

# **Inservice Reference Guide**

IMPORTANT: This guide is not intended to be a complete instruction. Consult the Instructions for Use for complete indications, contraindications, warnings and precautions.

### **Product Description**

The Filshie Tubal Ligation System consists of:

- A precalibrated, sterile Sterishot II Applicator in tray.
- A pair of Filshie clips, packaged within their own box that is placed under the Sterishot II tray. The box also contains patient lot labels to be placed in a patient's record, and a MRI card to be given to the patient after the procedure.
- As an option, Elite Kits which contain an 8mm port. An 8mm port is the ideal size for the Sterishot II applicator. This port size requires less tissue dilation than the commonly available 10mm ports, so is gentler to tissue and may reduce incidence of port site herniation or delayed site healing.

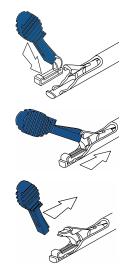
# Loading the Filshie Clip

Carefully remove the Sterishot II Filshie Clip Applicator from its packaging. Check the operation of the applicator prior to use. Users must be able to easily and fully compress the Sterishot II trigger to its stop.

As pictured, pick up the Filshie Clip with the blue plastic 'No Touch' handle already fitted.

Using a 'No Touch' technique, slide the bottom of the Filshie Clip along the floor of the applicator 'Clip Tray' until it is within the 'Side Guides' and against the 'Clip Stop'.

Detach the 'No Touch' handle by levering it backwards, and then discard the handle.



# Ensure the Clip is correctly loaded in the applicator

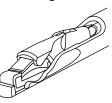
- 1. Check that the bottom portion of the Clip lies perfectly flat on the floor of the applicator 'Clip Tray', not rising up at the back or the front.
- 2. Check that the front end of the Clip lies directly behind the 'Clip Stop' of the applicator's lower jaw.
- 3. Check that the upper portion of the Clip is located between the 'Side Guides' of the applicator's upper jaw.
- 4. Gently tap the applicator against the palm of the hand to ensure the Clip is securely loaded.



#### Entering the Abdomen: The 'Half Closed' Position

A feature of the Sterishot II Applicator is a white visual guide located within the trigger housing, designed to help signal the 'Half Closed' position and hence avoid prematurely closing or distorting the Filshie Clip so that it may fail to close properly. To ensure the 'Half Closed' position is not exceeded, the edge of the black polished section of the trigger should not pass beyond the white visual guide located inside the black trigger housing.





Applicator jaws in 'Half Closed' position (clip not prematurely closed or distorted)

#### Application of the Filshie Clip

- Identify and inspect the Fallopian tube thoroughly.
- Ensure that the Filshie Clip can accommodate the whole diameter of the Fallopian tube.
- Locate the Filshie Clip over the isthmic portion of the Fallopian tube, 1-2cm from the cornu.
- Having established the best location for the Filshie Clip after insertion through the trocar, the applicator should be re-opened and advanced a few millimeters to move the Fallopian tube gently to the back of the Filshie Clip, close to the hinge.
- Close the Filshie Clip into position by applying firm, but gentle pressure on the trigger in a smooth action until the trigger reaches its mechanical stop.
- When the Filshie Clip is secured in position, gently release the trigger and the Filshie Clip will automatically free itself from the applicator 'Clip Tray'.
- Do not use an abrupt closure action or the tube might be transected. Should this occur, apply a second Filshie Clip on the proximal (uterine) side of the transection.

Digital photography and video recording of the closure process are encouraged to support the patient record case file.









d on tube Correct Closure



Clip open over tube Clip with applicator Clip closed on tube half closed

#### Removal of the Applicator from the Abdomen

Before the Sterishot II Applicator can be withdrawn from the abdomen it must be returned to the 'Half Closed' position so it can pass through the cannula.

# FILSHIE TUBAL LIGATION USING THE PATENTED\* STERISHOT II APPLICATORS – A HIGHLY EFFECTIVE CHOICE FOR PERMANENT CONTRACEPTION

- Quick & easy to apply
- Requires minimal laparoscopic ports
- Can be applied immediately following childbirth
- Non-hormonal, does not contain copper
- MRI compatible
- Permanent, yet has been shown to allow high reversal success
- Consistent, highly effective results with a precalibrated Filshie Clip closure mechanism for each patient
- No post-surgical cleaning, sterile processing, tracking between procedures or service required

# Order Reference:

Sterishot II Standard Laparoscopic Kit	.AVM-951
Sterishot II Minilaparotomy Kit	.AVM-951M
Sterishot II Elite Kit w/ Bladeless Port	.AVM-954
Filshie Clips (10 pairs)	.AVM-851J



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