OVALASTIC INSTRUCTIONS FOR USE

CE 0499

PRODUCT DESCRIPTION
The Ovalastic procedure is a non-incision, non-scarring hysteroscopic procedure for permanent female sterilisation with formed-in-place silicone rubber plugs.

Ovalastic is a proprietary LSR elastomer composition. The product is presented in a pre-filled, sterile, 5 ml dual syringe with 2 x 2.5 ml Ovalastic. It is supplied with static mixers which permit adequate pre-mixing to prevent component dissociation during injection, separately packaged catheters and a disposable dispenser gun for product application.

Ovalastic is easy to inject and polymerises in situ into a uniform elastomer within seconds of application. The product will remain flexible and adapt to the form of the environment during injection, reducing the chances of migration. It is not biodegradable, resulting in a long-term effect. As the product is clearly visible via ultrasonic imaging, it allows for retrospective investigation or removal in the event of an emergency.

MODE OF ACTION
Ovalastic is a two-component product supplied in a dual syringe, mixed in a static mixer and subsequently dispensed into the Fallopian tubes by using the Ovalastic catheter system, under visual guidance with a hysteroscope.

This implant is used in gynaecology to occlude the fallopian tubes, thus causing sterilization of women. It concerns a two-component product that is mixed through a static mixer. In just a few minutes after injection the material solidifies into a soft, flexible and rubbery material (elastomer) that fills the cavity.

INDICATION
Ovalastic is intended for human use with the purpose of contraception by mechanical action, i.e. blockage of the Fallopian tubes.
Ovalastic is a method for permanent birth control.
After instillation, contraceptive methods must be continued until an ultrasonic examination after three months confirms that the plugs are intact and correctly in place. Thereafter the woman may rely on Ovalastic for contraception. Dislocations in a later stage sometimes may occur (<2%).
Ovalastic is indicated for women who desire permanent contraception, who are of legal age and who give consent to perform the procedure. The woman must be in good general health, as determined by medical history and gynaecological examination and must have two patent fallopian tubes (oviducts). Women missing one tube, but with a patent other tube, can be included.
Ovalastic is a also indicated:

- when anaesthesia forms a risk
- for obese women
- for women with a history of multiple abdominal operations

Note: a pre-operative hystero salpingogram or hysteroscopic evaluation may be required to rule out history or presence of tubal, uterine or pelvic diseases or abnormalities. Insertion must take place shortly after the cessation of the menstrual period.

CONTRAINDICATIONS
Ovalastic is contraindicated in the following conditions:

- Pregnancy, or suspicion of pregnancy in the past three months.
- Any abnormalities noted upon examination like adhesions, fibroids, infections, genital bleeding, cysts or other pathological conditions that may interfere with the procedure.
- A significantly distorted or retro-flected uterus.
- Women who have not returned to their normal menstrual cycle after a recent partus.
- An unevaluated abnormal "PAP" smear.

WARNINGS / PRECAUTIONS
Ovalastic is only to be administered by trained qualified physicians with experience in hysteroscopic procedures. Early Ovalastic interventions of a physician should be strictly supervised. Experience of the physician is essential for the success of the method.

- Improper patient selection and/or improper surgical implantation of the implant may result in unsatisfactory performance.
- Ectopic deposits can occur due to the perforation of the uterotubal wall by the catheter tip. Such perforation is caused either by pushing (instead of positioning) the tip into the tubal orifice or by bad timing during the 2nd half of the menstrual cycle. To prevent perforation never use undue force during the placement of the tip.
- Fever of more than 38°C within 72 hours following the procedure requires taking a cervix culture. If positive, treatment is indicated until the infection is controlled.
- After Ovalastic sterilization, hysteroscopic techniques are recommended for intra-uterine diagnostic procedures. In case other procedures like ablation, dilatation & curettage (D&C) are used, the device status and its efficacy must be evaluated. Removal of the device is not mandatory in any case, but there is a risk of damaging or dislocating the device with blind intra-uterine manipulation.

If a pregnancy should occur with the device in situ, the location of the pregnancy must be identified. Out of 10 pregnancies, 4 are ectopic. In case of a tubal pregnancy in the presence of Ovalastic in situ, the oviduct must be removed. Surgical sterilisation (applying clips) on the other tube is then recommended. In case of an intra-uterine pregnancy, evaluation of the status of Ovalastic is not required because Ovalastic does not interfere with foetal growth.

A safe procedure can only be performed using the instruments and materials which are supplied by Urogyn BV. In the event of accidental contamination of the catheter after assembly, discard the device.

This product is single use only. In theory, multi-use can increase the risk of cross-infection. In practice multi-use is not possible because all product contacted components become unusable due to the curing of the silicone material during application. The co-packed dispenser gun is supplied as single use disposable and not considered to increase the risk of cross-infection through its extra-corporal use.
Providing the package is undamaged, sterility is guaranteed. Do not use package if it is damaged. Do not re-sterilise.
Note that (potentially) contaminated materials may be returned only following Urogyn's instructions, e.g. in a sealed container/bag. Apply hospital procedures to safely dispose of contaminated material and components, e.g. used catheters.

ADVERSE EVENTS
The following adverse reactions and side effects have been reported and may occur after the device is inserted:
- Slight tubal spasms may be noticed during influx of the siloxane mixture.
- Pregnancy (Pearl Index = 0.18 per 100 women-years of use).
- Ectopic pregnancy (out of 10 pregnancies, 4 are ectopic).
- Chronic abdominal pain and slight change of menstrual blood loss have been reported within 24 hours to 2 weeks following the insertion.
- Expulsion of the device into the abdomen can occur (3-4% of treated women). If so, this usually happens within 3 months following the procedure, and will be visible on the 3 months ultrasound image. In case of abdominal expulsion, the plugs will be encapsulated and usually do not cause discomfort. If necessary they can be removed by laparoscopy.

Any side-effects or adverse events thought to be related to the product should be reported to the manufacturer or local retailer.

PATIENT INFORMATION
The patient should be informed about the intended use, expected results, contraindications, precautions, warnings and potential adverse events.
The patient should be advised that Ovalastic has not been designed to be reversible.

METHOD OF ADMINISTRATION:
Ovalastic is a two-component product supplied in a dual syringe, mixed in a static mixer and subsequently dispensed into the Fallopian tubes by using the Ovalastic catheter system, under visual guidance with a hysteroscope.

The silicone rubber is inserted into a natural body orifice, namely the Fallopian tube, without crossing a tissue barrier. As the mechanical device occludes the Fallopian tubes over a major portion of their length, it

reduces the mobility of the oviducts and the motility of the ciliary epithelium. Thereby, the function of the Fallopian tubes, as a pathway for sperm and ova, is impeded. The device cannot be removed as a routine technique. Removal requires dislocation of the obturator tip by hysteroscopy and removal of the distal end of the device by laparoscopy and should only be carried out by a qualified physician.

The Ovalastic catheter can be placed under direct vision, using hysteroscopic instruments:

- Collins speculum
- Hegars up to 8 mm
- CF hysteroscope with 7 f working channel

PRE-OPERATIVE PROCEDURES

Prior to treatment the patient should undergo a physical examination and be thoroughly evaluated to ensure proper patient selection. The patient should receive pre-medication by taking one dose of an oral NSAID the evening before and 1-2 hours before the procedure. Make sure the product is conditioned at room temperature before use.

After iodising and, if required, applying a Para Cervical Block the cervix is dilated up to 8 mm (depending on the diameter), the hysteroscope is inserted and the tubal ostia are identified. Using aseptic technique, the Ovalastic catheter is removed from the package and inserted into the working channel of the hysteroscope and its guide wire obturator tip is gently placed in the tubal ostium. The tip should fit tight in the ostium (showing no leakage of rinsing fluid) through the catheter system) before proceeding with the procedure. If necessary, the physician can test the patency of the oviduct with a methylene blue perfusion test. Tubal spasm can be overcome by maintaining pressure in the syringe during the methylene blue perfusion test.

PERI-OPERATIVE PROCEDURES

Once the physician has positioned the Ovalastic catheter tip in the tubal ostium with no leakage of rinsing fluid visible, and if applicable patency of the oviduct is confirmed with the methylene blue perfusion test, the procedure is as follows:

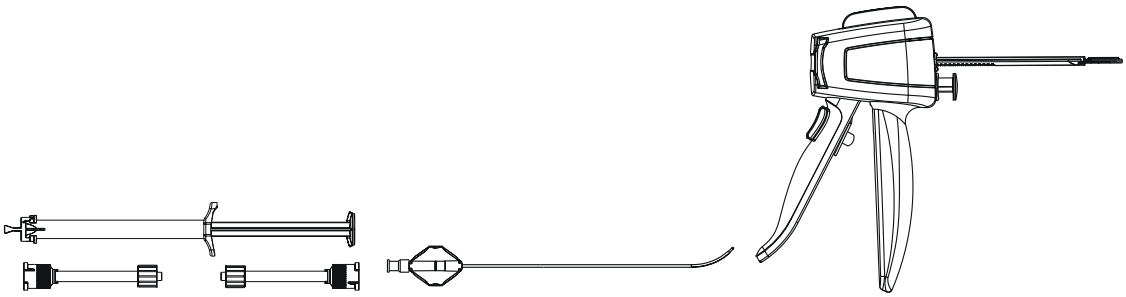
1. Peel open the blister and remove the Ovalastic dual syringe from the package. Keep the cap on the tip of the syringe while placing the syringe with the printed side up into the dispenser gun. Using aseptic technique, remove the static mixer from the package.
2. Remove the cap from the Ovalastic dual syringe and manipulate the gun to squeeze out a little bit of material. Wipe off with a sterile cloth. Attach the static mixer by firmly tightening the hub of the mixer onto the Ovalastic dual syringe's lock tip.
3. Attach the luer lock socket of the static mixer firmly to the catheter **while keeping the tip in position at the tubal ostium**.
4. Carefully express the Ovalastic material until visible at the tip of the catheter (release the gun trigger when material reaches the red mark). Check if the guide wire obturator tip is still in the right position. Start injecting within 2 minutes, before the increasing viscosity renders it too difficult.
5. Slowly inject the Ovalastic material. Selecting the toggle switch on the dispenser gun to accommodate a dosage of 0.1 ml per stroke will facilitate the injection of sufficient material (0.3 ml) in three strokes. After each stroke, hold the gun trigger for 20 seconds (total flow time of 60 seconds). Withdraw the catheter from the application site in accordance with the following step:
6. Release the obturator tip from the catheter (with the static mixer still attached to the catheter), by pressing the separator on the catheter. Carefully retract the catheter, with attached gun, making sure it really has separated from the obturator tip and take it out of the hysteroscope. Discard the used catheter and mixer, following hospital procedures.
7. Repeat the procedure to occlude the other Fallopian tube, using the unused catheter and static mixer (two of each are provided).

POST-OPERATIVE PROCEDURES

An ultrasonic examination of the occluded Fallopian tubes is to be performed immediately after the procedure and after three months following the procedure, to confirm that the plugs are intact and correctly in place.

HOW SUPPLIED

Ovalastic consists of one pre-filled 5 ml dual PP syringe with a lock fitting containing 2 x 2.5 ml (1:1) Ovalastic elastomer composition. The contents of the syringe are sterile. Two static mixers are co-packed with the syringe in a blister. Two Ovalastic catheter systems and a dispenser gun are packed separately and enclosed in the Ovalastic product box, containing the instructions for use and two patient labels.



Product syringe & static mixers *Catheter* *Dispenser gun*

The complete product configuration holding the above components comes ETO sterilized. All components are provided sterile, for single use only.

STORAGE CONDITIONS

Shelf life as indicated on package. Store at a temperature of up to 25ºC.
Do not use the product if the package is damaged. Symbol used on package:

These instructions for use are also available as a PDF file on www.urogynbv.com or by contacting Urogyn, see details below. Paper versions can be provided upon request within five working days at no additional cost.

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DISCLAIMER OF WARRANTIES
Urogyn excludes all warranties and responsibilities for the improper use of the product and/or the failure to follow the instructions in this insert.

This product is to be handled and/or implanted only by accordingly trained and qualified professionals.

Rev. 7 2014-10