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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 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 black laser mark 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 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 Trials 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.

RECOMMENDED STERILIZATION CYCLE:

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

WARNING: The REMEDY® Radel® Hip Spacer Trial must be used only to determine the anatomically correct size of the REMEDY® 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	RRTLSDM
REMEDY® Radel® Long Stem Trial large	RRTLSLG
REMEDY® Radel® Hip Spacer Trial (KIT)	RRKITHP

Symbols:

NONSTERILE

Nonsterile

REF

Catalog
Number

LOT

Batch
Number



Caution



Consult Instruction
For Use