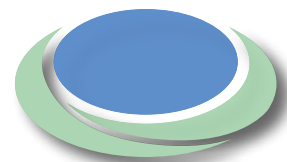


The Filshie Clip System

Female Surgical Contraception



Dispelling
the Myths!!



FEMCARE-NIKOMED
A FEMCARE GROUP COMPANY

From IUD's to contraceptive pills, from IUS to injectables, from implants to sterilisation – when it comes to contraception, today's women are spoiled for choice.

Much has been written and debated on the merits of these different products and this brochure is designed to dispel the myths. . .

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

1. How successful are modern day IUD's/IUS?

- Whilst many companies claim that their product can be left in place for up to 5 years - this rarely happens. Statistical data shows that on average the Levonorgestrel Intrauterine System (LNG-IUS) on average only stays in place for 3.32 years⁽¹⁷⁾. The most common reasons for removal are unacceptable vaginal bleeding and pain. Up to 60% of women stop using the LNG-IUS within 5 years⁽¹⁾.
- Once **Filshie Clips** are applied the patient need never worry about contraception again. With a success rate of 99.76% the **Filshie Clip** is a safe, simple and reliable method of surgical contraception⁽¹¹⁾.

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 states that "the gross rate of expulsion increased from 4.5 per 100 users at 12 months to 5.2 per 100 users at 24 months and up to 5.9 per 100 users at 60 months"⁽³⁾.
- Over a 5-year period, approximately 5.9% of LNG-IUS's are expelled from the body spontaneously⁽⁶⁾.
- During the use of the LNG-IUS, the symptoms most strongly associated with its premature removal were excessive bleeding and spotting, infection and pain⁽⁴⁾.
- Long term continuation rates for copper IUD's and the LNG-IUS in clinical trials have been 33-53%⁽⁴⁾.

3. Is female sterilisation reversible?

- Only 5% of patients regret sterilisation and only 1% of these regret it sufficiently to have the procedure 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).

4. What are the ectopic pregnancy rates?

- In the largest study of its type conducted in Finland, out of the 108 LNG-IUS failures reported, 44 were ectopic pregnancies. This equates to 40% of the failures reported in the study resulting in a potentially dangerous ectopic pregnancy⁽⁴⁾.
- In the rare event of a **Filshie Clip** failure, the ectopic pregnancy rate is just 4%⁽¹⁸⁾.

5. What are the costs of surgical contraception versus LARC?

- Analysis showed that at 15 years of contraceptive use, female and male sterilisation is more cost effective than all other methods of long-acting reversible contraception⁽¹⁰⁾.



Beautifully Simple...

When it comes to surgical contraception, women today have two options – laparoscopic or hysteroscopic sterilisation.

Laparoscopic sterilisation is the most common method of female surgical contraception. . .

Filshie Clip System versus Hysteroscopic approach

- The **Filshie Clip**, with over 25 years of proven success, has been applied more than 8 million times worldwide.
- The latest method of hysteroscopic sterilisation has only been used for permanent sterilisation in approximately 50,000 patients⁽²¹⁾.
- Although the **Filshie Clip** should be regarded as permanent, successful reversal is achievable in over 90% of patients⁽¹³⁾.
- Hysteroscopic sterilisation **MUST** be regarded as totally **PERMANENT**, as the latest method **DOES NOT** allow for reversibility.
- Following the successful application of **Filshie Clips** there is usually no need for a follow-up procedure.
- **THREE MONTHS** following hysteroscopic sterilisation (when using the **ESSURE** device) 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 tube the patient cannot rely on this hysteroscopic device for contraception and may require further surgery⁽¹⁹⁾.
- Laparoscopic sterilisation using **Filshie Clips** is usually carried out as a day surgery procedure and can be performed under local or general anaesthetic.
- Hysteroscopic sterilisation can be carried out using local anaesthetic. However, a recent study has shown that up to 77% of patients would prefer to have a laparoscopic sterilisation versus a hysteroscopic sterilisation⁽²⁾.
- The application of **Filshie Clips** is possible immediately following child birth. Hysteroscopic methods of sterilisation **CANNOT** be performed immediately following childbirth.
- Unusual uterine shape or uterine pathology does not affect female surgical contraception using the **Filshie Clip**. For hysteroscopic sterilisation uterine pathology or an unusual shaped uterus are contraindicated⁽²⁰⁾.
- A clinical study has shown that the **Filshie Clip** was successfully implanted in 100% of all patients, in comparison to only 81% of patients using the latest hysteroscopic method⁽¹⁴⁾.
- IVF is **NOT** contraindicated following the application of **Filshie Clips**.

Simply Beautiful...



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** 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 demonstrated 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 ⁽⁴⁾	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** 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

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

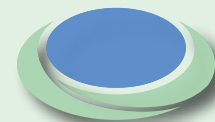
In accordance with the Royal College of Obstetricians and Gynaecologists Clinical Guidelines, patients should be given full information on the operation that they are having. This means that **Filshie Clip** data should be used when **Filshie Clips** are being applied.

- 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** as it was not available in the USA at the time the study was undertaken.
- Clinical data clearly shows that the failure rate of the **Filshie Clip** is significantly lower than other methods of surgical contraception.
- Any surgeon counselling a patient on the **Filshie Clip** should not use the data from the CREST study, but should use the clinical data readily available on the long term success of the **Filshie Clip**.

References:

- (1) NICE - Long-acting reversible contraception. Clinical Guideline 30, October 2006
- (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) Faculty of Family Planning and Reproductive Health Care Guidance (April 2004). The Levonorgestrel-releasing Intrauterine System (LNG-IUS) in contraception and reproductive health. The Journal of Family Planning and Reproductive Health Care 2004; Vol 30, No 2, p.99-108.
- (4) Backman T, Huhtala S, Blom T, Luoto R, Rauramo I, Koskenvuo M. Length of use and symptoms associated with premature removal of the Levonorgestrel Intrauterine System: A nationwide study of 17,360 users. BJOG 2000; Vol. 107, p.335-339.
- (5) Andersson K, Odland V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: A randomized comparative trial. Contraception, January 1994; 49, p.56-72.
- (6) Cox M, Tripp J, Blacksell S. Clinical performance of the Levonorgestrel Intrauterine System in routine use by the UK Family Planning and Reproductive Health Research Network: 5-year report. The Journal of Family Planning and Reproductive Health Care 2002; 28(2), p.73-77.
- (7) Filshie GM, Helson K, Teper S. Day case sterilization with the Filshie Clip in Nottingham. 10-year follow-up study: the first 200 cases. ISGE 7th Annual Meeting, March 1998.
- (8) Hulka JF, Noble AD, Letchworth AT, Lieberman B, Owen E, Gomel V, Taft RC, Haney AF, Wheelless CR, Imrie AH, Winston RL, Loeffler FE. Reversibility of clip sterilizations. Lancet 1982, Oct 23; 2(8304): 927
- (9) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Ratliff Tylor L, Trussell J. The risk of pregnancy after tubal sterilization: Findings for the US Collaborative Review of Sterilization. American Journal Obstetrics & Gynaecology, April 1996, 174:1161-1170 (CREST Study).
- (10) O'Brien S, Gupta J, Najia S, Yehia M. Update on female sterilisation: report from an international symposium at the 6th International Scientific Meeting of the Royal College of Obstetricians and Gynaecologists (to be published).
- (11) Kovacs GT, Krins AJ. Female sterilisations with Filshie Clips: what is the risk failure? A retrospective survey of 30,000 applications. The Journal of Family Planning & Reproductive Health Care 2002; 28(1):34-5.
- (12) Peterson HB, Xia Z, Hughes JM, Wilcox LS, Ratliff Tylor L, Trussell J. The risk of Ectopic Pregnancy after Tubal Sterilization: for The US Collaborative Review of Sterilization Working Group. The New England Journal of Medicine, 13 March 1997, Vol. 336(11):762-767.
- (13) Nwagbara PN, Stibbe HM, Browning AJ, Tonks AM. Reversal of female sterilisation experience in a district general hospital. Journal of Obstetrics and Gynaecology (1997), Vol. 17, No. 3, p.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, p.1522-1528.
- (15) Royal College of Obstetricians and Gynaecologists. Evidence-based Clinical Guideline Number 4, Male and Female Sterilisation. January 2004.
- (16) FDA Advisory Panel Meeting. Presentation made by Prof. Theodore King, 26 Feb 1996.
- (17) NICE - National cost-impact report. Implementing the NICE clinical guideline on long-acting reversible contraception. Clinical Guideline No. 30, December 2005.
- (18) Filshie GM. Long term experience with the Filshie Clip. Gynaecology Forum, Vol. 7, Issue 3, 2002.
- (19) Conceptus / Essure Patient Information Brochure (CC-0454-01, 14.03.03GB)
- (20) Cooper JM, Carignan CS, Cher D, Kerin JF. Microinsert non-incisional hysteroscopic sterilization. Obstetrics & Gynaecology 2003; 102(1):59-67.
- (21) Baxter AJ. New developments Advances in hysteroscopic sterilisation. The Obstetrician & Gynaecologist. 2006;8:103-106.

Distributor:



FEMCARE-NIKOMED

A FEMCARE GROUP COMPANY

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