essure®

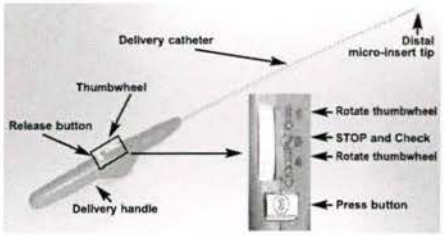
English GB/CA/AU/NZ only

INSTRUCTIONS FOR USE

I. Micro-insert description

The **Essure** Permanent Birth Control System is comprised of several components. The **Essure** micro-insert, a dynamically expanding micro-insert, is attached to a delivery wire and a release catheter. The entire assembly is sheathed within a delivery catheter. This system, (shown in Figure 1), is attached to a handle that facilitates micro-insert delivery and deployment. A Conceptus valved DryFlow™ Introducer is also provided with the **Essure** system. It is intended to help protect the **Essure** micro-insert as it is being passed through the rubber port of the hysteroscope working channel.

Figure 1
Essure Delivery System
Showing detail of placement procedure symbols
(NOT TO SCALE)



II. Mechanism of action

Under hysteroscopic visualisation, the **Essure** system delivers an **Essure** micro-insert to the proximal section of the fallopian tube lumen. When the **Essure** micro-insert expands on release, it acutely anchors itself in the fallopian tube. Subsequently, the micro-insert elicits an intended benign tissue response, resulting in tissue in-growth into the micro-insert that anchors the micro-insert firmly into the fallopian tube. This benign tissue response is local, fibrotic and occlusive in nature.

Essure system is intended for single use only. The **Essure** micro-inserts are permanent implants. The remaining components of the **Essure** system are disposable. The **Essure** System is supplied sterile. It is sterilised using ethylene oxide gas.

III. Indications for use

The **Essure** system is intended for use as a tubal occlusion micro-insert for purposes of permanent contraception.

IV. Contraindications for use

- Patient uncertainty about her desire to end fertility.
- Pregnancy or suspected pregnancy.
- Delivery or termination of a second trimester pregnancy less than 6 weeks before **Essure** micro-insert placement.
- Active or recent pelvic infection.
- Untreated acute cervicitis.
- Unexplained or severe vaginal bleeding.
- Gynaecological malignancy (suspected or known).
- Known abnormal uterine cavity or fallopian tubes that makes visualisation of the tubal ostia and/or cannulation of the proximal fallopian tube difficult or impossible.
- Allergy to contrast media (a hysterosalpingogram may be required three months post-micro-insert placement).
- Patient currently taking corticosteroids.

V. Warnings

- The **Essure** procedure should only be performed by skilled hysteroscopists who have completed the *Conceptus* training programme for this procedure.
- Persons allergic to nickel titanium may suffer an allergic reaction to the micro-insert.
- Do not use the **Essure** system if the package is open or damaged. Do not use if the micro-insert is damaged.
- When introducing the **Essure** micro-insert into the fallopian tube, never advance the micro-insert(s) against excessive resistance.
- Do not continue to advance the **Essure** system once the positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory micro-insert placement or tubal/uterine perforation.

  If a tubal perforation occurs or is suspected, do not continue with the **Essure** micro-insert placement attempt. A very small percentage of women in the **Essure** clinical trials (1.8% or 12/682 patients) were identified as having device related tubal perforations. Retrieval of perforating micro-inserts, if necessary, will require laparoscopy or other surgical methods.
- If **Essure** micro-insert placement attempts are not successful after 10 minutes of attempted cannulation per tube, the case should be discontinued and potentially rescheduled.
- Once the micro-insert has been placed (i.e., detached from the delivery wire), micro-insert removal should not be attempted hysteroscopically unless 18 or more coils of the **Essure** micro-insert are trailing into the uterine cavity. Removal of such a micro-insert should be attempted immediately following the placement. However, removal may not be possible.
- The patient must use alternative contraception until an x-ray performed three months post-micro-insert placement demonstrates satisfactory micro-insert location.
- Patients who undergo placement of the **Essure** micro-insert may, in future years, be offered intrauterine therapies that utilise electrical energy. It is recommended that electrocautery be avoided in surgical procedures undertaken on the uterine cornua and fallopian tubes. All other procedures in the pelvis should avoid the use of electrocautery within 4 cm of the micro-insert. Due to the presence of the **Essure** micro-inserts, there may be risks associated with such procedures that at this time have not been identified.
- Any intrauterine procedure such as endometrial biopsy, D&C, hysteroscopy (diagnostic or operative) including endometrial ablation, could interrupt the ability of the micro-inserts to prevent pregnancy. In addition, the presence of the **Essure** micro-inserts could entail risks associated with such procedures that at this time have not been identified.
- Bench and clinical studies demonstrated that endometrial ablation of the uterus can be performed safely and effectively with the GYNECARE THERMACHOICE* Uterine Balloon System, the Hologic NovaSure** Endometrial Ablation System and the Boston Scientific Hydro ThermAblator*** **immediately following Essure** micro-insert placement. No specific studies have been conducted to evaluate **Essure** micro-insert expulsion or contraception rates following combined **Essure** and endometrial ablation procedures.
- Patients may decide, in future years, to undergo in vitro fertilisation (IVF) to become pregnant. The effects of the **Essure** micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the micro-insert to the patient, to the foetus and to the continuation of the pregnancy are unknown.

* Trademark of ETHICON, INC.
** Trademark of Hologic, Inc.
*** Trademark of Boston Scientific Corporation

VI. Precautions

- Whenever possible, micro-insert placement should be performed during days 7-14 of the menstrual cycle (where day 1 represents the first day of bleeding) in order to enhance visualisation of the fallopian tube ostia and decrease the potential for micro-insert placement in a patient with an undiagnosed pregnancy.
- Unusual uterine anatomy may make it difficult to place the **Essure** micro-inserts.
- In order to reduce the risk of uterine perforation, the procedure should be discontinued if excessive force is required to achieve cervical dilatation.
- Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is accessible and patent.
- Performing endometrial ablation immediately following placement of **Essure** micro-inserts may increase the risk of post-ablation tubal sterilisation syndrome, a rare condition that has been reported in women with a history of tubal sterilisation who undergo endometrial ablation.
- Do not advance the **Essure** system if the patient is experiencing extraordinary pain or discomfort.
- Store the **Essure** system in a cool, dry place.

VII. Possible adverse effects

A. Pregnancy

There is a risk of pregnancy, ectopic pregnancy, and risks associated with the treatment for both. If the patient conceives and chooses to continue an intrauterine pregnancy, she should be informed that the risks of the micro-insert to the patient, to the foetus and to the continuation of the pregnancy are unknown.

B. Risks associated with the micro-insert placement procedure

- Local anaesthesia, oral analgesia/sedation, regional anaesthesia (i.e., spinal, epidural), oral or conscious (intravenous) sedation or general anaesthesia may be administered to the patient to prevent or reduce discomfort. Regardless of the type of anaesthesia, patients may not be able to resume normal activities for 12-24 hours following the procedure.
- Pain, cramping and vaginal bleeding may occur during and following the micro-insert placement procedure. Typically, these incidents are tolerable, transient and successfully treated with medication.
- During and/or directly following the micro-insert placement procedure, there is the risk that the patient will experience nausea or vomiting. This is expected to be transient and may be treated with medication as required.
- Patients may experience fainting or vasovagal response on the day of the procedure.
- There is a risk of perforation or dissection of the fallopian tube or uterine cornua. Bleeding and scarring may result from such a perforation or dissection; however, treatment is typically not required.
- There is a risk of uterine perforation by the hysteroscope, **Essure** system or other instruments used during the procedure with possible injury to the bowel, bladder and major blood vessels. Surgical intervention may be required, but is unlikely, if such injury were to occur. To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
- There is a risk that the **Essure** micro-insert may be inadvertently placed into the myometrium of the uterus and not into the fallopian tube lumen. If one micro-insert has already been properly placed in one fallopian tube, in addition to inadvertent placement into the myometrium, the physician may attempt to place a third micro-insert to complete the procedure. If bilateral fallopian tube placement is not achieved, this may result in the patient having one micro-insert in the fallopian tube and/or one micro-insert in the myometrium that cannot be relied upon for contraception. Placement of the micro-insert in the myometrium may result in post-operative pain or other adverse event. If surgical removal of the micro-insert(s) is required, salpingectomy or hysterectomy may be required.
- There is a risk that the **Essure** micro-insert may be placed too distally in the fallopian tube. If removal of the micro-insert is necessary, surgery (laparoscopy or laparotomy) will be required.
- There is a risk that the **Essure** micro-insert may be placed too proximally in the fallopian tube. If 18 or more coils of the **Essure** micro-insert are visible at the time of placement, an immediate attempt should be made to remove the micro-insert (see section XIII, **Essure** micro-insert removal). If micro-insert removal is attempted, there is a possibility that the removal will not be successful or that the **Essure** micro-insert may break, leaving a fragment of the micro-insert *in vivo*. If micro-insert removal is attempted and/or achieved, there is also a possibility that the patient may experience increased pain, cramping and bleeding during and following the **Essure** micro-insert placement procedure.
- There is a risk that the **Essure** micro-insert may perforate through the tubal wall or uterine cornua, which could result in the micro-insert being released into the peritoneal cavity. Post-operative pain and/or menstrual disturbance or other adverse event may occur as a result. If the patient elects to undergo incisional sterilisation or other surgical intervention, micro-insert retrieval from the peritoneal cavity may be attempted if the physician believes it is safe to do so. However, micro-insert retrieval may not be possible if the micro-insert cannot be visualised or accessed by the physician.
- There is a risk that **Essure** micro-insert placement will only be achieved in one fallopian tube. If this occurs, patients may be left with one micro-insert *in vivo* that cannot be relied upon for permanent contraception.
- There is a risk that **Essure** micro-insert placement will not be possible in either fallopian tube.
- There is a minimal risk of excess fluid absorption of the physiologic saline fluid used for distension of the uterus, to perform the hysteroscopic procedure.
- As with all invasive procedures, the micro-insert placement procedure can cause an infection. An infection could cause damage to the uterus, fallopian tubes or pelvic cavity. This could require antibiotic therapy, or rarely, hospitalisation or surgery, including hysterectomy.

C. Risks associated with Essure micro-insert wearing

- There is a risk that the **Essure** micro-insert could move out of the fallopian tubes. This movement could be expulsion (movement out of the fallopian tube and into the uterine cavity/cervix/vagina or out of the body) or migration (movement to the distal fallopian tube or out of the fallopian tube and into the peritoneal cavity). Additional x-rays may be required to identify the location of the micro-insert(s), and surgery may be required to remove the micro-insert(s). Device movement could result in pregnancy, ectopic pregnancy and/or pain/menstrual disturbance or other adverse events.
- As with currently available methods of mechanical permanent contraception (i.e., clips, rings), if the **Essure** micro-insert is to be removed, surgery will be required. Further, it is possible that surgical removal of the fallopian tubes (salpingectomy) and uterus (hysterectomy) may be required.
- Abdominal/pelvic pain and cramping may occur. Pain and cramping may be a more likely occurrence during the menstrual period, during and after sexual intercourse or with other physical activity.
- Intermenstrual bleeding or heavier than normal menstrual bleeding may be experienced.
- Occasionally, a woman may regret her decision to undergo permanent contraception and experience mild depression or other emotional disturbances as a result.

D. Risks associated with follow-up procedures

- There is the risk of radiation associated with the pelvic x-ray that is required three months following micro-insert placement to evaluate micro-insert location. There may also be a need for an **Essure** Confirmation Test (HSG). There are approximately .033 rads in the fluoroscopic portion (<30 seconds) of a hysterosalpingogram procedure. As a point of comparison, radiation exposure from a barium enema is 0.85 rads which is higher than the required **Essure** Confirmation Test (HSG). The amount of radiation exposure from one pelvic x-ray is about the same as the amount an individual would receive from one year of natural background radiation.
- The following additional risks are associated with the **Essure** Confirmation Test (HSG) procedure if needed: vasovagal response; infection, which may require antibiotic treatment and in rare cases could require hospitalisation; intravasation; perforation of the uterus; uterine cramping and/or bleeding; pain or discomfort; allergic reaction to latex. Latex exposure has been reported to be associated with anaphylactic reactions in rare cases, which may lead to death.
- The use of contrast media, used to perform the HSG, has been associated with allergic reaction in some patients. Allergic reaction can result in hives or difficulty breathing. In some individuals, an anaphylactic response may occur which may lead to death.

E. Risks associated with potential future procedures

- Patients who undergo placement of the **Essure** micro-insert may, in future years, be offered intrauterine therapies that utilise electrical energy. It is recommended that electrocautery be avoided in surgical procedures undertaken on the uterine cornua and fallopian tubes. All other procedures in the pelvis should avoid the use of electrocautery within 4 cm of the micro-insert. Due to the presence of the **Essure** micro-inserts, there may be risks associated with such procedures that, at this time, have not been identified.
- Any intrauterine procedure such as endometrial biopsy, D&C, hysteroscopy (diagnostic or operative) including endometrial ablation, could interrupt the ability of the micro-inserts to prevent pregnancy. In addition, the presence of the **Essure** micro-inserts could entail risks associated with such procedures that, at this time, have not been identified.
- Patients may decide, in future years, to undergo in vitro fertilisation (IVF) to become pregnant. The effects of the **Essure** micro-inserts on the success of IVF are unknown. If pregnancy is achieved, the risks of the micro-insert to the patient, to the foetus and to the continuation of a pregnancy are unknown.
- The **Essure** micro-inserts are MR-safe and radiopaque. The **Essure** micro-inserts are also MR-compatible, except for pelvic imaging where they may cause some artefacts.
- **There is the potential that unknown risks exist.**

VIII. Directions for use

A. Prior to micro-insert placement procedure

1. Micro-insert placement should be performed during days 7-14 of the menstrual cycle (where day 1 represents the first day of bleeding), in order to enhance visualisation of the fallopian tube ostia and decrease the potential for micro-insert placement in a patient with an undiagnosed pregnancy.
2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to or immediately preceding the micro-insert placement procedure.
3. Administration of a non-steroidal anti-inflammatory drug (NSAID) such as Indocid (orally or via suppository) is strongly recommended one to two hours before the micro-insert placement procedure, since clinical trial data demonstrate that the use of NSAIDs significantly increase the likelihood of placement success. If using only a paracervical block, Diazepam (PO) or a similar agent may also be offered 30 minutes prior to the procedure to reduce anxiety.

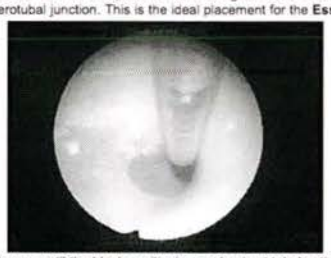
B. Essure micro-insert placement procedure

The **Essure** micro-insert placement procedure can be performed in an ambulatory or day surgery setting. Sterile techniques should be used during the micro-insert placement procedure. The amount of time required to complete the micro-insert placement procedure should not exceed 30 minutes.

1. Place the patient in the lithotomy position.
2. Introduce a speculum into the vagina to allow access to the cervix. Prep the cervix with betadine or other suitable antibacterial solution according to standard practice.
3. Local anaesthesia is the preferred method for implantation of the micro-inserts. A paracervical block may be administered. Midazolam (IV), or a similar agent, may also be administered to prevent or reduce discomfort if needed.
4. Insert a sterile hysteroscope, with attached camera and operating channel (≥ 5 French), through the cervix into the uterine cavity. If necessary, perform cervical dilation to allow insertion. In order to prevent uterine perforation, the procedure should be discontinued if excessive force is required to achieve cervical dilatation.
5. Uterine cavity distension should be accomplished with a physiologic saline infusion through the working channel of the hysteroscope. It is strongly recommended that the saline solution be pre-warmed to body temperature and introduced under gravity feed to minimise spasm of the fallopian tubes. Excellent uterine distension must be achieved and maintained throughout the procedure. Standard fluid monitoring procedures should be followed throughout the procedure. The fallopian tube ostia should be identified by hysteroscopic visualisation.
6. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** micro-insert placement. No attempt should be made to place a micro-insert in one tubal ostium unless there is a reasonable expectation that the opposite tube is patent.
7. Once the fallopian tube ostia have been identified, insert the introducer through the sealing cap on the hysteroscope working channel. The operating channel stopcock should remain in the open position (the device and/or introducer can be damaged if the stopcock closes on either device). Place the **Essure** delivery system through the introducer and advance through the operating channel of the hysteroscope. If undamaged from the first micro-insert placement, the valved introducer may remain in the operating channel throughout the **Essure** procedure.

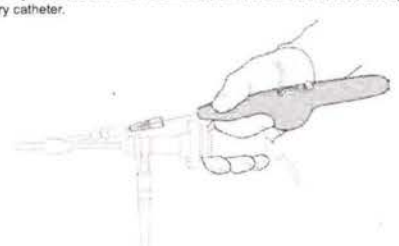
Insert the introducer through the sealing cap on the hysteroscope working channel, then place the **Essure** *delivery system through the introducer.*

8. Advance the **Essure** delivery system into the proximal fallopian tube with slow, steady movement to prevent tubal spasm. Advance the delivery system until the positioning marker on the delivery catheter reaches the fallopian tube ostium. This visual marker indicates that the **Essure** micro-insert is spanning the distal intramural to proximal isthmic segments of the fallopian tube, with the outer coil spanning the uterotubal junction. This is the ideal placement for the **Essure** micro-insert.



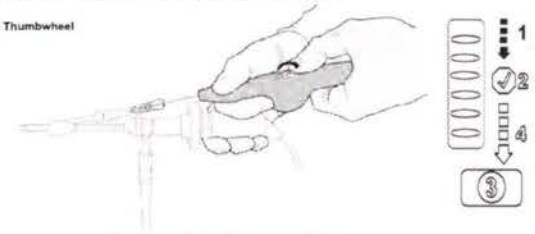
Advance until the black positioning marker is at tubal ostium. This is a visual indicator for proper position for deployment.

9. Proper concentric alignment of the delivery catheter with the tubal lumen is suggested by the ability to advance the catheter under direct visualisation without undue resistance. Resistance to advancement is usually apparent in two ways: 1) the black marker on the outside surface of the catheter is seen not to advance forward towards the tubal ostium, and/or 2) the delivery catheter bends or flexes excessively, thus preventing the physician from applying forward pressure on the catheter assembly. When such resistance to forward motion of the catheter is observed, no further attempts should be made to place the micro-insert in order to avoid the possibility of uterine perforation or inadvertently placing the micro-insert in the uterine musculature rather than within the tubal lumen. A follow-up **Essure** Confirmation Test (HSG) should be undertaken to determine tubal patency.
10. If it is not possible to advance the catheter to the positioning marker after several minutes, a perfusion test with a patency catheter may be employed, if it has not already been utilised, to determine tubal patency. If the tube is blocked or the catheter cannot be advanced to the positioning marker, the case should be terminated. If micro-insert placement is not successful after 10 minutes of attempted cannulation per tube, the case should be terminated.
11. When the delivery catheter has been advanced to the positioning marker, deploy the micro-insert. To do so, first stabilise the handle of the **Essure** micro-insert against the hysteroscope camera or some other fixed object, to prevent inadvertent forward movement of the **Essure** system during retraction of the delivery catheter.



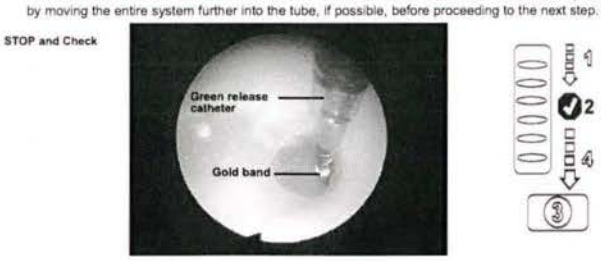
Stabilise handle against camera head or some other fixed object to prevent inadvertent forward movement of the **Essure** *system*

12. Being certain that the black positioning marker is at the fallopian tube ostium, rotate the thumbwheel on the handle toward you until the wheel no longer rotates. This operation corresponds to the symbol on the delivery system handle. This facilitates withdrawal of the delivery catheter. You will see the black positioning marker move away from the tubal ostium (towards the hysteroscope) and disappear into the operating channel. Withdrawal of the delivery catheter exposes the wound-down **Essure** micro-insert. Approximately 1 cm of the micro-insert (wound-down coils) should appear trailing into the uterus when the delivery catheter is withdrawn.



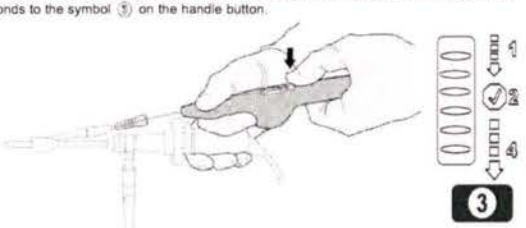
Rotate thumbwheel to retract catheter

13. To confirm proper positioning, place gold marker band just outside the ostium, which corresponds to the symbol on the delivery system handle. Visualisation of the gold band just outside the ostium, as well as visualisation of the distal tip of the green release catheter, will confirm proper positioning. If more than 1 cm of the micro-insert is visible in the uterus, then the micro-insert should be repositioned by moving the entire system further into the tube, if possible, before proceeding to the next step.



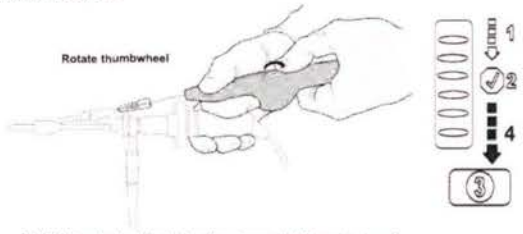
Visualise gold band at ostium

14. Press the button on the delivery handle to enable the thumbwheel to be further rotated, which corresponds to the symbol on the handle button.



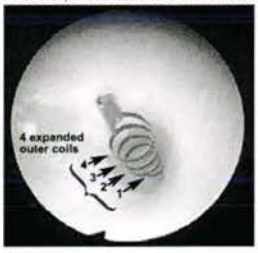
Press button to enable thumbwheel to rotate again.

15. Rotate the thumbwheel toward you to deploy the outer coil of the micro-insert, which corresponds to the symbol on the delivery system handle. Continue to rotate the thumbwheel until it stops rotating. When the thumbwheel cannot be rotated any further and the expanded outer coils are visible, withdraw the system.



Rotate thumbwheel to deploy the outer coil of the micro-insert

16. The position of the deployed **Essure** micro-insert will be assessed under hysteroscopic visualisation. There should ideally be 3 to 8 expanded outer coils of the **Essure** micro-insert trailing into the uterus.



Expanded outer coils of the **Essure** *micro-insert trailing into the uterus indicates ideal placement*

17. If the physician is dissatisfied with the micro-insert's placement based on the hysteroscopic view, or suspects tubal or uterine perforation, the micro-insert(s) should be left in place and evaluated via pelvic x-ray three months post device placement.

    WARNING: AFTER THE MICRO-INSERT HAS BEEN PLACED AND RELEASED INTO THE FALLOPIAN TUBE, DO NOT ATTEMPT TO REMOVE THE MICRO-INSERT HYSTEROSCOPICALLY UNLESS 18 OR MORE COILS OF THE ESSURE MICRO-INSERT ARE TRAILING IN THE UTERINE CAVITY. Removal of such a micro-insert should be attempted immediately during the placement attempt. However, removal may not be possible (see section XIII, **Essure** Micro-insert Removal). If the micro-insert was inadvertently deployed in the uterine cavity and not into the tube, the micro-insert should be removed from the uterus and another attempt made at micro-insert placement in the tube.
18. Repeat the **Essure** micro-insert placement procedure in the contralateral fallopian tube.
19. Record the length of the micro-insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concerns regarding potential perforation. These should be noted in patient records for subsequent reference when reviewing the 3-month x-ray (see *Section IX - Three-month pelvic x-ray*, below).
20. **Remind the patient to use an alternative form of contraception (except an IUD) for the first 3 months following the micro-insert placement procedure.**
21. Schedule the patient for a pelvic x-ray three months following the **Essure** micro-insert placement procedure to evaluate micro-insert retention and location.

IX. Three-month pelvic x-ray

A. An x-ray should be performed three months after micro-insert placement to evaluate micro-insert retention and location. The x-ray should be done within 24 hours prior to or the morning of the visit with the physician, so that the findings from the x-ray can be evaluated and discussed with the patient. The pelvic x-ray will be evaluated, in light of the issues described below in section B, as:

1. ***Satisfactory:*** micro-inserts appear to be in the tubal lumen and spanning the uterotubal junction, and appear relatively symmetrical. Patients whose x-rays are determined to be "satisfactory" may begin to rely on the **Essure** micro-insert for contraception.
2. ***Suspicious:*** one or both of the micro-inserts appear to be distal or proximal to the optimal position, or may be partially or completely perforated through the tube, and/or appear relatively asymmetrical. Patients whose x-rays are determined to be "suspicious" should be instructed to continue alternative contraception and undergo an **Essure** Confirmation Test (HSG) according to *Section X* below - *Performing and evaluating hysterosalpingograms.*
3. ***Unsatisfactory:*** obvious intraperitoneal micro-insert location or expulsion. Patients whose x-rays are determined to be "unsatisfactory" should be instructed to continue on alternative contraception. Patients who wish to be considered for a re-attempt should undergo an **Essure** Confirmation Test (HSG) (as described in Section X) and then be managed according to *Section XI - Management of Unsatisfactory Micro-insert Location (UML).*

B. Issues that should be carefully considered at the time of evaluating the 3-month x-ray for satisfactory micro-insert location, and should therefore be included in the procedure notes, are:

1. Concern at the time of placement of possible perforation due to excessive force required during micro-insert placement, a sudden loss of resistance or a trailing length of <0 mm.
2. The visible trailing length at the time of placement was <5 mm or >10 mm (3-8 expanded outer coils).
3. Identification of the tubal ostium was compromised during placement due to poor distension, poor lighting or endometrial debris that made identification of micro-insert positioning and trailing length difficult.
4. The patient has been complaining of persistent uterine cramping and/or bleeding/spotting since the procedure.

X. Performing and evaluating Confirmation Tests (HSG)s

The **Essure** Confirmation Test (HSG) is performed to further evaluate **Essure** micro-insert location and fallopian tube occlusion, if necessary based on the x-ray findings (see section IX). Based on the **Essure** Confirmation Test (HSG) findings, the physician will instruct the patient to discontinue alternative contraception and use only the **Essure** micro-inserts for pregnancy prevention if: 1) micro-insert retention is demonstrated; 2) micro-insert location is satisfactory and; 3) there is evidence of bilateral occlusion of the fallopian tubes.

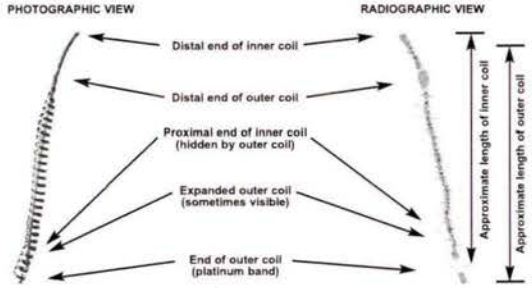
The following steps should be followed for performing and evaluating the **Essure** Confirmation Test (HSG).

A. Performing the Essure Confirmation Test (HSG)

One objective of the **Essure** Confirmation Test (HSG) is to evaluate the relationship of the proximal end of the inner coil of the micro-insert to the uterine cornua, thus verifying that the micro-insert spans the UTJ. In order to achieve this, the following guidelines should be adhered to:

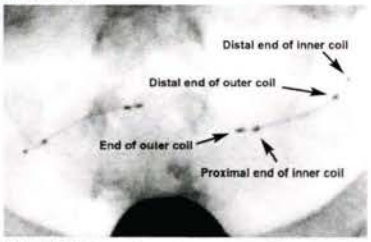
1. The uterine cavity silhouette must be clearly seen with good cornual filling.
2. The fluoroscopy beam with respect to the uterus should be as close to A/P projection as possible.
3. A good cervical seal should be maintained throughout the procedure to ensure good uterine distension.
4. Downward traction on the cervical tenaculum may be required in patients having a mid-positional uterus, to allow for ideal images of the uterine cavity.
5. A minimum of six still radiographs should be taken to assess micro-insert location and tubal occlusion. A description of each radiograph is provided below with associated pictures.

NOTE: Assessment of the location of the micro-inserts on **Essure** Confirmation Test (HSG) is not the same as noted at hysteroscopy. Therefore, a correctly placed micro-insert may appear to be more distal on **Essure** Confirmation Test (HSG) than noted at the time of hysteroscopy.

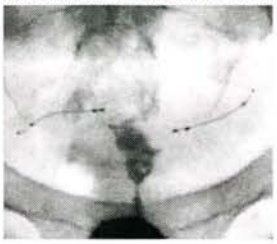


Corresponding radiographic view of the **Essure** *micro-insert*

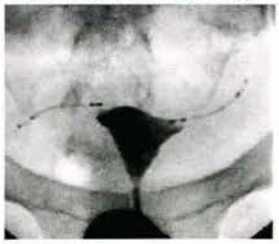
Radiograph 1 - "Scout film": capture an image of the uterus immediately prior to infusion of contrast into the uterine cavity. The **Essure** micro-inserts should be clearly seen. The lie and curvature of the micro-inserts should be noted.



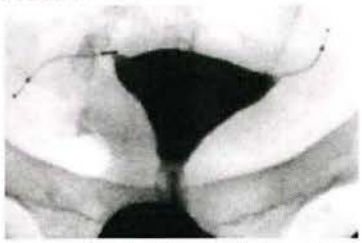
Radiograph 2 - Minimal fill of the cavity: capture an image of the uterus after a small amount of radioopaque contrast is instilled into the uterine cavity. This image should demonstrate evidence of an adequate seal of the uterine cervix and the beginning of opacification of the uterine cavity. In this radiograph, contrast material is likely not to have reached the uterine cornua. If the uterine cavity silhouette is not seen in a nearly A/P projection, the fluoroscopy beam and/or the patient need to be adjusted.



Radiograph 3 - Partial fill of the cavity: capture an image of the uterus when it is nearly full of contrast or opacified. The cornua may not yet have been adequately distended. Proximal (uterine) portions of the **Essure** micro-insert may not yet be obscured by the advancing dye.



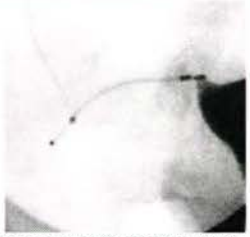
Radiograph 4 - Total fill of cavity: capture an image of the uterus when the uterine cavity is completely filled to patient tolerance or maximal distension of the cornua has been achieved, whichever comes first. In this image, the advance of contrast (i.e., opacification) is likely to meet or obscure the proximal (uterine) portions of the **Essure** micro-inserts.

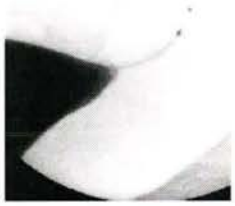


NOTE: An increase in volume of the intracavitary contrast, with resultant increase in intrauterine pressure, is often needed to allow for a satisfactory image.

CAUTION: An increase in intrauterine pressure beyond that needed to produce **Radiograph 4** serves no purpose and should be avoided, so as to avoid undue patient discomfort and the possibility of resultant vasovagal reaction such as profound bradycardia, lightheadedness, sweating and fainting.

Radiograph 5 & 6 - Magnifications of uterine cornua: once the uterine cornua are filled to maximum distension, magnified views of both right and left cornua should be obtained, highlighting the position of the micro-insert in relation to the uterine cornua.





B. Evaluating Essure Confirmation Test (HSG)s

When evaluating the **Essure** Confirmation Test (HSG), it is important to first confirm that the appropriate radiographs described above are provided, a good A/P image of the uterine silhouette is obtained, and the uterus is maximally distended in at least one view. The **Essure** Confirmation Test (HSG) will need to be immediately repeated if:

1. The appropriate sequence of radiographs has been captured but one or both uterine cornua are not maximally distended;
2. The projection of the silhouette is fundal rather than A/P;
3. The appropriate sequence of radiographs was not taken and/or the uterine cornua are not distended or are otherwise obscured, making evaluation of micro-insert position impossible or equivocal.

C. Essure micro-insert location

In evaluating micro-insert position, it is important to note the "markers" for the proximal end of the micro-insert (the end of the inner coil and the platinum band of the outer coil). Micro-insert position is then evaluated according to its relationship to the distended uterine cornua. **Ideal micro-insert location is when the inner coil of the micro-insert crosses the utero-tubal junction.**

The following scale should be used to categorise assessment of micro-insert location

1 - Micro-insert not present or expelled into uterine cavity.

2 - More than 50% of the length of the inner coil of the micro-insert is trailing into the uterus.

3 - Less than 50% of the length of the inner coil of the micro-insert is trailing into the contrast filling the uterine cornua.

4 - Proximal end of the inner coil is within the tube with no portion trailing into the uterus, and within 10 mm of the contrast filling the uterine cornua.

5 - Proximal end of the inner coil is within the tube but is 11-30 mm from the contrast filling the uterine cornua.

6 - Micro-insert is in the tube but the proximal end of the inner coil is more than 30 mm from the contrast filling the uterine cornua.

7 - Micro-insert is believed to be in the peritoneal cavity.

A patient with micro-insert location that is rated to be in categories 1, 2, 6 or 7 should not rely on the Essure micro-inserts for contraception.

D. Occlusion

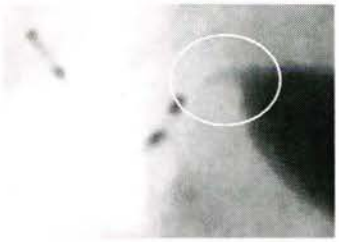
The most critical aspect of evaluating tubal occlusion is determining whether the contrast is visible in the tube beyond the micro-insert. It is also important to note any degree of proximal tubal filling with contrast even if the tube is occluded.

The following scale should be used to categorise assessment of tubal occlusion:

1 - Tube is occluded at the cornua.

2 - Contrast seen within the tube but not past any portion of the length of the outer coil of the micro-insert (i.e., past the distal end of the outer coil, see **Radiograph 7**).

Radiograph 7 - Contrast seen within the tube but not past any portion of the length of the outer coil of the micro-insert.



3 - Contrast seen past the distal end of the micro-insert or in the peritoneal cavity.

If tubal occlusion is rated to be in categories 1 or 2 above and micro-insert location is satisfactory (categories 3-5 above), the patient should be instructed to discontinue alternative contraception. If occlusion is rated 3 and micro-insert location is satisfactory, the patient should remain on alternative contraception for 3 more months and have a repeat **Essure** Confirmation Test (HSG). **If occlusion is again rated as a 3, then she should be advised to not rely on the Essure micro-inserts for contraception.**