

### **RADIOLOGÍA**



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**UPDATE IN RADIOLOGY** 

# Radiological assessment of placement of the hysteroscopically inserted Essure permanent birth control device\*



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#### **KEYWORDS**

Hysterosalpingography; Ultrasonography; Female sterilization; Hysteroscopic sterilization with Essure Abstract Essure is a permanent birth control device that is inserted through the cervix by hysteroscopy. The device is placed in the fallopian tubes, where it causes occlusion by stimulating fibrosis. Patients can be followed up with plain-film X-rays, hysterosalpingography, and ultrasonography, although the devices can also be identified incidentally on CT and MRI. The follow-up of Essure is based on checking the criteria for appropriate positioning and correct functioning (tubal occlusion) and on diagnosing complications. The most common complications are perforation, migration (toward the uterine or peritoneal cavity), and occlusion failure. In hysterosalpingography, vascular intravasation is the most common cause of diagnostic error. Radiologists need to know how to recognize the device on different imaging techniques, how to check that it is correctly placed and functioning, and how to diagnose complications.

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#### PALABRAS CLAVE

Histerosalpingografía; Ecografía; Esterilización femenina; Esterilización histeroscópica con Essure

#### Valoración radiológica del anticonceptivo permanente de inserción histeroscópica Essure

Resumen Essure es un dispositivo anticonceptivo permanente de inserción transcervical con histeroscopia. Se sitúa en las trompas a las que ocluye estimulando la fibrosis. Las técnicas para seguir a las pacientes son la radiografía simple, histerosalpingografía y ecografía, aunque los dispositivos se pueden identificar también incidentalmente con TC y RM. El seguimiento de Essure se basa en comprobar los criterios de posición adecuada y funcionamiento correcto (oclusión tubárica), y diagnosticar complicaciones. Las complicaciones más frecuentes son la perforación, migración (hacia la cavidad uterina o peritoneal), y fallo de la oclusión. La intravasación vascular es la causa más frecuente de error diagnóstico con la histerosalpingografía. Es importante que el radiólogo reconozca el dispositivo en las diferentes técnicas de imagen, los signos que indican que su situación y función son correctas y diagnosticar las complicaciones.

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#### Introduction

The Essure (Conceptus) system is one irreversible female anti-contraceptive method whose insertion through hysteroscopic approach does not require anesthesia and that can be used outpatiently. After two multicenter trials<sup>1,2</sup> it was approved by the European health authorities in 2001 and by the U.S. Food and Drug Administration in November of 2002.<sup>3</sup> This technique is way more cost-effective than laparoscopic tubal sterilization.<sup>4</sup> The complications described during insertion and in the coming days are pain–usually mild or moderate and some times vaginal bleeding. Chronic pain and infections are rare.<sup>5,6</sup> It is estimated that until 2010 around 450,000 Essure<sup>7</sup> devices had been placed worldwide and the rate of pregnancies published is almost non-existent.<sup>8</sup>

After the insertion of Essure the image modalities used for assessment purposed are simple radiology, ultrasound and hysterosalpingography with different protocols. The goal in all cases is determining the correct positioning or function of this device. We reviewed the radiologic tests of 550 patients sterilized with Essure in our institution between September of 2008 and December of 2013. The control protocol on our institution consists of one simple X-ray in all patients and one hysterosalpingography in cases of difficult insertion or doubtful images in the simple X-ray. Ultrasound is used in cases in which there is suspicion of complications. Our goal is to show the radiologic characteristics of the permanente anti-contraceptive Essure, the diagnostic difficulties associated and signs that would lead us to be suspicious of complications.

#### Essure device

The Essure device (Fig. 1) is a 40 mm-long-0.8 mm wide in diameter-flexible 26-coil system expanding up to 1.5–2 mm of diameter once the insertion system has been released. Each micro-insert consists of two parts. The exterior self-expandable coil consists of a nickel-titanium alloy (nitinol) that when expanding anchors the device to the Fallopian tube. The interior component is stainless steel and contains

and is surrounded by polyethylene terephthalate-dachron (PET) fibers. Each device has four radiopaque markers in the proximal and distal regions of the interior and exterior components.

Dacron fibers stimulate tissue growth and scarring. The mechanism of occlusion not only is the Fallopian tube lume occlusion but also the tissue barrier established approximately three months after the implantation due to the stimulation of tissue scarring through the device.<sup>6,9</sup> This is why it is important to remind patients the need to maintain other kind of anti-contraceptive method during the first three months.

#### **Essure insertion**

The Essure device is inserted through the cervix by hysteroscopy. No previous preparation, local or general anesthesia are needed. The insertion takes place in the first stage of the cycle or under hormone anti-contraceptive therapy. After the cannulation of the Fallopian tube orifice with direct vision one device is released in its interior leaving preferably 3–5 coils in the uterine cavity (Fig. 2). This is how the proximal regions of the Essure device internal and external components remain in the uterine horn.

## Image modalities to assess patients carrying the Essure device

The radiologic image modalities are performed to determine the position and function (tubal occlusion) of devices. In most European countries the follow-up takes place through a simple X-ray of ultrasound while the hysterosalpingography is used only in cases of hard insertion or doubtful images with other two modalities. In the United States the guidelines published by the Food and Drug Administration require performing hysterosalpingographies as part of the protocol before suppressing the anti-contraceptive. <sup>10</sup>

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