

REMEDY® SHOULDER SPACER

Temporary REMEDY® Shoulder Spacer with Gentamicin

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Overview

The REMEDY® Shoulder Spacer is part of the treatment foreseen in a two-stage procedure performed in the event of permanent prosthesis infection. The REMEDY® Shoulder Spacer implant is intended for temporary use only (180 days or less). 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 the REMEDY® Shoulder Spacer and replace it with a permanent shoulder joint implant.

The REMEDY® Shoulder Spacer consists of two individual implants (head and stem) which, when joined, allow to better fit the anatomy of the patient.

Each REMEDY® Modular Humeral Head can be combined with each REMEDY® Modular Humeral Stem.

Modularity is offered by selecting optional neck lengths (offset) and using a threaded connection featured on both implants. REMEDY® Modular Humeral Heads include a monomer (MMA) phial that serves as an adhesive (which binds the head and stem) and "cover cap". The liquid is sterilized by filtration.

REMEDY® Shoulder Spacers:

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

REMEDY® Modular Humeral Head

The REMEDY® Modular Humeral Head must be used together with the appropriate REMEDY® Modular Humeral Stem. When both head and stem are joined, the shape emulates an anatomically correct shoulder prosthesis. The REMEDY® Shoulder Spacer is temporary, implantable and composed of gentamicin bone cement.

REMEDY® Modular Humeral Stem

The REMEDY® Modular Humeral Stem is made of formed bone cement (PMMA) with gentamicin applied to a stainless steel reinforcing structure, with a straight profile and an oval cross-section. The combination of a stem with a head generates a device resembling a shoulder prosthesis. The REMEDY® Shoulder Spacer is temporary, implantable and composed of gentamicin bone cement.

REMEDY® Shoulder Spacer Indications

The REMEDY® Shoulder Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total or hemi-shoulder replacement in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organisms.

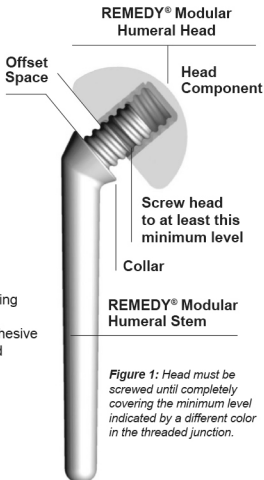


Figure 1: Head must be screwed until completely covering the minimum level indicated by a different color in the threaded junction.