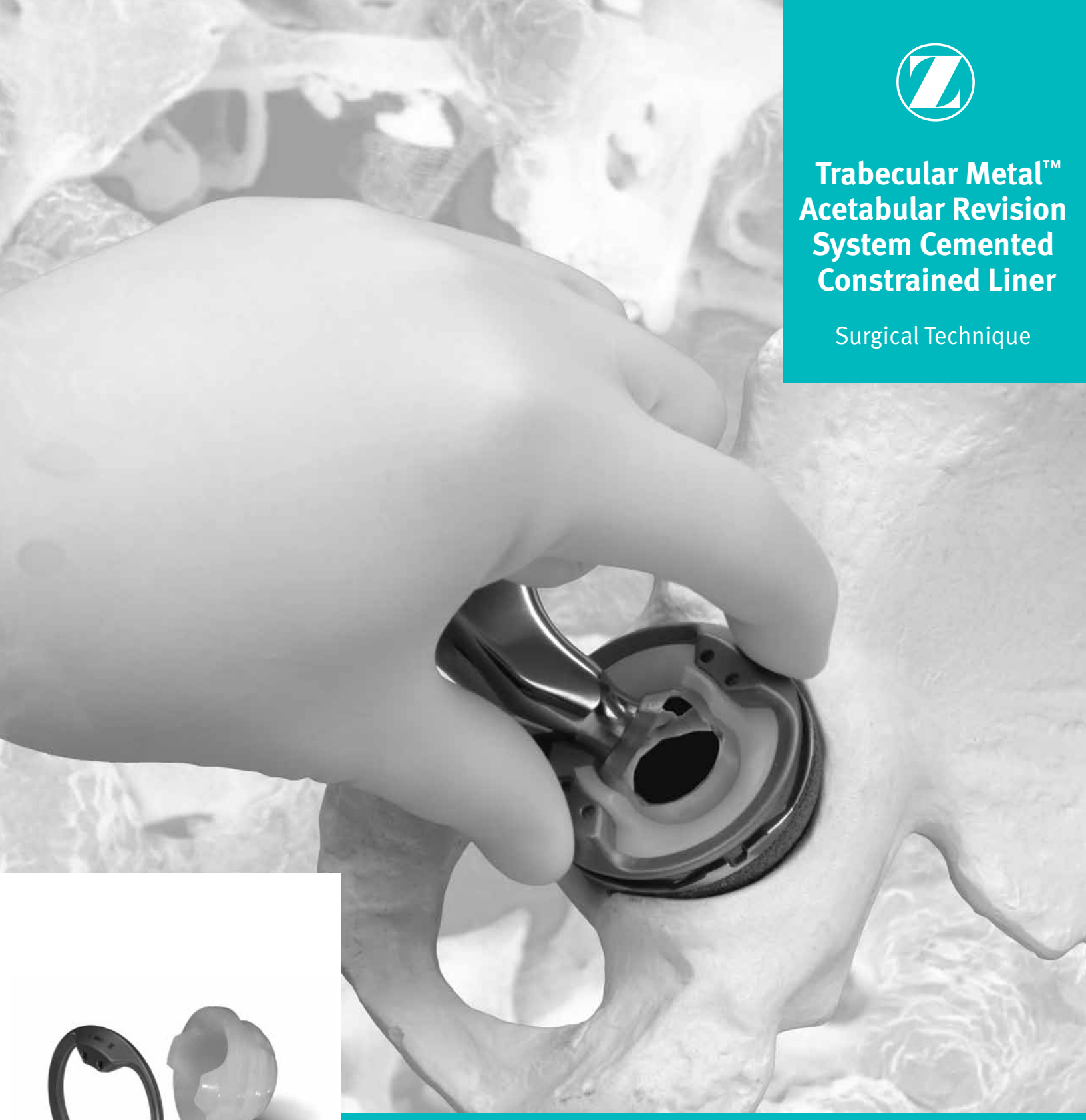
Trabecular Metal™ Acetabular Revision System Cemented Constrained Liner

Surgical Technique



zimmer

Trabecular Metal Acetabular Revision System Cemented Constrained Liner Surgical Technique

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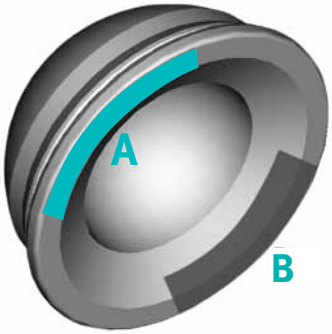
The Problem

Dislocation is the second most common major complication in THA, occurring after 0.4 - 7% of primary THAs and up to 19% of revision THAs.[1-4] Dislocation can be physically destructive, leading to abductor tissue damage. Reoperation results in stability in only 69% of cases.[5] Constrained inserts are designed to reduce the incidence of dislocation. However, the design of traditional constrained inserts severely restricts range of motion (ROM), leading to impingement. This may lead to component failure,[6,7] dislocation,[4,8] and implant loosening.[6]

Cut-Outs Increase Range of Motion Where it is Needed Most

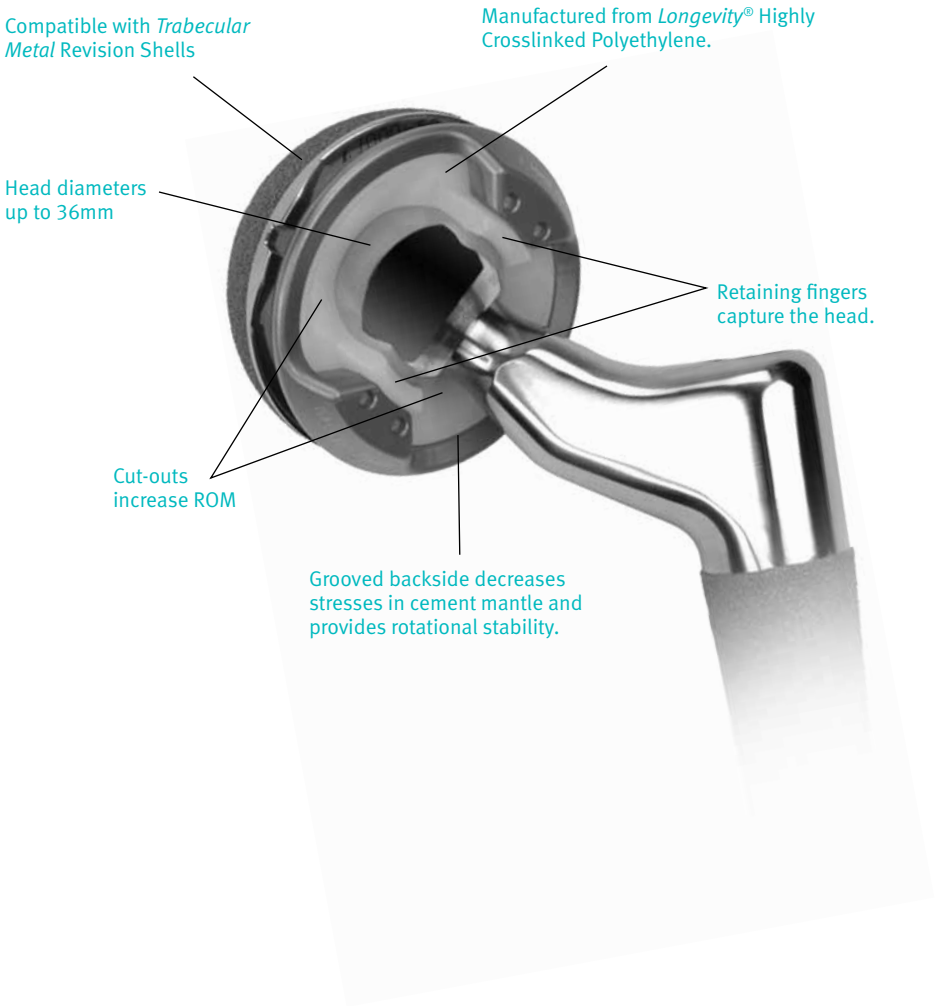
In a study of 111 retrieved acetabular components, researchers identified two primary sites of impingement damage.[9] One site occurred where the neck impinged during full flexion or flexion plus internal rotation **A** (anterior-superior). The second site occurred where the neck impinged during external rotation in extension **B** (posterior-inferior).



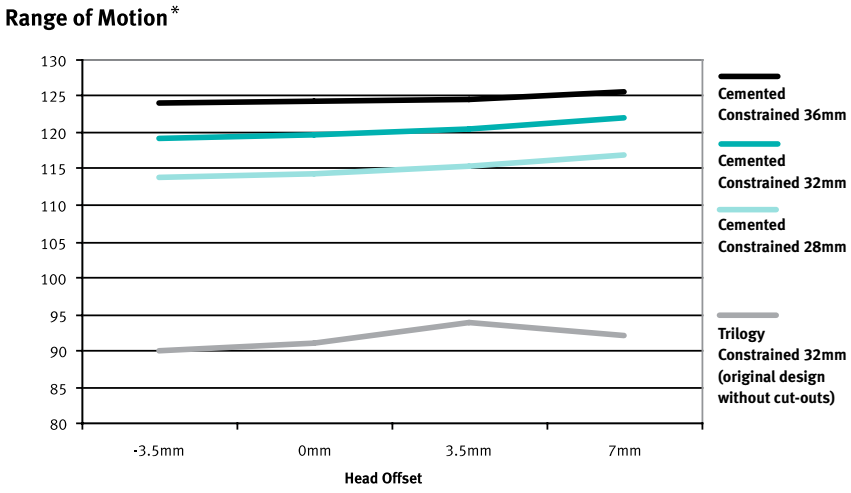
Based on these findings, the Cemented Constrained Liner was designed with cut-outs that can be placed where impingement is most likely to occur. For a left hip, the superior finger is placed at 1 o'clock, and for the right hip, it is placed at 11 o'clock to minimize the potential for impingement and optimize ROM.

The Solution

Cemented Constrained Liner



Range of Motion
Increase over Zimmer Trilogy Constrained Liner[10]



* Data on File at Zimmer

Functionality Maintained –Constraining Mechanism

The Cemented Constrained Liner is manufactured from *Longevity* Highly Crosslinked Polyethylene. It has the same constraining geometry features as the *Trilogy® Longevity* Constrained Liner and is designed to exhibit the same high performance characteristics.

Trabecular Metal Acetabular Revision System

Unique in the industry, the *Trabecular Metal* Acetabular Revision System sets new standards in the way surgeons perform revision surgery. It combines *Trabecular Metal* Technology with the ability to tailor individualized solutions for each patient – a combination no other competitive system offers.

1 Prepare the Acetabulum

Use progressively larger reamers to prepare the acetabulum. Hold the reamer steady in the same position in which the shell will be implanted (approximately 45° of abduction and 15° of anteversion) (Fig. 1). Minimize the amount of bone reaming, performing only that necessary to achieve creation of an adequate hemispherical cavity for support of the Revision Shell.

Fig. 1

2 Shell Sizing And Positioning

Provisional shell sizes match the outside dimensions of the acetabular reamers. The provisional shell has protruding 1mm teeth beyond the rim to stabilize it during trial reduction. It also has fenestrations so that shell seating within the acetabulum can be assessed (Fig. 2). The elliptical Revision Shell implant provides 2mm of interference fit at its periphery (Fig. 3).

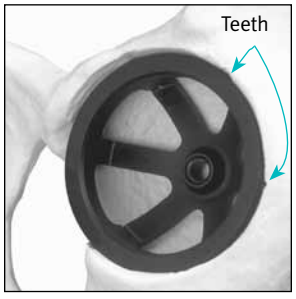


Fig. 2

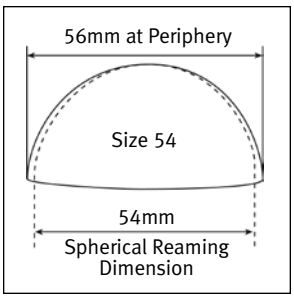


Fig. 3 Elliptical geometry of the shell provides a 2mm interference fit at the periphery and implant-bone contact at the dome.

Select the provisional shell that is the same size as the last even-numbered reamer used (the final implant size will match the size of the provisional shell that is used). Screw the Provisional Shell Impactor Handle onto the provisonal shell. Place the T-handled Version Guide into the slot on the Impactor Handle. When the Version Guide is perpendicular to the longitudinal axis of the patient, the provisional shell is properly positioned at 45° of abduction (Fig. 4).

Fig. 4

Once the version and contact are acceptable, acetabular preparation is complete. Note the position of the provisional shell so that the implant can be seated in the same position.

3 Instrument Assembly

For shells which have the Bayonet Adapter feature on the rim, assemble the Bayonet Adapter sized to match the implant on the Bayonet Handle (Fig. 5a).

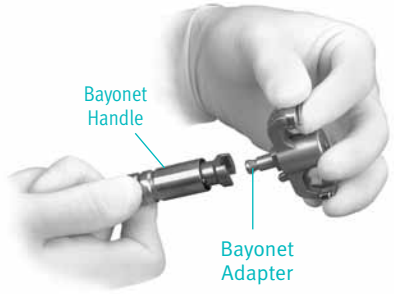


Fig. 5a

With the Bayonet Adapter positioned on the flat portion of the rim of the Revision Shell, turn the adapter until it locks into place (Fig. 5b). For Jumbo shells, 72-80mm, which do not have the Bayonet Adapter feature on the rim, utilize the Rim Impactor as shown in (Fig. 5c). Place the Version Guide on the Bayonet Handle (Fig. 5d). During impaction, the Version Guide should be perpendicular to the longitudinal axis of the patient and parallel to the Transverse axis of the patient.

Fig. 5b

Fig. 5c

Fig. 5d

4 Implant the Revision Shell

Orient the solid portion of the shell (devoid of screw holes) in an anterior-inferior position. Bring the Revision Shell to the appropriate version and inclination (approx. 45° of abduction and 15° of anteversion). Impact the Bayonet Handle to seat the shell in position. **Note:** Ensure that the Plunger is NOT in the Bayonet Handle during impaction.

To release the Bayonet Adapter from the cup, slide the Plunger into the Bayonet Handle. Depress the Plunger until the key lifts out of the slot in the shell, then rotate the Bayonet Handle 90° to free it from the cup locking slot (Fig. 6a). Alternatively, the shell can be disengaged by pushing the Locking Release Trigger at the distal end of the Bayonet Adapter, with or without the Bayonet Handle in place (Fig. 6b).

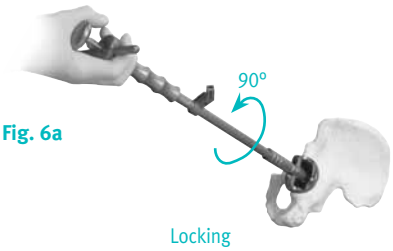


Fig. 6a

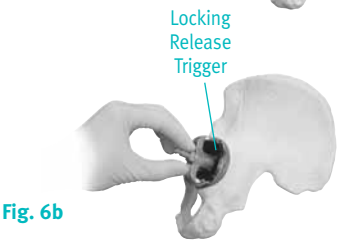


Fig. 6b

For shells which do not have the Bayonet Adapter feature on the rim, the size-matched Rim Impactor attached to the Provisional Shell Handle should be used to impact the shell (Fig. 6c). For shells which have the Bayonet Adapter feature on the rim, the Rim Impactor can be used for additional impaction following use of the Bayonet Adapter. The Cup Rim Impactor from the General Instrument Set can be used to adjust the face angle of the shell if it is well seated but requires repositioning. **Warning: The Bayonet is for impaction only. Use of this instrument to change the placement of the shell after partial or full seating, or to remove a seated shell, may cause damage to the implant construct. Only direct axial impaction loads should be applied.**

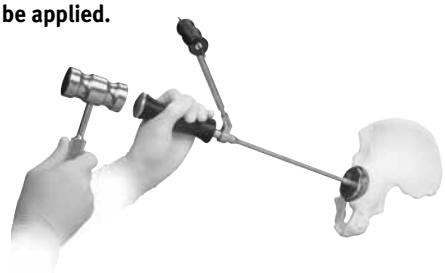


Fig. 6c

5 Screw Insertion

Warning: When used with the Cemented Constrained Liner, ancillary screw fixation of the shell is strongly recommended to assist in maintaining fixation at the shell/bone interface until biological fixation can occur.

Drill a pilot hole by placing the drill through the Drill Guide in the desired screw hole (Fig. 7a). Measure the hole's depth with the Depth Gauge (Fig. 7b).

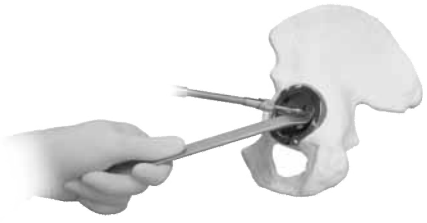


Fig. 7a

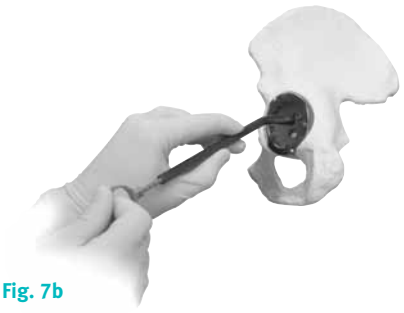


Fig. 7b

Attach the Torque Limiter to the Screwdriver (Fig. 7c). Avoid overtightening of screws and potential advancement through the shell screw hole. **Note:** The Torque Limiter does not eliminate the need for surgeon evaluation of bone quality, appropriate screw selection, and torque control.

Fig. 7c

Select the appropriate length 6.5mm HGPII screw and insert it in the hole with the Screwdriver/Torque Limiter construct (Fig. 7d). Place additional screws as necessary. **Note:** Unused screw holes should be plugged with bone wax or bone graft. Bone wax should also be used to fill the screw heads. This may assist bone cement removal if future need arises.

Warning: Avoid screw placement through the shell into the anterior-inferior quadrant of the acetabulum to prevent injury to intrapelvic neurovascular structures.

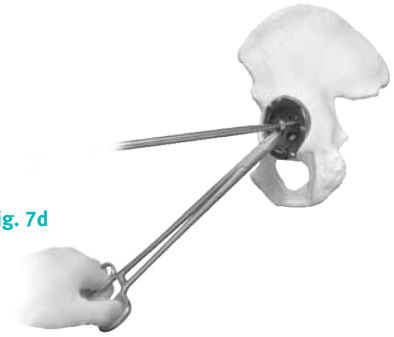


Fig. 7d

6 Provisional Liner and Trial Reduction

Select a Cemented Constrained provisional liner size that matches the shell. Provisional liners are used to assess joint stability and face-angle position. The purpose of the trial reduction is to locate the optimal rotational position of the constraining fingers to maximize range of motion.

This position may change from patient to patient because of variations in anatomy and shell placement.

For the initial trial range of motion, one of the constraining fingers of the appropriate-sized trial insert is placed at approximately 1:00 for a left hip or 11:00 for a right hip.

Adjust liner position to best fit the needs of the patient. Perform a trial reduction with the femoral stem and trial femoral head in place.

Important: The liner provisional is a direct representation of the assembled implant liner and constraining ring. Therefore, it is extremely important to make sure that all bone and soft tissue has been cleared from the periphery of the shell in order to help facilitate the proper seating of the liner provisional as well as the final implants. This is best accomplished by either direct visualization or by palpating the entire periphery of the shell.

Range of Motion

Note: The trial insert is used only to assess leg length and range of motion. It does not constrain the femoral head, as the actual implant does.

A trial femoral head with the appropriate neck length is placed on the trunion of the femoral component and reduced into the trial insert. After the leg length and femoral offset are verified, a trial range of motion is conducted.
The key ranges of motion should be assessed (Figs. 8a-8d), specifically:

- Maximum flexion in neutral rotation
- Maximum internal rotation with 90° of flexion
- Full extension (but not hyper-extension),
- Full external rotation in full extension.

Trial Reduction Range of Motion

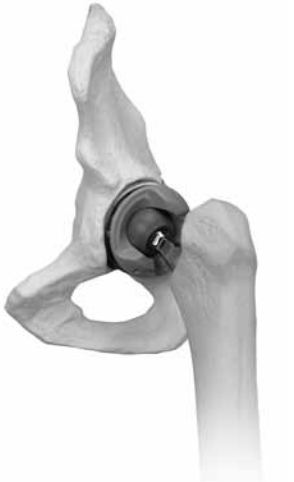


Fig. 8a Neutral Position - Full Extension. To optimize Range of Motion, the superior finger is placed at 1 o'clock for a left hip and 11 o'clock on a right hip

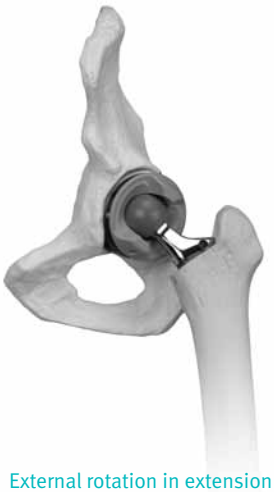


Fig. 8b External rotation in extension

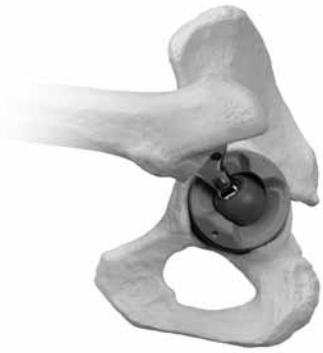


Fig. 8c Flexion plus internal rotation

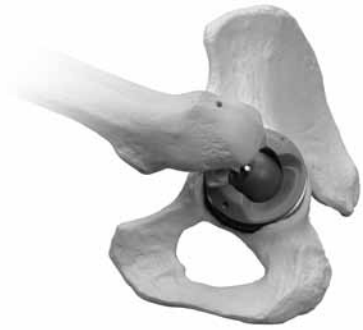


Fig. 8d Full flexion

If the trial range of motion indicates that the orientation of the constraining fingers does not optimize the range of motion such as might be indicated by premature impingement, the trial insert can be rotated to another position. **Note:** The Constrained Liner provisional does not lock into the Revision Shell. Rotation may occur during the trial reduction and should be monitored.

Once the optimum orientation of the trial insert is determined, the position of the center of the constraining fingers, shown by an engraved line, is noted on the acetabular shell. This mark will aid in reproducing the location of the constraining fingers with the implant (Fig. 9).

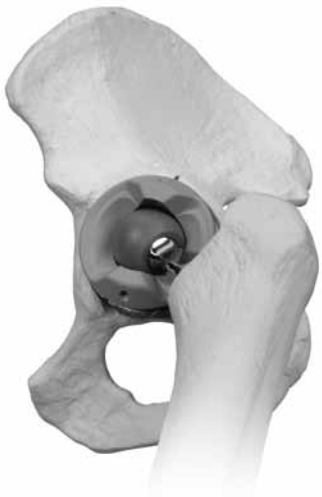


Fig. 9

7 Liner Insertion and Placement

Prepare PALACOS®* Bone Cement.Place cement in the Revision Shell while in a doughy state (Fig. 10). The Cemented Constrained Liner provides a nominal 2-3mm cement mantle. If desired, a thicker cement mantle can be achieved by dropping down a liner size (i.e. using a 54mm OD liner in a 56mm shell). An appropriately sized Constrained Liner Cement Shroud should be placed on the liner before liner insertion to protect the Constraining Ring locking geometry from being occluded by excess cement (Fig. 11). Place the polyethylene liner into position, making sure that the constraining fingers of the Cemented Constrained Liner are aligned in the Revision Shell to replicate the orientation that had provided optimum range of motion during the assessment of the trial insert. The liner insertion may be performed by hand or by use of the Cement Shroud Pusher attached to the Impactor Handle (Fig. 12). Maintain pressure on the Cement Shroud while the cement is curing. When the cement is cured, remove the Cement Shroud by lifting the center portion and remove any excess cement. **Note:** Care should be taken when removing the Cement Shroud to avoid damage to the articulating surface of the Constrained Liner. If the articulaing surface is damaged, the Constrained Liner should not be used.

* PALACOS® is a trademark of Heraeus Kulzer GmbH. Under license from Heraeus Kulzer GmbH, Hanau, Germany.

Fig. 10

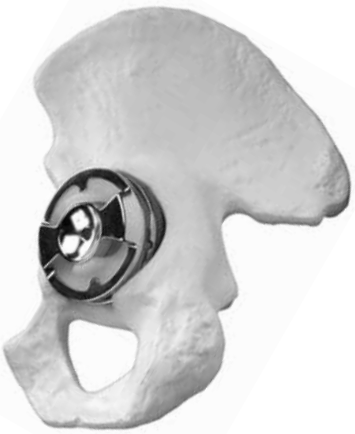


Fig. 11

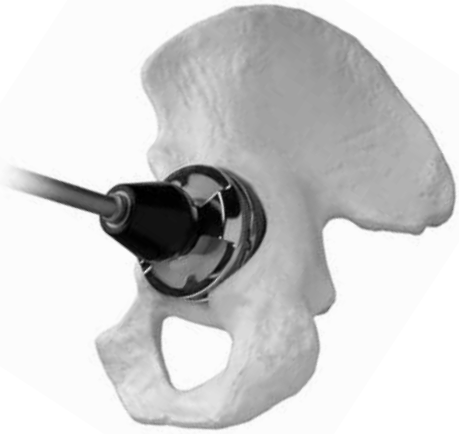


Fig. 12

8 Implant Assembly

Preparation of Constraining Ring

To assemble the Cemented Constrained Liner, place the Constraining Ring over the head of the femoral component in the proper orientation (Fig. 13). The top-side of the ring with the two protruding fingers must point toward the femur. The under-side of the ring, which will snap onto the face of the polyethylene liner, must be oriented toward the patient's acetabulum.

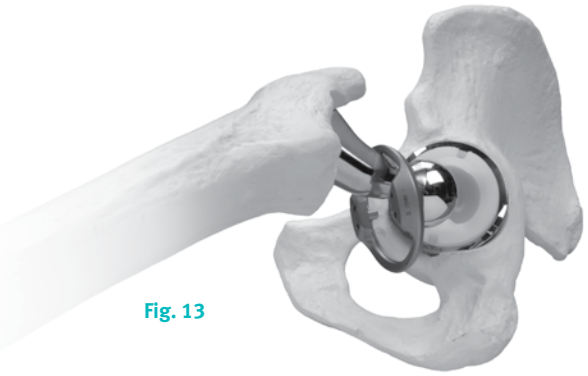


Fig. 13

Note: For clarification, the ring is engraved with "TOWARDS FEMUR" and "TOWARDS ACETABULUM" (Fig. 14).

Fig. 14

Femoral Head Reduction

Note: The constraining ring must be in place around the femoral neck before reducing the head into the liner.

Reduce the appropriately sized femoral head into the Cemented Constrained Liner by applying a continuous, steady force axially along the femur (Fig. 15). Attempts should not be made to reduce the femoral head into the insert with a sudden impaction force. Sudden impaction actually requires a higher force to be applied.

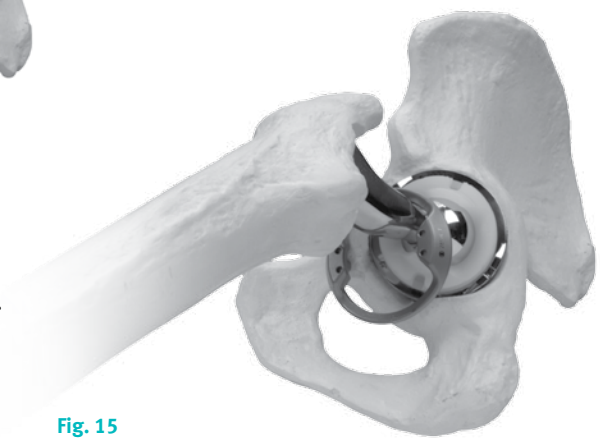


Fig. 15

Constraining Ring Assembly to Insert

To attach the Constraining Ring to the liner, advance the ring from around the femoral neck to the face of the liner. To ensure proper alignment of the ring, the titanium pegs on the flat side of the constraining ring must fit into the slots on the outside of the polyethylene liner. When properly positioned, the fingers on the ring are aligned with the fingers on the polyethylene liner (Fig. 16).

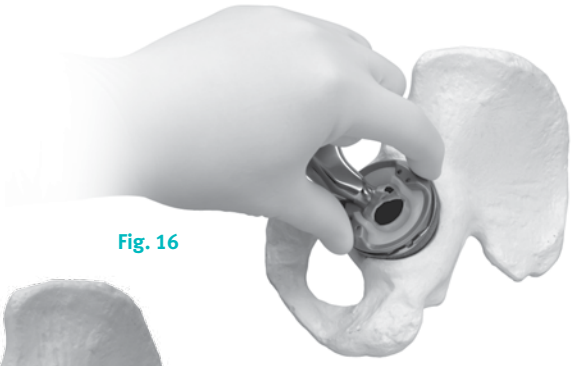


Fig. 16

An appropriately sized Ring Impactor is threaded onto the Impactor Handle until the threads are completely seated. The posts of the Ring Impactor are inserted into the holes on the Constraining Ring (Fig. 17). Two or three moderate impaction blows are applied with a surgical mallet to seat the ring onto the insert (Fig. 18).

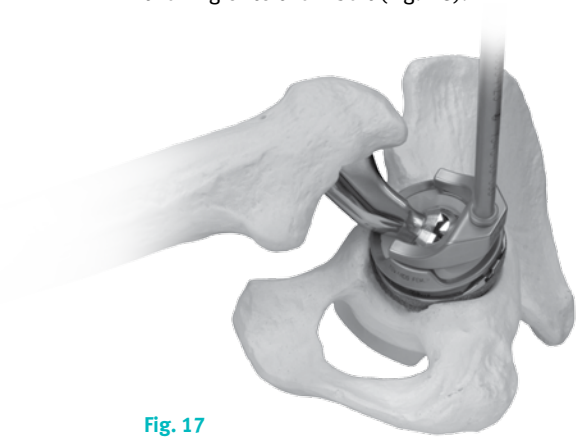


Fig. 17

Fig. 18

Note: The Ring Impactors are sized according to the inner diameter of the insert (28, 32, and 36mm).

The constraining ring is fully seated when the metal constraining fingers are seated either flush or slightly below the level of the polyethylene constraining fingers on the liner and are at a consistent level on both sides of the liner (Figure 19). This will be palpable if direct visualization is not possible. If the metal constraining fingers are not seated flush/slightly below the polyethylene on both sides (Figure 20), check that there is no soft tissue trapped between the constraining ring and the periphery of the shell or liner and repeat the impaction with the Ring Impactor.

Fig. 19

Fig. 20

Note: Soft tissue must be cleared from the periphery of the polyethylene insert in order to avoid trapping any soft tissue between the insert and the constraining ring. If difficulty in assembling the ring is encountered, check the periphery for soft tissue impingement.

After assembling the constraining ring to the liner, the range of motion is re-checked and joint stability is verified by applying traction on the femur. If both range of motion and stability are satisfactory, closure of the wound proceeds as usual.

Implant Disassembly (If Required)

To remove the constraining ring, insert a flat instrument, such as a quarter-inch osteotome, under the ring (Fig. 21). Apply rotational torque to the instrument in order to pry the constraining ring from the polyethylene snap feature. Carefully repeat this process at a few sites around the periphery of the ring until the ring is loosened from the liner.

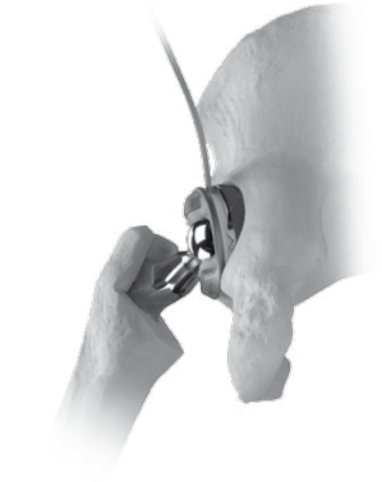


Fig. 21

Note: Do not reuse liner or ring if the part has been disassembled.

Follow standard liner removal procedure for liner extraction.

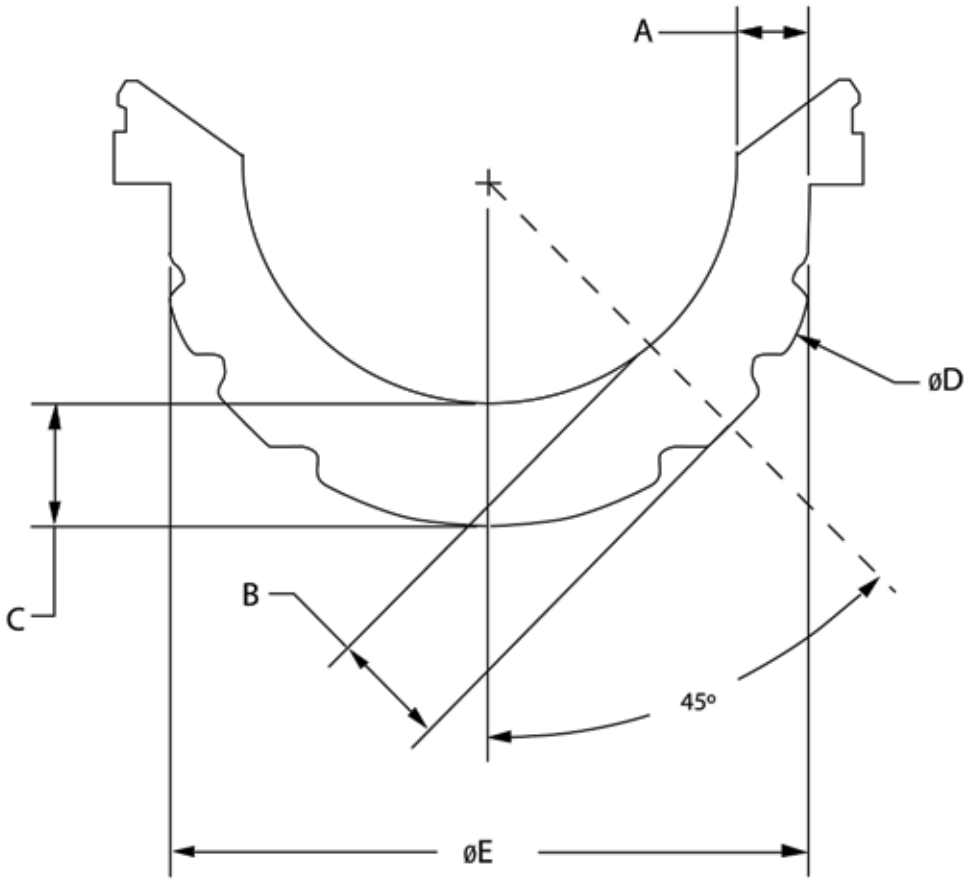
Trabecular Metal Acetabular Revision System Cemented Constrained Liner Dimentions Chart (mm)

Prod. No.	Description	A Rim Thickness	B 45° Thickness	C Pole Thickness	D Outer Diameter	E Rim Diameter	Shell Rim ID
00-7115-050-28	Cemented Constrained Liner 50mm x 28mm	4	8	8	41	38	38
00-7115-052-28	Cemented Constrained Liner 52mm x 28mm	6	9	9	43	40	40
00-7115-054-32	Cemented Constrained Liner 54mm x 32mm	5	7	8	44	42	42
00-7115-056-32	Cemented Constrained Liner 56mm x 32mm	6	8	9	46	45	45
00-7115-058-36	Cemented Constrained Liner 58mm x 36mm	4	7	8	48	46	46
00-7115-060-36	Cemented Constrained Liner 60mm x 36mm	5	8	8	49	48	48
00-7115-062-36	Cemented Constrained Liner 62/64mm x 36mm	7	9	9	51	50	50
00-7115-066-36	Cemented Constrained Liner 66/68/70mm x 36mm	8	11	11	55	54	54
00-7115-072-36	Cemented Constrained Liner 72/74mm x 36mm	10	13	14	60	58	58
00-7115-076-36	Cemented Constrained Liner 76/78/80mm x 36mm	12	15	15	63	62	62

-All dimensions are in millimeters, rounded to the nearest millimeter

-The offset of every Cemented Constrained Liner is 1.8mm (.072")

-The groove depth is 1.0mm



Order Information

Revision Shell

Prod. No.	Description
00-7000-050-20	50mm Cup Size
00-7000-052-20	52mm Cup Size
00-7000-054-20	54mm Cup Size
00-7000-056-20	56mm Cup Size
00-7000-058-20	58mm Cup Size
00-7000-060-20	60mm Cup Size
00-7000-062-20	62mm Cup Size
00-7000-064-20	64mm Cup Size
00-7000-066-20	66mm Cup Size
00-7000-068-20	68mm Cup Size
00-7000-070-20	70mm Cup Size
00-7000-072-70	72mm Cup Size
00-7000-074-70	74mm Cup Size
00-7000-076-70	76mm Cup Size
00-7000-078-70	78mm Cup Size
00-7000-080-70	80mm Cup Size

Cemented Constrained Liner

Prod. No.	Description
00-7115-050-28	Cemented Constrained Liner 50mm x 28mm
00-7115-052-28	Cemented Constrained Liner 52mm x 28mm
00-7115-054-32	Cemented Constrained Liner 54mm x 32mm
00-7115-056-32	Cemented Constrained Liner 56mm x 32mm
00-7115-058-36	Cemented Constrained Liner 58mm x 36mm
00-7115-060-36	Cemented Constrained Liner 60mm x 36mm
00-7115-062-36	Cemented Constrained Liner 62/64mm x 36mm
00-7115-066-36	Cemented Constrained Liner 66/68/70mm x 36mm
00-7115-072-36	Cemented Constrained Liner 72/74mm x 36mm
00-7115-076-36	Cemented Constrained Liner 76/78/80mm x 36mm

Instruments

Prod. No.	Description
00-7000-015-00	General Acetabular Instrument Set for both *Trabecular Metal* Revision Shell and Monoblock Cup (Includes one each of all items listed below)
00-7050-076-00	Instrument Case Base w/Lid (Outer Case)
00-7050-077-00	Instrument Case Bottom Tray
00-7050-078-00	Instrument Case Top Tray
Cup Adapter w/Bayonet	
00-7045-040-00 through 00-7045-070-00	40mm Cup Size through 70 mm Cup Size
Available in 2mm increments.	
General Instruments	
00-7050-030-00	Cup Rim Impactor
00-7050-031-00	Cup Version Guide
00-7050-032-00	Provisional Liner Extractor (Monoblock Cup only)
00-7050-033-00	Bayonet Handle w/Hudson Adapter (Plunger included)
00-7050-034-00	Provisional Shell Impactor Handle
00-7050-035-00	Medial Cup Impactor (Monoblock Cup only)
00-7050-036-00	Acetabular Impactor Head, 28mm
00-7050-038-00	Acetabular Impactor Head, 22mm
Provisional Shell	
00-7040-040-00 through 00-7040-070-00	40mm Cup Size through 70 mm Cup Size
Available in 2mm increments.	
Jumbo Shell Provisional Set	
6270-199-02	Jumbo Shell Provisional Set (includes one each of all items listed below)
6275-018	Mod Cup Provisional Shell Jumbo Tray
6242-072	Shell Provisional 72mm
6242-074	Shell Provisional 74mm
6242-076	Shell Provisional 76mm
6242-078	Shell Provisional 78mm
6242-080	Shell Provisional 80mm

HGP II Bone Screws

Prod. No.	Description
00-6624-065-15	6.5mm x 15mm
00-6624-065-20	6.5mm x 20mm
00-6624-065-25	6.5mm x 25mm
00-6624-065-30	6.5mm x 30mm
00-6624-065-35	6.5mm x 35mm
00-6624-065-40	6.5mm x 40mm
00-6624-065-50	6.5mm x 50mm
00-6624-065-60	6.5mm x 60mm

Screw Instruments

Prod. No.	Description
00-6260-099-02	*Trilogy* Holed Instrument Set (Includes one of each of all items listed below)
00-6260-002-00	Flex Shaft w/Modular Connector
00-6260-003-01	Drill Bit, 15mm Length
00-6260-003-02	Drill Bit, 30mm Length
00-6260-003-03	Drill Bit, 45mm Length
00-6260-006-00	Drill Guide
00-6260-007-01	Tap, 4.5mm Diameter
00-6260-008-01	Tap Guide, 4.5mm Diameter
00-6260-008-02	Tap Guide, 6.5mm Diameter
00-6260-010-00	Tap Handle
00-6260-024-00	Straight Screwdriver
00-6260-025-00	Universal Screwdriver
00-6260-026-00	Modular Universal Handle
00-6260-013-00	Screw Holding Forceps, 15°
00-6260-014-00	Screw Holding Forceps, 45°
00-6611-098-00	Depth Gauge
00-6260-085-01	Case (including base and lid)
00-4215-200-00	Screwdriver Torque Limiter (ordered separately, not in kit)

Instrument Sets

Prod. No.	Description
KT-7105-007-00	Cemented Constrained Liner Instrument Set
KT-7105-008-00	Cemented Constrained Jumbo Instrument Set
Cases	
00-7106-025-00	Cemented Constrained Liner Case
00-5900-099-00	Cemented Constrained Liner Lid
Provisionals	
00-7116-050-28	Cemented Constrained Liner Provisional 50mm x 28mm
00-7116-052-28	Cemented Constrained Liner Provisional 52mm x 28mm
00-7116-054-32	Cemented Constrained Liner Provisional 54mm x 32mm
00-7116-056-32	Cemented Constrained Liner Provisional 56mm x 32mm
00-7116-058-36	Cemented Constrained Liner Provisional 58mm x 36mm
00-7116-060-36	Cemented Constrained Liner Provisional 60mm x 36mm
00-7116-062-36	Cemented Constrained Liner Provisional 62/64mm x 36mm
00-7116-066-36	Cemented Constrained Liner Provisional 66/68/70mm x 36mm
00-7116-072-36	Cemented Constrained Liner Provisional 72/74mm x 36mm
00-7116-076-36	Cemented Constrained Liner Provisional 76/78/80mm x 36mm
Instruments	
00-7116-001-28	Constrained Liner Cement Shroud 28mm
00-7116-001-32	Constrained Liner Cement Shroud 32mm
00-7116-001-36	Constrained Liner Cement Shroud 36mm
00-6144-001-28	Ring Impactor 28mm
00-6144-001-32	Ring Impactor 32mm
00-6144-001-36	Ring Impactor 36mm
9375-00-061	Cement Shroud Pusher
9340-00-000	Impactor Handle

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10 Data on file at Zimmer

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