

stryker®

Orthopaedics

Exeter®

X3® RimFit® Acetabular Cup

Surgical Technique



Exeter X3 RimFit Acetabular Cup

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Indications

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, such as cementless fixation, as indicated by deficiencies of the acetabulum.

The Exeter X3 RimFit Acetabular cup is intended for Cemented use only.

Contraindications

- 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 cement mantle around 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 sterilization
- Instruments have been properly assembled post sterilization
- Instruments have maintained design integrity
- Proper size configuration is available

INTRODUCTION

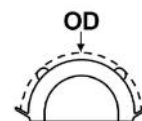
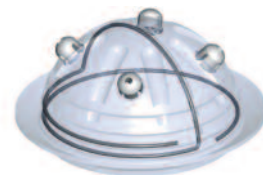
This surgical protocol is a guide to preparing the acetabulum for the Exeter X3 RimFit cup utilizing Exeter Contemporary instrumentation. There is the option for the surgeon to use the Rim Cutter instrument, as discussed in the protocol.

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.

Catalog Number	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

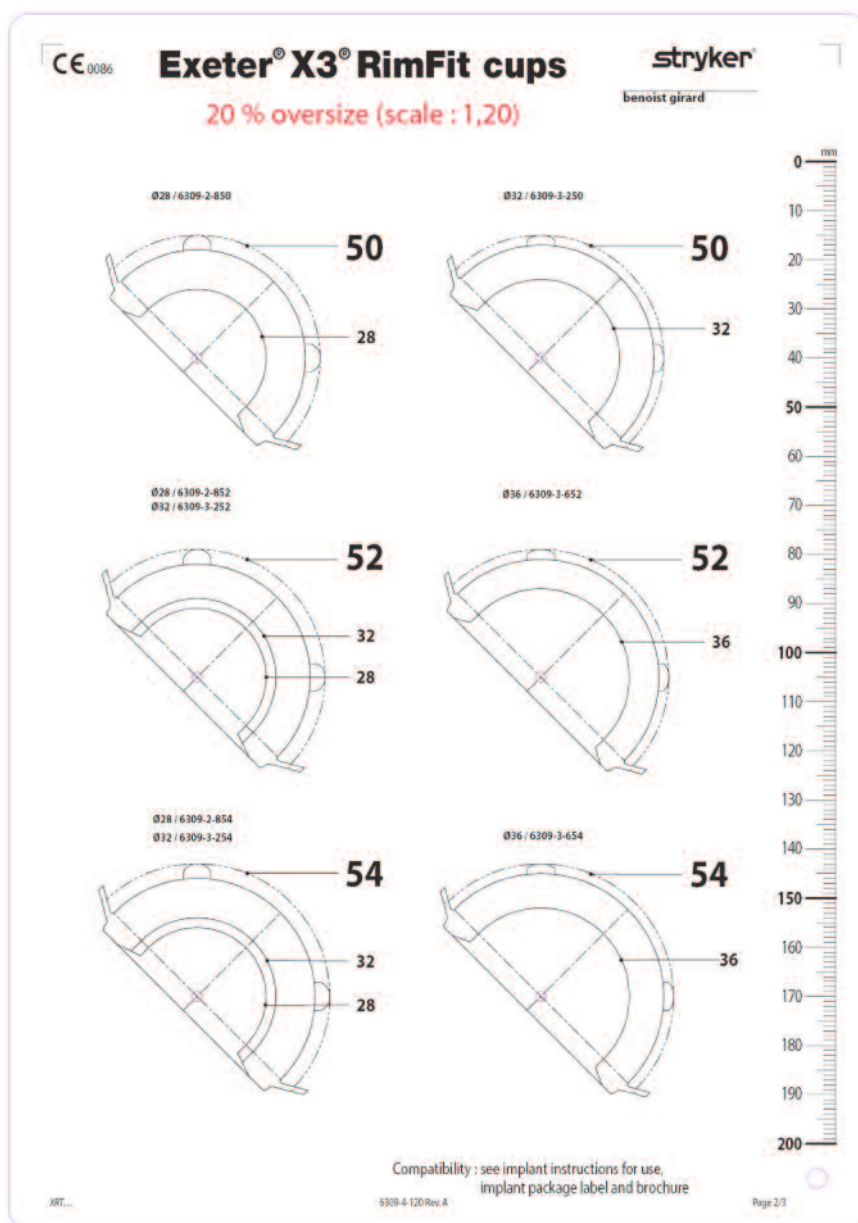
** Thickness between dome diameter and inner diameter

STEP 1

PRE-OPERATIVE PLANNING AND X-RAY EVALUATION

Pre-operative templating and X-ray evaluation using X-rays that have been suitably scaled for magnification allows the surgeon to predict the optimal size of implant for the patient's anatomy and hip pathology.

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



Instruments

Surgical Templates
 Scale 1 – 6309-4-100
 Scale 1.2 – 6309-4-120

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 (**Figure 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.

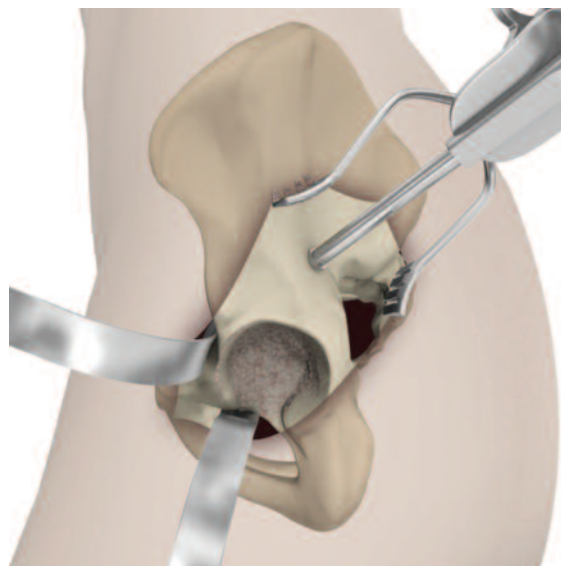


Figure 1



EXETER DESIGNER SURGEON GROUP

"For potentially improved exposure, a knife can be introduced between the labrum and capsule to release the reflected head of rectus femoris and the ilio-femoral ligament from the wing of the ilium" (Figure 2).

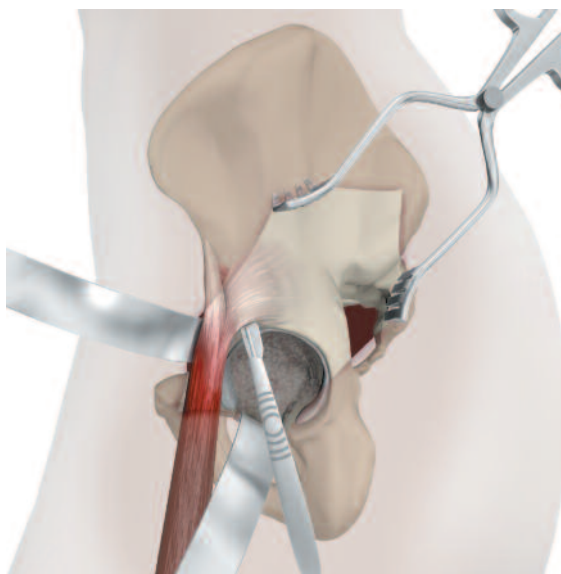


Figure 2

STEP 3

SOCKET PREPARATION

A. Spherical Reaming

To obtain optimal component positioning in the reaming process the reamer handle should be at 45° of abduction and 25° of anteversion (Figure 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 (Figure 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.



Figure 3

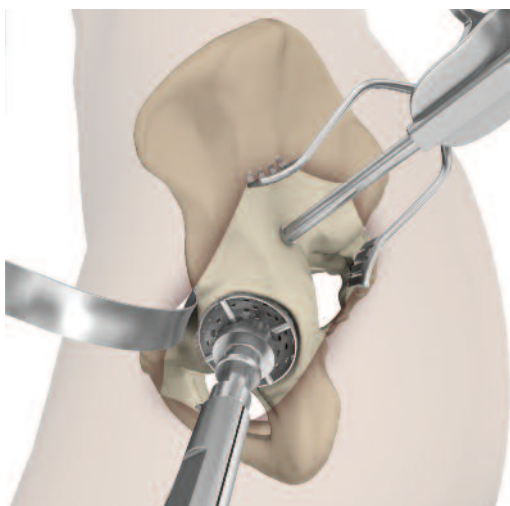


Figure 4

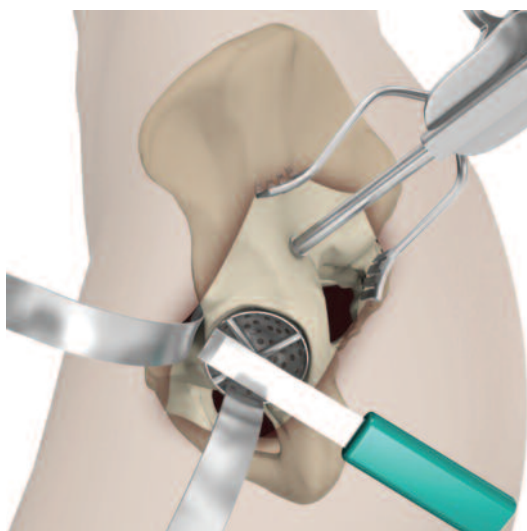


Figure 5



EXETER DESIGNER SURGEON GROUP

"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" (Figure 5).



Instruments

Contemporary
Instrument Tray
6304-4-080

Retractor
Aspirator
6781-8-560



STEP 4

USE OF RIM CUTTER

A. Optional Use of Rim Cutter Instrument

The Rim Cutter (an instrument 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 centralizes 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 (**Figure 6**).

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

The Rim Cutter is advanced to the fullest extent allowed by exerting pressure against the spring between the dome and cutting ring (**Figure 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.



Figure 6

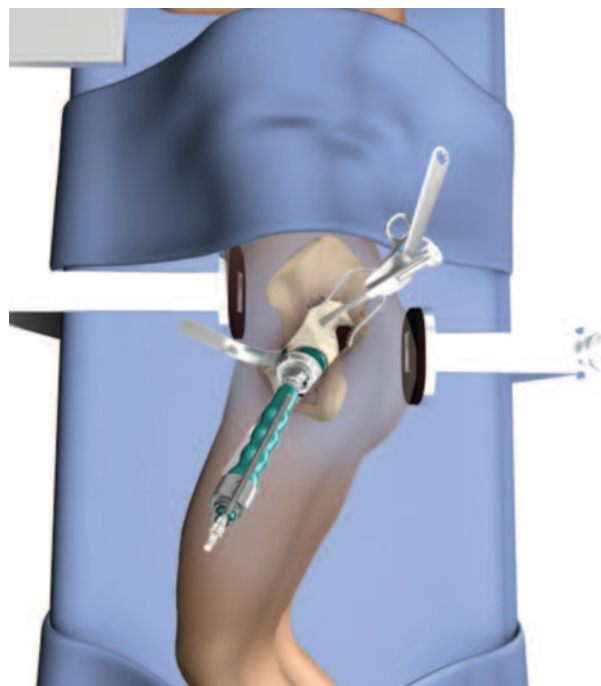


Figure 7



Instruments

Rim Cutter Handle
6309-5-100



Alignment Guide for Rim Cutter Handle
6309-5-300



Acetabular Rim Cutter + Guide
6309-5-2XX



STEP 4

USE OF RIM CUTTER *CONTINUED*

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 (**Figure 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.

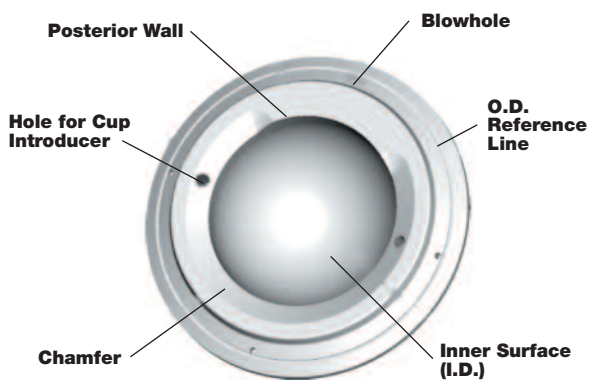


Figure 8



Instruments

**Exeter X3
RimFit Trials**
6309-7-XXX



**Trimmer
Scissors**
6304-4-140



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 (**Figure 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 (**Figure 10**). Fluid is sucked out of the wing of the ilium by the sucker aspirator (**Figure 11**).

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



EXETER DESIGNER SURGEON GROUP

"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."

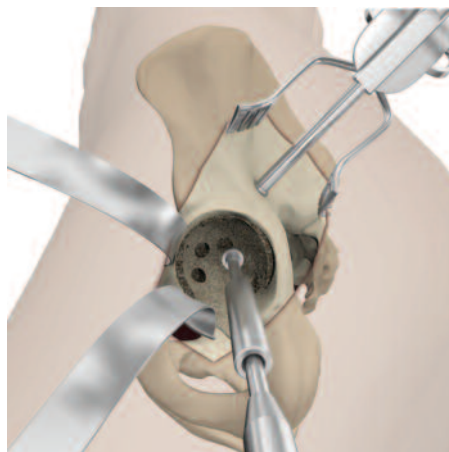


Figure 9

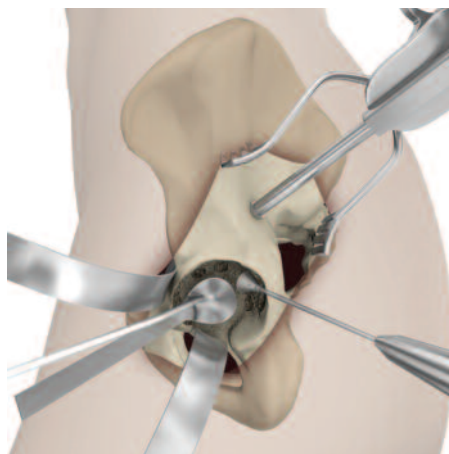


Figure 10

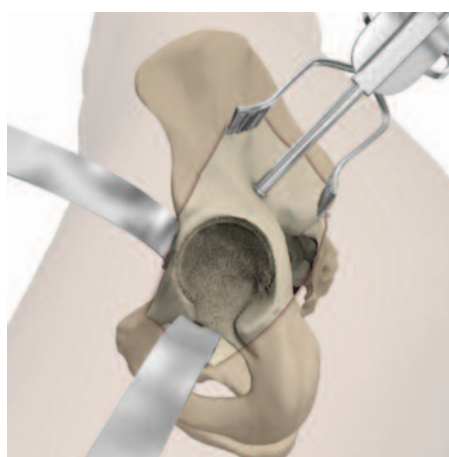


Figure 11



Instruments

**Contemporary
Instrument Tray (2 Level)**
6304-4-090

**Acetabular
Step Drill**
6781-8-750



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° C.). 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 pressurizer is used.

Pressurization of the cement is carried out using a disposable acetabular pressurizer on a handle (**Figure 12**).

Three diameters are available so that an adequate seal can always be established at the socket rim. The pressurizing 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 backbleeding from the host bone. The pressurizer 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 (**Figure 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 pressurized into the acetabulum and a further bolus is required on top of the initial cement. This will become apparent when the pressurizer is removed. If more cement is to be used, then the existing cement should be clean and dry before it is applied.

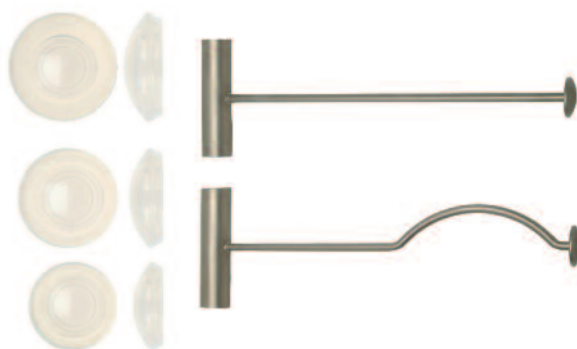


Figure 12

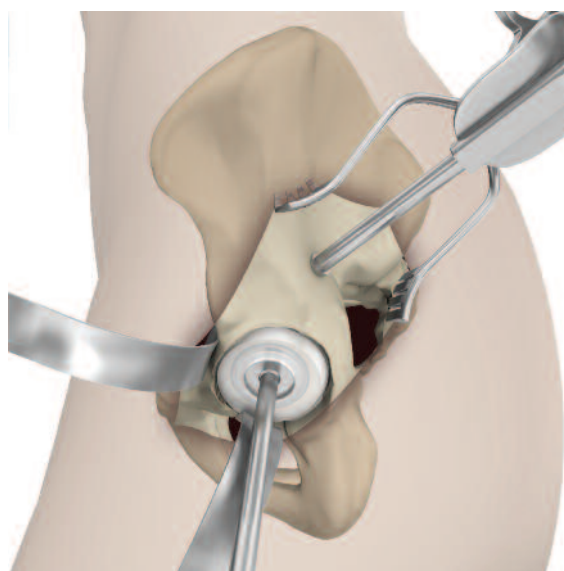
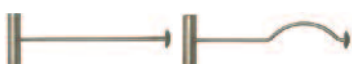


Figure 13



Instruments

Acetabular Cement Pressurizer Handle
Straight-0935-0-001
Curved-0935-0-002



Acetabular Cement Seal
0935-0-0XX



STEP 7

CUP IMPLANTATION

A. If the Rim Cutter has been used...

the orientation of the implant has already been established (Figure 14). The flanged cup is inserted using the introducer (Figure 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 (Figure 16).



Figure 14

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 prerehearsed 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 (Figure 16).



Figure 15



NOTE

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



NOTE

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 ») (Figure 17).

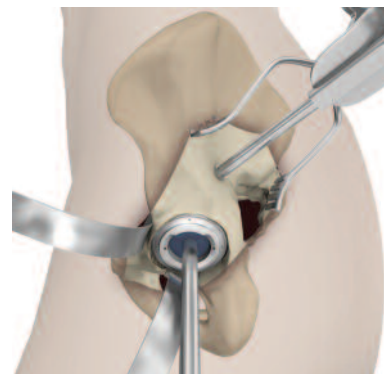


Figure 16

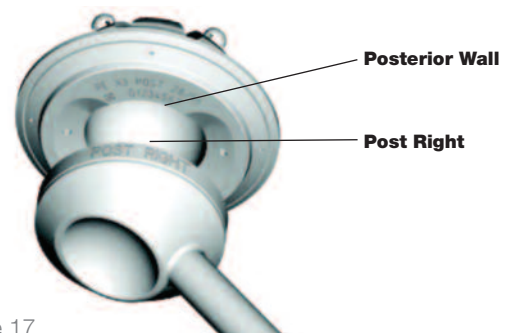


Figure 17



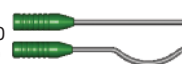
Instruments

Contemporary Instrument Tray (2 Level)
6304-4-090

Lateral Cup Introducer
6304-4-022



Cup Pusher
Straight – 6304-4-110
Curved – 6304-4-120



STEP 8

FINAL STEP

Clear any excess cement with a small curette (**Figure 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 (**Figure 19**).



Figure 18



Figure 19

INSTRUMENT LISTING

Exeter X3 RimFit Cup and Trial Cup Listing

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

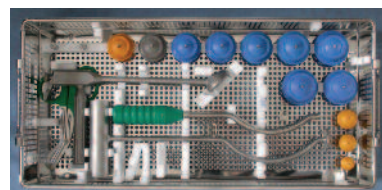
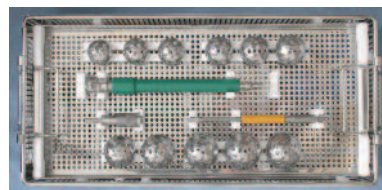
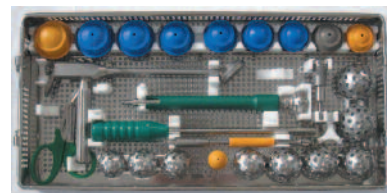
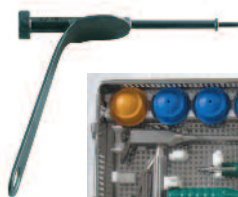
6781-8-560

Contemporary Instrument Tray

6304-4-080

Contemporary Instrument Tray (2 level)

6304-4-090



INSTRUMENT LISTING

Acetabular Step Drill

Ø 9mm	6781-8-750
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Trimming Scissors

6304-4-140

Lateral Cup Introducer

For cup O.D. 40/42	6304-4-022
For cup I.D. 36/40	6304-4-024
For other cups	6304-4-060

Cup Pusher Straight

6304-4-110

Cup Pusher Curved

6304-4-120

Heads for Cup Pusher

Ø 22.2mm	6304-4-122
Ø 28mm	6304-4-128
Ø 32mm	6304-4-132
Ø 36mm	6304-4-136
Ø 40mm	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 40	6309-5-240
Size 42	6309-5-242
Size 44	6309-5-244
Size 46	6309-5-246
Size 48	6309-5-248
Size 50	6309-5-250
Size 52	6309-5-252
Size 54	6309-5-254
Size 56	6309-5-256
Size 58	6309-5-258
Size 60	6309-5-260

Straight Handle (for acetabular cement pressurization)

0935-0-001

Curved Handle (for acetabular cement pressurization)

0935-0-002

Acetabular Cement Seal (5 pack)

Ø 54mm	0935-0-054
Ø 60mm	0935-0-060
Ø 66mm	0935-0-066



IMPLANT LISTING

Implant Listing

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

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



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