



ESSURE CONFIRMATION TEST WITH TRANSVAGINAL ULTRASOUND (TVU)

Chapter 3: Performing and Interpreting the Essure Confirmation Test with TVU

Please see [Important Safety Information about Essure®](#), including Boxed Warning, and refer to the [Essure® Instructions for Use](#)

PP-250-US-1387

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eLEARNING MODULE: CHAPTERS

Overview of the
Essure TVU/HSG
Confirmation Test
Algorithm

1

Understanding an
Essure Confirmation
Test with TVU

2

Performing and
Interpreting the Essure
Confirmation Test with
TVU

3

Example of TVU
Confirmation Test

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CHAPTER 3: PERFORMING AND INTERPRETING THE ESSURE CONFIRMATION TEST WITH TVU

**Performing
the Essure
Confirmation Test
with TVU**

**Interpreting
the Essure
Confirmation Test
with TVU**

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BEFORE PROCEEDING WITH THE ESSURE CONFIRMATION TEST WITH TVU



Review:

- Essure TVU/HSG Confirmation Test Algorithm
- Essure placement procedure note

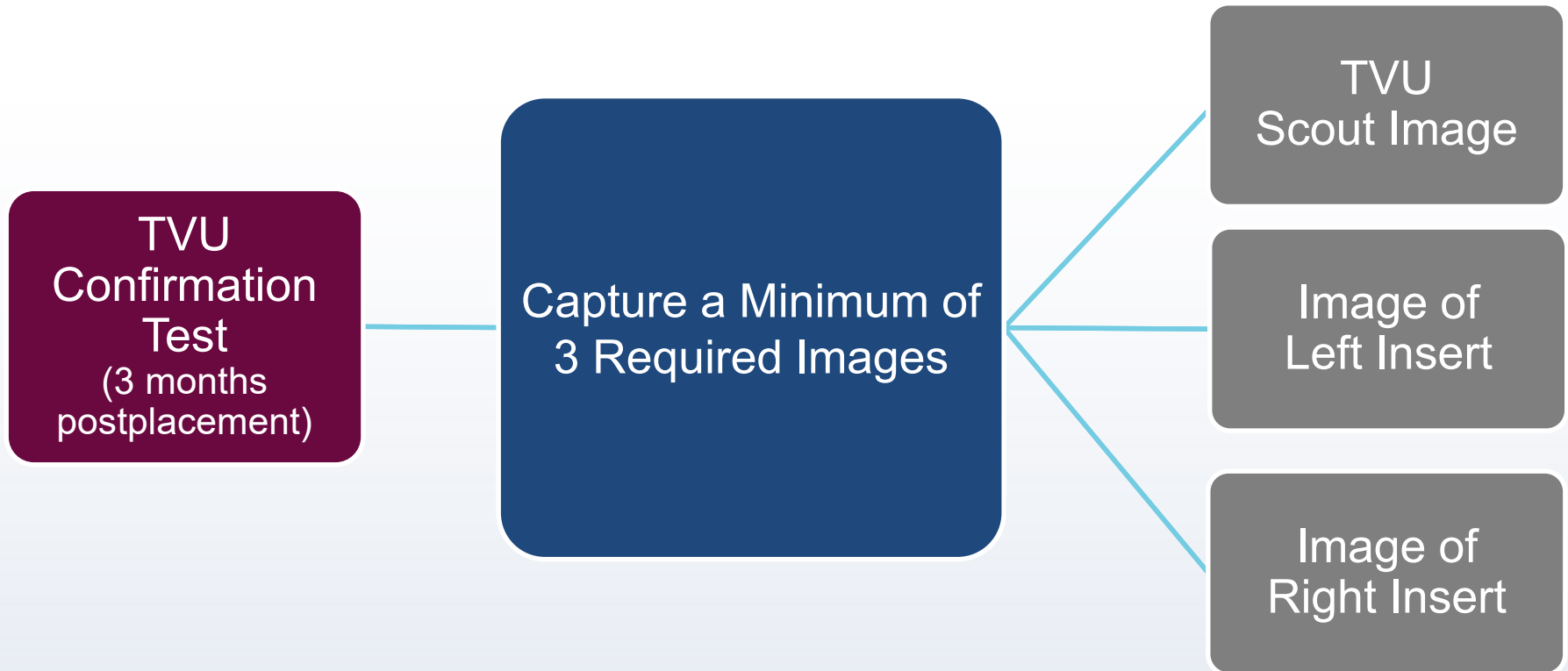


Confirm patient is an appropriate candidate for a TVU Confirmation Test

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DOCUMENTATION REQUIREMENTS



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PROCEDURE STEPS

For a transvaginal sonogram, the urinary bladder is preferably empty
The procedure can be divided into the following 3 components:

Orientation



Determination of uterine size and orientation

Identification



Visualization of a portion of each insert simultaneously within the cornua

Location



Determination of insert location and soft tissue relationships

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COMPONENT 1: ORIENTATION

Orientation



Determination of Uterine Size and Orientation

- Gently insert endovaginal probe
- Obtain midline sagittal view to determine uterine orientation
 - Note uterine orientation:
 - Anteverted,
 - Retroverted, or
 - Midline
- Obtain right and left sagittal sweep
- Correct midline sagittal view includes entire endometrial stripe and endocervix
- Linear axis of either insert should NOT be visualized in midline sagittal view
 - Suspect proximal placement if linear axis is visualized in the uterine cavity
 - Suspect fundal perforation if linear axis is visualized in the fundal myometrium
- Visualization of proximal end of 1 or both inserts in cross-section may indicate trailing coils in uterine cavity

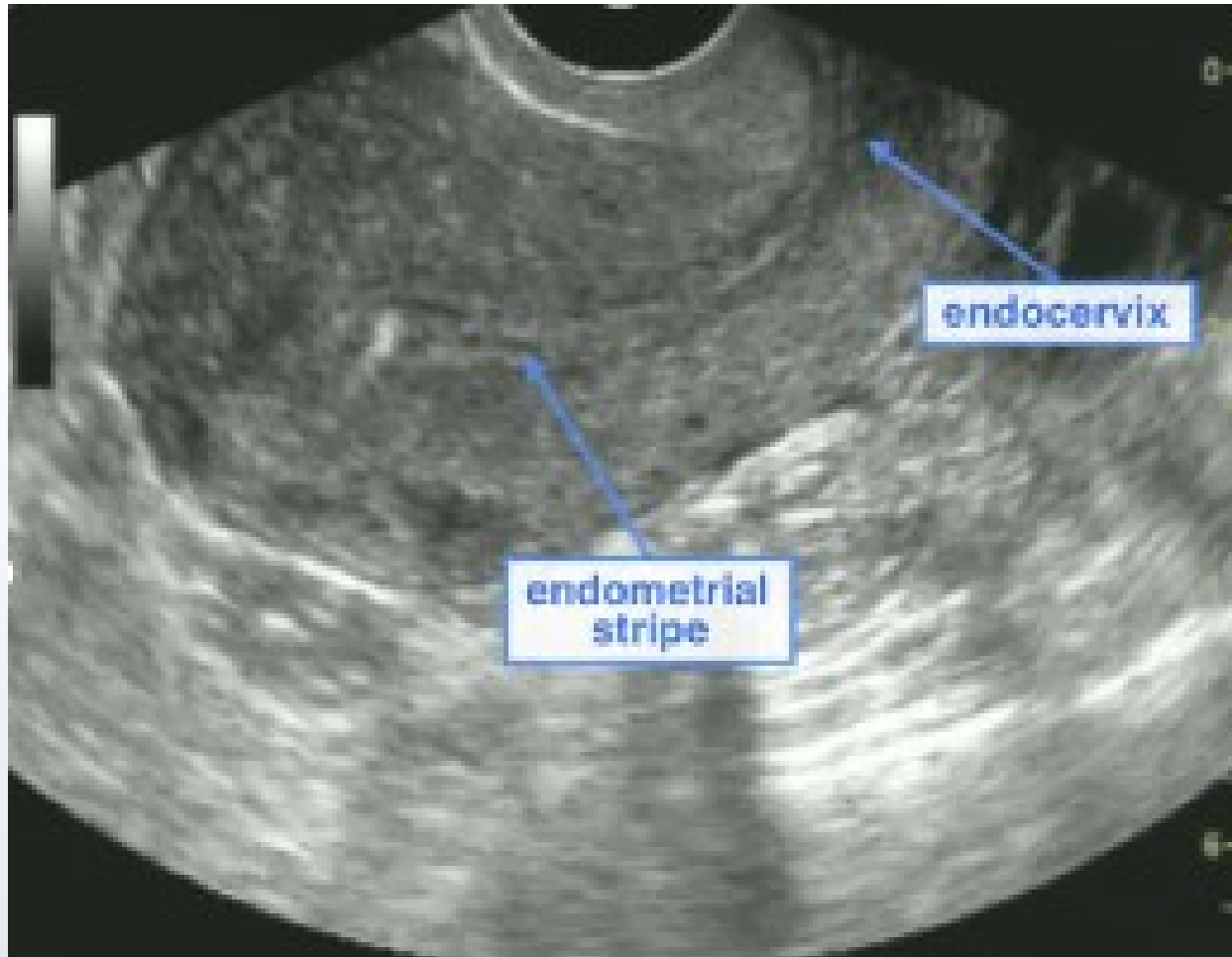
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ORIENTATION

Orientation



Orientation video
is available under
“Example TVU
Cases”



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COMPONENT 2: IDENTIFICATION

Identification



Visualization of a Portion of Each Insert Simultaneously Within the Cornua (Scout Image)

- Goal is to visualize a portion of each insert simultaneously
 - Within the cornua
 - In the transverse plane
 - At the level of the fundus
- Rotate probe 90 degrees from midline sagittal view to obtain transverse view
- Obtain transverse sweep of uterus
 - Starting at cervix
 - Moving to fundus
- Adjust probe to visualize maximum width of endometrium
 - Ensures the transverse view is at the fundus
- Slight probe rotation/adjustment may be required, or gentle endovaginal pressure applied, to improve tissue contact and visualization

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COMPONENT 2: IDENTIFICATION (CONT'D)

Identification



Visualization of a Portion of Each Insert Simultaneously Within the Cornua (Scout Image)

- A portion of each insert should be identified within the myometrium in the cornua
 - Suspect expulsion or perforation if 0 or only 1 insert is identified
- Both inserts **MUST** be identified in the fundal transverse view to reduce risk of duplicate imaging
- Linear axis of inserts should appear relatively symmetrical and on opposite sides of the uterus
 - Suspect uterine cavity location if the inserts are in contact with each other
- Location of the inserts on TVU may appear to be more distal than noted at time of hysteroscopy due to uterine distension during placement

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COMPONENT 2: IDENTIFICATION (CONT'D)

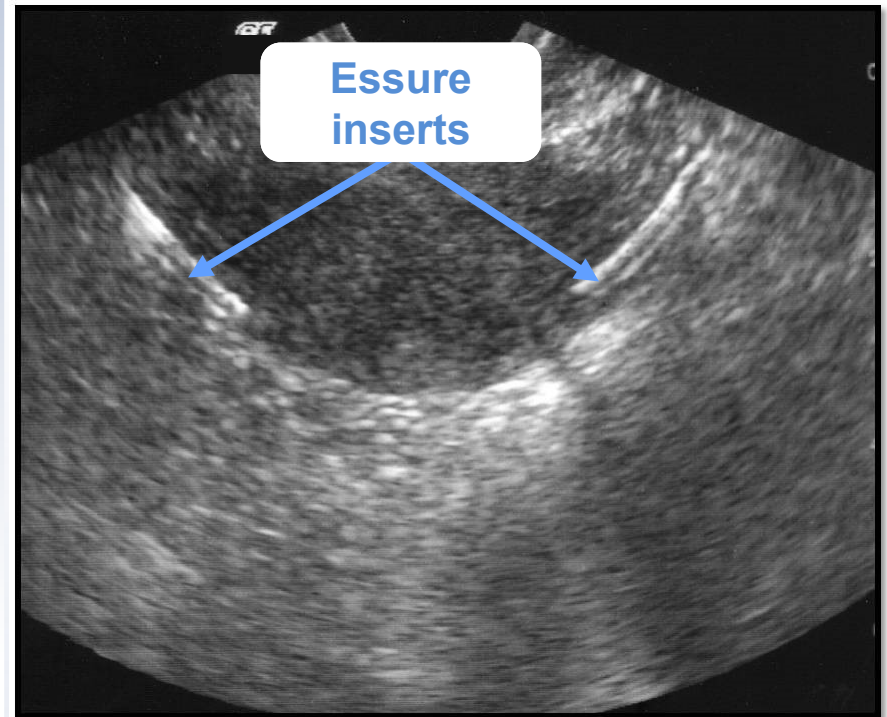
Identification



Capturing the TVU Scout Image

- A single image
 - In transverse or oblique transverse view
 - Demonstrating a portion of each insert in the cornua
- Ensure bilateral placement
- Reduce risk of duplicate imaging of the same insert

TVU Scout Image



Essure® Instructions for Use (with TVU)

Transverse Fundal View

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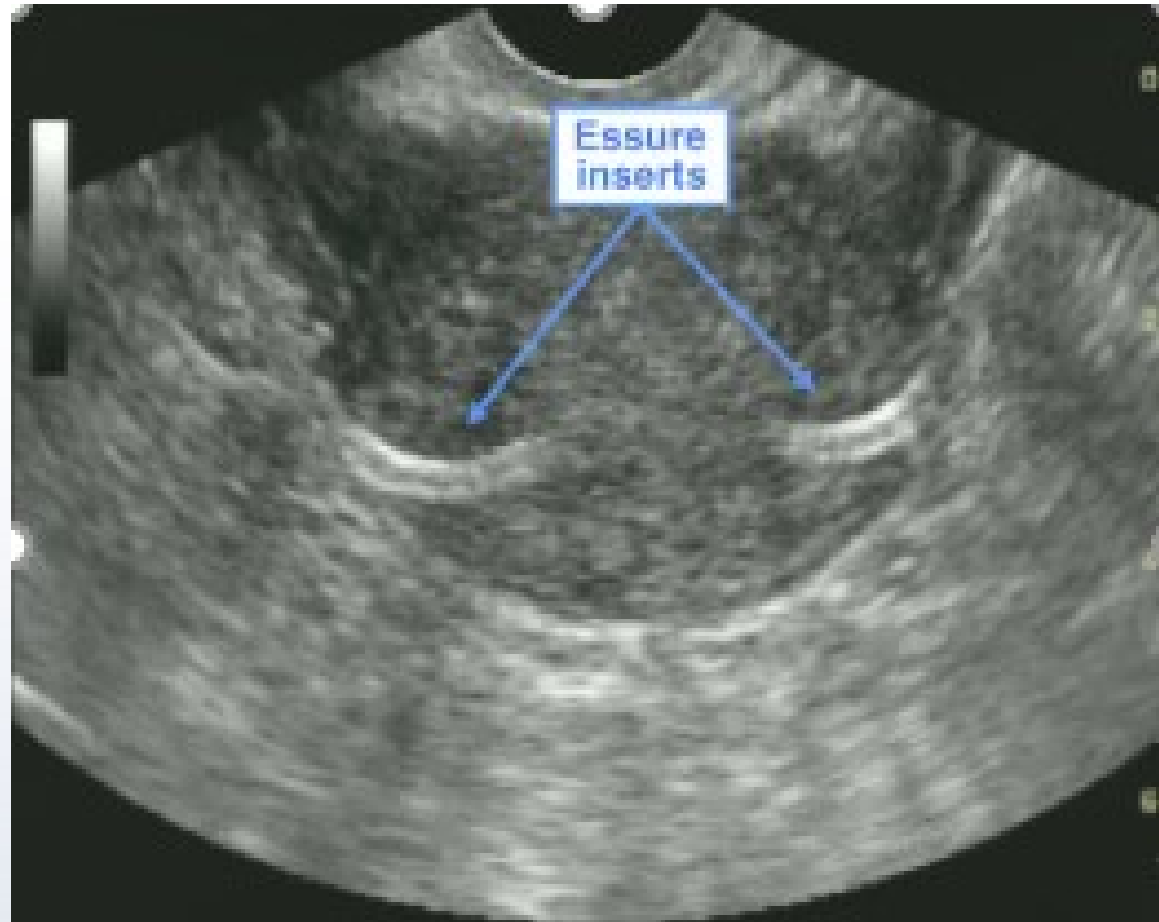
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IDENTIFICATION

Identification



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COMPONENT 3: LOCATION

Location



Determination of Insert Location and Soft Tissue Relationships

- Goal is to determine the location of each insert
 - With targeted transverse imaging
 - To highlight soft tissue relationships
- Maintaining transverse orientation, angle probe to focus on either insert
 - Obtain left/right targeted transverse image
- Identify linear axis of insert as a contiguous echogenic structure (will likely require slight rotation of probe to obtain transverse or oblique transverse view)
 - Mild pressure may be placed on abdominal wall to displace bowel and gently bring adnexa toward probe
 - Suspect unsatisfactory location if linear axis is not visualized (coiled, bent, or elongated configuration suggested)
- Position of insert in the cornua and relationship with the endometrium and SUTJ should be noted

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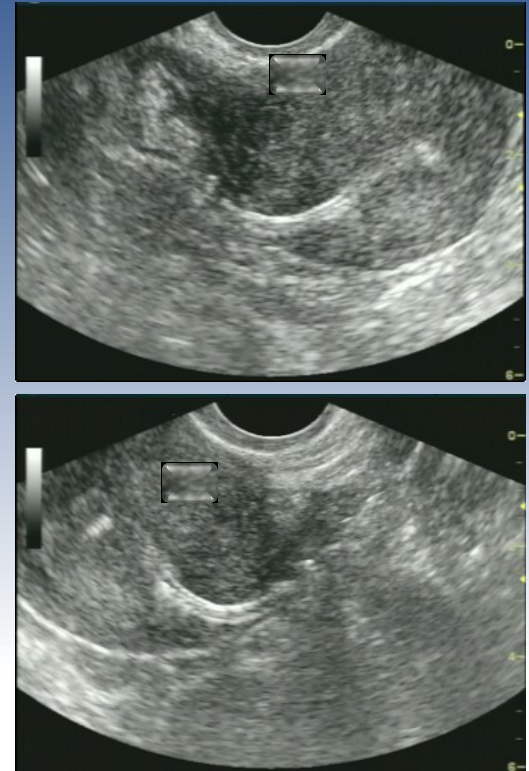
COMPONENT 3: LOCATION (CONT'D)

Location



Capturing Images of the Left and Right Inserts

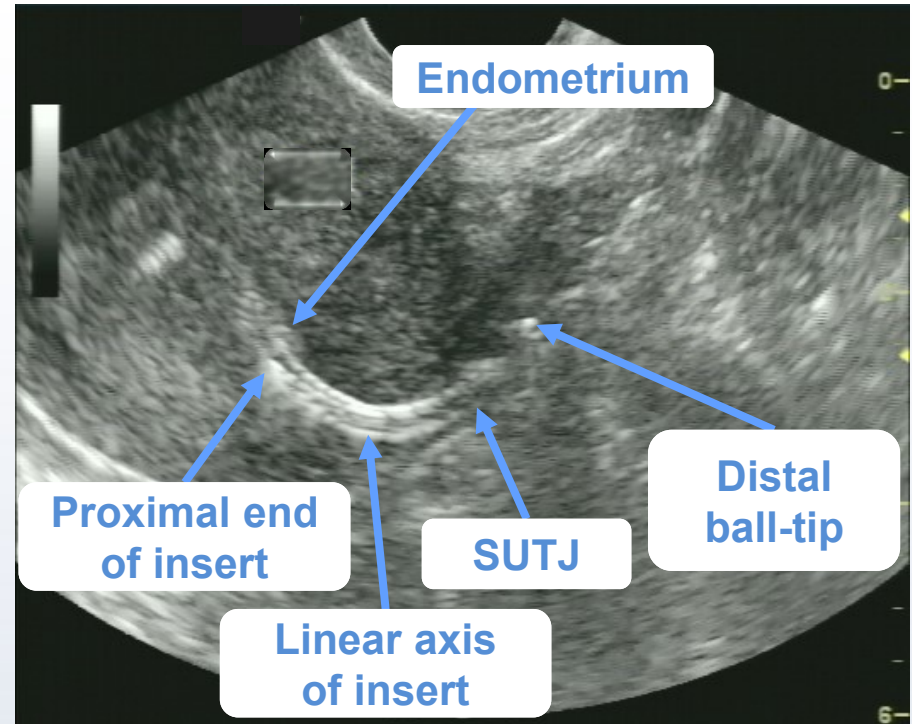
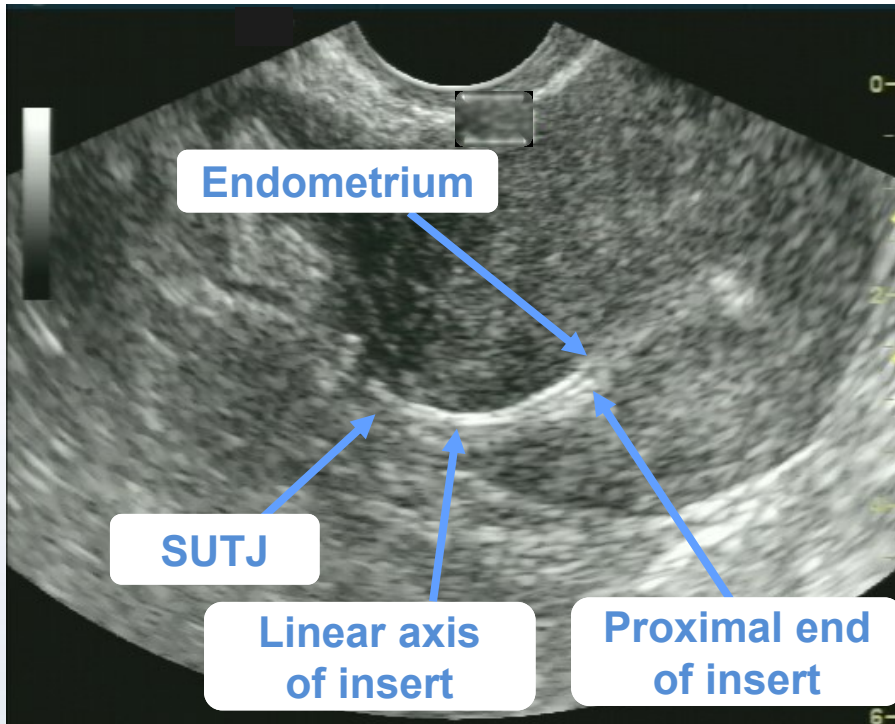
- Image of linear axis of left or right insert in transverse or oblique transverse view
 - Labeled “left” or “right,” accordingly
 - Demonstrates linear axis of insert crossing the myometrium in the cornua OR in contact with the SUTJ
- Repeat process on contralateral side and capture second labeled image



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COMPONENT 3: LOCATION (CONT'D)

Location



Transverse Focused View

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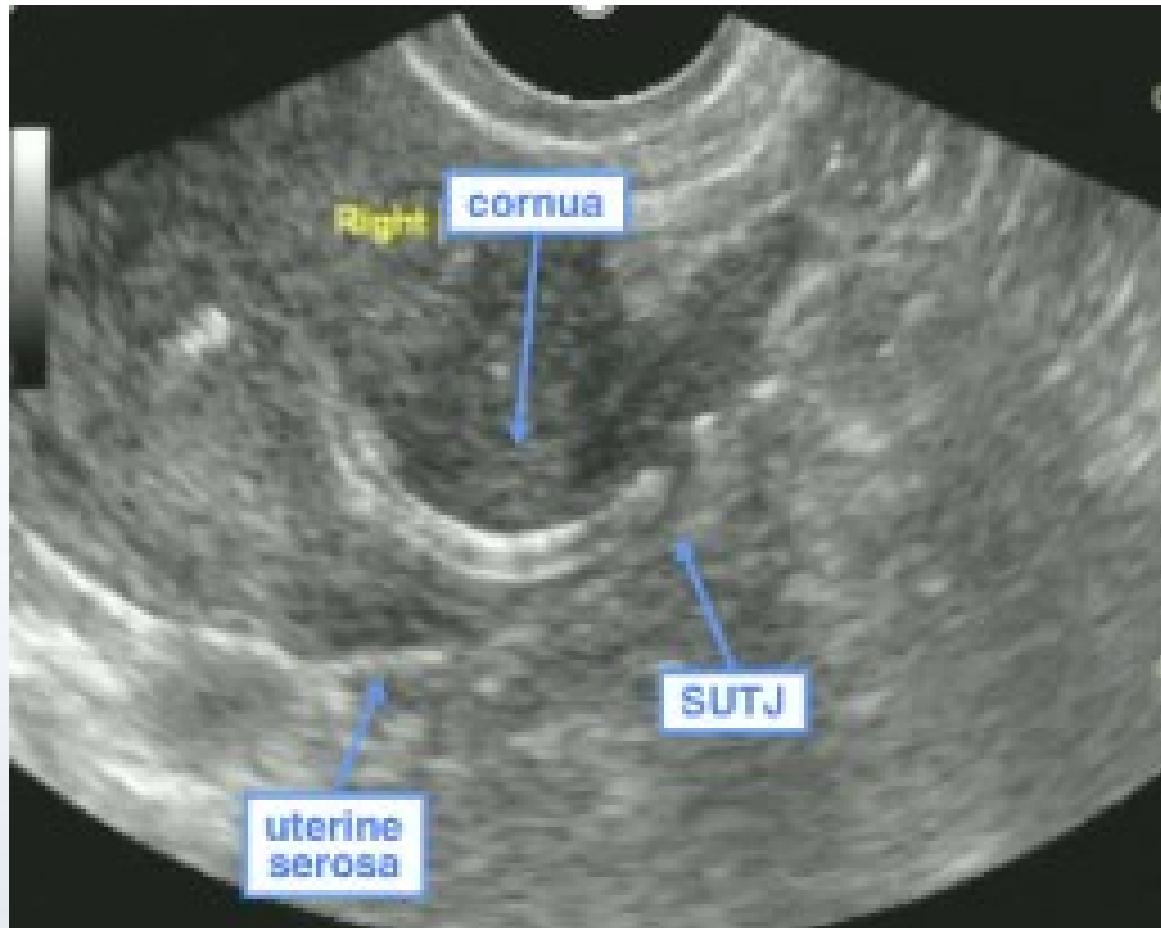
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LOCATION SUMMARY VIDEO

Location



Location video is available under “Example TVU Cases”



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CLASSIFICATION OF INSERT LOCATION WITH TVU

Optimal

Satisfactory

Unsatisfactory

Optimal or satisfactory location of both inserts required for:

- Discontinuation of alternative contraception
- Reliance on Essure® for birth control

Unsatisfactory location of inserts:

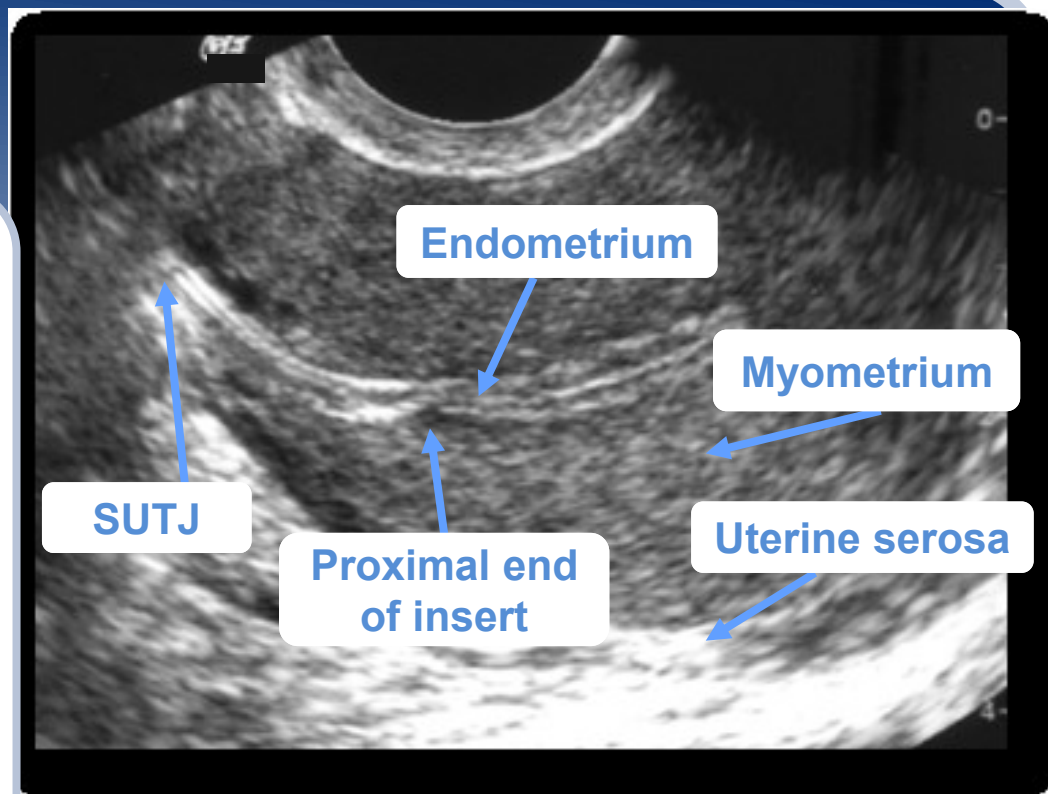
- Patient cannot rely on Essure® for birth control and must remain on alternative contraception
- Patient must proceed to a modified HSG Confirmation Test to evaluate insert location and tubal occlusion

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CLASSIFICATION OF INSERT LOCATION WITH TVU: OPTIMAL

Optimal

- Insert location is optimal when:
 - The proximal end of insert is in contact with uterine cavity or endometrium, and
 - Linear axis is within myometrium in the cornua and can be visualized at or crossing SUTJ
- The portion of insert in the fallopian tube may or may not be visualized
- Linear axis of insert must be visualized to confirm it is not coiled or elongated



Essure® Instructions for Use (with TVU)

Transverse Focused View

Optimal or satisfactory location of both inserts is required for discontinuation of alternative contraception and reliance on Essure® for birth control

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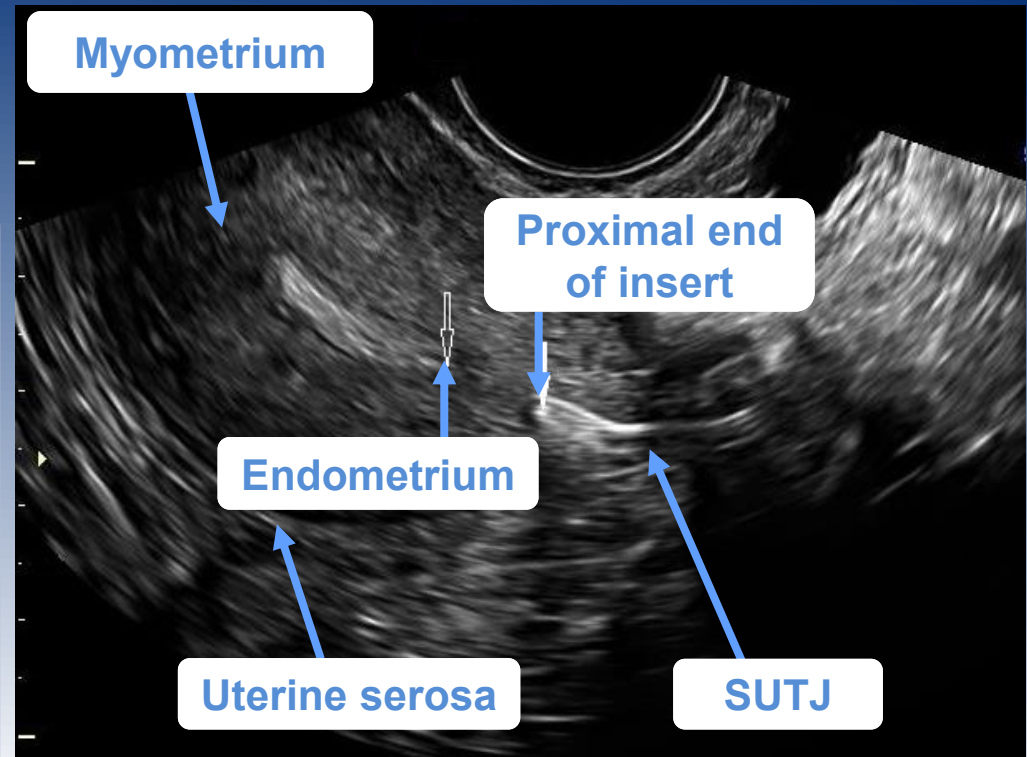


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CLASSIFICATION OF INSERT LOCATION WITH TVU: SATISFACTORY

Satisfactory

- Insert location is satisfactory when:
 - The proximal end of insert is distal to endometrium, but
 - Linear axis is within myometrium in the cornua and can be visualized at or crossing SUTJ
- The portion of insert in the fallopian tube may or may not be visualized
- Linear axis of insert must be visualized to confirm it is not coiled or elongated



Courtesy of Dr. Ian Suchet

Transverse Focused View

Optimal or satisfactory location of both inserts is required for discontinuation of alternative contraception and reliance on Essure® for birth control

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CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

Unsatisfactory

- Insert location is unsatisfactory if:
 - A portion of each insert cannot be visualized in the cornua in the transverse or oblique transverse view in 1 scout image
- If insert location is unsatisfactory:
 - Patient cannot rely on Essure® for birth control and must remain on alternative contraception
 - Patient must proceed to a modified HSG Confirmation Test to evaluate insert location and tubal occlusion

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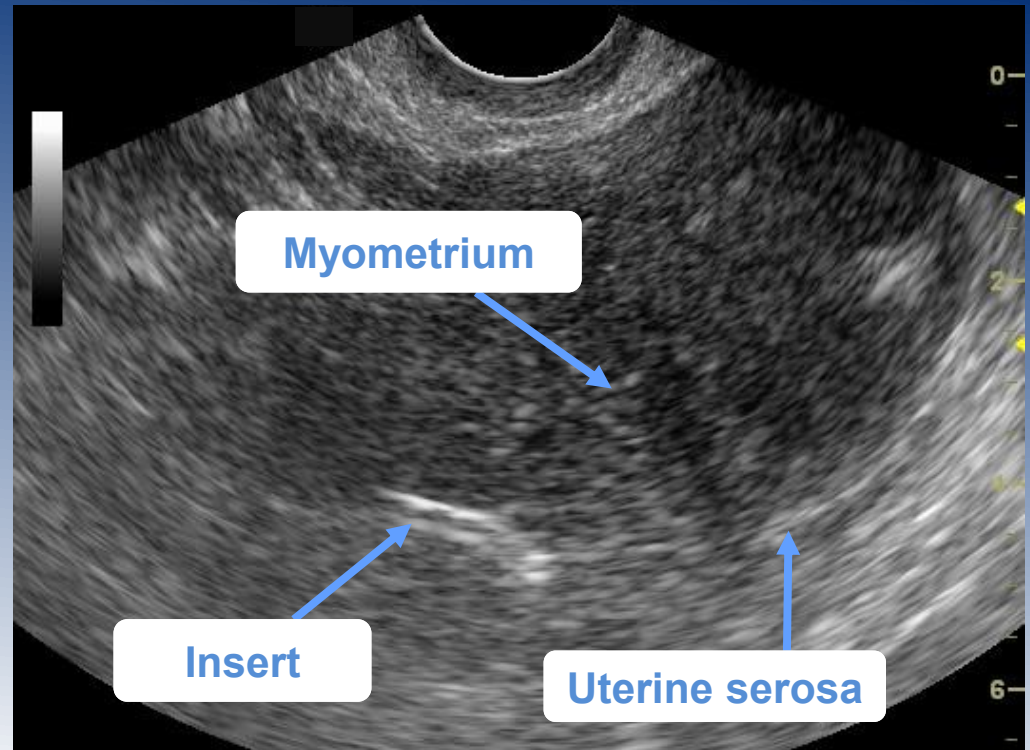
CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

Unsatisfactory

Distal is Suspected

Distal placement is suspected if:

- The proximal end of insert is not located in myometrium in the cornua and
- Is not crossing or in contact with SUTJ



Courtesy of Dr. Viviane Connor

Transverse Focused View

Patient cannot rely on Essure® for birth control and must remain on alternative contraception; patient must proceed to modified HSG to evaluate insert location and tubal occlusion

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CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

Unsatisfactory Proximal is Suspected

- Proximal placement is suspected if greater than 50% or majority of insert is visualized in uterine cavity, or if linear axis of insert(s) is visualized in midline sagittal view
- Distal end of insert must be seen in contact with or crossing SUTJ; if distal end terminates within myometrium, proximal placement is suspected

Orientation



- During Orientation step (midline sagittal view), if linear axis is visualized in uterine cavity, proximal placement should be suspected

Identification



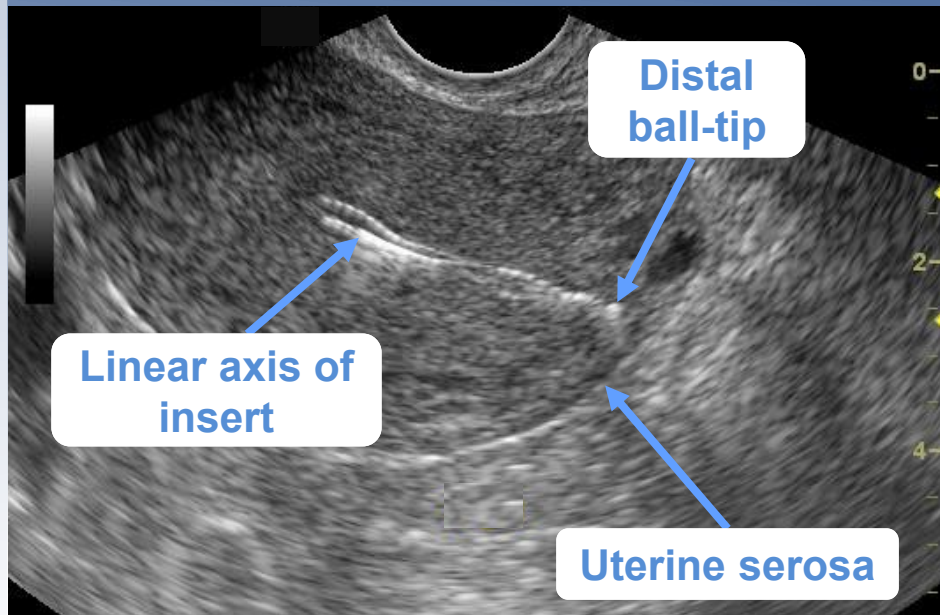
- During Identification step (transverse fundal view), if inserts are in contact with each other, uterine cavity location is suspected

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CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

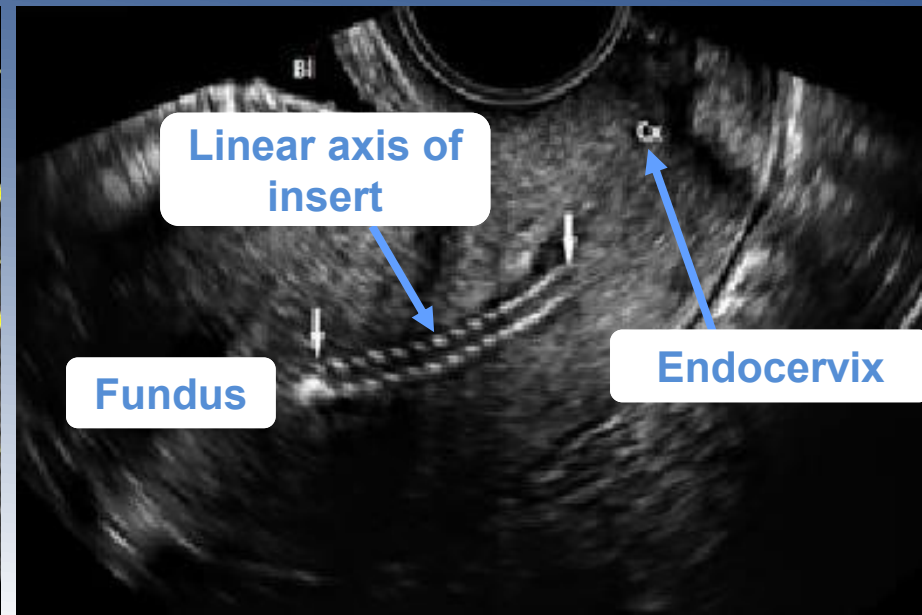
Unsatisfactory

Proximal is Suspected



Courtesy of Dr. Viviane Connor

Transverse Focused View



Courtesy of Dr. Ian Suchet

Midline Sagittal View

Patient cannot rely on Essure® for birth control and must remain on alternative contraception;
patient must proceed to modified HSG to evaluate insert location and tubal occlusion

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CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

Unsatisfactory

Perforation is Suspected

Perforation is suspected if:

- The linear axis of 1 or both inserts are parallel to endometrial stripe in sagittal view, or
- Linear axis of an insert is visualized crossing myometrium in midline sagittal view

Orientation

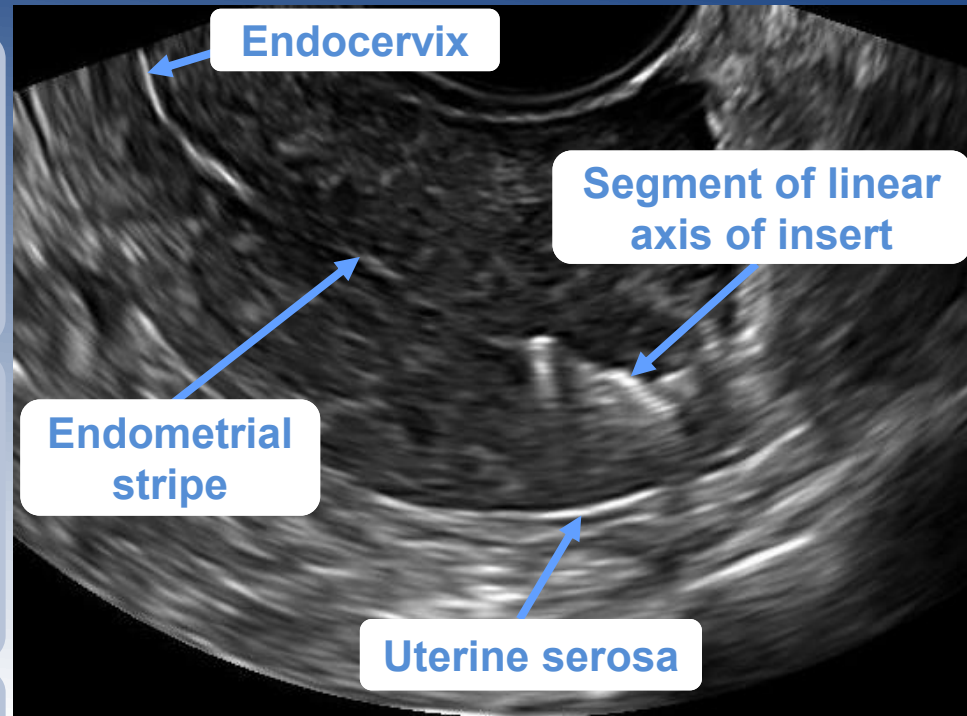


- During Orientation step (midline sagittal view), if linear axis of an insert is visualized in fundal myometrium, fundal perforation should be suspected

Identification



- During Identification step (transverse fundal view), if 0 or only 1 insert is identified, expulsion or perforation should be suspected



Courtesy of Dr. Ian Suchet

Midline Sagittal View

Patient cannot rely on Essure® for birth control and must remain on alternative contraception; patient must proceed to modified HSG to evaluate insert location and tubal occlusion

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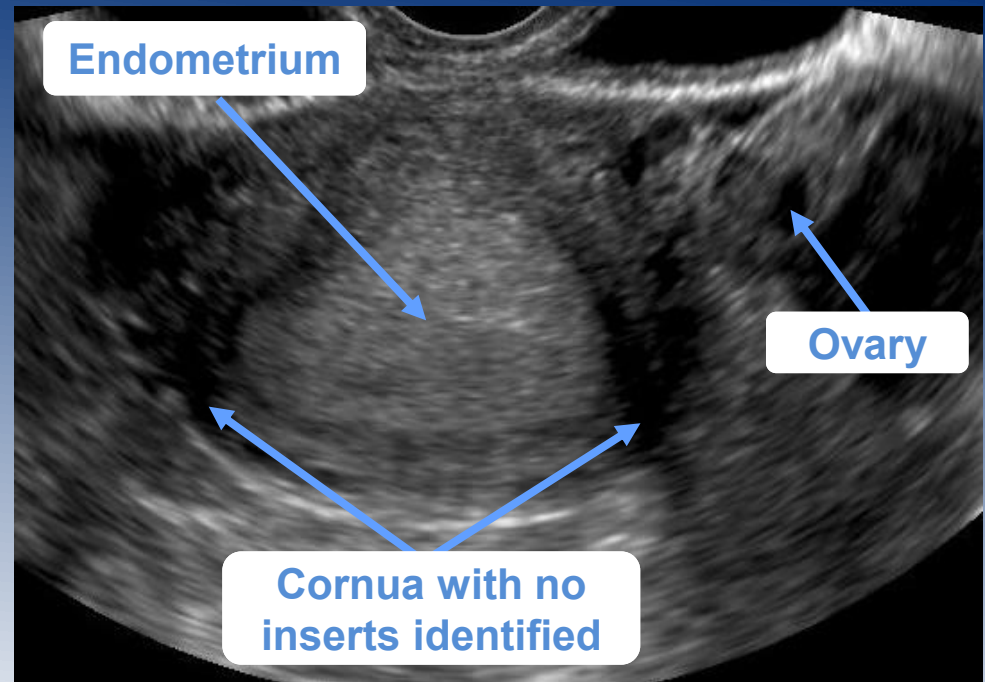
CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

Unsatisfactory

Expulsion is Suspected

Expulsion is suspected if:

- 1 or both inserts are not identified in the cornua in a transverse view in a single TVU scout image
- During Identification step (transverse fundal view), if 0 or only 1 insert is identified, expulsion or perforation should be suspected



Courtesy of Dr. Ian Suchet

Transverse Fundal View

Patient cannot rely on Essure® for birth control and must remain on alternative contraception; patient must proceed to modified HSG to evaluate insert location and tubal occlusion

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CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

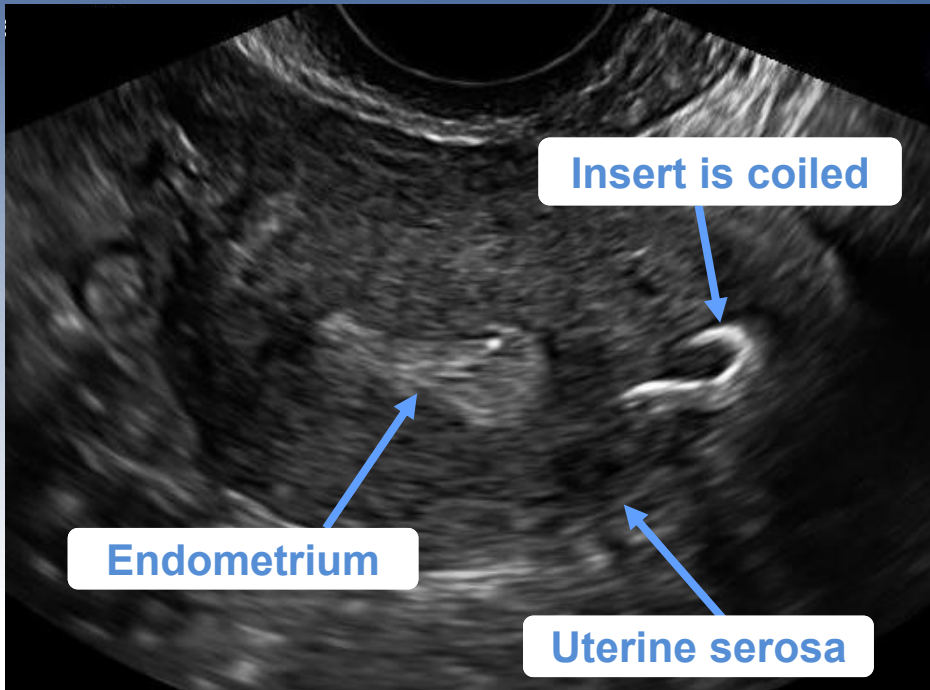
Unsatisfactory Unclassified

- Position is unsatisfactory and unclassified if:
 - Linear axis is not visualized or cannot be identified, suggesting a coiled, bent, or elongated configuration
 - Surrounding soft tissue cannot be clearly defined
- Patient cannot rely on Essure® for birth control and must remain on alternative contraception
- Patient must proceed to modified HSG to evaluate insert location and tubal occlusion

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CLASSIFICATION OF INSERT LOCATION WITH TVU: UNSATISFACTORY

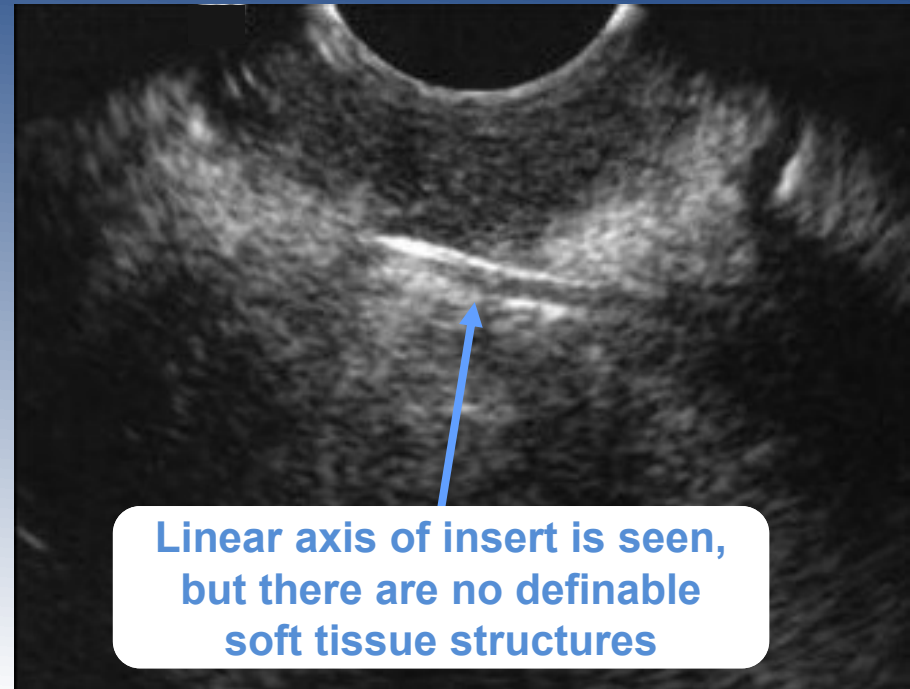
Unsatisfactory



Courtesy of Dr. Ian Suchet

Oblique Transverse View

Unclassified



Courtesy of Dr. Viviane Connor

Transverse View

Patient cannot rely on Essure® for birth control and must remain on alternative contraception;
patient must proceed to modified HSG to evaluate insert location and tubal occlusion

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RECOGNIZING AND MANAGING AN EQUIVOCAL OR UNSATISFACTORY TVU

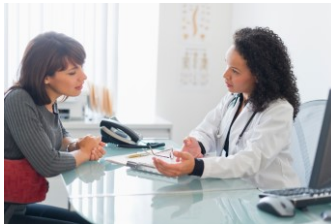
Unsatisfactory

If TVU is equivocal or unsatisfactory, it is important to:



Counsel patient that she cannot rely on Essure® for birth control and should remain on alternative contraception,

AND



Counsel patient that she must proceed to a modified HSG to evaluate insert location and tubal occlusion

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Chapter 3: Performing and Interpreting the Essure Confirmation Test with TVU

REVIEW QUESTIONS

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QUESTION 1

Which of the following must be done before proceeding with a TVU Confirmation Test? Select all correct answers.

- ☐ a. 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).
- ☐ b. Review the Essure TVU/HSG Confirmation Test Algorithm.
- ☐ c. Confirm whether the patient is an appropriate candidate for a TVU Confirmation Test.
- ☐ d. Check whether insert location was evaluated by TVU immediately postinsertion; if so, the patient will not need to undergo the Confirmation Test.

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EXPLANATION TO QUESTION 1

	Statement	Answer	Explanation
A	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).	CORRECT	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).
B	Review the Essure TVU/HSG Confirmation Test Algorithm.	CORRECT	Before proceeding with a TVU Confirmation Test, the procedure note and the Essure TVU/HSG Confirmation Test Algorithm must first be reviewed to determine whether the patient is a candidate for a TVU Confirmation Test.
C	Confirm whether the patient is an appropriate candidate for a TVU Confirmation Test.	CORRECT	
D	Check whether insert location was evaluated by TVU immediately postinsertion; if so, the patient will not need to undergo the Confirmation Test.	INCORRECT	The Essure Confirmation Test should be performed at 3 months postplacement, even if insert location was evaluated immediately postinsertion or at a postprocedure visit prior to 3 months postplacement.

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QUESTION 2

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

- ☐ a. A minimum of 3 required images must be captured during the performance of a TVU confirmation test at 3 months post-placement.
- ☐ b. The TVU scout image is a transverse fundal view demonstrating a portion of each insert in the cornua.
- ☐ c. A TVU scout image is not required if transverse or oblique transverse images of the left and right inserts are captured and documented.
- ☐ d. The images of the left and right insert must demonstrate the linear axis crossing the interstitial portion of the fallopian tube or in contact with the SUTJ.

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EXPLANATION TO QUESTION 2

	Statement	Answer	Explanation
A	A minimum of 3 required images must be captured during the performance of a TVU confirmation test at 3 months post-placement.	TRUE	A minimum of 3 required images must be captured during the performance of a TVU confirmation test at 3 months post-placement.
B	The TVU scout image is a transverse fundal view demonstrating a portion of each insert in the cornua.	TRUE	The scout image demonstrates a portion of each insert in the cornua in a transverse or oblique transverse view.
C	A TVU scout image is not required if transverse or oblique transverse images of the left and right inserts are captured and documented.	FALSE	The TVU scout image is required for documenting the presence of 2 inserts in a single image, thereby reducing the risk of duplicate imaging of the same insert.
D	The images of the left and right insert must demonstrate the linear axis crossing the interstitial portion of the fallopian tube or in contact with the SUTJ.	TRUE	The “left” and “right” insert images demonstrate, in a transverse or oblique transverse view, the linear axes of the inserts including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the SUTJ.

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QUESTION 3

For each underlined pair of words/phrases, select the correct one to complete the statements below.

Assessment of uterine orientation is typically done in a midline transverse / sagittal view.

In this view, the linear axis of either insert should / should not be visualized.

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EXPLANATION TO QUESTION 3

Statement	Answer	Explanation
Assessment of uterine orientation is typically done in a midline <u>transverse</u> / <u>sagittal</u> view.	SAGITTAL	In the “Orientation” step, uterine orientation is assessed in the midline sagittal view.
In this view, the linear axis of either insert <u>should</u> / <u>should not</u> be visualized.	SHOULD NOT	If the linear axis of the insert(s) is visualized in the midline sagittal view, proximal placement is suspected.

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QUESTION 4

For each underlined pair of words/phrases, select the correct one to complete the statements below.

Identification of the inserts is typically done in the fundal

transverse / sagittal view and should be documented in

a single image / separate images. If 0 or only 1 insert is identified,

perforation or expulsion / proximal location should be suspected.

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EXPLANATION TO QUESTION 4

Choice	Answer	Explanation
Identification of the inserts is typically done in the fundal <u>transverse</u> / <u>sagittal</u> view and should be documented in <u>a single image</u> / <u>separate images</u> .	TRANSVERSE A SINGLE IMAGE	In the “Identification” step, visualization of a portion of both inserts simultaneously should be documented in the fundal transverse view in a single image to reduce the risk of duplicate imaging of the same insert.
If 0 or only 1 insert is identified, <u>perforation or expulsion</u> / <u>proximal location</u> should be suspected.	PERFORATION OR EXPULSION	If 0 or only 1 insert is identified, expulsion or perforation should be suspected.

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QUESTION 5

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

True False

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | a. Assessment of insert location is done using targeted transverse or oblique transverse imaging. |
| <input type="checkbox"/> | <input type="checkbox"/> | b. An image of each insert should be captured and labeled “left” and “right”, accordingly. |
| <input type="checkbox"/> | <input type="checkbox"/> | c. As long as a location image showing the linear axis of the insert is captured, the relationship of the insert to the surrounding soft tissue does not have to be documented. |
| <input type="checkbox"/> | <input type="checkbox"/> | d. A coiled or elongated insert suggests an unsatisfactory insert location. |

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EXPLANATION TO QUESTION 5

	Statement	Answer	Explanation
A	Assessment of insert location is done using targeted transverse or oblique transverse imaging.	TRUE	The “left” and “right” insert images demonstrate the linear axes of the inserts including the proximal end crossing the myometrium in the cornua (interstitial portion of the fallopian tube) or in contact with the SUTJ in a transverse or oblique transverse view.
B	An image of each insert should be captured and labeled “left” and “right”, accordingly.	TRUE	These images should be labeled “left” or “right” accordingly and placed in the patient’s medical record, along with the scout image, to document satisfactory insert retention and location.
C	As long as a location image showing the linear axis of the insert is captured, the relationship of the insert to the surrounding soft tissue does not have to be documented.	FALSE	The image should document the soft tissue relationships with the linear axis of the insert.
D	A coiled or elongated insert suggests an unsatisfactory insert location.	TRUE	If the linear axis of an insert cannot be identified, suggesting it is coiled, bent or elongated, insert location is considered unsatisfactory.

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QUESTION 6

For each term in the left column, draw a line to the correct definition from the right column.

Distal
is suspected

One or both inserts are not identified in the cornua in a transverse view in a single TVU scout image.

Proximal
is suspected

The linear axis of 1 or both inserts are parallel to the endometrial stripe in the sagittal view, or the linear axis is visualized crossing the myometrium in the midline sagittal view.

Perforation
is suspected

The proximal end of the insert is not located in the myometrium in the cornua, and is not crossing or in contact with the SUTJ.

Expulsion
is suspected

Greater than 50% or the majority of the insert is visualized in the uterine cavity, or the linear axis is visualized in the midline sagittal view.

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EXPLANATION TO QUESTION 6

Term	Definition	Explanation
Distal is suspected	The proximal end of the insert is not located in the myometrium in the cornua, and is not crossing or in contact with the SUTJ.	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.
Proximal is suspected	Greater than 50% or the majority of the insert is visualized in the uterine cavity, or the linear axis is visualized in the midline sagittal view.	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.
Perforation is suspected	The linear axis of 1 or both inserts are parallel to the endometrial stripe in the sagittal view, or the linear axis is visualized crossing the myometrium in the midline sagittal view.	Perforation is suspected if the linear axis of 1 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.
Expulsion is suspected	One or both inserts are not identified in the cornua in a transverse view in a single TVU scout image.	Expulsion is suspected if 1 or both inserts are not identified in the cornua in a transverse view in a single scout image.

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