

# IN BRIEF



*In  
This  
Edition*

FDA Advisory  
Panel  
Convenes on  
Metal Hip Safety

J&J Pulls  
Pelvic Mesh  
Implants

Health Care  
Liens



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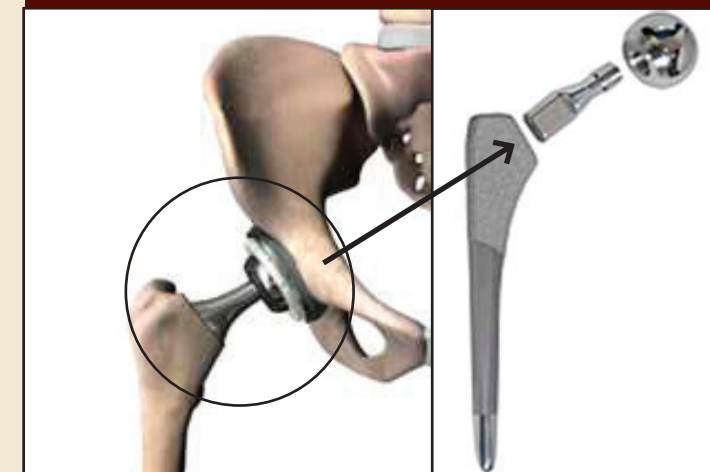
## STRYKER ANNOUNCES NEW HIP RECALL

Stryker Orthopaedics voluntarily recalled its **Rejuvenate** and **ABG II** modular neck hip implant stems on July 4, 2012. This voluntary recall was initiated due to widespread problems including pain, swelling, and tissue damage in patients with these metal-on-metal modular neck stems. According to Stryker, the risks include the potential for “fretting” and/or corrosion around the modular-neck junction which may result in adverse local tissue reactions. Post-market surveillance showed that a significant number of patients were experiencing a premature failure of their hips. Patients with the recalled hip implant components should schedule an appointment with their orthopedic surgeon immediately if they are experiencing pain and/or swelling at the joint site which may be a sign of a malfunctioning hip implant.



The law firm of **Alley, Clark & Greiwe** represents a large number of clients who have been injured by defective metal-on-metal hip replacement devices sold by various manufacturers. For the past two years, there has been much concern

Stryker Rejuvenate Modular Neck Stem Implant



that all-metal hip replacement devices are causing serious injuries to patients and account for a high failure rate. If you or a loved one have been implanted with the recalled Stryker hip implant components, please contact us for a free consultation about your legal rights.

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## HOT TOPICS

## IMPORTANT INFORMATION: HEALTH INSURANCE LIENS AND REIMBURSEMENT OBLIGATIONS

If you sustain personal injuries as a result of a third party and file a lawsuit, your health insurer has the right to be reimbursed for any expenses related to the injury that forms the basis of your lawsuit if you receive settlement funds or a jury verdict. Most people do not realize that their private health insurance policy includes reimbursement language. Whether you are insured by a private health care plan (Blue Cross, Aetna, etc.), an employee benefit plan, or government health program (Medicaid, Medicare, Tricare), your health insurer has the right to reimbursement. The process of resolving these obligations can be very time consuming and frustrating but it is required by law. In most instances, such liens and reimbursement obligations are reduced if the insurance policy language does not require 100% reimbursement.

## Health Care Liens - What You Need to Know

- Nearly all personal health care policies contain reimbursement language.
- Attorneys are bound by state and federal law to notify insurers of a pending lawsuit.
- Paying premiums and co-pays does not negate or have any effect on reimbursing an insurer.
- Failure to reimburse an insurer can result in fines, penalties, and loss of coverage for the insured.

## JOHNSON &amp; JOHNSON SUBSIDIARY TO STOP SELLING PELVIC MESH

On June 4, 2012, attorneys for Ethicon, a Johnson & Johnson subsidiary, sent letters to the judges overseeing transvaginal mesh claims in federal and state court. The letters provided notification that the company intends to stop marketing and selling the following vaginal mesh products: Gynecare TVT Secur, Gynecare Prosima Pelvic Floor System, Gynecare Prolift Pelvic Floor System, Gynecare Prolift+M Pelvic Floor System. The so-called phasing out of these products comes after the filing of hundreds of lawsuits over injuries associated with the synthetic mesh products.

The Ethicon mesh products, as well as mesh products manufactured by other companies, are used during surgical repair of pelvic organ prolapse and female stress urinary incontinence. Pelvic mesh products have been associated with a significant number of serious complications in women including mesh erosion, infection, pelvic pain, painful intercourse, hardening or shrinkage of the mesh, and urinary problems.

If you or a loved one have suffered a serious complication following mesh-repair surgery for pelvic organ prolapse or stress urinary incontinence, please contact the experienced trial attorneys at **Alley, Clark & Greiwe** for information about your legal rights.

In a company statement, Ethicon insisted that the move to stop marketing/selling the products was *not* a recall, but was based on the products' commercial viability "in light of changing market dynamics, and is not related to safety or efficacy."

**ETHICON**  
a Johnson & Johnson company

**Moving Soon? Please be sure to keep us updated with any changes to your address or phone numbers.**

## METAL-ON-METAL HIPS

## FDA ADVISORY PANEL CONVENES MEETING ON SAFETY OF METAL-ON-METAL HIPS

Metal-on-metal (MoM) hip replacements have been performed in approximately 500,000 patients across the United States. In June, the FDA held a public hearing to assist doctors in monitoring patients for health risks posed by all-metal replacement hips. The panel agreed that metal-on-metal hips were no better than metal-on-polyethylene hips.

Studies have shown that as metal-on-metal hip implant components wear down, they shed tiny particles of metallic debris that can cause pain, inflammation, swelling, the pseudotumor formation, muscle and tissue damage, and high levels of chromium and cobalt in patients' blood. Overall, the failure rate of all-metal hip implants has been much higher than with traditional hip implants. Thousands of patients have undergone extensive revision surgeries to remove one or more metal hip components. However, since the U.S. does not have an orthopedic joint registry system, it is nearly impossible to know the exact number of failures.

It is deeply troubling that the FDA is just *now* debating safety and design issues after more than a decade of these products being sold for use in the U.S. Under the FDA's controversial 510(k) approval process, the hip implant manufacturers did not have to run clinical trials of the hips before marketing them, nor were they required to follow patients post-operatively.

The attorneys at **Alley, Clark & Greiwe** have extensive experience in representing persons injured by defective joint replacement products and other defective medical devices. Please contact us for important information regarding your legal rights.



## Highlights of FDA Advisory Panel Recommendations for Persons With All-Metal Hip Implants

- All patients with MoM implants should undergo annual x-rays regardless of symptoms.
- Patients suffering from symptoms need to undergo regular x-rays and blood tests.
- Revision surgery recommended for patients whose implant showed signs of failure
- Baseline MRI or CT Scan for patients whose x-rays did not show failure
- Follow-up visits every 3 to 6 months for patients whose x-rays did not show failure

## FAQs for Patients with Metal Hip Implants

**How do I know if I have a metal-on-metal hip?**  
Contact the hospital where the surgery took place. If you are unable to determine the type of hip implant you received, our law firm will provide you with a medical authorization form so that we may obtain this information on your behalf.

**What should I discuss with my orthopedic surgeon?**  
It is critical that you talk to your surgeon about any new or worsening symptoms related to your hip, groin or legs since your last visit. This may include pain, swelling, numbness, and change in ability to walk.