ESSURE was approved for sale in the United States in 2002 based on the information provided to the Food and Drug Administration (FDA) from its Phase II and Pivotal premarket trials.

Major flaws with the studies included the lack of comparison to tubal ligation and the small size of the study groups, which included only 745 women.

Of the 745 women, less than 700 were followed for a year and less than 200 for two years.

Imagine the logic in that fact. Less than 200 women were followed for 2 years, in order to get approval for a medical device designed to be permanently implanted in the human body.

As such, the validity of the trials significantly suffered due to lack of patient follow-up.

Aside from the small size of the study groups, the data collected and presented to the FDA from these trials has been marred by controversy.

To this day, there continue to be allegations that patients' answers were intentionally doctored and falsified in order to get FDA approval.

The data from the trials demonstrated unacceptably high rates of tubal injury, implant migration, chronic pain, and abnormal uterine bleeding.

ESSURE works by intentionally inducing a foreign body reaction which causes scarring and closure of the Fallopian tubes. Yet, the trials failed to evaluate the incidence of any foreign body complication associated with the ESSURE device.

Autoimmune symptoms, as a known foreign body reaction, were not acknowledged as a potential risk until November 2016 when Bayer was forced by the FDA to include these in its Black Box Warning (BBW) labeling.

Despite this warning, medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and Planned Parenthood downplayed its importance.

Further, many doctors continued to hide the warning from their patients even after Bayer removed ESSURE from the market.

I cannot stress enough that any reasonably intelligent OBGYN could have looked at the premarket data and simply refused to offer the ESSURE based solely on its merits.

I believe that the majority of OBGYNs that placed the ESSURE were negligent in recommending Essure.  Unfortunately there have always been deeply ingrained misogynistic attitudes by the OBGYN specialty which is one reason ESSURE was able to thrive.

The other, and more importantly, was the financial benefit of implanting Essure, which Bayer counted on in selling the ESSURE myth.

In a future video, I will present the results of the postmarket interim data presented by Bayer to the FDA demonstrating the failures of the ESSURE device.