The Filshie Clip System
Female Surgical Contraception

Dispelling the Myths!!
From IUD’s to contraceptive pills, from IUS to injectables, from implants to sterilisation – when it comes to contraception, today’s women are spoilt for choice.

Much has been written and debated on the merits of these different products and this brochure is designed to dispel the myths...
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\(^{20}\).

- 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:

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Patients (No.)</th>
<th>Follow up (Yrs)</th>
<th>Failures (No.)</th>
<th>Failure Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filshie</td>
<td>434</td>
<td>6-15</td>
<td>1</td>
<td>0.23</td>
</tr>
<tr>
<td>Heslip</td>
<td>467</td>
<td>10</td>
<td>1</td>
<td>0.21</td>
</tr>
<tr>
<td>Yuzpe (Riou et al)</td>
<td>497</td>
<td>10</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Puraviappan et al</td>
<td>796</td>
<td>7</td>
<td>3</td>
<td>0.37</td>
</tr>
<tr>
<td>Kovacs &amp; Krins (^{(4)})</td>
<td>30,000</td>
<td>5</td>
<td>73</td>
<td>0.24</td>
</tr>
</tbody>
</table>

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 enviable low failure rate.

The CREST 10-year follow-up study indicates the following failure rates for comparative methods\(^{(9)}\):

<table>
<thead>
<tr>
<th>Method</th>
<th>Patients (No.)</th>
<th>Failure Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bi-Polar</td>
<td>2,267</td>
<td>2.48</td>
</tr>
<tr>
<td>Yoon Ring</td>
<td>3,329</td>
<td>1.77</td>
</tr>
<tr>
<td>Hulka Clip</td>
<td>1,595</td>
<td>3.65</td>
</tr>
</tbody>
</table>

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:

(10) O’Brien S, Gupta I, Naja S, Yeha 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).
(16) FDA Advisory Panel Meeting. Presentation made by Prof. Theodore King, 26 Feb 1996.
(19) Conceptus / Essure Patient Information Brochure (CC-0454-01. 14.03.03GB)

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