IMPORTANT SAFETY INFORMATION (continued)

Procedure Warnings

• Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or the patient reports symptoms of possible complications related to perforation which may include unusual post-operative pain.

• To reduce the risk of hysteroscopic procedure damage limit the Essure total hysteroscopic procedure time to 20 minutes. Excess fluid deficit may signal uterine or tubal perforation. If noted, discontinue procedure and reevaluate patient for possible perforation.

• Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more grading cubes are seen inside the uterine cavity due to risk of a fractured insert, holmium laser perforation, or other injury.

• DO NOT perform the Essure procedure concomitantly with diethylstilbestrol.

MRI Information

The Essure insert was determined to be MRI conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation F2250-03.

Adverse Events

The most common (≥10%) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events (≥5%) 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

IMPORTANT: The information presented within this guide is for your information only and does not guarantee that the codes will be appropriate or that coverage and reimbursement will result. You should consult with your provider to confirm their coverage, coding, and reimbursement requirements. It is the provider’s sole responsibility to verify coverage and reimbursement. This information is not intended as legal advice or as a substitute for independent professional judgment.

For additional information, please see the Instructions for Use available at EssureMD.com or speak to your Bayer Sales Consultant.
## Essure Procedure Coding


<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58665</td>
<td>Hysteroscopic, surgical, with bilateral fallopian tube occlusion achieved by placement of permanent implants</td>
</tr>
</tbody>
</table>

**Healthcare Common Procedure Coding System (HCPCS) Codes**

Level I HCPCS codes are published and updated annually by CMS. These alphanumeric codes are used to report drugs, supplies, and services. Please note that Medicare does not allow for separate reporting and billing of the permanent implantable contraceptive intratubal occlusion used by facilities and some Medicaid plans to report Essure is:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>HCPCS Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure</td>
<td>A4264</td>
<td>Permanent implantable contraceptive intratubal occlusion (device) and delivery system</td>
</tr>
</tbody>
</table>

### Diagnostic Codes

The International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes are used to classify diagnoses and conditions, and support medical necessity for specific procedures and services. They are used to indicate the reason for performing a given procedure and may be used by payers to determine coverage. The following ICD-10-CM codes may be applied to women who receive Essure:

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z30.2</td>
<td>Encountor for sterilization</td>
</tr>
</tbody>
</table>

### Important Safety Information (continued)

**Contraindications**

Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral tubal occlusion or suspected unilaterally occluded), have a known abnormal uterine cavity that makes visualizing the tubal ostia impossible, and/or abdominal anatomy or evidence of fallopian tube dysfunction (including failed ligation), are pregnant or suspect pregnancy, delivered or terminated a pregnancy 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.

**General Warnings**

The Essure procedure should be considered intolerable. A full course of antibiotics varies intensity and length of time may occur 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.

## Essure Confirmation Test Coding


The following codes may be used to report procedures associated with Essure:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58665</td>
<td>Hysteroscopic, surgical, with bilateral fallopian tube occlusion achieved by placement of permanent implants</td>
</tr>
<tr>
<td>TVU</td>
<td>76401</td>
<td>Ultrasound, Transabdominal</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>58340</td>
<td>Hysteroscopic and hysterosalpingocontrast with injection of saline or contrast material for saline-injection sonography (SIS) or HSG</td>
</tr>
<tr>
<td>Modified HSG, interpretation and supervision</td>
<td>76460</td>
<td>MLS, radiologic supervision and interpretation</td>
</tr>
<tr>
<td>Modified HSG, interpretation and supervision, professional component only</td>
<td>76460-TC</td>
<td>MLS, radiologic supervision and interpretation, technical component only</td>
</tr>
</tbody>
</table>

### ICD-10-CM Codes

For many payers, the following codes may be used to identify the Essure Confirmation Test as a preventive service:

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
<th>Recognized by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z30.0</td>
<td>Other specified contraceptive management</td>
<td>Most payers</td>
</tr>
<tr>
<td>Z30.1</td>
<td>Tubal ligation status</td>
<td>All</td>
</tr>
<tr>
<td>Z30.2</td>
<td>Encounter for surveillance of intrauterine contraceptive device</td>
<td>All</td>
</tr>
</tbody>
</table>

**CPT modifier 33** is applicable for the identification of preventive services without cost sharing and may be added to the following codes as shown below.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure, minimal services</td>
<td>58665-33</td>
<td>Hysteroscopic, surgical, with bilateral fallopian tube occlusion</td>
</tr>
<tr>
<td>TVU</td>
<td>76401-33</td>
<td>Ultrasound, Transabdominal</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>58340-33</td>
<td>Hysteroscopic and hysterosalpingocontrast with injection of saline or contrast material for saline-injection sonography (SIS) or HSG</td>
</tr>
<tr>
<td>TVU</td>
<td>76401-33</td>
<td>Ultrasound, Transabdominal</td>
</tr>
</tbody>
</table>

Note: Not all commercial payers will require the use of Modifier 33. Some will automatically process Essure® and the Essure Confirmation Test without patient cost sharing.

### Incomplete Procedures

In some cases, the Essure procedure is initiated but cannot be completed in these cases, it may be reasonable to bill within Medicare for 58412 for reporting essure insertion and the Essure Confirmation Test without patient cost sharing.

### Modifiers

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure, minimal services</td>
<td>58665-52</td>
<td>Hysteroscopic, surgical, with bilateral fallopian tube occlusion achieved by placement of permanent implants</td>
</tr>
</tbody>
</table>

Note: Not all commercial payers will require the use of Modifier 52. Some will automatically process Essure® and the Essure Confirmation Test without patient cost sharing.

### Important Safety Information (continued)

**General Warnings (continued)**

- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue ingrowth for tubal occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. These patients should be informed that TVU around tubes should be used as the Essure Confirmation Test, as an advanced device configuration of the fallopian tube is not guided.

**Pharmacologic**

- 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 undergo reinsertion.
- Counsel the patient on the need for the Essure Confirmation Test, the options for the confirmation test including risk and benefits, and the possibility the Essure Confirmation Test may be unsatisfactory.
- Effectiveness rates for the procedure are based on patients who had bilateral placement and a satisfactory Essure Confirmation Test.

Please see additional important safety information throughout including the boxed warnings on the cover.

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*Note: CPT codes, descriptions, and other data only are copyright 2015 American Medical Association. All rights reserved.*
Essure procedure 58565 Hysteroscopically-assisted, surgical bilateral fallopian tube cannulation and balloon inflation

TUV 76500 Ultrasonic Transvaginal

Modified HSG 89340 Hysterosalpingography; reduced services

Modified HSG, interpretation and evaluation 76760 MSL, radiologic supervision and interpretation, professional component only

Modified HSG, interpretation and evaluation 76760-TC MSL, radiologic supervision and interpretation, technical component only

ICD-10-CM Diagnoses

For many payers, the following codes may be used to identify the Essure Confirmation Test as a preventive service:

ICD-10-CM Code Code Description Recognized by:
Z30.2 Encounter for sterilization Cigna

230.0 Other specified contraceptive management Most payers

230.1 Tubal ligation status VHC

230.42 Encounter for surveillance of intrauterine contraceptive Cigna

230.5 Encounter for sterilization Cigna

CPT Modifier 33 is applicable for the identification of preventive services without patient cost sharing. In some cases, the Essure procedure is initiated but cannot be completed. In these cases, it may be appropriate to bill within Modifier 52 or 53 as described below.

Essure, procedure 58565-33

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Essure procedure, reduced services 58565-52

Essure procedure, discontinued 58565-53

This modifier is used to report a service or procedure that is discontinued by the physician because of extenuating circumstances or lack of patient cooperation. This coder should be added to the following codes as shown below.

Modified HSG 89340-33 Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or HSG

TUV 76500-33 Ultrasonic transvaginal

Essure procedure 58565-53

Please note that Medicare does not allow for separate reporting and billing of the permanent implantable contraceptive intratubal occlusion, and the Essure Confirmation Test without patient cost sharing.

Important Safety Information (continued)

Essure is contra-indicated in patients who are uncertain about ending fertility, can have only one insect placed (including contraindicated bilateral tubal occlusion or suspected contraindicated unilateral tubal occlusion), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal anatomy or unusual fallopian tube position (including bilaterally placed), are pregnant or suspect pregnancy, delivered or terminated a pregnancy 6 weeks or prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecologic malignancy, or have been known to have contrast media.

General Warnings: The Essure procedure should be considered in patients with a pelvic infection.

Parenteral administration of biodegradable material to the lumen of the fallopian tube is possible because the ostium of the fallopian tube is not visible.

The following code may be used to report procedures associated with Essure:

Product/Service CPT Code Code Description
Essure procedure 58565 Hysteroscopically-assisted, surgical bilateral fallopian tube cannulation and balloon inflation

Modular HSG 89340 Hysterosalpingography; reduced services

Modified HSG, interpretation and evaluation 76760 MSL, radiologic supervision and interpretation, professional component only

Modified HSG, interpretation and evaluation 76760-TC MSL, radiologic supervision and interpretation, technical component only

The following ICD-10-CM codes may be applicable to women who receive Essure:

ICD-10-CM Code Code Description
Z30.2 Encounter for sterilization Cigna

230.0 Other specified contraceptive management Most payers

230.1 Tubal ligation status VHC

230.42 Encounter for surveillance of intrauterine contraceptive Cigna

230.5 Encounter for sterilization Cigna

Important Safety Information (continued)

Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insect placed (including contraindicated bilateral tubal occlusion or suspected contraindicated unilateral tubal occlusion), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal anatomy or unusual fallopian tube position (including bilaterally placed), are pregnant or suspect pregnancy, delivered or terminated a pregnancy 6 weeks or prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecologic malignancy, or have been known to have contrast media.

General Warnings: The Essure procedure should be considered in patients with a pelvic infection.

Parenteral administration of biodegradable material to the lumen of the fallopian tube is possible because the ostium of the fallopian tube is not visible.

The following code may be used to report procedures associated with Essure:

Product/Service CPT Code Code Description
Essure procedure 58565 Hysteroscopically-assisted, surgical bilateral fallopian tube cannulation and balloon inflation

Modular HSG 89340 Hysterosalpingography; reduced services

Modified HSG, interpretation and evaluation 76760 MSL, radiologic supervision and interpretation, professional component only

Modified HSG, interpretation and evaluation 76760-TC MSL, radiologic supervision and interpretation, technical component only

The following ICD-10-CM codes may be applicable to women who receive Essure:

ICD-10-CM Code Code Description
Z30.2 Encounter for sterilization Cigna

230.0 Other specified contraceptive management Most payers

230.1 Tubal ligation status VHC

230.42 Encounter for surveillance of intrauterine contraceptive Cigna

230.5 Encounter for sterilization Cigna

Important Safety Information (continued)

Essure is contraindicated in patients who are uncertain about ending fertility, can have only one insect placed (including contraindicated bilateral tubal occlusion or suspected contraindicated unilateral tubal occlusion), have a known abnormal uterine cavity that makes visualization of the tubal ostia impossible, and/or abnormal anatomy or unusual fallopian tube position (including bilaterally placed), are pregnant or suspect pregnancy, delivered or terminated a pregnancy 6 weeks or prior to the Essure procedure, have an active upper or lower genital tract infection, have unexplained vaginal bleeding, have a gynecologic malignancy, or have been known to have contrast media.

General Warnings: The Essure procedure should be considered in patients with a pelvic infection.

Parenteral administration of biodegradable material to the lumen of the fallopian tube is possible because the ostium of the fallopian tube is not visible.

The following code may be used to report procedures associated with Essure:

Product/Service CPT Code Code Description
Essure procedure 58565 Hysteroscopically-assisted, surgical bilateral fallopian tube cannulation and balloon inflation

Modular HSG 89340 Hysterosalpingography; reduced services

Modified HSG, interpretation and evaluation 76760 MSL, radiologic supervision and interpretation, professional component only

Modified HSG, interpretation and evaluation 76760-TC MSL, radiologic supervision and interpretation, technical component only

The following ICD-10-CM codes may be applicable to women who receive Essure:
**ESSURE CONFIRMATION TEST CODING**


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<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58665</td>
<td>Hysteroscopic surgical with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>TVU</td>
<td>79600</td>
<td>Ultrasonic Transvaginal</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>78140</td>
<td>Radiographic interpretation of saline or contrast material for fallopian tube patency assessment (X-ray or HSG)</td>
</tr>
<tr>
<td>Modified HSG, interpretation and supervision</td>
<td>76730</td>
<td>HSG, radiologic supervision and interpretation, professional component only</td>
</tr>
<tr>
<td>Modified HSG, interpretation and supervision</td>
<td>76730-TC</td>
<td>HSG, radiologic supervision and interpretation, technical component only</td>
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</table>

**MODIFIERS**

<table>
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<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure, reduced services</td>
<td>58665-52</td>
<td>This modifier is used to report a procedure that is partially reduced or eliminated at the physician's election. An example of the correct use of Modifier 53 would be an Essure procedure being discontinued due to inadequate visualization, lack of visibility, or technical difficulty</td>
</tr>
</tbody>
</table>

**IMPORTANT SAFETY INFORMATION (continued)**

**General Warnings (continued)**

- Patients on immunosuppressive therapy may experience delay or failure of the necessary tissue ingrowth for tissue lumen occlusion. For these patients, physicians must use the modified HSG as the Essure Confirmation Test. This test, in addition to TVU should be used as the Essure Confirmation Test, as TVU cannot confirm tissue lumen occlusion.


diagnosis and conditions, and support medical necessity for specific procedures and services. They are used to indicate the reason for performing a given procedure and may be used by payers to determine coverage.

**ESSURE PROCEDURE CODING**


<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure procedure</td>
<td>58655</td>
<td>Hysteroscopic surgical with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants</td>
</tr>
<tr>
<td>TVU</td>
<td>79600</td>
<td>Ultrasonic Transvaginal</td>
</tr>
<tr>
<td>Modified HSG</td>
<td>78140</td>
<td>Radiographic interpretation of saline or contrast material for fallopian tube patency assessment (X-ray or HSG)</td>
</tr>
</tbody>
</table>

**Diagnosis Codes**

The International Classification of Diseases, 10th revision. Clinical Modification (ICD-10-CM) codes are used to classify diagnoses and conditions, and support medical necessity for specific procedures and services. They are used to indicate the reason for performing a given procedure and may be used by payers to determine coverage. The following ICD-10-CM codes may be applicable to women who receive Essure.

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<th>Code Description</th>
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<tbody>
<tr>
<td>Z30.2</td>
<td>Encounter for sterilization</td>
</tr>
<tr>
<td>Z30.3</td>
<td>Encounter for sterilization with tubal occlusion</td>
</tr>
<tr>
<td>Z30.4</td>
<td>Encounter for sterilization with tubal ligation</td>
</tr>
<tr>
<td>Z30.5</td>
<td>Encounter for sterilization with sterilization reversal</td>
</tr>
</tbody>
</table>

**IMPORTANCE SAFETY INFORMATION (continued)**

**Essure** is contraindicated in patients who are uncertain about ending fertility, can have only one insert placed (including contralateral tubal occlusion or suspected contralateral fallopian tubes), have a known abnormal uterine cavity that makes visualizing the fallopal tubal ostia impossible, and/or abnormal anatomy or evidence of fallopian tube disease (includiing failed tubes), 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.

**General Warnings**

- The Essure procedure should be considered irreversible. If the result of postprocedure varying intensity and length of time may occur 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.

**IMPORTANT SAFETY INFORMATION (continued)**

**General Warnings (continued)**

- 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 nickel or stainless steel. Patients should be instructed to report any reaction to nickel or stainless steel. Patients should be instructed to report any reaction to nickel or stainless steel. Please see additional important safety information throughout including the boxed warnings on the cover.
**LOCAL CODING**

Some state Medicaid programs may require the use of state-specific coding. Providers should research Medicaid coding guidelines on a state-specific basis.

To access state Medicaid coding and reimbursement information, please go to EssureMD.com.

**Place of Service (POS)**

The location where the clinician provides the medical service is referred to as the place of service (POS). All providers must include a POS code when submitting claims. The POS codes that pertain to the Essure procedure are as follows:

- POS #1 = office setting (OD)
- POS #2 = inpatient hospital (IP)
- POS #3 = outpatient hospital (HOPD)
- POS #4 = ambulatory surgical center (ASC)

**IMPORTANT SAFETY INFORMATION (continued)**

**Procedure Warnings**

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or it is suspected that the Essure 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 hypersensitivity, terephthalate fiber from the Essure insert contains a latex-free amount of total hysterectomy procedure time exceed 20 minutes. Excess fluid deficit may signal urinary or bowel perforation. If noted, discontinue procedure and reevaluate patient for possible perforation.
- Do not attempt hysteroscopic Essure insert removal during the placement procedure unless 18 or more months have passed since Essure device placement.
- Pain (acute or persistent) of varying intensity and length of time may occur following Essure placement. This product does not protect against HIV infection or other sexually transmitted diseases.
- The Essure procedure should be considered irreversible.
- Pain, including chronic pain, may occur following Essure placement. The most common (>10%) adverse events resulting from the placement procedure were cramping, pain, and nausea/vomiting. The most common adverse events (≥5%) 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

**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 and/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.

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 preceptorship in placement until competency is established, typically 5 cases.

For additional information, please see the Instructions for Use available at EssureMD.com or speak to your Bayer Sales Consultant.

LOCAL CODING

Some state Medicaid programs may require the use of state-specific coding. Providers should research Medicaid coding guidelines on a state-specific basis.

To access state Medicaid coding and reimbursement information, please go to EssureMD.com.

Place of Service (POS)

The location where the clinician provides the medical service is referred to as the place of service (POS). All providers must include a POS code when submitting claims. The POS codes that pertain to the Essure procedure are as follows:

- POS 1: F – office setting (OD)
- POS 2: B – hospital (HD)
- POS 4: A – ambulatory surgical center (ASC)

IMPORTANT SAFETY INFORMATION (continued)

Procedure Warnings

- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or pain, abdominal pain, and dyspareunia.
- Never attempt to advance Essure insert(s) against excessive resistance. If a perforation occurs or other injury.
- DO NOT perform the Essure procedure concomitantly with endometrial ablation.

Essure is an FDA-cleared, non-surgical sterilization procedure for women to permanently prevent pregnancy. The Essure procedure is a minimally invasive procedure that allows women to continue their active sex lives during and after the procedure.

Pregnancy Risk

- The Essure procedure is contraindicated in women who are pregnant or who may become pregnant within 60 days of the procedure.

WARNING:

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

IMPORTANT SAFETY INFORMATION

INDICATION

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

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IMPORTANT SAFETY INFORMATION

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/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 adverse events, 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.

Caution: Federal law restricts this device to sale by or on the order of a physician. Device is to be used only by physicians who are knowledgeable about hysteroscopies. You must have a license to practice and seek and be capable of identifying and treating adverse events. To be used only by physicians who are knowledgeable about hysteroscopies. You must have a license to practice and seek and be capable of identifying and treating adverse events.

For additional information, please see the Instructions for Use available at EssureMD.com or speak to your Bayer Sales Consultant.