Women report complications from Essure birth control
26 December 2013, by Julie Deardorff

Angie Derry knew that her Essure implants were designed to remain inside her body forever. But two years after a doctor inserted the tiny coils into her fallopian tubes to prevent pregnancy, the Rockford, Ill., woman wants them removed.

Derry, 35, isn't hoping to have more children. Instead, she wonders whether getting rid of the implants will somehow alleviate the mysterious ailments that she said began after seeking permanent birth control with Essure in 2011.

At the very least, Derry wants to rule out Essure as the cause of her joint, back and pelvic pain, chronic low-grade fever, cramping, numbness and tingling, hair thinning and extreme fatigue.

"It's the only thing that makes sense," said Derry, who has undergone a barrage of medical tests over the past two years but still has no diagnosis. "My doctors are grasping at straws."

Essure, on the market since 2002, has been hailed as the next generation of permanent contraception. Unlike a tubal ligation, which requires surgery, Essure can be inserted by catheter in a doctor's office, without anesthesia or incisions. Most patients return to normal activities in one or two days.

But complaints about Essure have recently surged. The U.S. Food and Drug Administration has received nearly 1,000 "adverse event" reports related to the device, with 500 arriving in 2013. The most common issues cited are pain, hemorrhaging, headaches, menstrual irregularities, weight fluctuation, device migration and suspected nickel allergy.

Thousands of women also have joined support groups on social media to discuss debilitating side effects and baffling medical problems they link to Essure. Some women have undergone a hysterectomy or other procedure to remove coils that were never meant to be taken out of the body.

Bayer Healthcare, which purchased Essure manufacturer Conceptus in June, said in a statement that Essure has a "well-documented benefit-risk profile" and has been placed in 750,000 women worldwide. "Patient safety is of utmost importance to Bayer," the statement said, adding that the company works with the FDA to update patients and physicians when new information about efficacy or safety becomes available.

In response to patients' complaints, the FDA over the last nine months re-examined the results of the manufacturer's safety studies along with reports of problems, including testimonials from the Internet. The agency found that Essure's labeling addresses some of the issues and that no conclusive evidence connects Essure to symptoms such as extreme fatigue, depression and weight change.

"Although there is evidence of complications, as there are with all medical devices, overall results from this study did not demonstrate any new safety problems or an increased incidence of problems already known," the agency said.

By year's end, however, Bayer will revise Essure's patient brochure to state that in rare cases coils can move from the fallopian tubes into the lower abdomen, according to the FDA. The brochure also will list chronic pain as a rare side effect.

Some women's health advocates are calling for more safety studies and say women deserve more information about Essure's potential long-term risks. They also disagree with the characterization of the adverse events as rare.

"They sell Essure like a cruise, hand you a pamphlet like you're going on vacation," said Angie Firmalino, 41, who founded a Facebook group called Essure Problems in 2011, two years after undergoing the procedure. She said she
experienced heavy periods, joint pain, sharp pelvic pain and other symptoms before learning that the coils had moved into her uterus and become embedded there.

Dr. James Presthus, a clinical assistant professor of obstetrics and gynecology at the University of Minnesota who has been implanting Essure for more than a decade, said he considers the device to be safe.

"Most patients have the expected outcome and do well," he said. "But for patients who have pain - and the device is placed correctly - we don't have an explanation."

Presthus said he removed Essure implants from five patients last month, including several who traveled from out of state to his office at Minnesota Gynecology and Surgery. "Something was wrong, they didn't feel comfortable, and they wanted it removed," he said.

In one case the device was found to have migrated into the uterine cavity; in another, it perforated the back of the uterus, Presthus said.

Over the last month at least five other women have called his office to ask about getting rid of the device. "It's most commonly related to pain or some discomfort," said Presthus. "But for the number of devices placed, it's a low number."

Some patients may have symptoms not because of Essure but because they stopped using oral contraceptives, noted Dr. Alexander Lin, co-medical director of Northwestern Memorial Physicians Group Division of Obstetrics and Gynecology.

Hormonal forms of birth control can mask underlying conditions such as fibroids and endometriosis that could later flare up and cause problems like heavy, painful periods and chronic pelvic pain, Lin said. After patients stop oral contraceptives, they may experience "irregular and at times heavy and prolonged menstrual bleeding," he said.

Lin said he has implanted hundreds of devices and no patient has requested removal. He recommended that women in pain seek out an opinion from a gynecologist who has experience with Essure to rule out other possible causes for pain. "Otherwise, the symptoms could persist even after having their Essure removed," he said.

Essure's coils are made from polyester fibers and metals, including nickel titanium and stainless steel, materials with a history of use in stents, valves and grafts. To insert the coils, a doctor passes a special catheter through the vagina and uterus into the fallopian tubes. The inserts trigger the body's inflammatory response. Over time, scar tissue forms around the coils and blocks the fallopian tubes, preventing sperm from fertilizing a woman's egg. Backup birth control must be used for at least three months, when a woman undergoes an X-ray to confirm the tubes are blocked.

A five-year follow-up study conducted by the manufacturer found that when Essure is correctly placed, it is 99.83 percent effective in preventing pregnancy and that serious side effects are rare, according to the FDA.

Bayer says its data show Essure is correctly placed on the first try 96.9 percent of the time. Other studies report the initial placement success at a rate of 84 percent to 98 percent, according to a 2011 review of Essure by Mayo Clinic researchers. The procedure is more difficult in women who have a misshapen uterus or abnormal fallopian tubes.

"Not all women will get successful insertion," said Dr. Keith Monteith of the Chapel Hill Tubal Reversal Center in North Carolina, who began removing Essure in 2009. "These studies are often done with carefully selected patients and doctors - some of the women were excluded because of improper placement or perforations. So the typical use rates are often very different from the study observations."

Some doctors are reluctant to remove a permanent device, especially without proof that it's causing problems. Removing the coils also is technically challenging and becomes more difficult after they have been in place at least three months, according to research published last year in the journal Contraception.
Doctors may also suggest a full hysterectomy, but others view that idea as overkill.

"A hysterectomy is a sure method of removal, but it's like having a problem with the right toenail and cutting off the toe. Is it necessary?" said Dr. Bala Bhagavath, an associate professor of obstetrics and gynecology at the University of Rochester Medical Center who co-authored the Contraception paper.

When Essure was initially approved, the only removal protocols for physicians involved cases when Essure was placed incorrectly and the issue could be immediately fixed. Bayer now recommends surgically removing part or all of the fallopian tube if a patient demands removal or she is suffering adverse effects.

The FDA approved Essure as a Class III medical device, a category that is subject to the agency's most rigorous review before the product can be marketed.

Patients who believe such a device harmed them cannot sue the manufacturers in state court because federal law gives the FDA the power to determine whether a device is safe, according to a 2008 Supreme Court ruling.

When the agency approved Essure in 2002, it noted that the unique nonsurgical approach "offered a significant advantage over existing alternatives." Because long-term data on safety and effectiveness were lacking, the FDA required Conceptus to conduct a five-year follow-up study.

The study was completed in 2007. Bayer declined to provide the Chicago Tribune with the results, citing pending publication.

Firmalino, of Tannersville, N.Y., said she started her Essure group on Facebook after feeling frustrated by doctors who dismissed her complaints. Today, Essure Problems, which has the support of consumer advocate Erin Brockovich, has nearly 5,000 members and is adding more than 100 members a week. On the site, the women compare symptoms, offer advice and share their medical records, pathology reports, X-rays, CT scans and photos of removed coils.

The group's administrators also keep records and databases documenting everything from individual symptoms and dates of removal surgery to a map of doctors who will remove Essure. This year, at least 435 members have reported undergoing removal surgery. There's also a growing list of women who have decided against Essure after reading testimonials.

Firmalino said she had her coils removed vaginally but X-rays still show several "foreign bodies" in her uterus. She believes these may be Essure fragments and plans to schedule a hysterectomy. "I don't know if this will make it any better, but I'm debilitated by pain," she said.

Rockford's Derry, also a member of Essure Problems, isn't sure if removal surgery will help her, either. But she's so discouraged by her declining health that she is willing to try anything. She said she recently sent an email to her primary-care doctor asking whether Essure could be causing her problems; Derry expects to discuss the issue at an appointment next month.

"I'm definitely thinking that now I want it out," said Derry, who plans to have a spinal tap in the meantime to rule out multiple sclerosis. "I just have to find the doctor who says, 'Yes, let's do it.' "

©2013 Chicago Tribune
Distributed by MCT Information Services