



OVABLOC Intra Tubal Device (ITD)
 Manufactured by:
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INDICATIONS

The Ovabloc ITD is a method for permanent birth control. It cannot be considered reversible. After instillation, contraceptive methods must be continued until an X-Ray image after three months proves that the plugs are **continuous and correctly in place**. Thereafter the woman may rely on the Ovabloc ITD's for contraception. Dislocations in a later stage sometimes may occur (<2%).

The Ovabloc ITD is indicated for women who desire permanent contraception, who are of legal age and who will 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.

Ovabloc is a solution in cases:

1. where the anaesthetic is a risk
2. for obese women
3. 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.

MODE OF ACTION

The siloxane rubber is inserted into a natural body orifice (the oviducts), without crossing a tissue barrier. The ITD's occlude the oviducts over a major portion of their length. They reduce the oviductal mobility as well as the motility of the ciliary epithelium. Thereby the function of the oviducts as a pathway for ova and sperm is impeded. The device has not been designed to be reversible. Removal requires dislocation of the soft rubber tip by hysteroscopy and removal of the distal end of the device by laparoscopy and should be only carried out by a qualified physician.

PRESENTATION

The Ovabloc ITD consists of 3 sterile components **for single use only**.

Component	Means of sterilisation	Storage conditions
Mixer-Dispenser syringe	A-septic procedure	- 18 to -22°C in a freezer
Catalyst syringe	A-septic procedure	Room temperature
Catheter system	ETO sterilisation	Room temperature

COMPOSITION

Component	Composition	Remarks
Mixer-Dispenser Syringe Plus appropriate plunger (calibrated to maximum 7 minutes cure time)	Content weight: 3 g Polydimethyl siloxane Crosslinker Medical Fluid Silver powder	The two component siloxane mixture vulcanises at room temperature without an exothermic reaction.
Catalyst syringe	Content weight: 1 ml Stannous octoate Medical fluid	A calibrated volume of catalyst is added in order to cure the siloxane mixture within 7 minutes in situ in the oviduct.
Catheter system	Inner catheter: 750 mm Outer catheter: 540 mm Soft silicone rubber tip	The Ovabloc catheter is used to deliver the mixture into the oviduct.

NOTE: by means of a co-packed plunger, the required amount of catalyst can be dispensed from the catalyst syringe. A pre-sale laboratory test determines for every batch the appropriate plunger-length.

INSTRUMENTS

The Ovabloc pump is used to dispense the siloxane mixture with a calibrated dispensing force. Pressure and cure time are calibrated such, that an Ovabloc ITD of approximately 200 milligrams (0.2 grams) is formed in the oviduct.

INSTRUCTIONS FOR USE

Material

The Ovabloc catheter can be placed either under direct vision, using hysteroscopic instruments, or under image intensifier. We distinguish between materials used by physician and those used by the assistant, who prepares the Ovabloc materials.

This is for single use only.
Sterility is guaranteed, if the package is undamaged.
Do not re-sterilise.

Materials used by the physician		Materials used by the assistant
Hysteroscopic	Image Intensifier (X-ray)	<ul style="list-style-type: none"> Ovabloc pump Chronometer Glass test plate Mixer-Dispenser syringe stored at -18 to -22°C at the place of the procedure Catalyst syringe Methylene Blue dye or Radio-opaque fluid
<ul style="list-style-type: none"> Collins Speculum Hegars upto 8 mm CF hysteroscope with 7 f working channel Ovabloc catheter 	<ul style="list-style-type: none"> Speculum Image intensifier, Technique 70-75 KV, maximal exposure time 5 minutes Ovabloc catheter 	

Pre-medication of patient	
Hysteroscopic	Image Intensifier (X-ray)
<ul style="list-style-type: none"> An NSAID orally the evening before and 1-2 hours before the procedure 	<ul style="list-style-type: none"> An NSAID orally the evening before and 1-2 hours before the procedure

INSTRUCTION FOR USE FOR THE PHYSICIAN

Hysteroscopic Procedure	Image Intensifier
<p>After iodising and, if needed, applying a Para Cervical Block the cervix is dilated upto 8 mm, (depending on the diameter) the hysteroscope is inserted and the tubal ostia identified. Then the Ovabloc catheter is inserted into the working channel of the hysteroscope and its soft hollow tip is gently placed in the tubal ostium. With a methylene blue perfusion test, the physician tests the patency of the oviduct and the assistant proceeds with the preparation of the siloxane material. Tubal spasm can be overcome by maintaining pressure in the syringe during the methylene blue perfusion test.</p>	<p>After iodising, the Ovabloc catheter is inserted into the uterus and gently placed in the cornua. In most cases the position is automatically correct. The assistant perfuses radio-opaque dye under imaging visualisation (15 sec). If necessary, the catheter is re-located and the perfusion repeated. With the catheter in place, the physician chooses a comfortable position and freezes. The assistant proceeds with the preparation of the siloxane material. When the silicone flow reaches the portio, imaging is switched-on again and visualisation shows when the material is at the catheter-tip (15 sec). Switch-off imaging and wait until the material is cured. Then again imaging during tip-separation (15 sec).</p>

Preparation of the materials by the assistant

Once the physician has positioned the Ovabloc catheter in the tubal ostium, and patency of the oviduct is confirmed with the methylene blue perfusion test or with radio-opaque dye, the assistant proceeds as follows:

- Unpack the catalyst syringe and attach the (separately packed) plunger.
- Remove the Mixer-Dispenser syringe from the freezer (-20 °C).
- Mix the Mixer-Dispenser syringe 5 times to remove vacuum pressure, keep plunger pressed after last stroke.
- Push the needle of the catalyst syringe through the septum of the Mixer-Dispenser syringe, keeping the two vertical, with the catalyst syringe on top.
- Inject catalyst pushing the co-packed plunger completely.
- Start the stopwatch and mix 45 times (full strokes) in maximum 45 seconds.
- Remove the insulating sleeve and unscrew the seal cap.
- Push some siloxane on the test plate (to monitor curing in vitro).
- Check before using the fixation of the blocking ball of the catheter.
- Connect the syringe to the Ovabloc catheter and place it in the Ovabloc pump.
- Wait until the stopwatch reads 1:00 minute, then pressurise quickly to 300 N.
- Keep that pressure until the siloxane material reaches the Catheter tip.
- Then stop pressurising, let the pressure drop by itself, but make sure it does not drop below 50 N.
- When the material on the test plate is cured (approximately 5 minutes), separate the catheter from the tip, by holding the outer catheter and pulling the inner catheter firmly.

WARNINGS

- Experience of the physician and assistant is essential for the success of the method.
- Early Ovabloc interventions of a physician should be strictly supervised.
- 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.
- 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 Ovabloc sterilisation, hysteroscopic techniques are recommended for intra-uterine diagnostic procedures. In case other procedures like dilatation & curettage(D&C) are used, the device status and its efficacy must be evaluated. Removal of the Intra Tubal Device is not mandatory in any case.
- If a pregnancy should occur with the ITD 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 the Ovabloc ITD 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 the Ovabloc ITD is not required because the Ovabloc ITD does not interfere with foetal growth.
- A safe procedure can only be performed using the equipment and materials which are supplied by EMCM BV.
- Insertion of the Ovabloc ITD, can only be performed by trained physicians, who meet the qualification criteria such as formulated in the companies training manual.

ADVERSE REACTIONS

The following adverse reactions and side effects have been reported and may occur after the device is inserted:

- Due to the low temperature of the mixture a slight tubal spasm might 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 noted on the 3 months X-ray. In Case of abdominal expulsion, the plugs will be encapsulated and usually do not cause discomfort. If necessary they can be removed by laparoscopy.

CONTRA INDICATIONS

- 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.
- Abnormal menstrual cycles after a recent partus.
- Women who have not returned to their normal menstrual cycle after a recent partus.
- An unevaluated abnormal "PAP" smear.

LITERATURE

1. Erb RA, Davis RH, Kyriazis GA, Balin H. Device and technique for blocking the fallopian tubes. *Contemp Obstet Gynecol* 1974; 3:92
2. Reed TP, Erb RA. Hysteroscopic oviductal blocking with formed-in-place silicone rubber plugs. II Clinical studies. *J.Reprod Med* 1979; 23:69.
3. Reed TP, Erb RA, De Maeyer JF: Tubal occlusion with silicone rubber: Update 1980. *J. Reprod Med* 1981;26_534
4. Reed TP, Erb RA, De Maeyer JF: Tubal occlusion with silicone rubber. *Obstet Gynecol* 1983;61:388-392
5. De Maeyer J. Transcervical hysteroscopic sterilization. *Congress Book Hysteroscopy*. Boston MTP Press, 1983
6. Loffer FD. Hysteroscopic sterilization with the use of formed-in-place silicone plugs. *Am J Obstet Gynecol* 1984;149:261-70
7. Cooper JM Hysteroscopic sterilization. *Clin Obstet Gynecol* 1992;35:282-98
8. Loffer FD, Loffer P: hysteroscopic tubal occlusion with the use of formed-in-place silicone devices: a long term follow-up. *Gynaecol Endoscopy* 1:203-205, 1992
9. Blok S de , Dijkman AB K. Hysteroscopic occlusion with Ovabloc ITD – results of 115 cases. *Gynaecol Endosc* 1992;1:151-4
10. Assaf A, Abdin F, Elkady A, Abd AlAziz A, abd Alhady M:Histopathological effect of silicone rubber Ovabloc on the human fallopian tube. *Int J Gynecol Obstet* 43:181-189, 1993
11. Van der Leij G, van Krimpen C: The impact of Ovabloc Intratubal polymer on the morphology of the fallopian tube. *Int J Gynecol Path* 14:167-173, 1995
12. Van der Leij G, Lammes FB. Office hysteroscopic tubal occlusion with siloxane intratubal devices (The Ovabloc method). *Int J. Gynecol Obstet* 1996;53:253-60
13. Van der Leij G, Lammes FB. Radiographic aspects of the office hysteroscopic tubal occlusion with siloxane intratubal devices (The Ovabloc method). *Int J Gynecol Obstet* 1997.

In compliance with the 93/42/EE4 Directive, this product is to be handled and/or implanted only by trained qualified persons having read these instructions for use.