OSTEOREMEDIES®
ADVANCED MEDICAL TECHNOLOGIES

SURGEON INFORMATION

REMEDY® RADEL® SHOULDER SPACER TRIAL

The REMEDY® Radel® Shoulder Spacer Trial

is a PPSU device composed of two independent articulating components (REMEDY® Radel® Head Trial and the REMEDY® Radel® Stem Trial) that must be combined with each other according to the anatomy of the patient. A REMEDY® Radel® Head and REMEDY® Radel® Stem components are available in three sizes each.

Each REMEDY® Radel® Head Trial component is matchable with each REMEDY® Radel® Stem Trial component. This provides a REMEDY® Radel® Shoulder Spacer Trial for the selection of the correct size and offset of the REMEDY® Shoulder Spacer to be implanted.

Step 1: Choose the REMEDY® Radel® Head and the REMEDY® Radel® Stem Trial components of the right size according to the dimension of the removed prosthesis.

Step 2: Connect the REMEDY® Radel® Head and the REMEDY® Radel® Stem Trial components by screwing the REMEDY® Radel® Head onto the threaded end of the REMEDY® Radel® Stem Trial component completely (until reaching the end of the thread).

Step 3: Test the device in the patient and make anatomical and stability evaluation. By unscrewing the REMEDY® Radel® Head Trial component the required offset may be obtained.

Note: The Head component has to be screwed until completely covering the groove in the threaded junction of the Stem component. This same minimum level is indicated in the corresponding implantable device.

Step 4: Once the device has been positively tested and verified, remove it from the patient, and use it as a reference to prepare the REMEDY® Shoulder Spacer device which will be implanted.

Step 5: After use, the device must be cleaned.

CLEANING & STERILIZATION

REMEDY® Radel® Shoulder Spacer Trial components are nonsterile.

Before 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® Radel® Shoulder Spacer Trial must be used only to determine the right size of the REMEDY® Shoulder Spacer to be implanted. The Trial device or the single component Trial must not to 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, pivots, racks, spring or torsional operation, cleanliness of holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete. Do not use if the device 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.

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® Radel® Humeral Head Trial 40mm	RRTSHDSM
REMEDY® Radel® Humeral Head Trial 45mm	RRTSHDMD
REMEDY® Radel® Humeral Head Trial 50mm	RRTSHDLG
REMEDY® Radel® Humeral Stem Trial Small	RRTSSTSM
REMEDY® Radel® Humeral Stem Trial Medium	RRTSSTMD
REMEDY® Radel® Humeral Stem Trial Large	RRTSSTLG
REMEDY® Radel® Shoulder Spacer Trial (Kit)	RRKITSH

Symbols:

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

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