DEMAS ROSENTHAL
A Plaintiff's Personal Injury Law Firm

Medical Device Recalls: Check the Brands You're Using

The last thing you need when you're sick or in pain is to discover that your doctor-prescribed medical device is currently being recalled. Ideally, the product's manufacturer or your doctor's office would immediately notify you of this fact and make alternate care arrangements for you. However, in this hectic and often chaotic world, that type of warning may never reach you.

Fortunately, the U. S. Federal Drug Administration (FDA) provides this updated information to the public on its Web site. Therefore, it's up to all of us or our caregivers to: (1) learn all we can about the health risks posed by each medical device we're currently using; (2) stay on top of all current recalls of these products; and (3) gain a better understanding of what each medical device recall level actually means.

Three Levels of Medical Device Recalls

There are basically three levels of medical device recalls. According to the FDA, Class I recalls involve products that pose "serious health problems or death." Manufacturers of Class I recall devices must issue press releases to warn the public about the recall status of their products. The FDA will also sometimes issue its own public health notices or press releases about Class I recalls.

Although frequently less serious than Class I recalls, the FDA has indicated that medical devices subject to Class II recalls can still cause "temporary or reversible health problems." Furthermore, on rare occasions, recalled Class II medical devices can cause serious health issues.

As for the responsibilities of Class II recalled product manufacturers, they must contact all of their distributors and vendors. However, they are not generally expected to issue any press releases to warn the public – except under special circumstances (like when it's known that a massive number of patients are currently using the defective products.)

Finally, recalled Class III medical devices usually won't harm patients in any manner. However, they must still be withdrawn from the marketplace. Press releases are generally not required for these products.

When medical device manufacturers recall their products, the FDA also expects them to: (1) contact all patients who directly received the products from them; (2) provide detailed information (such as serial or lot numbers) to consumers to help them properly identify each recalled device; and (3) take whatever steps are necessary to prevent the product's defects from being duplicated again in the future.

Sample Recall Listings from the Second Half of 2010

Fortunately, the U. S. Food and Drug Administration keeps a complete list of recalled medical devices on its Web site. As already noted above, this means we must each check this list (or have one of our caregivers do this for us) on a regular basis.
Recent 2010 recalled devices (and their corresponding Class levels) include:

- **Arrow IABs** (**Intra Aortic Balloons**) and **IAB Catheters –** Class I
- **Westmed Inc., BagEasy Manual Resuscitation Devices** – Class I. This manual device is used to provide critical emergency breathing support;
- **CareFusion Corporation, Alaris PC Units (Model 8015)** – Class I. These electronic infusion pumps are suppose to deliver carefully measured doses of drugs or fluids to patients through intravenous, intra-arterial, epidural and other medically proper means.
- **Medtronic Octopus Nuvo Tissue Stabilizer, Model TSMICS1** – Class I. During a minimally invasive cardiac procedure, this device is suppose to help stabilize and otherwise control aspects of the patient's heartbeat.
- **Alcon Research LTD doing business as Alcon Laboratories, Inc.** - CONSTELLATION Vision System – Class I. This ophthalmic device is used by eye surgeons while performing microsurgery

This sample list above of 2010 recalled medical devices clearly indicates the critical importance of many of these devices. They must be constantly monitored for malfunctions or structural weaknesses so that our lives can be adequately safeguarded.

In the future, we hope you'll always check on the recall status of the various medical devices you and your loved ones use on a regular basis.

* * *

Demas & Rosenthal remains one of Sacramento's most highly respected and accomplished personal injury law firms. We've been successfully representing clients for almost twenty years. Every Demas & Rosenthal attorney takes great pride in obtaining the full compensation and complete justice owed to each client.