

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 Clinical Efficacy

In hundreds of published studies, the Filshie System demonstrates an exemplary "typical use" success rate. The recognized 99.76%¹ effectiveness is superior to all methods studied in the CREST trials². Filshie Clips also have a very low rate of ectopic pregnancy.

Clear Protective Benefit for Ovarian Cancer

As with salpingectomy, the occlusive nature of the Filshie Clip has been shown to reduce the incidence of ovarian cancer³.

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. There is no sharp dissection or excision of tissue that increases surgical risks, and operating room costs are lower.

Permanent, Yet Reversible

Because Filshie Clips preserve almost the entire fallopian tube, reversal via reanastomosis is highly successful.

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 mitigated⁴ and port site infection, irritation and herniation is potentially reduced.

Well Known Long-Term Effectiveness

Since introduction in 1982, with over 13 million clips applied, knowledgeable gynecologists have relied on the Filshie Clip System for high effectiveness and limited complications, whereas the long-term benefits versus complications of prophylactic salpingectomy are not established. "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

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 sterilization⁷.

The Filshie System is the most common tubal occlusion method in Australia and New Zealand⁸, 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 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.

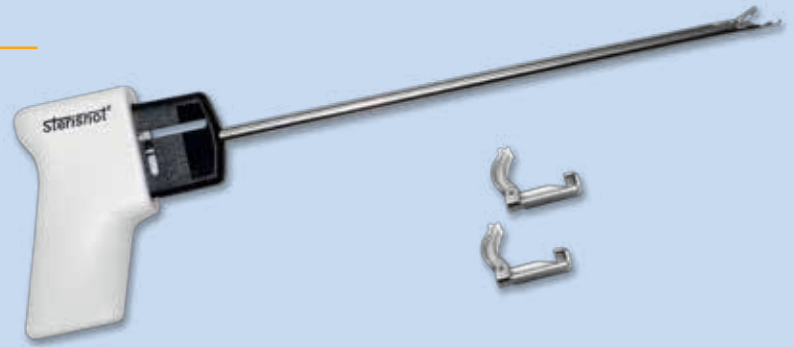
The Filshie System containing the Filshie Clips and Sterishot II applicator are immediately available and provide reliable results in every procedure.

Standard Laparoscopic Kit

The basic Filshie System procedure tray.

Item: FE-7SS-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: FE-7ML-951

- Sterishot II for Minilaparotomy
- One Pair Filshie Clips



Elite Kits

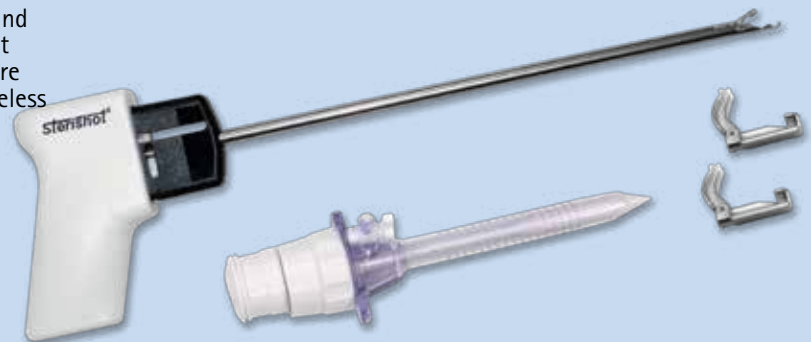
Filshie System Kits that contain one 8mm Trocar and Cannula for use as the secondary (instrument) port in dual-incision laparoscopic technique. Trocars are available with either safety shielded blade or bladeless configurations.

Item: FE-7SS-953

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

Item: FE-7SS-954

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



Elite Plus Kits

Filshie System Kits that contain both a primary (scope) port (either 5mm or 10mm) and an 8mm secondary (instrument) port. Choose either safety shielded blade or bladeless trocar configurations.

Item: FE-7SS-957

- Sterishot II Single Use Applicator
- One Pair Filshie Clips
- One 8mm Shielded Trocar and Cannula
- One 10mm Shielded Trocar and Cannula

Item: FE-7SS-958

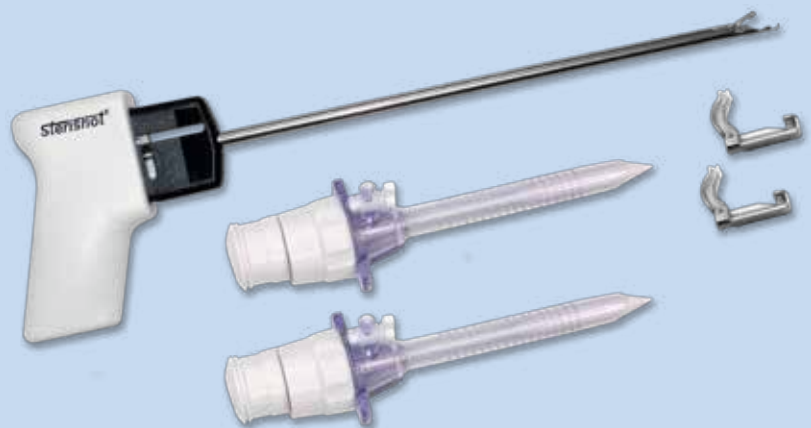
- Sterishot II Single Use Applicator
- One Pair Filshie Clips
- One 8mm Shielded Trocar and Cannula
- One 5mm Shielded Trocar and Cannula

Item: FE-7SS-959

- Sterishot II Single Use Applicator
- One Pair Filshie Clips
- One 8mm Bladeless Trocar and Cannula
- One 10mm Bladeless Trocar and Cannula

Item: FE-7SS-960

- Sterishot II Single Use Applicator
- One Pair Filshie Clips
- One 8mm Bladeless Trocar and Cannula
- One 5mm Bladeless Trocar and Cannula



References:

- 1 Kovacs GT, Krins AJ. Female sterilisations with Filshie clips: what is the risk of failure? A retrospective survey of 30,000 applications. J Fam Plann Reprod Health Care 2002;28(1):34-35
- 2 Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. Am J Obstet Gynecol 1996;174(4):1161-1170.
- 3 Benefits and risks of sterilization. Practice Bulletin No. 133. American College of Obstetricians and Gynecologists. Obstet Gynecol 2013;121(2):392-404.
- 4 Bhoyrul S, Vierra MA, Nezhat CR, et al. Trocar injuries in laparoscopic surgery. J Am Coll Surg 2001;192(6):677-683.
- 5 Backes FJ, Salpingectomy, why not? Am J Obstet Gynecol 2014;210(5):385-386
- 6 Castellano T, Zerden M, March L, et al. Risks and benefits of salpingectomy at the time of sterilization. Obstet Gynecol Surv 2017;72(11):663-668
- 7 Faculty of Sexual & Reproductive Healthcare, Royal College of Obstetricians & Gynaecologists, Male and Female Sterilisation, 2014 Sep.
- 8 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Female sterilisation by Filshie clip tubal occlusion (C-Gyn 22), 2014 Nov.



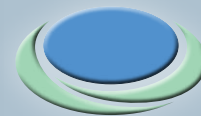
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