OsteoRemedies®
ADVANCED MEDICAL TECHNOLOGIES

SURGEON INFORMATION

REMEDY® ACETABULAR CUP TRIAL/HANDLE

The REMEDY® Acetabular Cup Trial/Handle is a Radel® (PPSU) device intended for the surgeon to check the dimensional suitability of the acetabular cavity before the implantation of the acetabular cup spacer and permit its correct positioning in situ (Figure 1).

It must be used only with REMEDY® Acetabular Cup. It is composed of a single element, which allows:

Trialing:
- check the dimensions of the native acetabulum using the TRIAL end
- establish the level of reaming needed
- check the correct cup positioning

Note: The thickness generated by the cement is not reflected in this trial.

Implant Positioning:
- apply the acetabular cup spacer with cement onto the native acetabulum;
- position the acetabular cup spacer using the IMPLANT end of the trial/handle

Figure 1:
REMEDY® Acetabular Cup Trial/Handle

Step 1: Use the TRIAL end to check if the native acetabulum is adequately sized to receive the acetabular cup spacer. If required, ream the acetabulum to create the space to accommodate the acetabular cup spacer and the cement used to affix it;

Step 2: With the acetabular cup spacer applied with cement onto the native acetabulum, use the IMPLANT end to position it.

Note: Do not use excessive pressure for device positioning.

Step 3: After use, the device must be cleaned.

CLEANING & STERILIZATION

REMEDY® Acetabular Cup Trial/Handle components are nonsterile.

Before each use, the device must be cleaned and sterilized.

CLEANING RECOMMENDATIONS:

1. Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.

2. Completely submerge the instrument in enzyme solution and allow it to soak for at least 1 minute, or the minimum soak time recommended by the cleaning agent manufacturer. Use a soft-bristled brush to gently clean the device (paying close attention to all threads, crevices and other hard-to-clean areas) until all visible soil has been removed. Any instruments with lumens or cannulas should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). The enzyme solution should be changed when it becomes grossly contaminated.

3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.

4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.

5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 40-45 kHz.

6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.

7. Repeat steps 5 and 6 with freshly prepared cleaning solution until the instruments are thoroughly clean.

8. Dry instrument with a clean, disposable, absorbent, non-shedding wipe.

In case of use of automatic cleaning cycle, check the compatibility with the above mentioned instructions.

RECOMMENDED STERILIZATION CYCLE*:

Method:	Moist Heat (steam)
Cycle:	Dynamic Air Removal (Prevacuum) Steam
Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Dry Time:	Wrapped Devices** – 30 Minutes

** An FDA-cleared sterilizer should be used.*
*** Prior to sterilization, the trials should be placed in an FDA-cleared wrap.*
The above sterilization cycle achieves a sterility assurance level (SAL) of 10^{-6}.

WARNING: The REMEDY® Acetabular Cup Trial/Handle must be used only to determine the anatomically correct size of the REMEDY® Acetabular Cup Spacer to be implanted. The trial device must not be implanted. Instruments must always be examined by the user pre/post cleaning and prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, cleanliness, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete.

Do not use the device if it appears damaged (deformation, loss of the information marked on the device, etc.). The device needs to be replaced if it appears damaged after a visual inspection. Use only in an operating environment.

DISPOSAL: When the device has to be disposed follow national or local guidelines for disposal of surgical waste materials.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Keep out of reach of children.

DESCRIPTION	REF CODE
REMEDY® Acetabular Cup 40mm ID/48mm OD Trial Handle	RHACTXS
REMEDY® Acetabular Cup 46mm ID/54mm OD Trial/Handle	RHACTSM

Symbols:

NONSTERILE	REF	LOT		
Nonsterile	Catalog Number	Batch Number	Caution	Consult Instructions For Use

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