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Essure: Out Of Sight, But Not Out Of Mind For Many Women

Though pulled off the market, Bayer stands behind its device

by Brian Bossetta

The Essure birth control device is no longer on the market, but that doesn't mean it is no longer an issue for women who received the device, including some that had it removed. Still, Bayer says Essure's safety profile remains positive.

At first, Theresa Ingram accepted severe back pain, cramping, and heavy bleeding as symptoms from the Essure birth control device that would soon subside, because that's what her doctors told her. It had only been a day since she had it implanted, so she decided to "deal with it" even though she could barely stand, she said.

But as the days went by, the pain intensified.

After her doctors realized one of the two coils wasn't properly placed and "corrected" the problem, Ingram believed she'd soon be back to feeling like the healthy woman in her early 30s she'd always been.

She was wrong.

"I noticed inflammation within my whole body, my hands, my feet, my legs," she said. "And I started to bruise very easily. Somebody would poke me and my whole arm would bruise. It was very weird."

After having three children, Ingram, a working mom from Minooka, IL, opted for Essure on her doctor's advice.

“I was told it was going to be an easy, 45-minute procedure, with no real heavy side effects, just maybe a little fatigue for a few days,” she said. “So for me there was nothing really more to look in to. It was a no brainer.”

The Essure device is actually two tiny spring-like coils, one for each fallopian tube, that block the fertilization of eggs. Manufactured by *Bayer AG*, Essure was approved by the US Food and Drug Administration in 2002 and quickly became a popular alternative to permanent birth control surgery.

However, in December 2018, after numerous complaints similar to Ingram’s, Bayer stopped selling the device but let providers continue to implant it for one year. As of December 2019, all unused Essure devices were returned to the company and no longer available for implantation. (Also see "*Essure Update: Almost All Unsold Units Back To Bayer; Postmarket Study Enrollment Complete*" - Medtech Insight, 15 Jan, 2020.)

December 2018 is also when Ingram had her Essure device removed after years of deteriorating health, a time she refers to as “E-hell.”

To have the coils removed, Ingram had a full hysterectomy on the advice of her new OB-GYN, Brett Cassidy, who is affiliated with the AMITA Health Medical Group serving the greater Chicago area.

> ***“I had seen a few Essure patients before her, but she had some of the worst symptoms I had ever seen.” – Brett Cassidy***

“I saw her back in 2018,” Cassidy told *Medtech Insight*. “I had seen a few Essure patients before her, but she had some of the worst symptoms I had ever seen.”

Some of the symptoms Ingram described that Cassidy confirmed, include those often associated with autoimmune conditions, such as joint pain, brain fog, fatigue, and migraines.

“But she had a particularly severe case,” Cassidy said, adding that Ingram had very low bone density and was having multiple bone fractures. “I had never seen anyone with bone fractures before.”

The bone fractures first appeared, Ingram said, after she began running.

“I started exercising because I was suddenly gaining a lot of weight,” she said. “When I started exercising, I began breaking bones in my toes.”

It was a pain in her side after a run, however, that brought her to the ER, where she was initially diagnosed with a “slight sprain.” But after the pain worsened, she went back to the ER and was told she had a broken femur.

“They asked me how I broke it and I said running. And they told me that nobody breaks their femur running,” Ingram said.

A year later, Ingram stepped in a hole in her backyard while gardening and broke her ankle. After another trip to the ER, Ingram was told she shattered her ankle and needed surgery, which included 13 screws, a rod, and a plate. As with her femur, Ingram says that doctors told her that fractures to this degree only happen from traumatic events, such as car accidents and major falls.

Eventually, Ingram saw a hematologist because she was developing severe bruises.

At this point, Ingram was struggling to walk and was always in tears as she tried to understand what was happening to her body, she said.

She was finally diagnosed at the Mayo Clinic with Cushing’s disease and a pituitary tumor that required brain surgery.

Essure Related?

Though Ingram said she was a perfectly healthy woman prior to getting Essure, there is no solid evidence to link her Cushing’s, severe bruising, and fractures to Essure. Ingram’s doctors at the Mayo said they could not talk about her case.

> *“I've probably seen over 300 patients that we've taken out their uterus with their fallopian tubes.” – Brett Cassidy*

But as Cassidy explained, Essure is made with various metals, including nickel, and is coated in a plastic fiber which, in his estimation, can cause autoimmune issues. “That coating is what causes the immune system to attack,” he said. “But then the immune system continues to attack and

that's what causes these autoimmune disorders where you're getting a lot of these symptoms of joint pain and brain fog."

Cassidy said he has received numerous referrals from the Essure patient's Facebook page – which has some 23,000 members.

"I've probably seen over 300 patients whose uterus and fallopian tubes we've removed," Cassidy said.

Kristin Malcer, one of the patients referred to Cassidy after she had Essure implanted in 2013, said she wasn't told by her doctors at the time that the device contained nickel, which she's allergic to. Though her symptoms were not as severe as Ingram's, Malcer also described sudden weight gain, lethargy, bloating, and heavy bleeding.

> *"While all birth control products and procedures have risks, the totality of scientific evidence on Essure demonstrates that its safety profile is positive." – Bayer*

"My belly on my right side was swollen for seven months," Malcer said. "Completely swollen."

Malcer also experienced extremely long periods – "26 days at a time, then 36 days, and finally the last period I had was 87 days."

In 2016, Malcer had a partial hysterectomy at age 36.

Not All Patients

Cassidy did note, however, that not all his patients with Essure have experienced problems.

Aside from the 300 or so patients that came to Cassidy with adverse events – those patients having had the device implanted by other doctors – Cassidy had placed some 100 or so devices in his own patients and wasn't made aware of any issues until 2015.

At that point, Cassidy said he sent letters to those 100 patients informing them of potential problems they could experience due to the device. Of those 100 patients, only three responded and came back for device removal.

"So it's not happening in all patients by any means," Cassidy said. "It's just that I'm seeing all the patients that are having the problems."

Bayer's Backing

Bayer continues to stand by Essure even after pulling it off the market, despite the numerous complaints from women such as Ingram and Malcer and being featured for its adverse effects in the 2018 documentary "The Bleeding Edge."

A Bayer spokesperson told *Medtech Insight* that the removal of Essure from the market doesn't mean the company no longer has an ethical responsibility to the many women who received the device, especially those suffering side effects.

"Bayer's highest priority is the safety and effectiveness of our products, and we have sympathy for anyone who has experienced health problems while using any of our products, regardless of cause," the spokesperson said. "While all birth control products and procedures have risks, the totality of scientific evidence on Essure demonstrates that its safety profile is positive, its risks have been appropriately disclosed since its 2002 approval by the FDA and its benefits and risks are comparable to other female permanent birth control options."

This body of data, according to Bayer's spokesperson, reinforces Essure's risk/benefit profile and includes the results of 10 clinical trials and more than 70 real-world observational studies conducted by Bayer and independent researchers over the past 20 years, in which more than 270,000 women participated.

> ***"We continue to ensure that Bayer meets its mandated postmarket study obligations for Essure, and that new information concerning the safety and effectiveness of Essure is publicly shared in a timely fashion." – The FDA***

Bayer also cited a recent *study* co-authored by a former expert for plaintiffs in Essure-related litigation, which found that "overall, hysteroscopic sterilization [Essure] was the safer procedure" over laparoscopic tubal ligation, with claims for hysterectomy, salpingectomy, and oophorectomy being "significantly higher among those who had laparoscopic sterilization."

Bayer also provided *Medtech Insight* with charts highlighting the overview of two studies comparing patients with Essure to those who chose tubal ligation. Those studies, according to

Bayer's spokesperson, show both procedures are compatible and that Essure patients experience lower rates of pelvic pain than tubal ligation patients, and "seven out of seven studies show that Essure patients are less likely to have a hysterectomy than are tubal ligation patients."

Litigation

Ingram was offered a settlement from Bayer, which she turned down because the offer, she said, was a "slap in the face" and did not cover the costs of her medical bills. But the main reason she did not accept the settlement, she said, was that it contained a confidentially agreement which would have prevented her from speaking about Essure.

Victoria Wispell, an attorney with the firm McCune, Wright, and Arevalo, based in Ontario, CA, confirmed that Ingram was a client and that she opted out of the Bayer settlement, but would not provide any further documentation or details.

> *"We trust the FDA when a device is approved and the studies are done, but it's difficult for us to look into all the details of every study." – Brett Cassidy*

"Somebody's got to take responsibility and obviously it's the manufacturer. And if they could just have some accountability for what it's done to us," Ingram said. "We're all human. We all try things. It didn't work. It was defective. Take responsibility for that."

According to the Bayer spokesperson, the company announced a settlement agreement in August 2020 to resolve some 39,000 filed and unfiled claims in the US. "Progress continues to be made in settling cases related to the Essure settlement," the spokesperson said, "and Bayer has reached agreements in principle with plaintiff law firms to resolve approximately 99% of the total claims."

Focus on the FDA

But studies and statements do little to lessen the physical pain of those Essure patients that have experienced severe side effects, including those like Ingram and Malcer who required hysterectomies.

And it certainly doesn't assuage the anger at the FDA for giving Essure the green light in the first place.

“We trust the FDA when a device is approved and the studies are done, but it's difficult for us to look into all the details of every study,” Cassidy said. “We have a lot of faith in what the FDA tells us. So after this I do more research when it's something new that comes on the market instead of just jumping on board.”

The FDA, however, stands by its approval process.

A spokesperson at the FDA told *Medtech Insight* that Essure, “a first of its kind device,” was approved after a “rigorous scientific and regulatory review, including input from an outside panel of experts.”

That panel, the agency’s Center for Devices and Radiological Health (CDRH) Obstetrics and Gynecological Devices Advisory Panel, recommended approval in July 2002.

Since its approval, the agency has continued to monitor Essure’s safety and effectiveness.

Continued Surveillance

In February, the FDA posted its most recent *update* on Essure, “Information for Patients and Health Care Providers: Essure,” based on data from patients who had completed one year of follow-up from the agency’s 2020 interim analysis. The next round of results is scheduled for release after all patients complete three years of follow-up.

According to that update, the FDA continues to advise that those women “using Essure successfully to prevent pregnancy can and should continue to do so.”

By continuing to collect long-term safety information in women who have received Essure, along with clinical data from postmarket surveillance, the FDA will be better able to help patients, health care providers, and the agency understand certain complications that women with the device have, the spokesperson said.

Essure-Related Complications Still A Problem, Latest FDA Data Show

By Brian Bossetta

15 Feb 2022
Interim data from two ongoing studies show more women have had the Essure birth control device removed while many are still experiencing adverse events, such as pain and bleeding.

Read the full article here

As the FDA noted, the agency has taken several steps concerning Essure – before and after it was removed from the market – such as investigating patients complaints, ordering Bayer to conduct its postmarket study, issuing guidance on the device, updating labeling to warn of risks, and then ultimately restricting sales and distribution of Essure “to help make certain that a woman

considering Essure receives and has full access to information about the benefits and risks of this type of device prior to undergoing treatment with this product."

In July 2018, Bayer notified the FDA that Essure would no longer be sold or distributed after 31 December 2018.

According to the FDA, Bayer decided to halt sales and distribution of the device due to commercial reasons.

For the women still dealing with the device, the FDA said their health and safety remain a top priority.

"We take concerns about Essure very seriously," the spokesperson said. "We continue to ensure that Bayer meets its mandated postmarket study obligations for Essure, and that new information concerning the safety and effectiveness of Essure is publicly shared in a timely fashion."

Cold Comfort

But in Cassidy's view, there remains a great unknown even for those women not having problems with the device now – that being what hazards, if any, the device might cause later in life considering women with the device are relatively young with many years of life expectancy in front of them.

"It's possible that the nickel could increase the risk of certain cancers down the road," he said. "We're just not sure. And that's what I tell patients that come in that don't have any symptoms. We just don't know."

The FDA's most recently approved labeling provides recommendations on device removal that providers and patients should be aware of, the agency spokesperson said, including patient counseling, device removal techniques, and other general considerations.

The postmarket ("522") study the agency mandated Bayer to conduct has included several modifications to strengthen the evidence collected and will be followed for five years, rather than the three years that was initially required, according to the FDA.

The FDA is also requiring additional blood testing of patients enrolled in follow-up visits during the study to learn more about levels of certain markers that can be indicators of increased inflammation. This, according to the agency spokesperson, could enhance the agency's ability to evaluate potential immune reactions to the device and whether these findings are associated with symptoms that patients have reported related to Essure.

“This significant extension follows the FDA’s request that the company go beyond the three-year period provided for by law,” the spokesperson said. “This extension will provide FDA with longer-term information on risks of the device, including issues that may lead women to have the device removed.”

But for Malcer, it’s simpler.

“The way I look at it, you don’t put foreign objects in your body,” she said. “That’s the one thing I learned from this.”