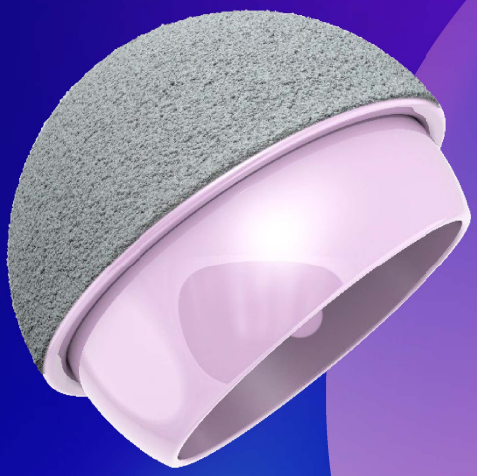
ReCerf®

ReCerf® Hip Resurfacing Arthroplasty

CLINICAL RATIONALE



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Contents

Summary Overview 3

Introduction 3

Benefits of Choosing Hip Resurfacing 4

Clinical Evidence on Ceramic Hip Resurfacing - ReCerf® 5

Survival and adverse events 5

Patient reported outcome measures for ReCerf® 6

Satisfaction 7

Crepitus 7

Stabilisation, an indication of long-term performance 7

Conclusion 7

References 8

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Summary Overview

Hip resurfacing offers certain clinical advantages over traditional hip replacement for appropriately selected patients who have osteoarthritis and need a hip replacement, and it can optimise their clinical care pathway.

ReCerf® is a next-generation hip resurfacing implant made with an advanced, biocompatible ceramic.

- It demonstrates a low revision rate of 2% at 5 years.
- Patients report high satisfaction, significant pain relief and return to recreational activities, sports, and heavy work at 6, 12 and 24 months post-operation.
- Radiographic evidence confirms stable implant fixation, indicating potential for longevity.
- Clinical outcomes are at least equivalent to those of contemporary hip replacement options in similar patient populations.

Introduction

Total hip replacement (THR) is a successful and well-established approach to replacing the diseased or damaged hip joint. THR removes the entire femoral head and neck to insert a modular ball head with a stem into the femoral cavity. However, more recent advances in metal and now ceramic implant technologies have allowed for the development of a more bone conserving concept that re-surfaces the hip joint, while retaining the native femoral anatomy.

Hip Resurfacing is now a viable alternative treatment to THR. Hip resurfacing aims to restore the normal functioning hip by removing just the worn surfaces of the femoral head and acetabular socket and replacing these with thin-walled monobloc components. Hip resurfacing offers the potential to delay or even eliminate the need for THR. For patients seeking to maintain an active lifestyle, hip resurfacing presents an ideal solution.

Following the early success of metal hip resurfacing in the early 2000s, several manufacturers brought new designs to market. However, some designs were poor, adoption was rapid, many surgeons performed hip resurfacing infrequently (compared to THR), and patient selection was variable. This led to a higher-than-anticipated rate of revision surgeries overall, which subsequently led to the withdrawal of many brands from the market and continued use narrowed to a small number of specialist surgeons. Nevertheless, for the most successful hip resurfacing devices (ADEPT® (not approved for use in Canada or the US) and BHR) a high proportion of patients enjoy active lives up to 20 years after receiving their implants[1-4] and the Australian Orthopaedic National Joint Replacement Registry (AOANJRR)[2] demonstrates comparable outcome for hip resurfacing used in males when compared to THR. With comparable longevity to THR, alongside numerous potential clinical advantages, hip resurfacing remains an attractive alternative to THR. However, despite the success of the concept with established metal resurfacing devices and specialist surgeons, adverse reaction to metal debris[1, 2] remains a concern for clinicians and patients.

Since September 2018, over 1,300 patients have received a new type of hip resurfacing made from an advanced ceramic material called BIOLOX® delta (CeramTec GmbH). This ceramic-on-ceramic hip resurfacing device, known as ReCerf®, was designed and produced by the same team that developed and manufactured the most successful and still-used metal-on-metal hip resurfacing devices (ADEPT® and BHR). BIOLOX® *delta* ceramic used in THR has the greatest longevity of all available materials - consistently ceramics, whether used with ceramic or polyethylene acetabular bearing, have the lowest revision rates reported to the registries over 20 years[1-2]. THR using large BIOLOX® *delta* heads are cited with 100% survivorship over 7 years[34,35], to feel more natural[36] and have high functionality (ability to sit in a squatting position and sit cross-legged) without dislocation or revision[34]. BIOLOX® *delta* is an attractive alternative to metal bearings in hip resurfacing because it can eliminate the incidence of revision associated with metal ions.

Benefits of Choosing Hip Resurfacing

Symptom Improvement and Functional Recovery

Hip resurfacing improves pre-clinical symptoms by reducing pain and enabling return to normal functional activities[3-12]. Performance outcomes depend on the patient population, however in well selected populations, metal-on-metal hip resurfacing devices demonstrate performance which is maintained over time with excellent results into the second decade[1-4].

Enhanced Stability and Reduced Dislocation Risk

Hip resurfacing uses large-diameter head components matched to the size of the patients' native hip. This offers an immediate advantage for the patient in terms of stability and significantly reduces the risk of dislocation as compared to total hip replacement[13,14]. In the UK National Joint Registry (NJR) the incidence rate of revision for dislocation within the first postoperative year is estimated at 2.5 to 5.5 times less for hip resurfacing as compared to THR. The incidence rate for dislocation of hip resurfacing remains lower at later time points[1].

Anatomical Restoration and Natural Gait

Resurfacing of the femoral head allows for better restoration of the anatomy[13,14] and a more natural gait[8, 15-18]. Hip resurfacing maintains a more symmetric gait, performs more consistently than THR under stressed gait conditions e.g. slope and fast walking, is more likely to have absence of limp or leg length discrepancy[8, 15-18] and may have less risk of thigh pain[8].

Patient Preference and Return to Activity

THR and hip resurfacing perform well in studies directly comparing device types, but there are often benefits observed for hip resurfacing over THR[3,5,6,8,10,11,19-27]. A bilateral hip study cites that 86% of patients preferred their hip resurfacing whilst just 6% preferred their THR and 8% had no preference[28]. Common reasons for preference for the hip resurfaced side were normality and reliability during activity and sports[28]. Expert surgeons agree that they allow their hip resurfacing patients to return to wider variety of sport and leisure activities without restriction[11] and return to activity is commonly much earlier in the postoperative recovery phase[9,11,29]. Patients expectations on return to activity should be managed and safe progression of activity in the first 6 to 12 months post-surgery minimises the risks of femoral neck fracture. Performance outcomes depend on the patient population, however in well selected patients metal-on-metal hip resurfacing patients report a high level of activity including running, and these outcomes are maintained into the second decade[3-6, 27-31].

Lower Infection Risk

The NJR shows that a hip resurfacing procedure is 2.0 to 4.6 times less likely to be revised for infection than a THR within one year post surgery[1]. Unlike a resurfacing procedure, a THR reams deep into the femoral shaft to make a cavity for the hip stem leaving the patient more vulnerable to infection. Revision for infection is associated with double the costs and twice the length of stay in hospital as compared to revision for aseptic causes[32]. Infection is associated with a higher level of complication, reoperation and morbidity[33] and so the benefits of reducing risk of infection are far-reaching.

Clinical Advantages of Ceramic-on-Ceramic Hip Resurfacing Devices

Ceramic-on-ceramic hip resurfacing devices have all the benefits of established metal-on-metal hip resurfacing devices whilst removing metal from the bearing surface. This eliminates the risk of biological reaction to the metal e.g. sensitisation reactions pseudotumour, tissue damage. Ceramics have the highest biocompatibility compared to metal or polyethylene in terms of reduced risk of adverse events and osteolysis[37] and extremely low wear, even when subject to adverse loading conditions including malalignment[39], and so are less likely than other bearing materials (metal or polyethylene) to generate the amount of debris required to elicit a biological response.

Clinical Evidence on Ceramic Hip Resurfacing - ReCerf®

Survival and adverse events

The following information includes ReCerf® procedures from 24 September 2018 to 30 January 2025.

ReCerf® was first used in September 2018 and there are 1,304 implanted, across five countries and by >20 surgeon users. At the time of reporting, the mean and maximum time to outcome was 2.5 years and 6.4 years, respectively, and the most frequent reason for surgery was osteoarthritis.

Overall, 17 hips have required revision surgery which as a percentage of the number implanted is 1.3%. The Kaplan Meier cumulative risk of revision was 1.66% (95% confidence interval 0.99% to 2.80%) at 4 (with 306 at risk at 4 years) and 2.00% (95% confidence interval 1.16% to 3.44% at 5 (with 133 at risk at 5 years). Revisions have been recorded for periprosthetic neck fracture (10), pain (5) and cup loosening (2). Adverse events for ReCerf® are not beyond that expected for similar procedures/devices. The risk of component fracture was tested extensively *in vitro* and found to be extremely low under standard and critical conditions[38], and this is supported by the absence of fracture within the clinical data.

Compared to metal-on-metal hip resurfacing which historically excluded small head sizes (and therefore restricts the treatment option for most females, who have smaller femoral anatomy), the ReCerf® range reintroduces a wider head size range. Differences that may lead to greater clinical success for patients with small femoral anatomy (and females) receiving ReCerf®, as compared to metal counterparts are; a higher thermal conductivity of BIOLOX® delta compared to metal which translates to a lower temperature rise on the bone during cementing (reduced risk of heat damage, necrosis) and this effect may be more notable for the smallest head sizes where heating for both metal and ceramic is incrementally higher than observed in larger sized heads[40] and the shorter, more proportional stem design for ReCerf® which theoretically reduces the risk of proximal stress shielding[41,42]. When assessing the risk of revision for patients receiving ReCerf® by gender, no statistically significant differences were found in outcome (p=0.6009).

It is useful to see how the revision rate for ReCerf® trends against similar devices and when used in similar populations. Figure 1 compares the cumulative revision risk for ReCerf® against similar device groups including ADEPT® metal-on-metal hip resurfacing (where current practice use means indication osteoarthritis, operation dates from January 2010 onwards and head sizes 48mm to 58mm) and well-performing THR groups by fixation, bearing material and gender when used in patients aged <55 or <65 years at surgery. The comparative data shows that ReCerf® performs as expected in the mid-term.

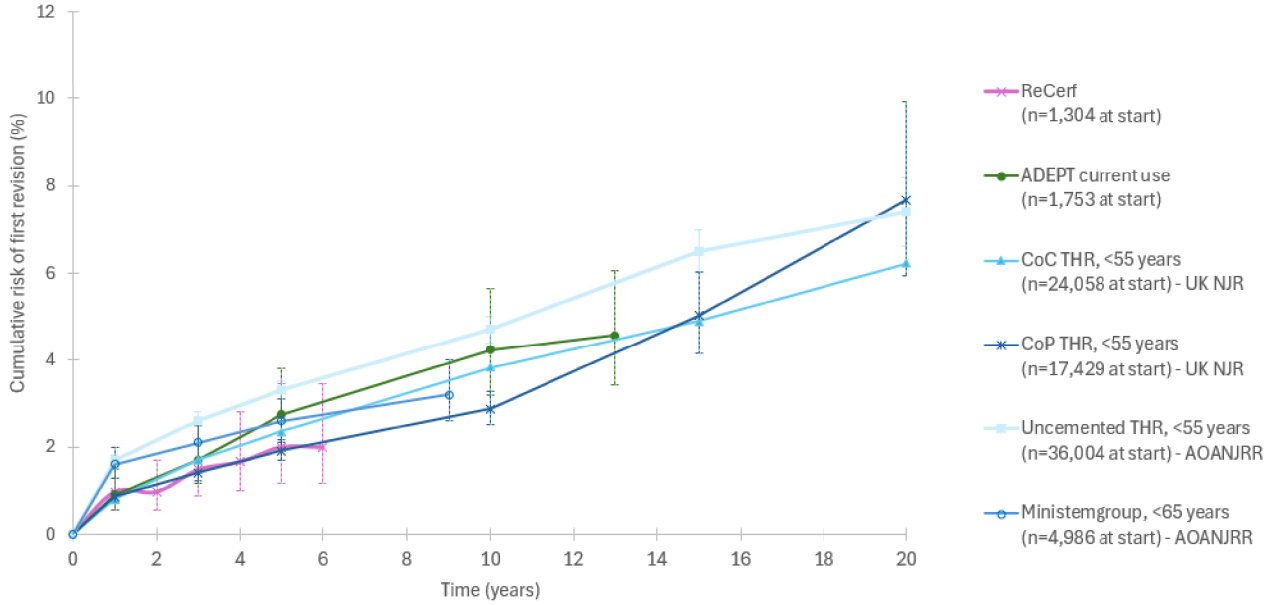

Figure 1 Figure 1 Cumulative revision rate for ReCerf®[43], ADEPT® (current practice use)[44], UK NJR data showing ceramic-on-ceramic (CoC) THR and ceramic-on-polyethylene (CoP) THR used in patients <55 years at surgery [1] and AOANJRR data showing uncemented THR used in patients <55 years[2] and minihip stemmed THR used in patients <65 years at surgery[2]

Patient reported outcome measures for ReCerf®

The following information includes a consecutive series implanted between 24 September 2018 and January 2022.

A variety of patient reported outcome measures (PROMs) were collected pre-operatively and at 6, 12 and 24 months post-operatively from 496 ReCerf® hips[43]. Patients had mean age at surgery of 50.4 years (range 23.4 to 80.0), were female in 43.6% of cases, had mean BMI at surgery of 27.6 (range 18.2 to 41.5) and were most often graded P1 ASA rating ('a normal healthy patient', 59.8% of cases). The most frequent reason for surgery was osteoarthritis (97.0%).

Table 1 shows the PROMs for the cohort and when assessed by gender, no notable differences are observed.

Table 1 Patient reported outcome measures for ReCerf®[47]

Mean (SD) *% completeness*	Pre-op	6months	12months	24months
Oxford Hip Score (OHS)	22.3(8.4) *98.4%*	43.5(6.0) *79.2%*	45.0(4.9) *85.7%*	45.2(5.1) *84.3%*
UCLA Activity Scale	5.0(2.3) *87.5%*	7.4 (1.7) *75.8%*	7.8(1.7) *81.7%*	8.0(1.8) *83.5%*
HOOS sports	29.8(19.7) *90.1%*	82.8(18.8) *79.2%*	87.8(16.7) *84.7%*	89.0(16.1) *84.1%*
HOOS QoL	22.4(16.8) *90.7%*	75.1(20.6) *79.2%*	81.6(18.7) *85.5%*	83.4(18.5) *84.3%*

HOOS = Hip Disability and Osteoarthritis Outcome Score and QoL is quality of life

National Joint Registry sources include Oxford Hip Scores at 6 months post-surgery and Table 2 demonstrates that ReCerf® results are excellent and perform in line with similar device groups.

Table 2 Oxford Hip Score reported for ReCerf® and registry data for other hip devices

Group	Pre-operative	6 month post-operative
ReCerf, mean (95% confidence intervals, SD)[43]	22.3 (4-47, 8.4)	– 43.5 (42.90 to 44.10, 6.0) – 97.5% scores improve – 92.6% excellent to good (≥34 points)
All total hip procedures, osteoarthritis only[2], mean (95% confidence intervals),		
– Male <65 years – Female <65 years	– 19.84 (18.33, 21.36) 17.89 (16.37, 19.40)	– 41.53 (39.56, 43.49) – 39.58 (38.06, 41.09)
All hip procedures[45], mean (range, SD)	Not reported	40.3 (0-48, 7.6) 84% excellent or good score (≥34 points)
UK NJR product reports[46], mean (95% confidence intervals), showing 6 month unadjusted scores		
– ADEPT 48-58mm heads – Other total hip replacement	– 22.5 (21.6 - 23.3) – 17.9 (17.9 - 17.9)	– 42.2 (41.5 – 42.9) and 97.5% scores improve – 39.6 (39.5 - 39.6) and 97.3% scores improve

Satisfaction following ReCerf® is excellent and this is demonstrated via a variety of visual analogue scale (VAS) questions and satisfaction questionnaires as follows:

- On a scale of 0 (least satisfied) to 10 (most satisfied), the mean outcome was 9.2 points (median 10 points) at 24 months.
- When asked about normality of the operated hip, 85% answered 80 points or more on a normal scale (where 0 is not normal and 100 is normal), and 81% answered 'yes it feels normal in everyday activities' when asked via a binary question.
- Relief of pain was rated excellent or very good in 93.1% of cases and 'very satisfied' in 90.9% of cases at 24 months.
- Satisfaction regarding ability to do regular and recreational activities was rated excellent or very good in 94.6% of cases and 'very satisfied' in 81.1% of cases at 24 months.
- Satisfaction regarding ability to perform heavy work or sports was rated excellent or very good in 85.8% of cases at 24 months.
- 95.7% said their problems were 'much better' at 24 months compared to before their operation.

Crepitus

Squeaking is a phenomenon most often associated with ceramic bearing THR and factors such as suboptimal inclination and/or anteversion, high femoral offset and lateralisation of the hip centre activity, BMI, femoral head size and gender have been reported to influence squeaking[35,47-53]. Squeaking is likely multifactorial and is reported in BIOLOX® *delta* ceramic bearing THR at generally low rates[35,47-53], where it is said to be well-tolerated and with no evidence that it leads to failure.

ReCerf® has been monitored closely including collection of clinical evidence of crepitus within adverse events, via a patient reported measure (HOOS symptoms) and a subset of patients who completed a specific noise questionnaire[43]. Crepitus, including squeaking, has been reported by ReCerf® patients, however, most often noises such as squeaking are not reproducible and most often associated with end range of motion activities such as bending. The incidence of crepitus (any noise) actually reduces significantly post-surgery when receiving ReCerf® (32.0% of patients reported noise often or always before surgery and this decreased to 5.7% at 24 months post-surgery).

Surgeon users agree that there has been no clinically problematic incidence of squeak, and the rate is not beyond that reported for other ceramic bearing THR. However, ReCerf® patients should be advised before surgery of the small risk of squeaking.

Stabilisation, an indication of long-term performance

Radiographic evidence can be a surrogate for longer-term survival data and radiographic data on ReCerf® (including interim radiostereometric analysis (RSA) results) provide clinical evidence of adequate device fixation and stabilisation[54].

Conclusion

Overall, the clinical evidence (adverse events, revisions, reasons for revision, PROMs, radiographs and RSA) support that ReCerf® performs as expected against similar device groups and populations, and that the performance is as intended at a maximum time to outcome of 6.1 years.

ReCerf® offers a treatment for the whole population, including females and patients with small femoral anatomy, who without ReCerf® are limited to the treatment option of THR.

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Part No. ML-300-200 | Issue 5

ML-300-200 (DOC-3422) Ver. 1

Approved By:

(CO-169) ML-300-200 Update

Description

Update ML-300-200 to add note that ADEPT is not cleared for use in the US or Canada, reword statements on performance outcomes, remove section 'Reduced Mortality Risk', and remove references 34-37 and re-number references accordingly.

Justification

Various updates required prior to submission to Health Canada.

Assigned To:	Initiated By:	Priority:	Impact:
Yasin Noormohamed	Yasin Noormohamed	Low	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Yasin Noormohamed	February 16, 2026 10:00 AM GMT	CO-169	1	Published
Alex Chalasova	September 4, 2025 11:15 AM BST	CO-16	0	Superseded