



# ESSURE CONFIRMATION TEST WITH TRANSVAGINAL ULTRASOUND (TVU)

## Chapter 4: Example of TVU Confirmation Test

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PP-250-US-1388

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## eLEARNING MODULE: CHAPTERS

Overview of the  
Essure TVU/HSG  
Confirmation Test  
Algorithm

1

Understanding an  
Essure Confirmation  
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Performing and  
Interpreting the Essure  
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TVU

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## CHAPTER 4: Example of TVU Confirmation Test

### Example: TVU Confirmation Test

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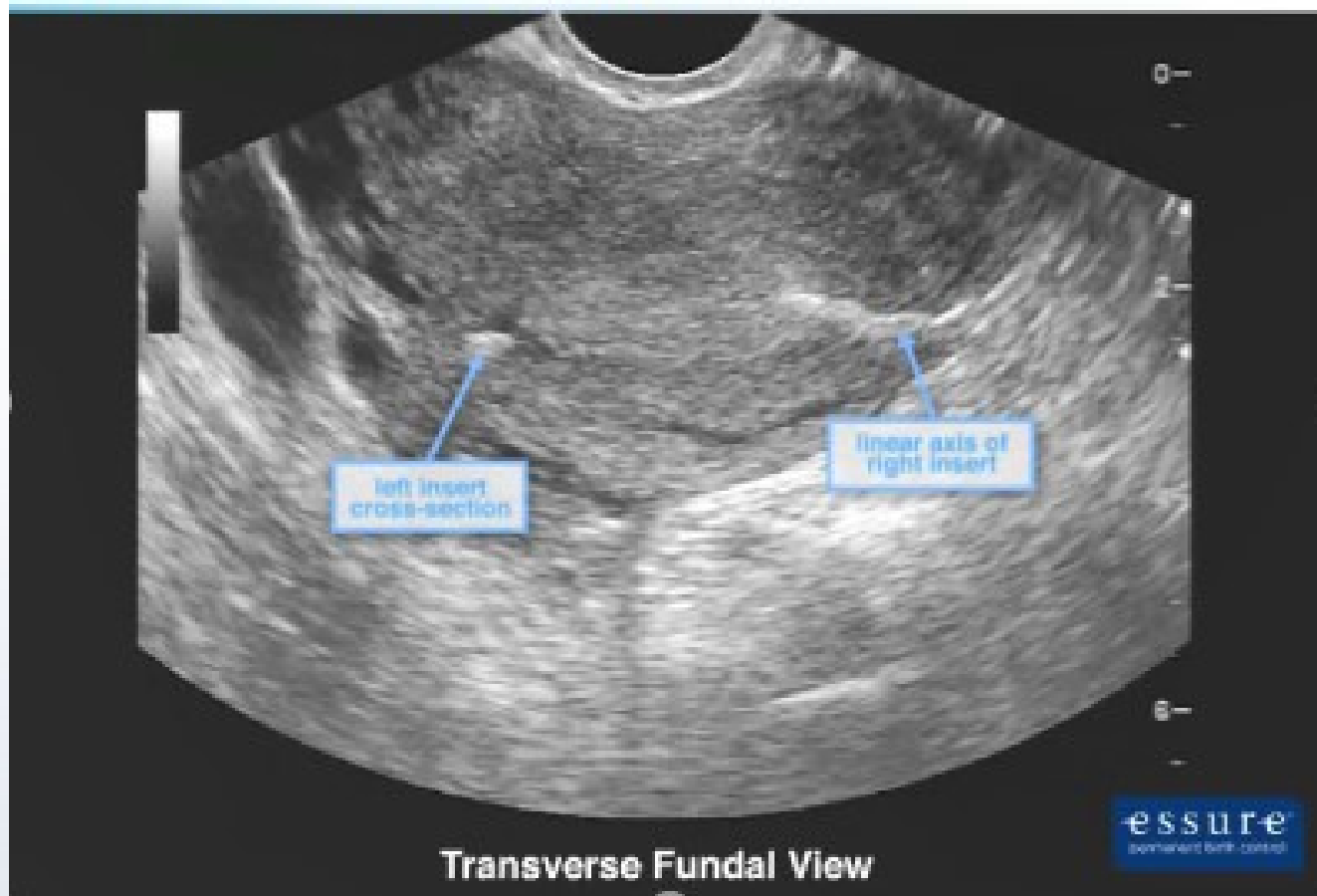
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## TVU CONFIRMATION TEST: EXAMPLE

### EXAMPLE 2: IDENTIFICATION



Video  
available  
under  
“TVU Case  
Examples”

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## THE ESSURE CONFIRMATION TEST WITH TVU: SUMMARY

TVU Confirmation  
Test in Clinical Study  
(3 months  
postplacement)

Orientation



Identification



Location



Capture a Minimum of  
3 Required Images

TVU  
Scout Image

Image of  
Left Insert

Image of  
Right Insert

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## Chapter 4: Examples of TVU Confirmation Tests REVIEW QUESTIONS

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## QUESTION 1

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

True False

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | a. The Essure Confirmation Test, either using TVU or a modified HSG, is required for all patients at 3 months postplacement.   |
| <input type="checkbox"/> | <input type="checkbox"/> | b. Consistent with the TVU/HSG Confirmation Test Algorithm, if the patient meets the criteria for TVU as a first-line option, she must proceed to a TVU Confirmation Test. |
| <input type="checkbox"/> | <input type="checkbox"/> | c. If bilateral insert location is satisfactory based on a modified HSG but 1 or both fallopian tubes are patent, the patient should proceed to a TVU Confirmation Test.   |
| <input type="checkbox"/> | <input type="checkbox"/> | d. If the TVU Confirmation Test shows both inserts in either optimal or satisfactory position, the patient may rely on Essure® for birth control.                          |

**Submit Answers**

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## EXPLANATION TO QUESTION 1

	Statement	Answer	Explanation
A	The Essure Confirmation Test, either using TVU or a modified HSG, is required for all patients at 3 months postplacement.	TRUE	An Essure Confirmation Test should be performed at 3 months postplacement to evaluate insert retention and location.
B	Consistent with the TVU/HSG Confirmation Test Algorithm, if the patient meets the criteria for TVU as a first-line option, she must proceed to a TVU Confirmation Test.	FALSE	A patient may proceed directly to a modified HSG Confirmation Test even if she meets the criteria for a TVU Confirmation Test.
C	If bilateral insert location is satisfactory based on a modified HSG but 1 or both fallopian tubes are patent, the patient should proceed to a TVU Confirmation Test.	FALSE	If insert location is satisfactory but tubal occlusion is unsatisfactory based on a modified HSG, the patient should be counseled to remain on alternative contraception and the Essure Confirmation Test using a modified HSG should be repeated in 3 months. If occlusion is still unsatisfactory, the patient should be instructed to not rely on Essure® for birth control.
D	If the TVU Confirmation Test shows both inserts in either optimal or satisfactory position, the patient may rely on Essure® for birth control.	TRUE	The Essure Confirmation Test must show bilateral satisfactory insert location when using TVU before the patient can rely on Essure® for birth control.

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## QUESTION 2

**A patient has just had an Essure Confirmation Test using TVU, with equivocal results. What should she be told? Select all correct answers.**

- ☐ a. Come back in 3 months and we will repeat the TVU Confirmation Test then.
- ☐ b. We'll need to schedule an appointment for you to have a Confirmation Test using a modified HSG to evaluate insert location and tubal occlusion.
- ☐ c. Some patients have successfully relied on Essure® without having had a satisfactory Confirmation Test, so you can probably do so, too.
- ☐ d. You must continue to use an alternative form of contraception.

**Submit Answers**

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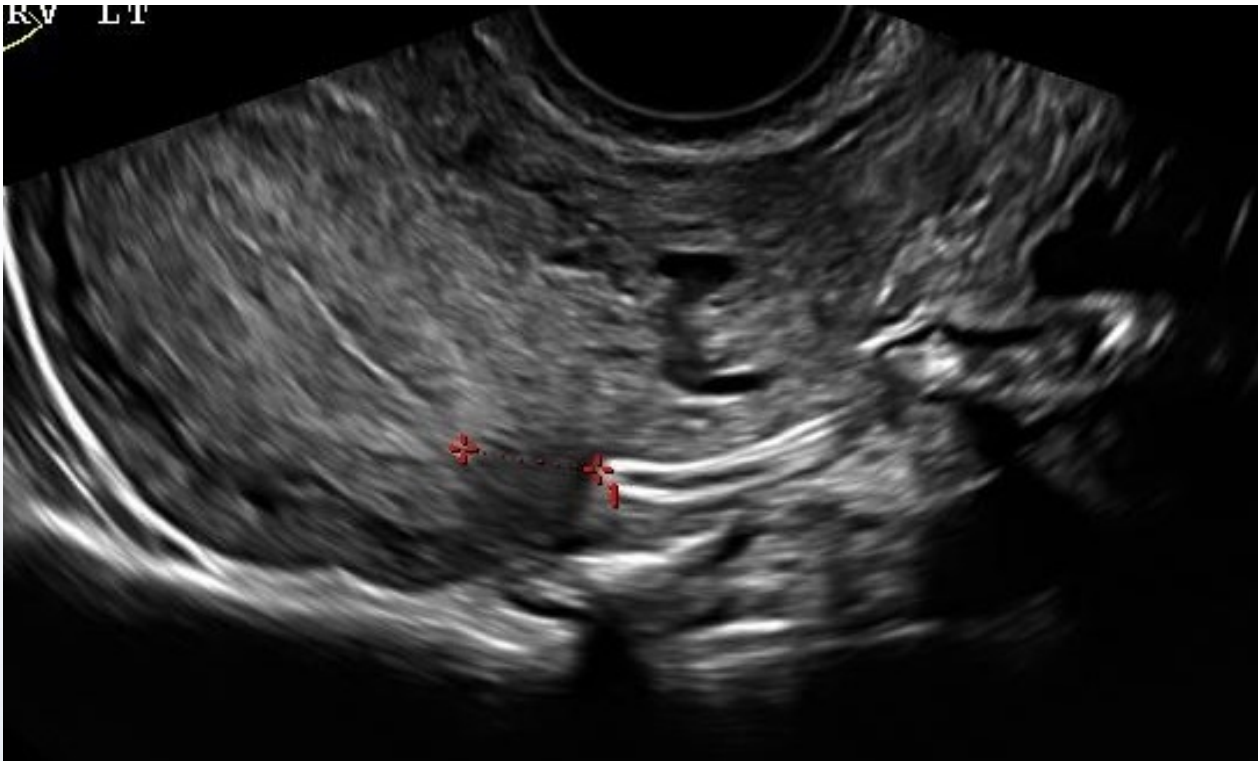
## EXPLANATION TO QUESTION 2

	Question	Answer	Explanation
A	Come back in 3 months and we will repeat the TVU Confirmation Test then.	<b>INCORRECT</b>	A patient who has a TVU Confirmation Test with equivocal results must proceed to a modified HSG to evaluate insert location and tubal occlusion.
B	We'll need to schedule an appointment for you to have a Confirmation Test using a modified HSG to evaluate insert location and tubal occlusion.	<b>CORRECT</b>	The patient must proceed to a modified HSG to evaluate bilateral insert location and tubal occlusion.
C	Some patients have successfully relied on Essure® without having had a satisfactory Confirmation Test, so you can probably do so, too.	<b>INCORRECT</b>	An Essure Confirmation Test demonstrating bilateral satisfactory insert location when using TVU, or both bilateral satisfactory insert location and occlusion when using a modified HSG, must be completed before the patient can rely on Essure® for birth control.
D	You must continue to use an alternative form of contraception.	<b>CORRECT</b>	The patient must continue using an alternative form of contraception until she has had a satisfactory Essure Confirmation Test.

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QUESTION 3

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Ian Suchet

Transverse Focused View

Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

Submit Answer

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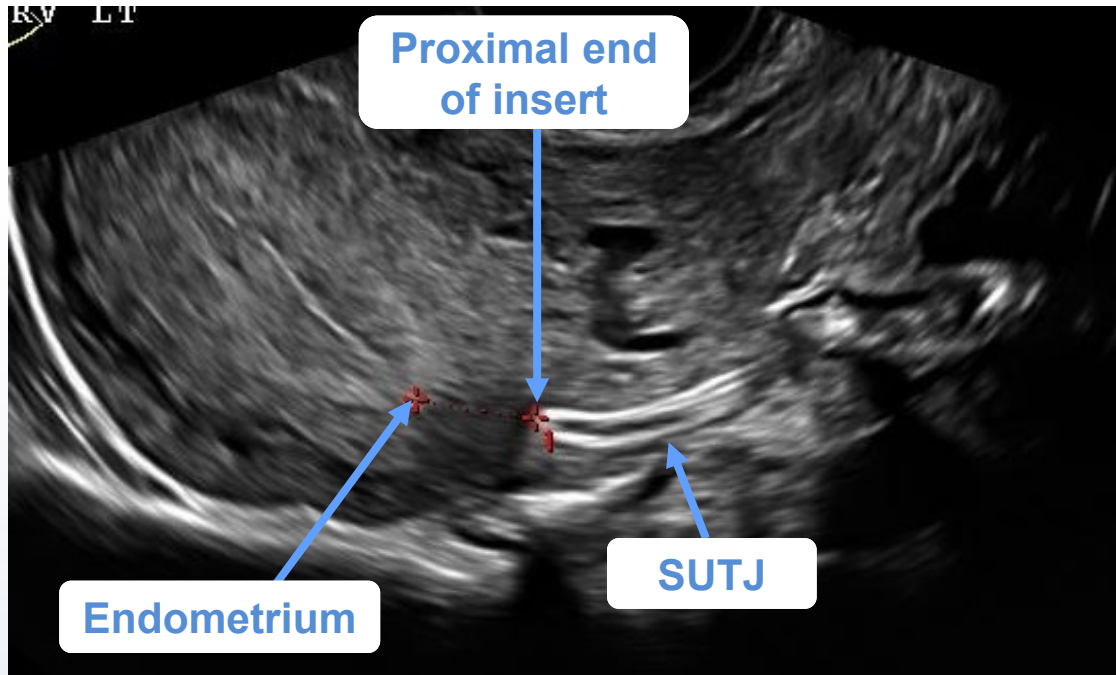
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## EXPLANATION TO QUESTION 3

### Essure® insert location is satisfactory.



Courtesy of  
Dr. Ian Suchet

### Transverse Focused View

- This image shows satisfactory placement of the Essure® insert.
- 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 SUTJ.
- As with an optimal TVU Confirmation Test, the portion of the insert located in the fallopian tube may or may not be visualized.
- Again, the linear axis of the insert must be visualized to confirm it is not coiled or elongated.
- The endometrium and the proximal end of the insert are identified here and there is some space between the 2 structures, which are not in contact. Thus, this is an image of a satisfactory location.

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QUESTION 4

Please classify the type of location of the Essure® insert.



Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

Submit Answer

Courtesy of  
Dr. Ian Suchet

**Transverse Focused View**

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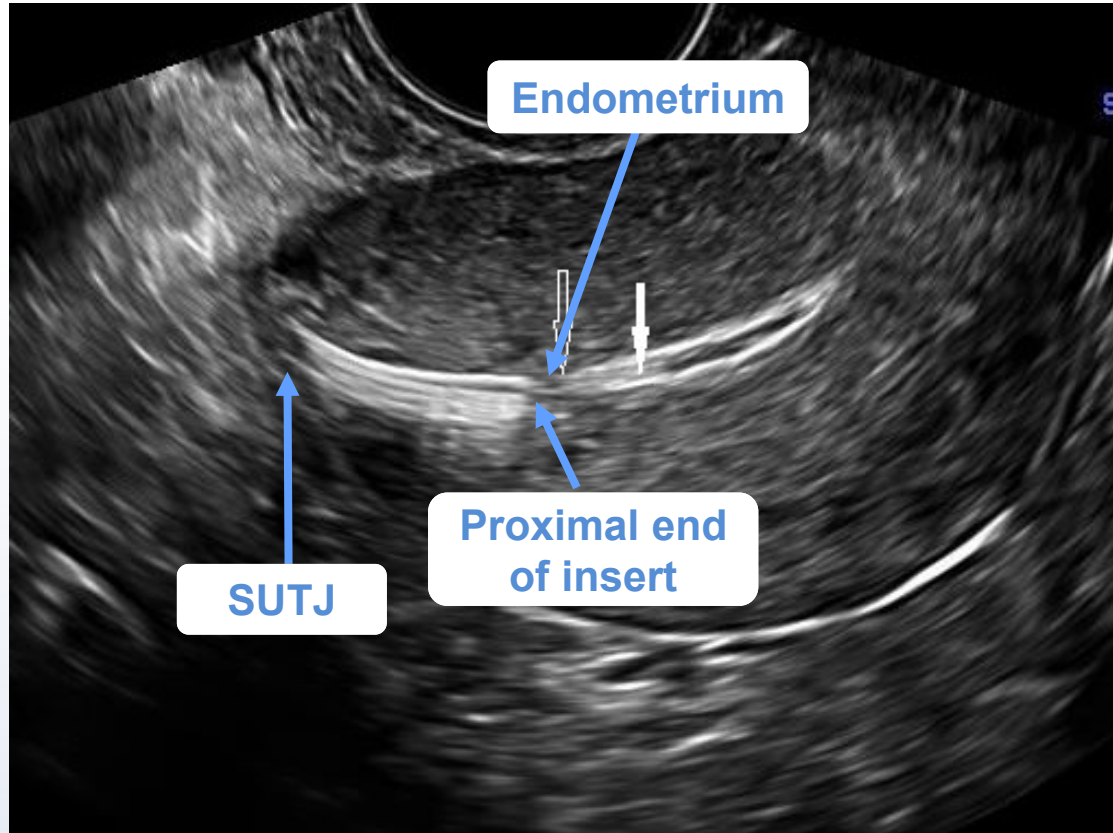


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## EXPLANATION TO QUESTION 4

### Essure® insert location is optimal.



Courtesy of  
Dr. Ian Suchet

### Transverse Focused View

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- This image shows optimal placement of the Essure® insert.
- Insert location is optimal when, in the transverse or oblique transverse view,
  - 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 SUTJ.
- Note that 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 as a contiguous linear echogenic structure to confirm it is not coiled or elongated.
- The endometrium is visualized here and the proximal end of the insert is noted making contact with the endometrium.

QUESTION 5

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Viviane Connor

**Transverse Focused View**

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Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

Submit Answer

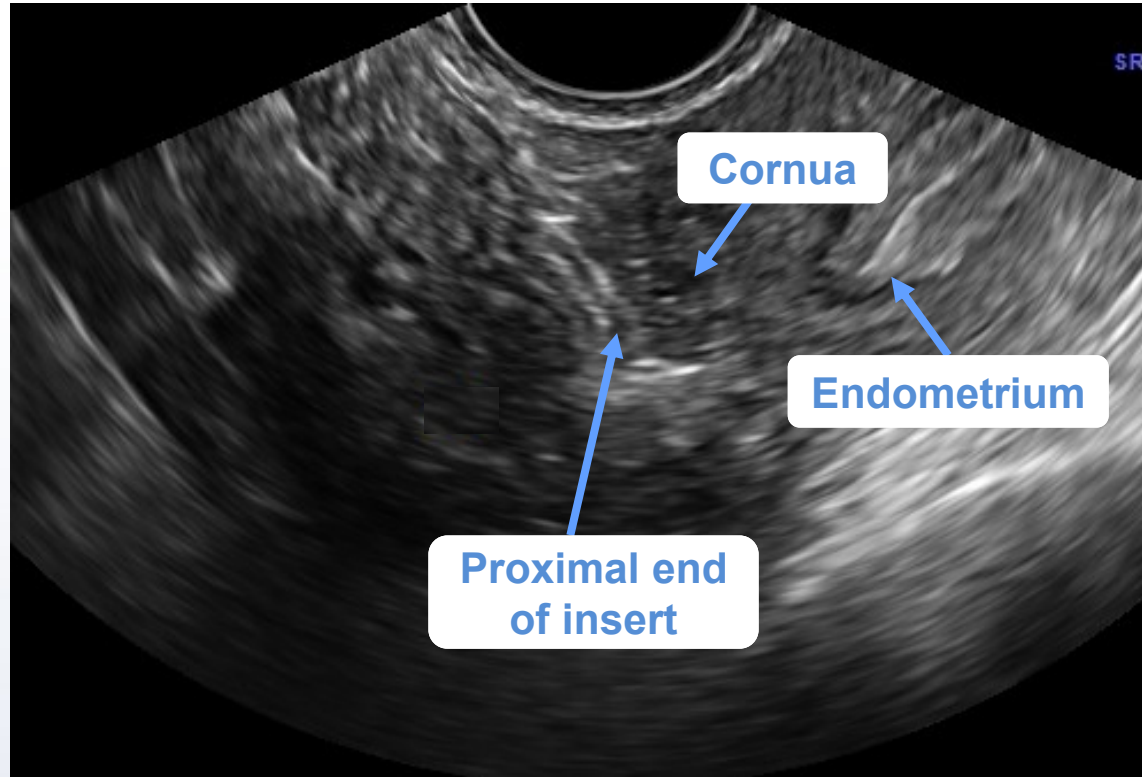
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## EXPLANATION TO QUESTION 5

### Essure® insert location is unsatisfactory: distal is suspected.



Courtesy of  
Dr. Viviane Connor

#### Transverse Focused View

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

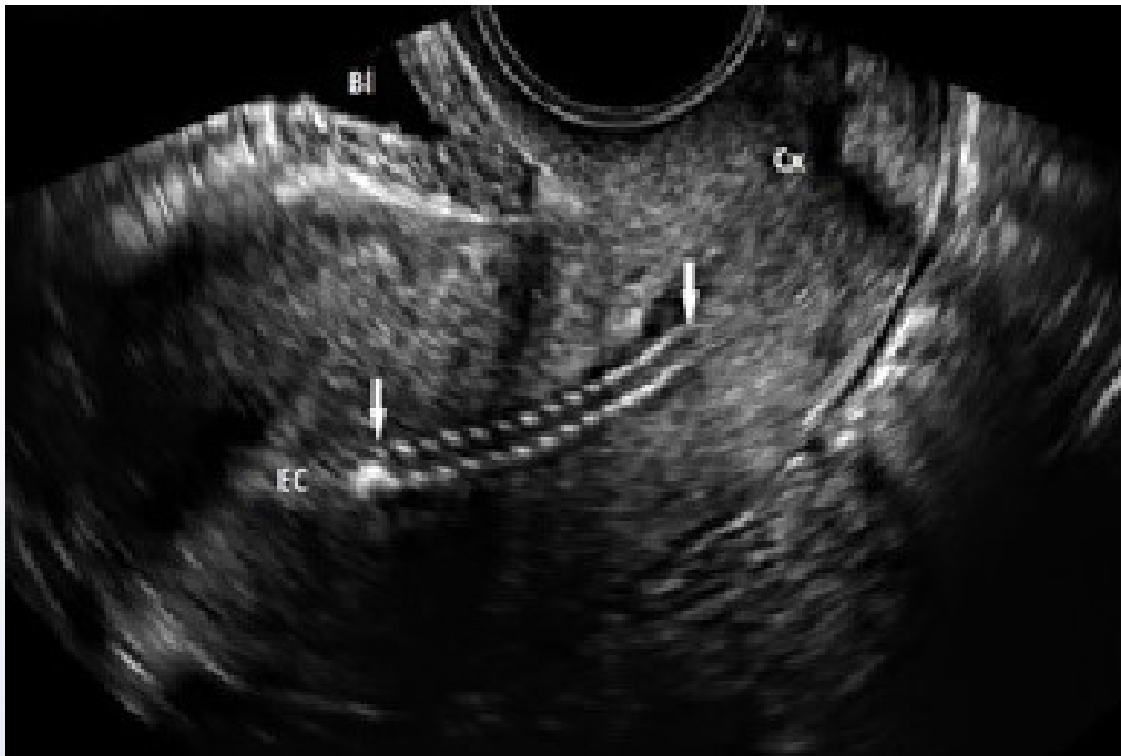
- This image shows unsatisfactory location of the Essure® insert, with distal placement suspected.
- Distal placement is suspected if the proximal end of the insert is not located in the myometrium in the cornua (interstitial portion of the fallopian tube), and is not crossing or in contact with the SUTJ.
- The width and prominence of the endometrial cavity suggest that we are at the level of the cornua. The myometrium in the cornua is well-defined lateral to the endometrial cavity, but the insert is even more distal and its proximal end is not located in the cornua.

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QUESTION 6

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Ian Suchet

Midline Sagittal View

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Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

Submit Answer

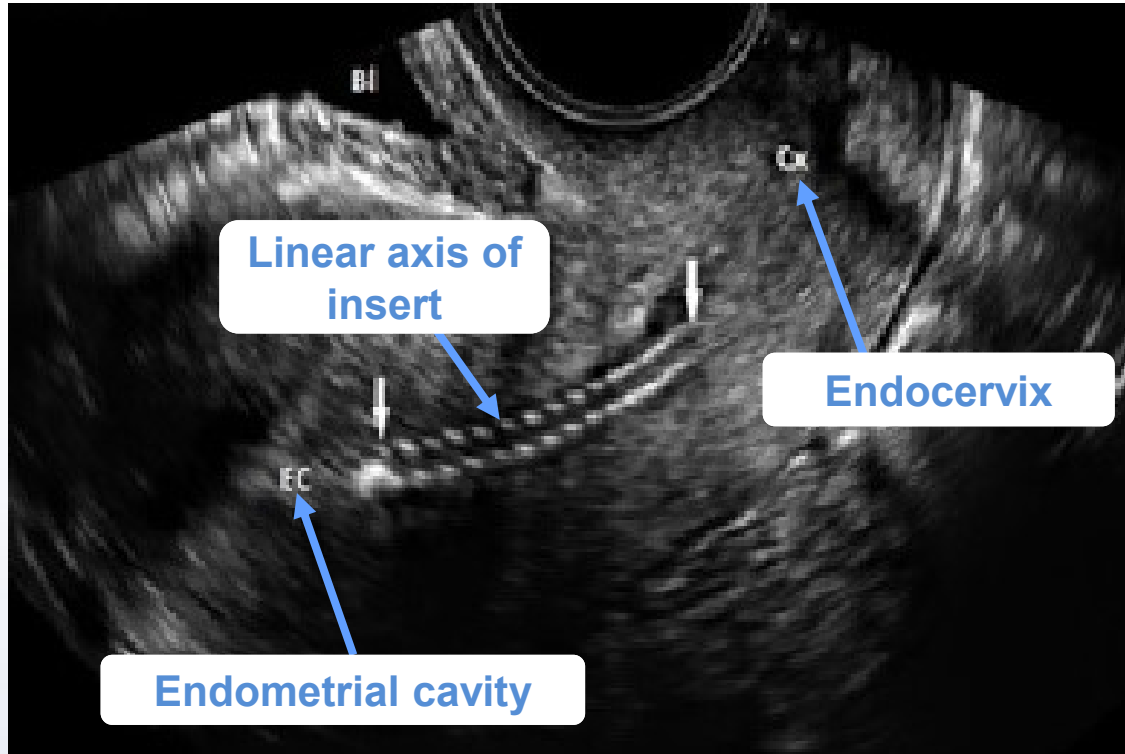
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## EXPLANATION TO QUESTION 6

### Essure® insert location is unsatisfactory: proximal is suspected.



Courtesy of  
Dr. Ian Suchet

#### Midline Sagittal View

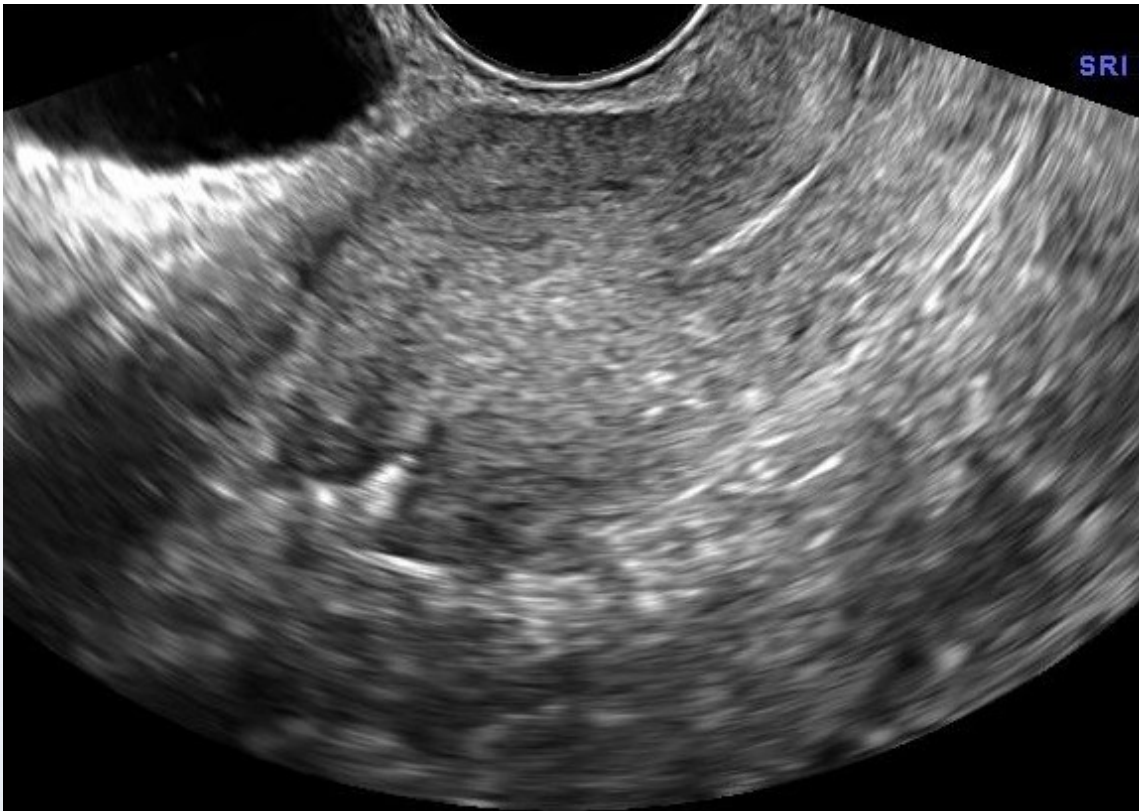
The patient cannot rely on Essure® for birth control and must remain on alternative contraception. The patient must proceed to a modified HSG Confirmation Test to evaluate insert location and tubal occlusion.

- This image shows unsatisfactory placement of the Essure® insert, with proximal placement suspected.
- Proximal placement is suspected if >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.
- It is important to recognize this as a view in the midline sagittal plane, and that the linear axis of the insert is very clear and lies within the endometrial cavity.

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QUESTION 7

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Ian Suchet

**Midline Sagittal View**

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Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

**Submit Answer**

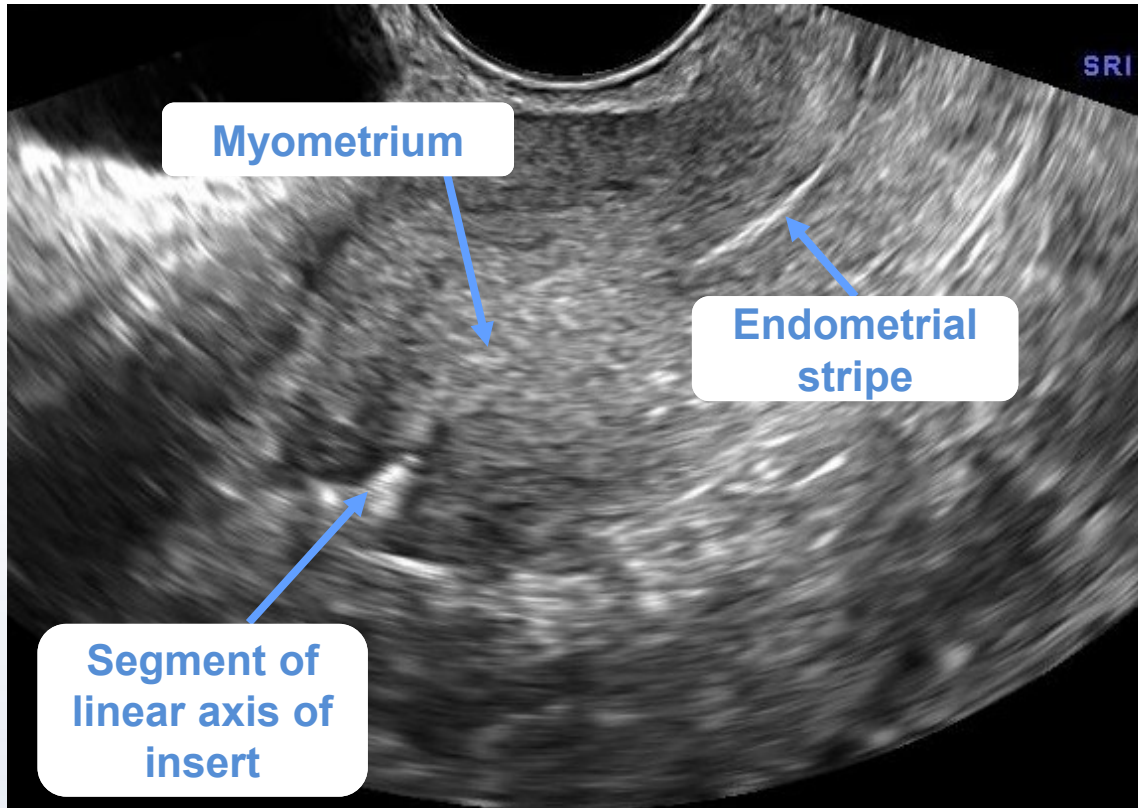
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## EXPLANATION TO QUESTION 7

### Essure® insert location is unsatisfactory: suggestive of perforation.



Courtesy of  
Dr. Ian Suchet

#### Midline Sagittal View

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

- This image shows unsatisfactory location of the Essure® insert, with perforation suspected.
- 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.
- Per the IFU, the description of a suspected perforation is limited to visualization in the sagittal plane. Here, the linear axis of the insert is crossing the myometrium and is also parallel to the endometrial stripe.

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QUESTION 8

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Ian Suchet

**Transverse Fundal View**

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Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

Submit Answer

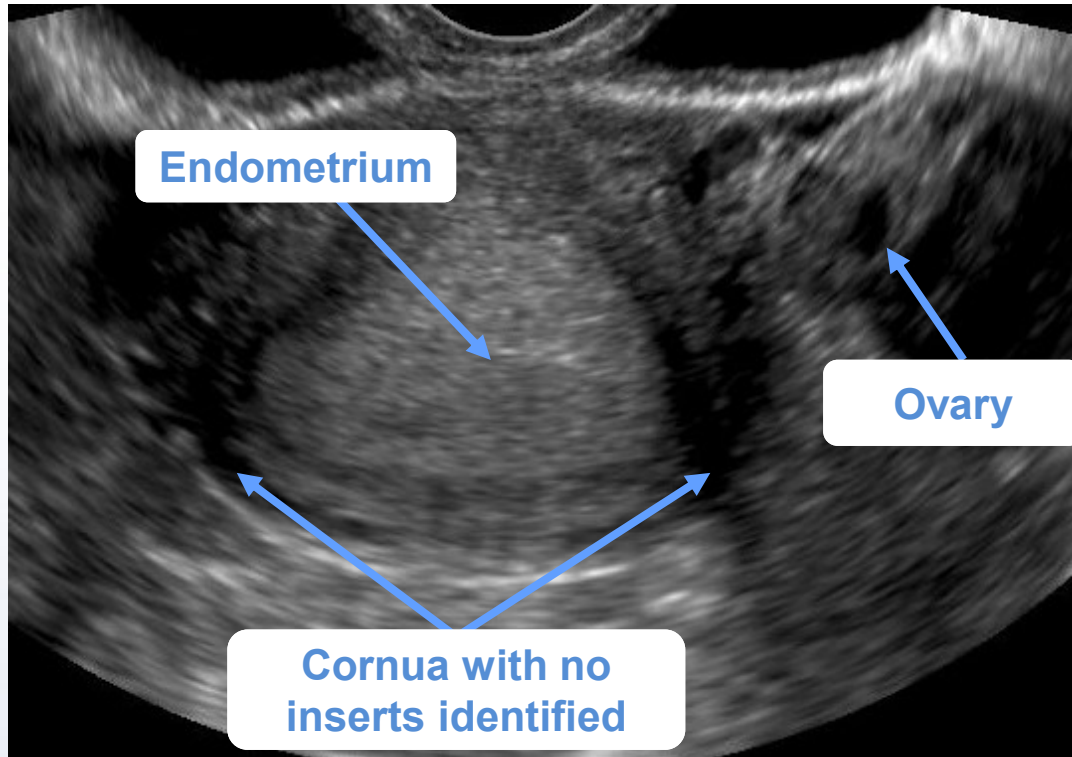
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## EXPLANATION TO QUESTION 8

### Essure® insert location is unsatisfactory: suggestive of expulsion.



Courtesy of  
Dr. Ian Suchet

### Transverse Fundal View

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

- This image shows unsatisfactory location of the Essure® insert, with expulsion suspected.
- An expulsion is suspected if one or both inserts are not identified in the cornua in a transverse view in a single TVU scout image.
- In this transverse fundal view of the uterus, the inserts are not visualized.

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QUESTION 9

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Ian Suchet

Transverse View

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Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

Submit Answer

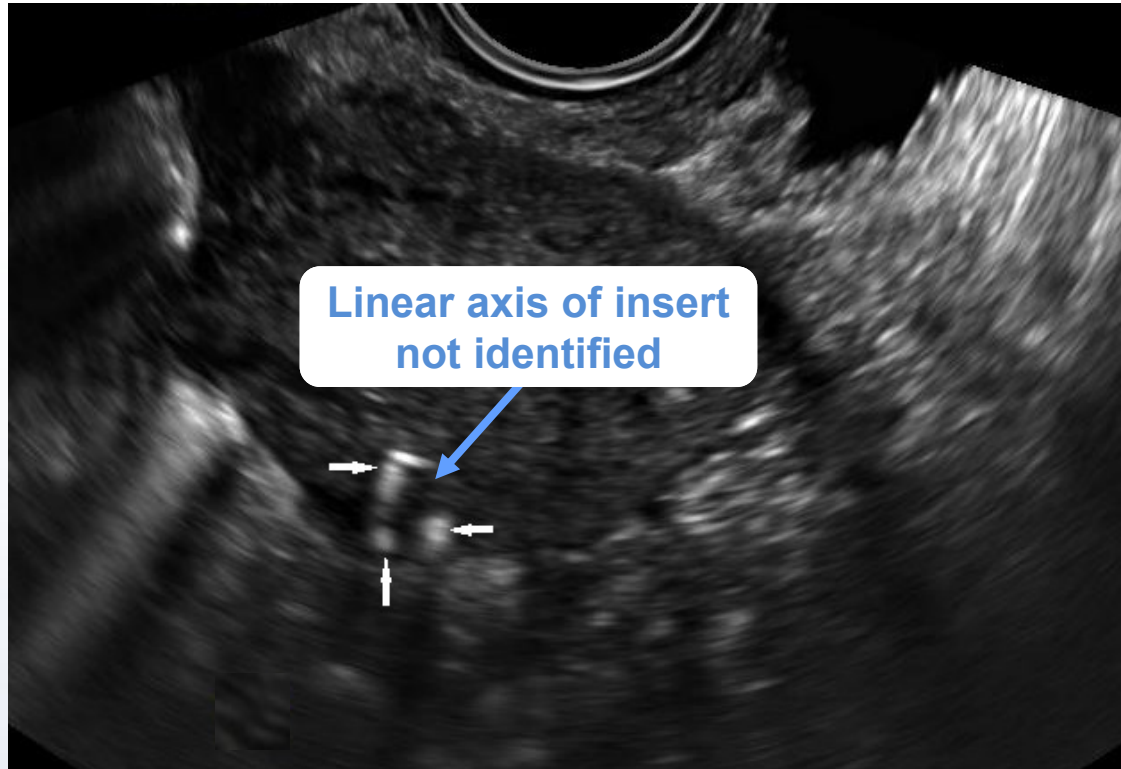
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## EXPLANATION TO QUESTION 9

### Essure® insert location is unsatisfactory: unclassified.



Courtesy of  
Dr. Ian Suchet

#### Transverse View

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

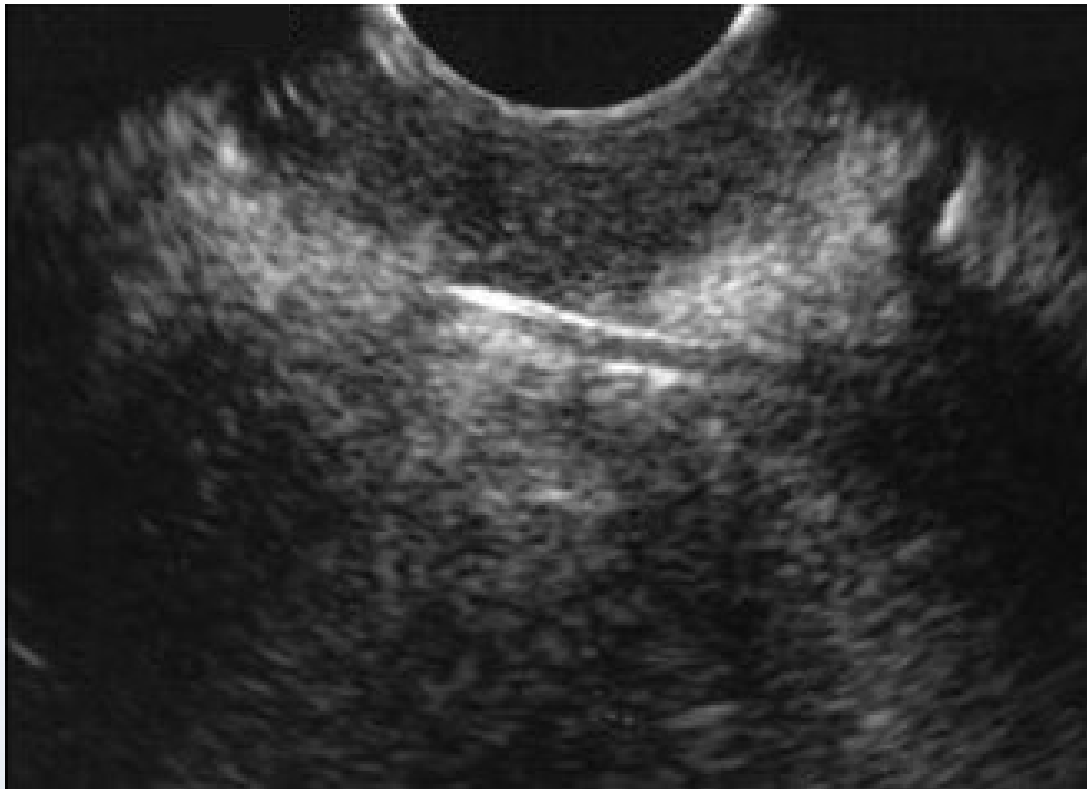
- This image shows unsatisfactory location of the Essure® insert that is unclassified.
- Insert placement is considered unsatisfactory, with an unclassified location:
  - If the linear axis of an insert cannot be identified, suggesting it is coiled, bent, or elongated.
  - If the surrounding soft tissue cannot be clearly defined.
- In this image, the insert is identified and noted to be within the myometrium. However, there is no clearly defined linear axis, suggesting the insert is coiled or bent.

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QUESTION 10

Please classify the type of location of the Essure® insert.



Courtesy of  
Dr. Viviane Connor

**Transverse View**

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Optimal

Satisfactory

Unsatisfactory  
Select one:

Distal Suspected

Expulsion Suspected

Perforation Suspected

Proximal Suspected

Unclassified

**Submit Answer**

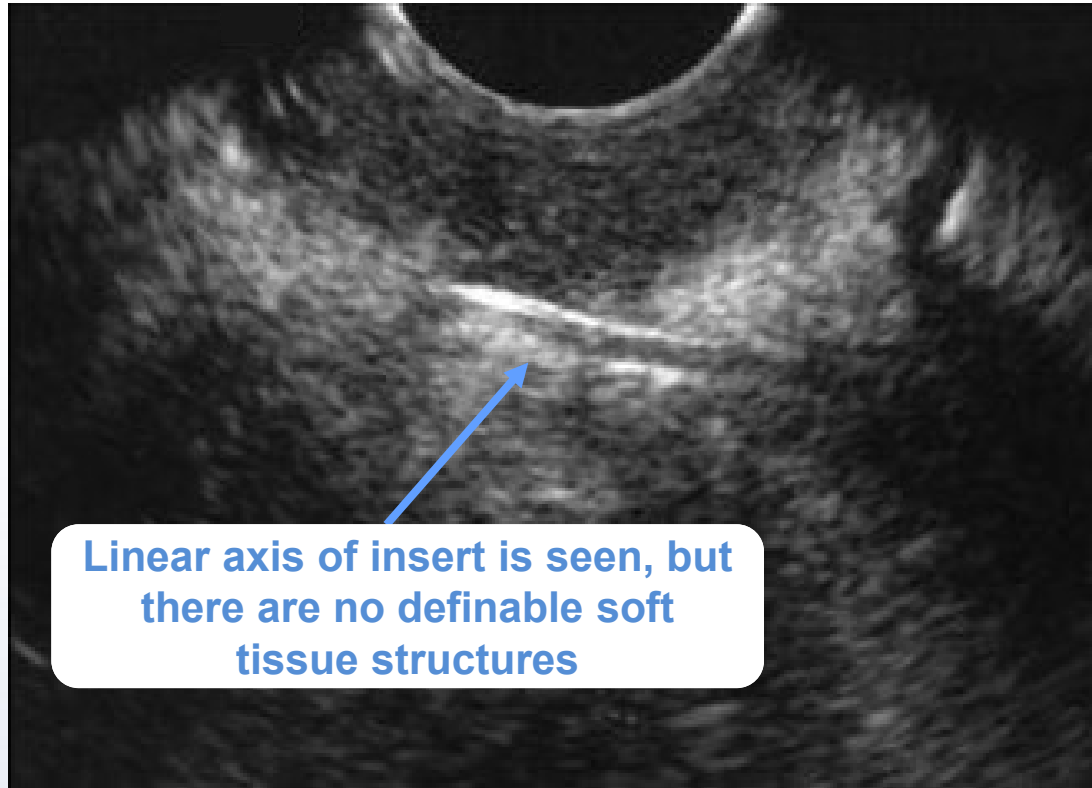
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## EXPLANATION TO QUESTION 10

### Essure® insert location is unsatisfactory: unclassified.



Linear axis of insert is seen, but there are no definable soft tissue structures

Courtesy of  
Dr. Viviane Connor

#### Transverse View

- This image shows unsatisfactory location of the Essure® insert that is unclassified.
- Insert placement is considered unsatisfactory, with an unclassified location:
  - If the linear axis of an insert cannot be identified, suggesting it is coiled, bent, or elongated.
  - If the surrounding soft tissue cannot be clearly defined.
- In this image, the linear axis of the insert is well-defined, but the surrounding soft tissue structures are not clearly defined.
- The patient cannot rely on Essure® for birth control and must remain on alternative contraception. The patient must proceed to a modified HSG Confirmation Test to evaluate insert location and tubal occlusion.

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## MARK CHAPTER 4 COMPLETE

- You have completed the final chapter of this module. 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
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