

REMEDY® RADEL® KNEE & REMEDY® STEMMED KNEE SPACER TRIALS

The **REMEDY® Radel® Knee Spacer Trial** are RADEL® PPSU devices composed of two independent articulating components (REMEDY® Radel® Femoral Trials, available in four sizes, and the REMEDY® Radel® Tibial Trial, available in three sizes) that must be combined to fit the anatomy of the patient. The **REMEDY® Stemmed Knee Spacer Trial** are RADEL® PPSU devices composed of two independent articulating components (REMEDY® Stemmed Femoral Trials, available in four sizes, and the REMEDY® Stemmed Tibial Trials, available in three sizes, or the REMEDY® Poly+Plus™ Tibial Trials, available in three sizes and two thickness) that must be combined to fit the anatomy of the patient. A REMEDY® Radel® Tibial Insert Wedge Trial is also available and comes in 3 different sizes. A REMEDY® Stem Extension Trial, matchable with the Remedy® Stemmed Knee Spacer Trial, is also available and comes in four sizes.

Each REMEDY® Radel® Femoral Trial is matchable to each REMEDY® Radel® Tibial Trial, while each REMEDY® Radel® Tibial Insert Wedge Trial is matchable with its corresponding size of the REMEDY® Radel® Tibial Trial.

Each REMEDY® Stemmed Femoral Trial is matchable to each REMEDY® Stemmed Tibial Trial or REMEDY® Poly+Plus™ Tibial Trial, while each REMEDY® Radel® Tibial Insert Wedge Trial is matchable with its corresponding size of the REMEDY® Stemmed Tibial Trial or REMEDY® Poly+Plus™ Tibial Trial. The Remedy® Stem Extension Trial is optional, and any size may be used with any size of the Remedy® Stemmed Femoral and Tibial Trial.

The correct combination of the REMEDY® Radel® Knee Spacer Trial or REMEDY® Stemmed Knee Spacer Trial enables the surgeon to select the appropriately sized REMEDY® Knee Spacer or REMEDY® Stemmed Knee Spacer to be implanted.

Step 1: Choose the appropriate femoral and tibial trial based on the dimension of the removed prosthesis. In case of a large tibial defect, include a REMEDY® Radel® Tibial Insert Wedge Trial. If a stem extension is necessary, select between the available lengths and place the stem through the opening of the femoral and/or tibial stemmed trial components to ensure the stem is able to be fully seated.

Step 2: Test the trials in the patient to determine if the prosthesis is anatomically correct and stable. Note: If trialing with the REMEDY® Stemmed Knee, ensure that the appropriate size stem trials can be fully seated within the canal.

Step 3: Once the trials have been tested and verified, remove it from the patient, and use them as a reference to prepare the REMEDY® Knee Spacer or REMEDY® Stemmed Knee Spacer implants which will be implanted.

Step 4: After use, the device must be cleaned.

CLEANING & STERILIZATION

All trials are provided nonsterile.

Before each use the trials 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 trials (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 trials 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 trials in cleaning solution and sonicate for 10 minutes, preferably at 40+/-6% 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: Strict surgical aseptic technique must be observed. The REMEDY® Radel® Knee Spacer Trial and the REMEDY® Stemmed Knee Spacer Trial must be used only to determine the anatomically correct size of the REMEDY® Knee Spacer or the REMEDY® Stemmed Knee Spacer to be implanted. The trials 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, 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 the trial if it appears damaged (deformation, loss of the information marked on the trial, etc.). The trial needs to be replaced if it appears damaged after a visual inspection.

DISPOSAL: When the device has to be disposed of 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. Store in cool and dry environments.

DESCRIPTION	REF CODE
REMEDY® RADEL® Tibial Trial Small	RRTTBSM
REMEDY® RADEL® Tibial Trial Medium	RRTTBMD
REMEDY® RADEL® Tibial Trial Large	RRTTBLG
REMEDY® RADEL® Femoral Trial Small	RRTFMSM
REMEDY® RADEL® Femoral Trial Medium	RRTFMMD
REMEDY® RADEL® Femoral Trial Large	RRTFMLG
REMEDY® RADEL® Femoral Trial X-Large	RRTFMXL
REMEDY® RADEL® Tibial Insert Wedge Trial Small	RRTINSM
REMEDY® RADEL® Tibial Insert Wedge Trial Medium	RRTINMD
REMEDY® RADEL® Tibial Insert Wedge Trial Large	RRTINLG
REMEDY® Radel® Knee Spacer Trial (KIT)	RKITKN
REMEDY® Stemmed Femoral Trial Small	RTSKFSM
REMEDY® Stemmed Femoral Trial Medium	RTSKFMD
REMEDY® Stemmed Femoral Trial Large	RTSKFLG
REMEDY® Stemmed Femoral Trial Extra Large	RTSKFXL
REMEDY® Stemmed Tibial Trial Small	RTSKTSM
REMEDY® Stemmed Tibial Trial Medium	RTSKTMD
REMEDY® Stemmed Tibial Trial Large	RTSKTLG
REMEDY® Stem Extension Trial 100 - 12/8 OD	RTS100
REMEDY® Stem Extension Trial 150 - 13/11 OD	RTS150
REMEDY® Stem Extension Trial 175 - 12/8 OD	RTS175
REMEDY® Stem Extension Trial 230 - 13/11 OD	RTS230
REMEDY® Stemmed Knee Tray Kit w/ Trials	RKITSK
REMEDY® Stemmed Knee - Adj. Kit w/ Trials	RKITSKAD
REMEDY® POLY+PLUS™ Tibial Trial SM 13 mm	RTPTSM13
REMEDY® POLY+PLUS™ Tibial Trial SM 17 mm	RTPTSM17
REMEDY® POLY+PLUS™ Tibial Trial MD 13 mm	RTPTMD13
REMEDY® POLY+PLUS™ Tibial Trial MD 17 mm	RTPTMD17
REMEDY® POLY+PLUS™ Tibial Trial LG 13 mm	RTPTLG13
REMEDY® POLY+PLUS™ Tibial Trial LG 17 mm	RTPTLG17
REMEDY® POLY+PLUS™ Tibia Kit w Trials	RKITPT

Symbols:

NONSTERILE

Nonsterile

REF

**Catalog
Number**

LOT

**Batch
Number**



Caution



**Consult Instruction
For Use**



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