

**ASR™ XL Acetabular System and  
DePuy ASR™ Hip Resurfacing System Recall**  
*Information for Patients*

DePuy makes patient safety and health a top priority and is continually evaluating data about its products. The ASR Hip is one of many hip implants available from DePuy Orthopedics. Most ASR hip replacement surgeries have been successful. However, data recently received by the company shows that more people than expected who received the ASR Hip System experienced pain and other symptoms that led to a second hip replacement surgery, called a revision surgery. New data shows that five years after implantation, approximately 12% of patients (1 in 8) who had received the ASR resurfacing device and 13% of patients (1 in 8) who had received the ASR total hip replacement needed to have a revision surgery.

For this reason, DePuy Orthopedics is recalling its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System. This recall means additional testing and monitoring may be necessary to ensure your hip implant is functioning well. In some cases patients may need additional surgery.

If you have received an ASR™ XL Acetabular System or DePuy ASR™ Hip Resurfacing System (both of which will be referred to as your hip implant), the following information will help you understand what this recall means to you and the steps you should take.

DePuy is recalling the ASR™ XL Acetabular Head System and DePuy ASR™ Hip Resurfacing System. These systems first became available in July 2003.

**SYMPTOMS, CAUSES AND TESTING**

The patients who reported problems in the first five years after their surgery and then had revision surgery reported a variety of symptoms. These symptoms included pain, swelling and problems walking. These symptoms are normal if you have just had a hip replacement. If the symptoms continue or come back, it is a sign that there may be a problem such as:

- Loosening, when the implant does not stay attached to the bone in the correct position
- Fracture, where the bone around the implant may have broken; and
- Dislocation, where the two parts of the implant that move against each other are no longer aligned

The ASR Hip is made up of ball and socket components that move against each other. These metal components wear over time and generate very small particles that can only be seen with a microscope. This is an expected process. These particles do not cause problems for most patients, but a small number of patients may react to these particles, causing fluid to collect in the joint and in the muscles around the joint. While this condition may initially be painless, if left untreated, this reaction may cause pain and swelling around the joint and could damage some of the muscles, bones and nerves around the hip.

Tests will help your surgeon determine if your hip is working as it should and whether you are having a reaction to the metal particles.

Your surgeon may take X-rays of your hip. Also, a blood test may be done to indicate the level of microscopic metal particles around your hip. Your surgeon may also use an ultrasound or an MRI scan to evaluate if you are having a reaction to the metal particles.

### **UNDERSTANDING THE ASR HIP RECALL**

If you received the ASR™ XL Acetabular System or DePuy ASR™ Hip Resurfacing System, you should schedule an appointment with your surgeon. Your surgeon will be able to evaluate how your ASR Hip System is functioning.

The “recall” of the ASR Hip does not necessarily mean you will need to have the hip implant removed. Most people with ASR hip implants do not experience problems. However, it is important that you follow up with your surgeon on an annual basis for the first five years after your ASR Hip surgery – even if you are not experiencing symptoms – to ensure that your hip continues to work well.

In some cases, your surgeon may order additional blood testing or imaging to evaluate how your hip is functioning. Your surgeon will determine the best monitoring plan for you and discuss treatment solutions should they be needed. If you don't know who performed your hip replacement surgery, ask your primary care physician/general practitioner or the hospital where the surgery took place.

### **WHAT TO EXPECT AT YOUR NEXT SURGEON VISIT**

- Your surgeon will evaluate how your ASR Hip System is functioning.
- If you are experiencing pain, difficulty walking, or other symptoms, your surgeon may want to take x-rays of your hip. X-rays will allow your surgeon to evaluate how the ASR Hip System is positioned, if there is any damage to the bone and if the ASR Hip System has remained attached to the bone. If the x-rays show problems with your ASR Hip System, your surgeon may recommend surgery to replace it.
- Your surgeon may request a blood test to ensure your ASR Hip System is functioning well.
- The blood test indicates the level of microscopic metal particles around your hip. If the blood test indicates a high level of these particles, your surgeon may want to do a second blood test three months later. These levels may be high even if you are not experiencing any symptoms, so this blood test is very important.
- If the second blood test still indicates a high level of these particles, your surgeon may want to do an MRI scan or ultrasound scan of your hip. If such tests show a reaction to the particles, your surgeon may recommend surgery to replace your implant. This is a decision that you and your surgeon need to discuss based on your own personal health needs.
- If you do not have any symptoms or test results that suggest you may need to have your implant replaced, then you should follow your surgeon's recommendations for continued follow-up.
- If you do need to have an additional surgery, several options are available and your surgeon will select the appropriate implant system for you.

Country	Toll Free Number*	Local Dial Number *	Local Operational Hours*
UK	0800 279 4865	+44 (0) 1908 302258	Mon-Fri 9am-5pm
Northern Ireland	*	+44 (0) 1908 302258	Mon-Fri 9am-5pm
Germany	*	+49 (0)211 95456 263	Mon-Fri 8am-5pm
Austria	*	+49 (0)211 95456 263	Mon-Fri 8am-5pm
Italy	800 14 6060	+39 (0)248 100 423	Mon-Fri 8am-5pm
South Africa	*	+27 (0)11 267 9023	Mon-Fri 8am-5pm

## CONTACT US

**DePuy Can Help:** Please call the most appropriate DePuy ASR Help Line.

Ireland	1 800 93 7999	+353 161 050 25	Mon-Fri 8am-5pm
Finland	*	+358 9 25 13 75 37	Mon-Fri 8am-5pm
Belgium	800 40 422	+32 272 596 80	Mon-Fri 8am-5pm
Luxembourg	*	+32 272 596 80	Mon-Fri 8am-5pm
France	*	+32 272 596 80	Mon-Fri 8am-5pm
Switzerland	*	+41 43 244 87 44	Mon-Fri 8am-5pm
Holland	0800 023 4733	+31 10 453 55 74	Mon-Fri 8am-5pm
Poland	*	+48 22 390 88 01	Mon-Fri 8am-5pm
Denmark	*	+45 3334 3075	Mon-Fri 8am-5pm
Sweden	200 883 377	+46 (0)8 514 200 00	Mon-Fri 8am-5pm
Israel	1 800 800 163	+972 3 562 8811	Mon-Fri 8am-5pm
Norway	*	+47 675 525 00	Mon-Fri 8am-5pm
Russia	*	+7 495 661 0380	Mon-Fri 8am-5pm
Czech Republic	*	+420 2 4148 3230	Mon-Fri 8am-5pm
Slovakia	*	+420 2 4148 3230	Mon-Fri 8am-5pm
Hungary	*	+36 302 416 828	Mon-Fri 8am-5pm
Turkey	*	+90 216 658 90 90	Mon-Fri 8am-5pm
Egypt	*	+97 142 236 370	Mon-Fri 8am-5pm
Libya	*	+97 142 236 370	Mon-Fri 8am-5pm
Middle East	*	+97 142 236 370	Mon-Fri 8am-5pm
Greece	*	+30 2 1095 77008	Mon-Fri 8am-5pm

**\*Please note:** Toll Free Numbers will be free of charge and Local Dial Numbers are charged at the local rate. Outside of operational hours, there will be either an answering service or a recording redirecting callers to an emergency 24 hour number.

Please check [www.depuy.com](http://www.depuy.com) on a regular basis for additional updates and information.