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A Summary of Hip Implant Recalls

Safe Patient Project

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In 2011 almost half million Americans got hip replacements.[1] And that number is expected to grow as baby boomers age and more people under 65 turn to hip implants to remain active. One study projected that the majority of patients with hip replacements are under 65 years old.[2] Younger people getting hip implants will likely require another one over their lifetime. Currently, no hip implant maker offers a warranty with their product. There is no official guarantee as to how long a new hip is expected to last or an official process for patients if their implant fails before that expected time.

Warranties are also important because some hip implants do fail. We gathered recall information from the last 10 years for the top makers of hip implants to demonstrate the various reasons for recalls related to hip implants. These six companies recalled a total of 578 hip implants or implant components. The Food and Drug Administration (FDA) has only used its recall authority three times in the last 20 years because the government procedure is lengthy and legally difficult.[3] Almost all recalls of medical devices are done voluntarily by the companies that make them—not the FDA. However, the law requires companies to report recalls that pose health risks to the FDA and the FDA documents and classifies the seriousness of a recall.[4] We used the FDA database for this analysis. [5]

(Figure 1)

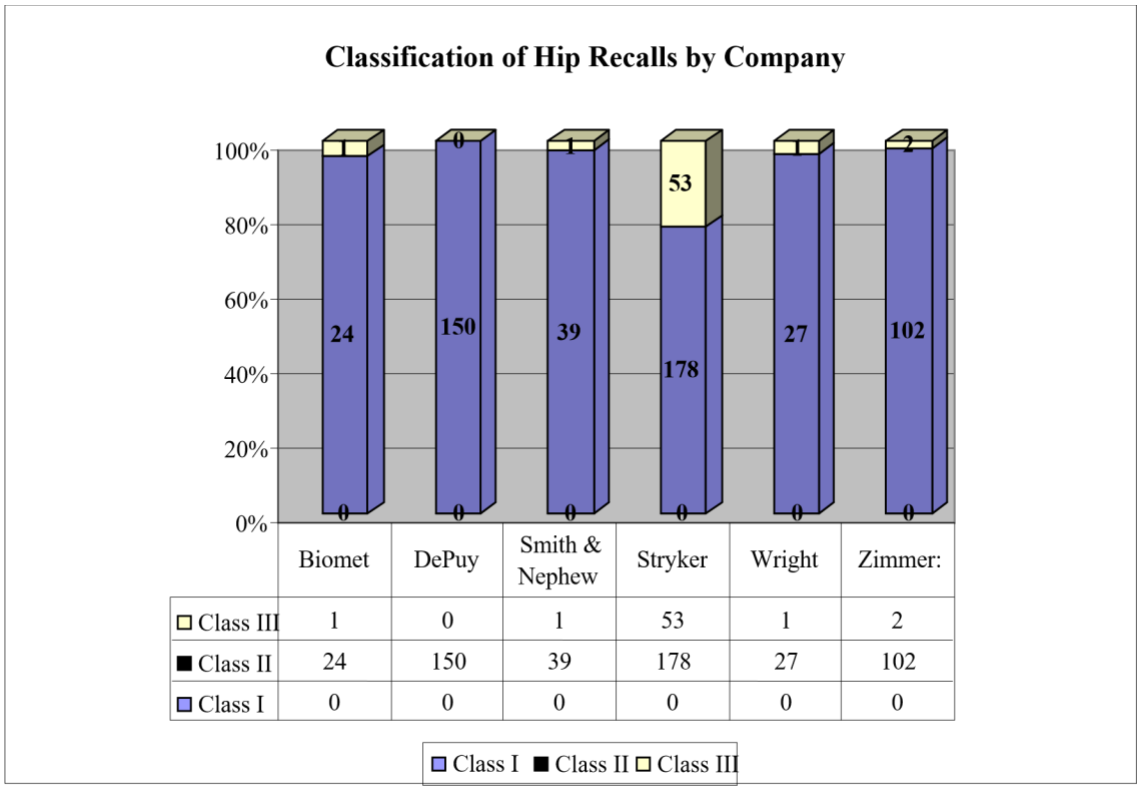
Number of Hip Recalls
Nov 1 2002 – Jul 23 2013

Biomet:	25	DePuy:	150		
Smith & Nephew:	40				
Stryker:	231	Wright:	28	Zimmer:	104
Total:	**578**				

There are three types of recalls for medical devices due to flaws:

- Class I recalls are the most serious and harmful. The FDA describes Class I recalls as "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." More than 10 percent of the hip recalls were this serious.
- Class II recalls are described by the FDA as "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." Most hip recalls fall into this category.

- Class III recalls are for problems that are unlikely to cause patient harm. The FDA describes a Class III recall as "a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences" None of the hip recalls fell into this category. (Source: FDA).



Overview of Recalls Companies Selling the Highest Volume of Hip Implants

Nov 2002 – July 2013

Biomet

Biomet recalled 25 hip devices. Most (24) were Class II recalls. Over two-thirds of the recalls were implanted devices rather than tools used during the procedure. The reasons for recalling the devices/components included:

- **Labeling Issues**: implant devices (head and shell) and components (bone screws) were incorrectly labeled/color coded by size; implant did not have a label instructing the removal of the protective shipping cap, which was accidentally implanted by a doctor
- **Fracturing**: flawed implant (head) can fracture; tools (cup inserter, femur torque handle) used during surgery could fracture

DePuy

DePuy had 150 Class II recalls. DePuy recalled the hip devices/tools/components because of:

- **Labeling Problems**: The size of the implant component (liner) was mislabeled[6]; bone screws were mislabeled; liner size was not "machined" correctly
- **Design flaw:** the implant device(femoral stem) may cause "impingement" and not allow the stem and to lock[7]; faulty femoral hip stems

- **"Ongoing post-market surveillance of all products"**due to high failure rate of metalon-metal hips, including femoral head and acetabular cup
- **Early Failure**: tools (broach handle) used during the surgery experienced early failure[8]
- **Packaging Issues**: surgical tools may not be properly sealed when shipped
- **Migration Issues**: screws used to repair femoral fractures may "migrate"[9]
- **Manufacturing Issues**: Liner was not "machined" to proper size

Smith & Nephew

Smith & Nephew recalled 40 hip devices/tools. Most of them (39) were class II recalls. The reasons for recalling the devices/components were:

- **Incorrect Parts/Instructions**: instruments for hip procedures came with the incorrect instructions
- **Manufacturing Issues**: the strength of the acetabular liner was compromised during manufacturing; procedural tools were not manufactured to specification and caused "interference"; screws used for procedural camera could not be properly sterilized
- **Design Flaws**: femoral head popped out of the liner during surgery; procedural tool to hold legs in place may break during surgery
- **Labeling Issues**: the sizes of the acetabular liners were mislabeled; acetabular cup sizes were mislabeled; screw plates used for hip fractures were mislabeled[10]

Stryker

Out of all the companies, Stryker has recalled the most hip devices in the last decade:178 Class II recalls and 53 Class III recalls, which are likely to cause serious and life threatening harm to patients. Stryker recalled the hip devices/ tools because of:

- **Fracturing**: surgical instruments (broach and rasp handle[11]) used to size the femur for the implant, may fracture during a surgery; hip stem demonstrated fractures
- **Cracking**: hip stem coating may crack
- **Labeling Issues**: the sizes of different implant components were mislabeled, which may lead to an incorrect implant being used; device components had incorrect expiration date; instructions for the femoral stem were not labeled
- **Manufacturing Issues**: acetabular shells too thick; acetabular shells have different thicknesses which can increase the gap between the shell and liner causing "interference"; hip stems didn't meet specifications for strength; components used for hip implants were made with a raw material that were not up to standards; "exceeded foreign materials standards"
- **Packaging Issues**: the sterility of the hip stem may be compromised because of poor packaging; the package of implant components had a "visual defect"; 16mm stem in 18mm stem package

Wright

Wright recalled 28 hip devices – one Class III and 27 Class II - for the following reasons:

- **Labeling Issues**: inaccuracies in labeled shelf life of components/parts; packaging missing labels for shelf life, manufactured date, and translations
- **Packaging issues**: debris from acetabular cup packaging may be implanted in patient thereby necessitating a revision procedure
- **Design flaw**: the acetabular cup may lock onto the femoral head

- **Manufacturing Issues**: implant coating had missing fragments

Zimmer

Zimmer recalled 104 hip devices/tools. Most of the recalls were Class II (102). The reasons for recalling the devices/components included:

- **Labeling Issues**: stem size was incorrectly labeled
- **Packaging Issues**: liner packaged in the wrong carton; "discrepancy between product labels and patient labels" for hip stem; femoral stems placed and distributed in wrong cartons; femoral head may be in a package that is labeled the wrong size; acetabular augment package may be breached and cause issues with sterility[12]; femoral head and neck not packed in sealed package
- **Manufacturing issues**: shell pore sizes were too small; shell missing hole threads; line may not stay in place; shell threads were not completely machined thereby causing difficulty attaching other implant components; manufacturing material may be left on the femoral head
- **Fit Issues**: femoral heads fit too loose/or too tight with stem and necks
- **Instruction Issues**: unclear "whether the device can be used based on the instructions"; acetabular cup instructions for use/surgical instructions are inadequate
- **Fracturing**: procedural instrument may fracture
- **Missing components**: acetabular system missed locking rings
- **Metal grain structure anomaly**: femoral components have "improper assurance of proper metal fatigue strength"