Aquacore®

Hydrophilic gel
Instruction for Use

Rev.1 dated 04.04.2018

Class III Medical device, Hydrophilic Gel for endoprothetics of human soft tissues

COMPOSITION (weight %):
97-99 % -water; sodium chloride;
copolyamide crosslinked structure.

DESCRIPTION

Aquacore® hydrophilic gel preparation is a sterile synthetic gel biocompatible with human soft tissues. Its supramolecular structure is based on multiple molecular cross links and hydrogen H-bonds, arising between carbonyl and amine groups. Aquacore® hydrophilic gel is compatible with human tissues. Due to its elasticity and plasticity properties the gel can be used as a volumizing soft tissue implantable gel to be used for body contouring procedures in aesthetic plastic surgery. Each container is terminally moist heat sterilized in its packaging and sealed. The products are for single use only. The gel volume contained in each container is stated on the container.

PHYSICAL AND CHEMICAL PROPERTIES

Transparent colorless gel

INDICATIONS FOR USE

Aquacore® hydrophilic gel is designed for soft tissue contouring at different parts of human body. Aquacore® hydrophilic gel can be used for the following indications only:

1. Soft tissue contour's correction
2. Breast muscle aplasia correction
3. Breast augmentation in hypomastia
4. Breast shape Improvement in case of mastoptosis 1st -2d degree
5. Breast asymmetry correction
6. Correction of soft tissue atrophy changes
7. Breast shape and volume improvement
8. Buttocks shape and volume improvement

Aquacore® hydrophilic gel is a filler that bears positive charge, does not change tissue conductivity, blocks negatively charged free radicals of active oxygen and improves resistance to aging proceses.

Aquacore® hydrophilic gel increases electric potential of surrounding tissues, normalizes microcirculation at the injection place. Due to its positive charge it attracts negatively charged molecules of collagen and elastin, thus providing skin with strength and long lasting elasticity. Because its main component is 0,9% solution of sodium chloride, gel does not cause allergic reactions, gel is slowly encapsulated in human body and maintain long lasting aesthetic volumizing effect.

Aquacore® hydrophilic gel volume can be adjusted in the area of previous injection in case of need for volume increase or in case if correction procedure is performed in stages. Additional volumes of gel must be injected inside the depth of already injected gel.

CONTRAINDICATIONS

1. Product is not to be used in case of damage of container, disruption of the packaging integrity or suspicion of product non-sterility.
2. The product is not to be applied in case of contra-indications related to general diseases or local pathological processes if there is a risk of some adverse events/effects or complications.
3. It is prohibited to perform Aquacore® hydrophilic gel injection procedure in following conditions:

General conditions:

- patient is younger 18 years
- general poor health conditions
- apparent breast ptosis (stages 2-3)
- presence of already implanted shell implants
- pregnancy
- less than nine months after child birth,
- patient is breast feeding or lactating
- planned pregnancy within next 12 months
- lack of mammary gland tissue between nipple and chest muscle
- blood coagulation problems
- menstrual cycle disruptions
- acute inflammatory disease
- various autoimmune diseases
- intolerability or allergy to medicines
- any kind of coagulopathy, prescribed intake of anticoagulants or aspirin at the date of procedure
- vascular diseases of various origin
- poor mental condition

Local conditions:

- active skin inflammation process in injected areas
- active subcutaneous inflammation process in injected areas;
- chronic dermatitis;
- chronic skin contagious diseases in sustained remission stage or recrudescence;
- nodular type mastopathy
- benign mammary diseases
- breast cancer
- acute mastitis
- acute soft tissue inflammatory process at the buttock region
- benign skin diseases in injected areas
- malignant skin diseases of any localization.
- mastoptosis 3d degree
- constricted lower pole of the breast
- tubular breast deformity

APPLICATION RESTRICTIONS

1. DO NOT INJECT PRODUCT INTRAVENOUSLY AND PREVENT INNTRAVASCULAR INJECTION

2. DON NOT INJECT IN THE AREAS OF VENOUS PLEXUSES AND INTO THE CAVERNOUS BODY INTRADERMALLY.

3. AVOID TO INJECT PRODUCT INTRADERMALLY IN EXESSIVE VOLUMES

4. AVOID HYPERCORRECTION

5. AVOID PRODUCT INJECTION BELOW SITTING LINE FOR BUTTOCKS AUGMENTATION

USAGE REQUIREMENTS

Open the secondary package and pull the sterile PVC container with a sterile instrument out the secondary pack. Check the integrity of the container with gel, check Luer-lock integrity. To open the PVC container with gel break the protective plastic sealing tip. After that, it is necessary to unscrew the plug on Luer-lock and push protective plastic sealing tip deep into PVC container with a sterile needle or cannula. Connect a disposable syringe to the Luer-lock gate and fill the syringe with the gel. It is necessary to repeat the procedure to fill all syringes needed for procedure. Avoid creation of air pockets inside syringe tube during the filling procedure. After a syringe is already filled it should be connected with appropriate cannula by the Luer- Lock combi-stopper. It is important to use an appropriate cannula which can be properly assembled to the syringe. Press and turn a cannula clockwise into the syringe Luer-lock until it is tight. Make sure that the cannula is tightly fixed to the bottom of the Luer-lock. Before injecting, the air should be removed from the syringe up to the point where a droplet is visible at the tip of the needle. The equipment is ready to be used.

NEEDLE/CANNULA

For safe aplication of Aquacore® hydrophilic gel it is important to use a sterile needle/cannula of the appropriate diameter depending on a type of a performed procedure. For corrections of minor skin irregularities thin needles G-27-30 are recommended. In case of any postoperative soft tissue deformities it is necessary to use G-24-27 needles. Thin 2-2,5 mm blunt cannula of 80-120 mm of length should be taken for breast augmentation and the 2.0-2.5 mm cannula of 100-150 mm of length should be used for buttock contouring.

FORBIDDEN TO USE AND STORAGE product if sterile container was open more than 2 hours ago.
FORBIDDEN to use product from one container for more than one patient.

TREATMENT PROCEDURE

The application of Aquacore® hydrophilic gel is to be performed by certified medical staff only, holding all appropriate qualification according to the above mentioned indications.

- Doctor should inform the patient about expected results, possible adverse events/effects or complications before any invasive medical procedure.
- A written informed consent for body contouring procedures should be obtained in accordance with local regulations (each medical institution uses its own version of the informed consent) before any medical procedure relevant to gel implantation\body contouring.
- Every medical facility that performs the procedure, must keep hardcopies of informed consent signed by patients as a sign of patient's understanding and acceptance of expected results and consequences of the procedure.
- Before treatment procedure it is necessary to take patient's photo.
- Before procedure a patient has to be examined for general health conditions: blood analysis, AIDs, Hbs Ag, Anti HVC, RW test, ECG, coagulogram, urine test, etc.
- Prior to the procedure all patients must be examined with ultrasound or mammography to make sure that mammary gland has no pathological changes.
- Before starting the procedure preliminary marking of the treatment area should be performed.
- All treatment procedures and manipulations are to be performed in strict aseptic and antiseptic conditions. Proper disinfection of the treatment area must be performed prior to injection.
- The body contouring procedures with Aquacore® hydrophilic gel usually are performed under local anesthesia by injecting e.g. 0.5% lidocaine at the injection point and into the area where contouring procedure is performed.
- The injection technique may vary with regard to the place of injection and the administered quantity of Aquacore® hydrophilic gel. A correct injection technique is important for the satisfactory final result of the treatment.

- If product injection is planned to be performed with cannula, use needle to prepare an injection opening for cannula insertion.
- During breast augmentation, gel should be injected strictly into the retromammary plane between mammary gland and chest muscule. After insertion of cannula, injection is performed from the center of retromammary space to periphery in an inversive, fan-shaped manner. Inject gel by changing the cannula direction. The injected gel must not cause excessive pressure on the tissue. Try to avoid injection of gel superficially especially on breast periphery. Carefully estimate the volume of Aquacore® hydrophilic gel to be injected and avoid overcorrection.
- For buttocks contouring with Aquacore® hydrophilic gel gel should be injected subfascially between buttock deep fascia and gluteus muscle. After insertion of cannula, gel injection is made from the center of the treated area to the periphery in an inversive maneuver. Inject the gel by changing the cannula direction making in a fan-shaped manner. Try to avoid injection of gel superficially or avoid overcorrection
- Do not apply extensive pressure to the syringe at any time. If such resistance is encountered the needle/cannula should be partially withdrawn and repositioned or fully withdrawn and checked for obstructions.
- Special caution should be exercised when treating areas in close proximity to vulnerable structures such as nerves, vessels, ligaments or muscles.
- Inject gel while pulling the cannula slowly outwards. Carefully consider the volume of gel to be injected depending on the area of injection. Perform gel injection in small portions and spread them around the area to be augmented and not inject gel in one whole portion. Injected gel must not cause excessive pressure on the tissue. Avoid overcorrection. When the desired volume of gel has been administered, release the pressure on the plunger before removing the cannula. If an injection had caused lumps at the treatment area remove any excess material from the injection channel before finishing procedure.
- To prevent gel leakage through the skin puncture opening to outside, soft tissues at the injection site should be pressed by a finger.
- If needed, perform a gentle massage after injection to achieve an even gel distribution.
- The injection opening should be closed with a sterile dressing.
- If it is necessary to perform additional injections of Aquacore® hydrophilic gel, they must be performed with 2-3 months' interval.

THE PRODUCT SHOULD BE USED WITHIN 2 HOURS AFTER OPENING OF THE PACKAGE. The syringes and container must be discarded immediately after the treatment session ends and must not be reused due to risk for contamination of the unused material and the associated risks, including infections.

Disposal should be performed in accordance with accepted medical practice and applicable national, local or institutional guidelines.

THE DETAILED PHOTOGRAPHIC DOCUMENTATION must be the part of medical documentation in accordance with local legislation.

POST-OPERATIVE PROCEDURES/RECOMMENDATIONS

Just after the treatment procedure it is necessary to take a photo of the patient.

To prevent bruising and oedema formation, cold application is recommended during the initial period for one to two hours.

If oedema occurs, a cold pack can be applied locally for at least 3-4 hours.

For all patients preventive antibiotic therapy are recommended for 48 hours after procedure.

The patient should be advised:

- not to wet the injection area for at least 2 days
- avoid mechanical injuries to breast or buttocks
- to avoid a risk of gel migration not to massage the treatment area for at least 2 weeks following an injection
- not to pierce or wax the skin in the area of gel injection
- to avoid exposure to direct sunlight (including solarium and other sun tanning devices) or extreme cold conditions in the first 4 weeks following an injection
- to avoid sunburn or frostbite in the area where Aquacore® hydrophilic gel is injected

The ultrasound examination must mandatory be performed after 7 and 30 days from injections day.

The patient must undergo the control procedure to locate the implanted gel and the quantity of the implanted material with the help of ultrasound examination. The results of such control procedure are the part of medical documentation for the patient and must be kept in accordance with the local legislation. Additional ultrasound examination is recommended in case of any adverse events/effect related to gel implant shape change is developed.

POSSIBLE ADVERSE EVENTS/EFFECTS:

As a rule, Aquacore® hydrophilic gel application is not accompanied with any adverse events/effects. The most often body contouring procedures are fully painless and are not followed by any unfavorable senses or reactions. However, sometimes fever and weakness or mild pain can be felt. In case of general signs of posttraumatic adverse reactions, it is recommended to take analgesic and anti-inflammatory drugs. Mostly these symptoms disappear in a few days.

In addition, some transient limited local adverse events/effects caused by the procedure can appear. In some cases, the local pain, post-operative swelling (very frequently), redness, tingling, itching, bruising (frequently), skin induration, skin pigmentation, gel fragmentation (rarely), hematoma, injection related inflammations (very rarely) can be observed. Allergic intolerability to the implant can be very rarely recorded.

Typically, injection related local reactions are resolved spontaneously within few days. In case of signs of posttraumatic local edema, bruising or hematoma it is recommended to apply cold therapy on an area of injection.

If uneven gel distribution, implant displacement or any irregularities have been observed the gel drainage can be attempted. Adequate soft tissue cover and support, as well as correct gel placement and injection technique are important parameters to minimize occurrence of these events.

If there are signs of local inflammation or infection process are suspected, the combination of anti-inflammatory treatment and antibiotic therapy for 5 to 7 days should be prescribed. For more severe cases of infections, removal of the gel by drainage must be used in addition to antibiotic therapy.

All adverse events/effects or complications must be reported directly to LLC Beauty Systems.

POSSIBLE COMPLICATIONS. RECOMMENDATIONS

Non-inflammatory complications

Subcutaneous haemorhage or hematoma

It may occur during the procedure and do not require any special treatment. If blood flows slowly through the small cannula or implantation needle out, implantation procedure the operation procedure should be stopped for 3-5 minutes. Tight compression by finger should be applied on the injection place. That way haemostasis is been controlled and then the procedure may be continued. In case of intensive continuous bleeding the procedure must be stopped completely and cannula pulled out.

Gel penetration among the segments of the mammary gland

It is not a serious complication. Gel penetration might occur due to involution weakness of mammary glands connective tissues, excessive amount of the injected gel or uneven distribution of the gel throughout the breast tissues. To manage appeared irregularities, it is recommended to redistribute them intraoperatively by light manual massage. In case of overcorrection if necessary it is possible to perform decompressive puncture and drain the gel.

Gel leakage through the skin puncture channel to outside

It might occur under the following conditions:

1. Excessive amount of the gel injected;
2. Failure to comply with rules during the procedure;
3. Excessive pressure over the treated zone in early postoperative period;
4. Breach of regime in the postoperative period (not prone to sleep etc.).

To prevent such complications, it is recommended to follow the recommendations for post-treatment period.

Gel fragmentation

It might occur with the patients who underwent lactational mastitis before and which resulted with severe cicatrical adhesions inside the breast.

In such cases during the preoperative planning the patient should be examined in detail and, if it is necessary, injection area should be investigated with an ultrasound or mammography. If such a complication happened, it is recommended to make decompressive puncture to remove the fragmented gel.

Inflammatory complications

Inflammatory complications might occur due to improper aseptic and antiseptic conditions while the treatment procedure is performed, or any violations of the techniques of implant injection.

- If there is a suspicion for latent inflammatory process, preventive antibiotic therapy should be given to the patient at least for 3-5 days
- besides that, it is recommended to apply bandage on the inflammatory zone with mixture of sol. dimexidi diluted in 0,5% lidocaine 1:5 with 1,0 g antibiotic from cephalosporins and 0,1 ml 1% hydrocortisone (1 mg) for a period from five to seven days.
- If conservative therapy (antibiotic + local treatment) did not stop the inflammation process, inflammation should be treated by means of decompressive puncture of inflamed area with aspiration of exudates and cleaning of the inflammation zone.

WARNING

To avoid aforementioned events/effects or complications:

Do not use Aquacore® hydrophilic gel if the package is damaged or the sterility of gel is compromised due to non-intendedly opened package.

Do not use the product after storage expiration date.

Do not use the product outside medical facilities.

Do not mix Aquacore® hydrophilic gel with any non-liquid substances.

Do not inject the product into superficial layer of skin.

Do not inject the gel intravascularly. This risk can be minimized by using appropriate blunt cannulas.

Do not inject the gel into venous cavernous plexus such as zone of genitals.

Do not inject the gel into mucous and submucous layers.

The Aquacore® hydrophilic gel container is intended for single use and for one patient only, reuse is strictly prohibited.

Do not re-sterilize Aquacore® hydrophilic gel.

Avoid hypercorrection while the gel is injected.

Use product Aquacore® hydrophilic gel only as it is stated in "INDICATIONS" section of this instruction.

PRODUCT FORM AND COMPLIENCE

PVC Container, 100 g/50 g with Luer-Lock cap.

The product is manufactured according to standards of quality EN ISO 13485: 2012.

PRODUCT STORAGE CONDITIONS

Store up between +5 °C and 40 °C. Protect from freezing and sunlight. In case of suspicion that the package is unsealed or damaged the gel is prohibited for application.

SHELFLIFE

Three years from manufacturing date.

MANUFACTURER

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