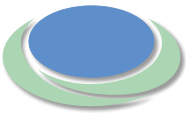
Patient Information

Female Surgical Contraception Explained

Beautifully simple...



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Contents

Nowadays, there is a huge variety of contraceptive methods to choose from, but all have the same aim - to prevent pregnancy. The method which is most suitable for you will depend on a number of factors such as your age, your sexual lifestyle, your current relationship, your family status, your medical history and how important it is to you - either medically or psychologically - to prevent pregnancy.

This booklet is for your general information and is not a substitute for medical advice. You should contact your doctor or other healthcare provider with any questions about your health, treatment, or care prior to and following surgical contraception.

Introduction

...What is surgical contraception?

Surgical contraception is a safe, highly effective, permanent, and convenient form of contraception. The most common surgical contraception procedure for women is called a tubal ligation or having the “tubes tied”.

A tubal ligation is usually performed by laparoscopic surgery (key-hole surgery), in which a visualising tube (laparoscope) is inserted through a small incision and used to view and operate inside a woman’s abdomen. It can also be performed by a minilaparotomy, where an incision is made in the abdomen. This is most often performed in women who have recently given birth, during the postpartum period.

The fallopian tubes are attached to the uterus and adjacent to the ovaries (Fig 1). The fallopian tubes are the site where the egg becomes fertilised by the male’s sperm prior to travelling to the uterus. In surgical contraception, the fallopian tubes are separated or sealed shut, thus preventing the egg and sperm from meeting.

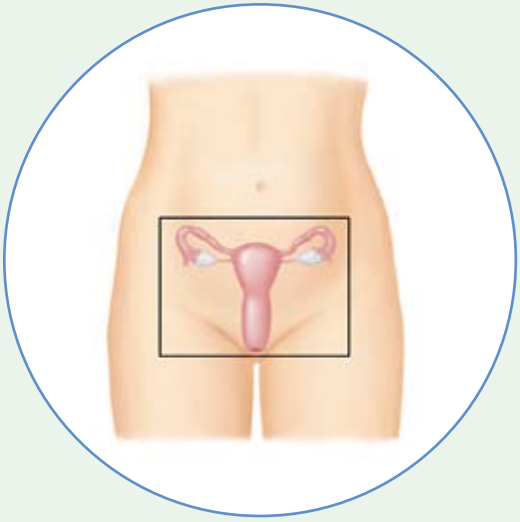
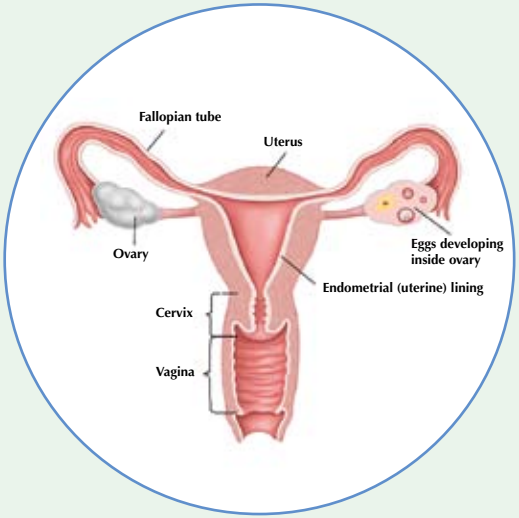


Fig 1



Contraception

...Making your decision

Surgical contraception is a major decision; it means that a woman does not want children at any time in the future. A woman's decision to undergo surgical contraception must be voluntary and not forced by her family, partner, or health care provider. Both partners should have an understanding of the procedure, as well as surgical contraception's benefits, alternatives and potential risks. The woman and her partner should review the risks and benefits of all methods of contraception. The doctor should provide an explanation of the details of the procedure, including anaesthesia (general, spinal or local), and the possibility of pregnancy following the procedure (failure rate), including the chance of ectopic pregnancy (when a pregnancy begins to grow outside the uterus, usually in the fallopian tubes). A woman may change her mind at any time before the procedure.

Tubal surgical contraception should be considered permanent. Reversing the procedure is possible but it does involve additional surgery.

There are five basic types of permanent and short/medium term contraceptive option:

1. Surgical Contraception (also known as female contraception, tubal ligation, or cutting and tying of the tubes)

Tubal Ligation (for women) or Vasectomy (for men) are considered to be the most reliable methods of preventing pregnancy. In tubal ligation this could either be using clips, rings or electro-surgery (burning the tubes).

2. Hormonal Methods

The traditional Pill (Combined Oral Contraceptive, COC), the Mini-Pill (Progesterone Only Pill, POP), hormonal injections and hormonal implants work by affecting either the release of the egg from the ovaries by altering the mucus in the cervix (making it difficult for the sperm to reach the egg) or thinning the lining of the womb (making it less receptive to a fertilised egg).

3. Intra-Uterine Devices (IUD's)

These are small plastic and copper devices, which are inserted into the uterus to prevent the embryo from implanting and developing into a baby.

Another device called Intra-Uterine System (IUS) also contains a hormone, Levonorgestrol (LNG).

4. Barrier Methods

Barrier methods prevent sperm from meeting the egg and include male and female Condoms and Diaphragms.

5. Natural Methods

Natural methods of contraception (such as checking body temperature and the state of cervical mucus to predict ovulation) tend to have a far higher failure rate than conventional contraception.

Why choose surgical contraception?

…For permanent peace of mind

Female surgical contraception is a permanent form of contraception suitable for women who are sure that they do not want to have any more children. When you have Filshie Clip's applied as your method of surgical contraception, the success rate is 99.76%[11] making it one of the most effective and popular methods of contraception worldwide.

Although surgical contraception should be considered a permanent option, it is possible to have the procedure reversed with additional surgery. Results following reversal of Filshie Clip's have demonstrated a very high success rate.

How does it work?

The operation itself is fairly straightforward - the Fallopian tubes (where the egg is fertilised by the sperm) are "blocked" by the surgeon either by use of Clips, Rings, or less commonly by plugging, cutting and tying or burning the tubes.

What are the benefits of surgical contraception:

- One of the most effective methods of contraception – with the Filshie Clip System, the clinically proven success rate is 99.76%[11].
- Permanent and extremely reliable.
- One time decision - once surgical contraception has been successfully completed, no further contraceptive decisions need to be made.
- Does not interfere with the spontaneity of sex.
- Simple procedure usually performed as a day case at a clinic or hospital outpatient department.
- Removal of worries about an unwanted pregnancy may increase a woman's sex drive!

What are the disadvantages of surgical contraception:

- Should be considered as a permanent method of birth control and only suitable for those who are 100% certain that their family is complete, do not wish to have children at all or wish to prevent future pregnancies.
- A surgical procedure is required.

Methods of Surgical Contraception

Female surgical contraception is a long-term permanent method of contraception, suitable for women who do not wish to become pregnant in the future.

There are three main forms of tubal ligation:

1. Laparoscopic tubal occlusion

Laparoscopic tubal occlusion is the most common surgical method for interval (at a time unrelated to pregnancy) tubal ligation. In laparoscopic surgery, a small incision is made near the belly button and in the lower abdomen. A viewing tube (laparoscope) is used to view the fallopian tubes and associated organs. The physician uses clips or rings to close the fallopian tubes or seals them shut using electro coagulation (a procedure in which the fallopian tubes are burned).

2. Minilaparotomy

A minilaparotomy is commonly used postpartum; a small incision (one to three inches long) is made in the abdomen, through which the procedure is performed on the fallopian tubes. General, regional or local anaesthesia can all be used for this procedure. Having this procedure DOES NOT lengthen the hospital stay.

One advantage of minilaparotomy is that a tissue specimen can be removed to prove the fallopian tubes have been completely occluded. Disadvantages of minilaparotomy include a greater need for pain medication, slightly longer recovery time, and a larger surgical incision than with a laparoscopic procedure.

3. Hysteroscopic sterilisation

It is possible to have a hysteroscopic procedure for permanent tubal blockage whereby a metal coil mechanism is inserted into the fallopian tube hysteroscopically. This procedure is usually performed as an outpatient procedure using local anaesthetic. Patients must use additional contraception until a procedure called a "hysterosalpingogram" (HSG) is performed three months after the metal coil placement confirms tubal blockage.

…Maximum Performance, Minimum Risk

Some patients will require a second procedure if the tubes are not completely blocked. When successful, hysteroscopic sterilisation is NOT reversable.

The Filshie Clip System (tubal ligation method)

The Filshie Clip is designed for permanent contraception, however, successful reversal is achievable in between 80-100% of patients. Once the surgeon has identified the fallopian tube the Filshie Clip is applied to the isthmic (thinnest part of the fallopian tube) portion by fully encapsulating the tube causing complete occlusion. The Filshie Clip procedure is usually performed under general, spinal or local anaesthetic; patients may go home a few hours after an outpatient procedure with the majority of patients being able to return to a normal routine within a couple of days.

- Filshie Clips have a low failure rate of just 0.24%[11]. This means that over 99% of sterilisations using Filshie Clips are successful. This is significantly higher than other methods of sterilisation. (Ref: American Food & Drugs Administration - PMA [1996] pg 2004 Pivotal Trials)
- Filshie Clips destroy a smaller part of the Fallopian tube than any other method of sterilisation. Because just 4mm of tube is affected by the application of Filshie Clips, a reversal procedure is successful in 80-100% restoring fertility[8].
- The use of Filshie Clips totally eliminates the risk of burns to internal organs such as the bowel or uterus during a sterilisation procedure.
- The Filshie Clip is recognised globally as the number one choice for female sterilisation.
- Accounts for more than 70% of all sterilisations in many western markets.
- Method of choice recommended by The Royal College of Obstetrians and Gynaecologists, England.
- In the region of 10 million Filshie Clips have been successfully applied worldwide.
- A simple, safe and reliable method of female surgical contraception.
- The application of Filshie Clips is possible immediately following childbirth.
- Lowest incidence of ectopic pregnancy - only 4% of the 0.24%[11] failures.
- Virtually no risk of tubal transection.
- Safe to have an MRI scan with clips in situ.

What does the procedure involve?

…it's beautifully simple

If you choose to be sterilised using Filshie Clips, following your doctors advice, you should normally be able to decide whether the procedure is done under a local or a general anaesthetic. A local anaesthetic numbs the region of the procedure and ensures that you do not feel pain, though you will usually remain awake. General anaesthetic is used to put you into a controlled sleep which ensures that you are completely unconscious during the procedure.

The Filshie Clip procedure is usually performed under general anaesthetic and patients may go home a few hours after an outpatient procedure.

Fig 1:

One or two punctures are made in the lower part of the abdomen, one just below the navel (belly button) and a second just above the pubic hair line to allow the surgeon to access the Fallopian tubes.

Fig 2:

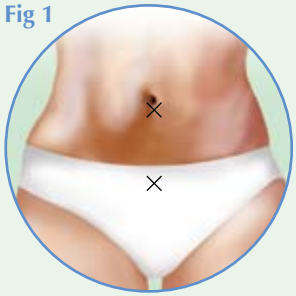
The surgeon blocks off the Fallopian tubes using Filshie Clips. A Clip is applied to each Fallopian tube in turn.

Fig 3:

After the sterilisation, the punctures are closed. Usually one stitch is applied to each incision, dissolvable stitches are commonly used.

The puncture(s) are covered with a plaster. You will be able to remove the plaster on the day following the procedure. You will be able to bathe and shower as usual, washing the incisions with mild, unscented soap. Because the punctures are so tiny, there will be minimal scarring.

Fig 1



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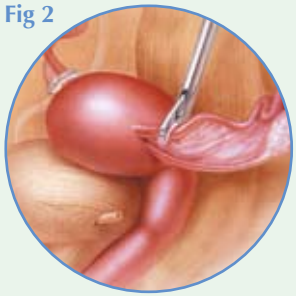

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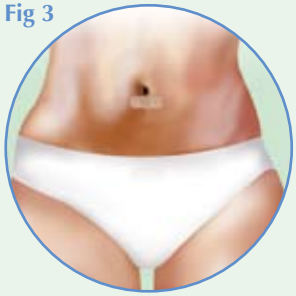


NB. The above are artists impressions only.

Your "Questions" Answered

...Before the procedure

This section is intended to help you to decide if surgical contraception is right for you and to put the record straight about the facts behind one of the most routine surgical procedures, but it does not replace the need for you to discuss the options with your own doctor or healthcare provider:-

Am I eligible for a tubal ligation?

Any woman who is older than 21 years and in generally good health may be considered for surgical contraception. Your healthcare provider would want to be 100% certain that you fully understand that tubal ligation is a long-term method of contraception suitable for women who do not want to become pregnant.

The operation itself is fairly straightforward - the Fallopian tubes (where the egg is fertilised by the sperm) are "blocked" either by use of Clips, Rings, or less commonly by plugging, cutting and tying or burning the tubes. Sperm is prevented from reaching - and fertilising - the egg by this "block" in the Fallopian tube. Once tubal ligation has taken place there is no need to worry about your contraception needs again.

What are the benefits of surgical contraception?

- One of the most effective methods of contraception – with the Filshie Clip System, the clinically proven success rate is 99.76%[11].
- Permanent and extremely reliable.
- One time decision - once surgical contraception has been successfully completed, no further contraceptive decisions need to be made.
- Does not interfere with the spontaneity of sex.
- Simple procedure usually performed as a day case at a clinic or hospital outpatient department.
- Removal of worries about an unwanted pregnancy may increase a woman's sex drive!

What are the risks associated with surgical contraception?

Surgical contraception is a very safe procedure. However, any anaesthetic or operation carries a slight risk.

Risks from surgical contraception?

The tubal ligation itself is usually a very straightforward and simple procedure. There is a very slight risk of damage to other internal organs such as the bowel or the uterus during a tubal ligation procedure, but this is extremely rare when Filshie Clips are used.

What is the failure rate for surgical contraception?

Surgical contraception is widely regarded as the safest of all contraceptive methods and considerably safer than non-permanent methods. However, very occasionally failures do occur. This is dependent upon the method of occlusion used.

The Filshie Clip System has been proven to be the most reliable method available, with a failure rate of just 0.24%[11]. This means that tubal ligation with Filshie Clips has a 99.76%[11] success rate.

Your "Questions" Answered

...Before the procedure

Is surgical contraception different to a hysterectomy?

Surgical contraception and hysterectomy are two completely different procedures.

Surgical contraception is a minor medical procedure which involves blocking the Fallopian tubes to prevent sperm from meeting and fertilising an egg. No glands or organs are removed during a tubal ligation - the ovaries, the uterus and the Fallopian tubes will remain in the woman's body after the procedure. Your hormones will continue to be produced naturally and your ovaries will still release an egg each month.

A **hysterectomy** is an operation to remove the uterus (womb) and sometimes the Fallopian tubes and the ovaries are also removed.

Will I be given an anaesthetic?

If you choose to be sterilised using Filshie Clips, you should normally be able to decide whether the procedure is done under a local or a general anaesthetic. A local anaesthetic numbs the region of the procedure and ensures that you do not feel pain, though you will usually remain awake. General anaesthetic is used to put you into a controlled sleep which ensures that you are completely unconcious during the sterilisation.

The Filshie Clip procedure is usually performed under general anaesthetic and patients may go home a few hours after an outpatient procedure.

What if I have a Latex Allergy?

The Filshie Clip is made from titanium and silicone and is completely inert (non-reactive) in the body. There is no latex present in the Filshie Clip.

What if I have a Nickel Allergy?

Metal sensitivities are not uncommon in patients and nickel is one of the most common. The metal components of the Filshie Clip are commercially pure titanium (ASTM B265-98; grades 1 and 2). Neither of these grades of titanium contain nickel. However, the silicone used to manufacture the Clip does contain trace levels.

If you are concerned about the possibility of a reaction ask your clinician to conduct a "patch test" before going into theatre.

To perform a "patch test", the Filshie Clip is taped to the patient's forearm using a non-allergenic adhesive tape and kept warm for two hours. After two hours, the tape and Clip are removed from the forearm and the site examined for evidence of localised histamine production. An inflamed patch on the skin will indicate this. If a positive "patch test" is obtained, this indicates that you may be sensitive to one of the constituents in the Filshie Clip.

Your "Questions" Answered

...After the procedure

What happens after my surgery?

Wherever possible, a sterilisation will be performed as a day case. Therefore, it is unlikely that you will need to spend a night in hospital.

Patients may go home a few hours after an outpatient procedure, but someone should be available to drive and help you as needed.

Will there be post operative discomfort?

You may experience some mild discomfort at the incision site and menstrual-type cramping; this can be treated with pain medication as prescribed by your doctor.

Women who are sterilised laparoscopically (using key-hole surgery) may experience some pain in the abdomen or shoulders in the days after the operation due to trapped gas. This is because the organs in the abdomen are very close together and during the procedure, the abdomen is filled with harmless gas to allow the surgeon to see the Fallopian tubes clearly. The gas is released when the sterilisation is complete, but some may remain trapped, causing discomfort. If this persists or worsens, contact your hospital or your family doctor.

Depending upon the type of procedure and anaesthesia, patients may encounter a sore throat (from a tube placed to help with breathing during general anaesthesia).

When can I resume normal activities?

You should try to resume your normal, daily routine as soon as possible after the procedure, but do avoid any vigorous exercise for two weeks after surgery.

After the sterilisation you should be able to return to work in 3-7 days, depending on when you feel ready to do so.

You can start driving again as soon as you feel able to do so, but not within the first 24 hours following the sterilisation.

It is perfectly safe to start having sex again as soon as you feel ready.

Do I need to continue taking contraceptive precautions after the operation?

You should continue to take your usual contraceptive precautions until AFTER your next period following your sterilisation operation.

The reason being, depending on what stage in your menstrual cycle you are at when the sterilisation procedure takes places, the egg released during your previous ovulation may have already passed beyond the site where the Filshie Clips are placed on the Fallopian tubes. In this instance, it is possible that the egg may be fertilised and you could become pregnant.

Once you have had a period following the sterilisation, you can discontinue other contraceptive methods.

Your "Questions" Answered

...The Facts – Not Fiction

What happens to the egg after a tubal ligation?

Your body will continue to produce an egg each month. The egg will travel down the Fallopian tube until it reaches the blockage. It will then be absorbed into the body through the walls of the Fallopian tube.

Will I still have periods after a tubal ligation?

Tubal ligation does not affect your menstrual cycle (period). No glands or organs are removed during a sterilisation, your hormones are still produced naturally and your ovaries still produce an egg each month. Therefore, your menstrual cycle (period) will continue to follow its pre-operative pattern until the natural menopause is reached. If you were using a contraceptive pill prior to your sterilisation and stop using it after the sterilisation then your periods should go back to how they were before you took your pill.

Will I feel "less of a woman" following sterilisation?

Sterilisation does not affect your sexuality or your femininity. Many women believe that a sterilisation is virtually the same procedure as a hysterectomy. This is not true - neither the ovaries nor the womb (uterus) are removed in the operation and female hormones are still produced naturally by the body after the operation.

Will I regret my decision to be sterilised?

The vast majority of women who are sterilised after informed consent and appropriate counselling do not regret their decision - in fact, many report a greater sex drive and a stronger relationship, as they no longer have to worry about the trauma of an unwanted pregnancy!

What if I change my mind after the operation and want more children – can the procedure be reversed?

No woman should consider a sterilisation unless she is certain she does not wish to become pregnant in the future. However, circumstances can and do change. Many women have more than one relationship or marriage and it is a real possibility that a sterilised woman may want a reversal of the operation in order to conceive a baby.

Although considered as a permanent method of birth control, reversal procedures where Filshie Clips have been applied are between 80-100% successful at restoring fertility.

Will sterilisation make me gain weight?

Sterilisation does not cause weight gain. No glands or organs are removed during a sterilisation and your hormones are still produced naturally. Nor are artificial hormones - which can cause symptoms such as weight gain - put into the body.

Will sterilisation bring on the menopause?

Sterilisation does not cause the menopause. Your menstrual cycle will continue until your natural menopause is reached.

Can I have an M.R.I. scan if I have Filshie Clips implanted?

Yes, it is possible to carry out an M.R.I. scan as the titanium contained within the Filshie Clip is non-magnetic.

Where can I go for further advice on surgical contraception?

Your doctor or local family planning clinic will offer you free and confidential advice about all aspects of surgical contraception. They will also be able to advise you of waiting lists for the procedure in your local area or direct you to a suitable private clinic that specialises in tubal ligation procedures.

What if I change my mind after the procedure?

…Reversibility explained

No woman should consider a sterilisation unless she is certain she does not wish to become pregnant in the future. However, circumstances can and do change. Many women have more than one relationship or marriage and it is a real possibility that a sterilised woman may want a reversal of the operation in order to conceive a baby.

A reversal of a sterilisation is when the Fallopian tubes, which were blocked, burnt or cut during the original sterilisation procedure, are surgically rejoined. This enables the egg to once again pass down the Fallopian tubes to the uterus and restores a woman's ability to have children.

Reversal of a sterilisation is possible, although **the success of the reversal largely depends upon the method of sterilisation used**, since different methods of sterilisation damage different amounts of Fallopian tube.

Electro-surgery (burning the Fallopian tubes) destroys the largest amount of Fallopian tube of any sterilisation method and is the least reversible. Filshie Clips show the highest reversal success rates - up to 90% restoration of fertility in women less than 40 years of age.

(Ref: AAGL seminar Report [1997] Female Sterilisation Revisited)

A sterilisation reversal operation is most likely to result in a successful pregnancy if:

- You are under 40.
- It is less than ten years since you were sterilised.
- You are in good general health.
- Only a small amount of the Fallopian tube was damaged in the sterilisation operation. This is most likely if you were sterilised using Filshie Clips - your medical records should show which method was used. The Filshie Clip destroys only 4mm of the fallopian tube.
- You have a fertile partner.

Note: A reversal procedure is not always readily available on the NHS (United Kingdom). It can, however, be carried out in the private sector.

Dispelling the Myths!

...the Clinical Facts !!

Filshie Clip System versus Long Acting Reversible Contraception (LARC) methods:

Fact 1. Just how successful are modern day IUD's/IUS?

- Many companies claim that their product can be left in place for up to 5 years but is this what really happens? Statistical data shows that the Levonorgestrel Intrauterine System (LNG-IUS) on average only stays in place for 3.32 years[5]. The most common reasons for stopping using the LNG-IUS are unacceptable vaginal bleeding and pain. Up to 60% of women stop using the LNG-IUS within 5 years[1].
- Once the Filshie Clips are in place there is no need to worry about your contraception needs again. With a success rate of 99.76%[11] the Filshie Clip System is a safe, simple and reliable method of surgical contraception.

Fact 2. What is the expulsion rate and continuation rate of the LNG-IUS?

- The Faculty of Family Planning and Reproductive Health Care has published a comprehensive review of the LNG-IUS and states the following[3]:

  The most likely cause of LNG-IUS failure is expulsion. The risk of this happening is around 1 in 20. The gross rate of expulsion increased from 4.5 per 100 users at 12 months and 5.2 at 24 months, up to 5.9 per 100 users at 60 months[3].

  A Finnish study involving 17,360 users of the LNG-IUS showed a premature removal of the device in 5175 women (29.8%). The one, two, three, four and five year continuation rates were 93%, 87%, 81%, 75% and 65% respectively. The symptoms during the use of the LNG-IUS most strongly associated with its premature removal were excessive bleeding/spotting and infections/pain[4].

Fact 3. Is female sterilisation reversible?

- Only 5% of patients regret sterilisation and only 1% of these regret it sufficiently to have it reversed[7].
- Reversal of Filshie Clip sterilisation is universally accepted as having an extremely high success rate of between 80-100% via a relatively minor surgical procedure[8,13].

Fact 4. What are the Ectopic pregnancy rates?

- In a large study of the LNG-IUS from Finland, of the 108 failures reported, 44 were ectopic pregnancies which equates to 40% of the failures reported in the study resulting in a potentially dangerous ectopic pregnancy[4].
- In the very unlikely event that the Filshie Clip fails, the ectopic rate is incredibly low – only 4% of the 0.24%[11] of failures results in an ectopic failure.

Filshie Clip System versus Hysteroscopic approach:

Fact 5:

- In the region of 10 million Filshie Clips have been applied worldwide, with over 25 years of proven clinical success.
- The latest method of hysteroscopic sterilisation has only been used for the permanent sterilisation in approximately 200,000 patients.

  (Ref: ESGE Meeting, Amsterdam, Oct '08 - Conceptus exhibition stand)

Fact 6:

- Although the Filshie Clip should be regarded as permanent, successful reversal is achievable in between 80-100% of patients[8,13].
- Hysteroscopic sterilisation MUST be regarded as totally PERMANENT, as this method IS NOT reversible.

Fact 7:

- Following the successful application of Filshie Clips there is usually no need for a follow-up procedure.
- Usually THREE MONTHS following hysteroscopic sterilisation a HSG (hysterosalpingogram) is necessary to check for the successful placement of the implants. During this period the patient must rely on an alternative method of contraception. If the HSG shows a non-occluded fallopian

Dispelling the Myths!

...the Clinical Facts !!

tube the patient cannot rely on the device for contraception and may require further surgery[6].

Fact 8:

- Laparoscopic sterilisation using the Filshie Clip System is usually carried out as a day surgery procedure. The use of a local anaesthetic is possible; however, most patients prefer a general anaesthetic.
- Hysteroscopic sterilisation can be carried out using local anaesthetic.
- A recent study has shown that up to 77% of patients would prefer to have a laparoscopic sterilisation versus a hysteroscopic sterilisation[2].

Fact 9:

- The application of Filshie Clips is possible immediately following childbirth.
- Hysteroscopic methods of sterilisation CANNOT be performed immediately following childbirth.

Fact 10:

- Unusual uterine shape or uterine pathology does not affect surgical contraception using the Filshie Clip System.
- For hysteroscopic sterilisation uterine pathology or an unusual shaped uterus are contraindicated[10].

Fact 11:

- A clinical study comparing hysteroscopic versus laparoscopic sterilisation showed that laparoscopic sterilisation was successful in 100% of all patients treated[14].
- This compared to only 81% of patients treated using the latest hysteroscopic method[14].

Fact 12:

- Unlike other methods of permanent contraception, once the Filshie Clips are applied the woman can have IVF treament if needed.

The Filshie Clip System versus other methods of surgical contraception:

1. What are the failure rates for the different surgical contraception methods?

The Filshie Clip System has demonstrated a success rate of 99.76%[11] making it an extremely effective method for female surgical contraception. Studies from around the world have consistently shown the low failure rate of the Filshie Clip. The table below highlights the success of the Filshie Clip.

Investigator	Patients (No.)	Follow Up (Yrs)	Failures (No.)	Failure Rate (%)
Filshie	434	6-15	1	0.23
Heslip	467	10	1	0.21
Yuzpe (Rioux et al)	497	10	0	0
Puraviappan et al	796	7	3	0.37
Kovacs & Krins[11]	30,000	5	73	0.24

Although not available in the USA when the CREST study was conducted, the above long-term follow-up studies of the Filshie Clip System confirm its enviably low failure rate.

The CREST 10-year follow-up study indicates the following failure rates for comparative methods[9]:

Method	Patients (No)	Failure Rate (%)
Bi-Polar	2,267	2.48
Yoon Ring	3,329	1.77
Hulka Clip	1,595	3.65

Dispelling the Myths!

...the Clinical Facts !!

2. Should a surgeon counsel patients based solely on the CREST study data?

In accordance with the Royal College of Obsterics and Gynaecology guidelines, patients should be given the information for the operation that they are having. This should mean that Filshie Clip data should be used when Filshie Clips are being applied.

- The CREST study highlighted higher than expected failure rates for sterilisation over a long period. However, the CREST study did not feature the Filshie Clip which was not available in the USA at the time the study was being conducted.
- Clinical data clearly shows that the failure rate of the Filshie Clip is significantly lower than with other methods of surgical contraception.
- Any surgeon counselling a patient on the Filshie Clip System should not use the data from the CREST study and should use the clinical data readily available on the long term success of the Filshie Clip.

References:

(1) NICE - CG30 Long-acting reversible contraception. October 2005.

(2) Baxter N, Hudson H, Rogerson L, Duffy S. Hysteroscopic sterilisation: a study of women's attitudes to a novel procedure. BJOG March 2005, Vol. 112, p.360-362.

(3) FFPRHC Guidance (April 2004). The Levonorgestrel-releasing intrauterine system (LNG-IUS) in contraception and reproductive health.The Journal of Family Planning and Reproductive Health Care. Vol 30, No 2, p.99-108. April 2004.

(4) Backman T, Huhtala S, Blom T, et al. Length of use and symptoms associated with premature removal of the Levonorgestrel Intrauterine System: a nation-wide study of 17,360 users. BJOG 2000; Vol. 107, p.335-339.

(5) NICE – National cost-impact report. Implementing the NICE clinical guideline on long-acting reversible contraception. Clinical Guideline No. 30, December 2005.

(6) Conceptus / Essure Patient Information Brochure (CC-0454-01. 14.03.03GB).

(7) Filshie GM, Helson K, Teper S. Day case sterilisation with the Filshie Clip in Nottingham. 10-year follow-up study: the first 200 cases. International Society for Gynecologic Endoscopy Annual Meeting, March 1998.

(8) Hulka JF, Noble AD, Letchworth AJ, Lieberman B, Owen E, Gomel V, Taft RC, Haney AF, Wheeless CR, Imrie AH, Winston RL and Loeffler FE. Reversibility of clip sterilizations. Lancet 1982, Oct 23; 2(8304): 927.

(9) Peterson HB, Xia Z, Hughes JM, Wilcox LS,Tylor L, Trussell J. The risk of pregnancy after tubal sterilisation: Findings for the US Collaborative Review of Sterilisation. American Journal of Obstetrics & Gynaecology. April 1996, 174:1161-1170 (CREST Study).

(10) Cooper JM, Carigan CS, Cher D, Kerin JF. Microinsert non-incisional hysteroscopic Sterilization. Obstetrics & Gynaecology 2003; 102(1): 59-67.

(11) Kovacs GT, Krins AJ. Female sterilisations with Filshie Clips: what is the risk of failure? A retrospective survey of 30,000 applications. Journal of Family Planning & Reproductive Health Care 2002; 28(1):34-5.

(12) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor L, Trussell J. The risk of ectopic pregnancy after tubal sterilization. U.S. Collaborative Review of Sterilization Working Group. N Engl J Med 1997; 336(11):762-7.

(13) PN Nwagbara, HM Stibbe, AJ Browning, AM Tonks. Reversal of female sterilisation experience in a district general hospital. Journal of Obstetrics & Gynaecology (1997) Vol. 17, No. 3, 293-297.

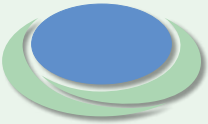
(14) Duffy S, Marsh F, Rogerson L, Hudson H, Cooper K, Jack S, Hunter D, Philips G. Female sterilisation: a cohort controlled comparative study of ESSURE versus laparoscopic sterilisation. BJOG, Nov 2005, Vol. 112, pp.1522-1528.

Glossary of Terms

...Medical terms explained

Anaesthesia	Medically induced partial or complete loss of sensation, in all or part of the body, with or without loss of consciousness. General anaesthesia is total loss of consciousness and sensation.
Cervix	The passageway that connects the vagina to the uterus.
Contraceptive	Any process, device, or method that reduces the likelihood of pregnancy.
Contraindicated	Rendering any particular line of treatment undesirable or improper.
Ectopic Pregnancy	The development of a fertilised egg outside of the uterus, but inside the body.
Endoscope	An instrument for examination of the interior of a cavity.
Fallopian Tubes	The tubes that carry the eggs from the ovaries to the uterus.
Hysterosalpingogram (HSG)	An x-ray of the uterus and fallopian tubes after they have been filled with dye (contrast medium).
Hysteroscope	An endoscope used for a direct visual examination of the canal of the uterine cervix and the cavity of the uterus.
Hysteroscopic	Endoscopic procedure for viewing the uterine cavity.
Hysterectomy	An operation involving removal of the entire uterus.
In Vitro Fertilization (IVF)	Fertilisation of an egg outside of the body, followed by placement of the fertilised egg into the uterus.
Intrauterine Device (IUD) Intrauterine System (IUS)	A medical device that is put into the uterus to prevent pregnancy.
Laparoscope	An endoscope used for a visual examination of the pelvic and abdominal cavity.
Laparoscopy	Examination of the interior of the abdomen by means of a laparoscope.
Laparotomy	An abdominal surgical incision.
Minilaparotomy	A very short laparotomy incision.

General Anaesthesia	A general anaesthetic is a sedative that is given, usually as a gas or by injection, during some operations (surgical procedures). A general anaesthetic makes you completely lose consciousness so that surgery can be performed without causing pain or distress.
Local Anaesthesia	A local anaesthetic is a medicine that causes a complete loss of feeling to a specific part of your body without causing you to lose consciousness.
Major Surgery	A procedure that requires general anaesthesia and surgical incisions in the body.
Micro-insert	A small, flexible, coil-type device that is put into your fallopian tube for permanent prevention of pregnancy.
Occlusion	A closed or blocked part of a tube.
Permanent	Not able to reverse.
Postpartum	After childbirth or after delivery.
Reversible	Able to change back.
Sterilisation	Female sterilisation is an effective and permanent form of contraception. This fairly simple operation, also known as tubal ligation, involves cutting, sealing or blocking the fallopian tubes (the tubes between the ovaries and the uterus, through which eggs travel). This prevents the eggs from reaching the sperm, becoming fertilised and resulting in a pregnancy. The operation is usually performed under general anaesthetic, with a recovery period of a few days.
Surgical Contraception	Any process, device, or method that reduces the likelihood of pregnancy via a surgical procedure.
Tubal Ligation	Permanent female sterilisation by means of cutting, tying, burning, or clipping the fallopian tubes.
Uterus	The womb in which a developing fetus grows.
Vasectomy	Permanent male sterilisation by means of cutting a segment of the vas deferens (the tubes that carry sperm).



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Femcare-Nikomed Limited
Stuart Court, Spursholt Place, Salisbury Road, Romsey, Hampshire, SO51 6DJ, UK
Tel: +44 (0)1794 525100 Fax: +44 (0)1794 525101
Email: enquiries@femcare-nikomed.co.uk Web: www.femcare-nikomed.co.uk