MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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10 June 2024

Catrina McGregor

By email: fyi-request-26326-31b956ce@requests.fyi.org.nz
Ref: H2024039036

Tēnā koe Catrina

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 5 April 2024 for information regarding Essure. Please find a response to each part of your request below.

> *Other than a recall notice being placed on the MedSafe website, did the Ministry of Health or MedSafe notify physicians or gynaecologists of the recall of the Essure permanent contraceptive implant recall in 2017? If so, when and how did this take place?*

Notification of any recall or hazard alert action is the responsibility of the company marketing the medicine or medical device. Medsafe reviews correspondence the company proposes to send out and may require the company to take additional actions such as contacting implanting physicians in the case of an issue with an implanted medical device. Guidance on the conduct of recalls and hazard alerts can be accessed in The New Zealand Medicines and Medical Devices Recall Code, available at: https://www.medsafe.govt.nz/safety/recall-code-2015.asp.

> *Other than a recall notice being placed on the MedSafe website, did the Ministry of Health or MedSafe notify physicians that Essure recipients were required to be monitored? If so, when and how?*

As above, this is the responsibility of the company marketing the medical device. Following the Essure recall notice and hazard alert, Medsafe asked for and received confirmation that all implanting doctors had been contacted. The advice that was given directly to implanting surgeons is provided in the recall letter and the hazard alert.

> *Would Ministry of Health or MedSafe please produce dated copies of the letters, emails or templates sent to notify physicians of the Essure device recall, and the requirement to monitor implant recipients?*

Copies of the recall notice and the hazard alert notice as sent by the company are attached and itemised in Appendix 1. Some information has been withheld under section 9(2)(a).

> *Did the Ministry of Health or MedSafe supply physicians with any updated information and advice for patients in relation to the previously unnotified side effects?*

This information was supplied in the hazard alert letter sent by the company and dated 11 September 2017. A copy of this is attached and is itemised in Appendix 1.

Did Ministry of Health or MedSafe notify physicians of the Black Box warning and updated list of side effects that was issued in the USA in 2016?

There is no legislative requirement for any pre-market assessment or approval of medical devices in New Zealand. Nor is there a requirement for product information such as 'Instructions for Use' to be approved, published and updated such as there is for data sheets for approved medicines. It would be for the company supplying the Essure device to ensure any important safety information relating to a medical device it supplied was made available to the users of the medical device.

Has the Ministry of Health made physicians aware of the Bayer/FDA extended 5-year post recall 522 study in relation to Essure?

No, the notification of this would be a decision for the company supplying and supporting the Essure device in New Zealand.

At any time, has Ministry of Health taken any steps to notify patients directly regarding the recall of Essure?

Medsafe does not hold information on patient treatment with a medical device. Ongoing patient care, if required, is the responsibility of the relevant health care professionals.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	11 September 2017	Medical Device Recall and Hazard Alert for Essure Permanent Birth Control	Released with some information withheld under section 9(2)(a) of the Act, to protect personal privacy
2	N/A	Response form	
3	N/A	Revised Instructions for Use	Released in full
4	July 2017	Updated Patient Information Brochure with a patient-doctor discussion checklist	
5	29 August 2017	Email correspondence: Revised Medical Device Recall letter and Attachment A Response Form	Released with some information withheld under section 9(2)(a) of the Act, to protect personal privacy
5A		Email attachment: Response form	
5B		Email attachment: Medical Device Recall and Hazard Alert for Essure Permanent Birth Control	Released with some information withheld under section 9(2)(a) of the Act, to protect personal privacy

Document 1

nzms
new zealand
medical & scientific

MEDICAL DEVICE RECALL AND HAZARD ALERT

ESSURE® Permanent Birth Control

Catalogue Number/Order code: ESS305

Batch Numbers: All

11 September 2017

Level of Recall: Hospital

To be distributed to Healthcare Professionals who have performed the ESSURE procedure.

ISSUE

New Zealand Medical & Scientific Ltd (NZMS), following consultation with Medsafe, is issuing a hazard alert for ESSURE. NZMS is also undertaking a recall of all unimplanted ESSURE in New Zealand.

Hazard Alert: It has been identified that some patients who have received the device may not have been fully informed of the possible device and procedure-related risks before choosing to have ESSURE implanted. There have been reports of changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of the device, allergy/hypersensitivity, or immune-type reactions. Some of these reports were considered serious and resulted in removal of the device, which involved abdominal surgery.

The labelling for ESSURE is being updated. The update includes revised Instructions for Use ("IFU") and the introduction of a "Patient Information Brochure" with a patient-doctor discussion checklist. The updated labelling provides warnings about potential adverse events and situations where device removal may be necessary.

Device recall: On 31 May 2017, Medsafe was informed about the manufacturer's decision to discontinue the supply of ESSURE in New Zealand for business reasons as a result of a low and declining trend in patient preference for this choice of permanent contraception which is not expected to change. On 3 August 2017, a temporary suspension of the EC certificates was placed on ESSURE in Europe for a period of 90 days during which the Notified Body and the manufacturer are working together to address outstanding issues. NZMS will be withdrawing remaining devices from the New Zealand market and there will be no further implantations of ESSURE in New Zealand.

ACTION

1. Please inspect your stocks and quarantine all unimplanted ESSURE kits.

2. Contact NZMS on 09 259 4062 so we may arrange your stock to be recovered. We require this information to reconcile this process.

P +64 259 4062
F +64 259 4067
E nzms@nzms.co.nz
W www.nzms.co.nz

2a Fisher Crescent
Mt Wellington, Auckland 1060
PO Box 132400, Sylvia Park
Auckland 1644, New Zealand

Document 1

3. If any of your stock has been transferred from your hospital to another, please immediately inform that hospital of the recall. Please then telephone us so that we can make contact with the hospital supplied.

4. Please forward this notice to all those who need to be aware of this information within your organisation.

5. Please review the updated "IFU" and new "Patient Information Brochure" attached. The updated "IFU" provides additional information, including a new section on patient counselling, as well as changes to sections about safety, clinical studies, directions for use and patient management. The "Patient Information Brochure" is intended to be reviewed by the patient with their doctor face-to-face, which may assist in identifying any device related issues.

6. Please consider whether patients who have ESSURE implanted should receive further advice, and take action as considered necessary to ensure women with ESSURE implanted are informed appropriately.

7. Please complete and return the attached acknowledgement form to confirm the receipt of this notice.

Bayer (the manufacturer of ESSURE) will continue to fully support women with ESSURE implanted in New Zealand as well as support healthcare professionals who have questions on the product or who need to report suspected adverse events associated with ESSURE.

NZMS sincerely regrets any inconvenience caused by the recall action and is fully committed to supporting you in this matter. If you have any questions regarding this notice, please contact:

s 9(2)(a) New Zealand Medical & Scientific Ltd (NZMS)

Phone: s 9(2)(a)
Mobile:
Email: s 9(2)(a) @nzms.co.nz

Yours sincerely,

s 9(2)(a)

s 9(2)(a)

Document 2

ATTACHMENT A

RESPONSE FORM
Urgent Medical Device Recall
Essure® Permanent Birth Control

Catalogue Number: ESS305
Batch Numbers: All

I acknowledge receipt of the Urgent Medical Device Recall notice (11 September 2017) relating to the above product.

FROM:

Organisation			
Name		Date	
Position		Telephone No.	
Email		Fax No.	
Signature			

Affected Stock

If you have no affected stock tick this box: ☐

If you have affected stock please complete the table below:

STOCK DETAILS:

Product	Batch/ Lot	Quantity
TOTAL AFFECTED PRODUCT:		
Other Relevant Details:		

Document continues next page.

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes (please supply names and contact information of the organisations):

OR

☐ Yes – I/We will forward all the recall action information to the suppliers/distributors/customers.

It is important that you complete and return this form by 22 September 2017

Please return the completed response to the attention of Ruth Hughes using one of the following methods:

- FAX: (09) 259 4067
- EMAIL SCANNED COPY: s 9(2)(a) @nzms.co.nz
- OR MAIL TO: NZMS
  PO Box 132400
  Sylvia Park, Auckland 1644

essure®

permanent birth control

BAYER

- **An Essure Confirmation Test should be performed three months after insert placement to evaluate insert retention and location. The patient must use alternative contraception until an Essure Confirmation Test demonstrates satisfactory results (see section XII 'Essure Confirmation Test').**
- **There have been reports of perforation of the uterus and/or fallopian tubes, inserts located in the intra-abdominal or pelvic cavity, persistent pain, and allergy or hypersensitivity reactions in some patients. Some of these reported events resulted in insert removal that required abdominal surgery. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered. This information should be shared with patients considering sterilization with Essure during discussion of the benefits and risks of the device.**

IMPORTANT: Device to be used only by physicians who are skilled hysteroscopists; have read and understood the Instructions for Use and Physician training materials; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.

INSTRUCTIONS FOR USE

I. Product Description

Overview of Essure Procedure and Principles of Operation

The **Essure (Essure®)** System for Permanent Birth Control Model ESS 305 is designed for permanent contraception by physical occlusion of the fallopian tubes. Using a transvaginal approach, one **Essure** insert is placed in the proximal portion of the fallopian tube lumen. When the insert expands upon release, it conforms to and acutely anchors in the lumen of the fallopian tube. Subsequently, the insert elicits a benign tissue in-growth that permanently occludes the lumen of the fallopian tube, resulting in permanent contraception.

Step 1: Essure insert placement procedure.

NOTE: Patient must remain on alternative contraception until a satisfactory **Essure** Confirmation Test is documented.

Step 2: Essure Confirmation Test must show fallopian tube(s) with either satisfactory insert location (when using a transvaginal ultrasound (TVU) and/or X-ray) or both satisfactory insert location and occlusion (when using a modified hysterosalpingogram (modified HSG)) before the patient can rely on **Essure** for contraception.

Device Description

The **Essure** Permanent Birth Control System is comprised of several components. The **Essure** insert, a dynamically expanding 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 1a), is attached to a handle that facilitates insert delivery and deployment. The insert is designed with a 15 degree angle at the tip to facilitate entry into the fallopian tube. A valved **DryFlow®** Introducer, (Figure 1d) is also provided with the **Essure** system. It is intended to help protect the **Essure** insert as it is being passed through the rubber port of the hysteroscope working channel.

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

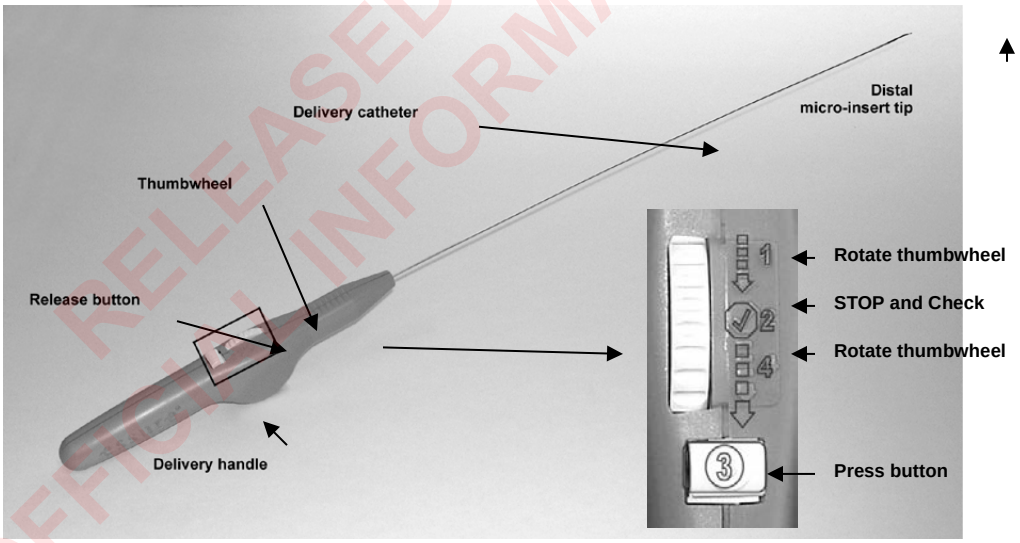


Figure 1b: Essure Insert: Wound-down configuration, attached to the delivery system. The wound-down insert is approximately 4 cm in length and 0.8 mm in diameter. **(NOT TO SCALE)**

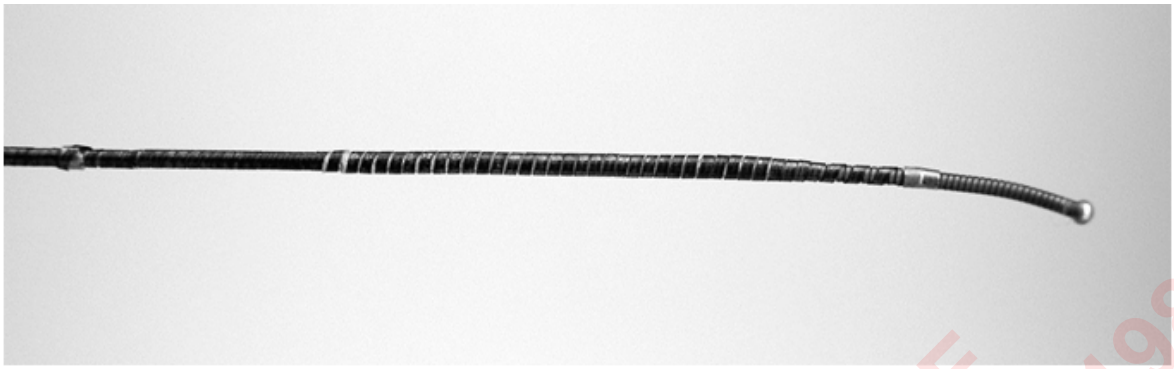


Figure 1c: Essure Insert: Expanded configuration, detached from the delivery system. When released, the outer coil expands up to 2.0 mm in diameter, conforming itself to the varied diameters and shapes of the fallopian tube. **(NOT TO SCALE)**

Each insert consists of a Nitinol (nickel-titanium alloy) outer coil, a 316L stainless steel inner coil wrapped in polyethylene terephthalate (PET) fibers, platinum marker bands (2) and a silver-tin solder.

Figure 1D: DryFlow Introducer
(NOT TO SCALE)

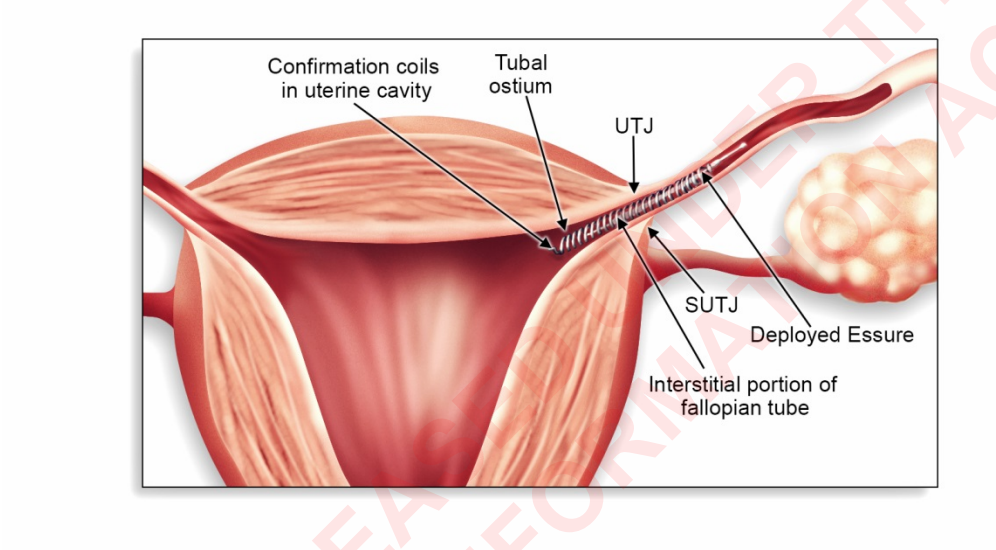
II. Mechanism of Action

Under hysteroscopic visualization, the **Essure** system is delivered by the physician to the proximal section of the fallopian tube utilizing the delivery system.

A. Placement at Utero-Tubal Junction

Optimal placement occurs when the insert spans the serosal utero-tubal junction (SUTJ), as viewed on transvaginal ultrasound (Figure) or the utero-tubal junction (UTJ) as visualized on a modified HSG. The serosal utero-tubal junction (SUTJ) refers to the anatomical location where the fallopian tube intersects with the serosal boundary of the uterus. This term is used when imaging is performed by ultrasound. The utero-tubal junction (UTJ) refers to the region identified by HSG where contrast material enters the proximal fallopian tube.

Figure 2: Optimal Essure Insert Placement



B. Dynamic Anchoring

The insert is a dynamic and flexible spring-like device. The outer coil expands upon deployment, conforms to and pushes against the fallopian tube wall, acutely anchoring the insert in the lumen of the fallopian tube.

C. Tubal Occlusion and Tissue In-Growth

Tubal occlusion is attributed to the space filling design of the device and the benign occlusive tissue response. PET fiber causes tissue in-growth into and around the insert, facilitating insert retention, resulting in tubal occlusion and contraception.

Each **Essure** system is sterilized using ethylene oxide and is supplied sterile for single use only. Do not reuse or resterilize. Resterilization may adversely affect proper mechanical function and could result in patient injury.

III. Indications for Use

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

IV. Contraindications for Use

- Patient uncertainty about her desire to end fertility.
- Pregnancy or suspected pregnancy.
- Delivery or a termination of a second trimester pregnancy less than 6 weeks before **Essure** insert placement.
- Active upper or lower genital tract infection.
- Unexplained vaginal bleeding.
- Gynecological malignancy (suspected or known).
- Known abnormal uterine cavity that makes visualization of the tubal ostia impossible and/or abnormal tubal anatomy or previous tubal ligation (including failed tubal ligation).
- Allergy to contrast media (a modified HSG may be required for the **Essure** Confirmation Test).

V. Warnings and Precautions

General

WARNINGS

- The **Essure** procedure should be considered irreversible. Safety and effectiveness of insert removal for restoration of tubal patency is unknown.
- Unilateral placement may be performed in patients with confirmed history of salpingectomy or unicornuate uterus. Unilateral tubal occlusion demonstrated by HSG alone is not sufficient evidence to allow for unilateral placement.
- Pain (acute or persistent) of varying intensity and length of time may occur and persist following **Essure** placement. Individuals with a history of pain are more likely to experience both acute and chronic pelvic pain following **Essure** placement. Unsatisfactory device location including perforation, uterine embedment and expulsion may result in pain. Patients should be advised to contact their physician if there is significant pain or if pain persists. Not all pain will be related to the **Essure** insert;

therefore, other unrelated gynecological (e.g. endometriosis, adenomyosis) or non-gynecological (e.g., irritable bowel syndrome, interstitial cystitis) conditions that may result in pain should be considered. (see section VII 'Adverse Effects', subsection 'Pain')

- Surgery including device removal, hysterectomy or other procedures may be required to treat the pain (see section XIV 'Essure Insert Removal'), (see section VII 'Adverse Effects', subsection 'Pain').
- Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.
- Patients with known hypersensitivities to nickel, platinum, titanium, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the **Essure** system (see section I 'Product Description') may experience an allergic reaction to the insert. This includes both patients with or without a history of metal allergies; there are no known diagnostic tests that are predictive of allergic reactions to any of the components of **Essure**. In addition, some patients may develop an allergy to nickel or other components of the insert following placement within the fallopian tube. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritis. Patients should be counseled on the materials contained in the insert prior to the **Essure** procedure.
- Patients on active immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) may experience delay or failure of the necessary tissue in-growth needed for tubal occlusion. For these patients, physicians must use the modified HSG as the **Essure** Confirmation Test. TVU or pelvic X-ray should not be utilized for confirmation, as these tests cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

PRECAUTIONS

- The **Essure** procedure should only be performed by skilled hysteroscopists who have completed the **Essure** training program (Clinical Pathway), including preceptoring in placement until competency is established, typically 5 cases.
- Women undergoing sterilization at a younger age are at greater risk of regretting their decision.
- Safety and effectiveness of **Essure** is not established in patients under 21 or over 45 years old at the time of placement.
- Do not use the **Essure** system if the package is open or damaged. Do not use if the insert is damaged.
- Never attempt to re-sterilize the **Essure** system as it is single use only. Resterilization may adversely affect device function or cause patient injury.

Pregnancy Risk

WARNINGS

- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the **Essure** procedure.
- The patient must use alternative contraception until an **Essure** Confirmation Test performed three months post- insert placement demonstrates satisfactory results.
- If the **Essure** inserts are not properly placed or are not in a satisfactory location, then the patient should be advised to not rely on **Essure** and use alternative contraception.
- In the case of unintended pregnancy with **Essure** *in situ*, **Essure** cannot be relied on for contraception and alternative contraception is required to prevent subsequent unintended pregnancies.
- Physicians must adhere to the **Essure** Confirmation Test protocol (see section XII '**Essure** Confirmation Test'). Incorrect execution and/or interpretation of the **Essure** Confirmation Test results have led to unintended pregnancy.
- Effectiveness rates for the **Essure** procedure are based on patients who had bilateral placement. Limited effectiveness data exist for unilateral insert placement in patients with, unicornuate uteri, or contralateral proximal tubal occlusion (PTO) or prior tubal surgery.
- If the patient conceives and chooses to continue an intrauterine pregnancy, she should be informed that there may be risks of an in situ insert to the patient, to the fetus, and to the continuation of the pregnancy. While most pregnancies with **Essure** *in situ* have been reported as healthy deliveries at term, pregnancy loss, pre-term labor, pre-term rupture of membranes, pre-term delivery, stillbirth, and neonatal complications have also been reported.

Procedure

WARNINGS

- In order to reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.
- Never attempt to advance **Essure** insert against excessive resistance. If a perforation occurs or is suspected, do not continue with **Essure** insert placement attempt and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain. If unusual post-operative pain occurs, imaging to localize the insert should be performed prior to the 3 month confirmation test. A very small percentage 12/682 (1.8%) of women in **Essure** clinical trials were identified as having device related perforations. Retrieval of perforating inserts, if necessary, will require surgical removal (see section XIV. '**Essure** Insert Removal'). A false positive modified HSG and pregnancy have been associated with tubal perforation by the insert in

the literature; evaluate **Essure** Confirmation Test for perforation if excessive resistance is experienced during the procedure.

- If **Essure** insert placement attempts are not successful after 10 minutes of attempted cannulation per tube or excessive resistance is encountered, avoid repeated attempts at cannulation, terminate the procedure and potentially reschedule the procedure.
- Terminate the procedure if distention fluid deficit exceeds 1500cc, to reduce the risk of hypervolemia. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- Once the insert has been placed (i.e., detached from the delivery wire), hysteroscopic insert removal (at the time of placement procedure) should not be attempted, unless 18 or more coils of the **Essure** insert are trailing into the uterine cavity indicating proximal placement. Removal of such an insert should be attempted immediately following the placement (see section XIV '**Essure** Insert Removal', subsection 'At time of Placement Procedure'). Attempted removal with less than 18 trailing coils may result in a fractured insert, fallopian tube perforation, or other injury.

PRECAUTIONS

- Adequate visualization of the uterine anatomy and tubal ostia is required.
- Timing of the procedure to the early proliferative phase of the menstrual cycle should:

  Enhance visualization of the uterine cavity and fallopian tube ostia.

  - Decrease the potential for insert placement in a patient with an undiagnosed pregnancy.
- Pre-treatment of the patient with medications that suppress endometrial proliferation may minimize intra-uterine debris and improve visualization during the procedure.
- Use an introducer to avoid insert tip damage.
- Unusual uterine anatomy may make it difficult to place the **Essure** insert(s).
- Keep the operating channel of the hysteroscope open to avoid damage to insert or introducer.
- All tubal ostia for which occlusion is planned should be identified and assessed hysteroscopically prior to proceeding to **Essure** insert placement. No attempt should be made to place an insert in the tubal ostium unless fallopian tube(s) appear to be accessible.
- When introducing the **Essure** insert into the fallopian tube, never advance the insert(s) against excessive resistance. Do not advance the **Essure** system if the patient is experiencing excessive pain or discomfort.
- Do not continue to advance the **Essure** system once the end of the black positioning marker on the catheter has reached the tubal ostium. Advancement beyond this point could result in unsatisfactory insert placement or tubal/uterine perforation.

- If breakage of any component (e.g., catheter or insert) occurs during placement, all fragments should be removed (see section XIV '**Essure** Insert Removal').
- Do not deploy more than one insert in a single fallopian tube during the same procedure. If a physician suspects that the device has not deployed in the tube (e.g., sees no trailing coils), the physician must ensure that the insert is not in the tube by inspection of the delivery system to verify deployment has not occurred. Refer to Figure 11 which shows delivery system before and after deployment. If needed, imaging (e.g. X-ray or TVU) may be used.

Interactions with Other Procedures

Patients who undergo placement of the **Essure** insert may, in future years, be offered gynecological therapies that may pose additional risk due to the presence of the insert:

WARNINGS

- DO NOT perform the **Essure** procedure concomitantly with endometrial ablation. Ablation causes intrauterine synechiae which can compromise (i.e., prevent the proper interpretation of) the modified HSG, which may be required for the **Essure** Confirmation Test. Women with inadequate confirmation tests cannot rely on **Essure** for contraception.
- Endometrial ablation can result in thermal injury to the gastrointestinal (GI) tract or abscess formation around the inserts. This could cause bowel or bladder injury if there is an unrecognized tubal perforation and part of the insert lies outside of the tubal serosa. Endometrial ablation (if medically appropriate) should only be performed after correct location of the **Essure** insert is confirmed by a satisfactory **Essure** Confirmation Test, in order to minimize the risk of injury to the surrounding tissue (e.g. bowel).
- During endometrial ablation, thermal injury to the proximal portion of the fibrotic in-growth that causes tubal occlusion may occur. It is unknown whether thermal injury will interfere with tubal occlusion. Bench and clinical studies have been conducted which demonstrate that endometrial ablation of the uterus can be safely performed with **Essure** insert in place after a satisfactory confirmation test has been performed. Contraception rates following NovaSure Endometrial Ablation System with **Essure** inserts in place are under investigation.
- Performing intrauterine procedure such as endometrial ablation, endometrial biopsy, dilation and curettage (D&C) and hysteroscopy (diagnostic or operative) may result in trailing coils of the insert being ensnared in another device. When the device/instrument is withdrawn, the insert may be stretched or removed and tubal patency may be restored.
- Some surgical instruments utilize energy sources such as electrical current, radio frequency, thermal energy, or freezing (e.g., cryotherapy). There is a risk of fragmentation of the insert and/or conduction of energy to surrounding structures if these energy sources are used adjacent to or in contact with the insert. There may be risks

associated with such procedures that, at this time, have not been identified. Avoid direct contact between the **Essure** inserts and monopolar radio frequency (RF) when performing endometrial ablation during operative hysteroscopy as this may cause injury to surrounding tissue.

- Endometrial ablation using microwave energy is contraindicated when an **Essure** insert is in place.

- Other surgical instruments such a morcellator, clamp, or scissors can result in fragmentation of the inserts and should therefore be avoided or used with caution in proximity to the insert. If fragmentation occurs, intra-operative imaging to localize the fragments should be performed and the fragments should be removed, as determined by the physician's judgment. Care must be taken to completely remove the insert(s) when performing a hysterectomy when the adnexa are being retained.

PRECAUTIONS

- Use caution and avoid the **Essure** inserts when undertaking blind intrauterine procedures as disturbing the inserts could interrupt their ability to prevent pregnancy. Direct visualization of inserts during intrauterine procedures is optimal. Insert retention and location may need to be verified following intrauterine procedures if there is a concern of entanglement with the insert. Modalities that may be used for this purpose include hysteroscopy, X-ray, HSG, or TVU. There could be risks associated with intrauterine procedures and the presence of inserts not currently identified.
- Performing endometrial ablation following placement of **Essure** inserts may increase the risk of post-ablation tubal sterilization syndrome, a rare condition that has been reported in women with a history of tubal sterilization who undergo endometrial ablation.
- There are limited data related to the effects, including risks, of **Essure** inserts on in vitro fertilization (IVF).

MRI Safety Information

Non-clinical testing has demonstrated the ESS305 insert is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3.0 T or less
- Maximum spatial gradient field of 720 Gauss/cm (7.2 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 3 W/kg (First Level Controlled Operating Mode)
- Using a transmit/receive RF body coil

- Under the scan conditions defined above, the ESS305 insert is expected to produce a maximum temperature rise of 1.7 °C after 15 minutes of continuous scanning.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the **Essure** insert. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.
Dimensions: Wound-down and expanded length: 4-cm
Expanded diameter: 1.5 to 2.0-mm

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	173-mm2	53-mm2	621-mm2	277-mm2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Post-procedural management

WARNINGS

- Counsel the patient on the need for the **Essure** Confirmation Test, the options for the confirmation test including their risks and benefits, and the possibility of an increased risk of unintended pregnancy, if the **Essure** Confirmation Test is unsatisfactory. If the **Essure** Confirmation Test is unsatisfactory, the patient must continue using an alternative form of birth control.
- Following **Essure** placement and prior to the confirmation test at three months, the patient must use alternative contraception and should use the most appropriate means of contraception for which she is a candidate during this time.

PRECAUTIONS

- Counsel the patient that **Essure** placement may not be successful and discuss management options in the event of this outcome.

VI. Patient Counseling Information

Important Factors to be discussed with the Patient

- Patient must be certain about her desire to end fertility.
- The procedure is permanent, and irreversible. Safety and effectiveness of insert removal for restoration of tubal patency is unknown.
- It is important that all patients seeking to undergo the **Essure** procedure understand the risks and benefits of **Essure**.

- No contraceptive method is 100% effective. Like all birth control methods, there is a risk of pregnancy; pregnancies have been reported with **Essure**.
- A complete medical and social history should be obtained to determine if the patient has a condition that may make her an unsuitable candidate or place her at increased risk for adverse events. Patients should be encouraged to discuss any history of chronic pain, mental health disorders including a clinical diagnosis of depression during her consultation visit. Results of an evaluation for pelvic infection, undiagnosed vaginal bleeding, anatomical variants and/or uterine pathology may make patient unsuitable for the procedure.
- Patients with known hypersensitivity to nickel, platinum, titanium, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the **Essure** system (see section I 'Product Description') may experience an allergic reaction to the insert. This includes both patients with or without a history of metal allergies; there are no known diagnostic tests that are predictive of allergic reactions to any of the components of Essure. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Typical allergic symptoms reported for this device include hives, urticaria, rash, angioedema, facial edema and pruritis. All patients should be counseled on the materials contained in the insert, as well as potential for allergy/hypersensitivity prior to the **Essure** procedure. Currently, there is no test that reliably predicts who may develop a hypersensitivity reaction to the materials contained in the insert.
- Patient must use alternative contraception for at least three months post-placement procedure, until a satisfactory **Essure** Confirmation Test is documented. Physician must counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all steps of the **Essure** procedure. Ensure patient is supplied with the most effective means of contraception for which she is a candidate during this time frame.
- Discuss the three methods utilized in the **Essure** Confirmation Test (Pelvic X-ray, TVU and modified HSG). Inform patients of the differences between the methods, including benefits and risks.
- The management of adverse events may include surgery and removal of the inserts. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered. The management of an unsatisfactory confirmation test may include a repeat of the **Essure** procedure or alternative contraception, including laparoscopic tubal sterilization.
- As with any procedure, hysteroscopic placement of **Essure** inserts into the fallopian tubes is NOT without risks. **Essure** placement is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship. The patient should read the Patient Information Booklet (PIB). While the PIB is not intended to replace appropriate physician counseling, each patient should receive the PIB during their initial visit/consultation to allow her sufficient time prior to the procedure to read and adequately understand the important information on the risks, the need for the

confirmation test, and the contraceptive benefit associated with **Essure**. Allow the patient adequate time after reviewing and considering this information before deciding whether to have the **Essure** procedure. The Patient-Doctor Discussion Checklist should be reviewed with the patient, and all of the patient's questions answered.

- Warnings, precautions, important factors to consider including possible adverse events.
- The decision to undergo treatment is at the patient's discretion, following physician counseling and informed consent.
- Following the procedure, the patient should be counseled to inform all of her healthcare providers that she has the inserts prior to any planned gynecological, lower abdominal surgical or imaging procedure.

IMPORTANT: Counsel patients that this product does not protect against either HIV infection or other sexually transmitted infections.

VII. Adverse Effects

ADVERSE EVENTS IN PHASE II/PIVOTAL PREMARKETING STUDIES

A. Patient Population

From November 1998 - June 2001, a total of 745 women underwent the **Essure** procedure in two clinical trials that evaluated safety and effectiveness (227 Phase II; 518 Pivotal[1]). Placement of at least one insert was achieved in 682 women (206 Phase II study; 476 Pivotal). If bilateral placement was not initially achieved, some women underwent additional procedure(s).

B. Observed Adverse Events

Adverse events resulting from the **placement procedure** are detailed in **Table 1**.

[1]Pivotal trial: 657 women initially enrolled; 518 underwent the procedure; 99 changed their minds about participating; 23 did not meet the inclusion criteria and were terminated from study; 17 failed screening tests.

Table 1
Adverse events reported day of placement procedure in Phase II & Pivotal Trials

Adverse Event/ Side Effect	Phase II Trial		Pivotal Trial	
	Number (N=233 procedures)	Percent	Number (N=544 procedures)	Percent
Cramping	**	**	161	29.6%
Pain	2	0.9%	70	12.9%
Nausea/vomiting	**	**	59	10.8%
Dizziness/light headed	**	**	48	8.8%
Bleeding/spotting	**	**	37	6.8%
Other	**	**	16*	2.9%
Vaso-vagal response	2	0.9%	7	1.3%
Hypervolemia	**	**	2	0.4%
Band Detachment	3	1.3%	2	0.4%

*Includes: ache (3), hot/hot flashes (2), shakiness (2), uncomfortable (1), weak (1), profuse perspiration (1), bowel pain (1), sleepiness (1), skin itching (1), loss of appetite (1), bloating (1), allergic reaction to saline used for distension (1).
**Data not collected

During and immediately following the procedure, the majority of participants experienced mild to moderate pain. The majority of participants experienced spotting for an average of 3 days after the procedure. Pain was managed with oral non-steroidal anti-inflammatory drugs (NSAIDs) or oral narcotic pain reliever.

Table 2 summarizes adverse events rated as "possibly" related to the insert or procedure during the first year of reliance in the Pivotal trial (approximately 15 months post-device placement). Percentages reflect the number of *events* divided by the number of *participants* in the trial. When numerous episodes of the same event were reported by one participant, each report was counted as a separate event. Therefore, percentages may over-represent the percentage of *women* who have experienced that event.

Table 2
Pivotal Trial
Adverse Events by Body Systems, First Year of Reliance*
(N=476 patients implanted with at least one insert)

Adverse Events by Body System	Number	Percent
Abdominal:		
Abdominal pain/abdominal cramps	18	3.8%
Gas/bloating	6	1.3%
Musculo-skeletal:		
Back pain/low back pain	43	9.0%
Arm/leg pain	4	0.8%
Nervous/Psychiatric:		
Headache	12	2.5%
Premenstrual Syndrome	4	0.8%
Genitourinary:		
Dysmenorrhea/menstrual cramps (severe)	14	2.9%
Pelvic/lower abdominal pain (severe)	12	2.5%
Persistent increase in menstrual flow	9**	1.9%
Vaginal discharge/vaginal infection	7	1.5%
Abnormal bleeding - timing not specified (severe)	9	1.9%
Menorrhagia/prolonged menses (severe)	5	1.1%
Dyspareunia	17	3.6%
Pain/discomfort - uncharacterized:	14	2.9%

* Only events occurring in $\geq$ 0.5% are reported
** Eight women reported persistent *decrease* in menstrual flow
In the Phase II trial, 12/206 (5.8%) women with at least one insert reported episodes of period pain, ovulatory pain, or changes in menstrual function.

OBSERVED AND POTENTIAL ADVERSE EVENTS

The following adverse events have occurred (in clinical trials and/or commercial usage) or may potentially occur during the **Essure** placement procedure and with wearing the insert; however, there is the potential that unknown risks exist. Symptoms other than those listed in the sections below have been reported by women implanted with **Essure**, although they were not seen in the clinical trials supporting **Essure** approval. The more common of these symptoms include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to **Essure** or other causes.

Document 3

Risks Associated with the Insert Placement Procedure

Possible adverse events that have been reported within 24 hours following the **Essure** placement procedure include; nausea/vomiting, dizziness/lightheadedness, vaso-vagal response/syncope, pain, dysmenorrhea, uterine bleeding/spotting, infection, fluid overload, anesthetic complications, detachment difficulties and unsatisfactory insert location.

Anesthesia:

- Local anesthesia, oral analgesia/sedation, regional anesthesia (i.e., spinal, epidural), oral or conscious (intravenous) sedation, or general anesthesia may be administered to the patient to prevent or reduce discomfort. Regardless of the type of anesthesia, patients may not be able to resume normal activities for 12-24 hours following the procedure.
- Serious reactions to anesthesia including general anesthesia and paracervical block have been reported. Risks and benefits associated with the planned anesthesia should be discussed prior to performing the procedure.

Intra-operative and post-operative symptoms:

- Pain, cramping, vaginal bleeding, nausea/vomiting, and dizziness, lightheaded, vasovagal response may occur during and following the insert placement procedure. Typically, these incidents are tolerable, transient and successfully treated with medication.

Device Properties and Deployment:

- Bending of the insert tip or catheter, breakage of the catheter during attempted insertion and difficulty in deployment or detachment can occur, especially in tubal ostia that are more laterally located or in cases of tubal spasm.

Unsatisfactory Insert Location:

- Any insert that is not satisfactorily located within the fallopian tube can NOT be relied on for effective contraception. Unusual pain or uterine bleeding after the placement procedure should prompt investigation of an unsatisfactory insert location.
- 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 at the time of placement

or shortly thereafter may be required, but is unlikely for most perforations. To reduce the risk of uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.

- Imaging may be required to identify the location of the insert(s). Removal of an unsatisfactorily located insert (perforation, embedment, migration expulsion, proximal or distal fallopian tube placement, or within the peritoneal cavity) may require surgery for removal (see section XIV. '**Essure** Insert Removal').

Fluid Overload:

- There is a minimal risk of excess fluid absorption of the physiologic saline fluid, used for distention of the uterus, to perform the hysteroscopic procedure.

Infection:

- As with all hysteroscopic procedures, the insert placement procedure can cause an infection. An infection could cause damage to the uterus, fallopian tubes, or pelvic structures which may require antibiotic therapy, or rarely, hospitalization or surgery, including hysterectomy.

Risks Associated with Essure Insert Wearing

Possible adverse events that have been reported (>24 hours) following the **Essure** placement procedure include; uterine bleeding, dysmenorrhea, dyspareunia, vaginal discharge/infection, headache, upper genital tract infection, lower abdominal pelvic and back pain, abdominal distention/bloating, unsatisfactory insert location, hypersensitivity and allergy including rash and urticaria.

Pregnancy:

- There is a possibility of pregnancy and ectopic pregnancy each of which has risks. Most intrauterine pregnancies in patients with **Essure** that were not electively terminated and progressed beyond the first trimester have resulted in full term births. Premature labor, premature rupture of membranes, preterm delivery, stillbirth, and genetic and developmental abnormalities have been reported in pregnancies with **Essure**. Removal of **Essure** may result in termination of pregnancy and is not recommended in patients who desire continuation of pregnancy.

Pain:

- Pain (acute or persistent) of varying intensity and length of time may occur and persist following **Essure** placement. Individuals with a history of pain are more likely to experience both acute and chronic pelvic pain following **Essure**

placement. Unsatisfactory device location including perforation, uterine embedment and expulsion may result in pain. Patients should be advised to contact their physician if there is significant pain or if pain persists. Not all pain will be related to the **Essure** insert; therefore, other unrelated gynecological (e.g. endometriosis, adenomyosis) or non-gynecological (e.g., irritable bowel syndrome, interstitial cystitis) conditions that may result in pain should be considered.

- Pain and cramping may be a more likely occurrence during the menstrual period, during and after sexual intercourse or with other physical activity.
- Surgery including device removal, hysterectomy or other procedures may be required to treat the pain (see section XIV '**Essure** Insert Removal').
- Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.

Bleeding:

- Changes in the pattern or amount of menstrual bleeding have been reported. (See Table 2). Changes in menstrual bleeding may occur following discontinuation of hormonal contraception.

Infection:

- Endometritis, and pelvic inflammatory disease, including tubo-ovarian abscesses, have been infrequently reported in individuals with **Essure**. Surgery including hysterectomy may be required for treatment.

Hypersensitivity:

- Hypersensitivity reactions including hives, urticaria, rash, angioedema, facial edema and pruritis have been reported with **Essure** (see section V 'Warnings And Precautions'). If a patient is experiencing a reaction suspected to be due to materials contained in the insert, removal of the insert should be considered (see section XIV '**Essure** Insert Removal').

Sterilization Regret:

- Sterilization regret can be associated with emotional disturbances including depression. Patients should be properly counseled prior to the **Essure** procedure (see section VI 'Patient Counseling Information')

Risks Associated with Follow-up Procedures

- There is the risk of radiation associated with the pelvic X-ray that may be performed three months following insert placement to evaluate insert location. There are approximately 0.033 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 modified 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 modified HSG: vasovagal response; infection, which may require antibiotic treatment and in rare cases could require hospitalization; intravasation; perforation of the uterus; uterine cramping and/or bleeding; and pain or discomfort.
- The use of contrast media, used to perform a modified HSG which may be required for the **Essure** Confirmation Test 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.
- Latex exposure may occur during a procedure, and in rare cases can lead to a hypersensitivity reaction.

Risks Associated with Future Procedures

- Patients who undergo placement of the **Essure** insert may, in future years, be offered gynecological therapies that may pose additional risk due to the presence of the insert.
- Some surgical instruments utilize energy sources such as electrical current, radio frequency, thermal energy, or freezing (e.g., cryotherapy). There is a risk of fragmentation of the insert and/or conduction of energy to surrounding structures if these energy sources are used adjacent to or in contact with the insert. There may be risks associated with such procedures that, at this time, have not been identified. Endometrial ablation using microwave energy must not be performed in the presence of the **Essure** insert.
- Other surgical instruments such a morcellator, clamp, or scissors can result in fragmentation of the inserts and should therefore be avoided or used with caution in proximity to the insert. Care must be taken to completely remove the insert(s) when performing a hysterectomy when the adnexa are being retained (see section XIV '**Essure** Insert Removal').

- Endometrial ablation (if medically appropriate) should only be performed after correct location of the **Essure** insert is confirmed by a satisfactory **Essure** Confirmation Test, in order to minimize injury to the surrounding tissue (e.g. bowel). Bench and clinical studies demonstrated that endometrial ablation of the uterus can be safely and effectively performed with properly located **Essure** inserts.
- Any intrauterine procedure such as endometrial biopsy, D&C, hysteroscopy (diagnostic or operative) including endometrial ablation could interrupt the ability of the inserts to prevent pregnancy. Endometrial ablation can result in thermal injury to the GI tract or abscess formation around the inserts. It may also cause intrauterine synechiae that can compromise conduct and interpretation of a modified HSG which may be needed for the **Essure** Confirmation Test.
- Performing endometrial ablation following placement of **Essure** inserts may increase the risk of post-ablation tubal sterilization syndrome, a rare condition that has been reported in women with a history of tubal sterilization who undergo endometrial ablation.
- There are limited data related to the effects, including risks of **Essure** inserts on in vitro fertilization (IVF).
- The **Essure** inserts are radiopaque. The **Essure** inserts are MR conditional, except for pelvic imaging, where they may cause some artifacts (see section V 'Warnings and Precautions', subsection 'MRI Safety Information').

Adverse Event Reporting

For reporting of adverse events, please contact your local **Essure** Representative

VIII. Clinical Studies

A. Purpose of the Study, Study Design, Primary Endpoints

Two clinical trials were conducted (Phase II Trial; Pivotal Trial) to demonstrate safety and effectiveness of the **Essure** system in providing permanent contraception prior to marketing. The ESSTVU study was conducted to evaluate the effectiveness of the **Essure** procedure when using the TVU/HSG Confirmation Test Algorithm. All clinical trials prior to ESSTVU study used the modified HSG only as the **Essure** Confirmation Test.

1. Phase II Trial with modified HSG confirmation testing

Phase II was a prospective, multi-center, single-arm, non-randomized, international study which evaluated:

- Participant's tolerance of, and recovery from, procedure
- Safety of the procedure
- Participant's tolerance of implanted inserts
- Long-term safety and stability of implanted inserts
- Effectiveness of the inserts in preventing pregnancy

2. Pivotal Trial with modified HSG confirmation testing

The Pivotal trial was a prospective, multi-center, single-arm, non-randomized, international study which used the U.S. Collaborative Review of Sterilization (CREST study) as a qualitative benchmark. The study included the following primary endpoints:

- Prevention of pregnancy
- Safety of insert procedure
- Safety of insert wearing

Secondary endpoints included:

- Participant satisfaction with procedure
- Participant satisfaction with insert wearing
- Bilateral device placement rate
- Profile development for appropriate procedure candidates

3. ESSTVU Study with TVU/HSG Confirmation Testing Algorithm

The ESSTVU Study was a prospective, multi-center, single-arm, non-randomized international study to evaluate the effectiveness of the **Essure** procedure when the TVU/HSG Confirmation Test Algorithm is used for confirmation testing. The study included the following primary endpoints:

- Occurrence of confirmed pregnancy at 1 year among subjects relying on **Essure** inserts for birth control on the basis of the **Essure** (TVU/HSG) Confirmation Test Algorithm.
- Intent-to-treat reliance rate 3 months following **Essure** (TVU/HSG) Confirmation Test Algorithm.

B. Patients Studied

Table 3
Age Distribution (Combined Data from Pivotal Study and Phase II Study); Average age: 33

<28 years old	28-33 years old	≥34 years old
14%	40%	46%

Table 4
Patient Demographics

	Phase II and Pivotal Studies Combined N=745
Race*	
White/Caucasian	428
Latin	31
Black	24
Other	9
Gravidity	Mean=2.91 (0 – 11)
Parity	Mean=2.23 (0 – 6)
Body Mass Index (BMI) (kg/m^2)	Mean=27 (16-57)

***Data from Pivotal study only; race not collected in Phase II study.**

1. The Phase II and Pivotal trials combined consisted of 664 participants in whom bilateral insert placement was achieved after one or more attempts (200 Phase II study; 464 Pivotal). **Tables 6 and 7** present patient demographic information. Participants were between 21 and 45 years of age and seeking permanent contraception. All participants had at least one live birth, regular menstrual cycles and were willing to use alternative contraception for the three months following the procedure.

2. The study population of the ESSTVU Study consisted of 597 women in whom insert placement was attempted. Subjects were enrolled at 20 sites (12 in the US and 8 outside of the US). All study participants were between 21 and 44 years of age and were seeking permanent contraception prior to enrollment.

C. Methods

All study participants were screened for eligibility. Medical history, physical examination and required laboratory tests were performed.

Insert placement was attempted in each fallopian tube. In the Phase II/Pivotal trial, pelvic X-rays were performed within 24 hours of placement to serve as a baseline evaluation of insert location. Participants used alternative contraception for three months following the procedure.

In the ESSTVU study, TVU, modified HSG, or both were utilized in the **Essure** Confirmation Test algorithm in accordance with the current labeling. For TVU confirmation tests done in this study, endovaginal ultrasound probes with center frequencies from 5.8 to 6.5 MHz were utilized. In all other trials, a modified HSG was performed three months post procedure to evaluate insert location and fallopian tube occlusion. If bilateral placement and occlusion were satisfactory, participants discontinued alternative contraception and relied on the inserts for contraception.

D. Results

As of the final 5-year follow-up data extracts of the Phase II study-(January 6, 2006) and Pivotal Study-(December 5, 2007), 643 trial participants with bilateral placement (194 Phase II; 449 Pivotal) contributed 35,633 months of follow-up time with zero pregnancies reported.

In the most recent clinical study, ESSTVU, 547 trial participants were instructed to rely on **Essure** for contraception. The TVU/HSG Confirmation Test Algorithm was used as the confirmation test. In this study, three pregnancies were reported in the 1 year follow up. All three pregnancies occurred in women who had TVUs to confirm **Essure** placement.

Adverse events reported in the Pivotal and Phase II clinical studies conducted prior to marketing are provided in **Tables 1 and 2** in Section VII B above. **Tables 5A, 5B and 6A and 6B** present principal effectiveness results.

Table 5A –Insert Placement Rate*
(ESSTVU Trial)

Placement Status	ESSTVU Study	
	Number	Percent
Procedure Initiated**	597	100%
Insert Placement Attempted***	594/597	99%
Bilateral Placement after first attempt	574/597	96%
Bilateral Placement after first or second attempt	582/597	97%

* Assessed at time of placement
** Intent-to-treat population in the ESSTVU trial includes all participants who had the **Essure** procedure initiated (i.e. all study subjects who entered the procedure room/operating room with the intent to undergo the procedure).
*** All subjects where the **Essure** system was passed through the working channel of the hysteroscope.

Table 5B – Insert Reliance Rates (Pivotal, Phase II and ESSTVU Trials)

Outcome	Number	Percent
Reliance Rate*: *Among women with bilateral placement* Phase II & Pivotal Trials Bilateral* Reliance Rate** (N=745)	643/664	97%
ESSTVU Trial Bilateral* Reliance Rate	547/582	94%
ESSTVU Trial Intent-To-Treat Reliance Rate*** (N=622)	547/597	92%

*The reliance rate is the number of women who relied on **Essure** for contraception divided by the number of women with bilateral insert placement.
In the Phase II trial, the following adverse events prevented reliance: Perforation (7/206; 3.4%, including one patient that relied for 31 months before laparotomy and cornual resection due to pain, the other six never relied); Expulsion (1/206; 0.5%); Unsatisfactory insert location (1/206; 0.5%); Initial tubal patency (7/200; 3.5%) was found at the 3-month **Essure Confirmation Test using a modified HSG, however, all had tubal occlusion at a 6-month repeat **Essure** Confirmation Test using a modified HSG. In the Pivotal trial, the following adverse events prevented reliance: Perforation (5/476; 1.1%); Expulsion (14/476; 2.9%, nine out of the fourteen underwent a successful second placement procedure; Unsatisfactory insert location (3/476; 0.6%); Initial tubal patency (16/456; 3.5%) was found at the 3-month**Essure** Confirmation Test using a modified HSG, however, all had tubal occlusion at a 6 or 7-month repeat **Essure** Confirmation Test using a modified HSG.
***In the ESSTVU Trial, the following prevented reliance: Non bilateral placement after 1 or 2 procedures (15/597; 2.5%), incomplete or no confirmation testing (28 /597; 4.7%); unsatisfactory device location/occlusion identified at confirmation testing (perforation, expulsion, distal placement, proximal placement) (7/ 597; 1.2%).

Table 6A Phase II / Pivotal with Modified HSG Confirmation Testing Effectiveness Results Among Women Told to Rely Cumulative Failure Rates

	One-Year	Two-Year	Three-Year	Four-Year	Five-Year
Phase II and Pivotal Trials Combined N=643[D]	**0% N=635[C]** (95% CI 0 – 0.10%) **[A, B]**	**0% N=605[C]** (95% CI 0 – 0.20%) **[A, B]**	**0% N=586[C]** (95% CI 0 – 0.30%)**[A, B]**	**0% N=567[C]** (95% CI 0 – 0.40%)**[A, B]**	**0% N=567[C]** (95% CI 0 – 0.50%)**[A, B]**

[A]95% confidence intervals are based on a "constant-hazard" exponential failure-time model, whose parameter is determined by the total number of woman-months accumulated during the trial as well as the observed number of pregnancies (0 in Phase II and Pivotal trials).
[B] Combined effectiveness data obtained using Bayesian statistics.
[C] The number of women "N" were considered to have completed follow-up at 1 year if patient contact occurred at ≥ 11 months, 2 years if contact occurred at ≥ 23 months, 3 years if contact occurred at ≥ 35 months, 4 years if contact occurred ≥ 47 months and 5 years if contact occurred at ≥ 59 months.
[D] The number of women "N" who were told to rely

No pregnancies were reported in the 5 years of follow up in the Phase II and Pivotal clinical trials based on 2,969 woman-years of follow up.

Table 6B ESSTVU Trial with TVU/HSG Confirmation Testing Algorithm
Effectiveness Results Among Women Told to Rely
Cumulative Failure Rates

	One-Year
ESSTVU Trial **N=547[A]**	0.67% N=503[B] (95% CI 0.16-1.53%)

[A] The number of women "N" who were told to rely

[B] The number of women "N" who attended follow-up at 1 year

Three pregnancies were reported in the 1 year follow up in the ESSTVU trial based on 518 woman–years of follow up. In all 3 pregnancies, TVU was utilized as the confirmation test, and the insert locations were deemed "optimal" in the initial assessment. In 2 of the 3 pregnancies, perforation not detected by initial TVU assessment was determined to be the cause. In the third pregnancy, insert placement was unsatisfactory, and not detected by initial TVU. One additional pregnancy was reported 16 months after the subject was told to rely. As it occurred after the 1-year follow up, this pregnancy was not included in the 1-year effectiveness rate calculation
No pregnancies were reported in the Phase II and Pivotal clinical trials, however all subjects in the Phase II and Pivotal trials underwent modified HSG prior to being counselled to discontinue alternative contraception and rely on **Essure**.

E. OBSERVATIONAL STUDY

SUCCESII is a single arm, multi-center, 5 year prospective, non-interventional, and observational study assessing patient satisfaction, safety and efficacy of the **Essure** procedure.

The study is currently ongoing and is being conducted in 14 French centers. Patients were enrolled between June 2008 and June 2011; 2575 patients had at least one attempt at placing **Essure**. Bilateral placement was achieved in 95.1% of the patients with two fallopian tubes. Unilateral placement was achieved in 96.9% of the patients with one fallopian tube (2.5% of the cohort).

Based on a satisfactory confirmation test utilizing pelvic X-Ray, TVU, and/or modified HSG, 2185 of the 2257 patients who returned for the confirmation test (96.8%) were able to rely on **Essure** for contraception.

Two pregnancies occurred in women who were told to rely on **Essure** for contraception, resulting in an efficacy rate of 99.9%.

IX. Essure Effectiveness In The Commercial Setting

In the commercial setting, unintended pregnancies have been reported in women who have worn the inserts.

Table 7 summarizes the reasons for pregnancy from reports received by Bayer HealthCare LLC and additional reports from the published scientific literature.

Table 7: Summary of Pregnancies Reported in Commercial Use of Essure*

Potential Contributing Factor	United States		Outside the United States**		Total	
	n	% of US causes	n	% of OUS causes	n	%
Patient Non-compliance (e.g., failure to use alternative contraception or return for **Essure** Confirmation Test)	213	32%	16	18%	229	31%
Perforation*** / #	91	14%	4	5%	95	13%
Unsatisfactory Placement***	32	5%	13	15%	45	6%
Physician Non-compliance	22	3%	13	15%	35	5%
Pregnant at time of Placement (Luteal)	26	4%	6	7%	32	4%
Inadequate Confirmation Test***	28	4%	0	0%	28	4%
Expulsion***	20	3%	4	5%	24	3%
Tubal Patency***	19	3%	1	1%	20	3%
Insufficient Information to determine	209	32%	31	35%	240	32%
Total	660		88		748****	

*Table includes pregnancy reports received directly by Bayer Healthcare LLC, recorded in the FDA MAUDE database and reported in the scientific literature; data reported to FDA in PMA Annual Reports. Pregnancies in **Essure** patients may be underreported.
Outside of the United States, during this reporting period, the **Essure Confirmation Test may have been an x-ray or transvaginal ultrasound; device location alone, not occlusion, is primarily used to determine whether the patient may rely on **Essure**.
*** Most of these pregnancies are due to misinterpreted **Essure** Confirmation Tests. Please note that many misinterpretations are due to the fact that occlusion is seen on the HSG films even though the insert is not properly located.
****Number of pregnancies reported from worldwide commercial launch in 2001 through end of 2010. 497,306**Essure** kits sold during this time. Note that an accurate pregnancy rate is difficult to obtain as the number of devices actually implanted is not known.
#The causal association cannot be established between the perforation and the pregnancy. However, perforations have been identified in pregnant women who were relying on **Essure** for contraception.

The majority of unintended pregnancies are preventable. Most unintended pregnancies are related to patient non-compliance and physician misinterpretation of the **Essure** Confirmation Test. In order to ensure maximum contraceptive effectiveness by **Essure**, the physician should ensure that the patient is counseled in accordance with Section VI 'Patient Counseling Information'.

It is important to evaluate insert location and, in some cases, occlusion carefully before telling the patient that she may rely on **Essure** for contraception.

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Table 8 provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

Table 8
Pregnancy Rates for Birth Control Methods
(For One Year of Use)

Method	**Typical Use Rate of Pregnancy**
Sterilization:	
Male Sterilization	0.15%
Female Sterilization	0.5%
Hormonal Methods:	
Implant *(Norplant ™ and Norplant ™ 2)*	0.05%
Hormone Shot *(Depo-Provera™)*	3%
Combined Pill *(Estrogen/Progestin)* and Progestin-only Pill	8%
NuvaRing	8%
Ortho Evra	8%
Intrauterine Devices (IUDs):	
Copper T (*ParaGard)*	0.8%
LNG-IUS (*Mirena)*	0.2%
Barrier Methods:	
Male Latex Condom[1]	15%
Diaphragm[2]	16%
Female Condom	21%
Spermicide: *(gel, foam, suppository, film)*	29%
Natural Methods:	
Withdrawal	27%
Natural Family Planning *(calendar, temperature, cervical mucus)*	25%
No Method:	85%

[1] Used Without Spermicide [2] Used With Spermicide

Data adapted from Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. *Contraceptive Technology: Nineteenth Revised Edition.* New York NY: Ardent Media, 2007.

X. Directions for Use

A. Prior to Insert Placement Procedure

1. Adequate visualization of the uterine and proximal tubal anatomy is required. In order to enhance visualization of the fallopian tube ostia and decrease the potential for insert placement in a patient with an undiagnosed pregnancy, insert placement should be performed during the early proliferative phase of the menstrual cycle. Women with menstrual cycles shorter than 28 days should undergo careful ovulation day calculations. Insert placement should not be performed during menstruation. Pretreatment of the patient with medications that suppress endometrial proliferation may enhance visualization and scheduling flexibility.

2. A pregnancy test administered by the physician or designee, should be conducted within 24 hours prior to or immediately preceding the insert placement procedure.

3. Administration of a non-steroidal anti-inflammatory drug (NSAID) should be considered one to two hours before the scheduled insert placement procedure, if appropriate for the patient. Local anesthesia is the preferred method for placement of the inserts. A paracervical block may be administered. Midazolam (IV), or a similar agent, may also be administered to prevent or reduce discomfort if needed (see section VII 'Adverse Effects', subsection 'Risks Associated with the Insert Placement Procedure').

B. Essure Insert Placement Procedure

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

1. Place the patient in the lithotomy position.

2. Prep the vagina and cervix with betadine or other suitable antibacterial solution according to standard practice. Introduce a speculum into the vagina to allow access to the cervix. Vaginoscopy may also be used to access the uterine cavity.

3. Administer anesthesia as required

4. Insert a sterile hysteroscope, with camera and operating channel (≥ 5 French), through the cervix into the uterine cavity. Do not perform cervical dilation unless necessary; if necessary, dilate only enough for hysteroscope insertion. In order to

prevent uterine perforation, the procedure should be terminated if excessive force is required to achieve cervical dilatation.

5. Uterine cavity distention 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 minimize spasm of the fallopian tubes. Excellent uterine distention 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 visualization.

6. Both tubal ostia should be identified and assessed hysteroscopically prior to proceeding to **Essure** insert placement except when there is a known unilateral salpingectomy or a unicornuate uterus. For patients with two fallopian tubes, no attempt should be made to place an 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 (see Figure 3). If undamaged from the first insert placement, the valved introducer may remain in the operating channel throughout the **Essure** procedure.

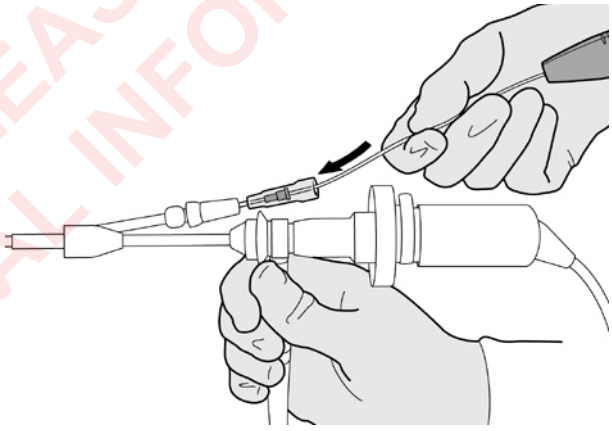

*Figure 3: Insert the introducer through sealing cap on the hysteroscope working channel, then place **Essure** delivery system through the introducer.*

8. Advance the **Essure** delivery system into the proximal fallopian tube with slow, steady movement to prevent tubal spasm. The **Essure** delivery system is designed with a 15 degree angle at the tip to facilitate placement within the fallopian tube. When advancing the catheter, direct the tip laterally following the contour of the fallopian tube. This should facilitate advancement of the catheter under direct visualization without undue resistance. Do not attempt to advance the delivery system if excessive resistance is encountered. If tubal spasm is suspected, move the hysteroscope closer to the tubal ostium. Apply **gentle**, constant forward pressure on the delivery catheter and wait. Repeatedly removing and attempting to re-cannulate may irritate the tube. It may take more than a minute for a spasm to resolve and the catheter to advance. If excessive resistance occurs, i.e., the catheter does not advance toward tubal ostium and/or catheter bends or flexes excessively, or if several minutes have passed, terminate the procedure to avoid perforation or placement into a false passage.

   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 toward 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 insert, in order to avoid the possibility of uterine or tubal perforation or inadvertently placing the insert in the uterine muscle rather than within the tubal lumen.

9. Advance the delivery system until the positioning marker on the delivery catheter reaches the fallopian tube ostium (see Figure 4). This visual marker indicates that the **Essure** 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** insert.

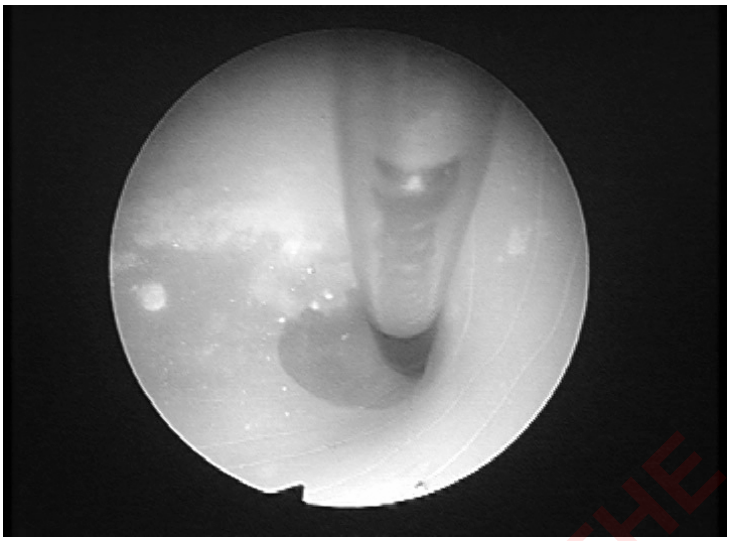

Figure 4: Advance until the black positioning marker is at tubal ostium. This is a visual indicator for proper position for deployment.

10. If the tube is blocked or the catheter cannot be advanced to the positioning marker, the procedure should be terminated. If insert placement is not successful after 10 minutes of attempted cannulation per tube, the procedure should be terminated.

11. When the delivery catheter has been advanced to the positioning marker, deploy the insert. To do so, first stabilize the handle of the **Essure** 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 (see Figure 5). Before proceeding with the **Essure** procedure, recall that two distinct operations will take place. The first is retraction of the delivery catheter away from the insert, prior to actual detachment of the insert. Full retraction is accomplished by rotating the thumb wheel to the point where you cannot rotate the thumbwheel any further. Actual detachment is accomplished after retraction by pressing the handle button and then continuing to rotate the thumbwheel. Only after detachment of the insert has occurred can you remove the delivery system.

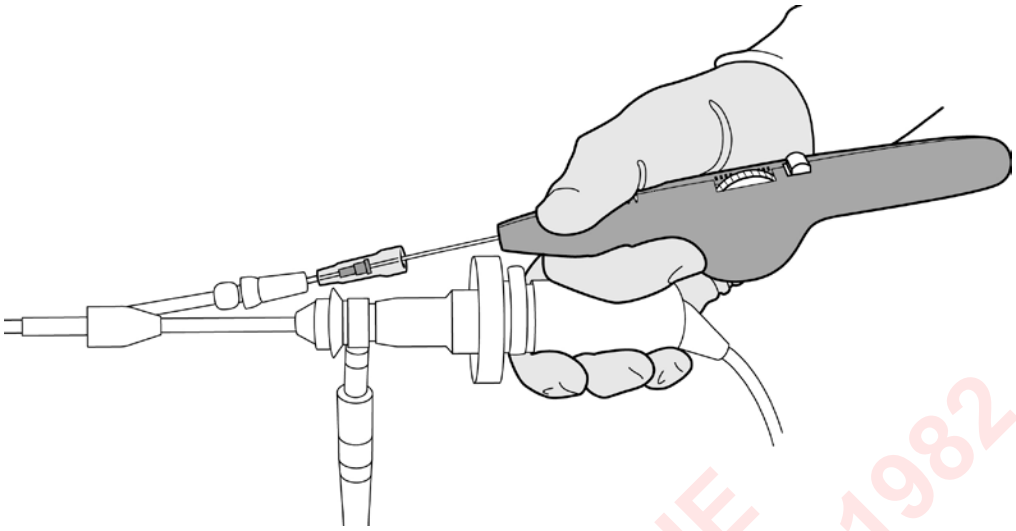

Figure 5: *Stabilize handle against camera head or some other fixed object to prevent inadvertent forward movement of the* ***Essure*** *system*

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 (see Figure 6). 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** insert. Approximately 1 cm of the insert (wound-down coils) should appear trailing into the uterus when the delivery catheter is withdrawn.

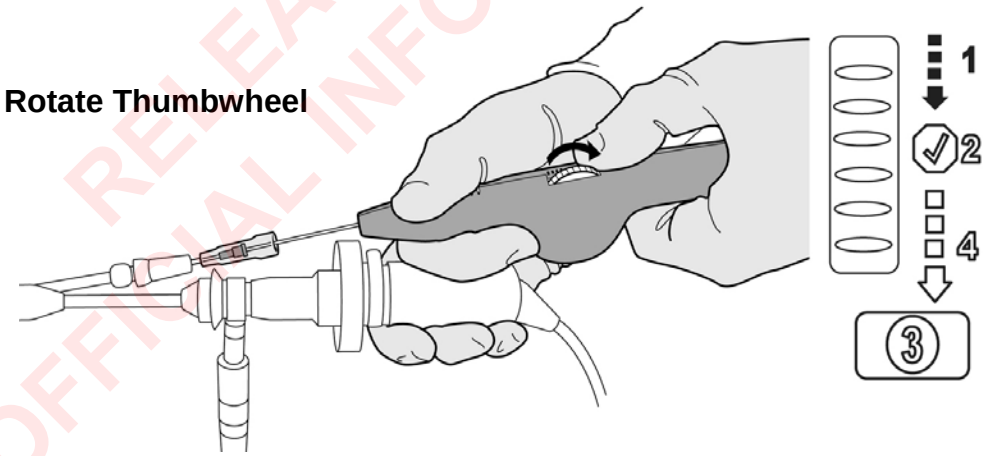

Figure 6: Rotate thumbwheel to retract catheter

13. To confirm proper positioning, place gold marker band just outside the ostium (see Figure 7), which corresponds to the symbol ✓2 on the delivery system handle. Visualization of the gold band just outside the ostium, as well as visualization of the distal tip of the green release catheter will confirm proper positioning. It is very important that the gold band is not inside of the tube at time of deployment. If gold band is not visible, do not deploy the device. Move the delivery catheter toward you until the gold band is visible. If more than 1 cm of the insert is visible in the uterus, then the insert should be repositioned by moving the entire system further into the tube, if possible, before proceeding to the next step.

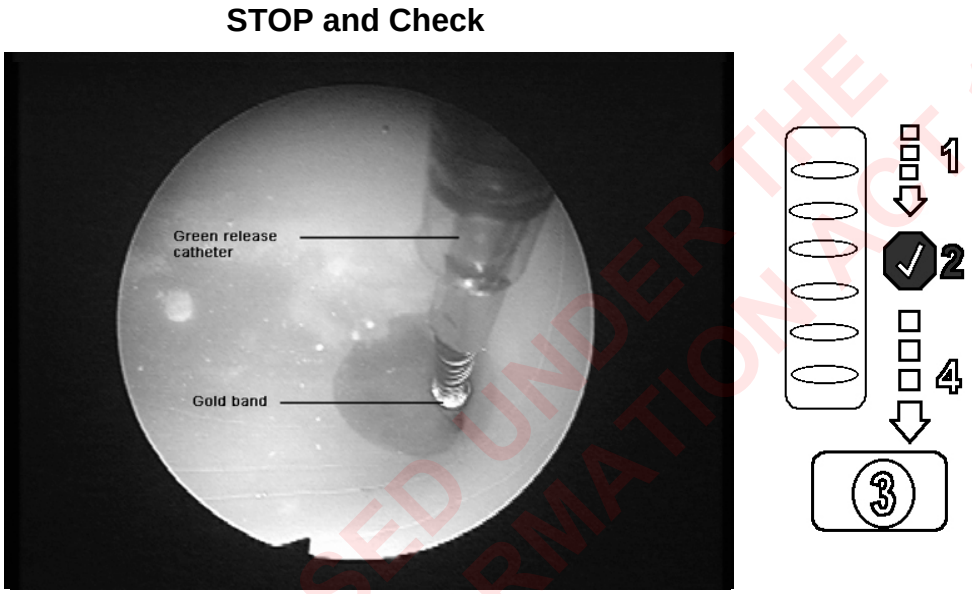

Figure 7: Visualize gold band at ostium

14. Press the button on the delivery handle to enable the thumbwheel to be further rotated which corresponds to the symbol ③ on the handle button.

15. Rotate the thumbwheel toward you to deploy the outer coil of the insert, which corresponds to the symbol 4 on the delivery system handle (see Figure 9). 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.

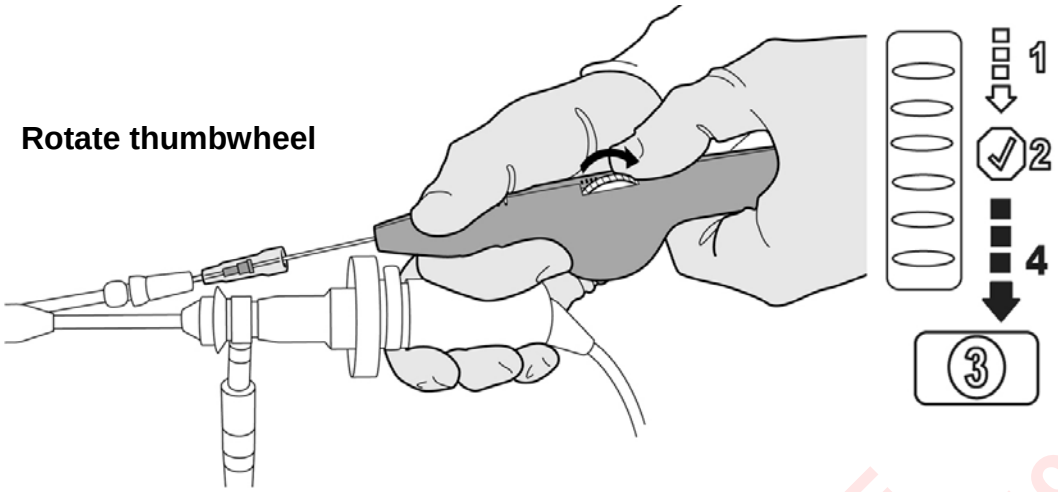

Figure 9: Rotate thumbwheel to deploy the outer coil of the insert

16. The position of the deployed **Essure** insert will be assessed under hysteroscopic visualization. There should ideally be 3 to 8 expanded outer coils of the **Essure** insert trailing into the uterine cavity (see Figure 10); however, 0 to 17 trailing coils is a satisfactory placement.

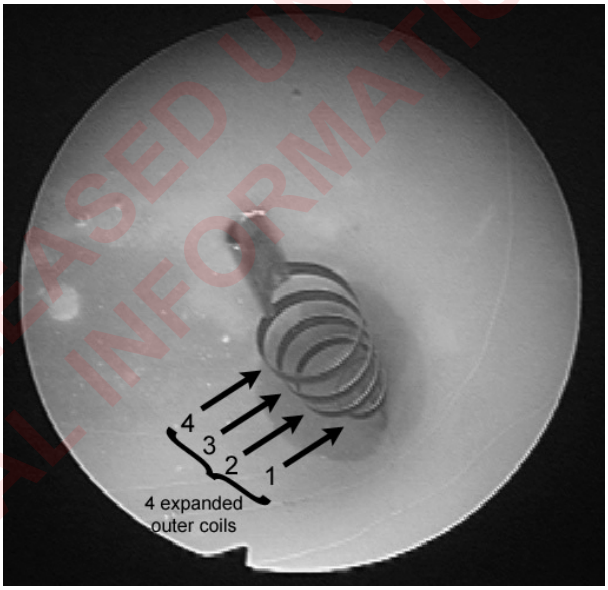

*Figure 10: Expanded outer coils of the **Essure** insert trailing into the uterus indicates ideal placement*

17. If the physician is dissatisfied with insert placement based on the hysteroscopic view, and there are fewer than 18 trailing coils, the insert(s) should be left in place and assessed during the **Essure** Confirmation Test. In cases of suspected perforation, monitor the patient for-signs and symptoms of possible complications related to perforation which may include unusual post-operative pain. If unusual post-operative pain occurs, imaging to localize the insert should be performed prior to the 3 month confirmation test. If no trailing coils are visible, examine the delivery system upon removal from the hysteroscope. Refer to Figure 11 below to determine if the insert has been deployed from the delivery system.
IMPORTANT: If insert was inadvertently deployed in the uterine cavity and not in the tube, remove from uterus and attempt another placement.

Figure 11*: Delivery systems showing absence of insert after deployment (top) and with insert attached (bottom)*

WARNING: AFTER THE INSERT HAS BEEN PLACED AND RELEASED INTO THE FALLOPIAN TUBE, DO NOT ATTEMPT TO REMOVE THE INSERT HYSTEROSCOPICALLY UNLESS 18 OR MORE COILS OF THE ESSURE INSERT ARE TRAILING IN THE UTERINE CAVITY. An attempted removal of inserts having fewer than 18 trailing coils may cause insert to fracture or patient injury. If 18 or more coils are trailing into the uterine cavity, removal should be attempted immediately during the placement attempt. However, removal may not be possible. Please refer to section XIV '**Essure** Insert Removal' for additional information. If the insert was inadvertently deployed in the uterine cavity and not into the tube, the insert should be removed from the uterus and another attempt made at insert placement in the tube.

18. If insert removal is indicated, perform removal immediately after failed placement as follows:

    a - As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.

    b - Introduce a grasping instrument through hysteroscope operating channel.

    c - Grasp both the outer and inner coils of the insert together.

    d - Withdraw the grasping instrument and hysteroscope simultaneously; the insert may stretch or elongate. Do not pull insert through the operating channel.

19. Repeat the **Essure** insert placement procedure in the contralateral fallopian tube when applicable.

20. Record the length of the insert trailing into the uterine cavity, noting any issues with identifying or confirming either tubal ostium or any concerns regarding potential perforation (see Figure 10). These should be noted in patient records and be provided to the physician performing the **Essure** Confirmation Test (See Section XII – '**Essure** Confirmation Test').

21. Document procedural concerns. Review during **Essure** Confirmation Test. Note possible perforations due to:

    a. excessive or sudden loss of resistance;

    b. inability to visualize coils;

    c. problems with identification of tubal ostium;

    d. poor distension;

    e. poor illumination;

    f. or poor visualization secondary to endometrial debris.

22. **Ensure patient uses alternative contraception until the Essure Confirmation Test.** Counsel patients regarding the risk of pregnancy (including ectopic pregnancy) attributable to non-compliance during all steps of the **Essure** procedure.

23. Schedule the patient for an **Essure** Confirmation Test three months following the **Essure** insert placement procedure to evaluate insert retention and location.

XI. Management Of Cases With Unsuccessful Essure Insert Placement During The Initial Procedure

Placement may not be achieved due to conditions such as temporary difficulty with visualization which could be satisfactorily managed prior to a second attempt. The patient should be informed that her permanent contraception has not been completed and should continue to use alternative contraception (see section XIII 'Management Of Patients Who Are Not Able To Rely').

Counsel patient on undergoing a second procedure, especially if unilateral placement was achieved. In the Pivotal trial, 83% of those who underwent a second procedure achieved bilateral placement. Before a second placement attempt, determine tubal patency by modified HSG which can be scheduled after patient's next menses. If patency is documented, a second attempt may be performed. If a second attempt fails, success with subsequent attempts is unlikely.

If the patient chooses laparoscopic sterilization, clip or coagulate both fallopian tubes distal or proximal to the insert. Do not perform clipping or coagulation adjacent to or over the insert.

XII. **Essure** Confirmation Test

A. An **Essure** Confirmation Test should be performed three months after insert placement to evaluate insert retention and location. The **Essure** Confirmation Tests (transvaginal ultrasound (TVU), pelvic x-ray or hysterosalpingogram (HSG)) should be performed only by an experienced gynecologist, ultrasonographer and/or radiologist.

B. For the first-line confirmation test, either a pelvic X-ray or a TVU may be performed three months after an insert placement procedure.

1. X-ray and TVU should not be used as the **Essure** Confirmation Test under the following circumstances:
    a) Difficult placement procedure including one or more of the following:
        (1) Concern at the time of placement of possible perforation due to excessive force required for insert delivery and/or a sudden loss of resistance.
        (2) Difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting or endometrial debris.
        (3) Physician is uncertain about placement.
    b) Procedure time > 15 minutes (scope in-scope out).
    c) Placement with zero or > 8 trailing coils
    d) Unusual post-operative pain, transient or persistent, or onset at some later time post procedure, without any other identifiable cause.

2. Patients on active immunosuppressive therapy (e.g. systemic corticosteroids or chemotherapy) may experience delay or failure of the necessary tissue in-growth needed for tubal occlusion. For these patients, physicians must use the modified HSG as the **Essure** Confirmation Test. TVU or pelvic X-ray should not be utilized for confirmation,

as these tests cannot confirm tubal occlusion. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.

3. Trans-abdominal ultrasound cannot be substituted for TVU. If X-ray or ultrasound is not indicated, the patient must proceed to a modified HSG to evaluate insert location and tubal occlusion. If X-ray or ultrasound evaluation is equivocal or unsatisfactory, the patient must proceed to an HSG to evaluate insert location and tubal occlusion.

C. Transvaginal Ultrasound

1. A minimum of three images must be obtained and retained for documentation:

a) A transverse or oblique transverse view demonstrating a portion of each insert in the cornua labeled “scout image”.

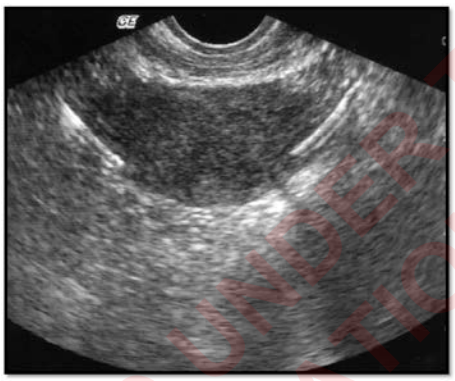

Figure 12: Bilateral inserts are identified in this transverse (coronal / oblique coronal) view.

b) A transverse or oblique transverse image of the linear axis of the left insert including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the serosal utero tubal junction and labeled “left”.

c) A transverse or oblique transverse image of the linear axis of the right insert crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the serosal utero tubal junction and labeled “right.”

d) All three images should be captured on film and placed in the subject’s medical record to document satisfactory insert retention and location.

2. Classification of Insert Location

a) Insert identification: In a single scout image, a portion of each insert must be visualized in the cornua in the transverse or oblique transverse view to ensure bilateral placement and reduce the risk of duplicate imaging of the same insert. The linear axis of the inserts should appear relatively symmetric.

b) Optimal Location

Insert location is optimal when the proximal end of the insert is in contact with the uterine cavity or endometrium, and the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or

crossing the serosal utero tubal junction (SUTJ). The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.

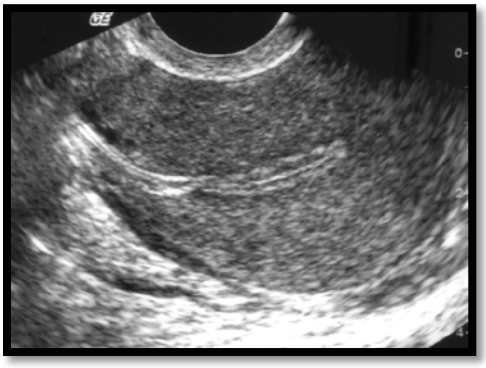

Figure 13: Optimal Location

c) Satisfactory Location

Insert location is satisfactory when the proximal end of the insert is distal to the endometrium, however the linear axis is within the myometrium in the cornua (interstitial portion of the fallopian tube) and can be visualized at or crossing the serosal utero tubal junction (SUTJ). The portion of the insert located in the fallopian tube may or may not be visualized. The linear axis of the insert must be visualized to confirm it is not coiled or elongated.

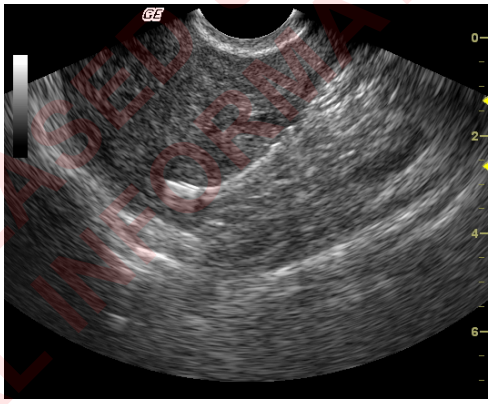

Figure 14: Satisfactory location

d) Unsatisfactory Location

(1) Insert location is unsatisfactory if a portion of each insert cannot be visualized in the cornua in the transverse or oblique transverse view in one scout image.

(2) Expulsion is suspected if one or both inserts are not identified in the cornua in a transverse view in a single scout image.

(3) Distal placement is suspected if the proximal end of the insert is not located in the myometrium in the cornua (interstitial portion of the fallopian tube), and not crossing or in contact with the SUTJ.
(4) Proximal placement is suspected if greater than 50% or the majority of the insert is visualized in the uterine cavity or if the linear axis of the insert(s) is visualized in the midline sagittal view.
(5) Perforation is suspected if the linear axis of one or both inserts are parallel to the endometrial stripe in the sagittal view, or if the linear axis of an insert is visualized crossing the myometrium in the midline sagittal view.
(6) Unclassified position: If the linear axis of an insert cannot be identified, suggesting it is coiled, bent or elongated, insert location is considered unsatisfactory. If the surrounding soft tissue cannot be clearly defined, position is considered unsatisfactory.

3. Assessing Ability to Rely- Can only be performed when TVU is indicated as per the **Essure** Confirmation Test protocol (see section XII. '**Essure** Confirmation Test', Subsection B).

1) If location of the inserts is rated as either satisfactory or optimal, instruct the patient to discontinue alternative contraception and that she can rely on **Essure** for contraception. The **Essure** Confirmation Test with TVU does not assess tubal occlusion. Both optimal and satisfactory locations of the insert are appropriate to elicit a benign tissue in-growth that permanently occludes the fallopian tube, resulting in contraception.

2) If ultrasound evaluation is equivocal or unsatisfactory, patient must proceed to a modified HSG to evaluate insert location and tubal occlusion. The patient must also be instructed not to discontinue her alternative contraception.

D. Pelvic X-ray
1. Capture an image of the uterus with both **Essure** inserts clearly seen. The lie and curvature of the inserts should be noted.

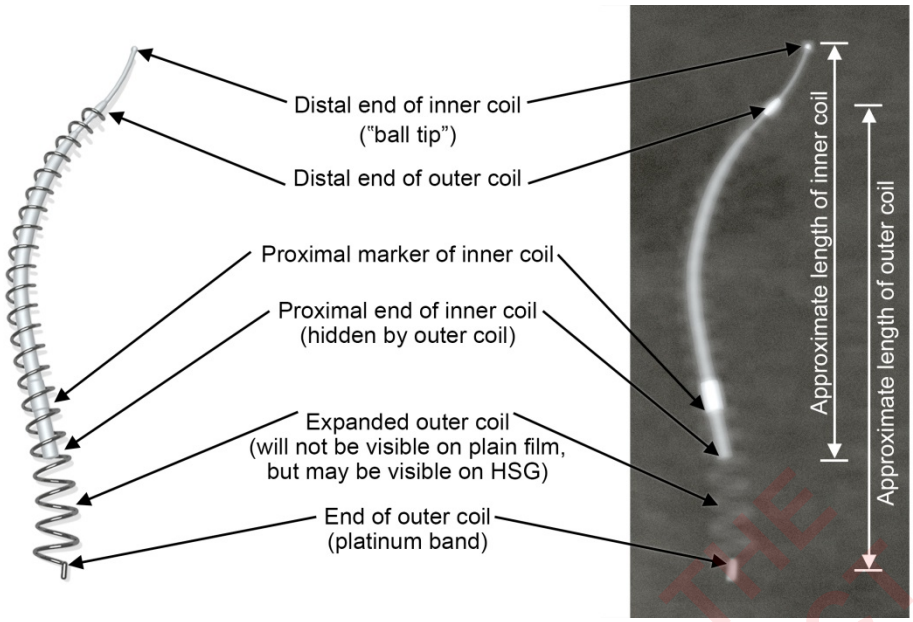

Figure 15: Corresponding radiographic view of the **Essure** insert

2. Evaluate pelvic X-ray as follows:
   a) Satisfactory: Inserts appear to be in the tubal lumen and spanning the SUTJ, and appear relatively symmetrical. Patients whose X-rays are determined to be "satisfactory" may begin to rely on the **Essure** insert for contraception.
   b) Suspicious: One or both of the inserts appear to be distal or proximal to optimal position, or may be partially or completely perforated through the tube, and/or appear relatively asymmetrical.
   c) Unsatisfactory: Obvious intraperitoneal insert location or expulsion.

3. If x-ray evaluation is unsatisfactory; or insert location is suspicious, or a satisfactory location cannot be confirmed, the patient must proceed to a modified HSG to evaluate insert location and tubal occlusion and should be instructed to continue alternative contraception.

E. Performing and Evaluating modified HSGs

A modified HSG is an HSG that is performed by instilling contrast slowly and gently until the uterine cornua are distended. An increase in intrauterine pressure beyond that needed to produce cornual distention serves no purpose and should be avoided.

1. The HSG is performed to evaluate **Essure** insert location and fallopian tube occlusion. Follow the instructions below for performing and evaluating the HSG.

2. Performing the HSG - Guidelines:

a) Obtain good cornual filling so that the uterine cavity silhouette is clearly seen.

b) Place fluoroscopy beam as close to A/P projection as possible.

c) Do not dilate cervix unless necessary; if dilation occurs, maintain a good cervical seal.

d) Downward traction on cervical tenaculum may be required for midpositional uteri. Remove speculum prior to fluoroscopy for best visualization of uterine anatomy.

e) Take a minimum of six radiographs to assess insert location and tubal occlusion.

(1) Radiograph 1 – "Scout Film" - Uterus and inserts without contrast (see Figure 16).

(2) Radiograph 2 – Minimal Fill of the Cavity – Uterus and inserts with small amount of contrast.

(3) Radiograph 3 – Partial Fill of the Cavity - Uterus and inserts when nearly full of contrast.

(4) Radiograph 4 – Total Fill of Cavity - Uterus and inserts when the cornua is distended by contrast (see Figure 17).

(5) Radiographs 5 & 6- Magnifications of uterine cornua – Insert within the fallopian tube with right (5) and left (6) cornua.

CAUTION: Avoid excessive intrauterine pressure beyond Radiograph 4 to avoid undue patient discomfort and vaso-vagal reaction.

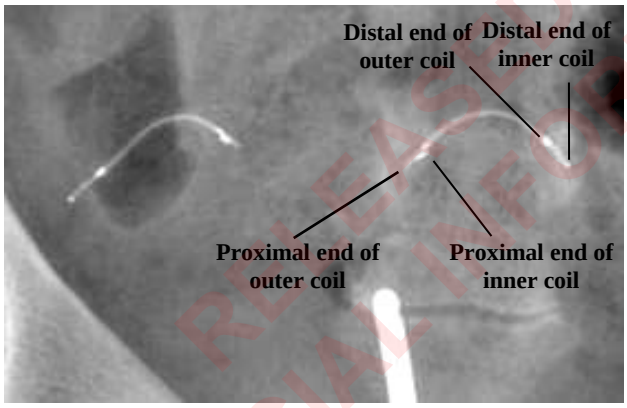

Figure 16: Radiograph 1: Scout Film

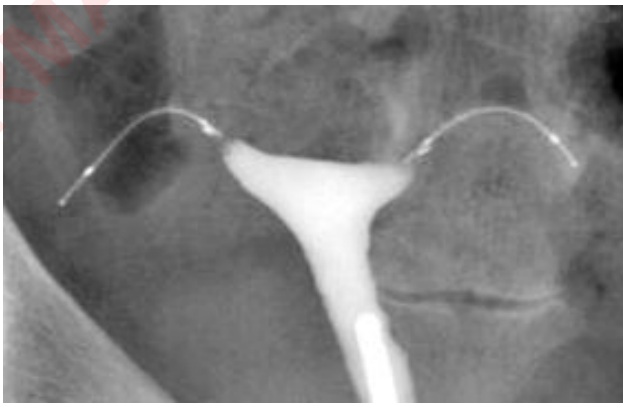

Figure 17 : Radiograph 4: Total Fill of Cavity

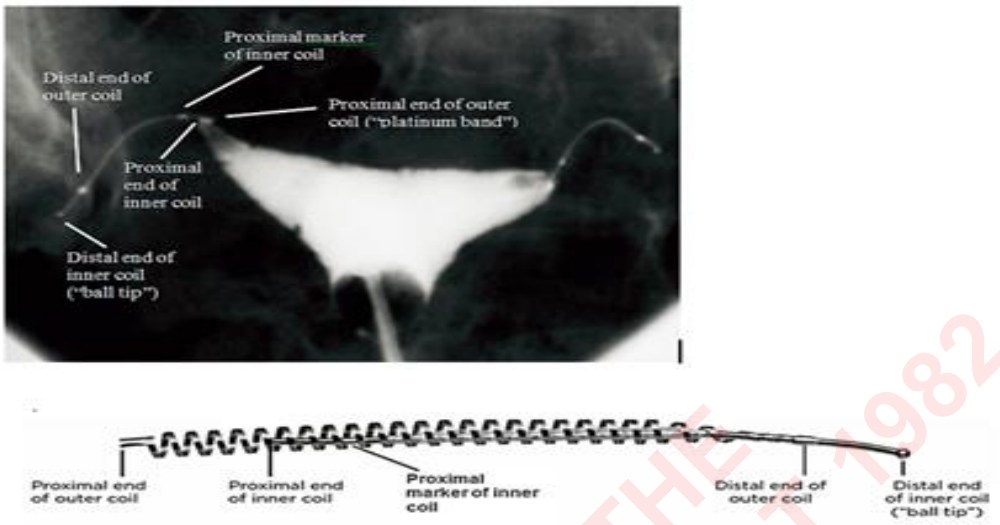

Figure 18: Assessing insert location on a modified HSG. Note: The outer coil may sometimes be visible on a modified HSG, if dye is present in the tube.

3. Assessing Insert Location

During evaluation, note four "markers" at each insert: two on the inner coil and two on the outer coil. The two distal markers and the proximal marker of the inner coil are fixed in relation to one another, but the proximal markers of the outer coil may move or seem stretched because of the flexibility of the outer coil

a) Satisfactory location: Distal end of inner coil is within the tube, with <50% of inner coil trailing into the uterine cavity, or proximal end of inner coil ≤30 mm into tube from where contrast fills cornua.
b) Proximal location (partial expulsion): ≥50% of the inner coil is trailing into the uterine cavity;
c) Distal location: Proximal end of the inner coil is >30 mm distal from where contrast fills cornua.
d) Peritoneal location: Insert is found within the peritoneal cavity and not located within the tube.
e) Expulsion: Insert lies completely in the uterine cavity or insert is not present in the radiographic images.
f) Perforation: The insert does not conform to the expected anatomical curvature of the tube (e.g., curves back on itself like a pigtail or has an acute angle to it) or the markers appear reversed).

4. Assessing Tubal Occlusion

a) Determine whether the contrast is visible beyond the insert and note any degree of proximal tubal filling even if the tube is occluded.

b) Assess tubal occlusion:

(1) Satisfactory occlusion: Tube is occluded at the cornua.

(2) Satisfactory occlusion: Contrast seen within tube but not past distal end of outer coil.

(3) Unsatisfactory occlusion: Contrast seen past the distal end of the insert or in the peritoneal cavity.

5. Assessing Ability to Rely

a) If location and tubal occlusion are both rated satisfactory, instruct patient to discontinue alternative contraception.

b) If location is unsatisfactory, instruct patient to not rely on the inserts for contraception.

c) If location is satisfactory but occlusion is unsatisfactory, instruct patient to remain on alternative contraception. Repeat the modified HSG in three months. If occlusion is still unsatisfactory, instruct patient to not rely on the inserts for contraception.

XIII. Management of Patients Who Are Not Able To Rely

In the event of unilateral or bilateral insert placement failure, the patient should be informed that her permanent contraception has not been completed. The location of all deployed inserts should be ascertained. Based on the insert location a decision should be made as to whether the insert should be left *in situ* or removed (see section XIV '**Essure** Insert Removal').

For patients who are not able to rely management may include, a second placement attempt, incisional sterilization, or remaining on alternative contraception. The patient should be informed that her permanent contraception has not been successful and she should continue to use alternative contraception.

Second Placement Attempt: If the insert is determined to be in unsatisfactory location (i.e., distal, perforation, and expulsion), tubal patency is seen on modified HSG, and no part of an **Essure** insert is detected within the proximal 30 mm of the fallopian tube, a second attempt to place an insert into the tube may be performed. If a portion of the insert is within the proximal 30 mm of the fallopian tube, counsel the patient on incisional sterilization or to remain on alternative contraception.

If the patient chooses laparoscopic sterilization (i.e., clip application, bipolar cautery, or salpingectomy, or other methodologies), the location of the insert(s) should be clearly identified prior to performing the sterilization procedure. Do not clamp, cut or coagulate directly over the insert to avoid transecting or fracturing the insert. In order to achieve complete ligation of the fallopian tube, insert removal may be required. (see section XIV '**Essure** Insert Removal'). Caution must be taken not to leave any perforations proximal to the tubal ligation.

XIV. Essure Insert Removal

WARNING: **Essure** inserts are intended to be left in place permanently. Do not remove insert(s) unless the patient is experiencing an adverse event(s) associated with its presence, if removal is clinically indicated (see section XIV '**Essure** Insert Removal, subsection 'Removal of insert located within the within peritoneal cavity') or if requested.by the patient. If insert removal is planned, the patient should be counseled on the risks of surgery. Clinical judgment as to the appropriate procedure must be used. Physicians should be thoroughly familiar with the characteristics and performance of any instrument they select for the removal procedure. Consultation with a physician familiar with removal techniques may be appropriate.

For all surgical removal procedures, care should be taken to avoid transecting the insert during removal. If the entire insert has not been removed, intra-operative imaging to localize the remaining fragments should be performed and the fragments should be removed, if indicated.

At Time of Placement Procedure

Hysteroscopic insert removal should not be attempted at the time of insert placement, unless 18 or more coils of the **Essure** insert are trailing into the uterine cavity indicating placement is too proximal. If 18 or more coils are trailing into the uterine cavity, removal should be attempted immediately during the placement attempt. However, if removal is not achieved with gentle traction, the insert may be left in place; subsequent hysteroscopic removal may be attempted at a later date.

Steps for Hysteroscopic Removal:

1. As necessary, administer analgesia/anesthesia to reduce or prevent patient discomfort.

2. Introduce a grasping instrument through the hysteroscope working channel.

3. Try to grasp the outer and inner coil of the insert together. Grasping both the inner and outer coils together may help prevent excessive stretching of the outer coil, which could result in fragmentation.

4. Gently pull back on the insert with the grasping instrument while extracting the insert in small increments to prevent fragmentation of the insert or excessive stretching of the coils. Once the insert has been removed from the fallopian tube, pull back on the hysteroscope and the grasping instrument at the same time. Do not attempt to pull the deployed insert through the working channel of the hysteroscope. The hysteroscope along with the grasper containing the deployed insert should be removed from the uterus together.

5. If upon inspection of the removed insert, if the physician is not completely satisfied that the entire **Essure** insert has been removed from the fallopian tube, an X-ray should be taken to determine if an insert fragment remains *in vivo*.

6. If complete insert removal is accomplished, an attempt should be made to place another **Essure** insert.

Subsequent to Placement Procedure

Location of **Essure** inserts should be confirmed through imaging prior to any attempted surgical removal as the appropriate surgical approach will be influenced by the location. Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during the removal procedure.

The physician should attempt to remove the entire insert to avoid the potential need for subsequent surgical procedures.

Insert removal may be performed along with, or independent of, an incisional sterilization procedure (e.g., tubal ligation). If following insert removal the patient should be counseled about risk of pregnancy, including ectopic pregnancy.

A. Removal of insert located within the fallopian tube(s):

Hysteroscopic Removal:

Limited case reports describe hysteroscopic insert removal subsequent to the placement procedure. In these cases, the proximal coils were visible within the uterine cavity and were easily removed with gentle traction.

Hysteroscopic removal should only be attempted when the proximal coils are visible within the uterine cavity. Refer to steps for 'Hysteroscopic Removal' (section XIV '**Essure** Insert Removal, subsection 'At time of Placement Procedure').

Combined hysteroscopic/laparoscopic removal:

When planning a laparoscopic removal, consideration should be given to first excising the most proximal part of the outer coil (the "platinum band") hysteroscopically with scissors (see section XII. '**Essure** Confirmation Test', see Figure 15). This may facilitate laparoscopic removal of the insert as the platinum band is the widest portion of the outer coil, which can be the most difficult portion to pass through the cornual region of the fallopian tube.

Laparoscopic removal:

Laparoscopic removal techniques for inserts within the fallopian tubes include salpingotomy, salpingectomy, and cornual resection. Visualization or palpation of the fallopian tube should be performed to confirm the location of the insert.

If electrocautery is employed, it should be used judiciously to avoid injury to adjacent structures or fracturing of the insert.

1. To perform a linear salpingotomy, make a small incision (approximately 2 cm in length) along the antimesenteric border of the fallopian tube, overlying the insert. Use of vasoconstrictive agents is at the discretion of the operating surgeon. The insert needs to be exposed and may need to be freed from the surrounding tissue prior to grasping the coils. During removal, the inner and outer coils should be grasped together. Once the insert is exposed, a grasping instrument may be used to extract the insert using gentle traction along the axis of the fallopian tube. The insert should be gently extracted in small increments to prevent fragmentation of the insert or excessive stretching of the coils. If excessive resistance is encountered, this may be due to the platinum band (largest diameter of the insert) not being able to pass through the cornual region. The platinum band may break off if excessive traction is applied during laparoscopic removal. Hysteroscopic excision of the platinum band may facilitate removal of the entire insert (see section XIV '**Essure** Insert Removal', subsection '*Combined hysteroscopic/laparoscopic removal*').

2. In some cases, a cornual resection of the proximal fallopian tube may be required for insert removal. In these cases patients should be counseled about the risk of hysterectomy in order to achieve hemostasis.

3. Removal via Salpingectomy:

Distally located inserts (all portions of the insert distal to the cornua):

When removing the insert via salpingectomy, the location of the proximal portion of the insert within the fallopian tube should be reconfirmed intra-operatively by palpation, visualization and/or imaging prior to removing the fallopian tube containing the insert to avoid transecting or fracturing the insert.

Insert(s) partially located within the cornual region of the tube:

When the proximal end of the insert is within the cornua, consideration should be given to performing a combined hysteroscopic/laparoscopic procedure (see section XIV '**Essure** Insert Removal, subsection 'Combined hysteroscopic/laparoscopic removal'). Laparoscopic exposure and visualization of the insert is then necessary. Based on case studies and expert opinion,

techniques include linear salpingotomy and circumferential incision adjacent to the cornua. Clinical judgment as to the appropriate procedure must be used.

To perform circumferential incision, the isthmic portion of the tube is circumscribed near the cornua, thus exposing the insert. Once the insert is exposed by salpingotomy or circumferential incision, it can be grasped with forceps and slowly extracted in small increments to prevent fragmentation of the insert or excessive stretching of the coils. After removal of the proximal portion of the insert from the cornual region, the salpingectomy can be completed.

B. Perforations:

The technique for removal of an insert that has perforated the uterus or tube will depend on the location of the insert. Localization should be assessed with imaging prior to the surgical procedure and confirmed intra-operatively.

Tubal Perforations:

Inserts perforating the fallopian tube but still partially within the tube can be removed by salpingotomy, salpingectomy, cornual resection, or combined hysteroscopic/laparoscopic procedures depending on the location of the insert (refer to 'Subsequent to Placement Procedure; Laparoscopic removal').

Uterine Perforations:

Inserts that penetrate the myometrium may be embedded and difficult to remove. For cases in which the insert is primarily within the uterine cavity, hysteroscopic removal should be attempted. For cases in which the insert is partially within the endometrial cavity/uterine wall and partially in the peritoneal cavity, hysteroscopic excision of the platinum band, if visible, should be considered prior to planned laparoscopic removal. Cornual resection may be required for perforations within or adjacent to the cornual region. If the primary removal procedure is not successful then hysterectomy may be required.

C. Removal of Insert located within peritoneal cavity:

The majority of insert(s) located within the peritoneal cavity are asymptomatic and do not require removal. If removal is planned, the technique for removal of an insert within the peritoneal cavity will depend on the location of the insert. As with all removal procedures, localization should be assessed with imaging prior to the surgical procedure and may need to be confirmed intraoperatively. Availability of intraoperative fluoroscopy and/or intraoperative x-ray is recommended to identify the location of the insert or fragments of the insert during the removal procedure.

In rare instances, the outer coil of the insert may stretch across the abdominal/pelvic cavity and create a situation in which the bowel may be entrapped. A stretched insert can be identified on X-ray by the location of the "platinum band" marker being several centimeters away from the remainder of the insert (see Figure 18). In this circumstance, consideration should be given to removing the insert, even if the patient is asymptomatic.

D. Hysterectomy:

While hysterectomy generally is not required to remove the **Essure** inserts, there may be situations when a hysterectomy is indicated. These may include inability to remove the insert using the techniques described above, excessive bleeding, or other concomitant gynecological pathology (e.g. uterine fibroids, uterine prolapse, chronic pain or bleeding) that may be best managed with hysterectomy.

When performing a hysterectomy, it is important that the insert(s) be identified prior to surgery and care used not to transect or cauterize the inserts as this may result in fragmentation. Removal of the insert(s) through one of the techniques outlined in Section XIV '**Essure** Insert Removal', subsection 'Subsequent to Placement Procedure' may be required prior to the completion of the hysterectomy in order to avoid transecting or fracturing the insert.

XV. Patient Identification Card

Each patient who has had **Essure** insert(s) implanted should be given a laminated, wallet-sized card stating that she has **Essure** insert(s) in place. **The card is enclosed in this package.** The card will additionally state that there may be risks associated with the participant undergoing future intrauterine procedures or abdominal surgery.

XVI. How Supplied and Product Handling

STERILE: Each **Essure** system is supplied sterile. Inspect each package and do not use if damaged.

STORAGE: Store in a cool, dry place. Keep away from sunlight.

Each **Essure** system is sterilized using ethylene oxide and is supplied sterile for single use only. Do not reuse or resterilize. Resterilization may adversely affect proper mechanical function and could result in patient injury.

XVII. Legend of Symbols

STERILE EO	Sterilized using ethylene oxide
LOT	Batch Code
	Do Not Reuse
REF	Catalog Number
	Attention, See Instructions for Use
	Use By Date
	Keep away from sunlight
	Do Not Use If Package Is Open Or Damaged
	MR Conditional
EC REP	Authorized European Representative in the European Community
CE 0050	Device complies with European Directive 93/42/EC
	Keep Dry
CONT	Content

Document 3

Manufactured by:
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Patient Information Brochure
Essure® System
for Permanent Birth Control

July 2017

- **An Essure Confirmation Test should be performed three months after insert placement to evaluate insert retention and location. The patient must use alternative contraception until an Essure Confirmation Test demonstrates satisfactory results.**
- **There have been reports of perforation of the uterus and/or fallopian tubes, inserts located in the intra-abdominal or pelvic cavity, persistent pain, and allergy or hypersensitivity reactions in some patients. Some of these reported events resulted in insert removal that required abdominal surgery. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered. This information should be shared with patients considering sterilization with Essure during discussion of the benefits and risks of the device.**

Read all of this leaflet carefully before you have Essure placed because it contains important information for you.

- **This information does not replace talking with your doctor.**
- **Keep this leaflet. You may need to read it again.**
- **You should have a consultation with your doctor to understand the risk/benefit of Essure.The Essure procedure has to be be performed by a doctor who is trained and competent in the Essure placement procedure.**
- **If you have any questions about Essure or the placement procedure, ask your doctor.**
- **If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 6.**
- **You should read the Patient-Doctor Discussion Checklist at the end of this document. Reviewing and completing the checklist is an important step in helping you decide whether or not to have Essure implanted. The patient and physician must sign the checklist to acknowledge and document the discussion.**

What is in this leaflet

1. What Essure® is and what it is used for?

Essure Model ESS 305 is a device for permanent birth control that works with your body to create a natural barrier against pregnancy. The Essure placement procedure involves using a delivery system that places a soft, flexible insert into your fallopian tubes. Over a period of about three months, tissue forms around the insert. The build-up of this tissue creates a barrier that stops sperm from reaching the eggs and prevents pregnancy. During the three month period after placement of Essure, you must either not have sex or continue using another form of birth control to prevent pregnancy until a doctor performs a test (the Essure Confirmation Test) to confirm that Essure is correctly placed and that you can rely on Essure for permanent birth control.

Components of the Essure System (insert)

The soft, flexible Essure inserts do not contain hormones. The Essure insert is made of Nitinol (nickel-titanium alloy), stainless steel, a type of polyester fibre (PET- polyethylene terephthalate), platinum and silver-tin *(see section 2).*

2. What you need to know before you have the Essure procedure

Essure may be right for you if:

- You want permanent birth control
- You are sure you are done having children

Essure is not right for you if:

- You are uncertain about ending your fertility.
- You are pregnant or you think you are pregnant.
- Within the last 6 weeks, you have had a baby or have terminated a pregnancy after the third month.
- You currently have an infection in the vagina, cervix, uterus or fallopian tube.
- You have unexplained vaginal bleeding.
- You have suspected or known cancer of the female reproductive organs such as vagina, cervix, uterus or fallopian tube.

- Your doctor has told you that your fallopian tube(s) are closed or blocked.
- You have had your “tubes tied” (tubal ligation).
- You are allergic to contrast dye used during x-ray examinations.
- You are unwilling to undergo the Essure Confirmation Test.

Your doctor will delay your Essure procedure if:

- You are or have been pregnant within the past 6 weeks.
- You have an active or recent infection in the vagina, cervix, uterus or fallopian tubes.
- You are in the second half (weeks 3 and 4) of your menstrual cycle because during that time, there is an increased risk of being pregnant.

Tell your doctor if:

- You were born with uterine abnormalities (e.g. unicornuate uterus) or if you have had one of your tubes removed (salpingectomy).

- Pain (e.g. acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. Women with a history of pain prior to placement of Essure are more likely to experience both acute and persistent pelvic pain following Essure placement. Not all pain will be related to the Essure insert. Other gynecological conditions (such as endometriosis) or non-gynecological conditions (such as irritable bowel syndrome) can cause pain. Contact your doctor if you are experiencing significant pain or if the pain persists.

  Surgery may be required to remove the insert. This may range from looking in the uterus (hysteroscopy), removal of the insert alone, or removal of the insert with the fallopian tube and/or uterus (hysterectomy). Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.

- You have, or think that you have an allergy to nickel, titanium, stainless steel, polyester fiber (PET), platinum or silver-tin or you have had metal allergies. You may experience an allergic reaction to the insert. In addition, some patients may develop an allergy to nickel or other components of the insert following placement. Typical allergic symptoms such as hives, rash, swelling, and itching have been reported in patients who have had Essure placed. Talk to your doctor if you think you may have a nickel allergy and he or she will help to determine if Essure is right for you.

- You are taking or have received medicines that suppress your immune system. Examples include chemotherapy or corticosteroids, such as prednisone or other medicines used to treat inflammatory disorders such as rheumatoid arthritis. Medicines that suppress the

immune system may make Essure less effective for birth control. If you are taking medicines that suppress your immune system, your doctor will advise you of the type of confirmation test that is right for you.

Talk to your doctor about Essure and if it is right for you. Refer to the Patient-Doctor Discussion Checklist in this brochure and review it with your doctor.

IMPORTANT: Essure inserts do not protect against HIV or other sexually transmitted diseases.

Important factors you need to be aware when considering Essure

- The Essure procedure is irreversible and should be considered a permanent method of birth control. No method of birth control is 100% effective. There is a chance that you can become pregnant after having Essure placed.
    - While most pregnancies in women who have Essure have been reported as healthy deliveries, there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, and neonatal complications. You should contact your doctor immediately if you think you may be pregnant.
    - Women who have Essure placed may have an extrauterine pregnancy (ectopic pregnancy) if they get pregnant. The pregnancy usually happens in one of the fallopian tubes. Extrauterine pregnancy is very serious and can be life-threatening
    - If pregnancy occurs while Essure is in place, it cannot be relied on for future birth control and alternative birth control is needed to prevent pregnancy.
- Your doctor will schedule an Essure Confirmation Test which is part of the Essure procedure which should be performed about 3 months after the placement procedure. Your doctor will inform you on the options for the Confirmation Test including their risks and benefits. **YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.**
- Part of an Essure insert may perforate the wall of the uterus or fallopian tube during the procedure. This occurred in 1 out of 50 women in the original premarket study for Essure. A perforation may lead to bleeding or injury to bowel or bladder, which may require surgery. If removal of the insert is necessary, surgery will be needed. In that case, your doctor may tell you that you must use another form of birth control to prevent pregnancy. This surgery may range from looking in the uterus (hysteroscopy), removal of

the insert alone, or removal of the insert with the fallopian tube and/or uterus (hysterectomy).

- If you are considering a gynecological procedure or (abdominal) surgery in the future, tell your doctor that you have had the Essure procedure.
- If you have already had, or are considering a procedure to reduce bleeding from the uterus (such as endometrial ablation) tell your doctor as it may affect the Essure procedure.
    - The ablation procedure should not be performed on the same day as your Essure placement procedure.
    - If you have Essure placed, your doctor must confirm that it is in a satisfactory location (via the Essure Confirmation Test) before performing an ablation procedure.
- The Essure procedure should be performed by a doctor who is trained and competent in the Essure placement procedure.
- The younger a woman is when she chooses to end her fertility, the more likely she is to regret her choice later
- If you have Essure placed, it does not prevent you from having an MRI of your pelvis . If you are prescribed such an examination, tell your radiologist that you have Essure in place.
- Read this Patient Information Brochure carefully and consult with your doctor before you decide if Essure is right for you.
- As with any procedure, the Essure procedure is NOT without risks. Talk with your doctor about the risks and benefits of Essure for you.
- Discuss and agree with your doctor on the adequate time to review and consider the information contained in this Patient Information Brochure before deciding whether to proceed with the Essure procedure.

3. Overview of the Essure Procedure

Step 1 – Having Essure placed

During the procedure, the doctor will place a tiny insert into your fallopian tubes. The inserts are soft and flexible, and are delivered through your vagina and cervix, and into your fallopian tubes. No incisions are needed.

Step 2 - Waiting for the natural barrier to form

Over the next 3 months, your body will form tissue around the Essure inserts. The tissue forms a natural barrier within the fallopian tubes. The barrier prevents sperm from reaching the eggs that are produced every month. During this initial 3-month period, you **must** either not have sex or continue using another form of birth control to prevent pregnancy.

Step 3 - Essure Confirmation Test

The Essure method for permanent birth control requires two distinct procedures in order to determine if it can be relied upon for permanent birth control. The first step is the placement of the insert(s) into the fallopian tubes and the second is the confirmation test. A satisfactory confirmation test performed **three months after the inserts are placed**, is required to determine that the Essure insert is in a satisfactory location and/or that the fallopian tubes are blocked and that you can rely on Essure for birth control. Your doctor will advise you of the type of test that is right for you. You may have pelvic X-Ray or an ultrasound that confirms that your Essure inserts are in a satisfactory location, or, your doctor may recommend a test that uses contrast dye and a special type of x-ray (modified HSG) to determine both that the insert is in a satisfactory location and that your fallopian tubes are appropriately blocked. Your doctor will advise you on which method or methods are best for you.

IMPORTANT:

YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.

FOR SOME WOMEN, IT MAY TAKE LONGER THAN 3 MONTHS FOR ESSURE TO COMPLETELY BLOCK THE FALLOPIAN TUBES, REQUIRING A REPEAT CONFIRMATION TEST AT 6 MONTHS.

Talk to your doctor about which method of birth control you should use for the 3 months after the placement procedure. Some women can continue using their current method of birth control.

4. What should I know about the Essure Confirmation Test

The Essure Confirmation Test verifies that the inserts are in a satisfactory location and sometimes tests whether the tubes are appropriately blocked. The Essure Confirmation Test can include pelvic X-ray, transvaginal ultrasound (TVU), or a special type of x-ray using a special

contrast dye in your uterus (modified HSG).Your doctor will advise you on which method or methods are best for you.

Some additional information on the confirmation tests that check the inserts are correctly placed is provided below:

- PELVIC X-RAY - test in which X-rays are used to obtain an image of the pelvis
- TRANSVAGINAL ULTRASOUND - test that uses sound waves to examine the genitals of a woman, including the uterus, ovaries and cervix. During this test, an ultrasound device will be placed inside the vagina. The ultrasound will create a picture that will enable your doctor to see the Essure inserts within your fallopian tubes and determine if the inserts are in the appropriate place.
- HYSTEROSALPINGOGRAM (HSG)*:* test that consists of a special x-ray in which a contrast medium is used to view the uterus and fallopian tubes. During this test, a healthcare provider injects a special contrast dye into your uterus. The dye is visible on x-rays. This lets the doctor look at your fallopian tubes to confirm that the inserts are properly placed and that your tubes are appropriately blocked.

If you have any further questions on the Essure Confirmation Test, ask your doctor.

5. What to expect with Essure

Preparing for your procedure
Your doctor will schedule your Essure procedure for a time soon after the end of your menstrual period. Your doctor may give you medication to make it easier to see the openings of your fallopian tubes and place the inserts.

The day of your procedure
You will be asked to take a pregnancy test before or on the day of your procedure to ensure you are not pregnant. Your doctor may also give you medication before your procedure to reduce any discomfort. Talk to your doctor prior to the procedure about the types of medications that are right for you and the associated benefits and risks.Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with this type of anesthesia.

During your procedure
Your doctor may first insert an instrument called a speculum inside your vagina. The speculum helps the doctor widen the opening of your vagina and see inside. Then your doctor will insert a narrow instrument (hysteroscope) through your cervix and into your uterus. A camera attached to the hysteroscope lets your doctor see the inside of your uterus. A salt water solution is used to expand the uterus. This makes it easier for your doctor to find the openings of your fallopian tubes.

The Essure insert is attached to the end of a small, flexible tube that passes through the hysteroscope and into your fallopian tube. Once the insert is placed, the flexible tube is removed.

IMPORTANT: Not all women will achieve successful placement of Essure inserts. In a recent post-marketing study, in only a few instances (about 1 out of 20 women), the doctor was unable to place one or both Essure inserts in the fallopian tubes. If this occurs, talk to your doctor about your contraceptive options.

After your procedure
Most women return to normal activities within one to two days following the procedure. Call your doctor if you experience pain, bleeding, fever, or vaginal discharge that worsen or do not go away following the procedure.

It takes about 3 months (sometimes longer) for your body to produce tissue around the inserts and form a barrier to prevent pregnancy. During that time you can still get pregnant.

IMPORTANT: YOU MUST SEE YOUR DOCTOR FOR THE ESSURE CONFIRMATION TEST BEFORE YOU CAN RELY ON ESSURE FOR BIRTH CONTROL. YOU MUST CONTINUE TO USE ANOTHER FORM OF BIRTH CONTROL TO PREVENT PREGNANCY UNTIL YOUR DOCTOR TELLS YOU THAT YOU CAN RELY ON ESSURE FOR BIRTH CONTROL.

Essure Confirmation Test
Your doctor will examine you **3 months after the placement procedure** to ensure that the inserts are correctly placed in your fallopian tubes. **This 3-month confirmation test (Essure Confirmation Test) is mandatory before you can rely on Essure for birth control** (see section 3 and 4).

Make sure you continue using another type of birth control until your doctor has reviewed your Essure Confirmation Test results and confirmed that you can rely on Essure for birth control.

6. Possible side effects and other Potential Risks

Like all methods of birth control, there are side effects and risks associated with the Essure procedure. These are described below, please also ask your doctor about them.

During the Essure placement procedure

- You may experience mild to moderate pain
- Your doctor may be unable to place Essure inserts correctly. If this happens a second attempt may be possible.

- Part of the Essure delivery system may break off. Although uncommon, if this happens, your doctor may remove the piece.
- The uterus or fallopian tubes can be perforated by the hysteroscope, Essure delivery system, Essure insert or other instrument. This occurred in 1 out of 50 women in the original premarket study for Essure. Most perforations do not result in symptoms. Some perforations may result in pain, bleeding or injury to the bowel, bladder or major blood vessel. You may have to have surgery to repair the perforation.
- Your body may absorb a large amount of the salt water solution used during the procedure which may make you feel short of breath.
- Your doctor may recommend a local anesthesia, which numbs the cervix. Ask your doctor about the risks associated with anesthesia prior to the placement procedure.

Immediately following the placement procedure

- You may experience mild to moderate pain and/or cramping, vaginal bleeding, for a few days after the procedure. Some women experience headaches, nausea and/or vomiting or dizziness and/or lightheadedness/ fainting. These reactions may be treated with medication.
- Unusual pain or uterine bleeding may occur after the placement procedure. If this happens your doctor may investigate and may decide that the insert should be removed. This would require surgery. Device removal may lead to improvement or resolution of symptoms when: the onset is shortly after placement, imaging indicates an unsatisfactory insert location, and other etiologies for these symptoms have been considered.
- There are reports of an Essure insert being located in the abdomen and pelvis. If this happens, you cannot rely on Essure for birth control and surgery may be necessary to remove the insert.
- As with all procedures that use a hysteroscope (an narrow instrument used to view the inside of the uterus) there is a risk of infection. An infection could cause damage to the uterus, fallopian tubes or pelvic structures which may require antibiotics or rarely hospitalization or surgery (including hysterectomy).
- In some instances, an Essure insert may be expelled from the body. This is usually detected during the Essure Confirmation Test.

During the Essure Confirmation Test

- If your doctor performs an x-ray during the Essure Confirmation Test (pelvic X-ray or modified HSG) three months following insert placement, you will be exposed to very low levels of radiation which are consistent with most standard X-rays. The following additional risks are associated with the modified HSG: some women may experience nausea and/or vomiting, dizziness and/or fainting, cramping, pain or discomfort. In rare instances, women may experience spotting and/or infection which may require treatment with antibiotic and in rare cases hospitalization.

- The use of contrast dye, used to perform a modified HSG has been associated with allergic reactions in some patients. An allergic reaction can result in hives or difficulty breathing. Some allergic reactions can be serious.

Long term

- No birth control method is 100% effective. There is a possibility that you can become pregnant after completing the Essure procedure. In the most recent clinical trial, 1 out of 150 women became pregnant within the first year of relying on Essure. While most pregnancies in women who have Essure have been reported as healthy deliveries, there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, and neonatal complications. You should contact your doctor immediately if you think you may be pregnant.

- Women who have the Essure procedure may become pregnant and/ or may have an extrauterine pregnancy. The pregnancy usually happens in one of the fallopian tubes. Extrauterine pregnancy is very serious and can be life-threatening If you think you are pregnant after you have had Essure placed, call your doctor.

- Pain. The following types of pain have been reported:
    - Pain (e.g. acute or persistent) of varying intensity and length of time may occur and continue following Essure placement. Women with a history of pain prior to placement of Essure are more likely to experience both acute and persistent pelvic pain following Essure placement. Not all pain will be related to the Essure insert. Other gynecological conditions (such as endometriosis) or non-gynecological conditions (such as irritable bowel syndrome) can cause pain. Contact your doctor if you are experiencing significant pain or if the pain persists.

    - Pain, abdominal or pelvic cramping (including during sexual intercourse or physical activity).

Surgery may be required to remove the insert. This may range from looking in the uterus (hysteroscopy), removal of the insert alone, or removal of the insert with the fallopian tube and/or uterus (hysterectomy).

- Bleeding between periods or heavier than usual bleeding during menstruation (this may be due to discontinuation of hormonal contraception).

- Risks of infection that may require medical treatment including surgery.

- Patients with a known hypersensitivity (allergy) to polyester fiber, nickel, titanium, stainless steel, platinum, silver-tin or any of the components of the Essure system may experience an allergic reaction to the insert. This includes patients who have had metal allergies. Some patients may develop an allergy to nickel or other components of the insert following placement. Typical allergic symptoms such as hives, rash, swelling and itching have been reported for this device. There is no reliable test to predict who may develop a reaction to the inserts.

- A woman may sometimes regret her decision to choose permanent birth control, and may experience mild depression or other emotional problems.

Risks Associated with Future Procedures

- If you have gynecological procedures including abdominal surgery in the future, tell your doctor that you have the inserts in your fallopian tube.The presence of the Essure inserts may need to be considered.
- If you have endometrial ablation, a procedure that removes the lining of the uterus to lighten or stop menstrual bleeding, after the Essure procedure, it is unknown if this will affect the blockage in your tubes, and effect your risk of pregnancy. Your doctor must confirm that the Essure insert is in a satisfactory location before performing this procedure.
- If you have Essure placed, it does not prevent you from having an MRI of your pelvis. If you are prescribed such an examination, tell your radiologist that you have Essure in place.

Unknown Risks:

- The safety and effectiveness of restoring fertility following the Essure procedure are not known.

- The safety and effectiveness of Essure has not been established in women under 21 or over 45 years old.

- Other symptoms have been reported by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common of these symptoms include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to Essure or other causes.

If you get any side effects, talk to your doctor including any possible side effects not listed in this leaflet.

7. Patient Identification Card

After your have had Essure placed, you will be given an ID card. The ID card tells doctors and others that you have Essure inserts in your fallopian tubes. Please ensure that you show the card when undergoing any procedure involving your abdomen, pelvis, uterus or fallopian tubes. This includes an MRI scan, dilation and curettage (D&C) - a procedure to remove tissue from inside your uterus, hysteroscopy, endometrial biopsy or endometrial ablation. The visibility of areas of the body near the inserts may be obscured when they are seen on x-rays, MRIs and other imaging.

8. Frequently Asked Questions to your doctor

If you are considering the Essure procedure as a permanent method of birth control, here are some questions you might want to ask your doctor:

- Is Essure the most appropriate method of birth control for my health and my expectations?
- What are the benefits and risks of this procedure?
- Where will this procedure be performed? How long will it take to place the inserts?
- What type of medications may be used before and/or during the procedure?
- Will the procedure require anesthesia? What are the risks of this?
- How should I prepare for the procedure?
- What are my options if inserts cannot be placed at the first attempt?
- What happens at the 3-month confirmation visit? When should I schedule it?
- Which birth control option can I use while I am waiting for confirmation that the procedure has been effective?
- Will someone need to take me home afterwards?

9. Methods of birth control

All methods of birth control have contraindications, precautions for use and side effects.For further information consult your doctor.

Of all of methods of birth control, only the condom (male or female) protects against HIV and most sexually transmitted diseases.

INTRA-UTERINE CONTRACEPTION

A device placed in the uterus with a T-shaped frame or other shapes. There are two types: progestin or copper. They are effective from 3 to 10 years depending on the models.

PERMANENT FEMALE CONTRACEPTION (STERILISATION)

Methods of birth control that cause a permanent and definitive blockage of the fallopian tubes, preventing conception. There are several types: tubal ligation, removal of the tubes, tubal clips performed by laparoscopy and the insertion of implants into the tubes.

INJECTABLE PROGESTINS

A synthetic progestin delivered with an intra-muscular injection every three months.

BIRTH CONTROL PILL

A pill taken daily at the same time for 21 or 28 days. There are two types: estrogen-progestin (two hormones), and progestin only (one hormone). The dose and the type of the hormones vary depending on the type of pill.

PATCH

A patch that the woman adheres to her skin once a week, renewed every week for 3 weeks; there is no patch in the 4th week, but protection is maintained. It contains two types of hormones.

VAGINAL RING

A flexible ring inserted by the woman into the vagina. It is left in place for 3 weeks (and removed at the start of the 4th week, though protection is maintained). Contains an estrogen and a progestin.

DIAPHRAGM

A dome-shaped silicone disc that the woman places in the vagina herself. Must be used in conjunction with a spermicide. It prevents sperm from reaching the uterus. It may be inserted a few hours before intercourse or just before. It must be left in place for 8 hours after intercourse. Re-usable.

FEMALE CONDOM

A sheath with a flexible ring at both ends, which is placed in the vagina. It may be put in place several hours before intercourse. It must be changed for every act of intercourse. Together with the male condom, the only method that protects against sexually transmitted diseases.

MALE CONDOM

A sheath placed over the penis that prevents passage of sperm. Applied immediately before intercourse and used only once. Together with the female condom, the only method that protects against sexually transmitted diseases.

Document 4

SPERMICIDES

Takes the form of a gel or suppository, is placed in the vagina a few minutes before intercourse and destroys the sperm.

CERVICAL CAP

A very fine dome-shaped silicone disc that covers the cervix. May be inserted a few hours before intercourse or just before. It must be left in place for 8 hours after intercourse. Re-usable.

EMERGENCY CONTRACEPTION

Method of birth control that prevent unwanted pregnancy after unprotected or poorly protected intercourse. A corrective method, not designed to be used regularly.

VASECTOMY

Permanent birth control for men that involves cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).

10. Patient-Doctor Discussion Checklist

To the patient considering the "Essure® System for Permanent Birth Control" ("Essure"):
The review and completion of this form is a critical step in helping you decide whether or not to have Essure implanted. You should carefully consider the benefits and risks associated with the device before you make that decision. After reviewing the Essure Patient Information Booklet, please read and discuss the items in this checklist with your doctor. You should not initial or sign the document, and should not undergo the procedure, if you do not understand each of the elements listed below.

Birth Control Options

I understand that Essure is a permanent form of birth control (referred to as "sterilization") I understand that sterilization must be considered permanent and not reversible.

I was told about other permanent sterilization procedures, such as surgical bilateral tubal ligation ("getting tubes tied"), and their benefits and risks.

I am aware that there are highly effective methods of birth control which are not permanent and which may allow me to become pregnant when stopped.

Patient Initials _____

Requirements for Essure
I understand that I am not a candidate for Essure if:

- I am uncertain about ending my fertility.
- I have had a tubal ligation procedure ("tubes tied").
- I cannot have my insert(s) placed because my fallopian tube(s) cannot be visualized or blocked.
- I am pregnant or suspect that I may be pregnant.
- I have delivered or terminated a pregnancy within the last 6 weeks.
- I have an active pelvic infection on the date of the scheduled implantation.
- I have unexplained vaginal bleeding.
- I have suspected or known cancer of the female reproductive organs.
- I have a known allergy to contrast dye used during x-ray procedures.

I understand that one or both inserts may not be able to be placed and my options if this occurs. I understand that if this is not possible in my case, I may need to undergo a repeat attempt at Essure placement or consider a different form of birth control.

I understand that the placement procedure is only the first step in relying on Essure for birth control. After placement I must:

- Use an alternative form of birth control until my doctor tells me I can stop (typically for 3 months).
- Schedule and undergo a confirmation test after three months to determine whether I may rely on Essure.

I understand that a satisfactory confirmation test is needed before I can rely on Essure alone. I also understand that after the confirmation test my doctor may inform me that I may not be able to rely on Essure. If this occurs, I will have to use an alternative form of contraception.

I understand that 8% of women who undergo attempts at Essure placement are not able to rely on the device.

Patient Initials _____

Pregnancy Risks

I understand that no form of birth control is 100% effective. Even if my doctor tells me I am able to rely on Essure, there is still a small chance that I may become pregnant. Based on clinical studies, the chance of unintended pregnancy for women who have been told they can rely on Essure is less than 1% at 5 years.

I understand that the risks of Essure on a developing fetus have not been established. If I become pregnant with Essure, there may be a risk for the pregnancy to occur outside of the uterus ("ectopic pregnancy"). This may result in serious and even life-threatening complications. I understand that I should contact my doctor immediately if I think I may be pregnant.

Patient Initials _____

What to Expect During and After the Procedure

I understand that in clinical studies supporting device approval, the following events were reported to occur during the Essure placement procedure and/or in the hours or days following placement:

- Cramping (Reported in 29.6% of procedures)
- Mild to moderate pain (9.3%) or moderate pain (12.9%)
- Nausea/Vomiting (10.8%)
- Dizziness/Lightheadedness (8.8%)
- Vaginal bleeding (6.8%)

If I experience worsening of any of the events listed above or I continue to have the symptoms, I understand that I should contact my doctor.

Patient Initials _____

Document 4

Long-Term Risks

I understand that some women may experience continued pain or develop new pain later after Essure placement. I understand that I should contact my doctor if abdominal, pelvic or back pain continues or worsens after placement or if I develop the onset of new pain..

I understand that the Essure inserts contain metals including nickel, titanium, stainless steel (iron, chromium, nickel), platinum and silver-tin, as well as a material called polyethylene terephthalate (PET). I understand that some women may develop allergic reactions to the inserts following implantation and have signs or symptoms such as rash and itching. This may occur even if there is no prior history of sensitivity to those materials. I also understand that there is no reliable test to predict ahead of time who may develop a reaction to the insert.

I understand that persistent or new pain, and/or allergic reaction may be a sign of an Essure-related problem which might require further evaluation and treatment, including possibly the need to have the inserts removed by surgery.

I recognize that other symptoms have been reported by women implanted with Essure, although they were not seen in the clinical trials supporting Essure approval. The more common symptoms reported include headache, fatigue, weight changes, hair loss and mood changes such as depression. It is unknown if these symptoms are related to Essure or other causes.

I understand that because Essure contains metals, I should tell all my doctors that I have the device before getting an MRI.

I understand there is a small possibility that the insert could poke through the wall of the uterus or fallopian tubes (“perforation”) during the procedure, and/or may be found in other locations in the abdomen or pelvis. The rate of perforation in the original premarket studies was 1.8%. The rate for an insert being found in the abdomen or pelvis has not been determined but its occurrence is uncommon. I understand that should one of these events occur, the insert may become ineffective in preventing pregnancy and may lead to serious adverse events such as bleeding or bowel damage, which may require surgery to address.

I understand that should my doctor and I decide that Essure should be removed after placement, an additional surgical procedure may be required. In complicated cases, my doctor may recommend a hysterectomy (removal of the entire uterus).

Patient Initials _____

Document 4

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the Essure Patient Information Brochure, and that I have had time to discuss the items in it and on this form with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of the device and procedure, and understand that alternative methods of birth control are available.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of Essure as described in the Essure System Patient Information Brochure as well as this form. I have also explained the benefits and risks of other birth control methods. Should device removal become necessary, I may perform the removal myself, or provide a referral to a physician who is willing and able to perform device removals. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date

References

1.Cooper JM, Carignan CS, Cher D, KerinJF. Microinsertnonincisionalhysteroscopicsterilization.*Obstet Gynecol*. 2003;102:59-67. **2.**Kerin JF, Cooper JM, Price T, et al. Hysteroscopic sterilization using a micro-insert device: results of a multicentre phase II study. *Hum Rep*. 2003;18:1223-1230. **3.** Syed R, Levy J, Childers ME. Pain associated with hysteroscopic sterilization. *JSLS*. 2007;11:63-65. **4.** PMA: P020014/S9. **5.** Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol*. 1996;174:1161-1170. **6.**Essure ESS305: Instructions For Use 2015: 1-10.

Manufactured by:

Bayer Healthcare LLC
1011 McCarthy Boulevard
Milpitas, CA, 95035
United States of America

Distributed by:

Australasian Medical & Scientific Ltd
2 McCabe Place
Chatswood NSW 2067
Australia

July 2017

Glossary

Anesthesia: Medically-induced partial or complete loss of sensation in all or part of the body. Loss of sensation may occur with or without loss of consciousness.

Cervix: The passageway that connects the vagina with the uterus.

Contraceptive: Any process, device, or method that reduces the likelihood of pregnancy.

Ectopic Pregnancy: The development of a fertilized egg outside the uterus, such as in a fallopian tube. Ectopic pregnancies can be dangerous and possibly life threatening.

Endometrial Ablation: A procedure that removes the lining of the uterus to lighten or stop your periods.

Essure Insert: The small, soft, flexible device that is placed in your fallopian tubes for permanent pregnancy prevention.

Fallopian Tubes: The tubes that carry the eggs from the ovaries to the uterus.

Hysteroscope: An instrument that is passed through the vagina and cervix to view the inside of the uterus.

Local Anesthesia: Medically-induced partial or complete loss of sensation of a certain part of the body.

Modified Hysterosalpingogram (modified HSG): An x-ray of the uterus and fallopian tubes after contrast dye has been given for the Essure Confirmation Test.

Occlusion: An obstruction or a closure of a passageway or a vessel.

Transvaginal Ultrasound (TVU): A test used to look at a woman's reproductive organs. An ultrasound device is placed into the vagina, and sound waves are used to see the uterus and fallopian tubes.

Tubal Ligation: A form of permanent birth control by means of cutting, tying, burning or clipping the fallopian tubes so that they are blocked.

Uterus: The womb, where a developing fetus grows.

Vasectomy: Permanent birth control for men that involves cutting or blocking a segment of the vas deferens (the tubes that carry the sperm).

Document 5

Sent
by: ruth.hughes@nzms.co.nz
29/08/2017 12:00 PM

To: '"kathy_daly@moh.govt.nz"' <kathy_daly@moh.govt.nz>
cc: '"Julie_Lagan@moh.govt.nz"' <Julie_Lagan@moh.govt[redacted]@bayer.com>[redacted]@bayer.com>
bcc:

Subject: Revised Medical Device Recall letter and Attachment A Response Form

Attachments
Rsponse Form A for Essure ESS305 2017.docx
Signed Copy of the Hazard Alert letter August 2017.pdf

Refer to Documents 5A and 5B

Good afternoon everyone,

I have attached the Medical Device Hazard Alert and the Response Form A for your approval.

I look forward to your reply.

Kind regards [redacted]

[redacted]

Medical Division Manager

nzms medical

[redacted]

[redacted]@nzms.co.nz

Web: www.nzms.co.nz

2a Fisher Crescent, Mt Wellington, Auckland 1060

PO Box 132400, Sylvia Park, Auckland 1644, New Zealand

Document 5A

new zealand
medical & scientific

ATTACHMENT A

RESPONSE FORM
Urgent Medical Device Recall
Essure ®Permanent Birth Control

Catalogue Number: ESS305
Batch Numbers: All

Affected Stock

*If you have **no affected** stock tick this box ( )*

If you have affected stock please complete the table below

Stock details		
Product	Batch/ Lot	Quantity
TOTAL AFFECTED PRODUCT		
Other Relevant Details		

Has your organisation supplied potentially affected product to any other organisation?
( ) No
( ) Yes (please supply names and contact information of the organisations)

OR
( ) Yes – I / We will forward all the recall action information to the suppliers/ distributors/ customers

P +64 259 4062
F +64 259 4067
E nzms@nzms.co.nz
W www.nzms.co.nz

2a Fisher Crescent
Mt Wellington, Auckland 1060
PO Box 132400, Sylvia Park
Auckland 1644, New Zealand

Document 5A

It is important that you complete and return this form by 8 September 2017

PLEASE RETURN THE COMPLETED RESPONSE TO THE ATTENTION OF Ruth Hughes USING ONE OF THE FOLLOWING METHODS:

- FAX: (09) 259 4067
- EMAIL SCANNED COPY: s 9(2)(a) @nzms.co.nz
- OR MAIL TO: NZMS
  PO BOX 132400
  SYLVIA PARK, AUCKLAND 1644

I acknowledge receipt of the Urgent Medical Device Recall notice (29 August 2017) relating to the above product.

FROM

Organisation			
Name		**Date**	
Position		**Telephone No.**	
Email		**Fax.No**	
Signature			

Document 5B

MEDICAL DEVICE HAZARD ALERT

ESSURE® Permanent Birth Control

Catalogue Number/Order code: ESS305

Batch Numbers: All

29 August 2017

Level of Recall: Hospital

ISSUE

New Zealand Medical & Scientific Ltd (NZMS), following consultation with Medsafe, is undertaking a recall of all unimplanted ESSURE in New Zealand following the decision to discontinue the supply of ESSURE in New Zealand as a result of a low and declining trend in patient preference for this choice of permanent contraception which is not expected to change.

Women who currently have ESSURE in place can continue to rely on the device and should have no concern based on this decision. NZMS will continue to fully support women with an ESSURE in place in New Zealand as well as support healthcare professionals who have questions on the product or who need to report suspected adverse events associated with ESSURE.

ACTION

1. This notice should be forwarded to all those who need to be aware of this information within your organisation. Ensure all relevant staff members are informed of this hazard alert who may need to monitor for adverse events, as applicable

   of the recalled stock could have been transferred from your hospital to another, mmediately let that hospital know of the recall. Please then telephone us so that ... make contact with the hospital supplied from your hospital.

3. Inform patient implanted with ESSURE as applicable. If a woman with Essure implanted has any concerns with the product she should discuss these with her Healthcare Professional.

4. Please complete and return the attached acknowledgement form to confirm the receipt of this notice.

Document 5B

NZMS sincerely regrets any inconvenience caused by the recall action and is fully committed to supporting you in this matter. If you have any questions regarding this recall, please contact:

s 9(2)(a) New Zealand Medical & Scientific Ltd (NZMS)
2a Fisher Crescent, Mt Wellington, Auckland 1060
s 9(2)(a)