**All** **You Need to Know About Essure Lawsuits**

Birth control, or contraception, is the deliberate prevention of pregnancy. The [Centers for Disease Control and Prevention (CDC)](https://www.cdc.gov/nchs/fastats/contraceptive.htm) reports that 15.9% of women in the United States are currently using the pill and 8% are using a contraceptive implant or intrauterine device (long-acting reversible contraception). In 2011 to 2013, of the 60.9 million women aged 15 to 44 in the U.S., [61.7% were using contraception](https://www.cdc.gov/nchs/data/databriefs/db173.htm). The most common methods of contraception that were currently being used were contraceptive pills (16%), female sterilization (15.5%), long-acting reversible contraceptives (7.2%), and male condoms (9.4%).

**Essure Birth Control Device**

Essure is a birth control device that consists of two small metal coils that prevent eggs from moving through the fallopian tubes when it is implanted. It thus prevents fertilization and implantation. Although it does not involve “tying” the fallopian tubes, it is technically a form of tubal ligation. The contraceptive device is manufactured by Bayer Healthcare, the medical device-making giant. The company markets Essure as a “permanent contraceptive.” The same was said by the device’s previous company, Conceptus Inc., which was bought by Bayer in 2013.

Bayer claims that only a minimally invasive procedure is required for Essure devices and that the procedure can be performed right in a doctor’s office. However, women who receive the device must continue to use other birth control forms for a minimum for 3 months after insertion to confirm that it is effective.

Unfortunately, there are many people who have reported experiencing severe side effects and complications after implantation of Essure. These issues include everything from allergic reactions and pelvic pain to needing additional surgeries for the removal of the device or repairing organs that have been damaged due to the birth control implant.

**Common Side Effects and Complications of Essure**

The most common side effects and complications of Essure include the following:

* Rashes or itching
* Hair loss
* Migraine headaches
* Menstruation problems
* Weight gain
* Back pain
* Brain fog
* Metal allergies
* Chronic fatigue
* Chronic or severe pain
* Scar tissue
* Unwanted or unintended pregnancy
* Ectopic pregnancy
* Autoimmune disorders
* Perforation of the colon, uterus or another organ
* Fetal death
* Breakage, migration or expulsion of the device
* Hysterectomy
* Additional surgeries

**Is Essure Reversible or Removable?**

According to the label of the contraceptive device, the Essure procedure is a permanent one and irreversible. While some claims have been made about successful removal of the birth control device and restoration of fertility, the procedure for Essure implantation remains untested in a reliable clinical trial or other methods that can be scientifically verified.

In cases where women have experienced side effects, the coils of the Essure device can be surgically removed. However, the device’s effects are not guaranteed to be reversed. They may require additional surgeries, especially if the device breaks apart, or if there is the formation of scar tissue or perforation of an organ.

**Why are Women Filing Essure Lawsuits?**

From late 2002 through late 2017, there were 26,773 complaints filed with the U.S. Food and Drug Administration about Essure. As a result, in April 2018, the agency restricted sales of the device. Bayer Healthcare announced in July 2018 that it would discontinue the sale of Essure permanent birth control devices in the U.S. by December 31, 2018.

There are more than 16,000 lawsuits that have been filed against Essure. Plaintiffs claim that Bayer did not warn patients of the potential severe complications. Women are filing lawsuits against the manufacturer because of the numerous complications that they went through after an implantation of the company’s sterilization device. These complaints range from minor to major problems resulting from breaking of the devices, device migration, and in some cases, even expulsion of the implant.

As part of the complaint, a large number of women are seeking damages for medical care costs to treat symptoms and complications caused by the contraceptive implant’s malfunction as well as related expenses. There are many women who are also seeking non-economic damages that are related to physical pain and emotional as well as mental anguish. These patients are also expecting to receive punitive damages. This will allow them to punish Bayer Healthcare for the development, manufacture and promotion of an unsafe medical device.

Apart from failure to warn of side effects, Essure lawsuits allege that Bayer lied to the FDA in order to get approval for the device. They also say that the company failed to train doctors properly on how to use Essure.

Bayer attempted to blame physicians, using the term “learned intermediary doctrine” to say that it is the responsibility of the doctor to warn women about the potential risks and complications that come with Essure birth control implants.

The allegations in Essure lawsuits against Bayer include:

* Failing to report and actively concealing adverse events of the device
* Manufacturing the device without a license for 3 years
* Failing to have a complete risk analysis for the birth control device
* Failing to track complications caused by Essure
* Failing to disclose 16,047 medical device complaints of suspected malfunction of Essure to the FDA
* Distributing Essure equipment for sale to physicians who are unqualified
* Encouraging physicians to “sell” the device to patients
* Failing to properly train physicians on how to use the birth control device

**Side Effects Mentioned in Essure Lawsuits**

There are several side effects mentioned in Essure lawsuits. For many women, the side effects of the device started immediately after it was implanted. Some women underwent several surgeries due to complications caused by Essure. As of January 2018, there were 26,272 reports of adverse events for the device filed to the FDA. Doctors have seen a decline in the demand for Essure due to the lawsuits filed by women injured by the device.

Side effects mentioned in Essure lawsuits include the following:

* Allergies to nickel
* Bleeding
* Bloating
* Depression
* Heavy periods
* Severe pelvic pain
* Death

These are in addition to the side effects mentioned earlier.

**FDA Adverse Actions and Events**

Essure was originally approved as a Class III medical device in 2002 by the FDA. After the initial approval of the device, Bayer has to submit detailed reports related to not just the efficacy but also the safety of the device. Bayer also had to submit any reports of adverse events, on a regular basis. Despite these requirements, the FDA cited the company a number of times for violations of those conditions, some of which resulted in the regulatory agency’s future actions:

* **June** **2008**: The FDA notified Bayer about a discovery it made about the company making Essure devices in an unlicensed factory at least since 2005, and that the medical device maker had failed to appropriately document their procedures.
* **January 2011**: The FDA cited Bayer for using materials that were not approved in the Essure implant. This was a violation of the premarket approval, which required the manufacturer to seek additional approval for any changes in design.
* **February 2016**: Bayer was ordered by the FDA to conduct a new clinical trial to determine whether Essure had any heightened risks for certain women, based on reports of adverse events that were filed to the regulatory agency.
* **November** **2016**: The FDA required the addition of a black box warning on the labels of the Essure device indicating the risks of allergy, abdominal pain, and the peroration, among other potential complications.
* **April 2018**: The sales of Essure was restricted by the FDA to medical centers and doctors that promised to conduct a conversation and go through a checklist with the patient before they prescribed the birth control implant.

**Will Essure Lawsuits be Stopped by Preemption Laws?**

Bayer Healthcare has made attempts to get many Essure lawsuits as a result of certain laws that are known as preemption laws. According to the company, it cannot be held liable for problems with the contraceptive device because the FDA conducts a rigorous series of tests on medical devices before approving them and deemed Essure to be generally safe.

There are a number of levels on which this argument is problematic, especially since it is clear that Bayer did not always follow its obligations on post market regulations. Nonetheless, using this argument, the company has succeeded in getting some product liability lawsuits dismissed while others have been allowed to move forward, with modified complaints in many cases.

**Essure Litigation in Process**

According to the most recent financial reports of Bayer Healthcare, approximately 16,100 lawsuits have been filed in state and federal courts across the U.S. At this time, all of these lawsuits are individual legal actions. There are no current Essure class action lawsuit or any MDL (multidistrict litigation) processes that have been established. As of April 2018, a report from Bayer Healthcare stated that there were two lawsuits in Canada seeking class action certification.

**Essure Multidistrict Litigation (MDL 2739)**

A group of 28 plaintiffs had submitted a petition in 2016 to transfer their cases using the MDL process that was overseen by the Judicial Panel on Multidistrict Litigation. However, a short time after the petition was filed, a judge in the Eastern District of Pennsylvania – where 23 cases of the 28 had been filed – agreed to the consolidation of the cases in that court. The motion for a multidistrict litigation was withdrawn, resulting in the cases to remain separate.

In some cases, such as California, processes that use MDL system-like processes have been established to coordinate Essure cases. However, so far, there have been no efforts made so as to enforce a federal MDL for the Essure lawsuits. There is a possibility of an MDL being created in the future due to the rise in the number of actions that are being filed.

**Verdicts and Settlements in Essure Lawsuits**

To this day, there have been no major publicized verdicts or settlements in Essure lawsuits awarding large amounts of compensation to women who have been injured by the contraceptive devices. However, Bayer could decide to try to settle them due to the large number of lawsuits that are currently going through the court system. This decision could come if it looks like the medical device maker is likely to lose cases based on the claims’ legal merits.

In recent years, there have been reports from some outlets that Bayer lost $413 million as a result of legal issues with Essure. This estimation comes from the financial records of the corporation, which claimed “impairment losses” of €391 million related to “intangible assets” that were connected to the birth control device. The latest annual report does not list any kind of impairment losses individually for this device, but does tabulate that €258 million (roughly $308 million) was incurred by the company in “expenses related to significant legal risks” for its products including Essure, Avelox, Cipro and Xarelto.

There should be no confusion between losses noted on corporate financial statements and compensation paid to women injured by Essure. Based on the amount of money that Bayer is willing to spend in defense against personal injury claims, it is clear that the medical device manufacturer thinks that losing such cases could lead to much higher losses for victims of the defective birth control devices.

Essure lawsuits are ongoing. Trials have not been set, so, as mentioned earlier, there are no jury verdicts or settlements. Lawsuits in California may be the first to go to trial. Jury verdicts from the first Essure lawsuits may have an influence on jury verdicts in other states.

In May 2018, both sides were ordered to name Special Settlement Masters by Judge John R. Padova in Pennsylvania in the event of a settlement. Special Settlement Masters is a firm that handles any potential settlement in lawsuits.

Potential compensation from Essure lawsuits will result from damages that include:

* Medical bills
* Pain and suffering
* Lost time from work
* Loss of income
* Loss of quality of life
* Loss of companionship

**Status of Essure Lawsuits**

Women and their families continue to file Essure lawsuits in state courts across the United States. Most of the lawsuits are in Pennsylvania, California, North Carolina and Missouri. In February and April 2018, the latest Essure lawsuits were filed by plaintiffs in Pennsylvania federal court.

Women who filed Essure lawsuits in Pennsylvania said that the device migrates from the fallopian tubes, breaks into pieces, perforates organs, and/or corrodes and wreaks havoc on the female body.

In March 2018, Judge Winifred Y. Smith of California made it mandatory for plaintiffs to submit a master complaint in which allegations against Bayer should be combined. She also stated that both parties should begin their preparations for trial. As of March 2018, Judge Smith presided over more than 13,000 California Essure lawsuits.

**Essure Cases that have been Dismissed**

There have been some judges that have dismissed Essure cases for preemption. This puts a limit on product liability in state lawsuits after approval from the FDA. As mentioned earlier, Judge Smith permitted Essure lawsuits in California to proceed in spite of preemption.

Other cases have been dismissed for failing to meet requirements of the court. For example, in January 2018, Judge Stephen Lambaugh of Missouri federal court threw 92 out of 95 plaintiffs from an Essure case.

**Filing an Essure Lawsuit**

To file an Essure lawsuit, the first thing you need to do is contact a reputable lawyer with experience in Essure cases and handling cases against major companies like Bayer Healthcare. You should arrange a meeting and provide the lawyer all your medical records and other documents to present as evidence in your Essure case. The lawyer will review your case to determine whether there is sufficient viable evidence to file a lawsuit against Bayer for side effects or a complication caused by the birth control device. Most Essure lawyers will conduct a review of your case for free.

Once the free case evaluation is done, your lawyer will inform you if you can file an Essure lawsuit. If so, they will begin to prepare your case and take the necessary steps to file the claim against the manufacturer of the device. Keep in mind that lawsuits against large corporations like Bayer can be extremely challenging as they have high-power lawyers defending them against any legal action taken against them. It will be an arduous, complex process that could take a long period of time, even years, to conclude.

Once your lawyer begins the process of filing an Essure lawsuit, they will do everything required to prove your case in court. They will collect all the evidence needed and also get expert witnesses to testify that your injuries were caused by the implantation of the birth control device. It is important to prove to the jury that you were harmed by Essure to obtain a favorable outcome. It is also critical to make sure that the proper steps are taken to file your Essure lawsuit and prevent your case from being tossed out by a judge. This is why you need to hire a skilled and experienced lawyer who has handled Essure cases prior to yours.

If your case is a strong one, it is likely that Bayer’s lawyers will approach you and offer a settlement. You and your lawyer should discuss matters properly before making any decision. If you think that you have a strong case and can get a larger amount of compensation from a jury verdict, you can turn them down and continue with the trial. Your lawyer is the best person to advise you as they have the knowledge and experience to tell when to accept a settlement and when to continue fighting in court. They have your best interest in mind and will make sure that your rights are protected, and that the company does not take advantage of you.

You will not have to pay an Essure lawyer for their services if they take on your case as they usually work on a contingency basis. This means that you will not pay anything until there is a jury verdict or settlement. When you obtain your award from the Essure lawsuit, your lawyer will receive an amount for fees and expenses.

**Time Limit for Filing an Essure Lawsuit**

An Essure lawyer can determine the statute of limitations, or time limit, for filing each Essure case. The statute of limitations varies from state to state. Your lawyer will find out the time limit in your state and make sure that you file your Essure lawsuit before that time limit. It is important to file your claim before the statute of limitations ends or your case will be thrown out by the judge immediately.

Women have 2 to 3 years to file an Essure lawsuit in some states. If someone died due to the contraceptive device, families generally have about 2 years to file an Essure lawsuit for wrongful death. However, in some states like California, the time limit to file a lawsuit against Essure may only be one year. You should contact an Essure lawyer immediately to find out your eligibility to file the lawsuit against the device manufacturer.

**Get Expert Legal Assistance for Essure Lawsuits**

If you or a loved one has experienced side effects or suffered complications as a result of an Essure birth control device, you should immediately seek the help of a skilled and experienced Essure lawyer. You can file a lawsuit against the manufacturer of the device for compensation for the injury and damage you have gone through after receiving the birth control implant. Depending on the circumstances, you can be awarded a jury verdict or get a settlement offer from the company.

You can file an Essure lawsuit for damages including medical bills for present and future medical treatments, pain and suffering, loss of income, loss of quality of life, punitive damages and more. In wrongful death cases, damages can include medical bills, loss of income, loss of benefits, loss of consortium, survivors’ pain and suffering and punitive damages. With the help of a reputable Essure lawyer, you can make sure that you receive the compensation you deserve for the harm caused by Essure side effects and that you are legally entitled to.