

Device family MedCare Intimate Shower for treating the female vagina

Clinical evaluation according to Annex 10, Decree 16/2006.(III.27) EüM of the Ministry of Health.

1.1.1. Relating scientific literature, critical evaluation of applied technical solutions

Scientific literature has dealt for long with the effectiveness of LOCAL vaginal treatment as opposed to orally administered medical treatment.

For local treatment of different vaginal changes, different medicaments that can be placed within the vagina are particularly applied. Investigations among patients evidence that the use of medicaments applied within the vagina is evaluated positively (1). Presently, vaginal contraceptives, antimycotics, antimicrobial ingredients, and different purifying and lubricating preparations are applied locally in the vagina. These preparations are applied in several forms: vaginal tablets, capsules, creams, suppositories, foam, solutions and gel.

Instead of medicaments, the use of herbs, the importance of ordinary daily hygiene (irrigation with physiological saline solution) as well as the importance of prevention and maintenance are facts that are medically supported as well.

Vaginal discharge and the offensive odour of vaginal secretion are the most common reasons for gynaecological visits (2). The three most common changes causing vaginal discharge are the following: bacterial vaginosis, trichomoniasis and vaginal candida infection (3,4). Vaginal discharge may occur in healthy females as well. The quantity of vaginal discharge varies individually and during the menstrual cycle as well. Normal vaginal discharge may have an irritating odour as well (5). Although the most common reason for vaginal discharge and offensive odour is bacterial vaginosis (6), tests proved that in 1/3 of irritating vaginal discharges no type of pathogens can be detected (7,8). In everyday practice the fact that there is no obvious pathogenic reason for vaginal discharge often causes a problem. Tests showed that in such cases vaginal irrigation with the use of physiological saline solution or different herbs efficiently reduces the irritating vaginal discharge without changing the ecosystem of the vagina.

Technical solutions applied in the device – as opposed to the devices that have been used so far:

1./ providing the appropriate pressure for outflowing water

During experiments (Annex 1) it was proved that in normal use the pressure of outflowing water in devices operated by the pumping method is 0.7 and 0.8 bar. This high pressure alone could have critical and harmful effects on the epidermis of the vagina and also in the direction of the cervix. In the case of the device Lady-Pharma that can be fitted on the location of the shower irrigation happens at the current pressure of flowing water.

In these devices it is not possible to control the pressure of outflowing water.

In the device MEDCARE INTIMATE SHOWER the appropriate pressure of outflowing water is provided by multi-point pressure reduction built into the device.

2./ free exit for water entering the vagina

Presently marketed devices have smooth-surfaced heads which fit close to the wall of the vagina thus water having entered the vagina at high pressure cannot freely flow out.

3D ultrasound images (Annex) prove that the vagina will blow up like a ball then in response to the effect of pressure water will force its way out of the vagina – which is the better case, or towards the orifice of the uterus – which is the worse situation. Considering the fact that the liquid of undesired composition which we would like to remove will force its way right in the direction of the uterus it can be concluded that the reason for repeated pelvic inflammatory diseases is not irrigation itself but the wrong and improper method of application and device. The device MEDCARE INTIMATE SHOWER has been designed and implemented to eliminate the above problem.

It provides immediate and free exit for the liquid having entered the vagina through external routes built into the head.

3./ one-way flow to eliminate the danger of re-infection

The main point in irrigation is to remove the latent vaginal secretion formed in the vagina that is of improper PH, just excessive, or maybe contaminated with fungi or bacteria.

During irrigation by the pumping method the washing liquid will be introduced by a powerful hand movement. Releasing your handgrip before removing the device from the vagina will result in also sucking back the undesired vaginal secretion into the balloon, then blending it with the liquid to be used for purifying irrigation, thus causing the potential for re-infection yourself already at the second hand movement of irrigation. This makes the whole action completely unnecessary.

In the case of vaginal treatment device MEDCARE INTIMATE SHOWER the above phenomenon is excluded as one-way water flow will provide an irrigation liquid supply of predefined quantity and quality that is clean at every moment, and it will exclude the potential for re-infection by providing exit for the liquid in the above mentioned way.

4./ introducing ingredients into the vagina in a controlled quantity and quality

The duration of irrigation, i.e. the extent of washing out vaginal flora is a highly important issue. If irrigation lasts longer than permitted, it can cause more problems than benefits. In the case of every device marketed so far the user may decide on the actual duration of treatment. The device MEDCARE INTIMATE SHOWER has been designed in a way that during its application in the first phase the dimensions of NACL crystals, and the dimensions of openings formed for entering water determine a constant (approximately half a litre of) flowing water quantity. Following the dissolution of NACL crystals water flowing will automatically stop. This prevents over-irrigation, and creates a constant physiological saline solution of predefined, approximately 0.9% concentration, which is identical to the stock of infusion. The same principle applies to the different fillings filled in the second phase.

5./ introducing the desired ingredients to the appropriate place

The head dimensions of the device MEDCARE INTIMATE SHOWER and the locations of openings used in the irrigation phase have been designed according to female anatomy. During irrigation washing liquid flows out all round the head through... channels, from... holes. In the second phase the treating, i.e. active ingredient introduced into the vagina will leave the device

through one route, exclusively at the head end thus at the upper part of the vagina. So far suppository has been the most common form of introducing a medicament, however, forwarding the suppository to the upper part of the vagina by the user has been rather unsuccessful than successful in most cases. The device MEDCARE INTIMATE SHOWER solves this problem.

6./ excluding the case of improper operation

The problems mentioned above are highly important alone as well as the occurrence of any segment or its improper application may mean serious danger to the user. The device MEDCARE INTIMATE SHOWER operates and will only operate if it is used professionally as described in the instructions for use. The device does not operate without an original capsule. The operation of the device will automatically stop following the end of treatment.

It is an essential and basic requirement that a device that is safe from all aspects should be given to the patient. Based on the above mentioned parameters of the device MEDCARE INTIMATE SHOWER it can be stated that it complies with the criteria intended by the manufacturer, and means a modern and safe treatment device to its user.

2. Clinical trial

2.1. The objective of clinical trial:

a) to prove that during its proper use the device complies with the capacity intended by the manufacturer for:

aa) preventing diseases, and abating symptoms

With the proper use of the device MEDCARE INTIMATE SHOWER abnormal discharge caused by different vaginal pathogens can be prevented.

ab) abating the symptoms of injuries (epidermal injuries of the vagina)

In the cases of epidermal injuries of the vagina – vaginal epidermis is particularly more exposed to injuries in menopause – irrigation with pot marigold/sage will result in healing of epidermal micro-injuries.

ac) replacing or supplementing the physiological process (recovery of PH level)

In normal cases the vagina has an acidic pH which can be neutralized by several factors, and it can become abnormally alkaline. In such cases it is important to use gel MEDCARE INTIMATE SHOWER containing lactic acid, which will recover the normal acidic pH of the vagina.

b) determining POSSIBLE undesired adverse effects occurring during proper use (if there are any!! ???) and assessing the risks caused by them, with the planned capacity of the device taken into consideration.

MEDCARE INTIMATE SHOWER eliminates the unfavourable effects of previously used vaginal irrigation devices as it does not cause overpressure thus pathogens cannot get into the uterus and the abdominal cavity through the orifice of the uterus. Due to the above benefit pelvic inflammatory diseases (PID) will not enhance. The device also eliminates the potential for reflux.

2.3. Methods

2.3.1. The clinical trial shall be performed based on a study plan that reflects and prove the latest scientific and technical knowledge, or contravene manufacturer's statements related to the device. For the scientific authenticity of final conclusions, the trial shall include the appropriate number of observations.

Study plan for the clinical tests of device family MEDCARE INTIMATE SHOWER

- 1./ testing the appropriate pressure of water flowing out of the device (see Patent Data)
- 2./ free exit from the vagina for the outflowing water (ultrasound images)
- 3./ eliminating the danger of re-infection by one-way flow
By means of an apparatus designed for testing the device which makes observation of one-way flow possible.

4./ applying ingredients in a controlled quantity and quality during the treatment

Compiling prescriptions for the most common vaginal problems:

a) before each treatment purifying the vagina surface shall be provided by irrigation with saline solution

The beneficial effect of irrigation with saline solution in the first phase of MEDCARE INTIMATE SHOWER is provided by purifying the vagina wall from the abnormal discharge thus the active ingredient used in the second phase will spread evenly on the already cleaned vaginal epidermis and thus can elicit its effect in a more efficient way.

The first phase is always NACL crystals due to the dissolution of which physiological saline solution will be produced (Annex: trial records)

Filling: 8 gr NACL

b) irrigation with LACTIC ACID recommended for recovering vaginal PH, and creating the healthy flora, thus preventing diseases

Irrigation with lactic acid by means of MEDCARE INTIMATE SHOWER will recover and provide the normal pH of the vagina, thus recover its natural protective ability.

Lactic acid filling:	8 ml
Acidum lacticum	0.5 %
Methylcellulosum	2.5%
Solutio conservans	1.0%
Aqua destillata	ad 100 %

c) irrigation with LAVENDER aromatic water recommended for abating the symptoms of vaginal discharge caused by taking antibiotics or medical contraception:

Irrigation with lavender aromatic water reduces inflammation and relaxes vaginal epidermis. Besides its fungicide and virus killing effect has also been reported.

Lavender filling:	8 ml
Aetheroleum lavandulae	0.02 %
Polysorbat 20	0.2%
Solutio conservans	
Methylcellulosum	
Aqua destillata	ad 100%

d) irrigation with pot marigold/sage extract is recommended for abating the symptoms of vaginal epidermis and other injuries, and for pre/post-treatment of gynaecological operations.

The beneficial application of pot marigold, sage is possible in the cases of epidermal injuries (mainly during menopause), and it also has an inflammation reducing effect.

Pot marigold/ sage filling:	
Calendula Officinalis (extract with 20% propylene glycol)	0.2 %
Salvia Officinalis (extract with 20% propylene glycol)	0.2 %
Solutio conservans	1.0%
Acidum lacticum	0.2 %
Methylcellulosum	2.5%
Aqua destillata	ad 100%

e) yarrow/thyme filling is recommended for abating the symptoms of fungal infections, and vaginal dryness (in menopause), and to increase the resistance of the vagina.

Yarrow and thyme have an antibacterial effect and they can also be considered as a complementary treatment in the cases of fungal infections.

Yarrow/thyme filling:	
Achilleum millefolium (extract with 20% propylene glycol)	0.5%
Tymus vulgaris (extract with 20% propylene glycol)	0.1 %
Acidum lacticum	0.2%
Methylcellulosum	2.5%
Aqua destillata	ad 100%

Based on the above compiled prescriptions, a permanent introduction of ingredients in a controlled quality and in a constant quantity due to the automatic filling is provided.

5./ introducing the desired active ingredients to the appropriate place

During the design work of the device the opinions in the available special literature as well as those of practising gynaecologists were also taken into consideration for precise dimensioning and creating the desired form. Consequently, outflow openings used during irrigation can be found all round the head and at the top of the head as well, while the outflow opening for the ingredient leaving the second phase of the capsule can only be found at the top of the head. Thus introduction to the appropriate place is provided.

6./ excluding the possibility of improper operation

Already during design work great attention was paid to creating the simplest and safest device to the user. Components can only be assembled in one way, and they do not work without one another. Operation of the device will automatically stop following the end of treatment. The device does not operate if it is used in an improper way.

Based on the above mentioned facts it can be stated that the device MEDCARE INTIMATE SHOWER – considering the relating scientific literature and harmonized standards as well - during its proper use complies with the requirements stated in sub-points 1 and 3 of point A.I in Annex 1.

LITERATURE

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Prof. Dr. István Rákóczi
Head Physician and Director of Institute
Szent Imre Hospital, Matrix Organization of Operative Professions
Hungary, Budapest