

Conceptus[®]

info-canada@conceptus.com
www.essure.com

1. Hatcher R et al. Contraceptive Technology, 17th Edition. New York : Ardent Media, 1998. 2. Bhiwandiwalla PP et al. A comparison of different laparoscopic sterilization occlusion techniques in 24,439 procedures. Am J Obstet Gynecol 1982; 144: 319–21. 3. Destefano F et al. Complications of interval laparoscopic tubal sterilization, Obstet Gynecol 1983; 61(2): 153–58. 4. Layde PM et al. Risk factors for complications of interval tubal sterilization by laparotomy. Obstet Gynecol, 1983; 62(2): 180–84. 5. Summary of Safety and Effectiveness of the Filshie Clip, Pre-Market Application approved by the U.S. Food & Drug Administration in 1996.

Essure[™] is a trademark of Conceptus, Inc.
The Essure system is covered under U.S. Patent N° 6.176.240. Other patents pending.
FDA approval : 4/11/2002 • CE mark • CE G7 01 12 31 649 008

CC-0652-01 • 16.10.03F

meqare



essure[™]

*Female sterilization
by the natural pathways*

patient information

A gentler approach to permanent birth control

Essure is a new method of permanent birth control developed by Conceptus. Because it is intended to permanently prevent pregnancy, it is similar to other permanent birth control methods such as vasectomy or tubal ligation ('having your tubes tied').

Essure is gentler on your body

Essure is a lower impact approach to permanent birth control than vasectomy or tubal ligation because it does not involve cutting through the skin, can be performed without general anaesthesia, and recovery is quick.

Is Essure right for you?

The Essure procedure is only appropriate if you:

- Are sure that you don't want children or that your family is complete
- Would like to have permanent birth control
- Believe you will not change your mind

You should be aware that there are other methods of birth control, both temporary/reversible and permanent. Your doctor will explain these to you and advise you whether Essure is a suitable option for you. It is your right to decide what method suits you. If, at any time before the Essure procedure you decide not to have it, you should tell your doctor and cancel the procedure. You do not have to provide any explanation for your decision.

As with all procedures, there are risks associated with Essure. You should be aware of these risks and discuss them in detail with your doctor.

There is a list of risks detailed in this brochure on page 10 & 11.

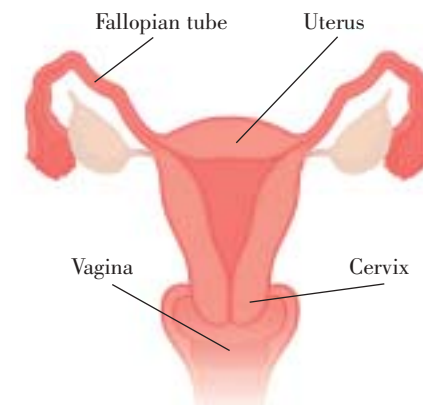
'With three children under the age of six, I was well satisfied with my precious brood. I was booked for a tubal ligation when I read a timely article about the Essure permanent birth control method. It sounded infinitely less invasive than its counterpart'.

Lois, 38



What is the Essure procedure?

The Essure procedure involves placing a small, flexible device called a micro-insert into each of your two fallopian tubes. (Your eggs travel down these tubes from your ovaries to your uterus.) Once the micro-inserts are in place, connective tissue grows into the micro-inserts over a three-month period, blocking the fallopian tubes. Blocking the tubes is intended to prevent sperm from fertilising the egg, thereby preventing pregnancy.



The female reproductive organs

'I think the procedure took about 30 minutes. My mother drove me home and I was up and about doing housework that evening'.

Karen, 33



What are the benefits of Essure?

- **Fast recovery:** on average, you are able to go home within 45 minutes of the procedure and the majority of women are expected to return to regular physical activities in one day or less. In the most recent clinical study called the Pivotal Trial, 92% of women employed outside the home returned to work in 24 hours or less after the day of the procedure.
- **Quick:** your procedure time should be about 30 minutes, with only about 13 minutes typically required to place the micro-inserts into the fallopian tubes.
- **No side effects from hormones:** the micro-inserts do not contain or release birth control hormones such as oestrogen and progestogen.
- **General anaesthesia is not required:** the procedure is typically done using a local anaesthetic and/or intravenous sedation (where the sedating drug is administered through a needle in your arm and you remain awake throughout the procedure).
- **No scars:** you will not have any scars because it does not involve cutting into the skin.

'We knew for sure that we weren't going to have more children, so something permanent was certainly the answer for me. But I didn't like the thought of having my tubes tied and did not want to have any cuts or scars.'

Grazyna, 45

'I have now been wearing the Essure micro-insert for two years and truthfully, I don't even think about it any more. That's the great thing for me, that it's not something I need to think about or be aware of.'

Grazyna, 45



What are the key considerations for Essure?

The procedure is not expected to be reversible

There are no data on the safety or effectiveness of surgery to reverse the Essure procedure.

It is only for women who are certain that they no longer want to have children. There are also no data on the safety or effectiveness of in vitro fertilisation (IVF) after the Essure procedure has been performed.

Like all methods of birth control, it should not be considered 100% effective

During clinical trials, the effectiveness rate of Essure is 99,8% at two years of follow-up. However, no method of birth control is 100% effective so there is a small chance that you could become pregnant.

There is a waiting period after the procedure

It takes three months* before your specialist advises you whether the Essure micro-insert can be relied on for permanent birth control. You will need a pelvic X-ray, and sometimes a second test called a hysterosalpingogram or HSG, before your specialist can make this recommendation. You will need to talk to your doctor about alternative contraceptive options to cover this time.

*The waiting period is occasionally longer than three months

The Essure procedure is newer than other procedures

Essure is one of the newest methods of permanent birth control so it hasn't been studied in as many women or for as long as most birth control methods.



'The decision to have Essure was mine. It's my body and I always want to take control of my own body and life.'

Meredyth, 33

The Essure procedure: step by step

Step 1

One to two hours before the procedure, you are given medication to reduce tubal spasms and uterine cramping during the procedure.

Step 2

After a local anaesthetic is applied to the area, the doctor inserts a narrow telescope, called a hysteroscope, through your vagina and cervix (the entrance to the uterus from the vagina) and into the uterus. The doctor may need to gently expand the opening of your cervix to do this. The hysteroscope is attached to a video camera and monitor so the doctor is able to see exactly what he/she is doing. Fluid, called normal saline, flows through the hysteroscope and into your uterus. The fluid is used to expand the uterus so the doctor can see the openings to your fallopian tubes. You might feel cramping from this.

Step 3

A narrow inserter, called a catheter, is passed through the hysteroscope and into your fallopian tube. The micro-insert is attached to the end of the inserter.

Step 4

The micro-insert is placed in the fallopian tube and the inserter is removed. The process is repeated in the other fallopian tube.

The entire procedure should take about 30 minutes with only 13 minutes typically required to place the micro-inserts into the fallopian tubes.

Step 5

During the next three months, connective tissue will begin to grow into the micro-insert, eventually blocking your fallopian tubes. You will need to use another form of birth control during this period until your specialist confirms that the procedure has worked.

Step 6

After three months, you need to have an X-ray of your pelvis. You may also need another test if the X-ray suggests that the micro-inserts may not be in the ideal position. The additional test is called a hystero-salpingogram or HSG. In this test, a dye is injected into the uterus through the vagina and cervix and an X-ray is taken to see if the fallopian tubes are blocked and whether the micro-inserts are in a satisfactory location. Your doctor will confirm with you if you need to have this dye test or not.

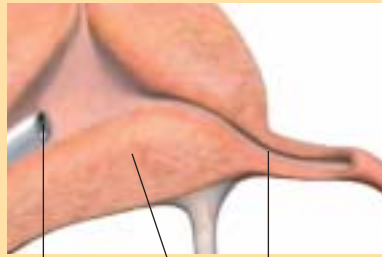
After the pelvic X-ray and/or HSG, your doctor will tell you if you can rely on Essure for birth control.

The micro-inserts are made from proven surgical materials



The micro-inserts are soft, flexible and made from medical grade materials. These materials have been well studied and safely used in the body over long periods of time in several medical procedures, including:

- Heart surgery – in heart valve replacements
- Hernia repair
- Blood vessel grafts



Hysteroscope Uterus Fallopian tube



Catheter/Inserter



Essure micro-insert in fallopian tube



Body tissue grows into the Essure micro-insert, blocking the fallopian tube

What do women think of the Essure procedure?

The Essure procedure has undergone significant clinical testing in Australia, Europe and the United States. To date, it has been tested by over 600 women in two studies; the Phase II Study and the Pivotal Trial.

The women who have taken part in the Pivotal Trial have found the Essure procedure to be:

- **Effective:** during clinical trials, the effectiveness rate of Essure is 99,8% at two years of follow-up.

- **Quick:** the average procedure time was about 30 minutes, with only 13 minutes required to place micro-inserts into the fallopian tubes.
- **Highly rated:**
 - 92% of women resumed work in 24 hours or less after the day of the procedure
 - 96% of women rated their comfort with the procedure as 'good' to 'excellent' within one week of the procedure
 - 99% of women rated their longer-term comfort with the micro-inserts as 'good' to 'excellent'.

Patient enrolment in both the Phase II Study and the Pivotal Trial was completed by 28 February 2001, and patients are now in the follow-up period. New data may become available as these women continue to be followed by Conceptus.

*'My family life is very important to me. Getting back to normal as fast as possible is something I wanted. With two kids to look after, having time off to recover would have been a big disruption to our family'.**

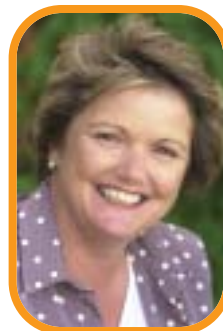
Karen, 33



'Essure appealed to me because it seemed so simple. The fact that you could be in and out of hospital on the same day and it didn't ruin your normal routine at home was wonderful for me. I knew immediately this was the right choice for me'.

Karen, 33

*After the Essure procedure, the majority of women are expected to return to regular physical activities in one day or less.



Amanda Gustan: Why did I decide on Essure?

After the Caesarean birth of our two children, my dear husband decided that after my numerous operations (laparoscopy/laparotomy to try and conceive), he would take control of our permanent birth control and have a vasectomy. Four referrals later and me still taking the pill, I decided it was time to act! I had heard about a procedure with no surgical incisions and non-reversible, it sounded just what I wanted. Tubal ligation was out, IUDs have to be changed every four years.

I contacted my local GP and she referred me to an obstetrician/gynaecologist who had helped me 12 years earlier when I was trying to conceive; now I wanted the reverse. After an initial visit I was booked in for my Essure procedure.

I drove myself there, and the whole procedure took about 30-40 minutes, with sandwiches and a cup of tea following, I was back in my car driving home about 2 hours later. My life carried on as normal, cooking tea and playing tennis the next day.

I felt the whole process was like a big PAP smear, and the only discomfort* was having my legs up in stirrups. I would certainly recommend this to anyone considering permanent birth control.

*Many women in clinical trials have reported experiencing pain during an Essure procedure. Please see the risks/considerations on page 11 for more information regarding pain reported by women in clinical trials.

Risks associated with other female permanent birth control methods

A published clinical study of laparoscopic tubal ligation² (the most common method of tubal ligation) showed:

- Surgical difficulties in 5.1%² of women, primarily due to existing conditions such as obesity, a pathological condition or a problem with the anaesthesia equipment.
- Major complications in 1.7%³ of women, mainly as a result of injury to the fallopian tube, perforation of the uterus or injuries to the bowel.

Studies of tubal ligation have shown that:

- The most common result of complications in laparoscopic procedures was unintended laparotomy surgery (open

surgery) in 1.1%⁴ of women.

- The overall complication rate in tubal ligations performed under laparotomy was 5.7%¹.
- Common side effects were:
 - pelvic pain in 39% of women⁵
 - scarring, discharge, or inflammation around the cut in 9.9% of women⁵
 - menstrual/vaginal bleeding not present before the procedure in 8.3% of women⁵
 - pain, tenderness or enlargement of the fallopian tubes or ovaries in 5.2% of women⁵
 - nausea or vomiting in 4.2% of women⁵.

As with all procedures, there are risks/considerations associated with Essure

You should be aware of these risks/considerations and discuss them in detail with your doctor before you make your decision. Some of them are rare. You should talk to your doctor about the likelihood of these risks, particularly in relation to your own situation, and your doctor may advise you that the Essure procedure is not suitable for you.

- For three months after the procedure, and occasionally for longer, you must use another method of birth control.
- The procedure is one of the newest birth control alternatives, and while the data demonstrate that Essure is effective, no method of birth control is expected to be 100% effective.

- The clinical research on Essure has not involved as many patients as other forms of birth control, nor has the on-going follow-up period been as long.
- The procedure may be stopped, without an attempt to place the micro-inserts, if the openings of the fallopian tubes cannot be visualised with the hysteroscope. In the Pivotal Trial (one of two major trials assessing the procedure), this occurred in 2% of women.
- Some women who undergo a placement procedure will not be able to have the micro-inserts placed in both fallopian tubes. In the Pivotal Trial, 90% of the women who underwent a placement procedure had micro-inserts placed in both tubes and 2.6% had only one micro-insert placed. Failure to place the micro-inserts was often due to pre-existing conditions: sometimes the fallopian tubes and cervix were already damaged or the opening of the tubes was not visible or was blocked, or the lining of the uterus was covering the opening of the tube.
- Despite placement of one or both micro-inserts, some women will still not be able to rely on the micro-inserts for birth control. In the Pivotal Trial, 2.6% of women who had two micro-inserts placed were not able to rely on them for birth control and the majority of these women elected to have a tubal ligation.
- Some women need to have the placement procedure more than once before relying on the micro-inserts for birth control. In the Pivotal Trial, 6% of women relying on micro-inserts for birth control had multiple placement procedures:
 - 4% had more than one procedure to place micro-inserts
 - 2% had to have a replacement procedure after expulsion of the micro-inserts.
- Many women in the Pivotal Trial reported having pain during and immediately following the Essure procedure: the majority of women reported no pain or mild pain, some reported moderate pain, and severe pain was reported rarely.
- In the Pivotal Trial, many women reported cramping, bleeding/spotting, dizziness, or fainting on the day of the procedure. 2% of women experienced other side effects following the procedure, but these cleared up by the time they went home. There was one exception where a woman was hospitalised overnight due to a reaction to pain medication.
- In the Pivotal Trial, the majority of women also reported some level of pain, cramping and/or bleeding/spotting for a few days following the procedure. In addition after the day of the procedure, minor side effects such as back/abdominal pain, gas and bloating and headache were also infrequently reported.