OSTEOREMEDIES®
ADVANCED MEDICAL TECHNOLOGIES

SURGEON INFORMATION

REMEDY® RADEL® HIP SPACER TRIAL

The REMEDY® Radel® Hip Spacer Trial is a PPSU device composed of two independent articulating components (REMEDY® Radel® Head Trial and REMEDY® Radel® Stem Trial) that must be combined to fit the anatomy of the patient. The REMEDY® Radel® Head Trial is available in three sizes; the REMEDY® Radel® Stem Trials are available in short length (REMEDY® Radel® Stem Trial, in three sizes) and long length (REMEDY® Radel® Long Stem Trial, in three sizes).

Each REMEDY® Radel® Head Trial is matchable to each REMEDY® Radel® Stem Trial and enables the surgeon to select the appropriately sized REMEDY® Hip Spacer or the REMEDY SPECTRUM™ GV Hip Spacer to be implanted.

Step 1: Choose the REMEDY® Radel® Head Trial and REMEDY® Radel® Stem Trial based on the dimension of the removed prosthesis.

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

Step 3: Test the device in the patient to determine if the prosthesis is anatomically correct and stable. By unscrewing the REMEDY® Radel® Head Trial the required offset may be obtained.

Note: The head component must be screwed down to completely cover the minimum level indicated by the groove in the threaded junction of the stem component. This same minimum level is indicated also in the corresponding implantable device.

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

CLEANING & STERILIZATION

REMEDY® Radel® Hip Spacer Trial components are nonsterile.

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

The REMEDY® Radel® Hip Spacer Trial components must be cleaned by the means of most commonly used disinfectants (e.g. bleach solutions, isopropyl alcohol, hydrogen peroxide, phenols) and detergents. It is recommended to avoid the contact of the material with chemicals as esters, aromatic hydrocarbons, chlorinated hydrocarbons and ketones.

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® Hip Spacer Trial must be used only to determine the anatomically correct size of the REMEDY® Hip Spacer or the REMEDY SPECTRUM™ GV Hip Spacer to be implanted. The trial device or the single component trial must not be implanted. 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.

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® Head Trial 46mm	RRTHDSM
REMEDY® Radel® Head Trial 54mm	RRTHDMD
REMEDY® Radel® Head Trial 60mm	RRTHDLG
REMEDY® Radel® Stem Trial small	RRTSTSM
REMEDY® Radel® Stem Trial medium	RRTSTMD
REMEDY® Radel® Stem Trial large	RRTSTLG
REMEDY® Radel® Long Stem Trial small	RRTLSSM
REMEDY® Radel® Long Stem Trial medium	RRTLSMD
REMEDY® Radel® Long Stem Trial large	RRTLSLG
REMEDY® Radel® Hip Spacer Trial (KIT)	RRKITHP

Symbols:

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

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