**FDA REGULATION OF HIP RESURFACING IMPLANTS WE USE James W Pritchett MD**

**Background:** On May 28, 1976 Medical Device Amendments were passed bringing the regulation of medical devices under the FDA. Orthopedic implants were then regulated as interstate commerce and were sold to hospitals and surgery centers but not to surgeons and patients. Prior to 1976 surgeons such as my mentor Charles O Townley MD sold implants directly to their patients. Innovators designed implants and the manufacturer made them. I started practice in 1984. **I have never made or sold an implant**. Hospitals and surgery centers form contractual relationships with manufacturers and they provide implants to patients. Surgeons may have input to the process but increasingly decisions are made by administrators. There is little if any choice in resurfacing implants because of availability.

**FDA Hip Resurfacing Regulation May 28, 1976 to January 3, 2005:**

Implants that were in use prior to 1976 could continue in use. New implants could be put in use if they were substantially equivalent. The FDA would control labelling, advertising claims and the intended use. The FDA would also review manufacturing and collect data on implant related problems. Most hip implants were Class II (special controls). Class III (premarket approval) suggested a higher level of risk. Hip resurfacing implants were Class II. Hip Resurfacing is by its nature more demanding with a higher expected early failure rate due to:

1. Difficult surgery to gain exposure to place the acetabular component
2. The implants must fit the femoral head and there is just one socket that must match. This socket must then be fitted to the acetabular bone. Rarely, if ever, is a perfect fit possible.
3. The acetabular component is necessarily thin and there is deformation during insertion.
4. The femoral head and neck must stay viable under the cap and not break.
5. The natural femoral neck is larger by comparison to a total hip and may impinge.
6. There is more frictional torque from the larger femoral head size. This may lead to loosening and implant wear. With the high frictional torque and a large femoral head dimension a seroma may form as the body struggles to produce the necessary natural lubricant.
7. Resurfacing patients are younger with higher demands than hip replacement patients.

The FDA found hip resurfacing had more complications and more revisions compared to hip replacement. All the resurfacing implants they reviewed were two-part cemented with thin acetabular polyethylene articulating with a metal or ceramic femoral cap. The FDA reviewed the TARA (Townley), THARIES (Amstutz), Indiana Conservative Hip (Eicher and Capello) and the Wagner (Heinz Wagner). The FDA found unfavorable results compared to hip replacement. They published this in the Federal Register on March 5, 2004. The FDA presented to the Orthopedics Device Classification Panel their recommendation to reclassify resurfacing implants from Class II to Class III. The panel disagreed. The FDA went forward with the Class III on October 4, 2004 in the Federal Register.

**FDA REGULATION AFTER January 3 2005 for the Buechel-Pappas (New Jersey Hip Resurfacing)**

A few manufactures had femoral head only resurfacing systems and these could continue to be sold as Class II with a hemiarthroplasty intended use. The BP had an acetabular system that was used for both resurfacing and replacement and this remained. The FDA clears or not an implant for the intended use. FDA Resurfacing clearances after 2005 were Class III and all were metal on metal implants. The results are disappointing. If a resurfacing femoral head was combined with the total hip acetabular component this would not be for the intended, use. **This is an OFF LABEL use.** The FDA described all the hip resurfacing systems in use prior to 2004 except the BP. On page 59134 Vol 60 Federal Register No 191 the FDA writes: “Because the (resurfacing) device has fallen out of use the FDA is not aware of any firm marketing the device”. The FDA continued to audit and renew the registration for the BP implants.

Both the femoral and acetabular components were for cemented use. Sintered beads were used for the femoral component and plasma spray or sintered beads for the acetabular components. Dr. Buechel recommends cementless use. Highly cross linked polyethylene was added and the plasma spray was extended to the femoral components. The owners of the 510K clearances and names (New Jersey Hip Resurfacing and Acetabular Component) changed over the years from Protek to Endotec to Synovo Production. BioCore 9 began offering an exact BP duplicate in 2024 to the distributor.

The FDA published warning letters in 2023 and 2024. Synovo Production had a voluntary **recall** in 2024. **FAILURES WERE NOT THE REASON. Lack of compliance with FDA policies and procedures was the reason. FDA language is statutory and looks worrisome. The FDA statement was potentially unsafe. There was no recommendation by the manufacturer or FDA for implant removal.** The violations were:

1. OFF LABEL USE.
2. Labelling and IFU violations
3. Change to highly cross linked polyethylene
4. Change from sintered beads to plasma spray
5. Cementless use.

The labelling and IFU (instructions for use) were corrected. **No patient** every saw either the packaging or IFU. The change to plasma spray and highly cross linked polyethylene were supported by additional testing. OFF LABEL and cementless use are at the discretion of the surgeon. Follow-up of the implants continues to show acceptable failure rates. The recall closure awaits the FDA backlog.

OFF LABEL use is common in orthopedics. 75% of reverse total shoulders are off label use. While hip resurfacing was an intended use for the BP hip before 2005 it is now OFF LABEL.

**CONCLUSIONS**

The BP hip is a two-part acetabular component and a single part femoral component. It is therefore a three-part system. Two-part acetabular components are safer and perform better than one-part acetabular components. The BP hip was not included in the by the FDA analysis in 2004. There was no notification by the FDA to the BP manufacturer. Cementless fixation, plasma spray and highly cross linked polyethylene are all well accepted methods. The BP Acetabular and Femoral Components have:

1. Long term clinical Data showing successful outcomes (including the plasma spray and cross link)
2. Long term retrieval data showing good performance.
3. Testing data supporting both sintered beads, plasma spray and highly cross linked polyethylene.

There is no advertising or promotion by any company for the BP resurfacing implant. There are no advertising claims. BP implants are only sold through the distributor. **No surgeons buy or sell implants**. No surgeons are paid to consult or use BP implants. **The FDA does not regulate physicians**. The BP resurfacing hip is the only polyethylene resurfacing implant that has been available for sizes above 44 mm since 2005. The choice was not the BP or not but rather resurfacing or not, or metal on metal.