervical intraepithelial neoplasia
CRP — C-reactive protein
D&C — dilation and curettage
ERα — estrogen receptor alpha
HPV — human papillomavirus
HSG — hysterosalpingography
IFN-γ — interferon-gamma
IL — interleukin
IUD — intrauterine device
IVF — in vitro fertilisation
LFUS — low-frequency ultrasound
LFUSC — low-frequency ultrasonic cavitation
MMR — maternal mortality ratio
NBT test — induced test of nitroblue tetrasolium recovery
PCR — polymerase chain reaction
PID — pelvic inflammatory disease
POP — pelvic organ prolapse
PSI — purulent-septic infections
RH — reproductive health
RPL — refractory pregnancy loss
TNF-α — tumor necrosis factor alpha
US — ultrasound, ultrasonic
USC — ultrasonic cavitation
VLS — vulvar lichen sclerosus (vulvar lichen sclerosus et atrophicus)

INTRODUCTION

Postpartum purulent-septic diseases are one of the most common causes of maternal morbidity and mortality [19, 25, 68, 31]. According to various sources, the postpartum disease incidence ranges from 5 to 26%. In the Russian Federation, maternal mortality ranks 2–4th. Moreover, maternal sepsis accounts for 13–15% of maternal mortality [39, 40, 68]. Recently, diagnosis, rational combination therapy, and prevention of severe postpartum infection (sepsis, peritonitis, suppurative mastitis) have been improved [41, 45, 68, 90, 97, 101]. However, the frequency of the most common pyo-inflammatory diseases in puerperas, endometritis and wound infection tends to increase. Early diagnosis and rational therapy of localized postpartum pyo-inflammatory diseases helps to prevent their further spread [17, 22, 23, 39, 45, 109, 111].

Pelvic inflammatory diseases (PID) in gynecology account for 60–65% among outpatients and up to 30% of inpatients [40,101]. Gynecological operations, including minimally invasive interventions (abortion, diagnostic curettage, hysteroscopy, etc.), prevail among the risk factors for PID [4, 6, 9, 19, 25, 47, 48, 68, 100]. Mortality due to unsafe abortion in Russia accounts for almost a third of maternal deaths. The reduction in maternal mortality is ensured by the standardization of medical examination and treatment of septic abortion. The lack of clinical suspicions of vaginal microecological disorders as a significant risk factor for endometritis determines a decrease in women reproductive health [9, 15, 41, 45, 104].

A significant increase in the number of non-developing pregnancies over the past five years is often the result of surgical abortion. Pathogenesis of postabortion complications is usually a chronic endometrial inflammation associated with contamination of the uterine cavity with the vaginal and cervical microflora [8, 38, 49, 51, 68, 77, 84, 86, 105, 111]. It is well-known that under postabortion endometritis complicated by pathogenic bacteria of the genital tract in 100% of cases women have abnormal production of embryotropic autoantibodies. This fact allows one to better understand the cause of autoimmune reactions associated with chronic inflammatory processes. It has been established that excessive production of embryotropic autoantibodies without microbial infection is a diagnostic criteria for chronic endometritis [67, 100, 109].

Although the role of the microbial factor in acute endometritis is obvious, the question of its importance for the persistence of the inflammatory process is still debatable. It is not ascertained whether the microbial factor loses its deleterious effects during or after therapy. Typically, chronic endometritis is a consequence of postabortion or postpartum endometritis or a complication after intrauterine manipulations (hysteroscopy, curettage, endometrial biopsy, hysterosalpingography, etc.) [6, 7, 25, 77, 104, 105, 106]. It is a widely

held view that the development of chronic endometrial inflammation often precedes subclinical forms of PID. Chronic endometritis is considered a frequent outcome of PID. In modern PID treatment, cases of complicated and recurrent forms as well as immunity to treatment with pharmacological agents are often found [104, 105, 106].

In barren women, chronic endometritis occurs in 12–68% of cases, reaching its maximum at tuboperitoneal infertility. In patients with failed IVF and embryo transfer, the frequency of chronic endometritis increases to 60% or more. The highest prevalence rates of chronic endometritis were observed in patients with RPL (more than 70%) [19, 25, 45, 86, 109, 111, 106].

Treatment of uterine form of infertility is considered the most time-consuming due to the lack of effective treatment protocol. Besides, it is not known whether the treatment will help or not. Frequent change of antibacterial drugs is not effective enough in the treatment of infertility. Increasingly, fertility doctors draw their attention to physical therapy, in particular to low-frequency ultrasound (LFUS) [6, 7, 24, 63, 84, 123].

Since in the female genital tract the vagina and cervical canal are the main place of pathogenic and opportunistic microflora localization, the lavage of these organs is paramount [22, 27, 55, 59, 77, 82, 122]. Despite the active development of the pharmaceutical industry, the lavage methods of the female genital tract has not changed significantly. These are vaginal suppositories or douche using antiseptic solutions. The effectiveness of these methods does not always satisfy both the doctor and the patient with the terms of treatment, labor input, or remission period [49, 77, 92].

Thus, further improvement of prevention and treatment of PID is relevant. Recent developments in medical science and technology make it possible not only to create effective medicines, but also apparatuses and instruments for treating inflammatory diseases. A special focus is on the use in obstetrics and gynecology of LFUS [7, 56, 60, 63, 66, 77, 84, 91, 92, 99, 115, 122]. This type of treatment has long been successfully used in surgery, in particular, during the treatment of purulent wounds, burns, trophic ulcers, and abdominal surgery [55, 56, 66, 92]. Methods of ultrasound therapy reduce the incidence of complications and relapses, increase the period of remission. The combined use of ultrasound and drugs, in which they interact, allows one to save expensive drugs. Among such methods, the intrauterine drug administration can be distinguished [7, 11, 77, 88, 91]. The combination of drugs and LFUS generated by the ultrasonic surgery cavitational device «FOTEK» contributes to the successful prevention and treatment of PIDs that differ in etiology and localization [21, 77, 78, 88, 91].

These guidelines allow practicing obstetrician-gynecologists to understand the application possibilities and treatment regimens for LFUS in combination with drug solutions and to successfully use them in work.

1 EFFECTS OF LFUS AND ITS USE IN MEDICINE

1.1 The use of ultrasound in medicine

Ultrasound is defined as sound waves with frequencies of over 20 000 Hz (cycles per second). LFUS spans the range between 20 and 80 kHz and has longer wavelengths and greater amplitude for given input energy, which results in greater movement of molecules within tissues.

Many authors have described the complex mechanism of ultrasonic action [93, 14]. By activating a sound-transmitting medium, mechanical vibrations have a physical, biological, and biochemical effect on tissues.

Most biological effects of ultrasound (US) are associated with **ultrasonic cavitation (USC)**. USC is the formation of microscopic vapor bubbles with an electric charge on its surface in a sound-transmission medium. Bubbles' "explosions" lead to the occurrence of shock waves, which mechanically destroy bacterial films and microorganisms' cell membranes [85, 117]. Water molecules in cavitated cavities degrade into hydrogen H+ and hydroxide OH- ions, which have a bactericidal effect against pathogenic bacteria and viruses [1, 65]. Due to their to its microscopic size, cavitation bubbles penetrate areas, which are inaccessible to conventional methods, and carry out thorough and gentle lavage.

LFUS cavitation has a bactericidal and bacteriostatic action and improves the impregnation of antibiotics and other drugs into the deeper layers of tissues [55]. Also, LFUS increases the sensitivity of microflora to antibacterial drugs [114]. Due to the biological and physical effects of LFUS, it is used to treat inflammatory processes of various localizations. Currently, ultrasound treatment methods are used for many diseases.

The use of LFUS in the complex treatment of **surgical infection** stops inflammation in a shorter time, accelerates the process of cleansing from purulent-necrotic deposits, contributes to a significant reduction in microbial contamination of the wound bed and improves microcirculation in the inflammatory foci [65]. Surgeons of purulent, abdominal, thoracic, vascular surgery and combustiology departments actively apply LFUS in the treatment of purulent wounds of various etiologies [2, 43, 57, 65, 92].

LFUS also found application in **ENT medicine**. Many modern ENT offices have an ultrasonic cavitation device. In inflammatory diseases of the oropharynx and nasopharynx, ultrasound is used to quickly stop the inflammatory process [70, 75].

Ultrasound offers great potential in **dentistry**. The ability of cavitation bubbles to penetrate hard-to-reach areas allows dentists to conduct deep cleaning of the root canal

system before tooth filling and implant placement. The property of US to clean teeth from plaque and tartar without damaging tooth enamel is widely used for professional oral hygiene [44, 74, 94].

The potential use of LFUS in **obstetrics and gynecology** has been studied since 1977. Since then, many effective treatment and prevention methods of PID have been developed. The treatment regimens using LFUS have undeniable advantages over conventional methods. The immediate and long-term results of ultrasound exposure confirm this: the healing time is reduced, the period of remission is increased, the pill burden is reduced. The use of LFUS for prevention also contributes to a significant reduction in infectious complications in the postpartum and postoperative periods [35, 62, 77, 78, 91, 102].

1.2 Effects of LFUS on biological tissues

1.2.1 Physicochemical effects of LFUS

There are the following physicochemical effects of LFUS in drug solutions:

- **Ultrasonic cavitation (USC)**
- **Cavitation bubbling**
- **Acoustic streaming**
- **The disintegration of water molecules**

Ultrasonic cavitation

The extreme pressure reduction "rips" the water molecules apart and creates bubbles. These bubbles contain gas that had been dissolved in the liquid. When there is an external excitation, such as an ultrasonic wave, cavitation bubbles are nucleated from gas pockets in the liquid (Fig. 1). This process is called **ultrasonic cavitation** [1, 54].

During the vacuum phase, numerous bubbles of gas are formed in the liquid and which enlarge for the duration of the acoustic vacuum phase (negative pressure). This formation of microscopic bubbles of gas is the start of cavitation. In the second phase of ultrasonic compression, the enormous pressure (exerted on the newly expanded bubble) compresses the same, hugely increasing the temperature of the gas contained in it. The process is continued until the bubble collapses on itself imploding with a consequent vast release of impact energy [46].

The impact energy leads to the removal of purulent-necrotic coating, mechanical destruction of bacterial films, disintegration of microorganisms' cell membranes, micromassage of adjacent tissues [32, 85, 117]. Due to their microscopic size, cavitation bubbles penetrate areas, which are inaccessible to conventional methods, and improves the impregnation of antibiotics and other drugs into the deeper layers of tissues [55].

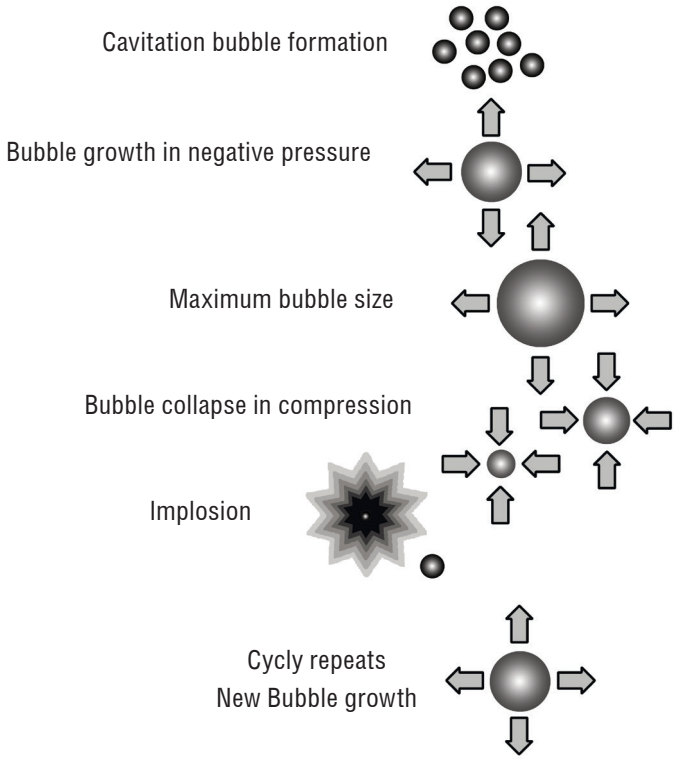


Fig.1 — The ultrasonic cavitation and implosion cvcle

Cavitation bubbling

Cavitation bubbling is the process of mixing liquid in a cavity by cavitation bubbles' flows which are created by an ultrasonic wave. Cavitation bubbling promotes greater contact of the drug with infected tissue. It allows the impregnation of drugs into the deeper layers of tissues due to the hydrodynamic impulse of the cavitated flows. Due to cavitation bubbling, the treated surface is cleaned of purulence, detritus, fibrin, etc. [116].

The disintegration of water molecules

A local increase in extreme temperature and pressure leads to the decomposition of water vapor into hydroxyl radicals and hydrogen atoms. Hydroxyl radicals can form hydrogen peroxide (H_2O_2), which can initiate different biochemical reactions, i.e., the cascade of free radicals' production. As a result, there is the formation of free radicals like hydrogen peroxide, singlet oxygen, and superoxide ions [32, 70], which have a bactericidal and bacteriostatic action.

Acoustic streaming

Acoustic streaming is a steady flow in liquids and gases driven by the absorption of high amplitude acoustic oscillations.

1.2.2 Biological effects of LFUS

Biological effects depend on the frequency, power, and exposure of ultrasound, which make it possible to get effects from stimulation to destruction [65, 121]. It is also determined by the type and functional state of the exposed tissue. The biological effects of ultrasound can be conditionally divided into the following [91]:

- bactericidal effect;
- phonophoresis;
- thermal effect;
- necrolytic effect;
- selective tissue destruction;
- effect of US on nerve conduction;
- micromassage effect;
- anti-inflammatory effect;
- immunomodulatory effect.

Bactericidal effect

The bactericidal effect has several causes:

- mechanical action of USC — direct **disruption of bacterial and fungal cell membranes**;
- cavitation bubble collapse — thorough cleaning of tissues from purulent and pathological deposits, from pathogenic microorganisms and their metabolic products [29, 37];
- bactericidal properties of free radicals and hydrogen peroxide [12, 16, 79, 108, 112].

To date, there is **no adaptation** of the microorganisms to the action of cavitated solutions [32, 43, 53]. LFUS efficiency on the degradation of many types of bacteria (*Staphylococcus, Proteus, P. aeruginosa, E. coli*, etc.) [55, 103] has been proven. The total number of pathogens after a 5-minute cavitated solution exposure is significantly reduced. For example, *P. aeruginosa* reduce in CFU/ml from $3x10^{11}$ to $5x10^{6}$, *Streptococcus* by 300 times [121]. When the cavitated solution is applied to *Trichomoniasis, E. coli*, and *Proteus vulgaris*, irreversible changes in the structure of microorganisms cause their death [61].

LFUS has a significant effect on **drug-resistant mycobacteria strains**. Later bacterial growth and a decrease in the number of new colonies (3–4 times) were recorded.

A decrease in the resistance of microorganisms to the drug activity has also been described [3, 95, 107, 121].

Microbial cell membrane damage during cavitation weakens pathogens; as a result, their **sensitivity** to antibiotics and disinfectants **increases** [16, 93]. Under these conditions, the usual therapeutic doses of drugs have a more noticeable therapeutic effect [79, 120].

The combined use of LFUS with antiseptics is known. Exposure to *Staphylococcus aureus* with hydrogen peroxide for 10 min reduces the number of microbial cells by 5–6%, and in combination with ultrasound — by 80% [81]. The application of LFUS with the drug enhances its antibacterial effect by 1.7–10.8 times. Thus, the **combined effect** of the antibiotic and LFUS is exceeding their total effect by several times [121].

Phonophoresis

LFUS is recommended to be combined with various drug solutions. To **potentiate the therapeutic effect**, liquid antiseptics, antibiotics, or immunomodulators are used [18, 33, 52, 65, 88].

Via LFUS, the drug reaches the deep tissues. The level of tissue penetration depends on the functional state and type of tissue, on the time and power of US exposure, on the type and amount of drug [62].

Improvement of tissue penetration occurs due to the ability of LFUS to actively stimulate fluid movement in porous structures (skin, mucous membranes, etc.). With ultrasonic phonophoresis, the drug can penetrate the subcutaneous fat to a depth of 6.3 mm and into the muscles by 4 mm. In inflammation, LFUS allows the drug to penetrate tissues to a depth of 9 mm [65].

LFUS, initiating the water molecules disintegration, affects the concentration of ions around the cell membrane. Active diffusion of components from the extracellular medium into the cell increases. The mechanical force of focused ultrasound via cavitation can change the permeability of cell membranes and enhance the absorption of these molecules [96, 119].

Another important property of LFUS is the **development of microflows** inside cells [46]. The acoustic streamings in the microscopic cell volume move intracellular formations, exposing the enzymes. These changes **stimulate the cell functional activity** and its sensitivity to physical and chemical factors.

A successful decrease in inflammation and tissue cleaning also occurs, in particular, due to the rapid normalization of the medium pH [98, 110].

Thermal effect

The thermal effect occurs mainly during the contact of the ultrasonic instrument (sonotrode) with the tissue. The mechanical vibrations' energy of the instrument turns into a heat and at a low power causes the expansion of the microvasculature's vessels,

at high power causes the coagulation of tissues [43]. US can raise tissue temperature by up to 1.5 °C.

Necrolytic effect

Ultrasound destruction is used for necrotomy. **Controlled necrotomy** preserves intact tissues, vessels, and nerves. At the same time, since tissues, depleted in the liquid, do not collapse under the ultrasonic influence, stromal elements are preserved [65].

During cavitation, the cellular elements of the wound exudate are destroyed with the release of lysosomal enzymes and bactericidal cationic proteins. These substances fragment and exfoliate necrotic tissues, **enhance proteolytic activity** in wound exudate. In the wound, phagocytosis by neutrophils and antibacterial activity of leukocytes increase, which accelerates the process of tissue regeneration [5, 118].

Selective tissue destruction

LFUS can destroy or fragment soft and hard tissues. This occurs both when the sonotrode is in direct contact with the tissue, and when a cavitated jet process the wound bed. At certain powers, US reaches selective tissue destruction: it destroys one structures while preserving others [43, 65].

Effect of US on nerve conduction

Fluctuations in nerve fibers disrupt their conduction and block nerve synapses. As a result, analgesic and hyposensitizing effects are observed [1, 62].

Micromassage effect

USC and micro-vibrations in the medium perform a kind of tissue micromassage. LFUS causes the vasodilation and the increase in local blood flow by 2–3 times, initiates the development of collateral blood flow. The energy of mechanical vibrations turns into a heat and causes the expansion of the microvasculature's vessels [18, 63, 65]. Acoustic streaming and diffusion improve blood and lymphatic circulation and stimulate reparative processes [55].

Anti-inflammatory effect

LFUS has a pronounced anti-inflammatory effect due to its bactericidal effect, rapid cleansing of the tissue, normalization of microcirculation in the focus of inflammation [20, 65].

Immunomodulatory effect

LFUS normalizes the activity and number of phagocytic cells. Ultrasonic cavitation in the treatment of chronic vulvovaginitis improves granulocyte functions [28]. The described effects of LFUS are the basis for the **treatment for PID**.

Thus, the impact of LFUS on the tissue of the cervix, uterus, vagina, and perineum provides:

- complete cleaning of treated surfaces from bacterial films and pathological detritus;

- deep penetration of drugs into tissues;
- reduction of microbial contamination of tissues, reduction of toxin absorption;
- improvement of microcirculation and metabolic processes in tissues (micro-massage).

2 TECHNICAL MEANS OF ULTRASONIC CAVITATION FOR TREATMENT AND PREVENTION OF INFLAMMATORY DISEASES IN OBSTETRICS AND GYNECOLOGY

2.1 Tools and Supplies

To perform the procedure, the obstetrician-gynecologist needs the following equipment:

- gynecological examination chair (preferably with adjustable height);
- gynecological instruments: vaginal specula, gynecological forceps, aural and vulsellum forceps, Hegar dilators may be needed;
- ultrasonic surgery cavitational device “FOTEK” (ACTITON-A model);
- antiseptics for skin;
- antiseptics for mucous membranes;
- drug solution for ultrasonic cavitation;
- gauze and cotton swabs;
- medical instruments sterilization containers;
- disposal containers;
- equipment for sterilization and preservation of sterility.



Fig. 2 — Ultrasonic surgery cavitation device “FOTEK” (ACTION-A model)

2.2 Overview of the ultrasonic surgery cavitational device “FOTEK”

The ultrasonic surgery cavitational device “FOTEK” (Fig. 2) is intended for the infection foci irrigation during various therapeutic and surgical procedures. The device uses low-frequency ultrasonic vibrations and cavitated drug solutions to irrigate the mucous membranes, clean them from pathological secretions, as well as disintegrate and remove necrotic tissues.

The device is easy to use. The trolley for the device (Fig. 2) and the set of ultrasonic handpieces and tips (Fig. 3) are included in the delivery set.



Fig. 3 — Ultrasonic handpieces and tips

Operating principle of the device

The ultrasonic generator produces an alternating current of ultrasonic frequency (Fig. 4).It also sets and automatically maintains the operating mode of the ultrasonic tip. Piezo electronics convert the electrical signals from the ultrasonic generator into mechanical energy that can result in the vibration of the sonotrode at an ultrasonic frequency of 25 kHz (Fig. 5).

The required irrigation which is provided by an irrigation channel is incorporated into the ultrasonic tip. The solution is supplied to the handpiece through the infusion system.



Fig. 4 — Operating principle of the ultrasonic generator

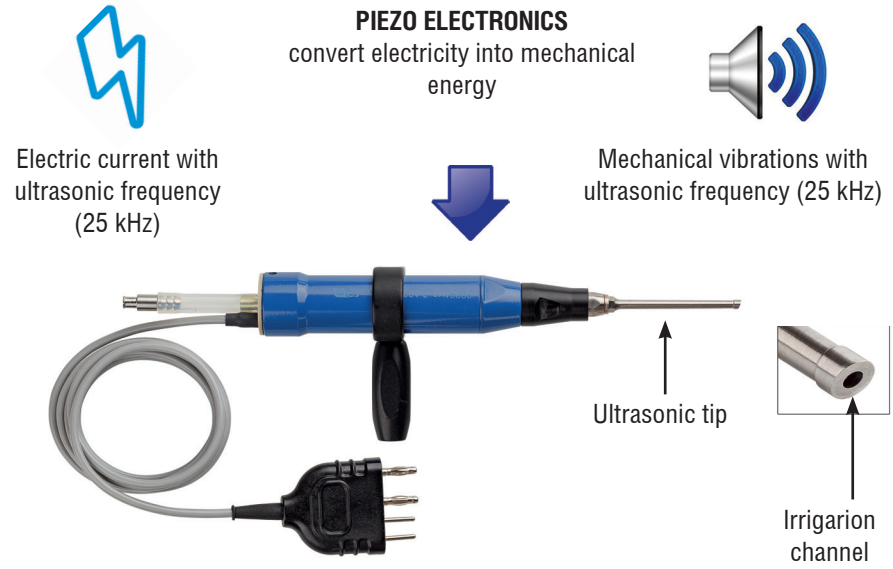


Fig. 5 — Operating principle of the ultrasonic tip

The amplitude of the sonotrode's mechanical vibrations is a few tens of micrometers. Although this oscillatory process is hardly visible, but a lot of mechanical energy is concentrated on the sonotrode's tip. Direct contact of the sonotrode with tissue can cause damage. In this regard, in most ultrasonic handpieces, a special protective cover is put on the sonotrode. It protects tissues from accidental damage with an ultrasonic tip (Fig. 6).

The irrigation channel inside the ultrasonic handpiece and tip is designed to supply the drug solution to the treated area, as well as to effectively cool the ultrasonic handpiece during the procedure (Fig. 5). The solution is supplied to the handpiece through the infusion system and special adapter (Fig. 6).

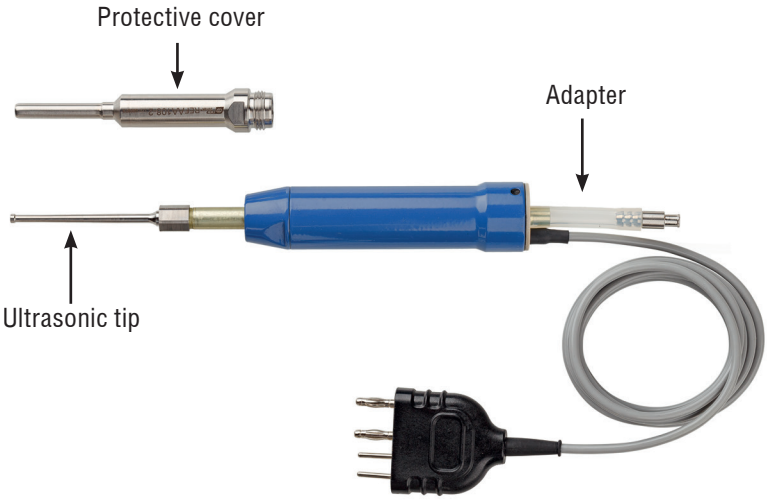


Fig. 6 — Parts of the ultrasonic handpiece

The drug solution supplied through the ultrasonic tip transforms into a directed finely dispersed jet (Fig. 7). The required liquid flow rate is set by the roller clamp on the infusion system.

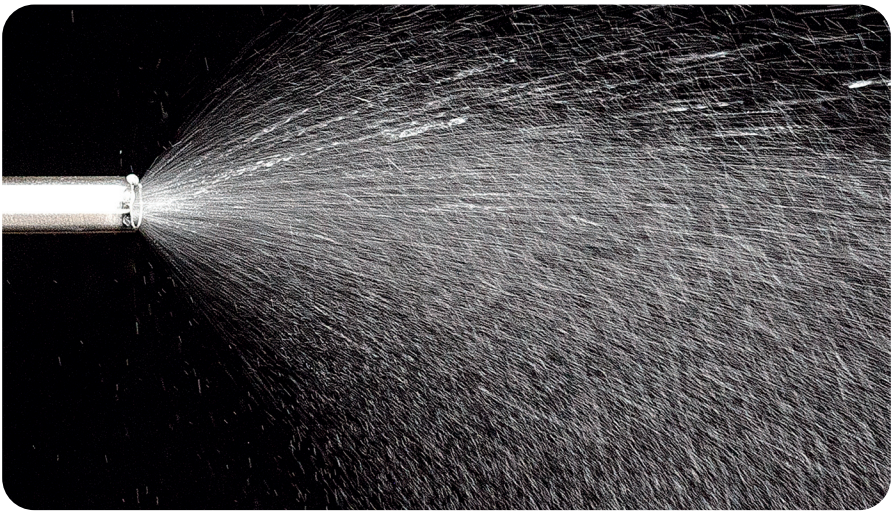


Fig. 7 — Cavitation jet

The ultrasonic power is adjusted from 1 to 100 units. It determines the amplitude of the sonotrode's mechanical vibrations. When working with some types of the ultrasonic

handpieces (AA207.5, AA211.5), the level of ultrasonic vibrations is set automatically by the device.

The lower the liquid flow rate is established, the lower level of ultrasonic vibrations should be set. The optimal liquid flow rates and the levels of ultrasonic vibrations in the treatment of various pathologies are indicated below (see Chapter 3).

The ultrasonic debridement is triggered by a footswitch.

See Annex A for the device assembly and preparation for work.
See Annex B for disinfection and sterilization of the ultrasonic unit and accessories.

2.3 Operating modes of the ultrasonic surgery cavitational device "FOTEK"

In the ultrasonic surgery cavitational device "FOTEK" (Fig. 8) there are two modes for ultrasonic exposure: "BASIC" and "SELECTIVE". Depending on the model, the cavitation system has "IRRIGATION" and "SUCTION" modes (ACTITON-A) or only "IRRIGATION" mode (ACTITON). Table 1 gives a comparative description of these modes. The mode switch buttons are located on the device's touch screen (Fig. 8).



Fig. 8 — Front and rear sides the ultrasonic surgery cavitational device “FOTEK”:
1 — button for switching on the “ULTRASOUND” mode; 2 — button for switching on the “SUCTION” mode; 3 — button for switching on the “IRRIGATION” mode; 4 — display of the ultrasonic power; 5 — button for adjusting the “TIMER” function; 6 — buttons for adjusting the ultrasonic power; 7 — button for calling up information about the connected ultrasonic handpiece; 8 — irrigation control valve; 9 — information about the connected footswitch and assignment of its functions; 10 — “STB” button (Stand-by — sleep mode); 11 — “ULTRASOUND” connector socket for an ultrasonic handpiece; 12 — connector socket for a footswitch; 13 — “SUCTION” connector for the suction tubing; 14 — mains switch; 15 — connector socket for the mains cable

Table 1 — Operating modes of the ultrasonic surgery cavitational device «FOTEK» (ACTITON and ACTITON-A models)

- • the mode is presented in this device model
- — there is no mode in this device model

OPERATING MODES	ACTITON-A model	ACTITON model
Modes for ultrasonic exposure:		
The "BASIC" mode — intensive ultrasonic acoustic oscillations effect on biological tissues. **Applications:** • irrigation of the lower genital tract (vulva, vagina, cervix); • lavage of the uterine cavity; • intensive cleansing of purulent wounds from necrosis; • phonophoresis	•	•
The "SELECTIVE" mode — gentle, selective ultrasonic exposure to tissues due to the pulsed supply of ultrasonic vibrations' energy. **Applications:** • clearance of purulent wounds from necrotic tissues (for example, when treating wounds are near the neurovascular structures or fresh granulations); • phonophoresis	•	•
Modes for liquid:		
The "IRRIGATION" mode supplies drug solution through the internal irrigation channel of the ultrasonic handpiece simultaneously with the activation of ultrasonic exposure.	•	•

The "SUCTION" mode is designed to remove fluid from the treated area. In gynecology, it is convenient for vaginal sanation. The fluid does not accumulate in the vagina and does not interfere with the processing of the posterior vaginal vault.	•	—

2.4 Types of ultrasonic exposure

Depending on the tools and modes, the ultrasonic system allows to implement:

1. The impact without the transmission of ultrasonic vibrations (non-contact spraying) — there is no direct ultrasonic action on tissues, but there is a combined mechanical effect of a liquid jet and a cavitated solution (Fig. 9, a). The cavitated solution contains cavitation bubbles and active chemicals: hydrogen peroxide, ions of hydrogen and oxygen. This type of impact is used for local lavage of tissue inflammation.

2. The impact with the transmission of ultrasonic vibrations (contact debridement) is the action of ultrasonic vibrations on tissues through a sound-transmission medium (Fig. 9, b), or directly with a sonotrode (Fig. 9, c). It can be used for washing cavities filled with a drug solution, as well as for cleaning purulent wounds from fibrin coating and necrotic tissues.

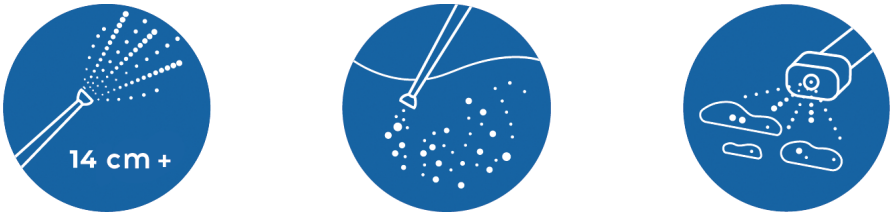


Fig. 9 — Types of ultrasonic action on tissues:
a — without the transmission of ultrasonic vibrations (non-contact spraying);
b — through a sound-transmission medium;
c — directly with a sonotrode

2.4.1. The impact without the transmission of ultrasonic vibrations (non-contact spraying)

1. Non-contact spraying

Ultrasonic vibrations transform the drug solution, supplied through the ultrasonic tip, into a directed fine jet of liquid (so-called cavitation jet), which contains many cavitation bubbles filled with gas and/or steam (Fig. 9, a).

Under the influence of ultrasonic waves, the structure of the aqueous solution changes, active chemicals with bactericidal properties appear in it. The lifetime of these substances is limited, therefore, the closer the ultrasonic tip is to the surface to be treated, the stronger the bactericidal effect.

Cavitation bubbles in the jet move at high speed. The collapse of many such vesicles, which is occurring at the border with the tissue, leads to high-quality cleaning of the inflammation foci from pathologic discharge, destroying bacterial films. At the same time, a drug solution is injected into the deep layers of tissues under the action of a collapsing bubbles' shock wave.

As a result of the cavitation jet's soft exposure, the fibrin coating is removed, the microcirculation and drugs' tissue penetration are improved. Active chemicals, formed in the spay jet, have a bactericidal effect on the infectious agents and normalize redox processes in the tissues.

The intensity of the cavitation jet is determined by the power level of ultrasonic vibrations, the set liquid flow rate, and hydrostatic pressure of the liquid in the handpiece's irrigation channel. Hydrostatic pressure depends on the height of the infusion bottle.

The closer the ultrasonic tip is to the surface to be treated, the stronger the bactericidal effect.

Recommended conditions of non-contact ultrasonic exposure in the treatment of various pathologies are defined in chapter 3.

In obstetrics and gynecology, the non-contact spraying is used for local sanation of the lower genital tract (perineum, vulva, vagina, cervix). During the lavage of the uterine cavity, non-contact ultrasound exposure is combined with cavitation bubbling of the solution, which is described in the following section.

2.4.2 The impact with the transmission of ultrasonic vibrations (contact debridement)

The action of ultrasonic vibrations on tissues through a sound-transmission medium (liquid)

When exposed to tissue through an intermediate medium (liquid), an activated ultrasonic tip is immersed in a cavity filled with a solution (Fig. 9, b In this case, the cavitated flows is mixing the liquid effectively (mainly along the tip axis). It is called cavitation bubbling in a cavity.

Ultrasonic vibrations through the liquid are partially transmitted to the tissues. It occurs micromassage of tissues, separation of necrotic plaque from living tissues, as well as mechanical destruction of bacteria cell membranes. This is also facilitated by acoustic streaming, cavitation bubbles' flows, variable sound pressure, the effect of free radicals, and hydrogen peroxide. The combination of all factors leads to gentle cleansing

of tissues, normalization of microcirculation processes, and acceleration of reparative processes.

The application of this exposure in obstetrics and gynecology is the lavage of the uterine cavity. In this case, the solution is mixed in the uterine cavity using an ultrasonic tip with a special protective cover. Also, the cavitation bubbling method is used to cleanse the purulent wounds of the anterior abdominal wall from necrosis. In this case, the activated ultrasonic tip is immersed in the wound cavity filled with the solution.

The action of ultrasonic vibrations on tissues directly with a sonotrode

When exposed to the tissue directly with an ultrasonic tip, the working surface of the sonotrode touches the treated area (Fig. 9, c). Moreover, tips with an irrigation channel provide a combined effect of the ultrasonic tip itself, which performs reciprocating motions (like a jackhammer) with an amplitude of several tens of micrometers, and of a cavitated solution with cavitation bubbles and active chemicals (hydrogen peroxide and free radicals).

This type of exposure provides a strictly dosed controlled necrotomy with the preservation of intact tissues, vessels, and nerves. This allows for gentle necrotomy with minimal blood loss and minimal damage to healthy tissue.

In surgery, contact ultrasonic debridement cleans wounds from necrosis; in obstetrics and gynecology, the postoperative purulent wounds of the anterior abdominal wall are treated similarly (after Cesarean section or abdominal gynecological operations).

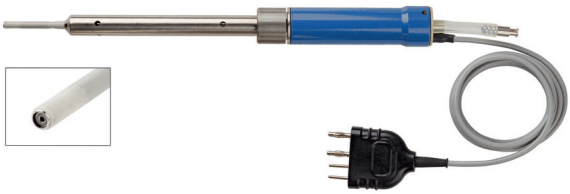
Also, the contact ultrasonic debridement is used to conduct the drug phonophoresis procedure. Due to the oscillations of an ultrasonic tip, the impregnation of drugs into the deeper layers and micromassage of the treated area are ensured. For phonophoresis, as a rule, ultrasonic tips with a large working surface (for example, a “Disk”) are used.

In obstetrics and gynecology, the drug phonophoresis is used to treat vulvar dystrophy, decubitus ulcers of the vagina and cervix.

2.5 Ultrasonic handpieces

For ultrasonic exposure to tissues, ultrasonic handpieces of various functional purpose and design are used (see Table 2).

Table 2 — Types of ultrasonic handpieces and their applications in obstetrics and gynecology

handpiece AA208.5 With the protective cover AA108–2: irrigation of the vulva, vagina, cervix With the protective cover AA108–4: lavage of the cervical canal and uterine cavity	 with cover AA108-2 with cover AA108-4
handpiece AA211.5 lavage of the uterine cavity in acute and chronic endometritis	
узел AA207.5 lavage of the uterine cavity in postpartum endometritis (including for its prevention)	

handpiece AA201.5 (with an ultrasonic tip and a handle AA116)	
With tips AA112.1, AA113.1, AA114.1: purulent wounds debridement With tip AA127.1: phonophoresis	

2.5.1 Ultrasonic handpiece for irrigation of the vulva, vagina, cervix, cervical canal, uterine cavity (AA208.5)

The ultrasonic handpiece AA208.5 with an ultrasonic tip and replaceable protective cover AA108–2 (Fig. 11) has an internal irrigation channel. It is designed for the irrigation of the lower genital tract with cavitated drug solutions for the treatment and prevention of genital infections.



Fig. 10 — Ultrasonic handpiece AA208.5 (with protective cover AA108–2)

Applications of the ultrasonic handpiece AA208.5 with different protective covers:

With protective cover AA108-2	With protective cover AA108-4
• Irrigation of the vulva, vagina, vaginal portion of the cervix for the treatment and prevention of genital infections • Debridement of partial postoperative suture line disruption	• Lavage of the cervical canal and / or uterine cavity in the treatment of cervicitis and / or endometritis

Features of the ultrasonic handpiece AA208.5 with protective cover AA108-2 work:

The cover AA108–2 (Fig. 11) is put on an ultrasonic tip and screwed onto the housing of the ultrasonic handpiece AA208.5 (Fig. 12). For each ultrasonic treatment procedure, a **sterile** protective cover is used.



Fig. 11 — Protective cover AA108–2

Applications of the cover AA108–2:

1) Protecting tissues from accidental damage by an ultrasonic tip.

2) Prevention of ultrasonic tip contamination with a **non-contact method** of exposure. This allows the use of an ultrasonic handpiece AA208.5 more than once after sterilization if:

- tissue processing is carried out by a non-contact method;
- a sterile protective cover is used for each procedure;
- an ultrasonic handpiece during the procedure **does not touch** the patient's tissues and contaminated instruments, and **is not immersed in** liquids in contact with the patient;
- after each procedure, the tip which is located under the protective cover (Fig. 12) and the housing of the ultrasonic handpiece are wiped with disinfecting wipes (wipes allowed for skin disinfection should be used).

If the above conditions were not met during the treatment, then after the procedure the ultrasonic handpiece must be disinfected and sterilized disassembled (see Fig. 12).

When using the cover AA108–2, tissue sanation is carried out by a fine jet of cavitated

drug solution (Fig. 7).

The cover AA108–2 is included in the ultrasonic handpiece AA208.5 set, but also can be supplied separately.

A detailed description of the procedures and treatment regimens with this cover are described in Section 3.2.

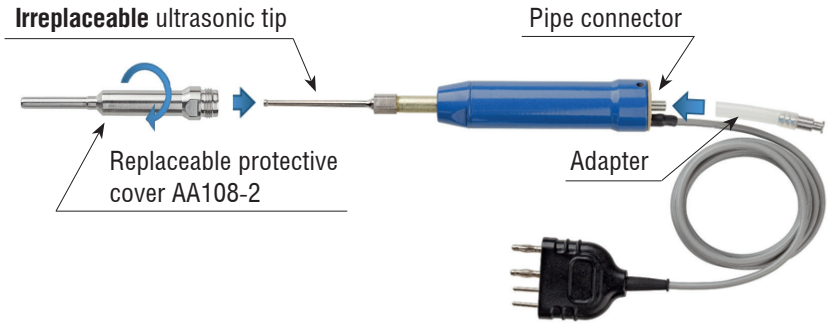


Fig. 12 — Disassembled ultrasonic handpiece AA208.5 with protective cover AA108–2

Features of the ultrasonic handpiece AA208.5 with protective cover AA108-4 work:

Features of using the AA208.5 assembly with the AA108–4 cover:

The cover AA108–4 is put on top of the ultrasonic instrument and screwed onto the housing of the ultrasonic handpiece AA208.5 (Fig. 15).

This cover has a taper connector of the “record” type (Fig. 13).



Fig. 13 — Protective cover AA108–4

The “record” connector is fitted with a distal segment of a single-use female Nelaton urethral catheter measuring 10 CH/FR (the outer diameter of this catheter is 3.3 mm) or 12 CH/FR (the outer diameter is 4 mm).

The length of the catheter segment is selected in order to the tip of the catheter with lateral holes (from which the solution will flow) is located inside the treated area (in the cervical canal or in the uterine cavity, depending on the location of the nidus). In case of cervical canal sanation, the length of the segment should be approximately 4–5 cm, and in case of uterine cavity sanation — 6–8 cm. A schematic representation of the procedure for the sanitation of the uterine cavity is shown in Fig. 28, b.



Fig. 14 — Female Nelaton urethral catheter

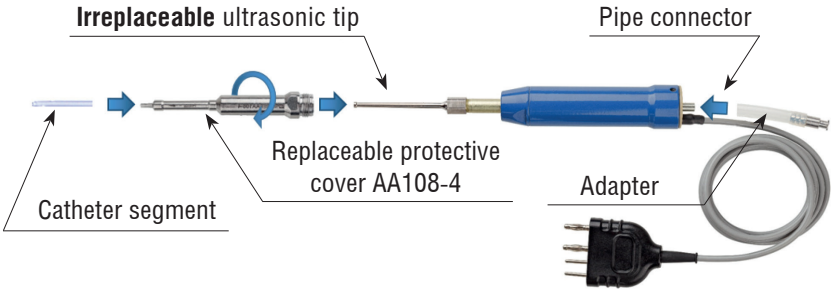


Fig. 15 — Disassembled ultrasonic handpiece AA208.5 with protective cover AA108–4 and Nelaton catheter segment

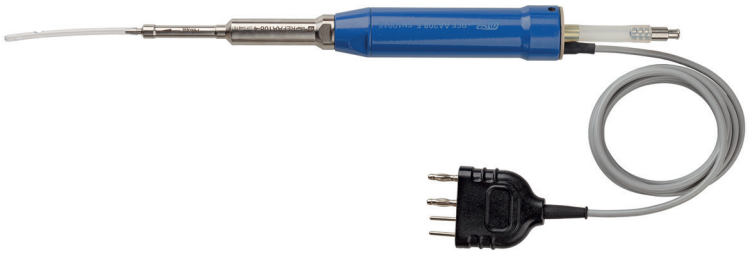


Fig. 16 — Assembled ultrasonic handpiece AA208.5 with protective cover AA108–4 and Nelaton catheter segment

When using the cover AA108–4, tissue sanation is carried out by delivering a cavitated solution to the inflammatory site through the lateral holes of the urological catheter segment (Fig. 17).

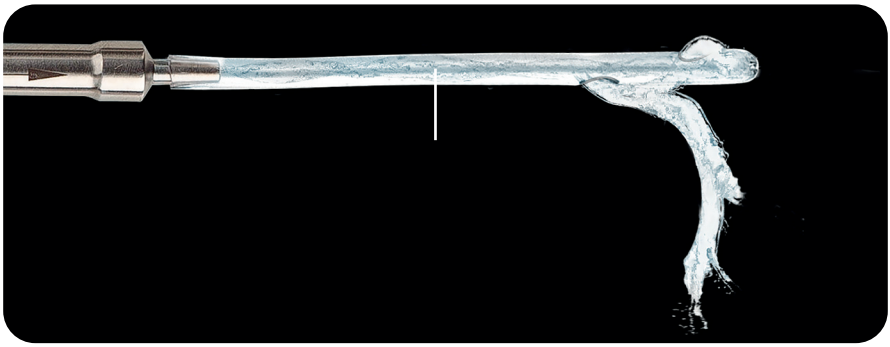


Fig. 17 — Cavitated solution flowing out of the lateral holes of the catheter segment

An alternative technology of uterine cavity ultrasound sanation is implemented using handpieces, which provide a more intense effect on the tissues with a cavitation jet (Fig. 7), their description is given in the next section. But these handpieces have a larger diameter of the working part inserted into the cervical canal (5 and 7 mm). Sanation of the uterus with a cavitated solution through a segment of a urological catheter allows women with a very narrow cervical canal to carry out the procedure almost painlessly. But the therapeutic effect may be less pronounced.

After the procedure, the catheter segment is disposed of, and **disassembled** ultrasonic handpiece is disinfected and sterilized (Fig. 15).

The cover AA108–4 is not included in AA208.5 set, it is supplied separately.

For a detailed description of the procedure using cover AA108–4, see sections 3.3, 3.4.

2.5.2 Ultrasonic handpieces for the uterine cavity lavage (AA207.5, AA211.5)

2.5.2.1 Ultrasonic handpiece for the treatment of postpartum endometritis (AA207.5)

The ultrasonic handpiece AA207.5 is an elongated ultrasonic handpiece with an internal irrigation channel complete with an ultrasonic tip and a protective cover (Fig. 18, Fig. 19).

Applications:

The handpiece is used for the uterine cavity lavage with cavitated drug solutions in the postpartum period to treat and prevent postpartum endometritis.

Features of the ultrasonic handpiece AA207.5 work:

- the protective cover, included in the ultrasonic handpiece set (Fig. 19), protects tissues from accidental damage by an ultrasonic tip;
- drain holes in the protective cover ensure the outflow of fluid from the uterine cavity during the procedure (Fig. 19);

- the cover can only be used with the ultrasonic handpiece that is supplied in one set. The numbers indicated on the cover and the housing of the ultrasonic handpiece **must necessarily coincide** (Fig. 20);
- the external diameter of the ultrasonic handpiece AA207.5 cover inserted into the cervical canal is 7 mm (Fig. 18), therefore, the procedure with this cover can be performed only for women with a cervical canal of **at least 10–12 mm in diameter**. Otherwise, there may be a weak outflow of fluid from the uterine cavity and, therefore, the infected contents may traverse the fallopian tubes into the abdominal cavity;
- the ultrasonic handpiece AA207.5 allows you to create a powerful cavitation jet, which is important for processing the entire cavity of the postpartum uterus;
- after each procedure, the ultrasonic handpiece is disinfected and sterilized disassembled (Fig. 19).

When connecting the ultrasonic handpiece AA207.5 to the ultrasonic unit, the level of ultrasonic vibrations is set automatically by the device (the inscription “AUTO” appears on the touch screen).

A detailed description of the procedures and treatment regimens with this handpiece is described in Section 3.4 Treatment of postoperative purulent wounds using USC.

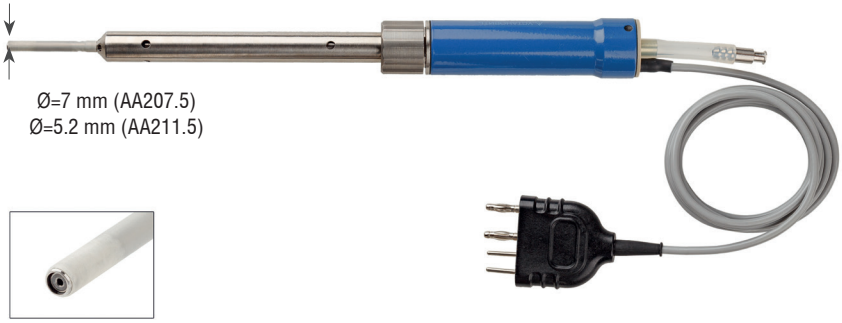


Fig. 18 — Assembled ultrasonic handpiece AA207.5 (AA211.5)

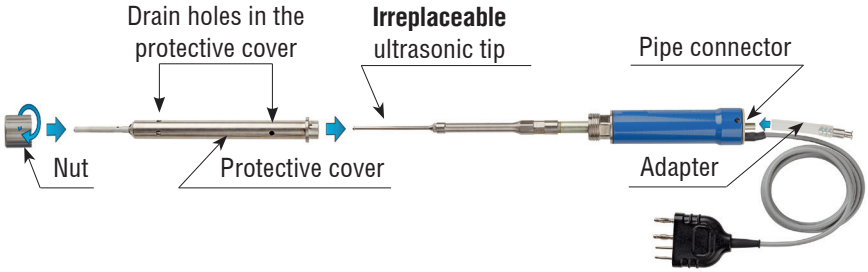


Fig. 19 — Disassembled ultrasonic handpiece AA207.5 (AA211.5)



The serial numbers (SN) indicated on the cover and the housing of the ultrasonic handpiece AA207.5 (AA211.5) must necessarily coincide

Fig. 20 — The serial numbers on the ultrasonic handpiece AA207.5 (AA211.5)

2.5.2.2 Ultrasonic handpiece for the treatment of acute and chronic endometritis (AA211.5)

The ultrasonic handpiece AA211.5 is an elongated ultrasonic handpiece with an internal irrigation channel complete with an ultrasonic tip and a protective cover (Fig. 18, Fig. 19).

Applications:

The handpiece is used for the uterine cavity lavage with cavitated drug solutions for the treatment of acute and chronic endometritis.

Features of the ultrasonic handpiece AA211.5 work:

- the protective cover, included in the ultrasonic handpiece set (Fig. 19), protects tissues from accidental damage by an ultrasonic tip;
- drain holes in the protective cover ensure the outflow of fluid from the uterine cavity during the procedure (Fig. 19);
- the cover can only be used with the ultrasonic handpiece that is supplied in one set. The numbers indicated on the cover and the housing of the ultrasonic handpiece **must necessarily coincide** (Fig. 20);
- unlike the ultrasonic handpiece AA207.5, the external diameter of the ultrasonic handpiece AA211.5 cover inserted into the cervical canal is 5 mm (Fig. 18), which is comparable to the external diameter of an office hysteroscope. This allows you to carry out the uterine cavity lavage without additional expansion of the cervical canal or after its minimum expansion;
- the cavitation jet created by the handpiece AA211.5 is less powerful than that of the AA207.5, since this handpiece is designed to treat the uterine cavity of small sizes;
- after each procedure, the ultrasonic handpiece is disinfected and sterilized disassembled (Fig. 19).

When connecting the ultrasonic handpiece AA211.5 to the ultrasonic unit, the level of ultrasonic vibrations is set automatically by the device (the inscription “AUTO” appears on the touch screen).

A detailed description of the procedures and treatment regimens with this handpiece is described in Section 3.4 Treatment of postoperative purulent wounds using USC.

2.5.3 Ultrasonic handpiece for phonophoresis and purulent wound debridement (AA201.5)

The ultrasonic handpiece AA201.5 is an ultrasonic handpiece with an internal irrigation channel. It is used with replaceable ultrasonic tips for purulent wound debridement (AA112.1 "Hoof", AA113.1 "Ball" and AA114.1 "Spatula") and with a replaceable ultrasonic tip for phonophoresis (AA127.1 "Disk"), see Fig. 21, Fig. 23.

Applications of the ultrasonic handpiece AA201.5 with the different types of ultrasonic tips:

The use of a handpiece with tips for the purulent wound debridement (AA112.1, AA113.1, AA114.1)	The use of a handpiece with a phonophoresis tip (AA127.1)
The perineum or anterior abdominal wall purulent wounds debridement	Treatment of vulvar dystrophy, decubitus ulcers of the vagina and cervix

Features of the ultrasonic handpiece AA201.5 work:

- ultrasonic tips AA112.1, AA113.1, and AA114.1 (Fig. 23) are attached to the ultrasonic handpiece AA201.5 using a key for fixing ultrasonic replaceable tips AA102 (Fig. 22);
- when connecting the tip to the ultrasonic handpiece, do not twist the threaded connection;
- it is more convenient to connect and disconnect the tip using the handle for ultrasonic handpiece AA116, which is installed on the ultrasonic handpiece (Fig. 21, 22);
- if the cavitation of the solution is absent or unstable, it is necessary to tighten the threaded connection between the tip and the ultrasonic handpiece with a key AA102 slightly;
- after the procedure is completed, the ultrasonic tip is unscrewed from the ultrasonic handpiece using the key AA102. The ultrasonic handpiece, tip, key, handle are disinfected and sterilized disassembled (Fig. 22).

Replaceable ultrasonic tips AA112.1, AA113.1, AA114.1 for purulent wound debridement:

Replaceable ultrasonic tip with irrigation channel AA112.1 "Hoof" (Fig. 23) is used to treat wounds covered with loose fibrinopurulent deposits. Contact cleansing of the wound is carried out by a flat platform of the tip or its tapered pointed part. Due to an irrigation channel, purulent plaque can be washed out from the wound bed with a jet of

cavitated solution. The tip can be used for wound cavities debridement by cavitation bubbling.

Replaceable ultrasonic tip with irrigation channel AA113.1 "Ball" (Fig. 23) is used for the gentle (soft) treatment of cavity wounds, as well as granulating wounds in the 2nd — 3rd phase of inflammation. The smooth edges of the "Ball" do not injure granulation. This tip can be used for the gentle (soft) treatment of nooks and cavities.

Replaceable ultrasonic tip with irrigation channel AA114.1 "Spatula" (Fig. 23) is used to affect wounds covered with dense fibrinous plaque. Purulent discharges are removed with the sharp edge of the tip, a hard-to-remove necrotic coating is separated by the supply of the drug solution. This tip is better not to use for cavitation bubbling because splatter may form.

A detailed description of the procedures and treatment regimens with these tips are described in Section 3.5.

Replaceable ultrasonic tip AA127.1 for phonophoresis:

Replaceable ultrasonic tip AA127.1 "Disk" (Fig. 23) is used for the treatment of vulvar dystrophy, decubitus ulcers of the vagina and cervix.



Fig. 21 — Assembled ultrasonic handpiece AA201.5

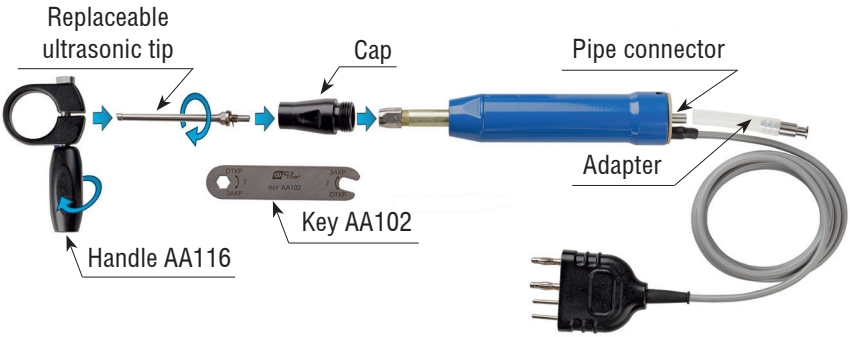


Fig. 22 — Disassembled ultrasonic handpiece AA201.5 with accessories



Ultrasonic tip AA112.1 “Hoof”



Ultrasonic tip AA113.1 “Ball”



Ultrasonic tip AA114.1 “Spatula”

a



Ultrasonic tip AA127.1 “Disk”

b

Fig. 23 — Replaceable ultrasonic tips for handpiece AA201.5:
a — for purulent wound debridement (AA112.1, AA113.1, AA114.1);
b — for phonophoresis (AA127.1)

3 ULTRASONIC PID PREVENTION AND TREATMENT METHODS

3.1 Indications and contraindications. Medicines

Indications for the USC method in gynecology:

- infection and inflammation of the cervix, vagina and vulva (vulvovaginitis, cervicitis, bacterial vaginosis, vulvovaginal candidiasis, aerobic vaginitis, etc.);
- chronic endometritis (for infertility treatment, in preparation for ART, for rehabilitation after non-developing pregnancy);
- acute endometritis (after abortion, miscarriage, non-developing pregnancy);
- decubitus ulcers in uterine prolapse;
- vulvar disorders (vulvar lichen sclerosus et atrophicus, burns after photodynamic therapy);
- preoperative preparation of the genital tract before gynecologic surgery or other manipulations for the prevention of infectious complications:
  - before intrauterine manipulations (artificial termination of pregnancy, D&C, hysteroscopy, insertion of the IUD, etc.);
  - preparation for transvaginal operations (prolapse surgery, surgical treatment of cicatricial deformity of the uterine cervix, vaginoplasty, hysterectomy, etc.);
  - surgical procedure for cervical pathology (conization, excision, diathermy, etc.);
  - vaginal irrigation with long-term pessary use;
- postoperative irrigation of the genital tract to accelerate recovery and prevent complications after surgery;
- suppuration of postoperative wounds.

Indications for the USC method in obstetrics:

- postpartum endometritis;
- vaginal irrigation during a cervical cerclage procedure, as well as during vaginal pessary installation in case of cervical insufficiency;
- prevention of postpartum perineal wound suppuration with:
  - extensive vaginal tears during childbirth;
  - infiltration and pain of suture sites after episiotomy;
  - anterior abdominal wall suture line disruption;
  - acute symptoms of postpartum hemorrhoids;
- postpartum perineal, vaginal, and anterior abdominal wall wound suppuration.

Contraindications to the method:

- blood disorders (leukemia);
- pronounced uterine excitability and hyperstimulation during pregnancy;
- bleeding of unknown origin;
- menstruation;
- decompensated heart failure and neurological decompensation;
- allergic reactions to drugs used for processing;
- mature granulation tissues in the wound (for contact debridement of the wound surface).

Ultrasonic management should be used with caution:

- in oncological purulent-necrotic processes in treatment areas;
- in the first trimester of pregnancy.

Infectious safety

Infectious safety during the procedure is achieved by complying several requirements:

- procedure must be carried out in a treatment room or operating room;
- staff wears medical uniform and footwear;
- personal protective equipment must be used (gloves, masks, shields, glasses);
- sterile instruments and consumables must be used;
- **the protective cover after vaginal irrigation and the entire ultrasonic handpiece after intrauterine procedures must be replaced (sterilized) for each patient.**

Medications recommended for USC:

- Sodium Chloride 0.9% solution (sterile Saline solution, hereinafter referred to as Saline);
- Chlorhexidine Gluconate 0.05% aqueous solution;
- Betadine 10% solution in 1:20 or 1:50 dilution with sterile Saline;
- Sodium Bicarbonate 3% solution (baking soda);
- Octenisept solution in 1:10 dilution with sterile Saline;
- Dioxidine 0.5% or 1% solution in 1:20 dilution with sterile Saline (10 ml (1 vial) of 0.5% or 1% Dioxidine per 200 ml of Saline);
- Nitrofural 0.02% aqueous solution (1:5000);
- Benzydamine Hydrochloride 0.1% or 0.05% aqueous solution;
- Imunofan 0.005% solution in 1:50 or 1:100 dilution with sterile Saline (1–2 ml (1–2 vials) of 0.005% Imunofan per 100 ml of Saline);
- Allokin-alpha solution (1 mg (1 vial) of the medicine Allokin-alpha per 100 ml of

Saline);
- Roncoleukin 0.5 mg solution in 1:100 dilution with sterile Saline (1 ml (1 vial) of Roncoleukin in dose 0.5 mg per 100 ml of Saline);
- Betaleikin solution (1 μg of the medicine per 400 ml of Saline);
- Metronidazole 5.0 mg/ml solution (100 ml vials);
- Ciprofloxacin 2 mg/ml solution (100 ml vials);
- Lidocaine 2% solution in 1:25 dilution with sterile Saline (10 ml of 2% lidocaine per 250 ml of Saline);
- Prednisolone 30 mg/ml solution in 1:250 dilution with Saline (1 ml (1 vial) of Prednisolone per 250 ml of Saline);
- other antiseptics, antibiotics or immunomodulators diluted in sterile Saline.

NOTE: Medicines may have contraindications, it is necessary to read the information leaflet before using them. If the medicines used are not included in the list above, then before diluting them in Saline, you must make sure that the medicine can be used with Saline.

3.2 Local sanation of the vulva, vagina, vaginal portion of the cervix using USC for the treatment and prevention of genital infections

3.2.1 The technique of local sanation of the vulva, vagina, vaginal portion of the cervix using USC

The procedure can be carried out in the gynecologist's office or procedure room. The patient is placed on a gynecological examination chair. Anesthesia is not required.

Treatment parameters:

The ultrasonic handpiece: AA208.5 with cover AA108–2.

For each procedure, the sterile protective cover AA108–2 is put on an ultrasonic tip and screwed onto the housing of the ultrasonic handpiece AA208.5 (Fig. 12).

A detailed description of the ultrasonic handpiece AA208.5 and protective cover AA108–2 is described in Section 2.5 "Ultrasonic handpieces".

The power level of ultrasonic vibrations: 30–50 units.

The operating modes of the device: "ULTRASOUND", "SUCTION", "IRRIGATION".

The ultrasonic exposure: "BASIC".

The liquid flow rate: maximum flow rate (jet supply) is for the power level of ultrasonic vibrations of 50 units; average flow rate (drip supply) is for the power level of ultrasonic vibrations of 30 units. The flow rate is set by the roller clamp of the infusion system and controlled by the drip chamber on the system (Annex A, Fig. A.6, pos. 3, 4).

Features of the procedure:

A vaginal speculum is inserted into the vagina to view the vagina and cervix. If you need to irrigate only the vulva or prolapsed uterus, then a vaginal speculum is not used (Fig. 24).

A solution spray test is conducted outside the body. The distal end of the ultrasonic handpiece is located near the treatment surface. Tissue irrigation is carried out by a non-contact spraying using a cavitation jet (Fig. 7).

If it is necessary to cleanse the genital tract from abnormal vaginal discharge, then the vibration level of 50 units is selected and the maximum flow rate (jet supply) is established.

If it is necessary to evenly apply the drug solution to the tissues with a fine jet, then the vibration level of 30 units and the average flow rate (drip supply) are set. This method of exposure can be used with expensive drugs as the second phase of treatment after the genital tract ultrasonic irrigation with solutions of conventional antiseptics or Saline.

After the procedure is completed, the protective cover AA108–2 is unscrewed from the ultrasonic handpiece AA208.5, disinfected and sterilized. The ultrasonic tip which is located under the protective cover and the housing of the ultrasonic handpiece is wiped with disinfecting wipes (wipes allowed for skin disinfection should be used). If the conditions for the non-contact method (see Section 2.5.1) using the cover AA108–2 are not met during the treatment, then after the procedure the ultrasonic handpiece AA208.5 must be disinfected and sterilized disassembled (see Fig. 12).

Genital tract irrigation in pregnant women can be carried out using medications safe to take during pregnancy. In the first trimester of pregnancy, the procedure should be performed with caution. Irrigation of the vagina and cervix is contraindicated in case of pronounced uterine excitability and hyperstimulation during pregnancy.

Suction of the solution from the vagina: during the procedure, the excess fluid can be removed from the vagina using special reusable or disposable suction nozzles (Annex A, Fig. A.10, c). The suction mode is activated simultaneously with the ultrasonic exposure by pressing the footswitch. After releasing the footswitch, the suction lasts for 3–4 seconds, which allows removing the remaining fluid from the treated cavity.

Solution volume for procedure: 100–500 ml.

Duration of ultrasonic exposure: 1–5 minutes.

Number of procedures: for patients with PID, depending on the form and stage of the disease, an average of 3–8 procedures are required. Preoperative preparation of the genital tract before gynecologic surgery or other manipulations to prevent infectious complications requires 1–3 procedures or more.

Specific treatment regimens for irrigation of the vulva, vagina, vaginal portion of

the cervix for various indications are described in the following section. The ultrasonic treatment results of the lower genital tract are shown in Fig. 25, 26.

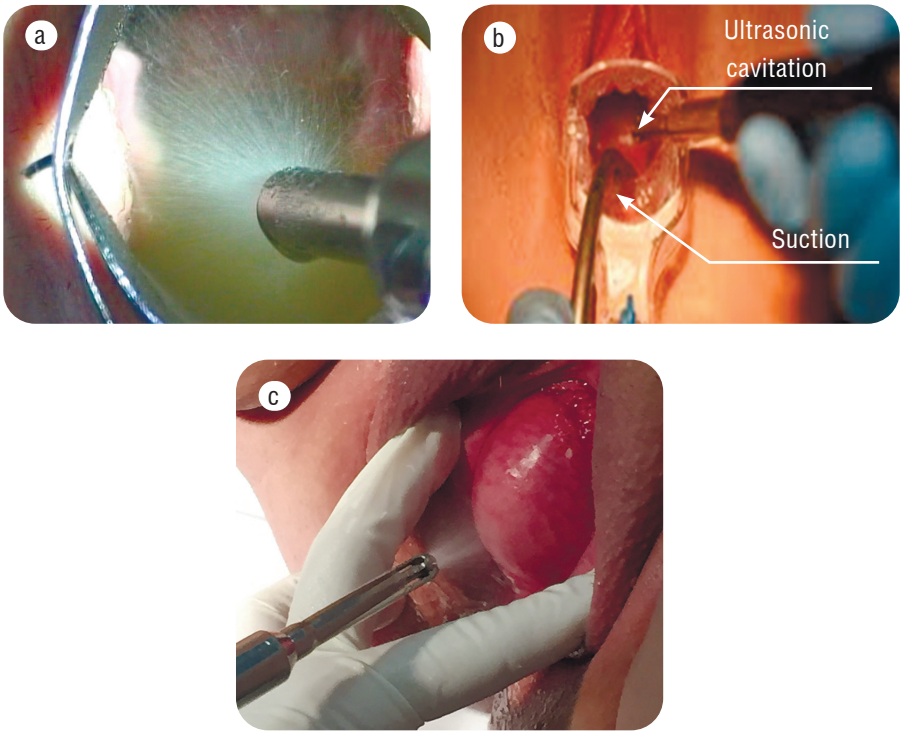


Fig. 24 — Ultrasonic sanation of the lower genital tract using cavitated solutions:
a — tissue irrigation with a cavitation jet;
b — irrigation of the vagina and cervix using vaginal speculum;
c — irrigation of the prolapsed uterus and decubitus ulcers in uterine prolapse

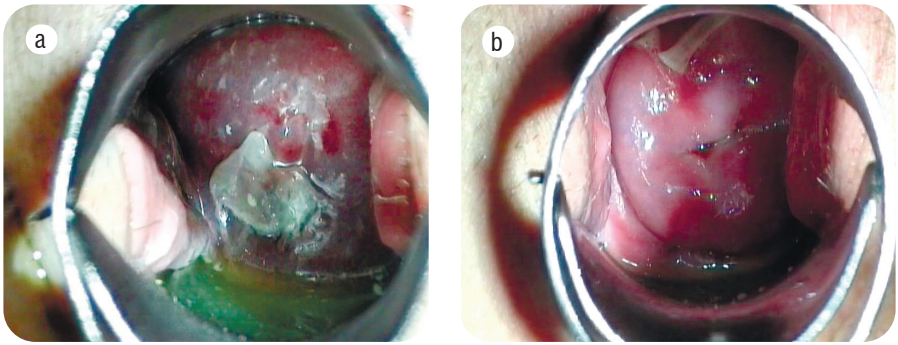


Fig. 25 — The results of ultrasonic sanation of the vagina after the cervical cerclage procedure in case of cervical insufficiency:
a — the cervix before treatment (the second day after cervical cerclage procedure);
b — the cervix one day after sanation

Video of the vaginal ultrasonic irrigation:
https://youtu.be/fOe88Nh32jM

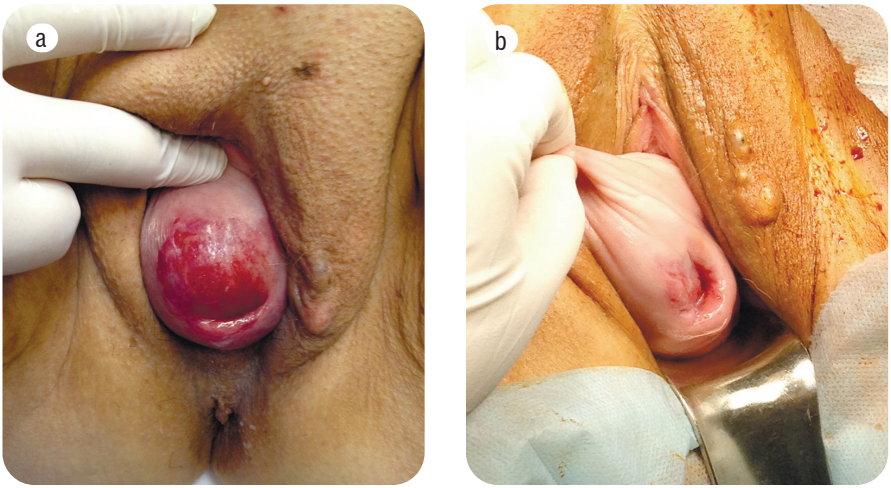


Fig. 26 — The results of the prolapsed uterus ultrasonic sanation (preoperative preparation for surgery):
a — the cervix before treatment;
b — the cervix after a course of ultrasonic sanation (procedures were carried out twice a day for 3 days)



Video of the prolapsed uterus ultrasonic irrigation:
https://youtu.be/GNky3MkYb20



3.2.2 Exemplary treatment regimens for ultrasonic sanation of the vulva, vagina, vaginal portion of the cervix by USC

Treatment regimens of vaginal sanation for vulvovaginal infections, cervicitis, bacterial vaginosis

Treatment is carried out using antiseptic solutions recommended for USC (see Section 3.1) or Saline. Solution volume for procedure: 200–500 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–5 minutes. Number of procedures: 3–8 procedures (carried out once daily).

Treatment regimens of vaginal sanation before intrauterine manipulations (artificial termination of pregnancy, hysteroscopy, etc.)

Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution. Solution volume for procedure: 100–200 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 1–2 minutes. Number of procedures: 1–5 procedures (carried out once daily).

To prevent postoperative infectious complications after intrauterine manipulations, preoperative preparation can be carried out for all patients (regardless of the bacterial contamination of the vagina), and especially for patients with nonspecific vaginitis and vaginosis before surgery.

Treatment regimens of vaginal sanation for preoperative preparation of the genital tract before gynecologic surgery (vaginoplasty, prolapse surgery, etc.)

The purpose of the treatment is to prepare the operating field to reduce infectious complications. Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution or Saline once a day before surgery or on the day of surgery (it is allowed to perform the procedure immediately before surgery). Solution volume for procedure: 200–500 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 2–5 minutes.

Treatment regimen for decubitus ulcers of the vagina and cervix (to prepare for prolapse surgery or vaginal pessary installation)

Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution or Saline. Solution volume for procedure: 500 ml. The power level of ultrasonic

vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 4–5 minutes. Number of procedures: 3–8 procedures (carried out once or twice daily, for 3 days or more).

Immediately after sanation with the above solutions, tissue can be additionally treated with antibiotic solutions: Metronidazole 5.0 mg/ml solution or Ciprofloxacin 2 mg/ml solution. In this case, 100 ml (1 vial) of the solution is used for the procedure. The power level of ultrasonic vibrations: 30 units. Average liquid flow rate. Duration of ultrasonic exposure: 2 minutes.

After sanation of a prolapsed uterus with cavitated solutions, it is recommended to apply a water-soluble ointment (Levomekol ointment, Levosin ointment, etc.) to the vaginal mucosa and install vaginal pessary.

The above treatment regimen for decubitus ulcers is relevant as a preoperative preparation for patients admitted for prolapse surgery without outpatient preparation. In such cases, incomplete epithelialization is quite enough to perform surgery. The last sanation procedure is carried out on the day of surgery.

For outpatient treatment, procedures are carried out every other day according to the above regimens. Number of procedures: 5–7 procedures or more. During treatment, patients are advised to wear loose-fitting clothing that does not limit movement.

In the treatment of decubital ulcers with purulent discharge and hyperkeratotic tissue, it is recommended to use the drug phonophoresis method (see Section 3.5) to enhance the exposure effect and achieve the fastest tissue cleansing.

Treatment regimens of vaginal sanation after transvaginal operations (prolapse surgery, vaginoplasty, hysterectomy, etc.)

Local sanation begins in the first postoperative day, once daily. Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution or Saline. Solution volume for procedure: 500 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–4 minutes. The number of procedures depends on the timing of achieving an acceptable bacterial contamination of the vagina.

Treatment regimens of hygienic vaginal sanation during pessary use

Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution or Saline. Solution volume for procedure: 300–500 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–5 minutes. The procedures are carried out once every 1–3 weeks during the entire period of pessary use. Before the ultrasonic sanation, the vaginal pessary (supports areas of pelvic organ prolapse) should be removed from the vagina and treated with antiseptic solutions; it is installed back after the procedure. The cervical pessary (treats cervical insufficient during pregnancy) should not be removed from the vagina during the procedure.

This method allows you to completely cleanse the mucosa of the genital organs from the discharges formed during long-term pessary use and prevents infectious complications.

Treatment regimens of vaginal and cervical sanation for CIN associated with HPV to eliminate the virus

Treatment is carried out using immunomodulator Imunofan 0.005% solution in 1:50 dilution with sterile Saline (2 ml of 0.005% Imunofan per 100 ml of Saline) or Allokin-alpha solution (1 mg of the medicine Allokin-alpha per 100 ml of Saline). Solution volume for procedure: 100 ml. The power level of ultrasonic vibrations: 30 units. Average liquid flow rate. Duration of ultrasonic exposure: 2–3 minutes.

Number of procedures: 3–5 procedures before surgery; 3 procedures can be performed 10 days after surgery based on individual discretion. The procedures can be performed at intervals of 2–3 days.

Treatment regimens of vaginal and cervical sanation after surgical procedure for cervical pathology (conization, excision, diathermy, etc.)

Local sanation begins no earlier than 10–12 days after surgery to stimulate epithelialization of the wound bed. The indication for the procedure is a significant amount of removed tissue and histologic confirmation of chronic cervicitis as biopsy result, as well as is copious purulent discharge after surgery. Treatment is carried out using Saline. Solution volume for procedure: 100–300 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 2–3 minutes. Number of procedures: 1–3 procedures.

Treatment regimens for sanation of postpartum perineal, vaginal, and anterior abdominal wall suture lines to prevention suppuration

Local sanation begins in the second postoperative (childbirth) day. Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution or Metronidazole 5.0 mg/ml solution. Solution volume for procedure: 100–200 ml. The power level of ultrasonic vibrations: 50 units (or 30 units if antibiotics are used). Maximum (or average if antibiotics are used) liquid flow rate. Duration of ultrasonic exposure: 2–5 minutes. Number of procedures: 2–3 procedures (carried out once daily).

Treatment regimens of vaginal and vulva sanation for suppuration of postoperative wounds

Treatment is carried out using Chlorhexidine Gluconate 0.05% aqueous solution or Saline or Betadine 10% solution in 1:10 or 1:20 dilution with sterile Saline or Octenisept solution in 1:10 dilution with sterile Saline. Antibiotic solutions (Metronidazole 5.0 mg/ml solution or others) can also be used. Solution volume for procedure: 500 ml. The procedure can be performed twice a day with different solutions. For example, the first treatment is

carried out with Chlorhexidine Gluconate 0.05% aqueous solution (solution volume for procedure: 300–500 ml), after a few hours, treatment with antibiotic solutions (100 ml of Metronidazole 5.0 mg/ml solution or Ciprofloxacin 2 mg/ml solution) is performed. It is also allowed to carry out the procedure once a day. The power level of ultrasonic vibrations: 50 units (or 30 units if antibiotics are used). Maximum (or average if antibiotics are used) liquid flow rate. Duration of ultrasonic exposure: 2–5 minutes. The procedures are carried out within 2–10 days.

In the case of ulcers in postpartum, after wound cleansing and fresh granulation formation, it is possible to apply secondary sutures to the perineum or heal a wound by secondary intention.

As a result of the cavitation jet's exposure, the fibrin coating is removed, the blood supply in the adjacent area is increased, the tissues are saturated with the drug solution.

If there is a large amount of purulent-necrotic coating in the wound, it is recommended to use contact ultrasonic debridement (see Section 3.4). In comparison with the non-contact spraying, contact debridement allows you to more effectively clean the wound bed.

Treatment regimens of sanation for postpartum hemorrhoids

Hemorrhoids are irrigated in the first day following childbirth using Lidocaine 2% solution in 1:25 dilution with sterile Saline (10 ml of 2% Lidocaine per 250 ml of Saline) or Chlorhexidine Gluconate 0.05% aqueous solution. Solution volume for procedure: 200–300 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 2–3 minutes. Number of procedures: 2–5 procedures (once or twice daily). The size of hemorrhoids decreases significantly during treatment. A detailed description of case reports is described in Section 5.4.

Treatment regimens of genital tract sanation for cervical cerclage

The procedures are carried out before cervical cerclage and 24 hours after. Treatment is carried out using Betadine 10% solution in 1:20 dilution with sterile Saline. Solution volume for procedure: 300–500 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–5 minutes. Number of procedures: it is recommended to carry out 1–2 procedures before cervical cerclage and 2–3 procedures after, once daily.

Treatment regimens of sanation for vulvar lichen sclerosus et atrophicus (VLS)

Treatment is carried out using Benzydamine Hydrochloride 0.1% aqueous solution. To prepare the solution, you can use the Tantum Rosa granules for vaginal solution. One bag Tantum Rosa granules (500 mg of Benzydamine Hydrochloride) are dissolved in 500ml lukewarm sterile water for injection or Saline. The infusion system is connected to the bottle with a ready-made solution. Instead of Tantum Rosa, you can also use Nitrofural 0.02% aqueous solution (1:5000) or Chlorhexidine Gluconate 0.05% aqueous solution.

Solution volume for procedure: 150–300 ml. The power level of ultrasonic vibrations: 50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–5 minutes. Number of procedures: 7 procedures (carried out once daily).

The USC method in the complex treatment of patients with VLS provides a manageable and stable clinical effect and reduces the number and frequency of relapses. The method has not any unwanted side effects. It can be used in the treatment of VLS in girls. A detailed description is described in Section 4.13.

Thus, the USC method allows for the complete cleaning of the vagina and cervix from pathologic discharge and ensures deep penetration of drugs into inflamed tissues.

Cleansing the infection foci from pathologic discharge, inactivating pathogenic microflora, itchy, burning, and reducing microbial contamination of the vaginal mucosa lead to a decrease in the absorption of toxins and activate local and general immunity. After the first procedure, many women note a decrease in the manifestations of the disease (itchy, burning, and/or painful feelings). Also, the USC method can significantly reduce the number and frequency of disease relapses. Carrying out vaginal ultrasonic sanation in postpartum reduces infectious complications, promotes earlier healing of the wound bed, reduces swelling and pain.

Treatment regimens for sanation of the vulva, vagina, vaginal portion of the cervix using USC are summarized in Annex C, Table C.1.

3.3 Local uterine cavity lavage using USC in acute and chronic endometritis

3.3.1 The technique of local uterine cavity lavage using USC in acute and chronic endometritis

The procedure can be carried out in the gynecologist's office or procedure room. The patient is placed on a gynecological examination chair (see Fig. 27).



Fig. 27 — The patient's position during US uterine cavity lavage

Treatment parameters:

The ultrasonic handpiece: Depending on the case, the ultrasonic handpiece AA207.5 or AA211.5 or AA208.5 (with protective cover AA108–4 and Nelaton catheter segment) is used. The difference between the handpieces is presented in Table 3.

The ultrasonic handpiece	Diameter of the protective cover inserted into the cervical canal, mm	Application
AA207.5	7	Lavage of the large uterine cavity in the postpartum period (when the cervical canal is freely passable) to prevent and treat postpartum endometritis
AA211.5	5	Lavage of the uterine cavity in case of acute and chronic endometritis
AA208.5 (with protective cover AA108-4 and Nelaton catheter segment)	3.3-4 (в зависимости от размера катетера)	Lavage of the uterine cavity in case of acute and chronic endometritis (in patients with a narrow cervical canal)

More intense effect on the endometrial mucosa is provided in case of using AA207.5 and AA211.5 handpieces, than using the AA208.5 handpiece (with the AA108–4 cover and Nelaton catheter segment). The effect depends on type of cavitated jet delivery to the focus of inflammation. When the cavitated fluid passes through the conductor — a segment of the urological catheter, there is a "weakening" of the jet, and therefore the therapeutic effect may be weaker.

A detailed description of the ultrasonic handpieces is described in Section 2.5 "Ultrasonic handpieces".

The power level of ultrasonic vibrations:

When connecting the ultrasonic handpiece AA207.5 or AA211.5 to the ultrasonic unit, the level of ultrasonic vibrations is set automatically by the device (the inscription "AUTO" appears on the touch screen). If necessary, the level of ultrasonic vibrations can be reduced by pressing the "LOW AUTO" button (Annex A, Fig. A.14).

For AA208.5 (with protective cover AA108–4 and Nelaton catheter segment), the power level of ultrasonic vibrations is 40–50 units.

The operating modes of the device: "ULTRASOUND", "SUCTION", "IRRIGATION".

The ultrasonic exposure: "BASIC".

Infusion bottle location: the infusion bottle holder is adjusted so that during the procedure the distance between the lower edge of the infusion bottle and the ultrasonic handpiece inserted into the uterine cavity is **at least 90 cm**. This is necessary for a sufficient solution flow rate.

The liquid flow rate: maximum flow rate. The roller clamp on the infusion system must be fully open. It is necessary to ensure that the solution is supplied to the irrigation channel of the ultrasonic handpiece without interruption. The solution flow rate should be jet, or at least 4 drops per second (controlled using the drip chamber of the infusion system).

Features of the procedure:

Before starting the procedure, it is necessary to establish the size and position of the uterus, as well as the diameter and length of the cervical canal (using a bimanual exam, uterine sounding, or ultrasonography).

Before the insert of the ultrasonic handpiece into the uterine cavity, the vulva is treated with an antiseptic solution. A vaginal speculum is inserted into the vagina, the vagina and cervix are treated with an antiseptic solution.

If the cervical canal is closed, it needs to be dilated (cervical dilatation). First, local anesthesia of the cervix is performed.

For local anesthesia, a Lidocaine 10% spray or a gel for external use (e.q. Cathejell Lidocaine, Instillagel, Lidochlor) can be used. The gel is applied to the vaginal portion of

the cervix. The analgesic effect occurs within 5–10 minutes after the application.

After anesthesia, the upper part of the cervix is grasped with bullet forceps, and the cervix is dilated with Hegar dilators to Hegar 6 or more to use handpiece AA211.5 or to Hegar 4 or more to use handpiece AA208.5 (with protective cover AA108–4 and Nelaton catheter segment).

The ultrasonic handpiece AA207.5 is used only in the postpartum period (the cervical canal is freely passable), therefore, when working with it, the cervical dilatation is usually not required. During treatment, the cervical canal begins to close, then it is recommended to use the ultrasonic handpiece AA211.5 with a smaller diameter to continue treatment.

In the case of acute cervicouterine angulation, it is recommended to straighten the cervical canal (so that the distal end of the ultrasonic tip does not rest against the uterine wall). For this, the upper part of the cervix is grasped with bullet forceps and pulled up to the anterior vaginal wall (in retroflection of the uterus) or the posterior vaginal wall (in anteflexion of the uterus).

When the cervical canal is prepared, a solution spray test conducted outside the body is mandatory. Make sure that the spray temperature is comfortable for the patient (by exposing it to the palm of your hand).

The distal end of the ultrasonic handpiece AA207.5 or AA211.5 (Fig. 28, a) or catheter segment (connected to AA108–4 cover and handpiece AA208.5) (Fig. 28, b), without touching the vaginal walls, is inserted through the cervical canal into the uterine cavity, based on the bending of the uterus (anteflection, retroflection, lateroflection).

When passing the cervical canal with the selected handpiece, it is recommended to spray the solution through it to moisten and slightly dilate the cervical canal to facilitate handpiece insertion.

During the procedure, the ultrasonic handpiece is held by the doctor's hands to prevent its displacement in the uterine cavity. The uterine cavity is irrigated with a cavitated solution (Fig. 29).

Throughout the entire procedure, it is necessary to ensure that the solution is supplied to the irrigation channel of the ultrasonic handpiece without interruption (using the drip chamber of the infusion system).

WARNING! DO NOT continue the procedure at a solution flow rate of **less than 4 drops per second**, because this can cause overheating of the instrument, as well as the solution supplied into the uterine cavity, which can lead to tissue burns.

The solution flow rate may be insufficient (less than 4 drops per second) for the following reasons:

- a partial vacuum was formed in the infusion bottle during emptying (in this case, the bottle should be pierced with a needle);
- an inflection or twisting of infusion tubing occurs;
- the drip chamber filtration rate is reduced (in this case, the infusion system must be replaced);
- the roller clamp on the system is not fully open;
- the distance between the lower edge of the infusion bottle and the ultrasonic handpiece inserted into the uterine cavity is less than 90 cm;
- the irrigation hole at the distal end of the ultrasonic handpiece is blocked by tissues.

Do not continue the procedure if the supplied solution runs out. Even a short-term ultrasonic exposure (within 3–5 seconds) without the solution delivery can lead to heating of the ultrasonic handpiece and thermal burns of the patient's tissues.

In the process of ultrasonic treatment when using handpieces AA211.5, AA207.5, the outflow of fluid from the uterine cavity during the procedure is ensured by drain holes in the protective cover (Fig. 19). Additional outflow of fluid is also carried out between the walls of the cervical canal and the protective cover, so the walls of the cervical canal should not too tightly extend over the cover inserted into the uterine cavity. Free fluid outflow from the uterine cavity is a prerequisite for the procedure. Otherwise, the contents of the uterine cavity may traverse the fallopian tubes into the abdominal cavity and the patient may experience pain during the procedure.

It is necessary to ensure that during the entire procedure of ultrasonic lavage, the volume of solution supplied to the uterine cavity approximately coincides with the volume of fluid flowing from it. If the volume of the solution entering the cavity is visually greater than flowing out fluid, it is necessary to suspend the procedure, remove the ultrasonic handpiece from the cervical canal and ensure the outflow of fluid accumulated in the uterus. Then remove the protective cover from the ultrasonic handpiece and check if the drain holes in it are clogged.

Fluid, which is leaking the uterine cavity, usually accumulates in the vagina. It can be removed from the vagina using suction nozzles.

After the procedure, the ultrasonic handpiece is removed from the uterine cavity, disassembled (Fig. 19), disinfected, and sterilized.

Solution volume for procedure depends on the size of the uterus and the disease pattern, the average is 200–800 ml.

Duration of ultrasonic exposure: 3–10 minutes.

Number of procedures: depending on form and stage of the disease, on average,

5–7 procedures are performed once daily. For some pathologies, several courses of procedures are required.

Specific treatment regimens for the uterine cavity lavage for various indications are described in the following section.

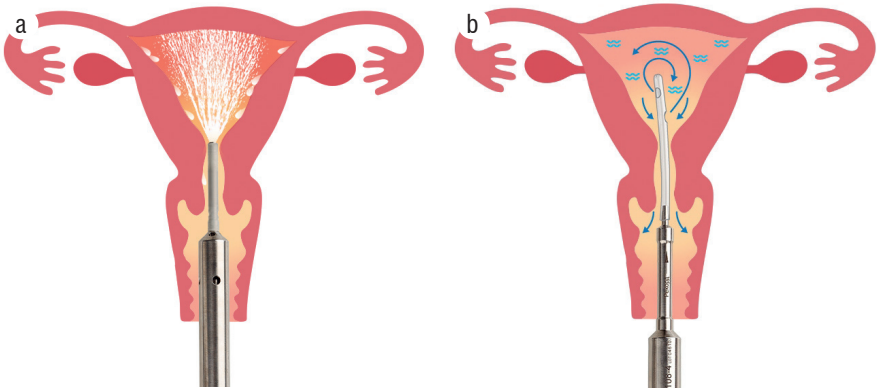


Fig. 28 — Ultrasonic lavage of the uterine cavity with a cavitated solution using
a — the ultrasonic handpiece AA211.5 or AA207.5
b — the ultrasonic handpiece AA208.5 (with protective cover AA108–4 and Nelaton catheter segment)

Video of the ultrasonic intrauterine lavage:
https://youtu.be/Z_SIBwlebFk

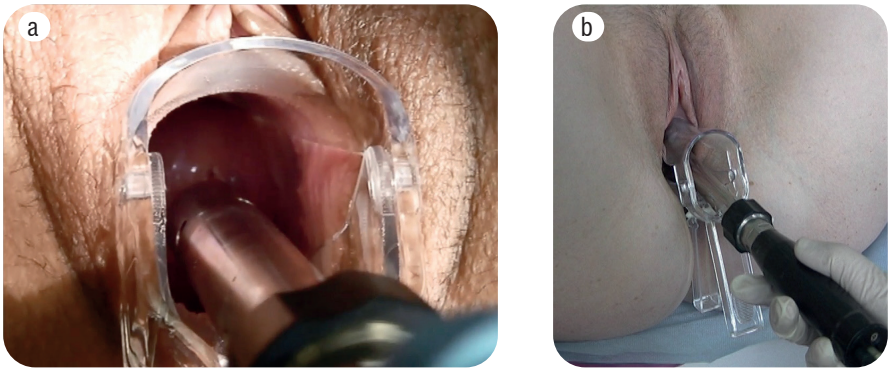


Fig. 29 — Ultrasonic intrauterine lavage with a cavitated solution:
a — the distal end of the ultrasonic handpiece AA207.5 or AA211.5 is inserted through the cervical canal into the uterine cavity
b — the ultrasonic handpiece is held by the doctor's hands during the procedure

The results of ultrasonic intrauterine lavage in the treatment of chronic endometritis are shown in Fig. 30.

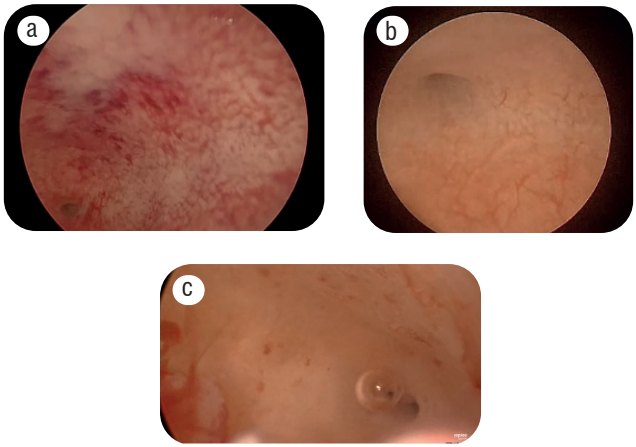


Fig. 30 — The results of ultrasonic intrauterine lavage in the treatment of chronic endometritis:
a — the endometrium before treatment;
b — the endometrium after one course of ultrasonic intrauterine lavage;
c — the endometrium after 3 courses of ultrasonic intrauterine lavage

3.3.2 Exemplary treatment regimens for ultrasonic intrauterine lavage by USC

Treatment regimens of uterine cavity lavage for postpartum endometritis

The procedure is carried out using the ultrasonic handpiece AA207.5. If the cervical

canal begins to close, and the size of the uterus after childbirth is significantly reduced, then **the ultrasonic handpiece AA211.5 with a smaller diameter is used**.

Treatment is carried out using Dioxidine 0.5% or 1% solution in 1:20 dilution with sterile Saline, Chlorhexidine Gluconate 0.05% aqueous solution, Saline, or Betaleikin solution (1 μg of the medicine per 400 ml of Saline). Solution volume for procedure: 300–800 ml. The power level of ultrasonic vibrations for the ultrasonic handpieces AA207.5 and AA211.5 is set automatically by the device. Maximum liquid flow rate. Duration of ultrasonic exposure: 5–10 minutes. Number of procedures: 3–8 procedures.

Treatment regimens of uterine cavity lavage for the prevention of postpartum endometritis

Ultrasound treatment of the uterine cavity is performed for women with a high risk of postpartum purulent-septic complications.

The indications for the procedure:

- uterine subinvolution, lochiometra;
- hyperthermia during labor;
- long latency period in labor;
- assisted vaginal delivery (vacuum-assisted fetal delivery with the Kiwi vacuum delivery device for poor uterine contraction strength, manual examination of the uterine cavity for placental defect, bleeding);
- cervical pessary use, cervical cerclage.

The procedures are performed from 2 days after spontaneous vaginal delivery, and from 3–4 days after caesarean section, once daily.

The procedure is carried out using the ultrasonic handpiece AA207.5. Treatment is carried out using Dioxidine 0.5% or 1% solution in 1:20 dilution with sterile Saline, Chlorhexidine Gluconate 0.05% aqueous solution, or Saline. Solution volume for procedure: 300–800 ml. The power level of ultrasonic vibrations for the ultrasonic handpiece AA207.5 is set automatically by the device. Maximum liquid flow rate. Duration of ultrasonic exposure: 5–10 minutes. Number of procedures: 1–3 procedures.

Treatment regimens of uterine cavity lavage for the endometritis after abortion, miscarriage, non-developing pregnancy

Treatment of the uterine cavity after abortion, miscarriage, non-developing pregnancy is recommended to start on the second or third day after removal of an embryo or fetus. In women who previously had non-developing pregnancy, the procedure is recommended to be carried out since the 7–9th day of the menstrual cycle.

The procedure is carried out using the ultrasonic handpiece AA211.5. Treatment is carried out using Dioxidine 0.5% or 1% solution in 1:20 dilution with sterile Saline, Chlorhexidine Gluconate 0.05% aqueous solution, or Saline. Solution volume for

procedure: 200–300 ml. The power level of ultrasonic vibrations for the ultrasonic handpiece AA211.5 is set automatically by the device. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–5 minutes. Number of procedures: 3–5 procedures. The course of treatment can be repeated after the normalizing of the menstrual cycle, in this case, treatment is carried out in the first phase of the menstrual cycle.

Treatment regimens of uterine cavity lavage for chronic endometritis, endometrial hypoplasia, in preparation for ART (IVF, embryo transfer)

Within individual complex therapy of individual complex therapy, the patients are given a local treatment of the endometrium with a cavitated medicinal solution. The procedure is carried out using the ultrasonic handpiece AA211.5 or AA208.5 (with protective cover AA108–4 and Nelaton catheter segment in patients with a narrow cervical canal). The procedure is recommended to be carried out since the 5–9th day of the menstrual cycle.

Before starting treatment, it is necessary to perform the uterine sounding to determine the size of the uterus and the length of the cervical canal. Before the first procedures using the ultrasonic handpiece AA211.5 in nulliparous women, cervical dilatation is usually required. For this, the upper part of the cervix is grasped with bullet forceps, and the cervix is dilated to 6–7 mm. In case of using ultrasonic handpiece AA208.5 (with protective cover AA108–4 and Nelaton catheter segment), the cervix is dilated to 4–5 mm. Because the cervical dilatation procedure can be painful, local anesthesia of the cervix is performed.

Ultrasound treatment is carried out in two or three courses of treatment. Solutions recommended for each course:

- 1st course: Saline, Chlorhexidine Gluconate 0.05% aqueous solution, Dioxidine 0.5% or 1% solution in 1:20 dilution with sterile Saline (10 ml (1 vial) of 0.5% or 1% Dioxidine per 200 ml of Saline);
- 2nd course: above–stated solutions, Imunofan 0.005% solution in 1:50 dilution with sterile Saline (5 ml (5 vials) of 0.005% Imunofan per 250 ml of Saline);
- 3rd course: Saline or Imunofan 0.005% solution in 1:50 dilution with sterile Saline.

The courses of treatment are recommended to be carried out in each menstrual cycle. Solution volume for procedure: 200–300 ml. The power level of ultrasonic vibrations for the ultrasonic handpiece AA211.5 is set automatically by the device. For AA208.5 (with protective cover AA108–4 and Nelaton catheter segment), the power level of ultrasonic vibrations is 40–50 units. Maximum liquid flow rate. Duration of ultrasonic exposure: 3–5 minutes. Number of procedures: 5–10 procedures, once daily.

The local treatment of the endometrium by ultrasonic intrauterine lavage with cavitated medicinal solutions allows to increase the effectiveness of treatment, reduce the pill burden, the number of surgical procedures in the uterus, and the treatment

duration by 2–3 times. The use of the method in the treatment of chronic endometritis and preparation for the IVF procedure helps to restore fertility, increases chances for a successful pregnancy (both when natural conception, and when using ART). At the same time, the treatment procedure is quite comfortable and safe for patients, it is quick and low–cost.

Treatment regimens for uterine cavity lavage using USC are summarized in Annex C, Table C.2.

3.4 Treatment of postoperative purulent wounds using USC

The procedure can be carried out in the gynecologist's office or procedure room. The patient is placed on a gynecological examination chair or examination table.

Treatment parameters:

The ultrasonic handpiece and tips:

For this manipulation, the ultrasonic handpiece AA201.5 is used with the selected ultrasonic tip. If the wound is covered with loose fibrinopurulent deposits, then the ultrasonic tip with irrigation channel AA112.1 "Hoof" is used. If it is necessary to affect wounds covered with dense fibrinous plaque, it is more convenient to use the ultrasonic tip with irrigation channel AA114.1 "Spatula". For the gentle (soft) treatment of cavity wounds, as well as granulating wounds in the 2nd – 3rd phase of inflammation the ultrasonic tip with irrigation channel AA113.1 "Ball" is used. Tips AA113.1 and AA112.1 can be used in the treatment of wound cavities by the cavitation bubbling.

The ultrasonic handpiece, tip, and key for fixing tips must be sterile. The required sterile ultrasonic tip is attached to the ultrasonic handpiece using a sterile key.

A detailed description of the ultrasonic handpiece and tips is described in Section 2.5 "Ultrasonic handpieces».

The power level of ultrasonic vibrations: 20–50 units.

The operating modes of the device: "ULTRASOUND", "SUCTION", "IRRIGATION".

The ultrasonic exposure:

Treatment should be started in the "SELECTIVE" mode. If there are no neurovascular structures or fresh granulations near the treated area, or the wound is treated with a non–contact spraying, you can switch to the "BASIC" mode. A detailed description of setting the desired ultrasonic exposure mode is described in Annex A.

The liquid flow rate: maximum (jet supply) or average flow rate (drip supply). The flow rate is set by the roller clamp of the infusion system and controlled using the drip chamber on the system (Annex A, Fig. A.6, pos. 3, 4).

Solutions for USC: Saline, Chlorhexidine Gluconate 0.05% aqueous solution, or other antiseptics and antibiotics.

Features of the procedure:

After the solution spray test, treatment is started in the "SELECTIVE" mode by light touches of the tip to the wound (Fig. 31, a). The handpiece cleans tissues from purulent deposits with the mechanical action of the ultrasonic tip and/or cavitated jet supplied through the irrigation channel. For a more productive cleaning, purulent discharges can be removed with the sharp edge of the tip. If the effect is not enough to cleanse the wound and there are no neurovascular structures or fresh granulations nearby, then you can switch to the "BASIC" mode or increase the power level of ultrasonic vibrations.

Besides, in a confined cavity of an abscess or phlegmon, cavitation bubbling in the wound cavity can be part of the ultrasonic treatment. For this, it is necessary to fill the wound cavity with a medicinal solution and immerse an activated ultrasonic tip into it (Fig. 31, b). Vortexes and cavitation bubbles will appear and collapse in the liquid, which provides a therapeutic effect.

Areas with granulation tissue can be treated with a non–contact cavitation jet (so as not to damage fresh granulations).

During the procedure, the fluid from the wound cavity can be removed using sterile suction nozzles (if the "SUCTION" mode is turned on the touch screen).

After the procedure is completed, the ultrasonic tip is unscrewed from the ultrasonic handpiece using the key. The ultrasonic handpiece, tip, key, handle and adapter are disinfected and sterilized disassembled (Fig. 22).

Solution volume for procedure: 200–300 ml, depending on the size of the wound defect and purulent deposits.

Duration of ultrasonic exposure: 5–10 minutes.

Number of procedures: 5–7, carried out every day or every other day. After a course of ultrasonic treatment, secondary sutures are applied to the wound, or the wound heals by secondary intention (depending on the wound size). A prerequisite for the application of secondary sutures is the complete cleansing of the wound and the appearance of fresh granulations.

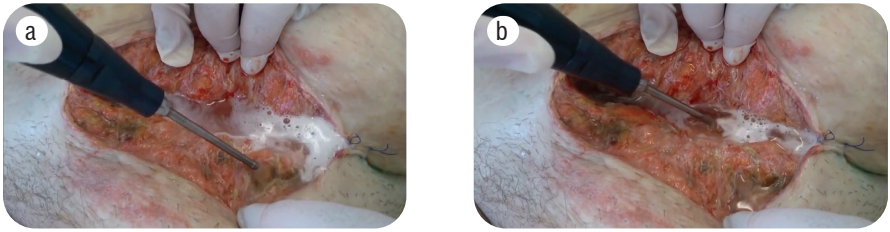


Fig. 31 — Ultrasonic debridement of an anterior abdominal wall purulent wound:
a — contact wound debridement with the ultrasonic tip;
b — cavitation bubbling of the solution in the wound cavity

The results of ultrasonic debridement of an anterior abdominal wall purulent wound are shown in Fig. 32.

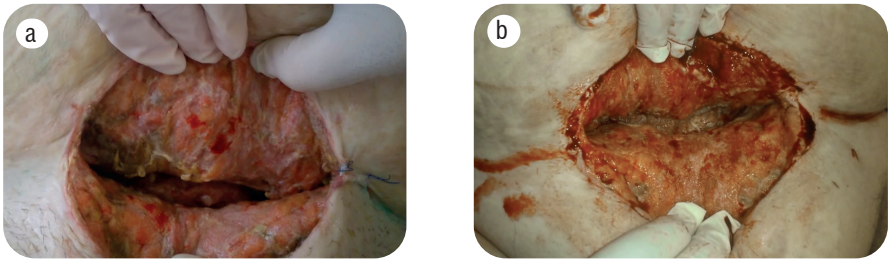


Fig. 32 — The results of ultrasonic debridement of an anterior abdominal wall purulent wound:
a — wound on the 7th day after Cesarean section, before the first ultrasonic treatment;
b — wound after 4 ultrasonic treatment procedures (on the 4th day from the start of treatment): there is a complete wound cleansing, the appearance of bright granulations

Video of ultrasonic debridement of an anterior abdominal wall purulent wound: **https://youtu.be/KB4RWrh1vWk**

When using the purulent wound debridement with antiseptic cavitated solutions, the wound is cleared faster and the inflammation stops in a shorter time. This technique is especially relevant in the treatment of abscesses and phlegmons of the anterior abdominal wall of a complex and irregular shape, with pus leaks under the subcutaneous tissue, under the aponeurosis and rectus abdominal muscles. The standard treatment protocol for such wounds is not always effective, and often in the future, repeated surgical treatment, debridement, and emptying of pus leaks are required. When using cavitation, an ultrasonic wave, and a cavitated antiseptic solution, penetrates all hard-to-reach wound loci, effectively removes the purulent-necrotic deposits, relieves inflammation, and accelerates reparative processes (Fig. 32).

3.5 Drug phonophoresis for the treatment of vulvar dystrophy, decubitus ulcers of the vagina and cervix

The procedure can be carried out in the gynecologist's office or procedure room. The patient is placed on a gynecological examination chair.

The ultrasonic handpiece and tips:

For treatment of vulvar dystrophy, decubitus ulcers of the vagina and cervix, the

ultrasonic handpiece AA201.5 is used with the ultrasonic tip with irrigation channel AA127.1 “Disk”. The sterile ultrasonic tip is attached to the ultrasonic handpiece using a sterile key. A detailed description of the ultrasonic handpiece and tips is described in Section 2.5 “Ultrasonic handpieces”.

1) Treatment parameters in the treatment of vulvar dystrophy:

The power level of ultrasonic vibrations: 1–20 units (depending on the individual sensitivity of a patient).

The operating modes of the device: “ULTRASOUND”, “IRRIGATION”, “SUCTION” (if necessary).

The ultrasonic exposure: “BASIC” or “SELECTIVE”.

The liquid flow rate: average flow rate (about 3 drops per second). The flow rate is controlled using the drip chamber on the system.

Solutions for USC (according to indications): Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Imunofan 0.005% solution in 1:50 dilution with sterile Saline; Prednisolone 30 mg/ml solution in 1:250 dilution with Saline (1 ml (1 vial) of Prednisolone per 250 ml of Saline); other solutions of antiseptics, immunomodulators, hormone-containing drugs.

Solution volume for procedure: 100–300 ml.

Duration of ultrasonic exposure: 3–5 minutes.

Number of procedures: 5–10 (carried out once daily).

Features of the procedure:

The vulva is covered up with 1–3 layers of gauze pads. The infusion system is connected to the ultrasonic handpiece. The drug solution is supplied through the internal irrigation channel of the ultrasonic handpiece. The tip is gently pressed against the tissues through gauze and moved along in a circular motion (Fig. 33). The tip must be kept at right angles to the tissues. The entire distal surface of the tip must be in contact with gauze. During the entire procedure, the tip must be in motion to avoid heating the tissues.

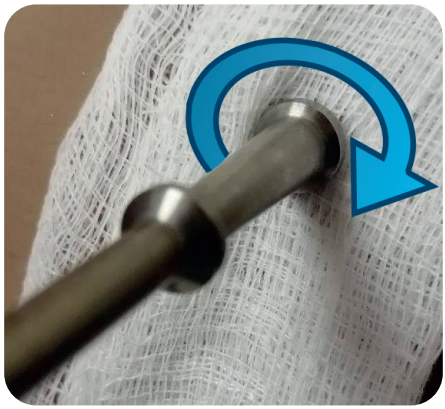


Fig. 33 — Drug phonophoresis for the treatment of vulvar dystrophy

In the treated patients, after the first few procedures, there is a significant decrease in the manifestations of the disease, the stimulation of cell proliferation. The number of disease relapses is reduced. The procedure is generally well tolerated by patients.

2) Treatment parameters in the treatment of vaginal and cervical decubitus ulcers:

The power level of ultrasonic vibrations: 20–50 units (depending on the individual sensitivity of a patient).

The operating modes of the device: "ULTRASOUND", "IRRIGATION", "SUCTION" (if necessary).

The ultrasonic exposure: "BASIC" or "SELECTIVE".

The liquid flow rate: maximum flow rate (jet supply).

Solutions for USC (according to indications): Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Octenisept solution in 1:10 dilution with sterile Saline; Prednisolone 30 mg/ml solution in 1:250 dilution with Saline (1 ml (1 vial) of Prednisolone per 250 ml of Saline); other solutions of antiseptics, immunomodulators, hormone-containing drugs.

Solution volume for procedure: 300–500 ml.

Duration of ultrasonic exposure: 4–5 minutes.

Number of procedures: 3–10 (carried out once daily).

Features of the procedure:

The procedure is effective in treating decubital ulcers with purulent deposits and severe trophic disorders of the mucous membrane. It allows to achieve the epithelization of ulcerative defects in a short time.

The infusion system is connected to the ultrasonic handpiece. The drug solution is supplied through the internal irrigation channel of the ultrasonic handpiece. During the procedure, both non-contact and contact exposures are performed. When the ultrasonic

tip moves along the mucous membrane, keratinized layers are “scraped off”, and purulent deposits are washed out. The areas of the mucous membrane that are sensitive to contact are treated with a non-contact cavitation jet created by the tip. As a result, there is an intensive and quick cleaning of tissues, micromassage of tissues with trophic disorders, which ensures the fast healing and epithelization of the vaginal and cervical mucous membranes.

Treatment regimens for the treatment of vulvar dystrophy, decubitus ulcers of the vagina and cervix using drug phonophoresis are summarized in Annex C, Table C.4.



Video of drug phonophoresis in case of vaginal and cervical decubitus ulcers:
https:// https://youtu.be/D-4sil4NSYM



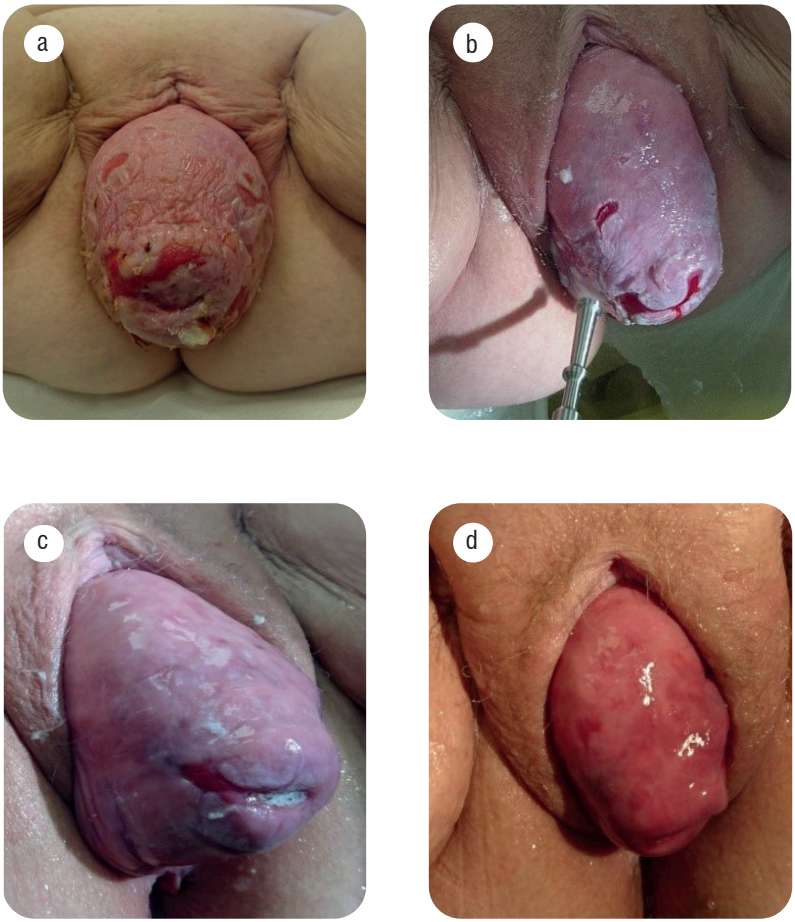


Fig. 34 — Treatment of decubital ulcers of the vagina and cervix with drug phonophoresis:
a — before treatment;
b — carrying out the procedure (the 4th US treatment);
c – 2 weeks from the start of treatment (the 8th US treatment);
d – 3 weeks from the start of treatment (the 11th US treatment)

4 RESULTS OF USC IN THE TREATMENT OF GYNECOLOGICAL DISEASES

4.1 Nonspecific vaginitis

The effectiveness of the treatment method was evaluated in 68 patients [77]. Group I (n=38) received local ultrasonic irrigation with a cavitated Chlorhexidine Gluconate 0.05% aqueous solution. Group II (n=30) received a sitz bath with the same solution, but without USC. Women with candidiasis received additional treatment with fluconazole 150 mg/once.

After the completion of therapy, in group I the signs of inflammation and leukocytosis significantly decreased, normal lactoflora recovered in 78.9% of women, while in group II only in 28.9%.

Thus, according to our data, in the treatment of nonspecific vaginitis, the therapeutic effect of LFUSC (low-frequency ultrasonic cavitation) is 2.7 times higher than that of conventional Chlorhexidine applying.

4.2 Chronic recurrent vulvovaginal candidiasis

The treatment group (n=60) of women with recurrent vulvovaginal candidiasis [30] received fluconazole 150 mg/weekly for 6 months in combination with vaginal irrigation with a cavitated Saline (total course: 10 procedures). The control group (n=50) received only fluconazole.

10 days after the completion of therapy in the treatment group, full recovery was observed in 87.3% of patients and was significantly higher than in the control group (74.0%).

A month after the completion of therapy, full cure, the disappearance of pseudomycelium, budding yeast forms of Candida, and leukocytosis were recorded in 93.3% of patients in the treatment group and only in 62.0% in the control group.

The relapse rate was assessed over one year using clinical presentation and microbiological diagnosis. The detection rate of *C.albicans* in the treatment group 6–12 months after therapy was 1.6% versus 20% in the control group.

Thus, the use of LFUSC in the complex therapy reduces the relapse rate in chronic recurrent vulvovaginal candidiasis by 12.5 times.

4.3 PID caused by Mycoplasma genitalium

The effectiveness of the treatment method for *M. genitalium* infection [60] showed

that the inclusion of ultrasonic cavitation in the complex therapy significantly increases the effectiveness of causal therapy.

The study included 210 women with mycoplasmosis. Group I (n = 50) received only causal therapy (josamycin 500 mg three times daily, 10 days). Group II (n = 45) received causal therapy and medicated vaginal tampons with rIL-2 solution (Roncoleukin solution, 0.5 mg) for 2 hours daily for 10 days. Group III (n = 60) received causal therapy and LFUSC with Saline. Group IV (n = 55) received causal therapy and LFUSC with Roncoleukin solution.

Positive PCR results for the presence of *M. genitalium* were observed for: 12% of patients in group I; 8% in group II; 6% in group III; 2% in group IV.

Analysis of the effect of treatment regimens on the functional and secretory activity of neutrophilic granulocytes showed that ultrasonic and cytokine therapy eliminates the imbalance in the neutrophilic granulocytes. In group IV, after treatment, a more significant improvement in innate immunity factors (lysosome activity of neutrophils, activity, and intensity of neutrophils according to the NBT test, phagocytic activity of neutrophils) was recorded than in the other groups. It is quite possible that by activating the phagocytes' functions in the inflammation foci, complex ultrasonic and cytokine therapy significantly increases the phagocytosis efficiencies and thereby contributes to the pathogen elimination under the action of causal therapy.

Thus, the use of USC in the complex therapy of women with PID caused by *M. genitalium* increases the efficiency of causal therapy and helps to restore the functional activity of neutrophils and humoral immunity of cervical mucus. This provides effective protection against recurrence of the inflammatory diseases in the future.

4.4 Urogenital mixed infections

The study [51] involved 432 patients. Group I (n=144, 33.3% of all patients) had an inflammation associated with *U. urealyticum, U. parvum, M. hominis, Candida fungi*. In group II (n=145, 33.6% of all patients), inflammation was caused by a combination of *U. urealyticum, U. parvum, M. hominis, Gardnerella vaginalis, Atopobium vaginae*. Group III (n=143, 33.1% of all patients) included women with inflammation caused by *U. urealyticum, U. parvum, M. hominis*. It was not possible to establish significant differences in the detection rate of *S. epidermidis, S. saprophyticus, Streptococcus spp., Corynebacterium xerosis*, however, the detection rate of these microorganisms was significantly higher ($p<0.05$) than in the control group (healthy women). Some of the patients received causal drug therapy, and some — complex ultrasonic and causal therapy.

Microbiological analysis of patients with urogenital *mixed* infections after treatment

showed a significant decrease in the number of microbial species, a decrease in the number of microorganisms. The average number of lactobacilli in patients treated with LFUSC significantly increased: $10^{5.61}$ CFU/ml in the vagina and $10^{5.23}$ CFU/ml in the cervical canal. In patients receiving causal therapy, the dynamics of resident flora restoration was less pronounced: the average number of lactobacilli was $10^{3.1}$ CFU/ml in the vagina and $10^{3.17}$ CFU/ml in the cervical canal ($p = 0.02$). After treatment, all treated groups showed a significant decrease in the number of neutrophils in the cervical mucus. The absolute and relative viable neutrophil count decreased, lysosomal enzyme activity and NBT test normalized. In patients treated with LFUSC, changes in immunoglobulin G (IgG) and secretory immunoglobulin A (sIgA) in the cervical mucus showed a significant increase, which indicates the restoration of the secretory activity of the genital tract mucosa.

Thus, complex ultrasonic and causal therapy in the treatment of urogenital mixed infections is significantly superior only to causal drug therapy. Complex therapy successfully heals immunological and microbiological disorders directly in the inflammation foci.

4.5 Cervical intraepithelial neoplasia (CIN), grade I or II, associated with HPV

The examination and treatment of 90 patients aged 20 to 39 years with a histologically confirmed CIN I, II grades [26] were performed. Group I ($n = 45$) at the first stage of treatment (before carrying out the destruction of lesions) underwent vaginal irrigation with a cavitated solution of the immunomodulator Imunofan. Group II ($n = 45$) underwent destruction without preoperative irrigation. The control group ($n = 30$), according to clinical and laboratory parameters, had no cervical pathology.

Clinical, anamnestic, and laboratory data analysis showed that 6 months after destruction in group I, HPV was detected in 17.3% of patients, in group II in 58.3%. After 1 year in 7.8 and 15.4% of patients ($p < 0.05$), respectively.

After completion of therapy, IFN-γ level in group I was 15.3 ± 3.2 pg/ml (approximately equal to the level in control group: 13.5 ± 1.8 pg/ml; $p > 0.05$), and in group II it remained decreased (5.4 ± 1.4 pg/ml; $p < 0.05$). IFN-γ level in cervical mucus in group I after treatment was 63.45 ± 3.13 pg/ml, in group II it was 30.6 ± 2.5 pg/ml and was lower than in control group (55.60 ± 2.12 pg/ml, $p > 0.05$). Since IFN-γ activates neutrophils, the microbicidal and tumoricidal functions of macrophages, and also stimulates the cytolytic activity of NK cells, the almost complete normalization of these indicators shows a positive effect of Imunofan and ultrasonic cavitation therapy on the cervical local immunity, while after destruction without irrigation, indicators remain changes in interferon status.

IL-1β, which is a mediator of the inflammatory response and modulator of acute-

phase proteins, after vaginal irrigation with Imunofan solution decreased to levels comparable to the control group. Meanwhile, the destruction of the cervix without the use of Imunofan led to a significant increase in this indicator, which showed an increase in inflammatory reactions. IL-6 indicators also changed.

Similar results were obtained by other authors when treating 60 women aged 18 to 45 years with CIN I, II grade [80].

Thus, the complex therapy of cervical diseases associated with HPV, using Imunofan and USC, is 2 times more effective in promoting the elimination of the viral infection from the body than only standard destruction, and has a positive effect on the cervical local immunity.

4.6 Preoperative preparation of the genital tract before prolapse surgery

The treatment method was used in 96 patients aged 67 to 80 years with complete uterine prolapse for up to 15 years, accompanied by trophic disorders of the vaginal and cervical mucous membrane [69]. Half of the patients (51.7%) had trophic ulcers of hernial sac mucosa, as well as decubitus ulcers on the cervix.

On the 3rd day from the start of ultrasonic treatment, 77.4% of patients achieved incomplete epithelialization of decubitus ulcers. The remaining 22.6% of patients continued the treatment for several more days. On the 4–6th day, the stage of incomplete mucosa epithelialization was reached in another 19.4%, which made it possible to carry out surgical treatment (colporrhaphy).

Thus, it was shown that LFUSC in 96.8% of patients with trophic ulcers allows in a short time to achieve epithelialization in preoperative preparation, to reduce the incidence of postoperative complications and improve wound healing processes.

4.7 Preoperative preparation for early abortion

The study involved 310 patients planning an artificial termination of pregnancy by vacuum aspiration at a period of 5–12 weeks after the last menstrual period [86]. Group I (n=170) received vaginal irrigation with a cavitated Chlorhexidine Gluconate 0.05% aqueous solution, and group II (n=140) received the same solution without cavitation. The number of procedures varied from one (with I–II grades of vaginal cleanliness and / or no manifestations of vaginitis or vaginosis) to three (with III grade of vaginal cleanliness and / or manifestations of vaginitis, cervicitis or bacterial vaginosis). The procedures were performed daily, the last procedure was carried out 1–2 hours before the abortion manipulation.

After treatment with a cavitated solution in group I, the vaginal flora normalized in more than half of the women, while in group II, flora normalized only in 29%. There were no postoperative complications in group I. In group II there were two cases of endometritis (1.4%) of mild and moderate disease.

Thus, vaginal sanation with a cavitated Chlorhexidine Gluconate 0.05% aqueous solution in pregnant women before surgical abortion increases the stability of vaginal normal flora and the effectiveness of preventing infectious complications.

4.8 Preoperative preparation of women with cicatricial deformity of the uterine cervix for plastic surgery

Cicatricial deformity of the cervix is accompanied by an inflammatory process that prevents surgical treatment. Persistence of the inflammation occurs due to a violation of the structural integrity of the cervix. In most cases, cicatricial deformity is accompanied by cervical ectropion, which is a gateway to infections. In the cicatricial deformity of the cervix, surgical treatment is the only way to restore normobiocenosis. Plastic surgery or cone-shaped amputation of the uterine cervix can remove the ectropion due to the formation of the external os and the creation of the anatomical integrity of the cervix. To improve tissue regeneration in the postoperative period, it is necessary to eliminate the acute inflammatory process during preoperative preparation.

The effectiveness of LFUSC during preoperative preparation was evaluated in 75 patients aged 20 to 45 years with cicatricial deformity of the uterine cervix [13]. All patients underwent preoperative preparation using vaginal suppositories to eliminate the inflammatory process. On an inpatient basis, all patients underwent cervical ultrasonic irrigation for 2 days. Then a control smear was taken from all patients to determine the grade of vaginal cleanliness.

After preoperative preparation with vaginal suppositories, in 30 patients (40%) the number of leukocytes in the smear was up to 30 in the objective field of view. In 45 (60%) patients, the number of leukocytes ranged from 30 to 80 in the objective field of view. All patients underwent vaginal and cervical ultrasonic irrigation with Chlorhexidine Gluconate 0.05% aqueous solution and Saline. Solution volume for procedure: 500 ml. The power level of ultrasonic vibrations: 50 units. Duration of ultrasonic exposure: 2–5 minutes. On the 2nd day after ultrasonic cavitation, a control smear was taken to determine the grade of vaginal cleanliness. In all patients (100%), the number of leukocytes decreased and was less than 20 in the objective field of view.

To improve tissue regeneration after plastic surgery on the cervix due to cicatricial deformity, correct preoperative preparation should be performed. It has been proven that LFUSC is effective in the treatment of acute inflammation of the cervix.

4.9 Thin endometrium during uterine factor infertility and miscarriage

The first study included 128 women with infertility due to chronic endometritis and endometrial hypoplasia [10, 11]. Patients in the treatment group (group I, n=64) received drug therapy (estradiol hemihydrate 4 mg per day from the 1st to the 25th day of the menstrual cycle, dydrogesterone 10 mg twice daily from the 11th to the 25th day for 6 cycles) and physiotherapy treatment (magnetic laser therapy over the lower abdomen for 10 minutes daily, 13–15 procedures per course; the course of magnetic laser therapy was repeated after 3 months) in combination with ultrasonic uterine cavity lavage with cavitated drug solutions (3 courses with the time interval of 1 month: 1st course — with Chlorhexidine Gluconate 0.05% aqueous solution, 2nd and 3rd — with Imunofan 0.005% solution in 1:50 dilution with sterile Saline). Patients in the control group (group II, n=64) received the same treatment without LFUSC.

In group I, sonographic findings in chronic endometritis after the 3rd course of procedures were absent in all women: the ultrasound image of the endometrium was completely normalized. At the same time, in group II, a normal ultrasound image after 6 months was determined only in 10 (15.6%) women.

After 3 months from the start of treatment in all 64 women of group I, the endometrial thickness corresponded to the menstrual cycle, there were no morphological features of chronic endometritis. In group II, after 6 months of treatment, the endometrial thickness corresponded to the cycle phase without features of chronic endometritis only in 18 (28.1%) women.

The mean endometrial thickness in women of group I after 3 courses of treatment significantly increased (from 5.8±0.8 to 8.6±0.3; $p < 0.05$). In the treatment group, normal endometrial thickness (≥7 mm) was observed in 100% of patients after 3 months from the start of treatment. In the control group, a significant increase in endometrial thickness was observed only after 6 months of treatment in 34.4% of patients, but its average value (6.4±0.9 mm) did not reach 7 mm.

During the 1st year after the end of therapy, spontaneous pregnancy occured significantly more often in women who received ultrasonic intrauterine lavage than in patients who did not receive it (45.3% versus 28.1%). Childbirth was observed in 89.7% of pregnancies in group I versus 44.4% in group II. In group I, miscarriage occurred 5.4 times less often than in group II: 10.3% versus 55.6% of the total number of pregnancies in the group.

Thus, after the treatment, an increase in the endometrial thickness and restoration of its structure were noted. The impact of LFUSC on the uterine cavity in women with chronic hypoplastic endometritis and infertility can improve all features of the endometrium. Positive changes are confirmed by a significant increase in the thickness

of the endometrium, as well as by an increase in pregnancy rates.

The second study included 116 patients. All women with infertility and miscarriage were divided into two cohorts [64]. Both cohorts received hormonal and antibiotic therapy. Cyclic hormone therapy was carried out with estradiol 17-β (1–4 mg per day from the 3rd to the 25th day of the menstrual cycle) and dydrogesterone (20 mg daily from the 14th to the 25th day of the cycle). If a bacteriological examination of the cervical discharge in a significant titer was detected, antibacterial elimination of pathogenic microflora was performed before ultrasonic uterine cavity lavage.

The 1st cohort consisted of 90 patients with uterine factor infertility and miscarriage due to endometrial hypoplasia. It was divided into two groups: group I (n=46) — patients with infertility due to endometrial hypoplasia; group II (n=44) patients with miscarriage caused by endometrial hypoplasia. While receiving hormonal therapy, ultrasonic intrauterine lavage with Saline was performed out in the first phase of the menstrual cycle, starting from the 7–9th day of the cycle for 3–5 minutes, 5 procedures per course. It was conducted 3 courses of procedures with a time interval of 1 month.

The 2nd cohort (n=26) consisted of patients with infertility and miscarriage caused by a thin endometrium. They did not receive ultrasonic uterine cavity lavage.

The use of USC in the complex therapy improves endometrial receptivity ($p < 0.05$), which is manifested by a restoration of morphofunctional endometrial structure (the endometrial glands are uniformly distributed in group I before treatment in 48.39% of patients versus 82.61% after therapy; in group II before treatment in 48.15% of patients versus 86.36% after therapy); an increase in endometrial thickness (in group I, the endometrial thickness increased by 3.55±0.45 mm from 5.3±0.39 to 8.85±0.53 mm, in group II – by 3.60±0.46 from 5.06 ± 0.34 to 8.71±0.51 mm; in patients without USC (the 2nd cohort), the thickness increased by 1.43±0.12 mm from 5.34±0.27 to 6.89±0.15 mm); an improvement of implantation potential due to an increase in the verification of mature pinopodia during the window of implantation; a significant increase in expression of LIF, LIF–R, CD34+, VGEF A ($p < 0.05$).

During the first year after complex therapy in group I, pregnancy occurred in 34 (73.91%) patients, in 76.47% of cases pregnancy occurred spontaneously, in other cases – as a result of ART. Birth in time was in 88.24% of pregnancies, in other cases were preterm births. In group II, pregnancy occurred in 35 (79.55%) patients, in 80% of cases occurred spontaneously, in other cases – as a result of ART. Birth in time was in 85.71% of pregnancies, preterm birth was in 5.71% of cases, and non–developing pregnancies in 8.57% of cases. In the 2nd cohort, pregnancy occurred in only 9 (34.62%) patients. Moreover, spontaneous pregnancy occurred in 66.67% of cases, as a result of ART – in 33.33% of cases. Birth in time was in 44.44% of pregnancies, preterm birth

was in 22.22% of cases, non–developing pregnancies were in 22.22% of cases, and miscarriage occurred in 11.11%.

It was found that complex therapy, using ultrasonic intrauterine lavage in patients with uterine factor infertility and miscarriage to restore the endometrial receptivity, more than doubles the frequency of reproductive outcomes compared to standard therapy (76.73% of cases of pregnancy in the 1st cohort against 34.62% in the 2nd cohort).

According to this study, a significant advantage in the effectiveness of the complex therapy using ultrasonic intrauterine lavage and cyclic hormone therapy was revealed compared to standard hormone therapy. The method made it possible to reduce the prevalence of chronic endometritis and morphological and immunohistochemical features of the immune and inflammatory responses in the endometrium, eradication of opportunistic and obligate pathogens, improve endometrial blood flow, restore cytoarchitectonics with uniform and timely pinopodia ripening during the window of implantation. Thus, complex therapy to restoring endometrial receptivity can be recommended for women with reproductive failures caused by endometrial hypoplasia.

4.10 Endometrial receptivity recovery in women after missed miscarriage

The study included 90 patients after vacuum aspiration of the uterine contents in the first trimester of pregnancy [83]. Patients were randomized into three groups: group I (n=30) underwent intrauterine lavage with cavitated solutions, pelotherapy, and antimicrobial therapy; group II (n=30) received a course of pelotherapy and antimicrobial therapy; group III (n=30) received just antimicrobial therapy. Besides, a control group (group IV, n=28) was formed of healthy women who previously had no missed miscarriage to control AMGF (α2-microglobulin of fertility).

During the 1st course, Chlorhexidine Gluconate 0.05% aqueous solution was used, in the 2nd and 3rd courses Imunofan 0.005% solution in 1:50 dilution with sterile Saline was used. The medicinal solution flow rate was 100–150 ml/min, the solution volume for procedure was 200–300 ml. The course consisted of five procedures, duration of procedure was 3–4 minutes. The first course of treatment was carried out in a cycle of vacuum aspiration, starting from the 5–7th day, and then in the next two menstruation cycles on the same days of the cycle, a total of 3 courses were carried out.

In group I, during the third course of intrauterine lavage, immediately after the procedure of USC, rectal tampons (200–250 g) were injected. In group II, rectal mud tampons were also used, and mud applications were applied to the lower abdomen (thickness of 2.5–3 cm). Mud tampons with a temperature of 38–42 °C were used in a third menstrual cycle after vacuum aspiration, starting from the 5–7th day of the course

for 15–20 minutes. Both groups received one course of 10 procedures.

An assessment of the endometrial ultrasound characteristics was carried out on the 21–23th day of the menstrual cycle. Before treatment, the endometrial thickness in groups I, II, and III was 5.2, 5.2, and 5.4 mm, respectively, and after treatment – 8.3, 6.4, and 6.2 mm. The significant increase in thickness was obtained only in group I who received complex treatment.

As a result of complex therapy, pregnancy occurred in 63.3% of patients in group I, in 43.3% in group II, in 36.7% in group III. Birth in time was 89.4%, 92.3%, and 72.7% of patients in groups I, II, and III, respectively. In other cases, miscarriages occurred. The observation was carried out for one year after treatment.

Fertility alpha-2-macroglobulin (A2M) levels in women after missed miscarriage before and after treatment changed from 12.6 to 44.1 μg/ml in group I, from 9.3 to 24.2 μg/ml in group II and from 9.3 to 9.5 μg/ml in group III. In the control group, the A2M level was on average 40.3 μg/ml. Obviously, in group I (complex ultrasonic and pelotherapy) it was possible to achieve a normal A2M level, in group II (one course of pelotherapy) it was not possible, in group III the dynamics in A2M level was practically not observed.

Thus, complex therapy with ultrasonic intrauterine lavage and pelotherapy in women after missed miscarriage leads to a significant increase in the fertility A2M level, comparable to the control group, and indicates the normalization of the morphofunctional endometrial structure. Positive changes are confirmed by a significant increase in the endometrial thickness, as well as an increase in pregnancy rates.

4.11 Rehabilitation after non-developing pregnancy

Endometrial restoration was studied using immunohistochemistry of estrogen receptor (ER) and progesterone receptor (PR) in two groups of women after embryo or fetus removal during non-developing pregnancy: group I received ultrasonic intrauterine lavage, group II did not receive it [6, 72]. H-score scoring system was used for IHC evaluation. ERα expression score in the endometrial glands in group I was 188.54±1.97, in group II — 177.01±5.29 ($p<0.05$); ERα expression in the endometrial stroma did not significantly differ in groups I and II, but were lower than in healthy women. PR expression score in the stroma in group I was 159.09±4.82, in group II — 143.01±8.19 ($p<0.05$), in the endometrial glands it was 196.18±1.94 and 181.66±3.18 ($p<0.01$), respectively. Ki67 expression score in the stroma was 107.45 ± 2.93 and 115.66±3.86 ($p<0.05$), respectively, in glands in group I was 145.63± 5.43, in group II — 168.33±4.59, which was significantly higher than in healthy women (132.51±4.25, $p<0.01$).

Thus, the uterine cavity lavage with USC is an effective rehabilitation therapy for

endometrial restoration after non-developing pregnancy.

4.12 Chronic endometritis as a result of non-developing pregnancy

This study compared the treatment results of women with non-developing pregnancy, who underwent rehabilitation immediately after pregnancy loss (group I) and in the long-term period (group II). Group I consisted of 70 women, 38 of them received a course of ultrasonic intrauterine lavage as part of complex therapy, and 32 did not receive it. Group II consisted of 22 women who previously had a non-developing pregnancy, currently suffering from histologically confirmed CE (chronic endometritis) [6, 72], who underwent a course of ultrasonic intrauterine lavage. Control group consisted of 8 healthy women.

The effectiveness of the USC method in group II (rehabilitation in the long-term period) was 54.5%, which is significantly lower than in the group I (immediate rehabilitation) — 66.7% ($p<0.05$), and higher than in the group of women, who did not receive USC (25.2%, $p<0.05$).

Thus, the method of intrauterine USC leads to the restoration of the window of implantation due to the normalization of morphofunctional endometrial structure and a decrease in the local primary immune response. The best results were achieved using the USC method in the first menstrual cycle after endometrial curettage for non-developing pregnancy.

4.13 Vulvar lichen sclerosus (VLS) in young girls

The study included 78 girls aged 3 to 9 years with visually confirmed VLS. The study was carried out in the FSBI "National Medical Research Center for Obstetrics, Gynecology, and Perinatology named after Academician V. I. Kulakov" Ministry of Health of the Russian Federation [21]. Medical history with the factors preceding the disease onset, the frequency of relapses, the complaint severity, the clinical features, the previous treatment regimens were analyzed.

After obtaining the informed consent of the parent/legal representative, all the girls underwent a course of ultrasonic cavitation irrigation of the VLS zone with benzydamine hydrochloride aqueous solution. The procedures were carried out once daily for 5 minutes, 7 procedures per course. The treatment result and side effects were assessed on the 7th day (the last therapy day), 1 and 3 months after the course of irrigations. Age at onset of VLS was 4–5 years, the number of relapses before treatment ranged from 2 to 4 in six months, with symptomatic relapse on average 1.5 weeks after the last course of therapy. Topical glucocorticosteroids and calcineurin inhibitors were used in

the past in 64.1%of girls, with a short-term positive effect in every second girl. Local medicinal applications of oil solutions with herbal extracts and vitamins or methyl uracil ointment were used in 36% of girls and were ineffective.

Complaints differed in the variety and severity of manifestations. Itching, burning, and pain in the perineum disturbed 97.7% of patients, fissures or ulcers in the vulvar skin — 92.3%, poor sleep, irritability, and dyschezia — 32.1%.

Against the background of ultrasonic cavitation with benzydamine hydrochloride solution, itching and burning disappeared on the 1–2nd day, fissures and ulcers healed by the 5–7th day. Mood improvement and normalization of sleep were noted already on the 2nd day. No side effects and complications of the applied therapy were noted.

The full effect of treatment with the disappearance of complaints and clinical manifestations persisted for 1 month in 91.1% and within 3 months in 89.1% of girls. The dynamics of the VLS clinical progression under the ultrasonic therapy is shown in Fig. 35.

Thus, the use of benzydamine hydrochloride solution cavitated by LFUS provided a controlled and stable effect, reducing the frequency of relapses (within 3 months after treatment, relapse was noted only in 10.9% of patients), and had no side effects in girls with VLS.

A description of the clinical research described in this chapter is presented in research articles posted on the website www.fotek-med.com (section Information Center >> Clinical results)



Fig. 35 — Dynamics of the VLS clinical progression in a 6-year-old female patient under the ultrasonic therapy

5 RESULTS OF USC IN THE TREATMENT OF OBSTETRIC DISEASES

5.1 Prevention of postpartum inflammatory infection

The first study analyzed 188 patients in the postpartum period with a high risk of postpartum endometritis (lochiometra, hyperthermia during labor, long latency period in labor, cervical pessary use, cervical cerclage, operative delivery) [35].

The patients were divided into two groups: group I (n=88, treatment group) received conventional therapy in combination with ultrasonic intrauterine lavage, group II (n=100, control group) was treated with conventional method. The uterine cavity lavage was carried out on the 2–3rd day after childbirth, once daily for 3–5 minutes, 2.0±1.2 procedures per course. Dioxidine 1% solution in 1:20 dilution with sterile Saline was used for procedures. Studies have shown that in group I there were no cases of postpartum endometritis, in group II 4 patients (4%, $p<0.05$) clinical and laboratory features of endometritis developed, which required antibiotic therapy and operative hysteroscopy with intrauterine lavage. According to the microbiological analysis after treatment, in group I, all women did not have an increase in pathogenic microflora, normal vaginal lactoflora recovered in 64.7% of women. In group II, only 13% of patients had normal vaginal lactoflora with the average number of lactobacilli less than 102 ($p<0.05$). Patients of group I, who had a spontaneous vaginal delivery, were in the hospital for 3.6±0.4 bed-days, in group II — for 4.8±0.5 bed-days ($p<0.05$). After the caesarean section, the average duration in group II was 6.7 bed-days, which was significantly longer ($p<0.05$) than in group I (5.2 bed-days).

Thus, intrauterine and vaginal treatment with an antiseptic solution cavitated by LFUS in the postpartum period in puerperas with a high risk of purulent-septic complications leads to a decrease of the postpartum endometritis and the number of postoperative bed-days, promotes the normalization of vaginal flora, and reduces the pill burden on a nursing mother and the cost of subsequent treatment.

The second study analyzed 40 patients with a high risk of infection after extremely preterm birth. In these patients, to prevent infectious and inflammatory complications, the ultrasonic uterine cavity lavage was used [102]. Group I (n=20) underwent cavitation of the uterine cavity. This group was compared with group II (n=20), who received conventional treatment (without USC). The control group (n=20) consisted of patients after term birth.

The uterine cavity lavage was carried out with Chlorhexidine Gluconate 0.05% aqueous solution of Sodium Chloride 0.9% solution. In patients after spontaneous vaginal delivery,

intrauterine cavitation was carried out from the second day, after Cesarean section — from the third day. The average solution volume was 400–600 ml per procedure, the exposure was conducted once daily for 3–5 minutes. The number of procedures was determined based on individual discretion and averaged 3–5 procedures.

All parturient women underwent transvaginal ultrasound screening on the 30th day after birth. In group I, the mean length (42.75±3.38 mm), width (36.1±2.4 mm) and anteroposterior diameter of the uterus (37.1±4.35 mm) were significantly less than in group II (55.15±9.6 mm, 50.91±11.02 mm and 51.03±9.6 mm, respectively). The uterine volume in group I was 2.5 times less than in group II (26.2 cm^3 versus 65.5 cm^3) and was comparable to the uterine volume of women after term birth (27.5 cm^3), which makes it possible not to allow the appearance of lochiometers in the postpartum period.

Microbiological analysis of cervical mucus on the 30th day after birth did not reveal the increase in the number of pathogenic and opportunistic microflora in 90% of patients in group I versus 60% of patients in group II. Normal flora occured in group II 5 times more often (in 25% of patients) than in group II (5% of patients). An increase in the number of opportunistic microflora, represented only by *E. coli*, was observed only in two patients of group I (10% of patients). In group II, a diverse microbial flora was represented by *Staphylococcus spp* (in 5% of patients), *Ent faecalis* (in 10%), and *E. coli* (in 25%).

The vaginal microbial flora analysis showed that there was no increase in the number of aerobic bacteria in group I, while in group II aerobes were detected in 65% of patients, 84.3% of them had mixed flora.

Also, the intrauterine cavitation reduced the significant number of anaerobic bacteria by 5 times (15% in group I versus 60% in group II) and completely excluded mixed infection by the 30th day of the postpartum period.

Thus, all indicators in women with a high risk of infection after extremely preterm birth, who received USC, are comparable to women after term birth. The use of cavitation prevents lochiometers in the postpartum period and, accordingly, prevents the development of infectious and inflammatory complications.

5.2 Postpartum endometritis and prevention of its long-term complications

The first study [35] involved 70 women treated for postpartum endometritis. In group I (n=25, 8 of them had a caesarean section), the ultrasonic surgery cavitational device “FOTEK” was used for treatment. In group II (n=21, 7 of them had a Cesarean section), the simple method of uterine cavity lavage with suction was performed. In group III (n=24, 6 of them had a Cesarean section), the method of vaginal irrigation using a fountain syringe with a Morozov nozzle was used in complex therapy. The complex

treatment of endometritis for women of all groups included antibacterial (ampicillin, gentamicin, metronidazole), anti-inflammatory (diclofenac), infusion, immunomodulatory (interferon-α-2), restorative (vitamins) and uterotonic (oxytocin) therapy.

Before treatment, women in all groups had lower abdominal pain, weakness, fever, vaginal blood-tinged, or purulent discharge of varying intensity. After the first day of treatment, there were no significant changes in the clinical manifestations of endometritis between the groups.

By the 5th day of treatment, 21 out of 25 (84.0%) women in group I noted the disappearance of manifestations of endometritis, while in group II there were only 7 out of 21 (33.3%) women, and in group III — just 4 out of 24 (16.7%) patients (p I–II = 0.012, p I–III = 0.007). In the rest of the women, the longest remaining complaints were bloody discharge and lower abdominal pain.

By the 7th day of treatment, symptoms remained in 5 (23.8%) women in group II, in 8 (33.3%) patients in group III. The average number of procedures, required to achieve cure, was 5.08±1.03 in group I, 6.04±0.9 in group II, and 6.4±0.5 in group III (p I–II<0.05; p I–III<0.001; p II–III>0.05).

During treatment in patients of group I, the average uterus volume after 3 procedures (the 3rd day of treatment) decreased by 2 times (up to 182.5±10 cm^3); similar results were obtained in group II by the 5th day, and in group III by the 8–9th day (p I–II<0.05, p I–III<0.05).

Despite complex therapy, 7 (28.0%) women from group I, 11 (52.4%) from group II, and 17 (70.8%) from group III needed to carry out hysteroscopic tissue removal (histologically identified residues of decidual cells and fibrin). Thus, the surgical intervention in the patients of the main group was significantly less frequent (p<0.05) than in the puerperas of groups I and II.

The average bed–day in group I was 13.1±1.3 days, in group II 17.2±0.9 days, and in group III 20.9±2.0 days (p I–II<0.001, p I–III<0.001, p II–III<0.001).

The use of LFUS for postpartum infection is more effective than the uterine cavity lavage with suction and vaginal irrigation using a fountain syringe with a Morozov nozzle. The use of LFUS in the treatment of postpartum endometritis can reduce the frequency of surgical intervention into the uterine cavity, shorten the hospital stay and reduce the pill burden on a nursing mother.

The second study included 60 puerperas with mild postpartum endometritis [88]: group I (n=20), as part of a complex therapy, underwent intrauterine lavage with a cavitated antiseptic solution (10 ml of 1% Dioxidine per 200 ml of Saline) for 3–5 minutes daily, 3 procedures per course; group II (n = 20) underwent intrauterine lavage with a cavitated Betaleikin solution (1 μg of Betaleikin medicine per 400 ml of

Saline) for 3–5 minutes every other day, 2 procedures per course; group III (n=20) did not receive ultrasonic intrauterine lavage. All patients were given antibiotics (cephalosporins, penicillins for 3–5 days), uterotonics, antianemia drugs (for indications).

In group I, temperature normalization and lochia color change occurred on the 2–3rd day of treatment in 92% of patients. The normalization in the level of leukocytes, CRP, IL-1, IL-6, and TNF–α was observed on the 5–6th day of treatment. After the procedures (on the 4th day of treatment) ultrasonic uterine size corresponded to the 9.0±1.5th week, there was no echogenic material in the uterine cavity.

In group II, after the first procedure, all patients showed a short–term increase in temperature by 0.5 °C, then the temperature returned to normal. Pain relief occurred on the 2–3rd day of treatment in 93% of patients in both groups I and II. On the 5–6th day of the observation, there was a normalization of the interleukin inflammatory status indicators, a more pronounced reduction in the expression of the proinflammatory cytokines TNF–α compared with group I. After the second procedure (on the 4th day of treatment), ultrasonic uterine size corresponded to the 9.0±1.5th week, there was no echogenic material in the uterine cavity.

In group III, temperature cutback, pain relief was observed on the 2–3rd day against the background of treatment in only 67% of patients. IL-1 and TNF–α levels remained increased ($p<0.05$ compared with groups I and II) and their normalization was noted only on the 7–9th day. On the 7th day of treatment, ultrasonic uterine size corresponded to the 9.0±1.5th week, there was no echogenic material in the uterine cavity, which is three days later than the groups that received LFUSC. The menstrual cycle in all patients recovered in 3–5 months after birth.

Complaints, clinical, functional, and laboratory features were assessed 6 months after the treatment of postpartum endometritis to analyze long–term results and identify chronic endometritis. In group I, echographic diagnosis revealed chronic endometritis in 25% of women, and histologically it was confirmed in 15% of patients. In group II, echographic diagnosis revealed chronic endometritis in 15% of women, in 5% of patients, it was histologically confirmed. In group III, echographic diagnosis revealed chronic endometritis in 85% of women, it was histologically confirmed in all cases.

Thus, the use of the intrauterine lavage with solutions cavitated by LFUS for patients with mild postpartum endometritis, in combination with local cytokine therapy (Betaleikin), is highly effective, since it contributes to the rapid and persistent relief of the acute inflammatory process, prevents relapses and the transition of the inflammatory process to a chronic stage.

5.3 Postpartum perineal ulcers

A comparative analysis of postpartum perineal ulcer treatment by complex therapy with Levomekol ointment applications and irrigation with antiseptic solutions cavitated by LFUS was carried out [76]. The study involved 30 women who were divided into 2 groups: in group I (n = 15), the perineal wound was treated with hydrogen peroxide 3% solution twice a day, followed by the application of a tampon with Levomekol ointment, in group II (n = 15) the wound was irrigated for 5 minutes with a cavitated Chlorhexidine Gluconate 0.05% aqueous solution. Conventional antibacterial and antifungal therapy was performed in all patients (since the primary disease was metroendometritis, and perineal ulcer was a concomitant disease).

Upon admission to the department, subjective symptoms were assessed on a 4 point scale and were identical in both groups: pain in the perineal region was assessed at 4.0 points in group I, in group II an average score was 3.8±0.2; itching by 2.5 points was assessed by the patients of both groups; burning — by 3.4 points. Also, all women had swelling of the perineum, fibrous plaque. Wound size in group I was 36±2 mm, in group II it was 38±3 mm.

On the 3rd day of treatment, complaints of patients in group II decreased significantly: pain was assessed by 1.0±0.1 points, while in patients of group — 3.3±0.1 points; itching in the II group characterized by 0.6±0.1, and the I group — by 1.8±0.2; burning was estimated at 0.3±0.5 points in group II and 2.4±0.3 points in group I.

By the 7th day of treatment, subjective and objective symptoms decreased in both groups, but more intensively in group II. In group I, secondary sutures were applied on average at the 7.8±1.0th day of treatment, in group II — at the 5.2±0.8th day.

Thus, ultrasonic irrigation of the damaged area with cavitated antiseptic solutions allows you to quickly stop the subjective symptoms (pain, itching, burning), cleanse the wound from fibrous plaque, stimulate the appearance of granulations and create conditions for the earlier application of secondary sutures, which ensures recovery of perineal tissue and prevents the development of genital prolapse in the future.

5.4 Acute postpartum hemorrhoids. Case reports

The authors of the case report below (E. Y. Glukhov, E. I. Neff) [91] have 5 years of experience in the treatment of acute postpartum hemorrhoids using cavitated antiseptic solutions. Treatment with a cavitated solution of the perianal region and perineum was carried out twice a day for 2–3 min using Chlorhexidine Gluconate aqueous solution. A decrease in clinical symptoms was observed by the end of the 1st day of treatment, swelling disappeared on the 2–3rd day. The high efficiency of the treatment regimen for

grade III and IV hemorrhoids (six cases of grade III and two with thrombosed hemorrhoids that avoided surgery) was especially clearly manifested.

Case report

Patient A., 27 years old woman, was admitted to the Regional Center of Postpartum Diseases (Department of Obstetrics and Gynecology of Municipal Budgetary Institution "Central City Hospital No.7", Ekaterinburg, Russia) from the maternity hospital on the 3rd day after spontaneous vaginal delivery at 38 weeks of pregnancy with time without amniotic fluid of 42 hours. The diagnosis at admission was "Postpartum endometritis. Acute hemorrhoids". The patient was multigravida, primigravida. In childbirth, a second-degree perineal tear occurred.

On admission, the patient complained of nagging lower abdominal pain, temperature rise to 38 °C. Also, 5–6 hours after birth, she noted itching and nagging pain in the rectum area, which later intensified.

Anamnesis morbi: the patient has been suffering from chronic hemorrhoids for 5 years. In the maternity hospital, antibiotic therapy and rectal suppositories were prescribed. On the 2nd day after childbirth, hemorrhoids appeared, which significantly increased by the 3rd day, the pain increased. According to the clinical examination, upon admission to the obstetric department, the patient noted swelling and looseness of the perineal sutures, which, in combination with acute endometritis (suppuration), often transforms into a puerperal ulcer. The surgeon diagnosed "Acute third-degree external-internal hemorrhoids".

The complex therapy included heparin ointment in combination with a rectum and perineum irrigation with Chlorhexidine Gluconate aqueous solution for 3–4 minutes (500 ml per procedure), daily for 8 days.

Results of the treatment

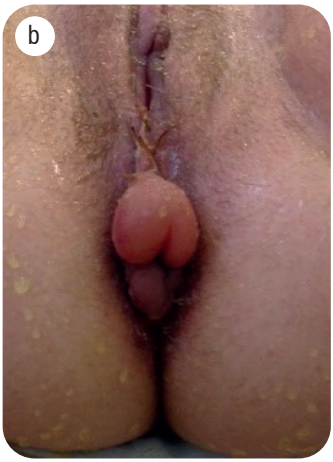
By the end of the 1st day of therapy, the patient noted a decrease in pain (it was completely stopped by the 3rd day of treatment) and in the tumor swelling.

Treatment with a rectum and perineum irrigation led to the complete disappearance of inflammation in the suture zone already by the 2nd day, the wound healed by primary intention. The complete elimination of acute hemorrhoids occurred by the 7th day, the patient was discharged on the 10th day in satisfactory condition.

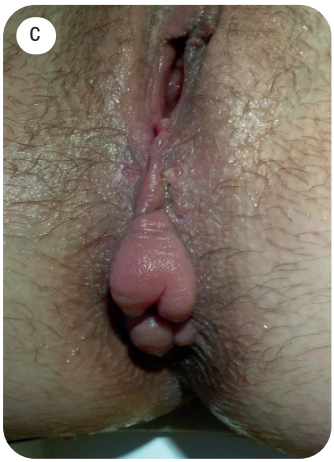
The dynamics of the clinical progression under the ultrasonic therapy is shown in Fig. 36.



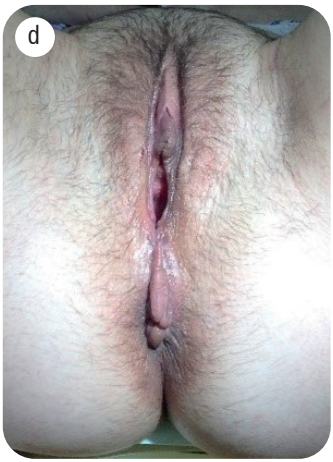
The 3rd day after spontaneous delivery. Postpartum endometritis. Acute third-degree hemorrhoids. Sutured second-degree tears. Acute pain



The 2nd day of ultrasonic treatment with a cavitated solution. Minimal pain



The 5th day of ultrasonic treatment. Perineal suture heals per primum. No pain. Minor tumor swelling



The 8th day of ultrasonic treatment. Completely collapsed hemorrhoids

Fig. 36 — The dynamics of the clinical progression of acute postpartum hemorrhoids under the ultrasonic therapy

5.5 Preparation for cervical cerclage procedure and vaginal pessary installation at risk of third-trimester miscarriage

The study involved 64 patients admitted to the department of pregnancy pathology for cervical cerclage due to cervical insufficiency [92].

The median gestational age was 19.7 weeks. Women complained of the lower abdomen pain (45.3%), smelling leucorrhoea (64.1%), and itching in the perineum (18.7%). Patients of group I (n = 34) received ultrasonic irrigation with a cavitated povidone-iodine solution in 1:20 dilution with sterile Saline. Group II (n = 30) were treated with a sitz bath with the same solution, but without LFUSC.

To achieve the result of treatment, on average, 2.8±0.6 procedures in group I and 3.7±0.8 in group II were required (p = 0.0002). Lower abdominal pain, leucorrhoea, and vaginal odor disappeared by the 3rd day of treatment in group I and by the 5th day in group II.

Thus, the use of LFUSC makes it possible to prepare for cervical cerclage procedure and vaginal pessary installation in women with cervical insufficiency in a shorter time.



A description of the clinical research described in this chapter is presented in research articles posted on the website www.fotek-med.com (section Information Center >> Clinical results).



CONCLUSION

Thus, the use of drug solutions cavitated by low-frequency ultrasound is an effective method of PID therapy.

The treatment of nonspecific vaginitis, recurrent candidiasis, and lower genital tract associated with mycoplasma using LFUSC makes it possible to heal a few days faster, restore normal flora 2.5 times more often, significantly reduce the frequency of relapses compared to conventional methods of treatment. These advantages make it possible to apply the USC method in the complex preparation for surgical interventions (vacuum aspiration, prolapse surgery, cervicoplasty, etc.), which reduces infectious complications.

LFUSC demonstrated a significant advantage in the prevention and treatment of chronic endometritis. After acute postpartum endometritis and the end of a non-developing pregnancy, chronic endometritis occurred 2.5–5 times less often than in those cases when the patients did not receive such treatment.

Therapy of chronic endometritis with endometrial hypoplasia using cavitated immunomodulatory solutions leads to its complete cure, an increase in the endometrial thickness, and the onset of pregnancy.

The impact on the immune system to reduce infectious and inflammatory diseases of various localization can be successfully implemented with the use of cavitated immunomodulatory drugs. The introduction of combined physio and pharmaco-therapy methods in the treatment and prevention of chronic genital tract inflammation makes it possible to make treatment regimens more effective, convenient to use, and less resource-intensive.

TEST TASKS AND CLINICAL CASE STUDIES

Two or more answers were allowed for some questions.

1. Ultrasonic vibrations include

a) any mechanical vibrations
b) mechanical vibrations of frequencies below 20 kHz
c) electric vibrations of high frequencies
d) mechanical vibrations of frequencies above 20 kHz

2. The formation of microscopic vapor bubbles in an ultrasound-transmission medium is called

a) ultrasonic cavitation
b) ultrasonic interference
c) ultrasonic diffraction
d) quasi-static process

3. The process of mixing liquid by cavitation bubbles' flows is called

a) fluctuation
b) cavitation bubbling
c) Brownian motion
d) emulsification

4. The biological effects of low-frequency ultrasound include

a) bactericidal
b) micromassage
c) necrolytic
d) phonophoretic
e) all answers above are correct

5. Under the influence of LFUS on aqueous drug solutions _____ occurs:

a) ultraviolet radiation
b) disintegration of water molecules
c) ultrasonic cavitation
d) crystallization
e) cavitation bubbling
f) acoustic streaming

6. The main function of the ultrasonic handpiece's protective cover is

a) decorative function

b) protection of the ultrasonic tip from cracking

c) protection of patient tissues from direct contact with an activated ultrasound tip

d) providing a better view of the treated area

7. Acoustic oscillations generated by the ultrasonic surgery cavitational device "FOTEK" are

a) high-frequency radio waves

b) high-frequency ultrasonic

c) low-frequency ultrasonic

d) infrasonic

8. The ultrasonic surgery cavitational device "FOTEK" allows to realize

a) impact on tissues without the transmission of ultrasonic vibrations (non-contact spraying)

b) impact on tissues through a sound-transmission medium (liquid)

c) impact on tissues directly with an ultrasound tip (contact debridement)

d) all answers above are correct

9. Contraindication to the ultrasonic cavitation method are

a) bleeding of unknown origin

b) acute hemorrhoids

c) postoperative purulent wounds

d) menstruation

e) pronounced uterine excitability during pregnancy

10. Indications to the ultrasonic cavitation method are

a) acute and chronic endometritis

b) postoperative purulent wounds

c) uterine hyperstimulation during pregnancy

d) endometriosis

e) decubital ulcers

11. Ultrasonic intrauterine lavage in the treatment of chronic endometritis during the menstrual cycle is recommended to be carried out since the

a) 5–9th day

b) 12–15th day
c) 17–20th day
d) 24–28th day

12. Indications for uterine cavity lavage after birth for the prevention of postpartum endometritis are
a) hyperthermia during labor
b) long latency period in labor
c) cervical pessary use, cervical cerclage
d) vaginal tear during labor

13. When exposed to tissue, LFUS provides
a) cleansing of the treated areas from bacterial films and pathological deposits
b) normalization of phosphorus and calcium metabolism
c) deep impregnation of drugs into tissue
d) normalization of water and salt balance in the organism
e) reduction of microbiological contamination of tissues
f) improving the mechanical strength of bone tissue
g) improving microcirculation and metabolic processes in tissues (micromassage)

14. Ultrasonic cavitation on the wound bed causes
a) suppression of bacterial growth
b) acceleration of reparative processes
c) faster cleansing of the wound from necrotic tissue
d) hypercoagulation

15. For the uterine cavity lavage in the treatment of chronic endometritis, which ultrasonic handpiece is intended?
a) AA211.5
b) AA207.5
c) AA201.5
d) AA208.5 with AA108–2 protective cover

16. For the ultrasonic irrigation of the lower genital tract, it is possible to use the ultrasonic handpiece AA208.5 more than once after sterilization if
a) tissue processing is carried out by a non-contact method
b) a sterile protective cover is used for each procedure

c) an ultrasonic handpiece during the procedure does not touch the patient's tissues and contaminated instruments, and is not immerse in liquids in contact with the patient
d) tissue processing is carried out without using a protective cover
e) tissue processing is carried out by the cavitation bubbling method
f) after each procedure, the ultrasonic tip which is located under the protective cover and the housing of the ultrasonic handpiece are wiped with disinfecting wipes (wipes allowed for skin disinfection should be used).

17. Drain holes in the protective cover for the uterine cavity lavage are provided for
a) air cooling of the ultrasonic tip
b) supply of solution into the uterine cavity
c) ensuring the outflow of fluid from the uterine cavity during the procedure
d) protection of the ultrasonic tip against external damage

18. The solution flow rate during the ultrasonic intrauterine lavage should be
a) no more than 2 drops per second
b) at least 4 drops per second
c) 5 drops per minute
d) 100 ml per hour

19. The required drug solution volume for one procedure of ultrasonic genital tract irrigation is
a) 20–50 ml
b) 5–10 ml
c) 1–2 l
d) 100–500 ml

20. The average duration of ultrasound exposure during the procedure of ultrasonic genital tract irrigation is
a) 10–20 seconds
b) 15–20 minutes
c) 3–5 minutes
d) 30 minutes

Answers to test questions

1	d
2	a
3	b
4	e
5	b, c, e, f
6	c
7	c
8	d
9	a, d, e
10	a, b, e
11	a
12	a, b, c
13	a, c, e, g
14	a, b, c
15	a
16	a, b, c, f
17	c
18	b
19	d
20	c

TEST CLINICAL CASE STUDIES

1. Patient R., 60 years old woman, complains of the appearance of a dome-shaped bulge coming out of the vagina. Anamnesis morbi: 3 vaginal deliveries, in the 1st birth — second-degree perineal tear, perineorrhaphy; in the 2nd birth — episiotomy, perineorrhaphy, complicated by postpartum ulcer, wound healing by secondary intention; the 3rd birth without complications. The birth weight of the babies was 3.8, 4.0 and 4.2 kg, respectively. Menopause lasts 10 years. Menopausal hormone therapy was not performed. 2 years ago, stress urinary incontinence and a dome-shaped painless bulge at the vaginal opening began to appear periodically, but the patient did not seek medical help.

Examination of the perineum showed: the interlabial space is gaping, at the vaginal opening there is a rounded soft-elastic formation with a diameter of 6 cm, extending beyond the vaginal opening. The formation's mucous membrane is rough, dry, with multiple petechial hemorrhages. On the right lateral wall of the formation, there is a defect of the mucous membrane with a diameter of 4 cm, rounded, red with small cracks, which appeared 3 months ago. The patient used ointment applications, with no effect.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;
- determine the treatment method for the mucous membrane;
- select the optimal ultrasonic cavitation mode.

2. Patient R., 25 years old woman, complained of pain in the perineum, pus-like vaginal discharge, vaginal odor. 3 weeks ago, a term vaginal birth took place with a birth weight of 3.9 kg, during which there was a second-degree perineal tear, posterior vaginal wall mucosa tear. The patient was discharged from the hospital on the 3rd day without complications, but soon there were nagging pains in the perineum, the bloody vaginal discharge was replaced by yellow-green thick discharge with an odor.

On examination: the perineum and posterior vagina wall sutures parted for 4 cm, remnants of the ligatures are visible, the wound is covered with flaccid granulations, bleeds easily, there is a fibrinous plaque. The edges of the wound are hyperemic.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;
- determine the treatment method for the vagina and perineum mucous membrane;
- select the optimal ultrasonic cavitation mode.

3. Patient U., 29 years old woman, complained of aching pains in the lower abdomen, copious purulent vaginal discharge, an increase in body temperature within 4 days to 37.2 °C. The patient took antipyretics and analgesics without effect. 2 weeks ago, there was a preterm vaginal birth at 35 weeks, vaginal birth with a birth weight of 2.1 kg. Amniotic fluid leaked out 48 hours before the onset of labor. During childbirth and in the early postpartum period, there were no abnormalities. The patient was discharged from the hospital on the 5th day.

On examination: the abdomen is soft, moderately painful above the pubis; behind the pubis, a rounded softish uterus is palpable, slightly painful on palpation. There was copious sanguinopurulent vaginal discharge with an unpleasant odor. Examination using vaginal speculum revealed that the vaginal and cervical mucosa are hyperemic, from the cervical canal there is a copious sanguinopurulent discharge. A bimanual exam revealed: the cervix is a 2 cm long canal, freely passable for the examining finger, movements behind the cervix are moderately painful. The uterus is enlarged up to 10 weeks, soft, painful on palpation.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;
- determine the treatment method for the vagina and perineum mucous membrane;
- select the optimal ultrasonic cavitation mode.

4. Patient T., 32 years old woman, complained of unsuccessful attempts to get pregnant for 9 years, the therapy for infertility was ineffective. Anamnesis morbi: medical-surgical abortion at 11 weeks at the age of 18 years, 4 years later, incomplete spontaneous abortion at 8 weeks with surgical curettage and subsequent antibiotic therapy. The patient has not used contraception for the last 10 years. Menstruation from the age of 12 was established immediately and was regular — after 28 days for 4 days.

3 years ago, after suffering a respiratory illness, the patient began to notice episodes of delayed onset of menstruation up to 14–25 days. Hormone therapy with progestogens in courses of 3–4 months gave an effect for 3–4 cycles, then disturbances arose again. 3 months ago, on the 10th day of the cycle, endometrial biopsy during hysteroscopy was performed: the endometrium is pale, with areas of thinning and focal hyperplasia. Morphologically: the endometrium is in the proliferative stage, the uterine glands are narrow, the pronounced stromal infiltration of leukocytes.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;

- determine the treatment method for the uterine pathology;
- select the optimal ultrasonic cavitation mode.

5. Patient A., 28 years old woman, applied for a surgical abortion at a gestational age of 10 weeks. Anamnesis morbi: this pregnancy is the second, 2 years ago there was a term birth by C-section without complications. The patient did not use contraception. This pregnancy is unwanted and unplanned. During the last year, episodes of vaginal candidiasis have occurred three times, the patient took systemic and local therapy with a short-term effect. On examination, slight hyperemia of the vaginal opening mucosa was revealed.

Examination using vaginal speculum revealed that the vaginal mucosa is hyperemic, edematous; leucorrhoea is white, flocculent, abundant; the cervix is cylindrical, hypertrophied, around the external os there is a 2 cm ectopia, from the canal there is cloudy discharge, in small quantities.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;
- determine the treatment method for the vaginal pathology;
- select the optimal ultrasonic cavitation mode.

6. Patient M., 23 years old woman, complained of pain in the postoperative suture after a caesarean section and liquid discharge from the wound. 10 days ago, there was a term birth by C-section due to the labor weakness, a long period without amniotic fluid (18 hours), meconium aspiration syndrome. Blood loss during labor was 1000 ml. Intravenous therapy with crystalloids was carried out, antianemic therapy was started. Hemoglobin before discharge was 105 g/l. On the 3rd day, a seroma was opened in the right corner of the postoperative suture, a rubber drain was inserted, and on the 3rd day, the drain was removed. On the 5th day after the Cesarean section, the patient was discharged.

On examination: the patient is obese, the skin is pale. The abdomen is enlarged due to the pronounced subcutaneous fat layer, soft, painful in the postoperative suture area after laparotomic transverse suprapubic incision. When the dressing was removed, it was found that the continuous intradermal suture was hyperimposed along the entire length, there was a fibrinous plaque. In the right corner, a suture defect for 4 cm was found, in the wound was purulent discharge. Wound probe showed that the depth of the wound was 5 cm, up to the aponeurosis. In the other sections of the seam, the purulent discharge was found. The skin suture was removed. The wound was a gray fiber, with

flaccid granulations, covered with a purulent-fibrinous discharge, which was poorly separated from the tissues.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;
- determine the treatment method for the wound in the postpartum period;
- select the optimal ultrasonic cavitation mode.

7. Patient N., 37 years old woman, was referred for electrosurgical destructive treatment of cervical intraepithelial neoplasia (CIN) grade 2. Anamnesis morbi: 5 years ago, HPV type 16 was detected. The patient took immunomodulatory and antiviral drugs. The virus has not been eliminated. During this time, oncocytology smear tests were normal, no abnormal colposcopic images were detected during the annual examination. 3 months ago, liquid-based cytology revealed a severe lesion in the cervix — HSIL according to the Bethesda system. Colposcopy also revealed a lesion grade 2 according to the Rio de Janeiro classification. Morphological examination of the cervical biopsy material established the presence of cervical intraepithelial neoplasia grade 2.

Tasks:

- make a clinical diagnosis;
- determine the treatment regimen;
- select the optimal ultrasonic cavitation mode.

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Annex A. Assembly of the ultrasonic surgery cavitational device «FOTEK»



Fig. A.1 — Ultrasonic surgery cavitational device «FOTEK» (ACTITON-A model)

I. Initial assembly stage

1. Install the **ultrasonic unit** on the upper shelf of the trolley (Fig. A.1).

2. Connect the **footswitch** to the connector socket on the rear side of the device (Fig. A.3, pos. 12).

3. Connect the **power cord** first to the connector socket for the mains cable (Fig. A.3, pos. 15), and then to the grounded outlet (Fig. A.2).

4. Connect the plug of the selected **ultrasonic handpiece** to the **"ULTRASOUND" connector socket** on the front side of the device (Fig. A.3, pos. 11).

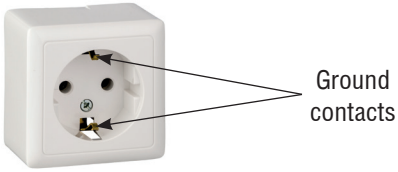


Fig. A.2 — Grounded outlet



Fig. A.3 — Front and rear sides of the ultrasonic surgery cavitational device “FOTEK”:
1 — button for switching on the “ULTRASOUND” mode; 2 — button for switching on the “SUCTION” mode; 3 — button for switching on the “IRRIGATION” mode; 4 — display of the ultrasonic power; 5 — button for adjusting the “TIMER” function; 6 — buttons for adjusting the ultrasonic power; 7 — button for calling up information about the connected ultrasonic handpiece; 8 — irrigation control valve; 9 — information about the connected footswitch and assignment of its functions; 10 — “STB” button (Stand-by — sleep mode); 11 — “ULTRASOUND” connector socket for an ultrasonic handpiece; 12 — connector socket for a footswitch; 13 — “SUCTION” connector socket for the suction tubing; 14 — mains switch; 15 — connector socket for the mains cable



Fig. A.4 — Ultrasonic handpiece holder on the trolley shelf

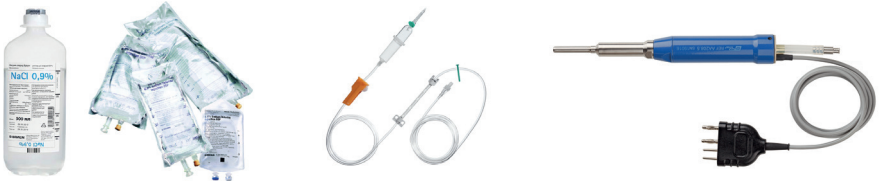
5. The **ultrasonic handpiece** can be placed in a special holder on the trolley shelf, if there is no need for its sterility (Fig. A.4).

6. Turn on the device by pressing the **mains switch** (Fig. A.3, pos. 14), the device will be in sleep mode. To start work, press the **"STB" button** on the front side of the device (Fig. A.3, pos. 10), then the light next to the button will go out and the touch screen will turn on. If it is necessary to put the device into sleep mode, press the **"STB" button** again (Fig. A.3, pos. 10), the light next to the button will go on and the touch screen will turn off.

II. Assembly of the irrigation path

The main components of the irrigation path are shown in Fig. A.5:

The "IRRIGATION" mode is recommended to be used only with the **infusion system "Infusomat Space Line"** (Fig. A.6) **AA120** (manufactured by B. Braun, 100 pcs.).



a b c

Fig. A.5 — The main components of the irrigation path:
a — container with a medicinal solution (bag or bottle); b — infusion system; c — ultrasonic handpiece

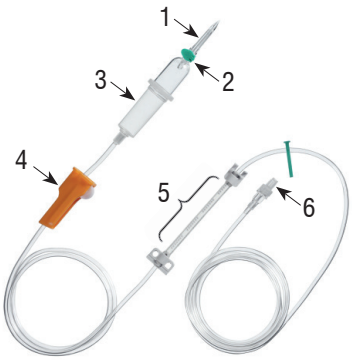
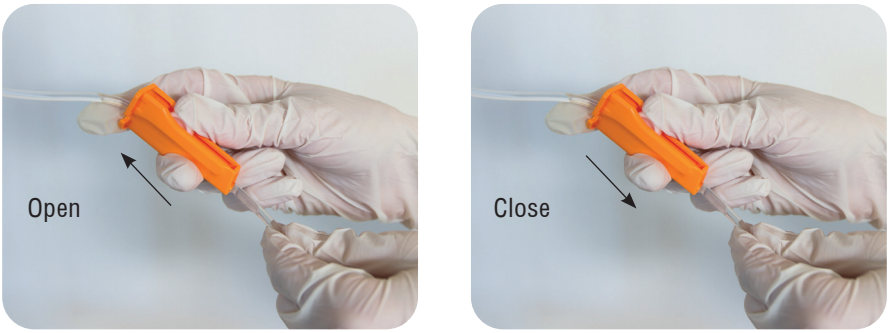


Fig. A.6 — "Infusomat Space Line" AA120:

1 — piercing spike;
2 — vent;
3 — drip chamber;
4 — roller clamp;
5 — silicone segment;
6 — Luer adapter

1. Close the roller clamp of the infusion system (Fig. A.7, b).



a b

Fig. A.7 — Opening (a) and closing (b) of the roller clamp of the infusion system

2. Insert the **piercing spike of the infusion system** (Fig. A.6, pos. 1) fully into the infusion bottle until it stops.

3. Hang the **infusion bottle** on the holder. The height of the infusion bottle holder is adjusted using the adjuster located on the holder (Fig. A.1).

4. On the pipe connector of the ultrasonic handpiece (Fig. A.8, pos. 1), put on the adapter AA121 (Fig. A.8, pos. 2), which is included in the delivery set. Screw the back-check valve **AA118** into the adapter (Fig. A.8, pos. 3), after removing the protective cap from it. Valves (50 pcs/pack) are included in the delivery set

Attach the **Luer adapter of the infusion system** to the valve (Fig. A.8, pos. 4), after removing the protective cap from it.

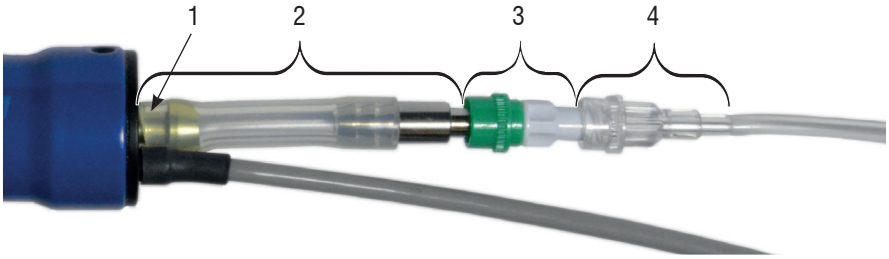


Fig. A.8 — Connecting irrigation accessories to the ultrasonic handpiece:
1 — pipe connector; 2 — adapter AA121; 3 — back-check valve AA118;
4 — distal end of the infusion system AA120

CAUTION! When the distal end of the ultrasonic tip is immersed in a cavity with liquid, liquid may produce backflow from the cavity into the irrigation channel of the handpiece

and in the infusion system connected to it. The valve does not allow fluid to rise along the channel of the ultrasonic handpiece in a reverse direction and prevents the possible entry of fluid from the treated cavity into the infusion system.

It is allowed to work without the AA118 adapter when using a sterile infusion system and a sterile ultrasonic handpiece for each procedure, as well as when performing non-contact ultrasonic debridement (when there is no contact between the patient's tissues and the handpiece elements during the procedure).

5. Open the **vent on the infusion system** (Fig. A.6, pos. 2).

6. Fill the drip chamber of the infusion system (Fig. A.6, pos. 3) with the solution approximately halfed by squeezing it.

7. To check if the irrigation path is working, place a container under the ultrasonic handpiece. **Open the roller clamp of the infusion system** (Fig. A.7, a), after which the system will begin to fill with the drug solution. When the solution fills the system and begins to flow out of the ultrasonic handpiece channel, close the roller clamp of the infusion system (Fig. A.7, b).

8. Insert the **silicone pump segment of the infusion system** (Fig. A.6, pos. 5) into the irrigation control valve on the front side of the devise by pressing the button in the center of the valve (Fig. A.9, a). Release the button and make sure that the gap of the silicone segment is closed by the valve (Fig. A.9, b).



a b

Fig. A.9 — To connect the infusion system to the irrigation control valve:
a — press the valve button; b — release the valve button

9. Open the **roller clamp** of the infusion system (Fig. A.7, a).

10. Turn on the "IRRIGATION" mode by pressing the "IRRIGATION" button (Fig. A.3, pos. 3) on the device's touch screen. Check that the "ULTRASOUND" and "SUCTION" modes are disabled (ie the buttons with the mode names (Fig. A.3, pos. 1 and 2) are not highlighted). Otherwise, they must be disabled by pressing the correspondingly lit button.

11. Activate the "IRRIGATION" mode by pressing any pedal of the double-pedal or

single-pedal footswitch. Make sure that the solution flows out of the handpiece channel in a thin jet.

12. Using a roller clamp (Fig. A.6, pos. 4), set the required liquid flow rate (for most applications it should be maximum).

13. When the pedal is released, the solution supply to the handpiece will stop.

NOTE: The **irrigation control valve** (Fig. A.9) has the function of automatical closing or opening the solution supply to the ultrasonic handpiece. At the moment of the "IRRIGATION" mode activation, the valve opens, the silicone pump segment is opened and the solution is supplied to the handpiece. At the moment of the "IRRIGATION" mode termination (releasing the pedal), the valve squeezes the silicone pump segment (Fig. A.9, b) and the solution supply is terminated.

CAUTION: When using **another infusion system**, it is necessary to close and open the solution supply **manually** (using a roller clamp). In this case, the "IRRIGATION" mode should be turned off.

III. Assembly of the suction path (for model ACTITON-A)

The main components of the suction path are shown in Fig. A.10.



Fig. A.10 — The main components of the suction path:
a — Suction tubings (d. 6 mm, lengths 0.9 m and 2 m); b — suction jar; c — suction nozzle (top — reusable, bottom — disposable)

1. Attach **elbows** to the jar vacuum ports (elbows are included in the jar set, Fig. A.10, b). Place the jar in the holder located at the back of the rack column.

2. A short suction tubing (0.9 m, Fig. A.10, a, the left one) is used to create a vacuum in the suction jar. Connect one end of it to the "SUCTION" connector socket on the rear side of the device (Fig. A.3, pos. 15), and the other end to the jar port marked "VACUUM" using the elbow.

3. A long suction tubing (2 m, Fig. A.10, a, the right one) is designed to remove fluid from the operating area. Attach one end of it through the elbow to the jar port "PATIENT". The other end of the tubing can be installed in a special holder on the trolley shelf

(Fig. A.11, the left one). For convenience, you can hang the excess tubing on a special hook (Fig. A.11, the right one).



Fig. A.11 — Suction tubing holder

NOTE: Improper connection of the tubings can lead to fluid entering the pump of the ultrasonic unit and damage to the device.

4. To remove fluid from the treated area, attach a **reusable or disposable suction nozzle** (Fig. A.10, c) to the distal end of the long suction tubing (Fig. A.12).



a b

Fig. A.12 — Connecting the suction nozzles to the suction tubing:
a — connection of a reusable nozzle; b — connection of a disposable nozzle

5. Switch on the "SUCTION" mode by pressing the "SUCTION" button on the device touch screen (Fig. A.3, pos. 2). **Activate the "SUCTION" mode** by pressing any pedal on

the double-pedal or single-pedal footswitch.

NOTE: The modes “IRRIGATION” and “SUCTION” can be activated simultaneously. Therefore, when the “SUCTION” mode is activated, solution will begin to flow out of the handpiece channel if the “IRRIGATION” mode is also on.

6. To check that the “SUCTION” mode is working, take a small container of liquid, lower the suction nozzle into it and make sure that liquid is aspirating from the container.

7. Releasing the pedal stops fluid suction.

IV. ACTIVATION OF THE ULTRASONIC MODES

1. On the device touch screen, **turn on the “ULTRASOUND” button** (Fig. A.3, pos. 1). The power level of ultrasonic vibrations (Fig. A.3, pos. 4) is regulated by buttons “+” / “-” on the touch screen (Fig. A.3, pos. 6).

Set the recommended power level for the procedure.

When connecting handpieces AA211.5, AA207.5, the level of ultrasonic vibrations is set automatically (the inscription “AUTO” appears on the touch screen). If necessary, the power level can be reduced by pressing the “LOW AUTO” button (Fig. A.14).

2. Activation of the “BASIC” mode is carried out by pressing the yellow pedal of the double-pedal footswitch, the “SELECT” mode — by pressing the blue pedal (Table 1 gives a comparative description of these modes).

If a single-pedal footswitch is connected, then at the bottom of the device screen there will be two images of a single-pedal footswitch: with yellow and blue pedal (Fig. A.13). If the yellow pedal is highlighted, the footswitch will activate the “BASIC” mode (Fig. A.13). If the blue pedal is highlighted, the footswitch will activate the “SELECT” mode.

If the device is assembled correctly, then after pressing the footswitch, a directed fine jet of liquid (cavitation jet) should come out of the handpiece’s irrigation channel (Fig. A.7).

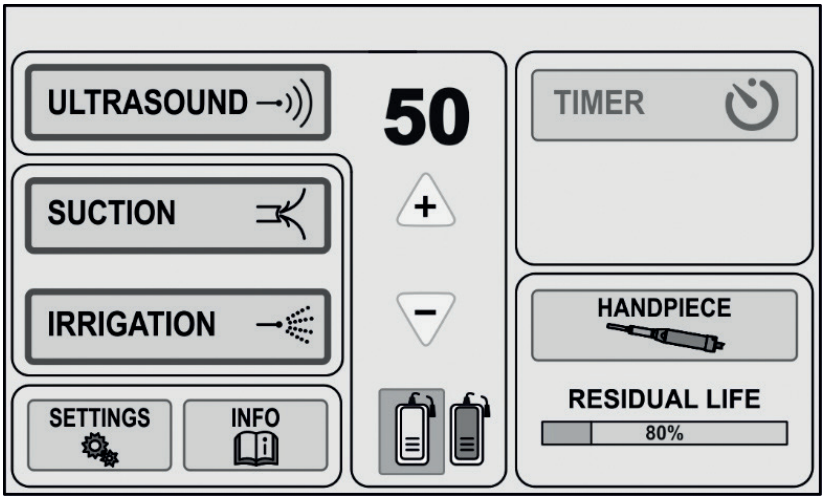


Fig. A.13 — Touch screen when connecting a single–pedal footswitch and an ultrasonic handpiece (except when connecting AA211.5, AA207.5 handpieces)

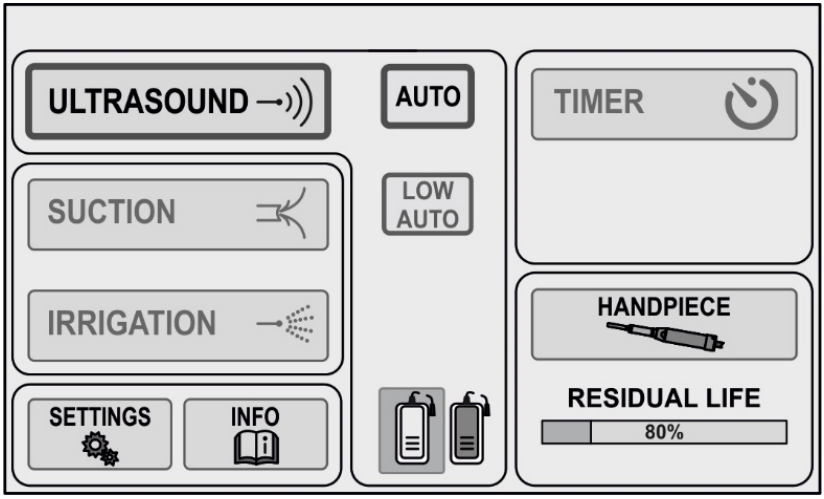


Fig. A.14 — Touch screen when connecting a single-pedal footswitch and an AA211.5 or AA207.5 ultrasonic handpiece

NOTE: The "IRRIGATION", "SUCTION" and "ULTRASOUND" modes can be activated both together and separately. For most procedures, all three modes are used simultaneously.

CAUTION: When the "ULTRASOUND" modes are activated, the solution must **necessarily** flow through the irrigation channel of the ultrasonic handpiece, otherwise the

handpiece will not be cooled and may overheat. To do this, the infusion system and the irrigation channel of the ultrasonic handpiece must be completely filled with a **medicinal solution before activating the "ULTRASOUND" modes** (see Annex A, section II Assembly of the irrigation path).

3. The intensity of the cavitation jet is determined by the power level of ultrasonic vibrations, the set liquid flow rate, and hydrostatic pressure of the liquid in the handpiece's irrigation channel. Hydrostatic pressure depends on the height of the infusion bottle: the higher the infusion bottle is, the more powerful the cavitation jet created by the device, and the stronger it strikes the tissues.

V. AUXILIARY FUNCTIONS

1. Timer

The "TIMER" function is designed to set the time of ultrasonic exposure. To do this, press the **"TIMER" button** on the display of the device (Fig. A.3, pos. 5) and set the required time, after which the activation of ultrasonic vibrations should stop. To resume work, you need to press the footswitch again. If the time on the timer has not expired, and the countdown must be restarted, then press the "RESET" button, then the timer will be updated.

If the "TIMER" function is disabled, then the device turns off automatically every minute for convenience of counting minutes. To resume the operation of the device, you must press the footswitch again.

2. Information about the connected ultrasonic handpiece

When the ultrasonic handpiece is connected, the screen under the **"ULTRASONIC HANDPIECE" button** will display information about the type of the connected handpiece, its serial number and the number of working cycles (Fig. A.13). Pressing the button will display help information about the connected ultrasonic handpiece.

3. Screen brightness and volume level

By pressing the **"SETTINGS" button** (Fig. A.3), you can change the screen brightness and the volume level of the device's beeps.

4. Background information

By pressing the **"INFO" button** (Fig. A.3), you can view brief information on the use of the device.

Annex B. Disinfection and sterilization of the ultrasonic unit and accessories

Disinfection and sterilization of the ultrasonic unit and accessories

1. The ultrasonic unit, double-pedal footswitch, and trolley must be chemically disinfected by wiping twice with disinfecting wipes.

2. The suction jar is disinfected by autoclaving for **20 min at 110 °C**, pre-sterilization cleaning using its manufacturer's recommended agents. The suction jar can be sterilized by autoclaving for **20 min at 121 °C**. Since there is no contact between the jar and the patient's tissues, it is allowed only to disinfect it.



Fig. B.1 — A rinse of the channels with a solution using a syringe

3. The infusion system AA120, back-check valve AA118, and suction nozzle AA117-1 are disposable and must be disposed of.

4. The ultrasonic handpieces and their accessories (adapters, protective covers, replaceable ultrasonic tips, keys for fixing tips, handles), as well as reusable suction nozzles and suction tubings (hereinafter referred to as "the accessories") included in the delivery set, are disinfected, pre-sterilized and sterilized in the disassembled form (Fig. 12, Fig. 14, Fig. 17) according to the recommendations below.

WARNING! Do not sterilize the ultrasonic handpiece with hot air ovens.

WARNING! Do not use ultrasonic cleaners.

WARNING! Do not use agents containing hydrogen peroxide for disinfection, pre-sterilization cleaning, and sterilization of accessories.

Disinfection

Disinfection is recommended to be performed using the steam method (autoclaving) for **20 min at 110 °C**. If it is not possible to perform the recommended autoclaving method of disinfection, it can be carried out chemical disinfection with agents recommended by their manufactures for medical products made of metal, plastic, and rubber. Chemical disinfection is carried out according to the instruction manual for the cleaning chemical used.

For manual disinfection, accessories must be completely immersed in the agent. All accessible irrigation channels must be filled without airlocks. Be sure to rinse the channels with a disinfectant agent from the side of the proximal end using a syringe (Fig. B.1) or other devices.

After chemical disinfection, the accessories must be **thoroughly washed from the agent**. Special attention should be paid to washing the internal channels of the ultrasonic handpiece. Accessory channels are rinsed with a syringe or a water jet pump for 3–5 minutes. The remaining contaminants are thoroughly washed mechanically (with wipes, brushes, ruffs, etc.).

Pre-sterilization cleaning

Pre-sterilization cleaning is carried out manually or by machine according to the instruction manual for the product used. Pre-sterilization cleaning can be combined with disinfection if this is indicated in the instruction manual for the product used.

After pre-sterilization cleaning, the accessories must be **thoroughly washed from the agent**. Special attention should be paid to washing the internal channels of the ultrasonic handpiece. Accessory channels are rinsed with a syringe or a water jet pump for 3–5 minutes.

Further, the wash water should be removed from the internal channels of the accessories with a syringe or medical balloon inflation device, accessories should be completely dried.

Sterilization

Sterilization is recommended to be performed using the **steam method** (autoclaving) for **5 min at 134 °C**.

If it is not possible to perform the recommended autoclaving method of disinfection, it can be carried out a chemical disinfection with agents recommended by their manufactures for medical products made of metal, plastic, and rubber.

During the manual chemical sterilization, all manipulations must be carried out following aseptic conditions, using sterile water containers, sterile water, instruments, as well as sterile gloves to protect the hands' skin.

Accessories must be completely immersed in the sterilization agent. All accessible irrigation channels must be filled without airlocks. Be sure to rinse the channels with a disinfectant agent from the side of the proximal end using a syringe (Fig. B.1) or other devices.

After chemical sterilization, the accessories must be **thoroughly washed from the agent**. Special attention should be paid to washing the internal channels of the ultrasonic handpiece. Accessory channels are rinsed with a syringe or a water jet pump for 3–5 minutes.

Further, the wash water should be removed from the internal channels of the accessories with a syringe or medical balloon inflation device, accessories should be completely dried.

Annex C. Treatment regimens for ultrasonic irrigation using ultrasonic surgery cavitational device “FOTEK”

Table C.1 — Treatment regimens for irrigation of the vulva, vagina, vaginal portion of the cervix

The ultrasonic handpiece AA208.5 with protective cover AA108-2 is used. The ultrasonic exposure: “BASIC”. The liquid flow rate: maximum (for the power level of ultrasonic vibrations of 50 units) or average (for 30 units)					
Indications	**Solution (one of the following)**	**Solution volume for procedure, ml**	**Duration of exposure, min**	**Power level of ultrasonic vibrations, units**	**Average number of procedures**
Vaginal irrigation for vulvovaginal infections, cervicitis, bacterial vaginosis	Saline or antiseptic solutions	200–500	3–5	50	3–8 procedures, carried out once daily
Vaginal irrigation before intrauterine manipulations (artificial termination of pregnancy, hysteroscopy, etc.)	Chlorhexidine Gluconate 0.05% aqueous solution or other antiseptic solutions	100–200	1–2	50	1–5 procedures, carried out once daily
Vaginal irrigation for preoperative preparation of the genital tract before gynecologic surgery (vaginoplasty, prolapse surgery, etc.)	Chlorhexidine Gluconate 0.05% aqueous solution or Saline	200–500	2–5	50	Once a day before surgery or on the day of surgery (it is allowed to perform the procedure immediately before surgery)
Irrigation for decubitus ulcers to prepare for prolapse surgery or vaginal pessary installation (for decubital ulcers with purulent discharge and hyperkeratotic tissue, it is recommended to use the drug phonophoresis method described in Table C.5)	**Stage I**				**On an inpatient basis:** 3 or more procedures once daily **On an outpatient basis:** 5–7 procedures or more every day or every other day
	Chlorhexidine Gluconate 0.05% aqueous solution or Saline	500	4–5	50	
	Stage II (carried out immediately after stage I, this stage is optional)				
	Metronidazole 5.0 mg/ml solution or Ciprofloxacin 2 mg/ml solution	100	2	30	

Vaginal irrigation after transvaginal operations (prolapse surgery, vaginoplasty, hysterectomy, etc.)	Chlorhexidine Gluconate 0.05% aqueous solution or Saline	500	3–4	50	Local irrigation begins in the first postoperative day, once daily. Number of procedures depends on the timing of achieving an acceptable bacterial contamination of the vagina
Hygienic vaginal irrigation during pessary use	Chlorhexidine Gluconate 0.05% aqueous solution or Saline	300–500	3–5	50	Once every 1–3 weeks during the entire period of pessary use
Vaginal and cervical irrigation for CIN associated with HPV to eliminate the virus	Imunofan 0.005% solution in 1:50 dilution with sterile Saline or Allokin-alpha solution (1 mg (1 vial) of the medicine per 100 ml of Saline)	100	2–3	30–40	3–5 procedures before surgery; 3 procedures can be performed 10 days after surgery. The procedures can be performed at intervals of 2–3 days
Vaginal and cervical irrigation after surgical procedure for cervical pathology (conization, excision, diathermy, etc.)	Saline	100–300	2–3	50	1–3 procedures. Local irrigation begins no earlier than 10–12 days after surgery. The indication for the procedure is a significant amount of removed tissue and histologic confirmation of chronic cervicitis as biopsy result, as well as is copious purulent discharge after surgery
Irrigation of postpartum perineal, vaginal, and anterior abdominal wall suture lines to prevention suppuration	Chlorhexidine Gluconate 0.05% aqueous solution or Metronidazole 5.0 mg/ml solution	100–200	2–5	30–50	2–3 procedures, once daily. Local irrigation begins in the second postoperative (childbirth) day

Vaginal and vulva irritation for suppuration of postoperative wounds	**Stage I**				Within 2–10 days, once or twice daily
	Chlorhexidine Gluconate 0.05% aqueous solution; Betadine 10% solution in 1:10 dilution with sterile Saline; Octenisept solution in 1:10 dilution with sterile Saline; Metronidazole 5.0 mg/ml solution; Saline	300–500	2–5	50	
	Stage II (carried out a few hours after stage I, this stage is optional)				
	Metronidazole 5.0 mg/ml solution or Ciprofloxacin 2 mg/ml solution	100	2	30	
Irrigation for postpartum hemorrhoids	lidocaine 2% solution in 1:25 dilution with sterile Saline or Chlorhexidine Gluconate 0.05% aqueous solution	300–500	3–5	50	2–5 procedures (once or twice daily)
Genital tract irrigation for cervical cerclage	Betadine 10% solution in 1:20 dilution with sterile Saline	300–500	3–5	50	1–2 procedures before cervical cerclage and 2–3 procedures after, once daily
Vulvar lichen sclerosus et atrophicus	benzydamine hydrochloride 0.1% aqueous solution; nitrofural 0.02% aqueous solution (1:5000); Chlorhexidine Gluconate 0.05% aqueous solution	150–300	3–5	50	7 procedures, once daily

Table C.2 — Treatment regimens for irrigation of the uterine cavity

The ultrasonic handpieces AA207.5 and AA211.5 are used. The level of ultrasonic vibrations is set automatically by the device. The ultrasonic exposure: "BASIC". The liquid flow rate: maximum				
Indications	**Solution (one of the following)**	**Solution volume for procedure, ml**	**Duration of exposure, min**	**Average number of procedures**
Postpartum endometritis	Dioxidine 0,5% or 1% solution in 1:20 dilution with sterile Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Saline; Betaleikin solution (1 μg of the medicine per 400 ml of Saline)	300–800	5–10	3–8 procedures, carried out once daily
Prevention of postpartum endometritis	Dioxidine 0,5% or 1% solution in 1:20 dilution with sterile Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Saline	300–800	5–10	1–3 procedures, carried out once daily. The procedures are performed from 2 days after spontaneous vaginal delivery, and from 3–4 days after C-section.
Endometritis after abortion, miscarriage, non-developing pregnancy	Dioxidine 0,5% or 1% solution in 1:20 dilution with sterile Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Saline	200–300	3–5	3–5 procedures are performed on the 2–3 day after removal of an embryo. In women who previously had non-developing pregnancy, the procedure is recommended to be carried out since the 7–9th day of the menstrual cycle.
Chronic endometritis, endometrial hypoplasia, in preparation for ART (IVF, embryo transfer)	**Stage I**			The procedure is recommended to be carried out since the 5–9th day of the menstrual cycle. In one course, 5–10 procedures are carried out, once daily. The courses are recommended to be carried out in each menstrual cycle.
	Dioxidine 0,5% solution in 1:20 dilution with sterile Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Saline,	200–300	3–5	
	Stage II (carried out in the next menstrual cycle after stage I)			
	The stage I solutions; Imunofan 0.005% solution in 1:50 dilution with sterile Saline	200–300	3–5	
	Stage III (carried out in the next menstrual cycle after stage II)			
	Saline or Imunofan 0.005% solution in 1:50 dilution with sterile Saline	200–300	3–5	

Table C.3 — Treatment regimens for postoperative purulent wounds

The ultrasonic handpiece AA201.5 with tips AA112.1 "Hoof", AA113.1 "Ball", or AA114.1 "Spatula" is used. The ultrasonic exposure: "BASIC" or "SELECTIVE". The liquid flow rate: maximum or average					
Indications	**Solution (one of the following)**	**Solution volume for procedure, ml**	**Duration of exposure, min**	**Power level of ultrasonic vibrations, units**	**Average number of procedures**
Purulent wounds of the anterior abdominal wall	Saline, Chlorhexidine Gluconate 0.05% aqueous solution, or other antiseptics and antibiotics	200–300	5–10	20–50	5–7 procedures (once or twice daily)

Table C.4 — Treatment regimens for drug phonophoresis in vulvar dystrophy, decubitus ulcers of the vagina and cervix

The ultrasonic handpiece AA201.5 with tip AA127.1 "Disk" is used. The ultrasonic exposure: "BASIC" or "SELECTIVE". The liquid flow rate: maximum or average					
Indications	**Solution (one of the following)**	**Solution volume for procedure, ml**	**Duration of exposure, min**	**Power level of ultrasonic vibrations, units**	**Average number of procedures**
Vulvar dystrophy	Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Imunofan 0.005% solution in 1:50 dilution with sterile Saline; prednisolone 30 mg/ml solution in 1:250 dilution with Saline; other solutions of antiseptics, immunomodulators, hormone-containing drugs (see the list of solutions below)	100–300	3–5	1–20 (depending on the individual sensitivity of a patient)	5–7 procedures (once or twice daily)
Decubitus ulcers of the vagina and cervix	Saline; Chlorhexidine Gluconate 0.05% aqueous solution; Octenisept solution in 1:10 dilution with sterile Saline; prednisolone 30 mg/ml solution in 1: 250 dilution with Saline; other solutions of antiseptics, immunomodulators, hormone-containing drugs (see the list of solutions below)	300–500	4–5	20–50 (depending on the individual sensitivity of a patient)	3–10 procedures (once or twice daily)

Medications recommended for ultrasonic cavitation:

- Sodium Chloride 0.9% solution (sterile Saline solution, hereinafter referred to as Saline);
- Chlorhexidine Gluconate 0.05% aqueous solution;
- Betadine 10% solution in 1:20 or 1:50 dilution with sterile Saline;
- Sodium Bicarbonate 3% solution;
- Octenisept solution in 1:10 dilution with sterile Saline;
- Dioxidine 0,5% or 1% solution in 1:20 dilution with sterile Saline (10 ml (1 vial) of 0.5% or 1% Dioxidine per 200 ml of Saline);
- Nitrofural 0.02% aqueous solution (1:5000);
- Benzydamine Hydrochloride 0.1% or 0.05% aqueous solution;
- Imunofan 0.005% solution in 1:50 or 1:100 dilution with sterile Saline (1–2 ml (1–2 vials) of 0.005% Imunofan per 100 ml of Saline);
- Allokin-alpha solution (1 mg (1 vial) of the medicine Allokin-alpha per 100 ml of Saline);
- Roncoleukin 0.5 mg solution in 1:100 dilution with sterile Saline (1 ml (1 vial) of Roncoleukin in dose 0.5 mg per 100 ml of Saline);
- Betaleikin solution (1 μg of the medicine per 400 ml of Saline);
- Metronidazole 5.0 mg/ml solution (100 ml vials);
- Ciprofloxacin 2 mg/ml solution (100 ml vials);
- Lidocaine 2% solution in 1:25 dilution with sterile Saline (10 ml of 2% Lidocaine per 250 ml of Saline);
- Prednisolone 30 mg/ml solution in 1: 250 dilution with Saline (1 ml (1 vial) of Prednisolone per 250 ml of Saline);
- other antiseptics, antibiotics or immunomodulators diluted in sterile Saline.

NOTE: Medicines may have contraindications, it is necessary to read the information leaflet before using them. If the medicines used are not included in the list above, then before diluting them in Saline, you must make sure that the medicine can be used with Saline.

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