Stryker Trident Hip Implant Component Recall Latest Bad News for Company since FDA Warning Letter

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Stryker Hip Implant components, made under the company's popular Trident line, are being recalled today, just months after Stryker Corp. received a **Food & Drug Administration** (FDA) warning letter about poor conditions at the Stryker plant in Mahwah, New Jersey. While the Stryker Hip Implant components covered in this recall where not made at the New Jersey facility, the action does little to inspire confidence in the quality controls Stryker employs in the manufacture of such **defective medical devices**.

The Stryker Hip Implant component recall involves two hip replacement cups – the Trident Acetabular PSL Cup and the Trident Hemispherical Cups – made at the Stryker facility in Cork, Ireland. Acetabular Cups are used in the socket portion of replacement hip components. The PSL version is the most commonly used Stryker cup in the U.S.

The Trident Hip Implant cup recall was implemented by Stryker amid concerns that the components could be contaminated with "manufacturing residuals" at levels that exceed company standards. However, Stryker maintains that the problems do not affect the sterility of the components, and that patients who have received the recalled Trident components will not need to have them replaced.

Both of the recalled Trident Hip Implant cups where among the Stryker components mentioned in the FDA warning letter Stryker received on November 28, 2007. The warning letter was issued to Stryker after FDA officials had spent 6 weeks inspecting its

New Jersey plant over the summer. During that inspection, the FDA found a range of problems. Among the most serious where instances of bacterial contamination at the Stryker plant. The contamination included “clusters” of Staphylococcus bacteria, the pathogen that causes staph infections.

The letter marked the second time that Stryker was warned by the FDA as a result of the inspection that took place last summer. The most recent FDA warning letter chastised Stryker for sending the FDA inadequate responses to the initial warning between August 1 and November 1, 2007. The November 28 letter states repeatedly that Stryker “failed to perform corrective and preventive actions in order to prevent the recurrence of nonconforming product or other quality problems.” For instance, in regards to the bacterial contamination, the letter states that Stryker “has not identified the root causes of the microorganism contamination and has not executed corrective and preventive action to prevent recurrence.”

According to the FDA warning letter, Stryker has been receiving complaints about components made at the New Jersey factory, including hip joints that did not fit properly, since 2005. Patients had been complaining about a range of problems, including pain, difficulty walking and “squeaky” joints, and some have had pieces of implant parts break off or wear down unevenly. The FDA warning letter said that the deficiencies uncovered at the Mahwah facility had contributed directly to the manufacture of faulty hip implants.

The Trident Hip Implant cup recall and the FDA warning letter are not the only problems Stryker has faced this year. According to the Associated Press, Stryker was among five companies that make joint replacements in the US that agreed in September to pay a $310 million fine and accept federal monitors to settle allegations they gave doctors kickbacks to use their products.