Product Recall Update:
Reverse Shoulder Implant

HRS Healthcare Recovery Solutions

On February 16, 2017, the FDA issued a Class I[1] recall of Zimmer Biomet Orthopedics LLC's Comprehensive Reverse Shoulder System. FDA findings show that the implants are fracturing at a substantially higher rate than indicated in the manufacturer's labeling.

More than 50,000 Reverse Shoulder Implants Sold Each Year

The Comprehensive Reverse Shoulder implants are intended to restore arm movement to individuals with torn rotator cuffs who had developed severe arthritis of the shoulder known as arthropathy. About 53,000 Americans undergo shoulder replacement surgery each year to relieve joint pain caused by arthropathy. Reverse shoulder replacement surgery is a relatively new procedure. The first implants were approved in 2004. The surgery involves the total replacement of the shoulder socket with a metal ball and the insertion of a plastic cup at the top of the humerus.

Biomet Skips Clinical Trials

Zimmer Biomet chose to follow the FDA's 510(K) fast track approval program for the implant device that is now implicated in the recall. The program allows for approval of devices without prior clinical trials if they are shown to have similar intended technological functions as a previously approved FDA device.

Device Failures Spike – Prompts Recall

Following FDA approval and introduction of the Zimmer Biomet shoulder implant, some patients complained of loosening, instability, and fracture of the baseplate. Subsequently, medical reports showed a high incidence of device fractures.

The 3,662 implants now being recalled were manufactured between August 25, 2008 and September 27, 2011 and distributed between October 2008 and September 2015. This includes all devices with product codes "KWS" and "PAO" and all lots with part number "115340." The FDA

[1] Class I means that the FDA determined there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death.

recall notice states that fractures are causing severe pain, permanent loss of function, increased risk of serious infection, as well as other injuries. You can read the recall in its entirety here.

Multiple Recalls – Promises of Corrective Action

This is not the first Biomet Orthopedics device to be recalled by the FDA, the company has had 43 recalls since January 9, 2016. As a result of the most recent recall, Zimmer Biomet states that it is investing $170 million to "harmonize and optimize" its supply chain and manufacturing and quality systems.

Healthcare Payers Should Not Pay for Manufacturers' Mistake

Some individuals who have experienced premature fracture of the Zimmer Biomet Comprehensive Reverse Shoulder System have already received settlements for their injuries.

Healthcare payers who have paid for medical treatment associated with the failure or replacement of recalled devices can seek reimbursement of these payments from pending actions or from the device manufacturer if the payers are able to promptly to identify the patients and procedures involved.

Start Identifying Recovery Opportunities Now

HRS allows healthcare payers to quickly and accurately identify each and every recovery opportunity associated with the Comprehensive Reverse Shoulder implant. Without HRS, payers risk losing hundreds-of-thousands of dollars in potential recoveries. To learn how to recover all expenses associated with dangerous drugs, medical devices and toxic exposures contact HRS.