Stryker Tritanium Hip Socket Replacement Lawsuits

As medical technology advances and our population ages, those suffering from arthritis and other chronic joint problems increasingly seek relief by undergoing hip replacement surgery. For many, hip implant surgery is uneventful and patients make a full recovery with a new hip that they can expect to survive for at least ten years. Others do not fare as well and do not recover fully following surgery. They experience pain, swelling, limited range of motion, leg length discrepancy, and other complications -- that oftentimes leads to more surgery.

In fact, serious complications following hip implant surgery have been reported by patients that have been implanted with the Stryker Orthopaedics Trident® Tritanium Acetabular System (Stryker Cup), a hip implant device for total hip replacements. According to Stryker, the Stryker Cup will provide patients with rotational stability to the affected hip joint and provide relief from the debilitating symptoms of arthritis and other diseases affecting the hip joint. However, lawsuits are being brought against Stryker by patients implanted with the Stryker Cup that has since loosened. This failure of the Stryker Tritanium Cup has been reported to cause pain, swelling, limited range of motion, lack of incorporation, aseptic device loosening, and total implant failure. Unfortunately, problems associated with this cup becoming loose had led surgeons to recommend additional surgery to remove and replace the failed device.

What is the Stryker Tritanium Acetabular Cup?

The Stryker Cup is a titanium cup that is designed to be implanted into a patient’s hip socket during hip replacement surgery. It is given to patients that:

- Experience pain from arthritis, including: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or have late stage avascular necrosis;
- Have had a previous unsuccessful hip surgery, femoral head replacement, or cup arthroplasty; and/or
- Where arthrodesis or other total hip reconstruction is less likely to be effective.

How Stryker Cups Fail

Loosening of the Tritanium Cup is the most commonly reported complication of failed hip replacement surgeries using this implant system. Loosening occurs when the Cup fails to stimulate the bone marrow growth that is needed to adhere the Cup in place. Symptoms of Cup loosening include:

- Pain
- Swelling
- Instability of the hip or hip “locks” in place
- Dislocation

Primary Cups and Revision Cups

Stryker manufactures two versions of the Tritanium Acetabular Cup, the Primary Cup and the Revision Cup using different materials. Unfortunately, independent studies indicates that the Primary Cup has been defectively designed and causes complications following surgery. In stark contrast, independent studies have indicated that the Revision Cup has a high efficacy rate. The studies conclude that the Primary Cup has an unacceptable failure rate because of its inability to promote bone marrow growth, which in turn leads to loosening of the Cup. These studies have concluded that the Revision Cup encourages bone growth, and that patients who have been implanted with the Revision Cup have reported more favorable outcomes and long
term survival of the Cup than patients implanted with the Primary Cup. More information about these studies is included below.

**How Wilentz Can Help**

Wilentz, Goldman, & Spitzer, P.A. is accepting cases from patients who have been injured by defective Stryker Tritanium Hip Implants. If you or a loved one has experienced pain following insertion of the Trident Tritanium Acetabular System Cup manufactured by Stryker, call us today to discuss your legal options.

**Stryker Cup Studies**

Five studies to determine the efficacy and life-span of Stryker’s Tritanium Acetabular Cups provide important information for patients and their physicians. The initial study conducted by Stryker itself yielded positive results about the efficacy of the Cup. However in stark contrast, four independent studies conducted to determine the efficacy of the Cup each indicated that: (1) the Primary Cup often exhibited signs of premature complications that led to loosening; (2) the Revision Cup had favorable longer-term results; (3) the Primary Cup caused loosening and other problems following surgery; and (4) the Revision Cup produced more favorable results because the materials used to manufacture the Revision Cup were effective in promoting bone tissue growth.

**Stryker’s Study**

In April 2013, Stryker published the results of its study of 288 hip replacements where surgeons implanted the Tritanium Acetabular Cup, and reported that all implants survived between 3-5 years. (Naziri, et al. 2013). The study does not indicate whether the patients were implanted with the Primary Cup or Revision Cup. Half of participating surgeons were paid royalties by Styker, according to the study.

Access the Stryker funded study.

However, four independent studies of patients with a Stryker Cup all concluded that the patients with the Primary Cup exhibited signs of early septic loosening, whereas patients implanted with the Revision Cup did not report early complications.

**Poor Primary Cup Results**

A study conducted by Carli et. al, published in the *Journal of Arthroplasty* examined 102 patients implanted with the Stryker Primary Cup found that within an average of about four years, 98.2% of the implants survived. However, the study also reported that 40% of these Cups experienced movement, which caused pain. (Carli et. al 2018).

This 2017 study indicated that the Primary Cup is prone to early septic loosening or movement of the implant, a sign of potential failure.

Read the Carli et. al study.

**Good Revision Cup Results**

A study conducted by Hosny et. al published in the August 2018 edition of the *Journal of Arthroplasty* found that out of 62 patients implanted with the Stryker Revision Cup, 98.4% of the Cups survived with minimal movement after 7-8 years. (Hosny, et al. n.d.).

This study established that the Revision Cups performed as expected on a mid to long-term basis.

Read the Honsy et. al study.

**Discovering the Difference Between the Primary and Revision Cup**
A study conducted by Long et. al, published in *Arthroplasty Today* in June 2018, found that the Primary Cup failed to encourage growth of bone marrow, concluding: “It is likely that the Tritanium Primary Cup loosening is at least in part due to [the] differences in the manufacturing process. Specifically, the pore structure and polymeric binding agent used in the Tritanium Primary Cup may be directly related to its increased tendency to fail in comparison with the Revision Cup.” (Long, et al. 2018, 173).

In the Long et. al study, scientists speculated that the materials used in the Revision Cup allow it to adhere to bone better than the materials used in the Primary Cup which reportedly do not encourage growth of bone tissue.

**Read the Long et. al study.**

**Movement is not Common Among All Stryker Cups**

A Japanese study conducted by Yoshioka et. al, published in the November 2018 *Journal of Orthopaedic Science* focused on two groups of patients to compare the materials of Stryker’s Tritanium Acetabular Primary Cups to another hip implant system, also manufactured by Stryker, but manufactured using different materials. Group A was comprised of 130 patients with the Tritanium Acetabular Primary Cup and Group B was comprised of 130 patients with the Stryker Trident PSL HA conventional Cup. The doctors used radiographs at each follow-up to examine degrees of Cup movement. The following results were reported:

- **Group A: Tritanium Acetabular Primary Cup Model** – At three months, movement was measured at 36.1% and at six months, movement had increased to 60.7%.
- **Group B: Stryker Trident® PSL® HA** – At three months, movement was measured at 2.5% and at six months, movement decreased to 0.8%.

In this study, the patients implanted with the Stryker Trident PSL HA had decreased movement of the Cup because the hip implant system allowed the bone tissue to grow onto the Cup and anchor it in place, whereas those implanted with the Stryker Tritanium Acetabular Primary Cup had high rates of Cup movement, reportedly because that Cup failed to create an environment conducive to adhesion of the Cup to the body. (Yoshioka, et al. 2018).

The Yoshioka et. al study shows the susceptibility of early loosening in the Primary Cup and how a non-defective Cup decreases movement over time, because the body anchors it into place.

**Read the Yoshioka et. al study.**

**New Jersey Law Protects Patients from Defective Hip Implants**

New Jersey recognizes that defective implants exist and has laws that allow injured patients to be compensated for their pain and suffering. Product liability cases may be brought on a *preponderance of the evidence* for a failure to warn, a manufacturing defect, or design defect. The New Jersey Product Liability Act states:

“A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product… was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical unites manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.”

The New Jersey Supreme Court held in 1998 that in order to establish a claim of defective design, the Plaintiff “must prove . . . that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of the harm.” *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570, 715 A.2d 967, 980 (1998). Furthermore, the The New Jersey Product Liability Act requires a manufacturer to produce an “adequate product warning.” N.J.S.A. § 2A:58C-4.
“An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.”

N.J.S.A. § 2A:58C-4, (emphasis added). Adequate product warnings warn of risks that manufacturers knew or should have known at the time the device was produced.

Stryker is required by law to monitor the FDA’s database where doctors report complications from failed Cups. Therefore, Stryker should have known of the reported complications caused by patients implanted with its Primary Cup.

Simply put, Stryker produces two Tritanium cups: the Primary Cup and the Revision Cup. Study results have indicated that the Primary Tritanium Cup performs poorly and often needs to be replaced with the Revision Cup. Studies indicate that the Tritanium Revision Cup performs as advertised. These studies strongly suggest that the design and materials used with the Primary Cup is the reason why the Cup does not anchor to the bone. This is a product liability case because these problems are not caused by a problem specific to any one patient or caused by doctor error.

**How Wilentz Can Help**

Wilentz, Goldman, & Spitzer, P.A. is accepting cases from patients who have been injured by defective Stryker Cups. If you or a loved one has been experiencing pain following insertion of the Trident Tritanium Acetabular System Cup manufactured by Stryker, call us to speak directly to an attorney about your legal options. There is no charge for the consultation.

**Call:** 732-855-0375