In 2016, due to the significant number of adverse effects with ESSURE and based on the recommendations from the FDA Advisory Committee meeting, the FDA ordered Bayer to conduct an ESSURE post-market study to evaluate its safety and efficacy as compared to laparoscopic tubal ligation.

This study is known as the ESSURE 522 study.

In July 2020, the FDA provided interim results from the post-market 522 study.

Interim results show that ESSURE patients have significantly higher rates of chronic lower abdominal and/or pelvic pain and abnormal uterine bleeding as compared to women who have had laparoscopic tubal ligation.

Hypersensitivity and allergic reactions and autoimmune symptoms were almost twice as high in the ESSURE group as compared to tubal ligation.

The rate of additional gynecological surgical procedures, which included ESSURE device removal was 6x higher for ESSURE patients than with tubal ligation.

The overall cumulative probability of removing ESSURE for any reason was approximately 14%.

That means that 1 out of 7 women with ESSURE may eventually need to have the device surgically removed.

Now remember, this was supposed to be a device that was permanent and would never need to be removed.

So, what is the take home message from the 522 study?

It is clear by the interim data that the benefits promoted by Bayer and the implanting surgeons as compared to laparoscopic tubal ligation are false.

What is clear by the interim data is that the ESSURE is far inferior compared to laparoscopic tubal ligation and the incidence of hypersensitivity or allergic reactions and autoimmune symptoms do exist with ESSURE.

I can assure you that by the 2025 completion of the 522 study, it will be shown that ESSURE is far inferior to tubal ligation; at times even dangerous and should never have been placed on the world market.

Less than 1 month after the interim data was made public, Bayer had agreed to settle the mass tort lawsuits with ESSURE victims for $1.6 Billion dollars.

Was the timing of a settlement shortly after the 522 interim data was made public coincidental? I don't think so.

In my next video, I will discuss the Bayer $1.6 Billion dollar offer in more detail.