Patient Implant Leaflet for the Howmedica Osteonics Insignia™ Hip Stem

Intended Use:

The **Insignia™ Hip Stem** replaces the hip joint. Hip stems are used for patients requiring a hip replacement. Replacing the hip joint is done to reduce pain and restore function. Replacing the hip joint may be needed in cases of bone disease (like arthritis).

Patients who should use this device:

The **Insignia™ Hip Stem** can only be implanted by your doctor. Joint replacement surgery is not right for patients with certain conditions. These conditions include:

- infections,
- unhealthy muscle, bone stock, or skin present,
- skeletal immaturity,
- any mental or neuromuscular issues that would lead to major risk of instability in the implant, or
- sensitivity and/or allergy to material in the implant

Tell your doctor if you are allergic to metals. Metal sensitivity reactions have been reported after joint replacement surgery. If you do not yet have a joint replacement, ask your doctor if a joint replacement is right for you.

Make health care providers and others (doctors, dentists, etc.) aware of your hip replacement, as it may affect their choices for your care. For example:

- Metal implants could set off the alarm in security screening machines like the ones in airports.
- Joint replacement implants may contain metal that may interact with an MRI scanner.
  - **What is an MRI?** A magnetic resonance imaging (MRI) scanner uses a very strong magnetic field and radio waves to produce images of the body. These images can be used for diagnosing a large number of medical conditions and used to plan treatments.
  - **Why is it important?** This interaction may cause the implant to move. It may also cause heating or damage to the tissue around the implant. The metal can distort the image taken by the MRI scanner which could make it harder for the doctor to make a diagnosis.
  - **Where is MRI safety information located?** Your hip replacement implant has an MRI status of MR Conditional, which means that you can safely undergo an MRI exam only under very specific conditions. Scanning under different conditions may result in injury or device malfunction. Full MRI safety information including MR scan conditions is available in the Instructions for Use (IFU) for this implant. Doctors and MRI technicians can find this information at ifu.stryker.com by searching through the catalogue number located on the patient implant card.

Lifetime of the Device:

The replacement hip joint will not be as flexible, strong, reliable or durable as a normal healthy hip. Too much activity or an injury could damage or break the hip implant.
Talk to your doctor about which activities you can do and when it is safe to do them. Doing strenuous activities can loosen or break the implant and damage the bone. If this happens, more surgeries may be needed. Follow all the instructions given by your doctor to make sure your hip implant lasts as long as possible.

The expected lifetime of the devices is based upon non-clinical testing designed to meet at least 10 years of simulated use. Patient factors such as weight, bone quality, activity level and other medical conditions and comorbidities may decrease the expected lifetime of this or any implantable orthopaedic device.

However, with normal wear, hip replacements may last for many years[1]. The lifetime of any hip replacement depends on several factors like weight and activity level. Your doctor will counsel you about strategies to possibly prolong the lifetime of the device, including avoiding high-impact activities, such as running, as well as maintaining a healthy weight. Talk with your doctor about the implant best suited for you.

Talk to your doctor about how often you should have checkups to make sure the hip implant is working properly. Talk to your doctor about what to do when the hip implant reaches the end of its expected life.

Reference

1. American Academy of Orthopaedic Surgeons. OrthoInfo Total Hip Replacement. https://orthoinfo.aaos.org/en/treatment/total-hip-replacement/ Accessed 25 August 2021.

The components of the Insignia™ Hip Stem contain the following materials:

- Titanium alloy
- Commercially pure titanium
- Hydroxyapatite

Other information:

Hip replacements, like most major surgeries, carry certain risks. The following risks have been associated with total joint replacements:

- Issues with the arteries and veins which can include blood clots; blockages; heart attack or death
- Nerve damage, problems with circulation, and/or abnormal bone growth
- Digestive issues
- Urinary or genital issues
- Infection

Other possible side effects or risks:

Other possible side effects that can happen during or after surgery include:

- injury to the joint,
- soft tissue tear near the bone,
- increased problems of the limb/joint,
- bone fracture, or
- decreased range of motion.

Over time and use, small particles from the hip implant may be present. Normally these particles stay in the joint. Sometimes, these particles can travel outside of the joint to different parts of the body including the lymph nodes. Long-term effects of moving particles are unknown. In theory, long-term problems could include cancer, disease of the lymph nodes or other disease. There is little or no scientific proof to support these theoretical effects.
It is believed that the benefits of hip implants are greater than the possible risks. Your doctor has determined that the benefits of joint replacement surgery outweigh the risks.

Call your doctor immediately if you experience any of the following:

- Fever of 38 °C (100.4 °F) or higher, or as advised
- Stiffness or inability to move the hip
- Increased swelling in your hip
- Drainage from the hip incision
- Increased hip pain
- Increased redness, tenderness, or swelling in or around the hip
- You feel the hip implant is not working properly or feel there is a change in how it is working

In the case of serious incidents:

If you have trouble with your implant, contact your doctor and/or the manufacturer right away. Contact information is provided below.

(For residents of Australia ONLY)

Contact the manufacturer and the Therapeutics Goods Administration at www.tga.gov.au/ or www.tga.gov.au/reporting-problems/ to fill out a reporting form.

Patient Implant Card:

Your doctor will provide you with a Patient Implant Card. Your implant card contains important safety information and the model of your device indicated by the numbers next to the REF symbol.

Patient Implant Card Symbol Glossary


Patient Identification


Legal Manufacturer


Healthcare Center or Doctor

Batch Code


Patient Information Website

Unique Device Identifier

Date (of Implantation)

Catalogue number

Device Name

MR Conditional

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430, USA
A Subsidiary of Stryker Corp.
stryker.com