

FILSHIE[®]

TUBAL LIGATION SYSTEM



The Most Effective and Patient-Friendly Long Term Solution for Permanent Female Sterilization

The choice of leading surgeons around the world



Excellent and Well Known Long Term Effectiveness

In hundreds of published studies, the Filshie System demonstrates an exemplary "typical use" success rate that is superior to all methods studied in the CREST trials¹. Filshie Clips also have a very low rate of ectopic pregnancy.

Since introduction in 1982, with over 12 million clips applied, knowledgeable gynecologists have relied on the Filshie Clip System for high effectiveness and limited complications, whereas numerous studies and even professional recommendations confirm that the long-term benefits versus complications of prophylactic salpingectomy are not established.²⁻⁴ "The risks of decreased ovarian function and/or premature surgical menopause [due to prophylactic salpingectomy] may outweigh the benefit of decreased ovarian cancer incidence."⁵ "Studies investigating patient-based outcomes [of prophylactic salpingectomy] are lacking."⁶

As with salpingectomy, the occlusive nature of the Filshie Clip has been shown to reduce the incidence of ovarian cancer⁷⁻⁹. However, the Filshie Clip System has significant advantages when compared to salpingectomy: Filshie Clip placement involves no electrocautery, sharp dissection or permanent excision of tissue. A well-known and clinically reported potential side effect of Filshie Clip tubal ligation is clip migration. There are no known serious clinical or life-threatening complications that relate directly or indirectly to the Filshie Clips or their migration.¹⁰

Quick and Easy to Apply

Laparoscopic application of Filshie Clips requires basic laparoscopic skills and takes just a few minutes. Compared to salpingectomy, the surgery is easier. In a recent postpartum study, bilateral salpingectomy was successfully completed in only 68% of cases vs 95% successful completion of tubal ligation. Tubal ligation also had a 15 minutes shorter operative time than bilateral salpingectomy.¹¹ In certain women salpingectomy may technically be very difficult, increase intraoperative complication rate or even impossible such as women with abnormal anatomy and women with severe adhesions due to pelvic inflammatory disease or endometriosis.¹² There is no sharp dissection or excision of tissue that increases surgical risks, and operating room costs are lower.

Patient Satisfaction

Many women prefer the least invasive approach when it involves removal of anatomy.

Permanent, Yet Reversible

Because Filshie Clips preserve almost the entire fallopian tube, reversal via reanastomosis has been shown to be highly successful.¹³

Minimal Laparoscopic Ports Required

Only a single central instrument port is required for placement. Multiple lateral instrumentation ports that are necessary for salpingectomy are not needed. Therefore risk of epigastric vessel injury is mitigated¹⁴ and port site infection, irritation and herniation is potentially reduced.

Non-Hormonal, Permanent Device

Filshie Clips maintain high effectiveness without replacement or maintenance. Clips do not leach copper or hormones and do not need replacement. Filshie Clips are less worrisome than IUDs for women who have completed their families.

Effective for Postpartum Application

The Filshie Clip's special silicone profile and clip length allows it to be placed onto edematous postpartum Fallopian tubes. The length is able to encompass a swollen tube, and the silicone maintains pressure on the clipped tube as the tube gradually compresses.

Globally Recognized and Recommended

The proven success of the Filshie Clip is the reason that the UK Royal College of Obstetricians and Gynaecologists, in conjunction with the National Health Service, continues to recommend Filshie Clips as the preferred method for laparoscopic female sterilization.¹⁵ The Filshie System is the most common tubal occlusion method in Australia and New Zealand¹⁶, and is one of the most popular permanent sterilization methods in the United States, Canada, and a significant number of other countries worldwide.

Achieving consistent Filshie Clip application: The Sterishot II series of single patient use applicators

Consistently effective results are obtained with a calibrated Filshie Clip closure mechanism confirmed for each application. Since 2008, the patented¹⁷ Sterishot II single patient use Filshie Clip applicator has been providing precise closure pressure and reliable locking of the clip. Compared to a reusable applicator, Sterishot II applicators

- eliminate potential for patient infection due to cross-contamination,
- eliminate annual calibration requirements,
- eliminate the risk of damage from handling and storage, and
- eliminate resources required for post-surgical cleaning, sterile processing and tracking between procedures.

The Filshie System containing the Filshie Clips and Sterishot II applicator are immediately available and provide reliable results in every procedure.

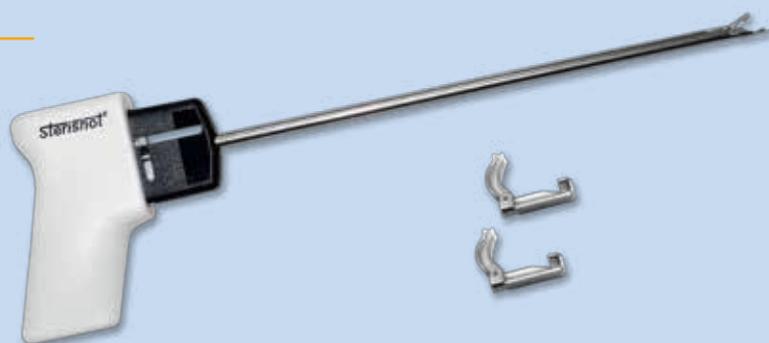


Standard Laparoscopic Kit

The basic Filshie System procedure tray.

Item: AVM-951

- Sterishot II Single Use Applicator
- One Pair Filshie Clips



Minilaparotomy Kit

The basic Filshie System procedure tray designed specifically for minilap Filshie Clip application.

Item: AVM-951M

- Sterishot II for Minilaparotomy
- One Pair Filshie Clips



Elite Kit

Filshie System Kit that contains one 8mm Bladeless Trocar and Cannula for use as the secondary (instrument) port in dual-incision laparoscopic technique. Bladeless trocar tip dilates tissue layers, which results in a smaller fascial defect and less trauma to the abdominal wall.

Item: AVM-954

- Sterishot II Single Use Applicator
- One Pair Filshie Clips
- One 8mm Bladeless Trocar and Cannula



Filshie Clips

Filshie Clips are available as individually packaged clip pairs for use as spares when needed.

Item: AVM-851J

- Ten Pairs Filshie Clips



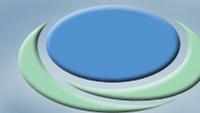
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- 17 U.S. Patents 9,451,966, 10,092,296



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