

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

The REMEDY[®] Radel[®] Knee Spacer Trial and the REMEDY[®] Stemmed Knee Spacer Trial are RADEL[®] PPSU devices composed of two independent articulating components (REMEDY[®] Radel[®] Femoral Trials or REMEDY[®] Stemmed Femoral Trials, available in four sizes and the REMEDY[®] Radel[®] Tibial Trial or REMEDY[®] Stemmed Tibial Trials, available in three sizes) 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 femoral and tibial components is also available and comes in two 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, while each REMEDY[®] Radel[®] Tibial Insert Wedge Trial is matchable with its corresponding size of the REMEDY[®] Stemmed 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.

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. 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 | RRTFMMSM |
| REMEDY® RADEL® Femoral Trial Medium | RRTFMMD |
| REMEDY® RADEL® Femoral Trial Large | RRTFMFLG |
| 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) | RRKITKN |
| REMEDY® Stemmed Femoral Trial Small | RTSKFMSM |
| REMEDY® Stemmed Femoral Trial Medium | RTSKFMMD |
| REMEDY® Stemmed Femoral Trial Large | RTSKFFLG |
| 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 | RTS100 |
| REMEDY® Stem Extension Trial 175 | RTS175 |

Symbols:

NONSTERILE

Nonsterile

REF

Catalog
Number

LOT

Batch
Number



Caution



Consult Instruction
For Use



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