Important Information about ReCerf® Hip Resurfacing

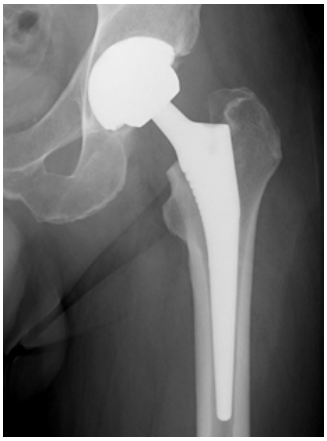
Introduction to ReCerf® Hip Resurfacing

You have been given this information sheet because you need a hip replacement and your surgeon has identified you as a suitable patient for a new hip resurfacing device called ReCerf®. ReCerf® has limited clinical use and is not yet approved for use by regulatory bodies in the UK, Europe, Australia or Canada.

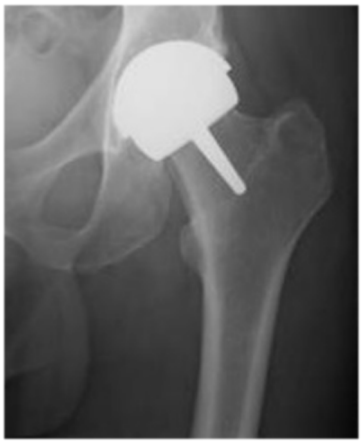
The purpose of this information sheet is to inform you about your procedure. At the end, it will ask you to confirm that you have understood the information. If you wish to receive a ReCerf® hip resurfacing implant, it will ask you to confirm that you consent to receiving an implant that has not yet been approved for use via standard regulatory routes and for specific information relating to your procedure to be collected by certain professionals.

What is Hip Resurfacing?

Hip resurfacing involves shaping the femoral head (ball) to remove only the worn cartilage and replace it with a spherical cap. The main difference to a total hip replacement is that a hip resurfacing device does not require removal of the top section of femoral (thigh) bone to receive a stemmed metal implant.



A traditional total hip replacement that removes the top section of the femur to insert a stem.



A metal-on-metal hip resurfacing that retains the femoral bone with a surface-only replacing cap.

The concept for hip resurfacing is not new, but until recently it has only been possible using metal-against-metal bearing devices. Many patients have had an extremely successful outcome with a metal hip resurfacing device and data from a National Register of hip operations has reported that the MatOrtho® metal-on-metal ADEPT® Hip Resurfacing System (currently available) demonstrates over 94% success at 10 years[2]. However despite its clinical success, there is a small risk of metal-related issues, where patients can be sensitive or have a localised reaction to wear particles produced by metal-on-metal bearings.

How is ReCerf® Hip Resurfacing Different to Currently Marketed Devices?

ReCerf® Hip Resurfacing Arthroplasty uses a ceramic material for the bearing surfaces, which until now has not been available for the hip resurfacing concept. The ceramic material is known as BIOLOX® delta (CeramTec www.ceramtec.com/ceramic-materials/biolox/delta).

Ceramic bearings have been commonplace in total hip replacements for many years and have demonstrated excellent success rates up to 16 years, the longest period that key National Joint Replacement Registers report on. Years of research and clinical experience have shown that this ceramic material wears more slowly, produces fewer wear particles, and that wear particles are far less likely to lead to tissue reactions when compared to other materials including metal.

The ReCerf® Hip Resurfacing device is based on a metal resurfacing design that is still commonly used by resurfacing surgeons (ADEPT® Hip Resurfacing System). Both the ADEPT® and ReCerf® were developed and are manufactured by MatOrtho® Limited.

ReCerf® Hip Resurfacing Arthroplasty (ceramic-on-ceramic)

ADEPT® Hip Resurfacing (metal-on-metal)

What Are The Perceived Benefits Of Hip Resurfacing?

Benefits of this type of surgery may include:

- The amount of cartilage and bone removed for the thin-shell ball-and-socket components is minimal compared to a standard total hip replacement and your surgeon can use the geometry of your natural anatomy to size, position and align the device components. Therefore restoration of your leg length and muscular stability may be more reliable and your hip may feel more normal.
- Unlike a total hip replacement, a hip resurfacing procedure retains the head (ball) of the healthy femoral bone. Therefore, if further surgery were required at a later date there is more bone stock available to enable an operation to convert to a standard hip replacement.
- The ball-and-socket bearing with a hip resurfacing will be close to the size of your natural hip joint, whereas a total hip replacement would introduce a smaller ball-and-socket articulation. For this reason, dislocation – which is a common complication after total hip replacement – is less likely with a hip resurfacing device compared to a conventional total hip replacement.
- Patients receiving hip resurfacing devices may be more able to return to demanding jobs and may achieve higher levels of activity including return to sport[1] than total hip replacement patients.
- The perceived benefit of receiving a ReCerf® Hip Resurfacing compared to another resurfacing device is reduced exposure to metal ions since the ceramic contains less metal than a metal-on-metal device. This is not yet proven because the device is new and there is limited clinical data on its use.

Note that these benefits are not guaranteed following hip resurfacing and, as with any type of surgery, your recovery and ability to return to activities will depend on many factors. Always follow the advice of your surgeon during rehabilitation to ensure you have the best chance of making a full recovery.

What Are The Risks?

All types of hip replacement surgery carry inherent risks which your surgeon will discuss with you.

Hip replacement devices that have been in use for some time have a dataset of clinical evidence for their performance.

There are general risks of hip surgery, for example wound healing delay, nerve/blood vessel damage, swelling or stiffness and deep vein thrombosis. These are not specific to ReCerf® and your surgeon will be happy to discuss these with you.

There are general risks of receiving a hip implant and these are reported in National Joint Registries by device type (total hip replacement and hip resurfacing replacement). The risks in the registries include (but are not limited to) fracture of the bone surrounding the implant, dislocation, implant fracture, infection, loosening and pain. Below are some useful links to data on the risks of receiving a hip implant:

UK patient National Joint Registry guides and annual report:

www.njrreports.org.uk/patient-guide

www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2015th%20Annual%20Report%202018.pdf

Australian and New Zealand National Joint Registries:

https://aoanjrr.sahmri.com/annual-reports-2018

https://nzoa.org.nz/nzoa-joint-registry

The ReCerf® design is based on a hip resurfacing device that has use over 13 years clinically (ADEPT®) and therefore the risks presented in National Joint Registry databases may be expected to be similar for ReCerf®, but without specific risks associated with the use of metal. However because ReCerf® is a new device, it does not yet have enough clinical data to predict all outcomes and no-one can know what unexpected issues may arise until a dataset of clinical evidence has been accumulated.

Patients receiving hip resurfacing may not be able to return to the level of activity expected and individual outcomes depend on many factors. Ceramic-on-ceramic bearings like ReCerf® may make a noise (clicking, squeaking, grinding) which might be frequent or intermittent and may develop early or late postoperatively. Noise generation can occur in up to 22% of patients[3]. Patients generally remain satisfied and there is no higher risk of failure associated with this noise generation.

It is important for to you understand that other unexpected issues (not discussed with your surgeon or above) can occur with all types of implant devices involving surgical interventions.

Adverse events can lead to the device being removed and replaced in a second surgical procedure (revision surgery). If your device fails and is replaced, then the clinical outcomes following secondary joint replacement may not be as favourable.

How Has ReCerf® Been Tested?

The materials used in the manufacture of ReCerf® hip resurfacing device have been used over many years.

State-of-the-art laboratory testing and computer simulations have been used to investigate all aspects of the device performance based on existing knowledge about hip replacement. Testing has included subjecting the device to forces that exceed those expected under normal activities and this indicates that ReCerf® is fit for its intended purpose.

Because ReCerf® is a new device, it does not yet have enough clinical data to predict all outcomes and no one can know what unexpected issues may arise until a dataset of clinical evidence has been accumulated; however the extensive testing supports the use of the device in patients.

What Clinical Evidence (Use In Patients) Is Available At This Time?

The first ReCerf® device was implanted on 24th September 2018 and a small number have been implanted since then. All patients continue to do well and their consultant's report no issues with the device. Patients are being followed up closely to ensure the continued success of the device and early reporting of any unexpected issues.

If new information becomes available that may affect you and your implant, you will be contacted directly by your surgeon. If you have any concerns following your operation please contact your surgeon.

References

1. Sandiford et al. Return to sporting activity after Birmingham hip resurfacing arthroplasty: Mid-term results. Indian J Orthop. 2015 Nov-Dec; 49(6): 595–601
2. England, Wales, Northern Ireland and Isle of Man National Joint Registry, product report February 2018 ref: Summary.Report.HP_Head_Adept Resurfacing Head (Sizes 48 - 58 only)_Onlabel.16/02/2018.13:43.
3. Goldhofer MI, Munir S, Levy YD, Walter WK, Zicat B, Walter WL. Increase in Benign Squeaking Rate at Five-Year Follow-Up: Results of a Large Diameter Ceramic-on-Ceramic Bearing in Total Hip Arthroplasty. J Arthroplasty. 2018; 33(4): 1210-1214.

Your Consent

What Am I Consenting To?

ReCerf® is approved for use in South Africa, however, outside of this country your surgeon has specifically requested the approval of the Health Authority to use ReCerf® for you before standard regulatory approvals have been gained in your country (this may be CE mark in Europe, TGA approval in Australia, for example).

MatOrtho® Limited is the manufacturer of ReCerf® and has agreed to supply the ReCerf® for your operation because your surgeon believes it is the best option for you. The decision to receive ReCerf® should be discussed between you and your surgeon but it is ultimately your choice. Your surgeon will be happy to discuss alternative treatment options with you.

MatOrtho® have supplied this information sheet to make you aware that standard regulatory approvals for ReCerf® are pending and that there is currently very limited clinical data on its

performance in patients. Your signature on this consent form indicates that you understand this information and that you are aware of the risks involved in receiving a new device.

Additional Information: Personal Information and Data Collection

To understand how the device performs, your surgeon will collect data from you including asking questions about your hip and taking radiographs. Data will be collected pre-surgery to set a baseline in your clinical outcomes and then post-surgery at various time-points. This allows your surgeon to track any improvements before and after your operation and to track any changes in performance over time. Your details will be stored securely by your healthcare system and those professionals who need to access personal data will be able to do so as part of your normal doctor-patient relationship.

The clinical data relating to the performance of your ReCerf® device will be shared with the manufacturer (MatOrtho®) so that they can be sure the device is functioning as intended. From time to time regulatory authorities may request to see the data and the data collected may support future regulatory applications. Regulatory authorities and the manufacturer of the device will be able to see the results of your clinical outcomes and basic information such as age, gender and BMI which will be linked to an identification number (ID) and anonymised. This patient identification (ID) number will be used to link you to your medical records and anonymised at the hospital, which are kept only by your health care team as part of normal doctor-patient relationships. The link to your personal records and this ID number will not be shared with the manufacturer. This consent form containing your name and signature may be shared with MatOrtho® and regulatory authorities as part of the application of use of the ReCerf® device before standard regulatory approvals are gained.

All patients receiving ReCerf® will be asked to complete the same outcome measures and to help your surgeon complete the data collection, external companies may be used. These external companies specialise in clinical data collection and are known as CRO's (Clinical Research Organisations) and software experts. The companies are currently Ortholink Pty, PRN Services and Northgate Public Service but we may engage others over time. The employees of these services will help to collect, process and analyse your data and provide software (an orthopaedic database) where the clinical data is stored securely. Every user of the selected data collection software has a log-in and secure password. These companies are required to keep patient confidentiality and process the data with the same strict controls as MatOrtho®. To assist with data collection and scheduling of follow-up appointments, employees of these services and only those third parties contracted directly by these services may have access to your name and contact details. These services may be responsible for sending you follow-up questionnaires directly to your email (or your preferred contact method).

Access to the database where your clinical data is stored and the level of personal data visible will be limited by user type (surgeon, manufacturer, CRO).

Your rights to access change or move your information are limited, as your information must be managed in a specific way in order for the clinical outcomes to be reliable and accurate. Your information will be processed and stored with the minimum personally-identifiable information possible at all times.

Your hospital care team will keep information about you for as long as they are in practice and the ReCerf® hip resurfacing device is on the market. Information transferred to the manufacturer, MatOrtho®, will be held on record throughout the lifespan of the product i.e. as long as the ReCerf® hip resurfacing device is available and on the market, and for a further 5 years if the ReCerf® hip resurfacing device were to be discontinued.

The data collected may be used in a number of verbal and written publications led by your surgeon. This will help to increase medical community knowledge on best treatment routes. Reports may also be used to inform surgeons and hospitals in other countries who are considering introducing the

device into their routine practice. None of these reports or publications will be able to identify you individually.

Patient Consent

By signing this consent form you are agreeing to receive a medical device called ReCerf® Hip Resurfacing System and you understand this device is new and therefore has very limited use in patients. The device is manufactured by MatOrtho® Limited (www.matortho.com) and ReCerf® is not yet approved for use under standard regulatory routes in most countries. It is at the discretion of your surgeon that you are being offered this device.

Please ensure that you have read and understood all the information available to you and that you have been given full opportunity to ask any questions you may have about the ReCerf® Hip Resurfacing System or your procedure.

Your legal rights are not affected by signing this consent form.

If you agree, please put a tick in the boxes by the following statements to indicate that you understand the information presented to you:

1. I confirm that I have read and understood this 'ReCerf® Pre-approval Consent Form, Issue 4', which details the risks and potential benefits of receiving a ReCerf® Hip Resurfacing System. ☐
2. I understand that the ReCerf® Hip Resurfacing System is not approved for use under normal regulatory routes in any country outside of South Africa. Therefore I understand that I may be receiving this device before the device has been approved using normal regulatory routes. ☐
3. I understand that there is very limited clinical data on how the ReCerf® performs in patients. ☐
4. I understand that the ReCerf® Hip Resurfacing System is being used at the discretion of my surgeon. ☐
5. I understand that relevant sections of my medical notes and clinical outcomes, such as adverse events, may be shared with MatOrtho® Limited (the manufacturer of the device), other orthopaedic specialist surgeons and regulatory authorities. I give permission for these individuals to have access to my records. ☐
6. I understand that this form, with my name and signature, will be shared and stored by MatOrtho® and regulatory authorities as part of the approval process to use this device. ☐
7. I understand that clinical research organisations and software companies will help my surgeon to collect, process and store my data and that these specialist companies will have access to limited personal information to facilitate data collection. This may include my name and contact details. ☐

8. I give my permission for these specialist companies to contact me directly on behalf of my surgeon with regards to this data collection. ☐

9. I understand that my data and summary data may be used as part of scientific and clinical publications and for podium presentations. ☐

10. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily by my surgeon. ☐

11. I understand that my signature below gives my permission to receive the ReCerf® Hip Resurfacing System. ☐

_____	_____	_____
Name of patient	Date	Signature

_____	_____	_____
Name of person taking consent	Date	Signature

Forms: 1 for patient; 1 (original) to be kept in medical notes, 1 for the manufacturer.