REX cement stop™ System

Expand your Options

zimmer
Personal Fit. Renewed Life.™

REX cement stop

A Unique Technology for Success

The use of cement restrictors have been shown to increase cement penetration into the trabecular bone, by allowing for cement pressurization. A number of bone cement restrictors are today available on the market. Traditionally, these cement restrictors come in a variety of press fit solutions, and today we see a presence of both resorbable and non-resorbable options.

The *REX cement stop* Implant differentiates from other existing cement plugs in that it is expanded inside the intramedullary canal; thereby adapting to irregularities of the canal, while at the same time allowing for controlled insertion.

With the insertion tool, the *REX cement stop* Implant is placed at the desired depth, where it is then expanded to fully occlude the intramedullary canal. Since the *REX cement stop* Implant is inserted at a smaller diameter than the canal, this can allow for placement below the isthmus* if desired in for example revision cases.

Key Features of the REX cement stop System

- Highly biocompatible
- Biodegradable within two weeks[1] (gelatin bushing)
- PMMA part bonds to the PMMA bone cement mantle, assuring easy removal in case of a revision
- Provides occlusion of the femoral canal – *REX cement stop* Implant expands and adapts to irregular shapes of the intramedullary canal
- Controlled insertion of the *REX cement stop* implant into the femoral canal – *REX Cement Stop* can be placed at desired depth, even below the isthmus[2]
- Reduced risk of fat embolism associated with the displacement of fat and bone marrow during plug insertion[3]
- Over seven years in-vivo and in-vitro experience
- Provides resistance to high pressures – during bone cement pressurization, cement restrictors are subjected to pressures up to 10 bar or more[4]
- Clinically shown to yield no leakage[2,4] and minimal migration[4]

* Provided that the canal diameter below the isthmus is within the expansion range for the chosen size of *REX cement stop* Implant.

Design Rationale

A Unique Solution for Existing Issues

The *REX cement stop* System not only meets the necessary demand for a successful cement restrictor, but also solves the limitations of existing bone cement restrictors on the market today as reported in literature[2,3].

The *REX cement stop* System can effectively seal the intramedullary canal prior to the introduction of bone cement during hip surgery. As it expands, the *REX cement stop* Implant adapts to irregularities within the intramedullary canal.

The *REX cement stop* Implant comprises a gelatin bushing centered around a PMMA locking device and a serrated center pin. The gelatin bushing expands under axial compression exerted by the insertion instrument after insertion in the intramedullary canal. By rotating the knob at the back of the insertion instrument handle, the washer and locking ring are pushed over the teeth of the serrated pin. The serrated pin is pulled into the tube of the insertion instrument, and the flexible bushing is compressed between the washers and expanded sideways.

The top of the *REX cement stop* Implant has a built-in safety mechanism to prevent the pressure on surrounding bone from becoming too high. As the plug is expanded, the pressure on the intramedullary canal walls will rise as will the resistance felt in the knob of the insertion tool. Once sufficient pressure has been built, indicating that the plug is securely seated against the intramedullary wall, the coupling head of the cement stop will snap off within the insertion tool. This will stop the further expansion of the cement stop. The coupling head will remain inside the insertion instrument until intentionally removed, away from the wound site.

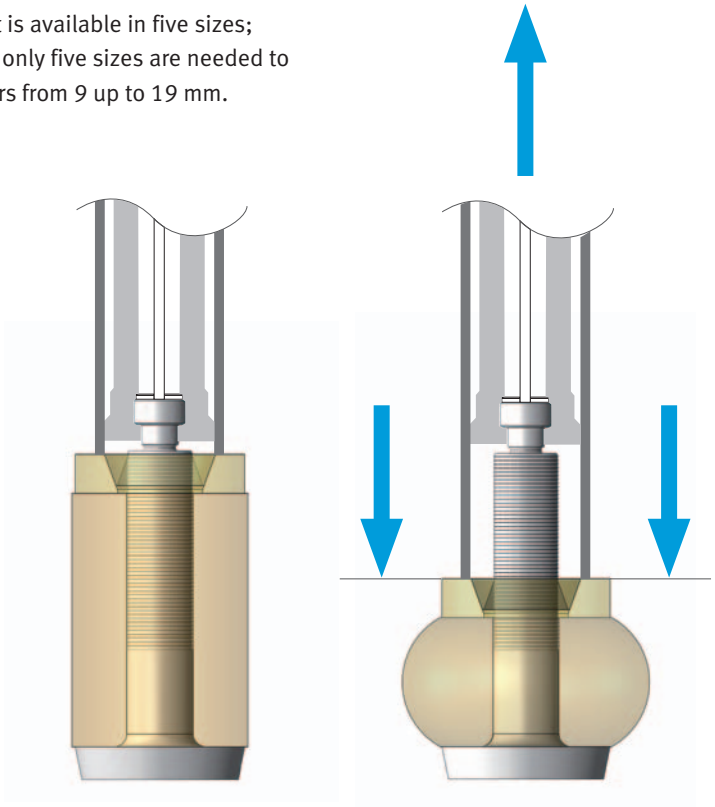
The *REX cement stop* Implant consists of two materials commonly used in implants: gelatin and PMMA. The gelatin bushing consists of: gelatin, glycerol and water for injections, which fully resorb within two weeks.[1] The serrated pin, washer and locking ring are made of transparent Polymethylmethacrylate (PMMA). The PMMA will chemically bond with the PMMA cement mantle, assuring easy removal in the case of a revision. Both the PMMA and the gelatin bushing used in the *REX cement stop* Implant are biocompatible, non-pyrogenetic and non-toxic.

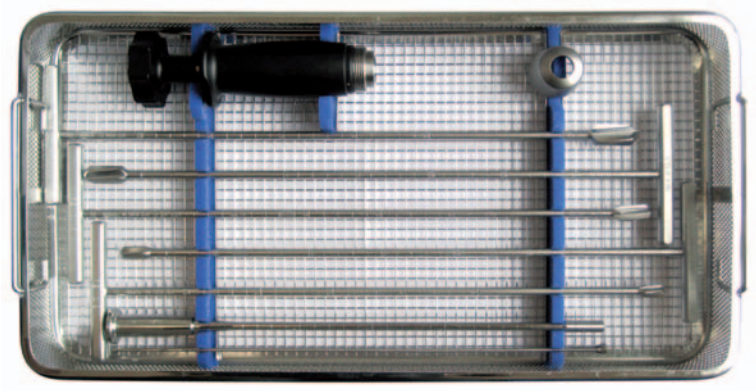
Instrumentation

Design does not stop with the Product

The *REX cement stop* Instrument is designed for inserting and fixating the *REX cement stop* Implant into the femoral intramedullary canal at its desired position.

The *REX cement stop* Implant is available in five sizes; because of its expandability only five sizes are needed to cover femoral canal diameters from 9 up to 19 mm.





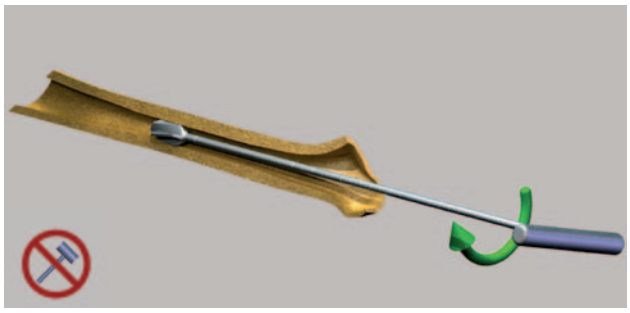
REX cement stop Instrument

Size	Expansion Range
∅ 9.0	∅ 09.0–10.0mm
∅ 10.0	∅ 10.0–11.5mm
∅ 11.5	∅ 11.5–13.5mm
∅ 13.5	∅ 13.5–16.0mm
∅ 16.0	∅ 16.0–19.0mm

Instructions for use

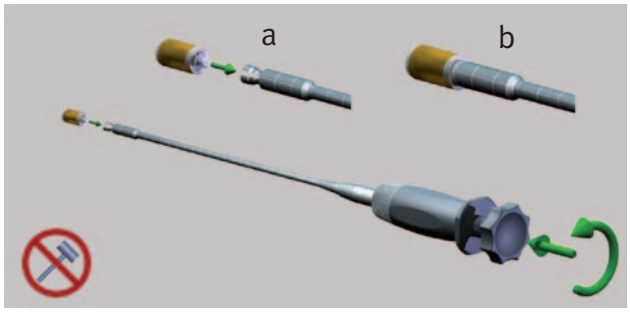
Step 1

Ream the femoral canal to the desired diameter and depth with a distinct turning motion of the reamer, therewith removing any trabecular bone protruding into the femoral canal. Such protruding trabeculae would cause incorrect measurement of the femoral canal, compromising the correct working of the *REX cement stop* System.
Choose the *REX cement stop* Implant size based on the largest reamer size used.



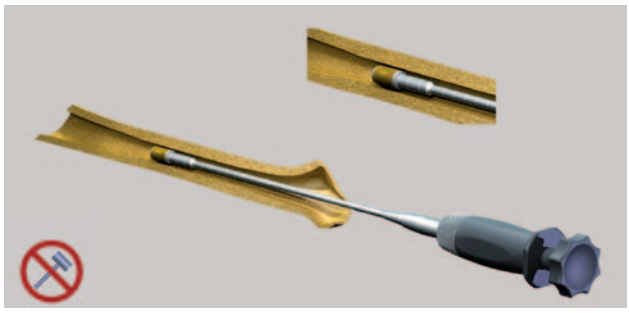
Step 2

Rotate the knob on the *REX cement stop* Instrument hand piece counter clockwise until resistance is met. Then rotate the knob further counter clockwise until the gripper on the inner rod is opened and keep this position. Place the *REX cement stop* Implant into the insertion instrument (a) and release the knob (b).



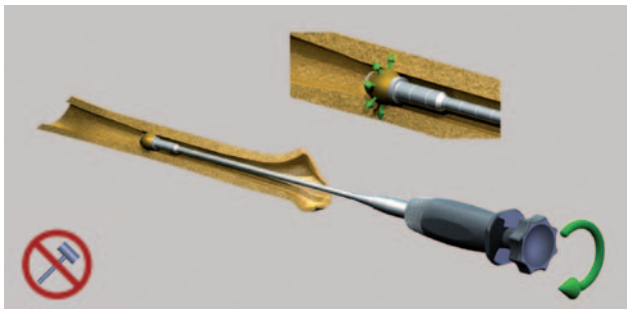
Step 3

Insert the instrument with the *REX cement stop* Implant into the femur to the desired depth using the markings on the tube. Insertion of the *REX cement stop* System **must** proceed smoothly.



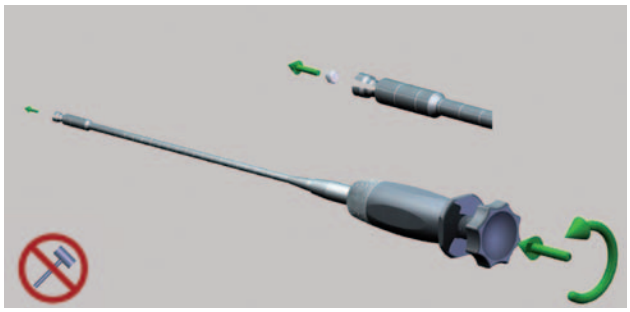
Step 4

At the desired depth expand the *REX cement stop* Implant by rotating the knob clockwise until the coupling head snaps off. The coupling head stays inside the instrument and the insertion instrument can be withdrawn, leaving the *REX cement stop* Implant in situ.

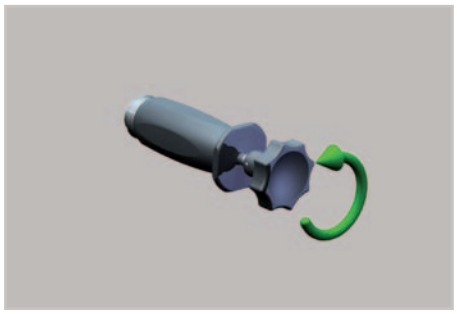


Step 5

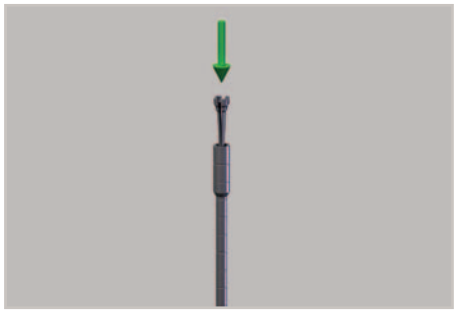
Remove the instrument from the intramedullary canal. Away from the wound site, rotate the knob counter clockwise until the coupling head of the *REX cement stop* Implant can be removed. Disassemble the instrument according to the disassembly instructions for cleaning and sterilization.



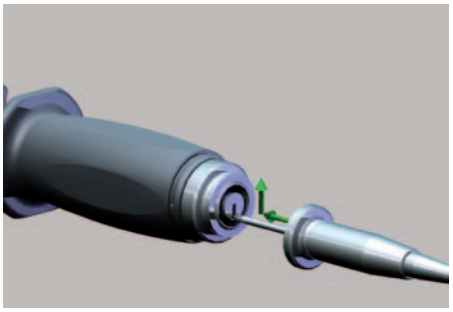
Assembly



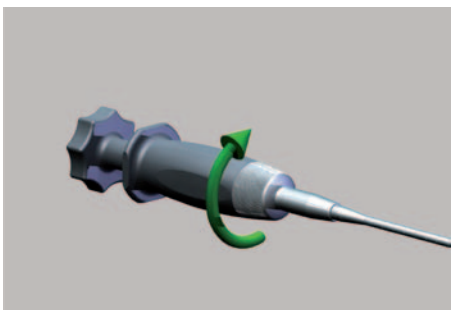
Step A
Rotate the knob of the *REX cement stop* Instrument handpiece in the direction “Release” until resistance is met.



Step B
Drop the inner rod completely into the outer tube.

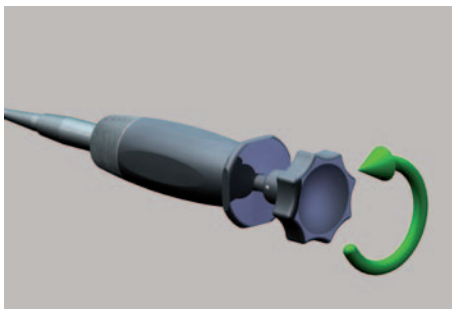


Step C
Slide the head of the inner rod into the groove of the handpiece.

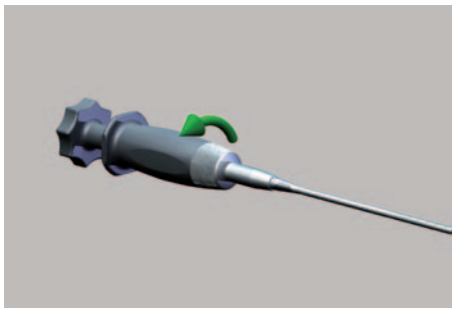


Step D
Screw the screw nut in place.

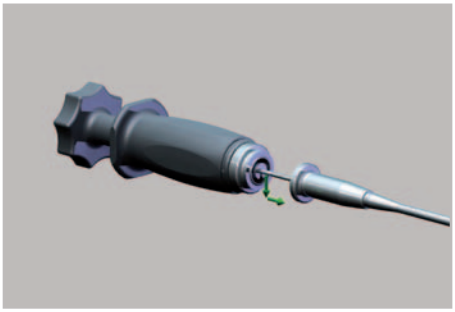
Disassembly



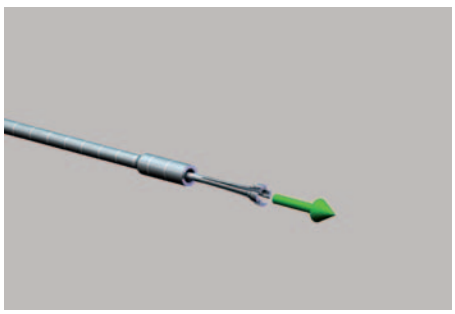
Step A
Rotate the knob of the *REX cement stop* Instrument handpiece in the direction “Release” until resistance is met.



Step B
Remove the screw nut.



Step C
Slide the head of thev inner rod out of the groove of the handpiece.



Step D
Remove the inner rod from the outer tube.

Ordering Information

REX cement stop Implants* (Sterile)

Quantity	∅ mm	REF
1/Ea	9.0	REX-0709-9
1/Ea	10.0	REX-0709-10
1/Ea	11.5	REX-0709-11.5
1/Ea	13.5	REX-0709-13.5
1/Ea	16.0	REX-0709-16

REX cement stop Instruments

Quantity	Article	REF
1/Ea	REX Sterilization Tray	REX-0802-02
1/Ea	REX Handpiece	REX-0601-03-A
1/Ea	REX Screw nut	REX-0601-03-B
1/Ea	REX Inner rod	REX-0601-03-C
1/Ea	REX Outer tube	REX-0601-03-D
1/Ea	Reamer ∅ 9.0 mm	REX-0208-08
1/Ea	Reamer ∅ 10.0 mm	REX-0208-09
1/Ea	Reamer ∅ 11.5 mm	REX-0208-10
1/Ea	Reamer ∅ 13.5 mm	REX-0208-11
1/Ea	Reamer ∅ 16.0 mm	REX-0208-12

References

1 Data on file (Spierings Ortopaedics B.V.)

2 Moran, M.; Heisel, C.; Rupp, R.; Simpson, A.H.R.W.; Breusch, S.J.: Cement Restrictor Function Below the Femoral Isthmus. Clinical Orthopaedics and Related Research, 2007;458:111-116

3 Breusch, S.J.; Heisel, C.: Insertion of an expandable cement restrictor reduces intramedullary fat displacement. The Journal of Arthroplasty, 2004;19(6):739-744

4 Heisel, C.; Norman, T.; Rupp, R.; Pritsch, M.; Ewerbeck, V.; Breusch, S.J.: In vitro performance of interamedullary cement restrictors in total hip arthroplasty. Journal of Biomechanics, 2003;36:835-843

Disclaimer

This documentation is intended exclusively for physicians and is not intended for laypersons.
Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

Contact your Zimmer representative or visit us at www.zimmer.com

zimmer
Personal Fit. Renewed Life.™

SPIERINGS
ORTHOPAEDICS

Spierings Medische Techniek B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands

Lit. No. 06.02240.012 – Ed. 2011-09 ZHUB
+H84406022400121/$110901I11V