CAUTION:
U.S. Federal law restricts this device to sale by or on the order of a physician.

FILSHIE TUBAL LIGATION SYSTEM™

A contraceptive device for permanent female sterilization

Care, Maintenance and Sterilization Manual

CooperSurgical
FILSHIE® Tubal Ligation System

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1. THE FILSHIE TUBAL LIGATION SYSTEM

The Filshie Tubal Ligation System includes the Filshie Clip and a series of applicators used to apply the Filshie Clip.

1.1 THE FILSHIE CLIP

The Filshie Clip is manufactured from titanium and is lined on the inner surface with silicone rubber (both are implantable grade). At one end there is a hinge and at the other a latch, allowing for manipulation of the Fallopian tube. The Filshie Clip is applied across the entire diameter of the Fallopian tube. When the Clip is fully closed, the upper jaw is flattened and is securely latched under the front end of the lower jaw. This acts as a clasp, securing the upper jaw of the Clip. The silicone rubber is in direct contact with the tissues and both are compressed under the force applied by the titanium. When avascular necrosis of the Fallopian tube occurs the compressed silicone expands to maintain complete occlusion of the lumen. This prevents re-canalisation and destroys approximately 4mm of the Fallopian tube. The Filshie Clip is supplied sterile and is non-magnetic, therefore, making it possible to carry out an M.R.I. scan once Clips have been applied.

The Filshie Clip is 13mm long, 3.5mm wide and when closed 4mm high.

Important: Before applying Filshie Clips, please carefully read the Filshie Clip Instructions For Use that is provided in all boxes of Filshie Clips, including the sections on Contraindications, Warnings, Precautions, Side Effects and Adverse Effects.

Filshie Clip Stages of Operation

Shown below is the appearance of the Filshie Clip at different stages of operation:

Clip fully open from the pack with the 'No Touch' loading handle fitted.
Clip half closed, giving a temporary grip on the tube; re-openable at this stage.
Clip half closed, as it goes down the cannula.
Clip open, as it sits in the loaded applicator.
Clip permanently secured after force has been applied to the applicator. Latching has occurred and the Clip cannot be opened.

How Supplied

Twenty (20) or Ten (10) pairs of Filshie Clips and prescribing information are contained in a single carton. Each pair is contained in a procedure package consisting of one pair of Filshie Clips in a sterile peelable pouch.
1.2. THE FILSHIE CLIP APPLICATOR RANGE

The Filshie Clip is applied using the following range of instrumentation:

- **Single Incision Applicator (5mm)**
  - AVM-880

- **Single Incision Applicator (7.3mm)**
  - AVM-857

- **Dual Incision Applicator (7mm)**
  - AVM-863

- **Minilap Applicator**
  - AVM-856

- **Clip Closure Checking Gauge**
  - AVM-909

**The Filshie Clip Applicators**

The Filshie Clip Applicators are made from medical grade stainless steel and are manufactured in the UK. They are available in various sizes and have been developed for a number of approaches to the Fallopian tubes including:

<table>
<thead>
<tr>
<th>Dual Puncture Laparoscopy</th>
<th>Single Puncture Laparoscopy</th>
<th>Minilaparotomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual Incision Applicator</td>
<td>Single Incision Applicators</td>
<td>Minilap Applicator</td>
</tr>
<tr>
<td>7mm: FE-7OA-863 / AVM-863</td>
<td>5mm: FE-5SI-880 / AVM-880</td>
<td>FE-8ML-856 / AVM-856</td>
</tr>
<tr>
<td>7.3mm: FE-7SI-857 / AVM-857</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- AVM-863, intended for dual incision laparoscopy and designed for use with the 7mm internal diameter Filshie trocar and cannula, is 355mm in length with a shaft that is 250mm long and 7mm in diameter.
- AVM-880, intended for a single-incision laparoscopy (the operating laparoscope should have a working channel of 5mm diameter, minimum), is 545mm long overall with a shaft of 440mm in length and 5mm in diameter.
- AVM-857, also intended for single-incision laparoscopy and is designed for an operating laparoscope having a working channel of 7mm in diameter minimum, is 520mm in length with a shaft of 415mm long and 7mm in diameter; and
- AVM-856, intended for minilaparotomy, is 200mm in overall length with an effective shaft length of 100mm;

The Closure Checking Gauge is included with ALL Filshie Clip Applicators and allows operators to monitor the performance of their Filshie Clip Applicators.

All Filshie Clip Applicators are designed for use by both left and right-handed operators and are constructed in two parts - the handle and the main shaft. They are simple to use and are easily assembled and disassembled for cleaning and maintenance purposes.
Unlike all of the other Filshie Clip Applicators, the 5mm Single Incision Applicator must be assembled through the instrument channel of the operating laparoscope.

The applicator shaft is inserted through the distal end of the operating laparoscope’s instrument channel until the top of the applicator shaft protrudes through the proximal end of the laparoscope. The applicator handle can then be screwed onto the protruding end of the applicator shaft.

The Minilap Applicator

This instrument is the applicator of choice when tubal occlusion is to be carried out using a minilaparotomy approach. It is particularly recommended for use in the immediate postpartum (including at Cesarean section) or postabortion period.

Important: Although a pneumoperitoneum is not induced in the minilaparotomy technique, the loading of the Filshie Clip and the principles of operation are identical to the Dual Incision Applicator.

2. INDICATION AND USAGE

The Filshie Tubal Ligation System is a contraceptive tubal occlusion device indicated for permanent female sterilization by occlusion of the Fallopian tubes.

3. CONTRAINDICATIONS

The Filshie Tubal Ligation System must not be applied if any of the following conditions are present in the patient:

- Existing (current) or suspected pregnancy.
- Significant peritubular adhesions obscuring the portion of the Fallopian tube to be occluded.
- Acute pelvic inflammatory disease (PID).
- Salpingitis isthmica nodosa or chronic isthmic induration.
- Hemoperitoneum or suspicion of ectopic pregnancy.
- Any conditions contraindicating the use of surgery, or local or general anaesthetic.

4. WARNINGS

4.1. PREGNANCY

- Pregnancy may rarely occur after placement of the Filshie Clip. The recognized failure rate for the Filshie Clip is 2.7/1000, but may be higher in women with certain pre-existing conditions (including pelvic inflammatory disease and obesity).
- Women sterilized postpartum or postabortion may be at increased risk of pregnancy. The pregnancy rate following tubal sterilization of postpartum patients is higher than that reported in interval patients. After two (2) years the annual pregnancy rate for patients sterilized with the Filshie Clip was 1.7% for postpartum patients.
- Pregnancy following occlusion of the Fallopian tubes using Clips may be associated with applications in which the Clip has not completely captured the Fallopian tube or applications which have inadvertently been placed on the wrong anatomical structure, such as the round or ovarian ligaments.

4.2. ECTOPIC PREGNANCY

- Rare instances of ectopic pregnancy subsequent to application of the Filshie Clip have been reported. The possibility of ectopic implantation must be considered in any patient becoming pregnant after sterilization using the Filshie Tubal Ligation System.
- Any patient presenting with delayed menstruation and/or unilateral pelvic pain must be carefully evaluated to determine whether an ectopic pregnancy exists.
4.3. UNINTENDED MAJOR SURGERY (LAPAROTOMY)

- Trauma may occur infrequently to pelvic organs during laparoscopic application of the Filshie Clip. This trauma may result in the need for major surgical intervention for the purpose of repair. The need to proceed to unintended major surgery also has been reported in some women with pre-existing intra-abdominal adhesions, obesity or history of pelvic inflammatory disease (PID). It is impossible to predict whether a patient has unusually friable Fallopian tubes. In a very small number of cases, the normal closure of the Filshie Clip may cause immediate transection. If such transection occurs, a second Clip should be carefully applied on the proximal (uterine) side of the lesion using a much slower closing action.

4.4. TRAUMA/BLEEDING

- Injuries to the Fallopian tube, mesosalpinx or cornua, though infrequent, may result from Filshie Clip application. Mesosalpingal or tubal injury is more likely among women with pre-existing peritubular adhesions, or thick or edematous tubes. The incidence of trauma/bleeding injuries decrease with physician experience and careful patient selection.
- Resection of the Fallopian tube, mesosalpinx or cornua, though infrequent, may result in bleeding and hematoma formation. If bleeding is uncontrolled, surgical intervention and repair or completion of the sterilization procedure using another tubal occlusion methodology may be required.

4.5. TECHNICAL FAILURES

- There may rarely be a need to change to an alternative procedure or abandon the sterilization procedure altogether during application of the Filshie Clip. Technical failures have been reported in women with enlarged uteri and pre-existing peritubular adhesions.
- Technical failures have been associated with equipment malfunction. Both the operator and support personnel should be familiar with the operation, sterilization, and maintenance of the Filshie Clip applicator and associated devices prior to use.
- Failures have also been attributed to the use of applicators that are out of calibration. The manufacturer recommends the instrument be recalibrated once a year or after every 100 uses, whichever comes first.

4.6. INFECTION

- Infection at the site of the incision may rarely follow tubal sterilization.
- Infections of the pelvic cavity may follow tubal sterilization.
- Urinary tract infections may follow tubal sterilization.

4.7. CLIP EXPULSION, FOREIGN BODY REACTIONS, AND ASYMPTOMATIC MIGRATION

- Instances of Clip expulsion per urethra, vaginal cuff and bowel, as well as foreign body reactions have been reported (3 expulsions and 2 foreign body reactions were reported in 5,326 women). Three instances of apparently asymptomatic migration of the Clip were observed as incidental findings, but the frequency of this event is not known.

5. PRECAUTIONS

5.1. PATIENT EVALUATION

- A complete medical history should be obtained to determine conditions that might influence the selection of the procedure, or are absolute or relative contraindications to surgery. A routine physical examination should be performed noting the integrity of the pelvic organs and, if indicated, a pregnancy test undertaken to determine an existing pregnancy. The patient should be evaluated for pelvic inflammatory disease, cardiovascular disease, severe ileus, acute peritonitis, previous pelvic surgery, significant hemoperitoneum and other conditions which contraindicate surgery or the use of anesthesia.

5.2. PATIENT COUNSELING

- Prior to any sterilization procedure being performed, the patient should be fully informed about alternative methods of contraception, the possible side effects of the procedure, any complications which may arise during and following the procedure and the risks and benefits associated with sterilization in general and the Filshie Tubal Ligation System procedure in particular. The patient should be encouraged to discuss openly and fully any questions she may have concerning the Filshie Tubal Ligation procedure.
- The patient should be advised that if any post-operative symptoms are severe or persist, she should see her physician.
- The patient should be informed that sterilization will not prevent sexually transmitted diseases (STDs). Additional precautions against STDs must still be taken after sterilization.

5.3. CLINICAL USAGE

- For each procedure, use only Clips enclosed in the sealed, sterile package. DO NOT USE IF THE PACKAGE HAS PASSED ITS EXPIRY DATE.
- Check the operation of the Filshie Clip Applicator prior to use (see operating instructions).
Physicians should be thoroughly familiar with the Filshie Tubal Ligation System, tubal sterilization procedures, and management of tubal sterilization complications before attempting its use. The supporting staff should be familiar with the maintenance, proper assembly and disassembly, cleaning, and sterilization of the Filshie Clip Applicator.

Improper loading and testing of the applicator may result in Filshie Clips being either inadvertently discharged into the peritoneal cavity or incorrectly placed. Refer to the Care, Maintenance and Sterilization Manual for the proper method for inserting the Filshie Clips into the applicator, and the recommended course of action for an incorrectly placed Filshie Clip. It is recommended that Filshie Clips accidentally dropped into peritoneal cavity be recovered.

Retrieval of a Dropped Clip: If this should occur the Filshie Clip should be immediately identified, grasped with the applicator and removed. The Filshie Clip should be grasped firmly (preferably near the hinge) and pulled to the mouth of the cannula. The applicator holding the Filshie Clip firmly, together with the cannula, should then be withdrawn from the abdomen simultaneously.

NOTE: If you are unable to find a dropped Filshie Clip, it is safer to leave it (open or closed) than to perform a laparotomy. The decision to perform a laparotomy is at the discretion of the physician. The Filshie Clip is intended for implantation; however rare cases of migration and inflammation have been reported.

Physicians are cautioned that they should confirm the location of the pelvic organs before Filshie Clip application to prevent inadvertent application to an inappropriate anatomical structure such as the round or ovarian ligament.

The safety and effectiveness of the Filshie Tubal Ligation System for permanent sterilization has only been tested and clinically evaluated using the Femcare-Nikomed Filshie Clip Applicators. Applicators from other manufacturers must not be used. Filshie Clip Applicators must be maintained regularly and serviced as per manufacturer's directions. The Filshie Clip Applicators must be tested with the Clip Closure Checking Gauge prior to every procedure.

5.4 SIDE EFFECTS

- Pain: Cramping, pelvic pain, shoulder pain or headache may occur during the procedure or in the immediate post operative period. These effects are usually short lived and subside in about 48-72 hours.

- Changes in Menstrual Flow: Changes in the amount and duration of menstrual flow as well as the length and regularity of the menstrual cycle have been observed following the application of the Filshie Clip. These changes have not, however, been causally linked to the Filshie Clip procedure and may be due to the concurrent removal of IUD, previous oral contraceptive use, age and previous menstrual history.

- Clip Migration and Expulsion: Instances of migrated Filshie Clips being expelled from the body per urethra, via vaginal cuff abscess and via bowel abscess have been reported. Rarely, migrated Filshie Clips may cause symptoms without expulsion.

5.5 LONG TERM IMPLANTATION AND SEQUELAE

- The silicone and titanium used in the manufacture of the Filshie Clip are generally regarded as safe materials for human implantation. Although no adverse toxic or tumorigenic effects due to the device or its materials have been reported, the effects of long term implantation are unknown.

- The long term effects of tubal sterilization on women are unclear. Several uncontrolled studies suggest that women undergoing tubal sterilization may be prone to gynecological problems. More recent controlled studies report that sterilization does not cause any long term effects. The rates of hospital referral for gynecological or psychiatric conditions appear to be similar for women undergoing tubal sterilization and women whose husbands underwent vasectomy.

- In the event of a subsequent hysterectomy, it has been recommended that the Filshie Clips be removed.

- Testing to ensure compatibility with Magnetic Resonance Imaging (MRI) has been conducted using a 1.5 Tesla magnet. No clinically significant attractive forces were observed at that strength. However, the presence of the Filshie Clips produces an MR artifact which will obscure imaging of local tissue. The Filshie Clips have been shown to be compatible with MRI procedures.
6. ADVERSE EFFECTS

The following adverse effects have been reported with the use of the Filshie Tubal Ligation System: Pregnancy (0.46%); ectopic pregnancy (0.016%); Clip migration or expulsion (0.13%); misapplication to ovarian ligament, broad ligament, omentum, bowel, tubal serosa, cornual or broad ligament (0.05%); pelvic pain (35.7%)1.

Other adverse experiences reported from surgical procedures to implant the Filshie Clip include the following: Musculoskeletal pain (6.0%); adnexal pain/enlargement/infection (5.0%); incisional inflammation, bleeding, abscess or pain (4.4%); nausea/vomiting (4.3%); keloids (3.9%); headache (3.0%); serious discharge (2.8%); vaginitis (1.1%); urinary tract infection (1.0%); and hematoma (1.0%). Menstrual pattern changes, involving the amount of blood flow, duration of flow, cycle regularity and cycle length, and dysmenorrhea, may occur following tubal sterilization. Menstrual disturbances not present at baseline in women who received the Filshie Clip were reported as follows: 6.9% excessive flow; 0.7% menorrhagia; 1.4% vaginal bleeding; 2.6% severe dysmenorrhea and 0.6% severe intermenstrual pelvic pain. These effects have been reported to be associated with other methods of tubal sterilization, and they often disappear within a year following sterilization.

6.1. ADVERSE EXPERIENCES EVER OCCURRING IN > 0.5% OF ALL PATIENTS POST-SURGERY

Table 1:

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Filshie Tubal Ligation System</th>
<th>Other Tubal Occlusion Device/Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N=5,454)</td>
<td>(%)</td>
</tr>
</tbody>
</table>
| Digestive      |                               | (N=3,845)                         |%
| Nausea/vomiting| 235                           | 4.3                                |
| Musculoskeletal|                               | 155                               | 4.0 |
| Back pain      | 52                            | 0.6                                |
| Shoulder Pain  | 295                           | 5.4                                |
| Nervous/Psychiatric |                         | 212                               | 5.5 |
| Headache       | 184                           | 3.3                                |
| Skin           |                               | 89                                | 2.3 |
| Keloid         | 274                           | 5.9                                |
| Serious Infection |                 | 198                               | 5.1 |
| Primal Incision Inflammation | 138 | 2.5 | 96 | 2.5 |
| Wound Abscess  | 29                            | 0.5                                |
| Wound Bleeding | 43                            | 0.8                                |
| Hematoma       | 35                            | 0.6                                |
| Incomplete Dehiscence | 24   | 0.4 | 30 | 0.8 |
| Incision Pain  | 81                            | 1.5                                |
| Urogenital      |                               | 93                                | 2.4 |
| Vaginitis       | 62                            | 1.1                                |
| Vaginal Abnormality | 29 | 0.6 | 25 | 0.7 |
| Dysplasia       | 32                            | 0.6                                |
| Uterine Abnormality Menses | 51 | 0.9 | 29 | 0.8 |
| Excessive Flow  | 279                           | 6.9                                |
| Severe Dysmenorrhea |                 | 299                               | 5.4 |
| Severe Intermenstrual Pelvic Pain | 144 | 2.6 | 57 | 1.3 |
| Menorrhagia     | 37                            | 0.7                                |
| Vaginal Bleeding| 79                            | 1.4                                |
| Infection in Adnexa |                     | 66                                | 1.7 |
| Tenderness / Enlarged Adnexa | 142 | 2.6 | 199 | 3.8 |
| Pelvic Pain     | 1,349                         | 35.7                               |
| Adnexal Pain    | 109                           | 2.0                                |
| Urinary Tract Infection | 51 | 1.0 | 29 | 0.8 |

Note: Multiple events may be reported per woman.

1 - Clinical data is on file at CooperSurgical and is available upon request.

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7. CLINICAL STUDIES

For the 5,754 women who were enrolled in the eleven clinical trials reported in the pre-market approval application (PMA) and who were sterilized using the Filshie Tubal Ligation System, only 22 pregnancies were reported. Only one ectopic pregnancy was reported. A list of the adverse events that were reported in the clinical study is provided in 6.1 Table 1.

Four of the clinical studies were designated “pivotal studies”. These studies are prospective, randomized, controlled clinical studies comparing the Filshie Tubal Ligation System to the Hulka Clip or the Falope Ring. The method of application was either laparoscopy or minilaparotomy. The 12-month follow-up results are shown in 7.1 Table 2. There was no statistically significant difference between the failure rates for the Filshie Tubal Ligation System as compared to the Hulka Clip or Falope Ring.

7.1. FILSHIE TUBAL LIGATION SYSTEM - GROSS CUMULATIVE LIVE - TABLE PREGNANCY RATES

Table 2:

<table>
<thead>
<tr>
<th>Pool Pivotal Studies</th>
<th>Months of follow up</th>
<th>12-Month Pregnancy Rate (Standard Error) Per 100 Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filshie vs Hulka Clip¹</td>
<td>12</td>
<td>Filshie Tubal Ligation System</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.1 (0.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=1,063</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% completing = 68.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comparison Device</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.7 (0.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=1,062</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% completing = 82.4%</td>
</tr>
<tr>
<td>Filshie vs Falope Ring²</td>
<td>12</td>
<td>0.2 (0.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=1,378</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% completing = 81.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.2 (0.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=1,355</td>
</tr>
<tr>
<td></td>
<td></td>
<td>% completing = 82.4%</td>
</tr>
</tbody>
</table>

¹ - The Hulka Clip™ is also known as the Wolf Clip™
² - The Falope Ring Band™ is also known as the Tubal Ring and the Yoon Ring™

Results from a single study suggest that the Filshie Tubal Ligation System may be less effective than the Pomeroy method in postpartum women. Of 1,400 women who were enrolled in a 24 month study, nine (9) reported pregnancies in the Filshie group, and two (2) in the Pomeroy group.
FILSHIE® Tubal Ligation System

7.2. PREGNANCY RATES FOR BIRTH CONTROL METHODS

Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year in the United States.

Table 3: Pregnancy Rates for Birth Control Methods - Summary Table of Contraceptive Efficacy

<table>
<thead>
<tr>
<th>Method</th>
<th>% of Women Experiencing an Unintended Pregnancy within the First Year of Use</th>
<th>% of Women Continuing Use at One Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Typical Use A</td>
<td>Perfect Use B</td>
</tr>
<tr>
<td>No Method</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>Spermicides</td>
<td>29</td>
<td>18</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>27</td>
<td>4</td>
</tr>
<tr>
<td>Fertility awareness-based methods</td>
<td>25</td>
<td>-</td>
</tr>
<tr>
<td>Standard Days Method</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Two Day Method</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Ovulation Method</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Sponge</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Parous women</td>
<td>32</td>
<td>20</td>
</tr>
<tr>
<td>Nulliparous women</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Condom</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Female (Reality)</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>Combined Pill and Progestin-Only Pill</td>
<td>8</td>
<td>0.3</td>
</tr>
<tr>
<td>Vaginal Contraceptive Patch</td>
<td>8</td>
<td>0.3</td>
</tr>
<tr>
<td>Female Male Sterilization</td>
<td>8</td>
<td>0.3</td>
</tr>
<tr>
<td>Depo-Provera</td>
<td>3</td>
<td>0.3</td>
</tr>
<tr>
<td>IUD</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ParaGard (Copper T)</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Mirena (LNG-IUS)</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Implant</td>
<td>0.05</td>
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<td>Female Sterilization</td>
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</tr>
<tr>
<td>Male Sterilization</td>
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<td>0.10</td>
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</table>


Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%. 4

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception. 1

For References See Page 23
8. INSTRUCTIONS FOR USE

8.1. APPLICATOR ASSEMBLY AND PRE-PROCEDURE CHECKS

Warning: All Filshie Clip Applicators must be serviced every 12 months or after every 100 procedures, whichever comes first. A poorly maintained or worn applicator may not close Clips tightly enough to fully occlude the Fallopian tube. If the service record does not comply with this, DO NOT USE the Filshie Clip Applicator.

Warning: Each applicator is individually calibrated by the manufacturer. No adjustments should be made to an applicator by unauthorized persons. Calibration and recalibration are critical operations which must only be performed by CooperSurgical. Always check that the serial numbers on the handle assembly and the shaft of the applicator are the same. If they are not, DO NOT USE THE APPLICATOR.

Warning: NEVER attempt to adjust or repair Filshie equipment yourself. Servicing or repair work will only be guaranteed if undertaken by CooperSurgical. The applicator is a finely adjusted instrument and no liability will be accepted for problems or failures as a result of any unauthorized repairs or adjustment.

Warning: All equipment should be sterilised before use by a validated method.

8.2. USING THE SILICONE SEAL TUBE

The Silicone Seal Tube, which is fitted over the end of the applicator Push Rod, is supplied separately along with each applicator. The purpose of the Silicone Seal Tube is to ensure that there is no gas leakage through applicators during insufflation and pneumoperitoneum. However, current insufflators are likely to compensate for gas loss, therefore, the Silicone Seal Tube is provided separately in order to be used at the discretion of the operator. If you wish to use the Silicone Seal Tube then it should be placed over the exposed Push Rod on the applicator shaft before attaching the handle. Ensure that it goes over the shoulder of the main tube, close up to the threaded portion as shown below:

Placement of the Seal Tube over the Push Rod:

NOTE: This is not applicable to 5mm Single Incision or Minilap Applicators which do not require a Silicone Seal Tube.

8.3. ATTACHING THE HANDLE

Using a clockwise motion, screw the handle assembly to the shaft of the applicator.

Use firm but gentle pressure to ensure a finger-tight connection.

Warning: Never use excessive force as this may cause cross-threading, permanently damaging the applicator.

Warning: Always check that the serial numbers on the handle assembly and the shaft of the applicator are the same. IF THEY ARE NOT, DO NOT USE THE APPLICATOR.

Important: Always ensure that the handle and shaft are screwed firmly together before the procedure begins and REMAIN SO throughout.

8.4 CHECKING THE ALIGNMENT

When the applicator is assembled the movable jaw should be in line with the finger bar, 20° to the left or right is acceptable.
8.6. USING THE CLOSURE CHECKING GAUGE

It is critical that applicator pressure is sufficient to ensure correct Filshie Clip closure. The Closure Checking Gauge is supplied with all new Filshie Clip Applicators and should be used prior to loading the Filshie Clip to ensure that the applicator will function correctly. Closure Checking Gauges are also available separately through CooperSurgical.

Check that the Filshie Clip Applicator has been correctly assembled. Hold the gauge by the flag and gently slide the base into the applicator ‘Clip tray’.

Make sure that it is positioned level in the applicator ‘Clip tray’ (within the ‘side guides’) and back against the ‘Clip stop’.

Close the ‘finger bar’ until the applicator jaw just holds onto the base of the gauge. Check that the gauge is located within the ‘side guides’ of the applicator top jaw.

Important: Do not use excessive force. Once the Closure Checking Gauge has been held do not squeeze the finger bar any further.

8.7. CHECKING THE RESULT

Once clamped, check for lengthways movement only (in the direction of the ‘Clip tray’ and applicator shaft). Sideways movement of the flag should not be considered.

Gauge held = OK
Applicator acceptable to use.

Gauge loose or lengthways movement = unacceptable
If there is movement lengthways then the applicator should not be used until it has been checked and re-adjusted by the CooperSurgical. If in any doubt – return the applicator.
LOADING THE FILSHIE CLIP USING THE ‘NO TOUCH’ TECHNIQUE

1. Pick up the Filshie Clip using the blue plastic ‘No Touch’ handle already fitted (Fig 1).

2. Using a ‘No Touch’ technique, slide the bottom of the Clip along the floor of the applicator ‘Clip Tray’ until it is within the ‘side guides’ and against the ‘Clip Stop’ (Fig 2).

3. Detach the ‘No Touch’ handle by levering it backwards and then discard it (Fig 3).

Warning: To maintain sterility, never touch the Filshie Clip. Do not use if the packaging is damp or damaged.

Note: The manufacturer recommends replacement of the Closure Checking Gauge every 2 years.

Warning: All Filshie Clip Applicators must be serviced every 12 months or after every 100 procedures, whichever comes first. A poorly maintained or worn applicator may not close Clips tightly enough to fully occlude the Fallopian tube. If the service record does not comply with this, DO NOT USE the Filshie Clip Applicator.

Important: The Closure Checking Gauge only indicates the minimum acceptable closing pressure.
FILSHIE® Tubal Ligation System

8.9. CHECK LOADING OF THE CLIP IN THE APPLICATOR JAWS

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.

Warning: Either of the two incorrect loadings pictured above may produce distorted Clips, which may lead to pregnancy.

8.10. ENTERING THE ABDOMEN USING THE 7mm DUAL INCISION APPLICATOR

Important: Follow the manufacturer’s Instructions For Use relevant to the trocar and cannula being used.

8.10.1. Insertion of the Applicator through the Cannula

The applicator is suited for both left and right-handed operators.

Important: Always ensure that the handle and the shaft of the applicator are screwed firmly together before the procedure begins and remains so throughout. Always check that the serial numbers on the handle assembly and the shaft of the applicator are the same. IF THEY ARE NOT, DO NOT USE THE APPLICATOR.

In order to pass the loaded applicator through the cannula it must be in a ‘half closed’ position.

To achieve the ‘half closed’ position gently squeeze the finger bar (Fig 1) until the moveable jaw is ‘half closed’ to allow smooth passage of the applicator through the cannula (Fig 2).

Maintain gentle pressure to keep the Clip ‘half closed’ (Fig 3) until visualised through the laparoscope. Slowly release the finger bar and the Clip will re-open ready for application.

Fig 1  Fig 2  Fig 3

Warning: Do not squeeze the applicator handle too tightly as this may cause the Clip to close prematurely or to become distorted so that it may fail to close properly. If this should occur remove the loaded applicator, dispose of the distorted Clip and load a replacement Clip.

Important: Obtaining the ‘half closed’ position should be practiced several times before clinical use.
8.11. ENTERING THE ABDOMEN USING A 5mm SINGLE INCISION APPLICATOR

Important: Unlike all other Filshie Applicators, the 5mm Single Incision Applicator must be assembled through the instrument channel of the operating laparoscope. The applicator shaft is inserted through the distal end of the operating laparoscope’s instrument channel until the top of the applicator shaft protrudes through the proximal end of the laparoscope. The applicator handle can then be screwed onto the protruding end of the applicator shaft, ensuring that the handle and the shaft of the applicator are screwed firmly together before the procedure begins and remains so throughout. Always check that the serial numbers on the handle assembly and the shaft of the applicator are the same. IF THEY ARE NOT, DO NOT USE THE APPLICATOR.

8.11.1 Insertion of the Operating Laparoscope and Applicator through the Cannula

In order to pass the loaded applicator/laparoscope combination through the cannula, the applicator must be in the ‘half closed’ position. This is achieved by gently squeezing the finger bar (Fig 1) until the moveable jaw closes just far enough to allow smooth passage of the applicator laparoscope combination through the cannula (Fig 2). Maintain gentle pressure to keep the Clip ‘half closed’ (Fig 3) until inside the abdominal cavity. Slowly release the finger bar and the Clip will re-open ready for application.

Warning: Do not squeeze the applicator handle too tightly as this may cause the Clip to close prematurely or to become distorted so that it may fail to close properly. If this should occur remove the loaded applicator, dispose of the distorted Clip and load a replacement Clip. Important: Obtaining the ‘half closed’ position should be practiced several times before clinical use.

8.12. ENTERING THE ABDOMEN USING A 7.3mm SINGLE INCISION APPLICATOR

Important: Always ensure that the handle and the shaft of the applicator are screwed firmly together before the procedure begins and remains so throughout. Always check that the serial numbers on the handle assembly and the shaft of the applicator are the same. IF THEY ARE NOT, DO NOT USE THE APPLICATOR.

8.12.1 Insertion of the Applicator through the Operating Laparoscope

Pass the laparoscope through the cannula into the abdomen. In order to pass the loaded applicator down the working channel of the laparoscope it must be in the ‘half closed’ position. This is achieved by gently squeezing the finger bar (Fig 1) until the moveable jaw closes just far enough to allow smooth passage of the applicator laparoscope combination through the cannula (Fig 2). Maintain gentle pressure to keep the Clip ‘half closed’ (Fig 3) until inside the abdominal cavity. Slowly release the finger bar and the Clip will re-open ready for application.

Warning: Do not squeeze the applicator handle too tightly as this may cause the Clip to close prematurely or to become distorted so that it may fail to close properly. If this should occur remove the loaded applicator, dispose of the distorted Clip and load a replacement Clip. Important: Obtaining the ‘half closed’ position should be practiced several times before clinical use.
### 8.13 IDENTIFYING AND MANIPULATING THE FALLOPIAN TUBE

It is possible to manipulate the Fallopian tube for identification purposes by gently using the loaded applicator as a pair of soft forceps, being very careful not to take the finger bar past the half closed position. Only use the applicator as a manipulator in the "half closed" position to avoid the possibility of dislodging the Filshie Clip from the applicator jaw. Heavy handed manipulation must be avoided as this could result in the Filshie Clip being dislodged from the applicator. The use of uterine manipulators may be helpful in exposing the tube, particularly so in the case of retroverted uterus.

To identify the Fallopian tube, pick the tube up with the applicator and track along towards the fimbria at the distal end. Once you have visualised the fimbria, track back towards the cornua to locate the application site of the Filshie Clip at the isthmus, 1-2cm from the cornua.

### 8.14 APPLYING THE FILSHIE CLIP

**Warning:** The Filshie Clip is not designed to be removed once it is in place. The physician should be certain of the exact placement prior to closing the Filshie Clip.

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

1. Identify and inspect the Fallopian tube thoroughly (Fig 1).
2. Ensure that the Filshie Clip can accommodate the whole diameter of the Fallopian tube.
3. Place the Filshie Clip on the isthmic portion of the Fallopian tube, 1-2cm from the cornua (Fig 2).
4. Having established the best location for the Filshie Clip, the applicator should be re-opened and advanced a few millimetres to move the Fallopian tube gently to the back of the Filshie Clip, close to the hinge.
5. Close the Filshie Clip into position by applying **firm, but gentle pressure**, on the trigger in a smooth action until the finger bar has completed its travel.
6. When the Filshie Clip is secured in position, gently release the finger bar and the Filshie Clip will automatically free itself from the applicator.
7. Do not use an abrupt action or the tube may be transected. Should this occur, apply a second Filshie Clip on the proximal (uterine) side of the transection.
8. If there is any doubt about the placement or performance of the Filshie Clip, it is strongly recommended that a second Filshie Clip is applied correctly, immediately adjacent to the first on the uterine side.
9. **ALWAYS CHECK THAT THE CLIP HAS BEEN PLACED ON THE RIGHT STRUCTURE AND IN THE CORRECT POSITION.**

**Warning:** In the unlikely event the tube is too large for the Filshie Clip, use an alternative method of tubal occlusion.

**Warning:** When placing the Filshie Clip on a larger tube this should be done very slowly to allow oedema to be milked away. Once the Filshie Clip has been closed, check to ensure the whole Fallopian tube has been encapsulated and occluded. If the surgeon is unsure, a second Filshie Clip must be placed.

**Important:** It is quite noticeable, but quite normal, for the muscle of the tube to ‘give’ during Filshie Clip application.

**Important:** For your convenience, enclosed within each box of Filshie Clips is a Patient LOT Label to be incorporated in the patient’s records as required for traceability purposes.
8.15. INSPECTION OF THE APPLIED FILSHIE CLIP

Using the empty closed jaws of the applicator as a probe, inspect the secured Filshie Clip both front and back to confirm that:

- The entire Fallopian tube has been captured (Fig 1).
- The upper jaw has been compressed and is securely latched under the nose of the lower jaw.
- The Filshie Clip is in the correct position on the Fallopian tube (isthmic portion, 1-2cm from the cornua) (Fig 2) and on the correct anatomical structure; not on either the round or ovarian ligament.
- The Fallopian tube has not been partially or fully transected.

Important: Once the first Filshie Clip is placed correctly in position withdraw the applicator, load a second Filshie Clip and repeat the procedure on the other Fallopian tube. Once both Filshie Clips have been applied, ALWAYS check that they have both been placed on the isthmic portion (1-2cm from the cornua) of each Fallopian tube and not on either the round or ovarian ligaments, or a fold in the mesosalpinx.

8.16. RETRIEVAL OF A DROPPED FILSHIE CLIP

If this should occur the Filshie Clip should be immediately identified, grasped with the applicator and removed. The Filshie Clip should be grasped firmly (preferably near the hinge) and pulled to the mouth of the cannula. The applicator holding the Filshie Clip firmly, together with the cannula, should then be withdrawn from the abdomen simultaneously.

Important: If you are unable to find a dropped Filshie Clip, it is safer to leave it (open or closed) than to perform a laparotomy. The decision to perform a laparotomy is at the discretion of the physician. The Filshie Clip is intended for implantation; however rare cases of migration and inflammation have been reported.

8.17. REMOVAL OF THE APPLICATOR AND DESUFFLATION

8.17.1 Removal of the Applicator from the Abdomen

Important: Before the 7mm Dual Incision Filshie Clip Applicator and the 7.3mm Single Incision Filshie Clip Applicator can be withdrawn from the abdomen they must be returned to the ‘half closed’ position so that they can pass through the cannula / operating laparoscope. For the 5mm Single Incision Filshie Clip Applicator both the applicator and laparoscope should be removed as a single unit, with the applicator in the ‘half closed’ position (Fig 1 & Fig 2).

8.17.2 Desufflation

When both Fallopian tubes have been clipped, carefully inspected and the applicator withdrawn, desufflation of the pneumoperitoneum is necessary. Depending on the trocar and cannula this can be achieved by either introducing the desufflation key into the cannula to open the trapdoor valve or by unscrewing the cannula barrel cap assembly to allow the dissipation of the gas. The cannula may then be removed. The Filshie Clip Applicator, trocar and cannula must then be cleaned and sterilized.
9. CLEANING AND STERILIZATION

9.1. DISASSEMBLY OF THE EQUIPMENT FOR CLEANING

9.1.1 7mm Dual Incision and 7.3mm Single Incision
• Withdraw the applicator from the laparoscope (if applicable).
• Unscrew the handle assembly from the shaft using a counter clockwise motion (Fig 1).

9.1.2 5mm Single Incision Applicator
• The handle assembly must be unscrewed from the shaft prior to withdrawal from the laparoscope.
• Withdraw the shaft from the bottom of the laparoscope.
• This applicator is not fitted with a gas seal tube.
• Unscrew the handle assembly from the shaft using a counter clockwise motion (Fig 1).

9.1.3 Minilap Applicator
• Since no pneumoperitoneum is induced in the minilaparotomy technique, the applicator is not fitted with a gas seal tube.
• Unscrew the handle assembly from the shaft using a counter clockwise motion (Fig 1).

9.2. SILICONE SEAL TUBE (AVM-011)
It is important to check that the seal tube is intact, as it is the seal tube that stops the leakage of gas through the applicator during surgery.

• When using the Silicone Seal Tube remove it from the exposed end of the Push Rod. If the seal is worn or damaged then it should be replaced. If the seal is undamaged, it may be reused later.
• Removal of the seal tube may be easily achieved by twisting the seal tube in a direction to slide the tube off of the applicator shaft.
• Following cleaning and sterilization reft the seal tube, seating the tube into place (Fig 2).

NOTE: This is not applicable to 5mm Single Incision or Minilap Applicators which do not require a Seal Tube.

9.2.1. Periodic Replacement of Seals
When any of the old seals show signs of damage or wear, they must be replaced. Applicators Use only genuine Filshie Clip Applicator replacement parts as others have not been tested and are not proven to work effectively. For disassembly and replacement of the applicator seal tube (code AVM-011) see above.

NO OTHER MAINTENANCE OR ADJUSTMENT should be performed other than by CooperSurgical.

The applicator is a finely calibrated instrument and no liability will be accepted by the manufacturer for problems or failures arising as a result of any unauthorized repair or adjustment. Like all mechanical equipment, the Filshie equipment will deteriorate with use and age.

It is strongly recommended that the equipment be serviced and recalibrated by CooperSurgical every 100 procedures or annually depending on your usage rate.
9.3. CLEANING THE SUB-ASSEMBLIES

Warning: DO NOT use a solution with a pH lower than 5.0. THOROUGHLY RINSE the applicator between cleaning treatments with distilled water to remove traces of any solutions, (many water supplies are chlorinated which causes corrosion). THOROUGHLY DRY the applicator before sterilization.

The ideal method of cleaning the various parts is:

- by total immersion in an ultrasonic bath using a suitable detergent (check with your sterile supply department),
- followed by thorough rinsing and flushing with clean water.

Important: Particular attention must be paid to the areas that may trap blood and tissue fluids, such as the jaw area.

If these cleaning facilities are not available, the sub-assemblies may be cleaned manually in a suitable detergent solution using the brush provided (Part # AVM-013).

After cleaning with the detergent solution, the sub-assemblies should be thoroughly rinsed and flushed with clean water. It is inevitable that blood and tissue fluids will become trapped inside the applicator main tube during use.

The Cleaning Adapter (Part # AVM-078) supplied will help you to flush these contaminants away, simplifying the cleaning process.

For best results the movable jaw should be held down whilst the adaptor is screwed onto the main tube section.

- Use a standard Luer Lok® syringe to force cleaning fluid or water down the shaft to remove debris that has been loosened by the initial cleaning processes.
- Regardless of which cleaning method is used, as much excess rinsing water as possible must be shaken off the sub-assemblies before they are reassembled for sterilization.

9.4. STERILIZATION

Warning: The particular EO cycle employed must be validated per the equipment manufacturer’s requirements.

Warning: Do not use a dry heat sterilization process or wet chemical sterilizing agents containing glutaraldehyde. Either of these will cause deterioration of the applicator.

Warning: Autoclave at 134° - 137°C, 2 bar pressure for a minimum of 4 minutes. Hospitals must re-validate this method with their own equipment.

The applicator should be sterilized in two parts - the handle and shaft.

These parts should be suitably packed for the sterilization method to be used and should be protected from any rubbing or knocking against other items during the process.
FILSHIE® Tubal Ligation System

10. SERVICING AND MAINTENANCE

Warning: If an applicator has not been serviced within the last twelve months or after 100 procedures, it should not be used. A poorly maintained and worn applicator may not close Clips tightly enough to fully occlude the Fallopian tube.

Warning: NEVER attempt to adjust or repair Filshie equipment yourself. Servicing or repair work will only be guaranteed if undertaken by CooperSurgical. The applicator is a finely adjusted instrument and no liability will be accepted for problems or failures as a result of any unauthorised repairs or adjustment.

Simple, routine maintenance of your equipment will maximize its performance and reliability. To gain the optimum performance from your equipment it is vitally important that you take the following points into consideration:

Important: Like any mechanical equipment the Filshie equipment will deteriorate with use and age. Therefore, it is strongly recommended that the equipment is serviced and re-adjusted AT LEAST once a year or after every 100 procedures - whichever occurs first.

Important: On completion of the procedure, routinely complete the Service Reminder Card supplied with all applicators. By recording EACH USAGE you can plan when your applicator needs to be returned for servicing.

Important: Use the Closure Checking Gauge prior to EVERY procedure to ensure that the applicator will function correctly. If the applicator fails the Closure Checking Gauge test it should not be used until it has been checked and re-adjusted by CooperSurgical.

Important: All Filshie Applicators that have been repaired or serviced by CooperSurgical have a tag attached to the handle stating the next due service date. It is important that customers make a note of this date as well as routinely recording each usage of their applicator (with the Service Reminder Card provided) thus enabling the smooth planning of future servicing schedules.
11. SPARE PARTS / RE-ORDER CODES

11.1 SPARE PARTS

Only genuine Filshie Tubal Ligation System spare parts should be used as others have not been tested and shown to work properly and may invalidate the warranty.

The following spare parts are available:

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>AVM-011</td>
<td>Applicator Silicone Seal Tube</td>
</tr>
<tr>
<td>AVM-013</td>
<td>Cleaning Brush</td>
</tr>
<tr>
<td>AVM-078</td>
<td>Cleaning Adapter for 7mm / 8mm Single and Dual Incision Applicators</td>
</tr>
<tr>
<td>AVM-329</td>
<td>Cleaning Adapter for 5mm Single Incision Applicators (for Serial Numbers S5S785 and below)</td>
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<tr>
<td>AVM-341</td>
<td>Cleaning Adapter for 5mm Single Incision Applicators (for Serial Numbers S5S786 and above)</td>
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<td>AVM-909</td>
<td>Applicator Clip Closure Checking Gauge</td>
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11.2 INSTRUMENTATION RE-ORDER CODES

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<th>Product Code</th>
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<tr>
<td>AVM-863</td>
<td>7mm Dual Incision Applicator</td>
</tr>
<tr>
<td>AVM-856</td>
<td>Minilap Applicator</td>
</tr>
<tr>
<td>AVM-880</td>
<td>5mm Single Incision Applicator</td>
</tr>
<tr>
<td>AVM-857</td>
<td>7.3mm Single Incision Applicator</td>
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FILSHIE® Tubal Ligation System

12. SYMBOLS AND GRAPHICS

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</thead>
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<tr>
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</tr>
<tr>
<td>QTY</td>
<td>Quantity</td>
</tr>
<tr>
<td>RX</td>
<td>Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.</td>
</tr>
</tbody>
</table>

- **Date of Manufacture**
- **Manufacturer**
- **Consult Instructions for Use**
- **Made in the UK**
- **Attention: See Instructions for Use**
- **Latex Free**
- **Irradiation Sterilization**
- **Expiration Date YYYY-MM**
- **Do Not Reuse**

Femcare® and Filshie® are registered trademarks of Femcare-Nikomed Limited

The Hulka Clip™ is also known as the Wolf Clip™ is a trademark of Richard Wolf Medical Instruments.

Fallope Ring Band® is a registered trademark of Gyrus ACMI.
FILSHIE® Tubal Ligation System

13. STATEMENT ON WARRANTIES AND LIABILITIES FOR INSTRUMENTATION

CooperSurgical undertakes to repair free of charge or (at its option) replace or refund or credit the value of goods or any part thereof which may be defective by reason of faulty workmanship or the use of defective material provided that:

- The buyer gives CooperSurgical written notice detailing the alleged defect within 14 days of the date upon which the Buyer shall reasonably have become aware of the same and in any event 12 months from the date of delivery to the customer.
- Defective or damaged goods are promptly returned by the Buyer to CooperSurgical freight and insurance paid, and in their original packaging.
- The goods have not been tampered with nor show signs of unauthorized repair or damage caused by misuse, abuse or accidental dropping.
- CooperSurgical or its representatives shall have had the opportunity to inspect the goods and is satisfied that the damage or defect existed at the time of delivery to the Buyer and has not arisen by reason of fair wear and tear, misuse, neglect, or accident after the passing of risk to the Buyer.
- If only some of the goods are defective as aforesaid the Buyer shall accept the remainder of the goods and be liable to pay the contract price prorated.
- Your Filshie Clip Applicator requires annual servicing or every 100 procedures, whichever comes first. Failure to complete this service could result in improper closing of the Filshie Clip. The warranty is absolutely VOID if service on Filshie Clip Applicators is performed by any other repair/service firm other than CooperSurgical.

CooperSurgical also strongly recommends that physicians seek education sources or information for the use and application of the Filshie Tubal Ligation System from institutions or fellow surgeons who are already familiar with the Filshie Tubal Ligation System. An educational video (conducted by a qualified surgeon) as well as a Care, Maintenance and Sterilization of Instruments video is available and provided at no charge to all customers and physicians. All physicians and medical personnel are requested to view the instructional video tapes prior to initial application of the Clip. Additional copies of these videos are available from CooperSurgical upon request. CooperSurgical DOES NOT provide training or credentialing.

Once the goods have left the hands of CooperSurgical, we have no control over the use to which they are put, how they are used, over their care and maintenance, and over how they are handled. All of these can be critical to the effectiveness and safe usage of any products. Therefore, this warranty does not extend to goods where the problems that have arisen are due to misuse, accident, tampering or to improper storage or use. This warranty also does not extend to goods that have been modified, without the authorization of the manufacturer and/or in a manner that cause or contributes to the alleged defect.

THIS WARRANTY IS EXCLUSIVE, AND COOPERSURGICAL MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED INCLUDING BUT NOT LIMITED TO ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

14. REFERENCES

Warnings and Precautions (Page 6 and 7)
1. PMA Vol 6B Protocols 6240, 6260, 6264, 6265, 6267.
3. PMA Vol 6B Protocols 6240, 6260, 6264, 6265.
4. PMA Vol 6B Protocols 6267, 6260, 6264, 6265.
5. PMA Vol 6B Protocols 6240, 6260, 6264.
7. PMA Vol 6B Protocols.
10. Clinical data is on file at CooperSurgical and is available on request.

Table 2: Pregnancy Rates for Birth Control Methods (Page 10)

Ligation System from institutions or fellow surgeons who are already familiar with the Filshie Tubal Ligation System. An educational video (conducted by a qualified surgeon) as well as a Care, Maintenance and Sterilization of Instruments video is available and provided at no charge to all customers and physicians. All physicians and medical personnel are requested to view the instructional video tapes prior to initial application of the Clip. Additional copies of these videos are available from CooperSurgical upon request. CooperSurgical DOES NOT provide training or credentialing.

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10. Clinical data is on file at CooperSurgical and is available on request.

Table 2: Pregnancy Rates for Birth Control Methods (Page 10)

A. Among couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, periodic abstinence, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods. B. Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimates for each method.
C. Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.
D. The percentage becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on an excellent method of contraception if they abandoned contraception altogether.
E. Foams, creams, gels, vaginal suppositories, and vaginal film.
F. The Ovulation and Two Day methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19.
G. With spermicidal cream or jelly.
H. Without spermicides.
I. The treatment schedule is one dose within 120 hours after unprotected intercourse, and a second dose 12 hours after the first dose. Both doses of Plan B can be taken at the same time. Run-B (1 dose is 1 white pill) is the only dedicated product specifically marketed for emergency contraception. The Food and Drug Administration has in addition declared the following 22 brands of oral contraceptives to be safe and effective for emergency contraception: Dignirol or Contraceptive (1 dose is 2 white pills), Levlen or OrthoTrin (1 dose is 4 light orange pills), CrystaLavida, Low-Ogestrel, LoLorina or Quasar (1 dose is 4 light orange pills), Triavil or Zovia (1 dose is 4 white pills), Triphasil or Plan B (1 dose is 4 yellow pills), Ovral, Portia, Seasonale or Thursa (1 dose is 4 pink pills), Saisonsile (1 dose is 4 light blue-green pills), Emprease (1 dose is 4 orange pills), Alaqua, Luvana or Un Vi (1 dose is 5 pink pills), Aviane (1 dose is 5 orange pills), and Lutera (1 dose is 5 white pills).
J. However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, or the baby reaches 6 months of age.

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