

REMEDY® ACETABULAR CUP

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Overview

The REMEDY® Acetabular Cup (Figure 1) is part of the treatment in a two-stage procedure performed in the event of permanent prosthesis infection.

The REMEDY® Acetabular Cup implant is intended for temporary use only (180 days or less) and only in combination with REMEDY® & REMEDY SPECTRUM® GV Modular Head. It allows basic joint mobility and releases antibiotic into the joint area to protect the implant from bacterial colonization. A second surgery will be required at a later date to remove REMEDY® Acetabular Cup and replace it with a permanent hip joint implant.

REMEDY® Acetabular Cup:

- single-use medical device/ethylene oxide sterile
- formed with bone cement (PMMA) and gentamicin
- releases gentamicin

Indications

The OsteoRemedies® Hip Spacer System consists of a modular head and stem, and an optional acetabular cup. The REMEDY® components of the OsteoRemedies® Hip Spacer System include gentamicin and the REMEDY SPECTRUM® GV components include gentamicin and vancomycin.

The OsteoRemedies® Hip Spacer System is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin or gentamicin/vancomycin are the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organisms.

Following removal of the existing acetabular and femoral components and radical debridement the head and stem components are inserted into the femoral medullary canal and can mate directly with the native acetabulum or an acetabular component which is placed in the acetabular cavity. The device is intended for use in conjunction with systemic antimicrobial therapy (standard treatment approach to an infection).

The OsteoRemedies® Hip Spacer System is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, etc.).

Contraindications

Contraindicated for use with:

- Deficiencies in the patient's vascular, nervous or muscular systems.
- Osteoporosis or poor bone quality may cause the implant to fracture existing bone or migrate.
- Patient's two-stage arthroplasty procedure is contraindicated based on decreased immune response or systemic clinical conditions.
- The infected THR devices cannot be removed.
- Patient exhibits hypersensitivity (allergy) to PMMA bone cement, aminoglycosides or gentamicin.



Figure 1: REMEDY®
Acetabular Cup