ESSURE CONFIRMATION TEST WITH TRANSVAGINAL ULTRASOUND (TVU)

Please see Important Safety Information about Essure®, including Boxed Warning, and refer to the Essure® Instructions for Use

PP-250-US-1864

eLEARNING MODULE: CHAPTERS

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INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

Essure® is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

Important Safety Information

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.

IMPORTANT

- **Caution:** Federal law restricts this device to sale by or on the order of a physician. Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.
- The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Contraindications

Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral proximal tubal occlusion or suspected unicornuate uterus), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal tubal anatomy or previous tubal ligation (including failed ligation), are pregnant or suspect pregnancy, delivered or terminated a pregnancy less than 6 weeks prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecological malignancy, or have a known allergy to contrast media.

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IMPORTANT SAFETY INFORMATION (CONT'D)

General Warnings

- The Essure procedure should be considered irreversible.
- Pain (acute or persistent) of varying intensity and length of time may occur and persist following Essure placement. This is also more likely to occur in individuals with a history of pain. If device removal is indicated, this will require surgery.
- Patients with known hypersensitivity to nickel, titanium, platinum, stainless steel, and PET (polyethylene terephthalate) fiber or any of the components of the Essure system 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. Symptoms reported for this device that may be associated with an allergic reaction include hives, urticaria, rash, angioedema, facial edema and pruritus. Patients should be counseled on the materials contained in the insert 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.
- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue in-growth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. Transvaginal ultrasound (TVU) should not be used as the Essure Confirmation Test, as TVU cannot confirm tubal occlusion.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Pregnancy Risk

- Pregnancies, including ectopic pregnancies, have been reported among women who have undergone the Essure procedure.
- The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented. 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 to use alternative contraception.
- 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 that the Essure Confirmation Test may be unsatisfactory.
- Effectiveness rates for the Essure procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Procedure Warnings

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or is suspected, discontinue procedure and monitor the patient for signs and symptoms of possible complications related to perforation which may include unusual post-operative pain.
- To reduce the risk of hypervolemia, terminate procedure if distension fluid deficit exceeds 1500cc or total hysteroscopic procedure time exceeds 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and evaluate patient for possible perforation.
- Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more trailing coils are seen inside the uterine cavity due to risk of a fractured insert, fallopian tube perforation, or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation.

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IMPORTANT SAFETY INFORMATION (CONT'D)

MRI Information

The Essure insert was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05.

Adverse Events

The most common (≥10%) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events (≥3%) in the first year of reliance were back pain, abdominal pain, and dyspareunia.

This product does not protect against HIV infection or other sexually transmitted diseases.

Prescription Only

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CHAPTER 1:
OVERVIEW OF THE ESSURE CONFIRMATION TEST TVU/HSG ALGORITHM

Essure® for birth control

Essure Confirmation Test (Including TVU)

Essure TVU/HSG Confirmation Test Algorithm

Please see Important Safety Information about Essure®, including Boxed Warning, and refer to the Essure® Instructions for Use

THE ESSURE CONFIRMATION TEST

Required for all patients at 3 months postplacement

Past

- A modified HSG was the only option in the United States for determining whether a patient can rely on Essure® for birth control

Present

- The Essure TVU/HSG Confirmation Test Algorithm:
  - Confirmation Test can be performed using TVU or modified HSG in patients meeting specific criteria
  - If TVU is not indicated, or results are equivocal or unsatisfactory, a modified HSG is required to evaluate insert location and tubal occlusion

The patient must use alternative contraception
until a satisfactory Essure Confirmation Test is documented

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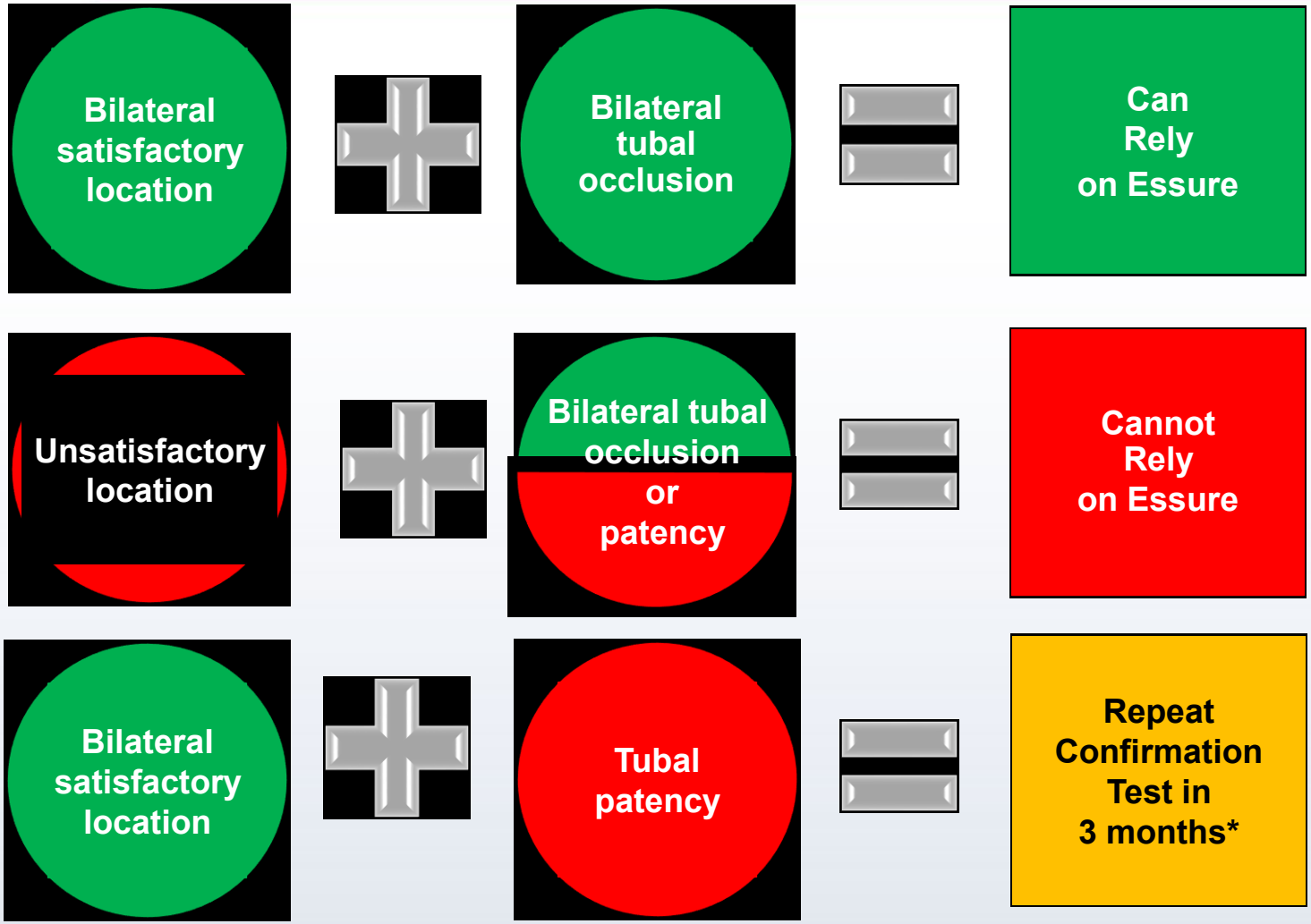
ESSURE CONFIRMATION TEST WITH MODIFIED HSG REQUIRES BOTH SATISFACTORY LOCATION AND OCCLUSION



***Continue alternate contraception**

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SAMPLE RADIOLOGIC REPORT

LOCATION	LEFT	RIGHT
☐ **Satisfactory location** Distal end of the inner coil is within the fallopian tube, with <50% of the inner coil trailing into the uterine cavity, OR the proximal end of the inner coil is ≤30 mm into the tube from where contrast fills the uterine cornua	☐	☐
☐ **Unsatisfactory location**	☐	☐
Proximal location: ≥50% of the inner coil is trailing into the uterine cavity	☐	☐
Distal location: insert is in the fallopian tube, but the proximal end of the inner coil is more than 30 mm from the contrast filling the uterine cornua	☐	☐
Expulsion: Insert is not present or lies completely in the uterine cavity	☐	☐
Perforation/Peritoneal location: Insert is completely or partially perforating the uterus or tube [Examples include: embedded in the myometrium, or completely in the peritoneal cavity]	☐	☐

OCCLUSION		
☐ **Satisfactory occlusion** Tube is occluded at the cornua OR contrast is visible within the tube but not past the distal end of the outer coil	☐	☐
☐ **Unsatisfactory occlusion** Contrast is visible past the insert OR in the peritoneal cavity	☐	☐

ABILITY TO RELY

Patient can rely on Essure® for birth control (satisfactory bilateral insert location and bilateral tubal occlusion)

Patient cannot rely on Essure® (unsatisfactory bilateral insert location with or without tubal patency)

Patient should return for a repeat Essure Confirmation Test in 3 months (satisfactory bilateral insert location with tubal patency)

A copy of this form can be found on the EssureMD.com website

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ESSTVU Clinical Trial

- To learn about the ESSTVU clinical trial click on the Resources tab

Trial design
Patient population studied

The TVU procedure
The primary endpoints

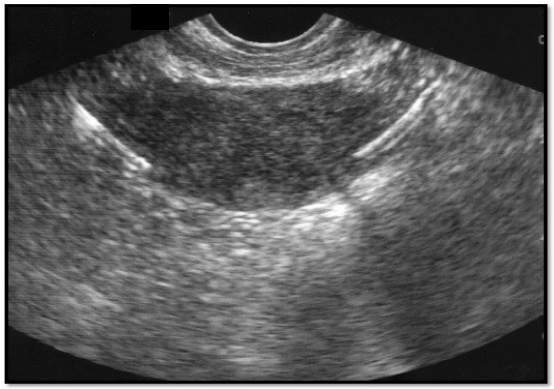
ESSURE TVU/HSG CONFIRMATION TEST ALGORITHM

Essure Bilateral Insert Placement

Option for patients meeting specific criteria

If TVU is not indicated, a modified HSG is required; a modified HSG is always an acceptable first-line option

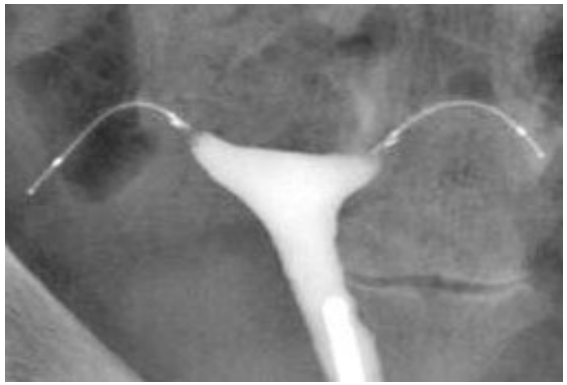
TVU
(at 3 months postplacement)



Essure Instructions for Use (with TVU)

If TVU results are equivocal or unsatisfactory, patient cannot rely on Essure® for birth control and a modified HSG is required to evaluate insert location and tubal occlusion

Modified HSG
(at 3 months postplacement)



Essure Instructions for Use (with TVU)

The patient must use alternative contraception until a satisfactory Essure Confirmation Test is documented

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CRITERIA FOR TVU AS A FIRST-LINE CONFIRMATION TEST AT 3 MONTHS POSTPLACEMENT

1 Placement procedure was not difficult:

- No concern at time of placement of possible perforation due to excessive force required for insert delivery and/or sudden loss of resistance
- No difficulty identifying tubal ostia during placement due to anatomical variation or technical factors such as poor distension, suboptimal lighting, or endometrial debris
- Physician is certain about placement

2 Procedure time ≤15 minutes (scope in-scope out)

3 Placement with 1-8 trailing coils for each insert

4 No unusual postoperative pain, transient or persistent, or onset at some later time postprocedure, without any other identifiable cause

Patients on active immunosuppressive therapy (eg systemic corticosteroids or chemotherapy) may experience delay or failure of the necessary tissue in-growth needed for tubal occlusion.

- Must use the modified HSG as the Essure Confirmation Test.
- TVU **should not** be utilized for confirmation
  - TVU cannot confirm tubal occlusion
  - No clinical trials conducted with patients undergoing immunosuppressive therapy

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ESSURE TVU/HSG CONFIRMATION TEST ALGORITHM

If ultrasound is not indicated, a modified HSG is required to evaluate insert location and tubal occlusion

Transabdominal ultrasound cannot be substituted for TVU

If ultrasound evaluation is equivocal or unsatisfactory, the patient must proceed to a modified HSG to evaluate insert location and tubal occlusion

The patient must use alternative contraception
until a satisfactory Essure Confirmation Test is documented

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ESSURE TVU/HSG CONFIRMATION TEST ALGORITHM

Procedure Note

Dr. Connor's expert opinion:

- Procedure note should be created immediately following Essure placement
- Procedure note is recommended to adequately document:
  - All required details of the procedure
  - Whether patient is a candidate for the TVU Confirmation Test

- Discuss with the patient the 2 methods utilized in the Essure Confirmation Test (TVU and a modified HSG)
- Inform patients about the differences between the methods, including benefits and risks (including possible increased risk of pregnancy if TVU is the only confirmation method used)
- In addition, patients need to be counseled that, in some cases after undergoing a TVU, a modified HSG may be required

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Chapter 1: Overview of the Essure TVU/HSG Confirmation Test Algorithm REVIEW QUESTIONS

QUESTION 1

Which of the following statements regarding the Essure Confirmation Test are true? Select all correct answers.

- [ ] a. A satisfactory result provides confirmation that the patient can rely on Essure® for birth control.
- [ ] b. Patients must use alternative contraception until a satisfactory Confirmation Test is documented.
- [ ] c. Selection of TVU or a modified HSG for the Essure Confirmation Test is dependent solely on patient and/or physician preference.
- [ ] d. If using TVU, the Essure Confirmation Test can be performed earlier than 3 months postplacement.

Submit Answers

EXPLANATION TO QUESTION 1

	Statement	Answer	Explanation
A	A satisfactory result provides confirmation that the patient can rely on Essure® for birth control.	TRUE	A satisfactory Confirmation Test result allows the patient to rely on Essure® for birth control.
B	Patients must use alternative contraception until a satisfactory Confirmation Test is documented.	TRUE	Until a satisfactory Confirmation Test is documented, patients must use alternative contraception,
C	Selection of TVU or a modified HSG for the Essure Confirmation Test is dependent solely on patient and/or physician preference.	FALSE	An Essure Confirmation Test with TVU is an option for patients meeting criteria specified in the Essure TVU/HSG Confirmation Test Algorithm, whereas a modified HSG is always an option.
D	If using TVU, the Essure Confirmation Test can be performed earlier than 3 months postplacement.	FALSE	The Essure Confirmation Test should be performed at 3 months postplacement, regardless of whether TVU or a modified HSG is used.

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QUESTION 2

Indicate whether each of the statements below applies to TVU or modified HSG.

TVU	Modified HSG		
☐	☐	a.	Is used for the Confirmation Test if there was difficulty in identifying tubal ostia during placement due to anatomical variation or technical factors such as poor distension, suboptimal lighting, or endometrial debris.
☐	☐	b.	Use requires that the patient meet specific criteria as determined by the TVU/HSG Confirmation Test Algorithm.
☐	☐	c.	Should be used for patients undergoing active immunosuppressive therapy.
☐	☐	d.	Requires documentation of satisfactory insert location and tubal occlusion.
☐	☐	e.	Enables assessment of the relationship between insert and soft tissue structures, such as the myometrium.

Submit Answers

EXPLANATION TO QUESTION 2

Statement	Answer	Explanation
Is used for the Confirmation Test if there was difficulty in identifying tubal ostia during placement due to anatomical variation or technical factors such as poor distension, suboptimal lighting, or endometrial debris	MODIFIED HSG	TVU should not be used as the Essure Confirmation Test if there was difficulty identifying the tubal ostia during placement due to anatomical variation or technical factors such as poor distention, suboptimal lighting, or endometrial debris.
Use requires that the patient meet specific criteria as determined by the TVU/HSG Confirmation Test Algorithm.	TVU	TVU may be performed as a first-line confirmation test for patients who meet criteria for using TVU specified in the TVU/HSG Confirmation Test Algorithm.
Must be used for patients undergoing active immunosuppressive therapy	MODIFIED HSG	TVU should not be used as the Essure Confirmation Test in patients undergoing active immunosuppressive therapy (eg, systemic corticosteroids or chemotherapy) because this test cannot confirm tubal occlusion in these patients. Clinical trials were not conducted with patients undergoing immunosuppressive therapy.
Requires documentation of satisfactory insert location and tubal occlusion	MODIFIED HSG	The Essure Confirmation Test must show bilateral satisfactory insert location when using TVU, and must show both bilateral satisfactory insert location and occlusion when using a modified HSG.
Enables assessment of the relationship between insert and soft tissue structures, such as the myometrium	TVU	TVU provides information regarding the relationship of the insert to the uterine cornua. The Essure® insert can be detected ultrasonographically because of its dense echogenic properties and its relative position can be determined because of the echogenic gradient between the insert and the endometrium and myometrium.

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QUESTION 3

Indicate whether each of the statements below is True or False.

True	False		
☐	☐	a.	A transabdominal ultrasound may be used as a substitute for a TVU.
☐	☐	b.	If TVU is not indicated, a modified HSG is required to evaluate insert location and tubal occlusion.
☐	☐	c.	If TVU evaluation is equivocal, the TVU should be repeated until conclusive results are obtained.
☐	☐	d.	TVU should not be used if the placement resulted in 0 or >8 trailing coils.

Submit Answers

EXPLANATION TO QUESTION 3

	Statement	Answer	Explanation
A	A transabdominal ultrasound may be used as a substitute for a TVU.	FALSE	A transabdominal ultrasound cannot be used as a substitute for a TVU.
B	If TVU is not indicated, a modified HSG is required to evaluate insert location and tubal occlusion.	TRUE	If ultrasound is not indicated, a modified HSG is required to evaluate insert location and tubal occlusion.
C	If TVU evaluation is equivocal, the TVU should be repeated until conclusive results are obtained.	FALSE	If a TVU evaluation is equivocal or unsatisfactory, the patient must proceed with a modified HSG to evaluate insert location and tubal occlusion.
D	TVU should not be used if the placement resulted in 0 or >8 trailing coils	TRUE	TVU should not be used as the Essure Confirmation Test if there were 0 or >8 trailing coils following placement.

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QUESTION 4

Review the sample procedure note from an Essure placement procedure below and indicate whether this patient is a candidate for a TVU Confirmation Test.

- I am certain of bilateral Essure® insert placement. Placement procedure was not difficult, and there was no concern of possible perforation due to excessive force and/or sudden loss of resistance. Patient was not undergoing immunosuppressive therapy.
  - Left insert: 5 trailing coils.
  - Right insert: 10 trailing coils.
- Total procedure time was 20 minutes. No unusual pain was reported during or after the procedure.
- Patient was counseled to return in 3 months for a Confirmation Test.

Candidate for TVU Confirmation Test

NOT a Candidate for TVU Confirmation Test

Submit Answer

EXPLANATION TO QUESTION 4

Sample Procedure Note	Answer	Explanation

• I am certain of bilateral Essure® insert placement. Placement procedure was not difficult, and there was no concern of possible perforation due to excessive force and/or sudden loss of resistance. Patient was not undergoing immunosuppressive therapy.
  • Left insert: 5 trailing coils.
  • Right insert: 10 trailing coils.
• Total procedure time was 20 minutes. No unusual pain was reported during or after the procedure.
• Patient was counseled to return in 3 months for a Confirmation Test.
	Not a candidate for TVU because:
	• Right insert had >8 trailing coils
	• Total procedure time exceeded 15 minutes
		Based on the procedure note, this patient is not a candidate for an Essure Confirmation Test with TVU because the right insert had >8 trailing coils and the total procedure time exceeded 15 minutes. A modified HSG is required to evaluate insert location and tubal occlusion.

MARK CHAPTER 1 COMPLETE

- You have completed this chapter. To review any of the information in this presentation, tap/click on the topic in the menu to the left
- When you are finished, please ensure that you tap/click the “Mark Complete” button below to mark this chapter complete and exit (DO NOT use the exit “X” in your browser)
- By marking complete, you acknowledge that you have reviewed and understand all of the content contained within this chapter. The chapter content may have included, but was not limited to, tabs, pop-ups, interactive exercises, and attachments
- For Important Safety Information about Essure®, including Boxed Warning, and refer to the Essure® Instructions for Use click on the hyperlinks here
- Please proceed to the next chapter:
  Chapter 2: Understanding an Essure® Confirmation Test with TVU

Mark Complete