

# The Dalkon Shield <sup>[1]</sup>

By: Horwitz, Rainey Keywords: [Contraception](#) <sup>[2]</sup>

The Dalkon Shield was an intrauterine contraceptive device (IUD) that women used in the early 1970s and 1980s. Produced by the A.H. Robins Company in the US, the Dalkon Shield was a contraceptive device placed directly into a woman's [uterus](#) <sup>[3]</sup> that was supposed to prevent [pregnancy](#) <sup>[4]</sup>. In the 1980s, researchers discovered that the Dalkon Shield caused an array of severe injuries, including pelvic infection, [infertility](#) <sup>[5]</sup>, unintended [pregnancy](#) <sup>[4]</sup>, and death. Eventually the A.H. Robins Company took the shield off the market, and the US Food and Drug Administration banned the device. Many users of the Dalkon Shield sued the production company and were awarded millions of dollars in compensation and punitive damages. After the dangers of the Dalkon Shield became public through those lawsuits, the popularity of intrauterine devices decreased significantly in the US.

In the early 1970s, Hugh J. Davis and Irwin Lerner invented the Dalkon Shield. At the time, Davis was a physician and professor of gynecology and obstetrics at [Johns Hopkins University](#) <sup>[6]</sup> in Baltimore, Maryland. Davis argued that [birth control](#) <sup>[7]</sup> pills were so hazardous that physicians prescribing them were behaving irresponsibly. The other inventor, Irwin Lerner, was an engineer and helped Davis design the Dalkon Shield as a safer alternative to [birth control](#) <sup>[7]</sup> pills.

As an intrauterine device, physicians placed the Dalkon Shield directly into a woman's [uterus](#) <sup>[3]</sup>. The Dalkon Shield consisted of a plastic five-pronged, crab-like shield, which prevented the [uterus](#) <sup>[3]</sup> from expelling the device. It also contained small amounts of copper that acted as a [spermicide](#) <sup>[8]</sup>, preventing [sperm](#) <sup>[9]</sup> from fertilizing an [egg](#) <sup>[10]</sup>. The device was attached at the base to a string made from various filaments, similar to the string of a tampon, which The was used to remove the device. In the early 1970s, when Davis and Irwin began selling the Dalkon Shield, the device was not subject to any extensive testing by the US Food and Drug Administration because it was not considered a drug.

The Dalkon Shield was originally produced by the Dalkon Corporation, founded by Davis soon after the invention of the IUD. In 1971, the A.H. Robins Company, producers of the cough medicine Robitussin, bought the device from Davis and put it on the market. The A.H. Robins Company began selling the Shields in the US and Puerto Rico and launched a large marketing campaign for the device. The campaign emphasized the safety of the IUD compared to traditional contraceptive pills. According to reporter Robert Thomas, prior to government [regulation](#) <sup>[11]</sup> of [birth control](#) <sup>[7]</sup>, many Americans were concerned with the safety of [birth control](#) <sup>[7]</sup> pills and sought safer alternatives. The manufacturers of the Dalkon Shield capitalized on that, claiming that the device was safer than existing methods of [birth control](#) <sup>[7]</sup>. Although physicians initially expressed skepticism about the effectiveness of the device, many of their reports did not identify safety issues with the device. After three years on the market, physicians had prescribed the Dalkon Shield to over 2.2 million women. According to Thomas, the Dalkon Shield was the most popular IUD on the US market in the 1970s.

However, by 1971, women who had used the device reported septic infections and other complications that led them to seek serious medical attention. Researchers discovered that the string attached to the Shield was not sealed at the end, causing the string to fray and disintegrate. The string drew vaginal bacteria into the [uterus](#) <sup>[3]</sup>, resulting in septic infection, [miscarriage](#) <sup>[12]</sup>, and an array of other related complications, including death. In response to claims about the dangers of the Dalkon Shield in the early 1970s, the A.H. Robins Company argued that any complications with the device should be attributed to the doctors who improperly inserted the devices. However, after several years of distribution, women reported that in addition to causing complications, the device did not protect them against [pregnancy](#) <sup>[4]</sup>. Instead, researchers found that the device led to increased risk of [pregnancy](#) <sup>[4]</sup> complications due to its design.

In June of 1973, the US Centers for Disease Control and Prevention, or CDC, conducted a study on the safety of IUDs, including the Dalkon Shield. Researchers at the CDC gathered information from 16,994 obstetricians and gynecologists regarding the frequency of hospitalizations, deaths, and other complications related to IUD use during a six-month period. During the six-month period, researchers found that the Dalkon Shield was the most popular IUD on the market. They also determined that the Dalkon Shield was correlated to an increased rate of [pregnancy](#) <sup>[4]</sup>-associated complications, including septic pregnancies, or a bacterial infection of the [placenta](#) <sup>[13]</sup> and [fetus](#) <sup>[14]</sup>. Those complications were serious enough that they usually led to hospitalization. Despite the CDC study released in 1973, around 2.5 million women were still using the Dalkon Shield the following year. In a separate study conducted by the University of Southampton Department of Human Reproduction and Obstetrics, in Southampton, England, researchers suggested that the Dalkon Shield was an advancement in IUD technology and had advantages compared to other IUDs.

In June of 1974, the medical director of the A.H. Robins Company, J.S. Templeton published a letter to the editor of the *British Medical Journal* in which he discussed the medical issues associated with the Dalkon Shield. In the report, the director claimed that the company was aware of the apparent trend of septic abortions and infections in women using the device, including several deaths. However, Templeton also stated that there was no direct evidence that the Dalkon Shield was responsible for

the bacterial septic poisoning and related issues. Rather, Templeton claimed that the increase of cases of septic abortions was due to the general increase in use of IUDs and not specifically the Dalkon Shield. On 28 June 1974, the A.H. Robins Company took the Dalkon Shield off the market. However, they did not recall the devices that had previously been sold.

In October of 1974, the journal *Obstetrics and Gynecology* published several studies on the high frequency septic pregnancies associated with the Dalkon Shield. A year later, in 1975, the CDC published a study in which the authors claimed that the Dalkon Shield came with a higher risk of [abortion](#)<sup>[15]</sup>-related deaths than other IUDs. After the publication of those studies, the A.H. Robins Company discontinued production of the Dalkon Shield. However, the company persisted in not recalling devices that had already been sold.

After several years of national distribution of the Dalkon Shield, over 200,000 women made claims that the device had caused serious medical consequences, including pelvic inflammatory disease, [miscarriage](#)<sup>[12]</sup>, and loss of fertility. There were at least eighteen reported deaths caused by the device. By 1976, the US Congress passed federal legislation mandating that the US Food and Drug Administration require safety and efficacy testing of IUDs prior to approval. Though the A.H. Robins Company claimed that the Shield was not any more dangerous than other IUDs, women filed over 300,000 lawsuits against the A.H. Robins Company. By the fall of 1984, the company's insurance firm had settled around 7,600 claims for around \$245 million dollars. In October of 1984, the A.H. Robins company released a media campaign advising women who were still wearing the Dalkon Shield to have it removed by a doctor. That campaign required the company to pay over 4,500 medical bills from doctors that had removed the device. By the end of 1985, the A.H. Robins company was facing lawsuits from people in every state of the US. The company filed for bankruptcy in 1985. Before being sold to American Home Products in 1989, the A.H. Robins company established a \$615 million-dollar fund to pay for the settlements of the remaining lawsuits.

After the dangers of the Dalkon Shield were publicized, rates of IUDs use decreased in the US, as women began distrusting the safety of all IUDs.

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## Subject

[Dalkon Shield \(Intrauterine contraceptive\)](#)<sup>[23]</sup> [Intrauterine contraceptives](#)<sup>[24]</sup> [IUCDs \(Contraceptives\)](#)<sup>[25]</sup> [Copper intrauterine contraceptives](#)<sup>[26]</sup> [Contraceptives](#)<sup>[27]</sup> [A.H. Robins Company](#)<sup>[28]</sup> [A.H. Robins Pharmaceutical Company](#)<sup>[29]</sup> [Birth control](#)<sup>[30]</sup> [Conception](#)<sup>[31]</sup> [U.S. Food and Drug Administration](#)<sup>[32]</sup> [Center for Disease Control](#)<sup>[33]</sup> [Intrauterine Devices](#)<sup>[34]</sup> [Contraceptive Devices, Intrauterine](#)<sup>[35]</sup> [Intrauterine Device Expulsion](#)<sup>[36]</sup> [Uterus](#)<sup>[37]</sup>

## Topic

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