Patient Implant Information Leaflet

ReCerf® Hip Resurfacing

This leaflet is provided to inform a discussion between you and your doctor about your decision to receive the joint replacement device described. It provides information about:

- the type of medical device being considered,
- the type of medical condition the device is used for,
- what may happen after the surgery,
- possible adverse events and malfunctions.

Device name

ReCerf® Hip Resurfacing System

Device model

ReCerf® Hip Resurfacing

Intended purpose (use) of the device

The ReCerf® Hip Resurfacing device is intended to treat severely worn and diseased articulating surfaces of the hip joint caused by end-stage arthritis or trauma where non-surgical treatment routes have become less viable and the condition leads to pain, disability and compromised quality of life.

Patient groups in which the device is intended to be used

The ReCerf® Hip Resurfacing device is intended for skeletally mature patients.

Special operating instructions for the use of the device

Operating instructions are provided to your healthcare provider and doctor for proper handling and implantation of the device. Talk to your doctor about self-care and physiotherapy in relation to your operation and the ReCerf® Hip Resurfacing device.

Intended performance

The ReCerf® Hip Resurfacing is intended to replace the worn or damaged cartilage within your hip joint. It is designed to work with the natural structures (ligaments and muscles) of your hip to provide you with a stable joint and a range of movement that allows you to perform normal everyday tasks with reduced or no pain.

Undesirable side effects and residual risks

As with any hip replacement procedure, undesirable side effects can occur although not everybody gets them. Residual risks can lead to failure of the joint replacement which requires a secondary operation and removal or exchange of one or more components of the joint.

Undesirable side effects may include:

- Loosening of parts,
- Early or delayed onset of infection,
- Abnormal bone formation following surgery,
- Fracture of the bone surrounding the implant,
- Stiffness, pain or instability,
- Limited range of motion,
- Biological (adverse) reaction to wear debris or materials used in the implant.

Residual risks include:

- Suboptimal component size selection or malpositioning during surgery,
- Excessive wear of the surfaces of the components,
- Increased time under anaesthetic,
- Other surgical injury or loss of function.

Risks associated with a ceramic hip resurfacing may be different to metal hip resurfacing. For metal resurfacing an elevated risk of revision overall is associated with females and patients who receive a small size component (<48mm bearing).

Other side effects and residual risks are possible.

Warnings and risks of device interaction with other equipment

The ReCerf® Hip Resurfacing device has not been tested for interaction with Magnetic Resonance Imaging (MRI) equipment. However, general recommendations for MR parameters which should not expose you to additional hazard during MRI are provided in the Instructions for Use which your healthcare provider can access here: https://info.matortho.com/reg/400-498.pdf. You should make your doctor aware of any other implants or known health considerations that may require reduction of the MRI limits. There are several different manufacturers and generations of MRI systems available and MatOrtho® cannot make any claims regarding the safety of MatOrtho® implants and devices with any specific MRI system.

Precautions and other measures that you or your doctor can take to further reduce risks

The lifespan of your joint replacement is finite and excessive activity, failure to control body weight, abnormal loading of the joint and trauma affecting the joint replacement can lead to early failure by loosening, fracture, and/or wear of the prosthetic implant. Loosening of the components can result in increased production of wear particles, as well as accelerate damage to the bone, making successful revision surgery more difficult. Postoperative care is important, and you should avoid putting unreasonable stresses through the joint and follow the instructions of your doctor with respect to follow-up care and treatment.

Your doctor should select the most appropriately sized implant components based on your anatomy and

optimise component placement, positioning, and fixation to ensure the lifetime of the device and avoid unusual stress conditions. Malalignment of the components can place inordinate forces on the components that may cause excessive wear. Your doctor is required to be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery.

Nature and frequency of regular or preventative examination, monitoring or maintenance of the device

Your operation and joint replacement should be followed up according to the normal practice of your healthcare provider. There is no unique monitoring or maintenance required for the ReCerf® Hip Resurfacing device.

Symptoms that could indicate that the device is malfunctioning

Unexpected pain, stiffness, instability or a general worsening of symptoms around your hip especially when compared to your preoperative condition may indicate that there is a problem with your joint replacement. An inflamed, hot, itchy or red area around your hip or wound may indicate infection.

Precautions and other measures to take if the performance of the device changes or the patient experiences any of the symptoms above

Follow any instructions provided by your doctor for self-care and physiotherapy in relation to your operation and the ReCerf® Hip Resurfacing device. Speak to your doctor if you experience any of the symptoms described above. If you think your joint could have become infected, speak to your doctor as soon as possible.

You or your doctor should report any serious incident or adverse event that occurs in relation to the device to the Therapeutic Goods Administration (TGA). Information for this can be found on the Therapeutic Goods Administration's website https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris. Your doctor should inform the manufacturer of any serious event by emailing per.admin@matortho.com.

Expected device lifetime

A well-performing device may last 10 years or more. However, as with any joint replacement device, individual or surgical factors can impact the device lifetime including, but not limited to:

- Diagnoses other than osteoarthritis,
- excessive activity,
- failure to control body weight,
- trauma such as a fall or impact to the joint,
- abnormal loading or unreasonable stresses through your joint,
- not following preoperative or postoperative rehabilitation advise,
- significant postoperative leg length discrepancy (>1cm),
- surgical technique including femoral neck notching, sub optimally sized implants, malalignment, inadequate fixation and/or cementing technique.

Precautions and other measures that you should take, or near, the end of the expected device lifetime

The precautions, risks and warnings described above are appropriate throughout the lifetime of the device up to and beyond 10 years.

Other circumstances in which you should contact a health professional in relation to the operation of the device

No further specific circumstances beyond those discussed above.

Materials and substances included in the device

The ReCerf® Hip Resurfacing device consists of two ceramic components (BIOLOX® *delta* ceramic). The femoral head (top of thighbone) is fixed to the thigh bone using a polymer (polymethylemethacrylate, PMMA) cement that cures when implanted. The acetabular cup (pelvis) component is press-fit into the bone which is shaped during surgery. A thin, porous titanium coating is applied to the outside of the acetabular cup, which has a ceramic coating called hydroxyapatite applied over the surface. The combination of porous surface and hydroxyapatite promote bone growth directly onto the implant.

Manufacturing residuals that could pose a risk to the patient

Manufacturing residuals are removed during validated cleaning processes before packaging and sterilisation of the product. No manufacturing residuals known to pose a risk to the patient remain.

Manufacturer

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