

stryker®

Exeter® X3® RimFit™

Acetabular Cup Surgical Protocol



Exeter X3 RimFit

Surgical Protocol

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Indications for Exeter X3 RimFit Acetabular Cup

The indications for use for total hip arthroplasty include:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.
- The Exeter X3 RimFit Acetabular cup is intended for Cemented use only.

Contraindications for Exeter X3 RimFit Acetabular Cup

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Warnings and Precautions

See implant package insert for warnings, precautions, adverse effects and other essential product information.

Before using instrumentation, verify:

- Instruments have been properly disassembled prior to cleaning and sterilisation
- Instruments have been properly assembled post sterilization
- Instruments have maintained design integrity
- Proper size configuration is available

This publication sets forth detailed recommended procedures for using Stryker Orthopaedics devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Introduction

This surgical protocol is a guide to preparing the acetabulum for the Exeter X3 RimFit cup utilizing Exeter Contemporary instrumentation. There is the option for the surgeon to use the Rim Cutter instrument, as discussed in the protocol.

The Exeter X3 RimFit cup is a highly cross-linked polyethylene cemented cup with 4 PMMA cement spacers and a mini flange design, with X-ray wire to help easily identify the cup position on an X-ray. Exeter X3 RimFit cups are available with an ID 22.2-40mm and an OD 40-60mm.

For sizing purposes the final Exeter X3 RimFit cup used is to be 2mm smaller than the final reamer. Thus, if the largest reamer used is 56mm, then the cup used should be 54mm. If use of the Rim Cutter is chosen, the Rim Cutter size selection is to be identical to the planned implant size, and thus for the above example a size 54 Rim Cutter would be used.

The chart below shows the sizes and the polyethylene thickness for the Exeter X3 RimFit cup. All Exeter X3 RimFit cups are neutral. All cup sizes (OD) include the cement spacers.

Catalogue N°	ID (mm)	OD* (mm)	Cement Spacer Size (mm)	Nominal Polyethylene Thickness** (mm)
6309-2-240	22.2	40	2	6.8
6309-2-242	22.2	42	2	7.8
6309-2-244	22.2	44	2	8.8
6309-2-844	28	44	2	5.9
6309-2-846	28	46	2	6.9
6309-2-848	28	48	3	6.9
6309-2-850	28	50	3	7.9
6309-2-852	28	52	3	8.9
6309-2-854	28	54	3	9.9
6309-2-856	28	56	3	10.9
6309-2-858	28	58	3	11.9
6309-2-860	28	60	3	12.9
6309-3-248	32	48	2	5.9
6309-3-250	32	50	2	6.9
6309-3-252	32	52	3	6.9
6309-3-254	32	54	3	7.9
6309-3-256	32	56	3	8.9
6309-3-258	32	58	3	9.9
6309-3-260	32	60	3	10.9
6309-3-652	36	52	2	5.9
6309-3-654	36	54	2	6.9
6309-3-656	36	56	3	6.9
6309-3-658	36	58	3	7.9
6309-3-660	36	60	3	8.9
6309-4-056	40	56	2	5.9
6309-4-058	40	58	2	6.9
6309-4-060	40	60	3	6.9



* OD = Diameter at the top of the cement spacers

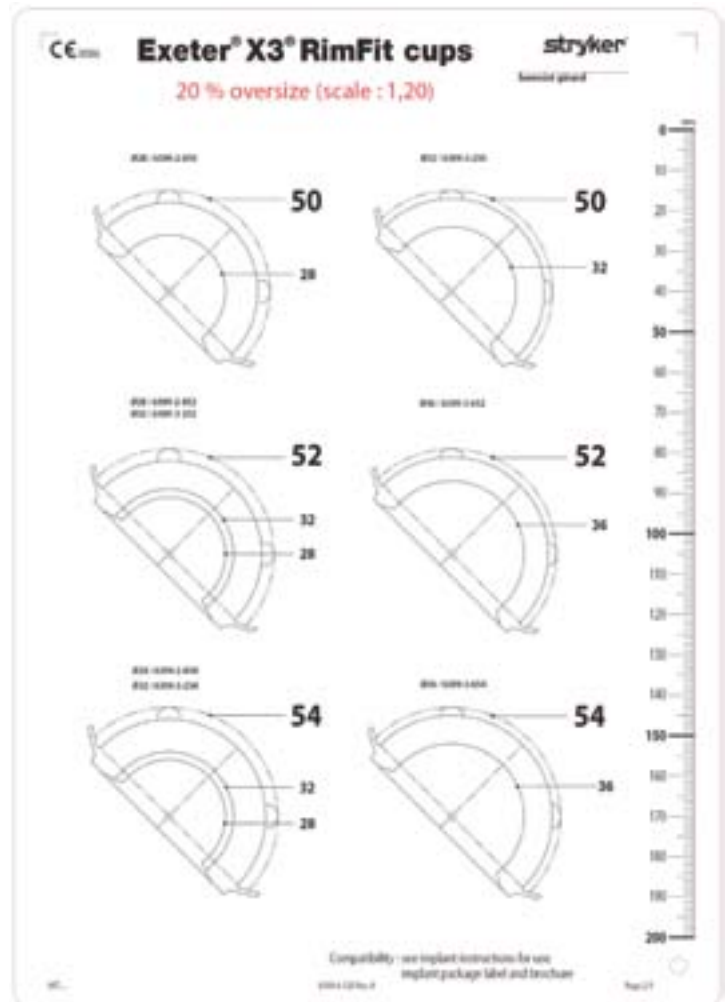
** Thickness between dome diameter and inner diameter

Surgical Protocol Pre-Operative Planning

Step 1: Pre-Operative Planning and X-ray Evaluation

Preoperative planning and X-ray evaluation aids in the selection of the most favorable implant style and optimal size for the patient's anatomy and hip pathology. Selecting potential implant styles and sizes can facilitate operating room preparation and assure availability of an appropriate size selection. X-ray evaluation may also help detect anatomic anomalies that could prevent the intraoperative achievement of the established preoperative goals.

Check all instruments and implants for any damage or defects before beginning the procedure.



Step 2: Acetabular Preparation

The acetabulum is prepared by the release and removal of soft tissue using the surgeon's preferred technique to gain adequate exposure for reaming. Excision of the labrum and osteophytes allows for proper visualization of the bony anatomy, and improves ease of reaming (Fig. 1).

Note: Careful identification and removal of osteophytes can help reduce the possibility of bone-to-bone or component-to-bone impingement.

With the acetabulum exposed, bony defects can be identified. If necessary, bone grafting options may be considered prior to reaming.



Fig. 1

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“For potentially improved exposure, a knife can be introduced between the labrum and capsule to release the reflected head of rectus femoris and the iliofemoral ligament from the wing of the ilium” (Fig. 2)



Fig. 2

Step 3: Socket Preparation

A. Spherical Reaming

To obtain optimal component positioning in the reaming process the reamer handle should be at 45 degrees of abduction and 25 degrees of anteversion (Fig. 3).

It is recommended that the initial reaming begin with a Reamer that is 4mm smaller than the templated or gauged size. Continue to ream up in 2mm increments (Fig. 4).



Fig. 3

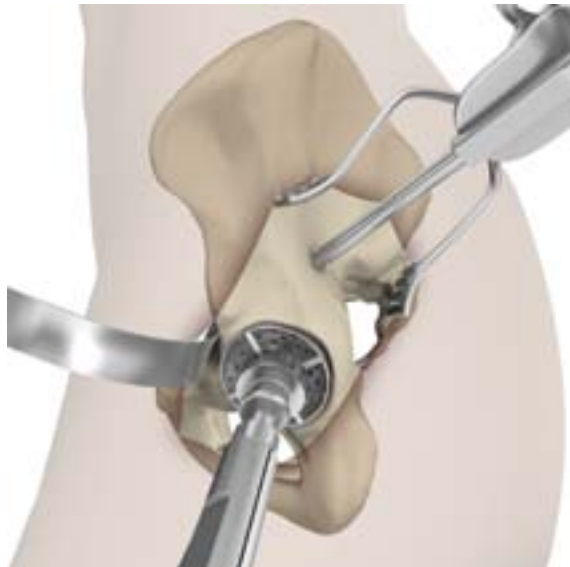


Fig. 4

B. Final Reaming

The full profile of the Stryker Spherical Reamer necessitates reaming to the full depth.

Care should be taken so as not to enlarge or distort the acetabulum by eccentric reaming. Final acetabular reaming ideally shows the hemispherical acetabulum denuded of cartilage, with the subchondral plate preferably intact. Where the subchondral bone is breached, cancellous bone will be exposed, which is an ideal surface for cement application. Holes will later be drilled into preserved subchondral bone for cement interdigitation.

Particular attention is paid to clear the rim of the acetabulum of cartilage and soft tissue and subchondral bone where possible, since it is important to achieve interdigitation of cement with bone in this area.

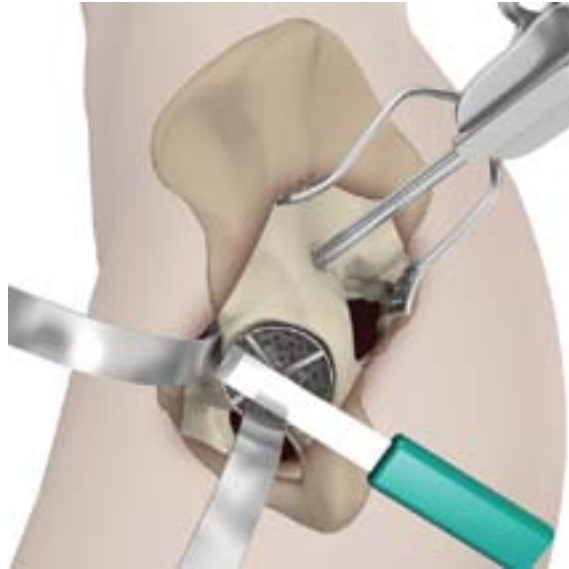


Fig. 5

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“After final reaming, it is useful to leave the final reamer in the socket in the correct orientation. The edge acts as a guide for the removal of excess osteophytes with an osteotome” (Fig. 5)

Step 4: Use of Rim Cutter

A. Optional Use of Rim Cutter Instrument

The Rim Cutter (an instrument, for cup sizes O.D. 44-60, which cuts a rim into the acetabulum and is not intended to cut the rim of the implant) marked with the same size as the cup OD to be inserted is attached to the power reamer. The Rim Cutter is designed to cut a groove in the periphery of the acetabulum of the appropriate diameter for the flange.

Do not use Rim Cutter if there is inadequate bone stock. The hemisphere on the Rim Cutter centralises the cutter in the reamed socket and sets the depth of the rim and thus the position of the cup. Each Rim Cutter has to be used with its correct hemispherical guide. If the acetabulum is reamed to 56mm, use Rim Cutter size 54 with 54 green hemispherical guide. The orientation of the Rim Cutter is shown by the alignment rod on the device to obtain optimal component positioning (Fig 6).

The cup should be orientated in a position of 45 degrees abduction (the handle of the Charnley-style introducer will point vertically upwards) and 25 degrees flexion (the handle in the longitudinal axis of the patient is rotated around the transverse axis of the patient by 25 degrees).

The Rim Cutter is advanced to the fullest extent allowed by exerting pressure against the spring between the dome and cutting ring (Fig. 7). Any debris created, including the innermost fibers of the transverse ligament, are removed.

Trial positioning is carried out to ensure that the cup can be introduced without difficulty through the soft tissues into the correct position, with flange resting on the rim. If the rim of the acetabulum has been cut in an incorrect position then the flange of the cup can be cut up to the line so it will sit within the Rim Cutter shelf.



Fig. 6

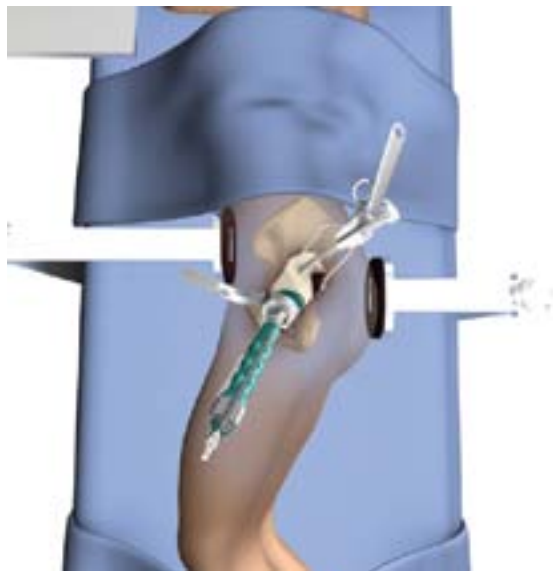


Fig. 7

Note: For the cups O.D. 40 & 42, the associated rim cutter is not available yet. This option will be offered at a later date.

B. Trialing

Following the reaming procedure, the appropriate cup trial of the same diameter as the final implant size is inserted into the reamed cavity. The trial is used to assess fit, contact, and congruency of the trial with the acetabulum.

After choosing the appropriate size acetabular component, the cup is mounted on the cup introducer. If necessary, the flange is trimmed appropriately so that the rim of the flange lies just within the mouth of the acetabulum. Specific trimming scissors are available to cut out the flange. The flange has a line marked. This line corresponds to the diameter of the cup at the top of the cement spacers and surgeons may cut up to this line if necessary (Fig. 8). A further rehearsal is made to ensure that the cup can be introduced through the soft tissues into the desired position without difficulty. If the flange is overtrimmed, discard and use a new cup.

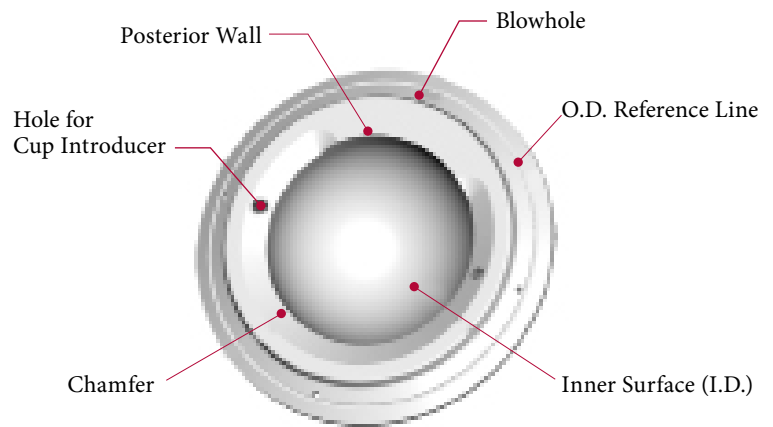


Fig. 8



Step 5: Cement Fixation Bone Preparation

After completion of reaming, multiple fixation holes should be made in the subchondral plate using the acetabular step drill. Smaller holes are made around the rim of the acetabulum using the distal end of the step drill (Fig. 9). Care should be taken not to perforate the inner table of the acetabulum. The wall is thinnest medially and anteriorly. If the cortex is breached, then bone graft should be used to fill the hole.

Thorough lavage of the socket is carried out to clean the interstices of the trabecular bone of bone debris, marrow and fat (Fig. 10). Fluid is sucked out of the wing of the ilium by the sucker aspirator (Fig. 11).

When the bone is clean, dry gauze swabs are packed into the acetabulum to further clean the bone and promote hemostasis.

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“At this stage bone graft reamings may be compacted onto the transverse ligament (to prevent cement egress through the acetabular notch) and against the smooth cortical medial wall since the cement cannot adequately gain fixation against this surface. The bone graft is covered by a folded small swab and compressed during lavage of the acetabulum to prevent it from being washed out of the acetabulum.”



Fig. 9

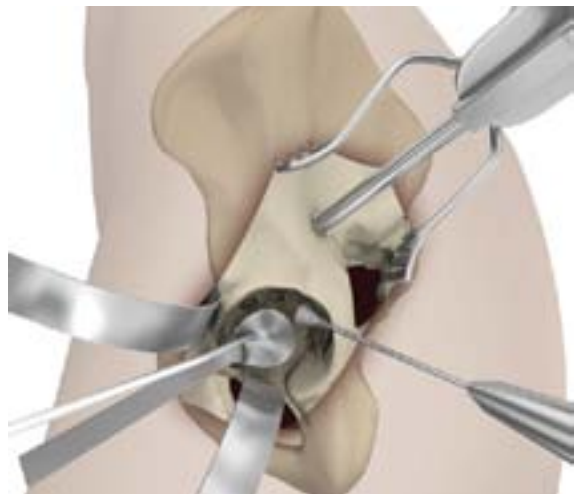


Fig. 10



Fig. 11

Step 6: Cement Introduction

Cement mixing is commenced during the final bony preparation of the acetabulum. The cement may be handled approximately 3.5 minutes after commencement of mixing (Simplex cement at 20 degrees centigrade). After introduction of the cement bolus, excess material is removed so the surface of the cement lies with a slightly concave surface within the mouth of the acetabulum. This step prevents escape of surplus cement into the soft tissues when the acetabular pressuriser is used.

Pressurisation of the cement is carried out using a disposable acetabular pressuriser on a handle (Fig. 12).

Three diameters are available so that an adequate seal can always be established at the socket rim. The pressurising technique entails applying significant force onto the device to drive the cement into the bone and, by maintaining pressure, protect the bone cement interface from back-bleeding from the host bone. The pressuriser is applied as soon as the cement has been placed in the acetabulum and full pressure is maintained until the cement viscosity has risen to a level suitable for cup insertion (Fig. 13), usually about 5 minutes after the commencement of mixing. In the elderly, or where a large surface area of open trabecular bone has been exposed, excess cement is pressurised into the acetabulum and a further bolus is required on top of the initial cement. This will become apparent when the pressuriser is removed. If more cement is to be used, then the existing cement should be clean and dry before it is applied.



Fig. 12



Fig. 13

Step 7: Cup Implantation

A. If the Rim Cutter has been used the orientation of the implant has already been established (Fig. 14). The flanged cup is inserted using the introducer (Fig. 15) and an axial pusher with head diameter corresponding to the cup ID to drive the cup to the stable seated position with the flange engaged in the cut rim. This exercise should require significant force and there should be a constant flow of cement around the edge of the cup. The introducer can now be removed and the axial pusher (with appropriate size head attached) should be applied. Constant pressure can be maintained until polymerization is complete (Fig. 16).

B. If the Rim Cutter has not been used then extra care should be taken to ensure the cup orientation is appropriately maintained and that the final position of the flange is at the pre-rehearsed position just within the mouth of the acetabulum. An axial cup pusher with head diameter corresponding to the cup ID is used to drive the cup into a stable seated position. Insertion is complete after the flange is flush with the acetabular rim and it becomes impossible to advance the cup further into the viscous cement (Fig. 16).

Note 1: The posterior wall of the cup has to be placed on the side of the cup introducer plate with the identification corresponding to the side of the operated hip.

Note 2: Cup has to be assembled on the appropriate size of lateral cup introducer:

- For cups I.D. 36/40mm, use cup introducer identified as I.D. 36/40
- For cups O.D. 40/42mm, use cup introducer identified as O.D. 40/42
- For all other cups, use the standard cup introducer.
- The posterior wall of the cup has to be placed on the side of the cup introducer plate with the identification corresponding to the side of the operated hip (« POST RIGHT » or « POST LEFT ») (Fig.17).



Fig. 14



Fig. 15



Fig. 16

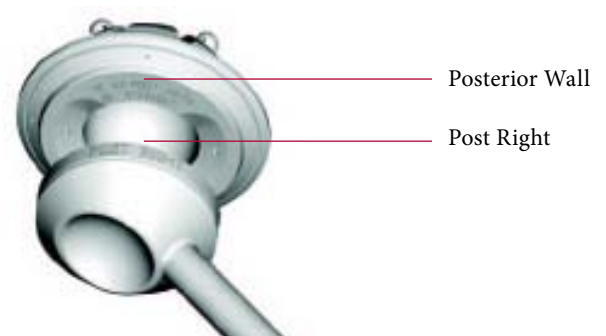


Fig. 17

Step 8: Final Step

Clear any excess cement with a small curette (Fig. 18).

The post-operative radiograph should show good cement penetration and no radiolucent lines in any zone. The X-ray wire will allow the surgeon to see the correct position of the cup (Fig. 19).

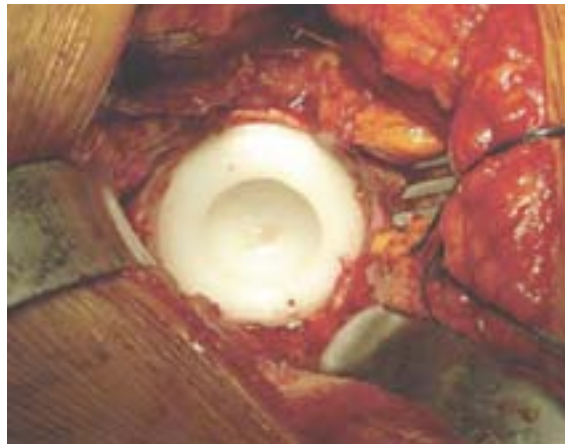


Fig. 18



Fig. 19

Instrument Listing

ID	OD	Exeter X3 RimFit Cups	Trial Cups
22.2	40*	6309-2-240	6304-7-240
	42*	6309-2-242	6304-7-242
	44*	6309-2-244	6304-7-244
28	44*	6309-2-844	6304-7-844
	46*	6309-2-846	6304-7-846
	48	6309-2-848	6304-7-848
	50	6309-2-850	6304-7-850
	52	6309-2-852	6304-7-852
	54	6309-2-854	6304-7-854
	56	6309-2-856	6304-7-856
	58	6309-2-858	6304-7-858
	60	6309-2-860	6304-7-860
32	48*	6309-3-248	6304-7-348
	50*	6309-3-250	6304-7-350
	52	6309-3-252	6304-7-352
	54	6309-3-254	6304-7-354
	56	6309-3-256	6304-7-356
	58	6309-3-258	6304-7-358
	60	6309-3-260	6304-7-360
36	52*	6309-3-652	6304-7-952
	54*	6309-3-654	6304-7-954
	56	6309-3-656	6304-7-956
	58	6309-3-658	6304-7-958
	60	6309-3-660	6304-7-960
40	56*	6309-4-056	6304-7-456
	58*	6309-4-058	6304-7-458
	60	6309-4-060	6304-7-460



*These cups have 2mm high cement spacers. All other cups have 3mm high cement spacers.

Surgical Templates (5 pack)	
Scale 1	6309-4-100
Scale 1.2	6309-4-120
Retractor Aspirator	6781-8-560
Contemporary Instrument Tray	6304-4-080
Contemporary Instrument Tray (2 level) (with acetabular reamer)	6304-4-090



Acetabular Step Drill Ø 9mm	6781-8-750
Trimming Scissors	6304-4-140
Lateral Cup Introducer For cup O.D. 40/42 For cup I.D. 36/40 For other cups	6304-4-022 6304-4-024 6304-4-060
Cup Pusher Straight	6304-4-110
Cup Pusher Curved	6304-4-120
Heads for Cup Pusher Ø 22.2mm Ø 28mm Ø 32mm Ø 36mm Ø 40mm	6304-4-122 6304-4-128 6304-4-132 6304-4-136 6304-4-240
Rim Cutter Tray	6309-5-400
Rim Cutter Handle	6309-5-100
Alignment Guide for Rim Cutter Handle	6309-5-300
Acetabular Rim Cutter + Guide Size 44 Size 46 Size 48 Size 50 Size 52 Size 54 Size 56 Size 58 Size 60	6309-5-244 6309-5-246 6309-5-248 6309-5-250 6309-5-252 6309-5-254 6309-5-256 6309-5-258 6309-5-260
Straight Handle (for acetabular cement pressurisation)	0935-0-001
Curved Handle (for acetabular cement pressurization)	0935-0-002
Acetabular Cement Seal (5 pack) Ø 54mm Ø 60mm Ø 66mm	0935-0-054 0935-0-060 0935-0-066



Implant Listing

ID	OD	Exeter X3 RimFit Cups
22.2	40*	6309-2-240
	42*	6309-2-242
	44*	6309-2-244
28	44*	6309-2-844
	46*	6309-2-846
	48	6309-2-848
	50	6309-2-850
	52	6309-2-852
	54	6309-2-854
	56	6309-2-856
	58	6309-2-858
	60	6309-2-860
32	48*	6309-3-248
	50*	6309-3-250
	52	6309-3-252
	54	6309-3-254
	56	6309-3-256
	58	6309-3-258
	60	6309-3-260
36	52*	6309-3-652
	54*	6309-3-654
	56	6309-3-656
	58	6309-3-658
	60	6309-3-660
40	56*	6309-4-056
	58*	6309-4-058
	60	6309-4-060

*These cups have 2mm high cement spacers. All other cups have 3mm high cement spacers.

References: US Patent 7,517,919

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