

Best practices for evaluating pelvic pain in patients with Essure tubal occlusion devices

The authors review adverse outcomes of tubal occlusion devices and data on how and when to remove them

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The evaluation and management of chronic pelvic pain in patients with a history of Essure device (Bayer HealthCare Pharmaceuticals Inc, Whippany, New Jersey) insertion have posed many challenges for both clinicians and patients. The availability of high-quality, evidence-based clinical guidance has been limited. We have reviewed the currently available published data, and here provide an overview of takeaways, as well as share our perspective and approach on evaluating and managing chronic pelvic pain in this unique patient population.

The device

The Essure microinsert is a hysteroscopically placed device that facilitates permanent sterilization by occluding the bilateral proximal fallopian tubes. The microinsert has an inner and outer nitinol coil that attaches the device to the proximal fallopian tube to ensure retention. The inner coil releases polyethylene terephthalate fibers that cause tubal fiber proliferation to occlude the lumen of the fallopian tube and achieve sterilization.

The device was first approved by the US Food and Drug Administration (FDA) in 2002. In subsequent years, the device was well received and widely used, with approximately 750,000 women

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worldwide undergoing Essure placement.^{1,2} Shortly after approval, many adverse events (AEs), including pelvic pain and abnormal uterine bleeding, were reported, resulting in a public meeting of the FDA Obstetrics and Gynecology Devices Panel in September 2015. A postmarket surveillance study on the device ensued to assess complication rates including unplanned pregnancy, pelvic pain, and surgery for removal. In February 2016, the FDA issued a black box warning and a patient decision checklist.^{3,4} In December 2018, Bayer stopped selling and distributing Essure in the United States.⁵ A 4-year follow-up surveillance study on Essure was submitted to the FDA in March 2020.

Adverse outcomes

Common AEs related to the Essure device include heavy uterine bleeding, pelvic pain, and other quality-of-life symptoms such as fatigue and weight gain.⁶⁻⁸ The main safety endpoints for the mandated FDA postmarket 522 surveillance studies were chronic lower abdominal and pelvic pain; abnormal uterine bleeding; hypersensitivity; allergic reaction, as well as autoimmune disorders incorporating inflammatory markers and human leukocyte antigen; and gynecologic surgery for device removal.⁹ Postmarket surveillance has shown that most AEs are related to placement complications or pelvic pain after Essure insertion. However, there have been several reports of autoimmune diseases categorized as serious AEs, such as new-onset systemic lupus erythematosus, rheumatoid arthritis, and worsening ulcerative colitis, after Essure insertion.⁵

Evaluation of symptoms

Prevalence of pelvic pain following device placement

We conducted a PubMed and MEDLINE search from January 2000 to May 2020, which identified 43 studies citing AEs related to device placement, including pelvic or abdominal pain, abnormal uterine bleeding, hypersensitivity, and autoimmune disorders. A particularly debilitating and frequently cited AE was new-onset pelvic pain or worsening of preexisting pelvic pain. Perforation of the

uterus or fallopian tube, resulting in displacement of the device into the peritoneal cavity, or fragmentation of the microinsert was reported as a serious AE that occurred after device placement. However, due to the complexity of chronic pelvic pain pathogenesis, the effect of the insert on patients with existing chronic pelvic pain remains unknown.

Authors of a large retrospective study found that approximately 2.7% of 1,430 patients developed new-onset or worsening pelvic pain after device placement. New-onset pelvic pain in 1% of patients was thought to be secondary to device placement, without a coexisting pathology or diagnosis.¹⁰

In a retrospective study by Clark and colleagues, 22 of 50 women (44%) with pelvic pain after microinsert placement were found to have at least one other cause of pelvic pain. The most common alternative diagnoses were endometriosis, adenomyosis, salpingitis, and adhesive disease. Nine of the 50 patients (18%) were found to have endometriosis upon surgical removal of the microinsert.⁷

Another case series examined outcomes in 29 patients undergoing laparoscopic device removal due to new-onset pelvic pain. Intraoperative findings included endometriosis in 5 patients (17.2%) and pelvic adhesions in 3 (10.3%).² Chronic pelvic pain secondary to endometriosis may be exacerbated with Essure insertion due to discontinuation of hormonal birth control after device placement,⁷ and this diagnosis along with adenomyosis should be strongly considered in patients whose pelvic pain began when hormonal contraception was discontinued after placement of the device.

Risk factors

Authors of a retrospective cohort study found that patients with prior diagnosis of a chronic pain syndrome, low back pain, headaches, or fibromyalgia were 5 to 6 times more likely to report acute and chronic pain after hysteroscopic sterilization with Essure.¹¹ Since chronic pain is often thought to be driven by a hyperalgesic state of the central nervous system, as previously shown in patients with conditions such as vulvodynia, interstitial cystitis, and fibromyalgia,¹² a hyperalgesic state can potentially

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Common reported AEs with Essure placement were heavy uterine bleeding, pelvic pain, fatigue, and weight gain; serious AEs were lupus erythematosus, rheumatoid arthritis, and worsening ulcerative colitis

explain why some patients are more susceptible to developing worsening pain.

Van Limburg and colleagues conducted a retrospective cohort study with prospective follow-up on 284 women who underwent Essure sterilization. Among these patients, 48% reported negative AEs; risk factors included young age at placement, increasing gravidity, and no prior abdominal surgery.¹³

Onset of pain

The timing and onset of pelvic pain vary widely, suggesting there is no particular time frame for this AE after device placement.^{2,6,14-18} A case series by Arjona and colleagues analyzed the incidence of chronic pelvic pain in 4,274 patients after Essure sterilization. Seven patients (0.16%) reported chronic pelvic pain that necessitated device removal. In 6 of the women, the pelvic pain began within 1 week of device placement. In 3 of the 6 cases, the surgeon reported the removal procedures as “difficult.” In all 6 cases, the level of pelvic pain increased with time and was not alleviated with standard analgesic medications.⁶

In another case series of 26 patients, the authors evaluated patients undergoing laparoscopic removal of Essure secondary to pelvic pain and reported that the time range for symptom presentation was immediate to 85 months. Thirteen of 26 patients (50%) reported pain onset within less than 1 month of device placement, 5 of 26 patients (19.2%) reported pain between 1 and 12 months after device placement, and 8 of 26 patients (30.8%) reported pain onset more than 12 months after microinsert placement.² In this study, 17.2% of operative reports indicated difficulty with device placement. It is unclear whether difficulty with placement was associated with development of subsequent abdominal or pelvic pain; however, the relevance of initial insertion difficulty diminished with longer follow-up.

Workup and evaluation

We found 5 studies that provided some framework for evaluating a patient with new-onset or worsening pelvic pain after microinsert placement. Overall, correct placement and functionality of the device should be con-

firmed by either hysterosalpingogram (HSG) or transvaginal ultrasonography (TVUS). The gold standard to determine tubal occlusion is the HSG. However, TVUS may be a dependable alternative, and either test can accurately demonstrate Essure location.¹⁹ Patients often prefer TVUS over HSG due to the low cost, minimal discomfort, and short examination time.¹ TVUS is a noninvasive and reasonable test to start the initial assessment. The Essure devices are highly echogenic on pelvic ultrasound and easily identifiable by the proximity of the device to the uterotubal junction and its relationship with the surrounding soft tissue. If the device perforates the peritoneal cavity, then the echogenic bowel can impede adequate visualization of the Essure microinsert. If the Essure insert is not visualized on TVUS, an HSG will not only confirm placement but also test insert functionality. After confirming correct placement of the device, the provider can proceed with standard workup for chronic pelvic pain.

If one or more of the devices are malpositioned, the devices are generally presumed to be the etiology of the new pain. Multiple case reports demonstrate pain due to Essure misconfiguration or perforation with subsequent resolution of symptoms after device removal.^{18,20,21} A case study by Alcantara and colleagues described a patient with chronic pelvic pain and an Essure coil that was curved in an elliptical shape, not adhering to the anatomic course of the fallopian tube. The patient reported pain resolution after laparoscopic removal of the device.²⁰ Another case report by Mahmoud et al described a subserosal malpositioned device that caused acute pelvic pain 4 months after sterilization. The patient reported resolution of pain after the microinsert was removed via laparoscopy.²¹ These reports highlight the importance of considering malpositioned devices as the etiology of new pelvic pain after Essure placement.

Device removal and patient outcomes

Removal

Several studies that we evaluated included a discussion on the methods for Essure

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TABLE Summary evidence for Essure removal

The following recommendations are based on limited patient-oriented evidence (level 2).

- Initial workup of new-onset or worsening chronic pelvic pain in patients with the Essure microinsert should begin with placement confirmation via either TVUS or HSG (See **FIGURE**, page 38).
- If the Essure device cannot be visualized using TVUS, evaluation with HSG should be considered.
- In the event the Essure microinsert is malpositioned, the device should be removed either via hysteroscopy or laparoscopy depending on the time after placement, location, and adequate visualization of the devices.
- Laparoscopic resection of the fallopian tubes with or without partial cornuectomy should be performed for management of pelvic pain after Essure placement of >12 weeks or if the device cannot be visualized in its entirety.

The following recommendations are based on expert opinion.

- An imaging modality should be available intraoperatively during device removal, such as the use of fluoroscopy or flat plate x-ray of the abdomen and pelvis or intraoperative x-ray of the removed device to allow for timely identification of retained fragments.
- Preoperative imaging should also be considered for patients undergoing hysterectomy for other indications with devices in situ.
- Hormonal management prior to surgical removal of the Essure device should be considered in patients with a history and physical examination suggestive of possible endometriosis or adenomyosis. This is particularly relevant for patients whose pain began after stopping hormonal contraception following Essure insertion.

Abbreviations: HSG, hysterosalpingogram; TVUS, transvaginal ultrasound.

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One risk with hysteroscopic removal of Essure is failure to remove fibers, which allows inflammation and fibrosis to continue

removal, which are divided into 2 general categories: hysteroscopy and laparoscopy.

Hysteroscopic removal is generally used when the device was placed less than 12 weeks prior to removal.^{7,19} After 12 weeks, removal is more difficult due to fibrosis within the fallopian tubes. A risk with hysteroscopic removal is failure to remove all fibers, which allows inflammation and fibrosis to continue.⁷ This risk is mitigated via laparoscopic hysterectomy or mini-cornuectomy with bilateral salpingectomy, where the devices can be removed en bloc and without excessive traction.

Laparoscopic Essure removal procedures described in the literature include salpingostomy and traction on the device, salpingectomy, and salpingectomy with mini-cornuectomy. The incision and traction method is typically performed via a 2- to 3-cm incision on the antimesial edge of the fallopian tube along with a circumferential incision to surround the interstitial tubal area. The implant is carefully extracted from the fallopian tube and cornua, and a salpingectomy is then performed.²² The implant is removed prior to the salpingectomy to ensure that the Essure device is removed in its entirety prior to performing a salpingectomy.

A prospective observational study evaluated laparoscopic removal of Essure devices in 80 women with or without cornual

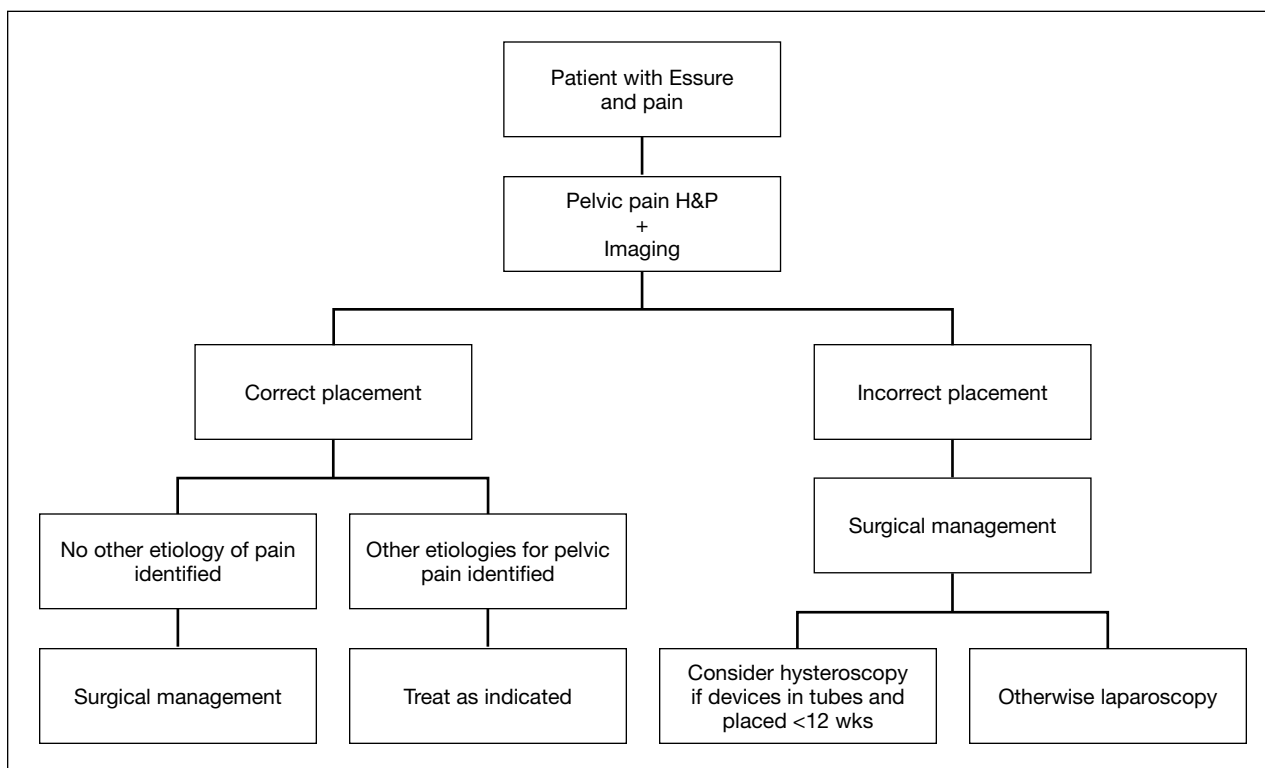
excision. Results suggest that the incision and traction method poses more technical difficulties than the cornuectomy approach.²³ Surgeons reported significant difficulty controlling the tensile pressure with traction, whereas use of the cornuectomy approach eliminated this risk and decreased the risk of fragmentation and incomplete removal.^{23,24}

Charavil and colleagues demonstrated in a prospective observational study that a vaginal hysterectomy with bilateral salpingectomy is a feasible approach to Essure removal. Twenty-six vaginal hysterectomies with bilateral salpingectomy and Essure removal were performed without conversion to laparoscopy or laparotomy. The surgeons performed an en bloc removal of each hemiuterus along with the ipsilateral tube, which ensured complete removal of the Essure device. Each case was confirmed with an x-ray of the surgical specimen.²⁵

If device fragmentation occurs, there are different methods recommended for locating fragments. A case report of bilateral uterine perforation after uncomplicated Essure placement used a preoperative computed tomography (CT) scan to locate the Essure fragments, but no intraoperative imaging was performed to confirm complete fragment removal.²⁶ The patient continued reporting chronic pelvic pain and ultimately underwent exploratory laparotomy with intraoperative fluoroscopy. Using

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FIGURE Work flow for evaluation of pelvic pain after Essure insertion



fluoroscopy, investigators identified omental fragments that were missed on preoperative CT imaging. Fluoroscopy is not commonly used intraoperatively, but it may have added benefit for localizing retained fragments.

A retrospective cohort study reviewed the use of intraoperative x-ray of the removed specimen to confirm complete Essure removal.²⁷ If an x-ray of the removed specimen showed incomplete removal, an intraoperative pelvic x-ray was performed to locate missing fragments. X-ray of the removed devices confirmed complete removal in 63 of 72 patients (87.5%). Six of 9 women with an unsatisfactory specimen x-ray had no residual fragments identified during pelvic x-ray, and the device removal was deemed adequate. The remaining 3 women had radiologic evidence of incomplete device removal and required additional dissection for complete removal. Overall, use of x-ray or fluoroscopy is a relatively safe and accessible way to ensure complete removal of the Essure device and is worth consideration, especially when retained device fragments are suspected.

Symptom resolution

We reviewed 5 studies that examined pain outcomes after removal of the Essure devices. Casey et al found that 23 of 26 patients (88.5%) reported significant pain relief at the postoperative visit, while 3 of 26 (11.5%) reported persistent pelvic pain.² Two of 3 case series examined other outcomes in addition to postoperative pelvic pain, including sexual function and activities of daily living.^{7,14} In the first case series by Brito and colleagues, 8 of 11 patients (72.7%) reported an improvement in pelvic pain, ability to perform daily activities, sexual life, and overall quality of life after Essure removal. For the remaining 3 patients with persistent pelvic pain after surgical removal of the device, 2 patients reported worsening pain symptoms and dyspareunia.¹⁴ In this study, 5 of 11 patients reported a history of chronic pelvic pain at baseline. In a retrospective case series by Clark et al, 28 of 32 women (87.5%) reported some improvement in all domains, with 24 of 32 patients (75%) reporting almost total or complete improvement in quality of life, sexual life, pelvic pain,

and scores related to activities of daily living. Pain and quality-of-life scores were similar for women who underwent uterine-preserving surgery and for those who underwent hysterectomy. Ten of 32 women (31.3%) reported persistent or worsening symptoms after the Essure removal surgery. In these patients, the authors recommended consideration of other autoimmune and hypersensitivity etiologies.⁷

In a retrospective cohort study by Kamencic et al from 2002 to 2013 of 1,430 patients who underwent Essure placement with postplacement imaging, 62 patients (4.3%) required a second surgery after Essure placement due to pelvic pain.¹⁰ This study also found that 4 of 62 patients (0.3%) had no other obvious cause for the pelvic pain. All 4 of these women had complete resolution of their pain with removal of the Essure microinsert device.

A prospective observational study by Chene et al examined health-related quality-of-life outcomes in 80 women who underwent laparoscopic Essure removal for pelvic pain. This survey study demonstrated significant improvement in the quality of life in both psychological and physical aspects, and these results were maintained at 3- and 6-month follow-up examinations.²³

Summary

Although Essure products were withdrawn from the market in the United States in 2018, many patients still experience significant AEs associated with the device. The goal of the perspectives and data presented here is to assist clinicians in addressing and managing the pain experienced by patients after device insertion. ●

References

- Connor VE. Essure: a review six years later. *J Minim Invasive Gynecol.* 2009;16:282-290. doi:10.1016/j.jmig.2009.02.009.
- Casey J, Aguirre F, Yunker A. Outcomes of laparoscopic removal of the Essure sterilization device for pelvic pain: a case series. *Contraception.* 2016;94:190-192. doi:10.1016/j.contraception.2016.03.017.
- Jackson I. Essure device removed entirely from market, with 99% of unused birth control implants retrieved: FDA. AboutLawsuits.com. January 13, 2020. <https://www.aboutlawsuits.com/Essure-removal-update-166509>. Accessed June 7, 2022.
- US Food and Drug Administration. Labeling for permanent hysteroscopically-placed tubal implants intended for sterilization. October 31, 2016. <https://www.fda.gov/media/96315/download>. Accessed June 7, 2022.
- US Food and Drug Administration. FDA activities related to Essure. March 14, 2022. <https://www.fda.gov/medical-devices/essure-permanent-birth-control/fda-activities-related-essure>. Accessed June 8, 2022.
- Arjona Berral JE, Rodríguez Jiménez B, Velasco Sánchez E, et al. Essure and chronic pelvic pain: a population-based cohort. *J Obstet Gynaecol.* 2014;34:712-713. doi:10.3109/01443615.2014.92075.
- Clark NV, Rademaker D, Mushinski AA, et al. Essure removal for the treatment of device-attributed symptoms: an expanded case series and follow-up survey. *J Minim Invasive Gynecol.* 2017;24:971-976. doi:10.1016/j.jmig.2017.05.015.
- Sills ES, Rickers NS, Li X. Surgical management after hysteroscopic sterilization: minimally invasive approach incorporating intraoperative fluoroscopy for symptomatic patients with >2 Essure devices. *Surg Technol Int.* 2018;32:156-161.
- Administration USF and D. 522 Postmarket Surveillance Studies. Center for Devices and Radiological Health; 2020.
- Kamencic H, Thiel L, Karreman E, et al. Does Essure cause significant de novo pain? A retrospective review of indications for second surgeries after Essure placement. *J Minim Invasive Gynecol.* 2016;23:1158-1162. doi:10.1016/j.jmig.2016.08.823.
- Yunker AC, Ritch JM, Robinson EF, et al. Incidence and risk factors for chronic pelvic pain after hysteroscopic sterilization. *J Minim Invasive Gynecol.* 2015;22:390-394. doi:10.1016/j.jmig.2014.06.007.
- Phillips K, Clauw DJ. Central pain mechanisms in chronic pain states--maybe it is all in their head. *Best Pract Res Clin Rheumatol.* 2011;25:141-154. doi:10.1016/j.berh.2011.02.005.
- van Limburg Stirum EVJ, Clark NV, Lindsey A, et al. Factors associated with negative patient experiences with Essure sterilization. *JSL.S.* 2020;24(1):e2019.00065. doi:10.4293/JSL.S.2019.00065.
- Brito LG, Cohen SL, Goggins ER, et al. Essure surgical removal and subsequent symptom resolution: case series and follow-up survey. *J Minim Invasive Gynecol.* 2015;22:910-913. doi:10.1016/j.jmig.2015.03.018.
- Maassen LW, van Gastel DM, Haveman I, et al. Removal of Essure sterilization devices: a retrospective cohort study in the Netherlands. *J Minim Invasive Gynecol.* 2019;26:1056-1062. doi:10.1016/j.jmig.2018.10.009.
- Sills ES, Palermo GD. Surgical excision of Essure devices with ESHRE class IIb uterine malformation: sequential hysteroscopic-laparoscopic approach to the septate uterus. *Facts Views Vis Obgyn.* 2016;8:49-52.
- Ricci G, Restaino S, Di Lorenzo G, et al. Risk of Essure microinsert abdominal migration: case report and review of literature. *Ther Clin Risk Manag.* 2014;10:963-968. doi:10.2147/TCRM.S65634.
- Borley J, Shabjee N, Tan TL. A kink is not always a perforation: assessing Essure hysteroscopic sterilization placement. *Fertil Steril.* 2011;95:2429.e15-7. doi:10.1016/j.fertnstert.2011.02.006.
- Djeffal H, Blouet M, Pizzoferrato AC, et al. Imaging findings in Essure-related complications: a pictorial review. *Br J Radiol.* 2018;91(1090):20170686. doi:10.1259/bjr.20170686.
- Lora Alcantara I, Rezaei S, Kirby C, et al. Essure surgical removal and subsequent resolution of chronic pelvic pain: a case report and review of the literature. *Case Rep Obstet Gynecol.* 2016;2016:6961202. doi:10.1155/2016/6961202.
- Mahmoud MS, Fridman D, Merhi ZO. Subserosal misplacement of Essure device manifested by late-onset acute pelvic pain. *Fertil Steril.* 2009;92:2038.e1-3. doi:10.1016/j.fertnstert.2009.07.1677.
- Tissot M, Petry S, Lecointre L, et al. Two surgical techniques for Essure device ablation: the hysteroscopic way and the laparoscopic way by salpingectomy with tubal interstitial resection. *J Minim Invasive Gynecol.* 2019;26(4):603. doi:10.1016/j.jmig.2018.07.017.
- Chene G, Cerruto E, Moret S, et al. Quality of life after laparoscopic removal of Essure sterilization devices. *Eur J Obstet Gynecol Reprod Biol X.* 2019;3:100054. doi:10.1016/j.eurox.2019.100054.
- Thiel L, Rattray D, Thiel J. Laparoscopic cornuectomy as a technique for removal of Essure microinserts. *J Minim Invasive Gynecol.* 2017;24(1):10. doi:10.1016/j.jmig.2016.07.004.
- Charavil A, Agostini A, Rambeaud C, et al. Vaginal hysterectomy with salpingectomy for Essure insert removal. *J Minim Invasive Gynecol.* 2019;2:695-701. doi:10.1016/j.jmig.2018.07.019.
- Howard DL, Christenson PJ, Strickland JL. Use of intraoperative fluoroscopy during laparotomy to identify fragments of retained Essure microinserts: case report. *J Minim Invasive Gynecol.* 2012;19:667-670. doi:10.1016/j.jmig.2012.04.007.
- Miquel L, Crochet P, Francini S, et al. Laparoscopic Essure device removal by en bloc salpingectomy-cornuectomy with intraoperative x-ray checking: a retrospective cohort study. *J Minim Invasive Gynecol.* 2020;27:697-703. doi:10.1016/j.jmig.2019.06.006.