OSTEOREMEDIES®
ADVANCED MEDICAL TECHNOLOGIES

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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.

CLEANING & STERILIZATION

REMEDY® Radel® Shoulder Spacer Trial components are nonsterile.

Before use the device must be cleaned and sterilized.

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

RECOMMENDED STERILIZATION CYCLE:

TEMPERATURE	PRESSURE	MINIMUM TIME
121° C	1 atm	15 Min
134° C	2 atm	4 Min

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. 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: