ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

A Summary of Knee Recalls
Consumers Union Safe Patient Project
September 9, 2013

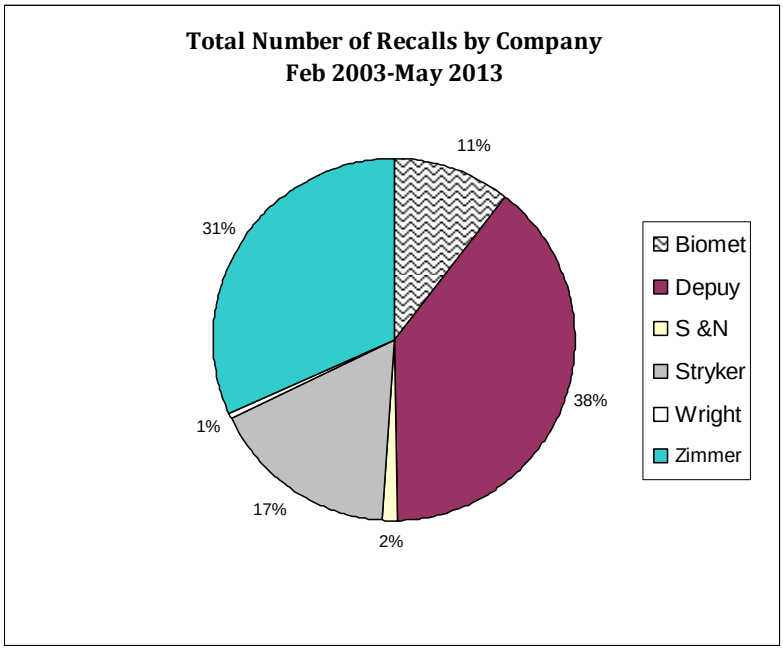
An estimated 4.4 million Americans are living with knee implants. In 2011, over 711,000[1] knee replacements were performed primarily for a diagnosis of knee osteoarthritis. An increasing life expectancy and more young adults getting knee implants have added to the growth.

Unfortunately, the growing number of knee implants has not been coupled with safety assurances to protect consumers. For example, most manufacturers of knee implants do not offer warranties on their devices. Only one company offers a warranty for one of its knee implants. When devices fail, patients have no guarantee that the company will replace them. An estimated 536,000 adults currently living with knee implants have undergone revision procedures to replace their implants. [2]

Over the last decade, the top six knee implant manufacturers have recalled 709 devices/components due to flaws (See Figure 1). 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 Recalls[12]	
Biomet:	75
DePuy:	277
Smith & Nephew:	11
Stryker:	118
Wright:	4
Zimmer:	224
Total:	**709**



There are three types of recalls for medical devices:

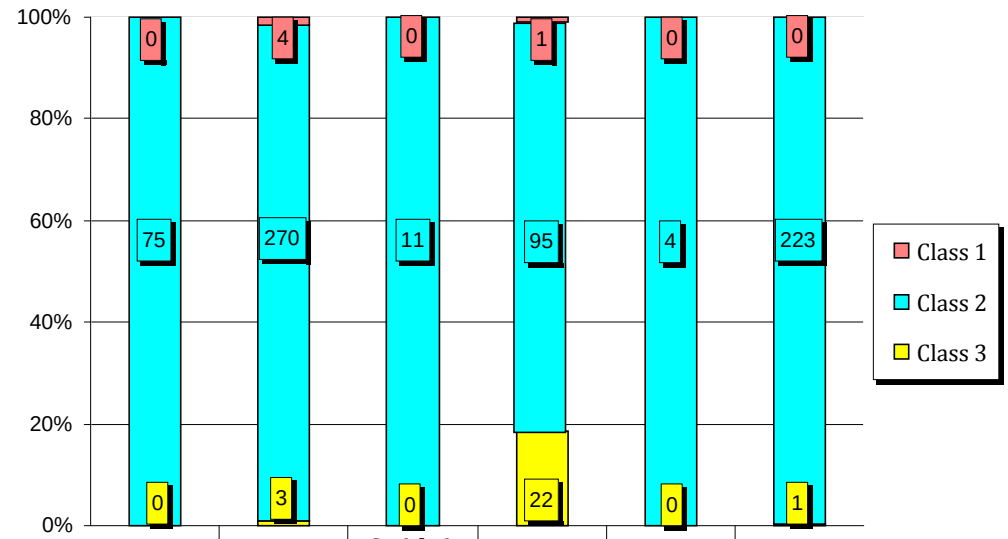
- Class I recalls are the most serious and harmful. The FDA describes Class I

[1] From February 2003 to May 2013 accessed on 7/24/13
[2] From 6 high-volume knee implant manufacturing companies

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."

- 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 knee 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" (Source: FDA).

Classification of Knee Implant Device/Component Recalls 2003-2013



	Biomet	DePuy	Smith & Nephew	Stryker	Wright	Zimmer
Class I	0	4	0	1	0	0
Class II	75	270	11	95	4	223
Class III	0	3	0	22	0	1

Knee implant devices/components are either implanted in the patient or they are used by surgeons (as a tool) during a knee implant procedure to align, measure, cut, or fit manufactured knee implants. More than three-fourths of all knee recalls were for devices/components that were implanted in patients rather than "procedural" devices.[6]

Both types of implant device/component failures can be dangerous to patients. For example, a flawed tool that is used to assist in screwing in a knee implant component can cause a 30 minute delay in surgery, putting a patient at a greater risk of problems such as infections. Examples of faulty implanted devices are those that can fracture, be improperly sized, or wear quickly.

Overview of Recalls
February 2003-May 2013[7]
Companies Selling the Highest Volume of Knee Implants

Biomet

Biomet had 75 recalls in the last decade. All were "Class II" recalls for devices and procedural components, or tools, which help the surgeon during a knee implant procedure. Common reasons for Biomet knee recalls were:

- **Sizing issues:** wrong sized tools may not fit properly with other components thereby causing delays during a surgery and increasing the risk of complications
- **Improper assembly:** improperly assembled tools used to guide bone cuts may cause reverse cuts on the femur and affect the performance of the implant[8]
- **Missing features:** faulty tools without specific features may wear the implant and shorten the life of the implant ("ion implantation feature: surface of the head may be softer and more prone to scratching which in turn could potentially cause higher wear of the poly bearing")

DePuy

DePuy recalled 477 devices/components. Four of the recalls were due to flaws that could seriously harm patients (Class I), 470 were Class II, and three were Class III recalls. DePuy recalled components/devices because of:

- **Possible fracturing:** recalled implant components may fracture during normal activities causing a need for a revision procedure; anchors may fracture [9]
- **Sizing issues:** screw sizes that came with the implant were the wrong size
- **Mislabeled components:** implanted femur components may be incorrectly labeled Left (L) and Right (R)[10]
- **Metal debris:** implanted anchors may have metal debris inside, possibly causing complications[11]
- **Assembly difficulties:** a defect in the device may make it difficult for the surgeon to seat the polyethylene insert, which acts like cartilage for the implant
- **Incomplete seal:** an incomplete seal may end in oxidation and affect the "performance" of the polyethylene insert

Smith & Nephew

Smith & Nephew issued 11 Class II recalls. The devices/tools were recalled because of:

- **Packaging issues:** the sterility of tools used in knee replacement procedure may be compromised; devices "mispackaged"
- **Labeling issues:** Markings for the drill guide are on the wrong side

Stryker

Stryker recalled 118 devices/components. Most were Class II (95). Over two/thirds of the recalled devices were implanted rather than procedural devices. Reasons for the recalls included:

- **Damaged component:** femoral components may be damaged thereby preventing the installing of a stem extension which compensates for bone loss[12]
- **Disassociation:** tools used to guide the surgeon may come apart from their placement on the knee during surgery
- **Mislabeled components:** packaged components may be mislabeled for the wrong side
- **Component seize:** trial components would seize and not disassemble
- **Early wear and delamination:** malfunctioning tibial inserts may show early wear which may lead to a revision procedure

Wright

Wright had four Class 2 recalls for components that were implanted. The reasons for the recalls were:

- **Improper length:** the screws that came with the device were the incorrect length
- **Co-mingled parts:** the right and left knee inserts (which act as the cartilage in implants) were mixed together [13]

Zimmer

Zimmer recalled 224 devices/components. Most of them (223) were Class 2 recalls. More than three-fourths of the recalled devices were implanted components rather than procedural tools. Zimmer recalled the devices/components because:

- **Faulty design:** implant may be prone to fracture; tool used to guide the bone cuts was incorrectly designed, thereby causing incorrect bone cuts; tools prone to fracture; tools may disassemble and fall into the surgical site, causing complications; implanted tibial component may get perforated and result in a fracture
- **Mislabeled components:** tools used to size components were incorrectly labeled; package containing left knee components contained right knee components and vice versa
- **Missing components:** tibial implant missed or had misplaced components that could lead to a delay of surgery or a revision procedure
- **Manufacturing issues:** the implant may not be polished, causing increased wear and debris generation; implant may contain debris(due to improper cleaning operation) which may cause allergic reaction
- **Difficulty with "insert":** flawed implant may make it difficult to insert the polyethylene insert(which acts like cartilage), thus damaging the implant in the process
- **Implant loosening:** implants loosened and needed to be replaced through a revision procedure ("Zimmer made a modification to the surgical technique and instructions for use. They added a warning to fully cement and pressurize the anterior and posterior surfaces of the tibial component and to strongly recommend the use of a drop down stem extension.")
- **Sterility issues:** components/devices may "lack assurance of sterility"

[1] Agency for Healthcare Quality Research, Healthcare cost and Utilization Project (HCUP): Outcomes for CCS principle category Arthroplasty of knee and hip replacements, total and partial, 2011 weighted national estimates from the HCUP Nationwide Inpatient Sample (NIS); http://www.hcup-us.ahrq.gov/reports.jsp
[2] Estimating the Burden of Total Knee Replacement in the United States; 2013 The Journal of Bone and Joint Surgery
[3] Institute of Medicine. 2011. "Medical Devices and the Public's Health: The FDA's 510(k) clearance process at 35 years." p. 46.
[4] 21 CFR Part 806; http://www.fda.gov/training/cdrhlearn/ucm209125.htm
[5] http://safepatientproject.org/knee_recalls.htm; Consumers Union built this database with information from the FDA recall database, accessed on 7/24/13, ; http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/
[6] Source: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
[7] FDA medical device recall database-Accessed 7-24-13; http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/
[8] Biomet Ascent surgical technique booklet http://www.biomet.com/orthopedics/getFile.cfm?id=15&rt=inline
[9] Manual for DePuy LPS system http://www.gsortho.org/files/dpy_lps_limb_preservation_sys_surgtech_0612-36-500r3.pdf
[10] Manual of DePuy PFC system http://www.rpa.spot.pt/getdoc/ec0df116-99a7-4874-88ff-7d3a00cbc7bb/PFC-Revision-Surgical-Technique-(DePuy).aspx
[11] Brochure of anchor http://www.depuy.com/sites/default/files/products/files/Gryphon_Peek_Brochure.pdf
[12] Example of Stryker stem extension http://www.stryker.com/en-us/GSDAMRetirement/index.htmstellent/groups/public/documents/web_prod/023609.pdf
[13] Example of Wright knee inserts http://www.wmt.com/evolution/physicians/system-options.asp

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