CONFORMIS®

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ACTERA™ HIP SYSTEM

Surgical Technique Guide

ACTERA™ Hip System

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Introduction

The ACTERA™ Hip System is a cementless, total hip replacement system composed of femoral components that is intended for use with the CORDERA™ Acetabular System. The ACTERA™ femoral component consists of a monoblock femoral stem body and neck, which mates with a standard femoral head. The CORDERA™ acetabular component consists of various shell options with three screw holes, a mating polyethylene liner, and cancellous screws. The acetabular component is designed for cementless use; initial implant fixation is achieved through press-fit design.

In addition to utilizing these implants in a standard capacity with two dimensional (2D) templating and reusable instrumentation, implants and instruments can be personalized for each patient. Personalized components can be ordered after review of a pre-operative surgical plan otherwise known as an iView®. iView's are developed using three dimensional (3D) data from a patient's CT scan and Conformis' proprietary iFit® Image-to-Implant® technology. This surgical technique guide will employ instructions for use with all Conformis options from standard, 2D imaging and instruments to the highest level of personalization for ACTERA™ implants and instrumentation: ACTERA™ HipRx™.

ACTERA™ can be supplied to the surgeon on their request in any of the following combinations offered by Conformis:

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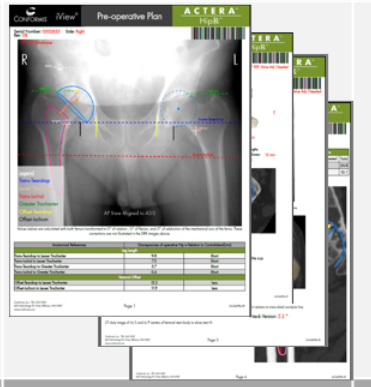
ACTERA™ THA OFFERINGS

	FEMORAL STEM OPTIONS		ACETABULAR OPTIONS	PATIENT SPECIFIC PLANNING	
	ACTERA™ HipRx™ Femoral Neck	ACTERA™ Hip Stem	CORDERA™ Acetabular System	Patient Specific iView®	iJigs® and Patient Specific Instrumentation
					
ACTERA™ HipRx™ Surgery-in-a-Box™	✓		✓	✓	✓
ACTERA™ MATCH Surgery-in-a-Box™		✓	✓	✓	✓
ACTERA™ PRO		✓	✓	✓	
ACTERA™		✓	✓		

Surgeon Design Team

The ACTERA™ Hip System Surgical Technique was developed in collaboration with:

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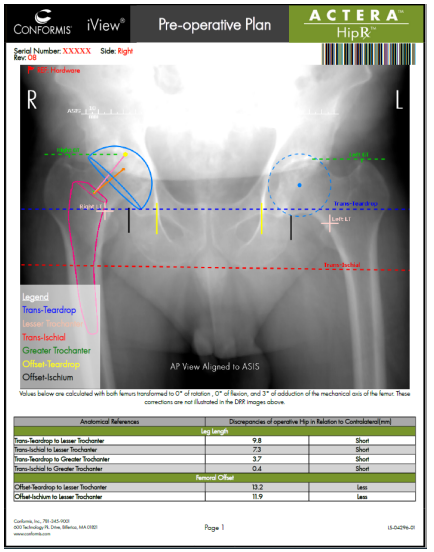
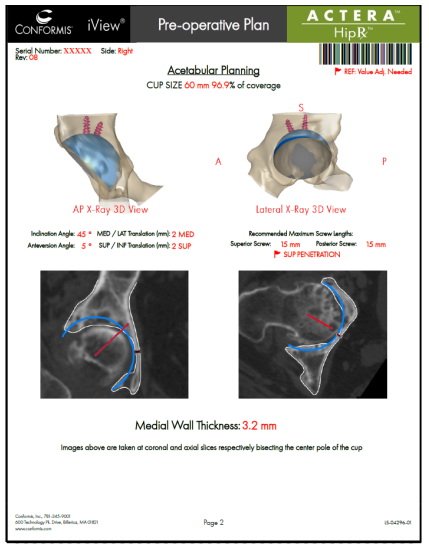
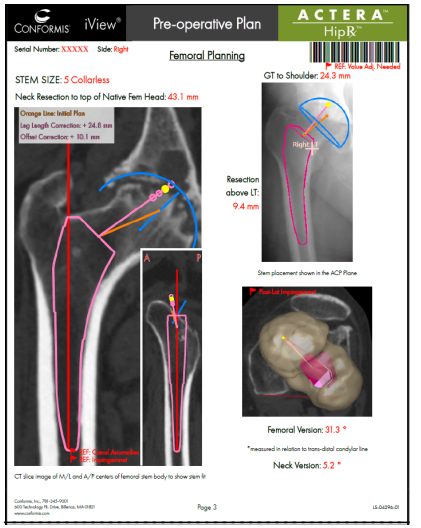
Pre-operative Image Review

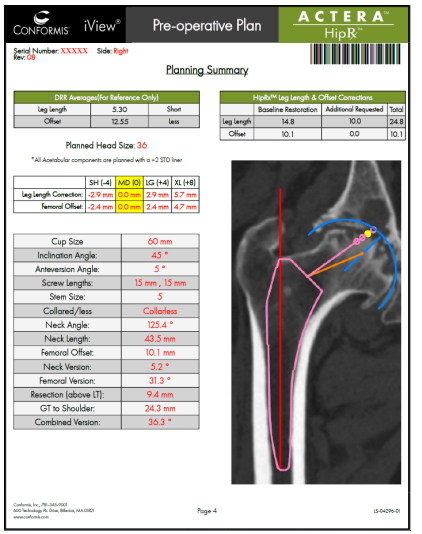


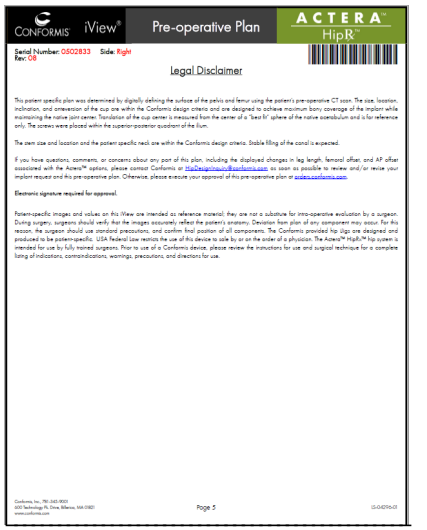
When Conformis' 3D planning is requested, pre-operative planning images called an iView® are provided preoperatively for review and approval by the surgeon. A surgical iView® is also provided with each implant. The images provide patient-specific dimensional information and final implant positioning.

iView® patient-specific planning images are intended as reference material and not a substitute for intra-operative evaluation by a surgeon. During surgery, physicians should verify that the images provided accurately reflect the patient's anatomy and evaluate the hip for range of motion and stability.









ACTERA™ Hip System

Pre-operative Image Review

Determination of Leg Length Discrepancy

Perform a clinical evaluation in conjunction with a radiographic analysis and/or Conformis Pre-Operative iView® to determine preoperative leg length discrepancy, and use both to determine intraoperative leg length management.

Acetabular Cup Sizing and Position

Acetabular sizing determination is made using the A/P radiograph of the hip or by recommendation of the Pre-operative iView®. When utilizing 2D radiograph, determine the optimal position for the acetabular component and estimate the size using template overlays. The acetabular teardrop can be referenced as the interior margin of the acetabular reconstruction. The goal in cementless acetabular fixation is to optimize position and bone contact. Once this is determined, mark the intended center of rotation of the bearing surface on the A/P radiograph.

Femoral Stem Selection

If using 2-D templates, select the template size that fits the proximal femur and manages leg length. The femoral template should be in line with the long axis of the femur, and the neck resection line drawn at the point where the selected stem provides the desired amount of leg length.

SURGICAL TECHNIQUE

WITH IJIGS®

The following surgical steps instruct how to use the personalized iJigs® and implants designed with Conformis' Image-to-Implant™ technology:

ACTERA™ HipRx™

Conformis' Surgery-in-a-Box™ ordering option which includes, personalized hip implants & single use instruments (iJigs®) provided based on, a surgeon approved, pre-operative surgical plan (iView®).

ACTERA™ MATCH

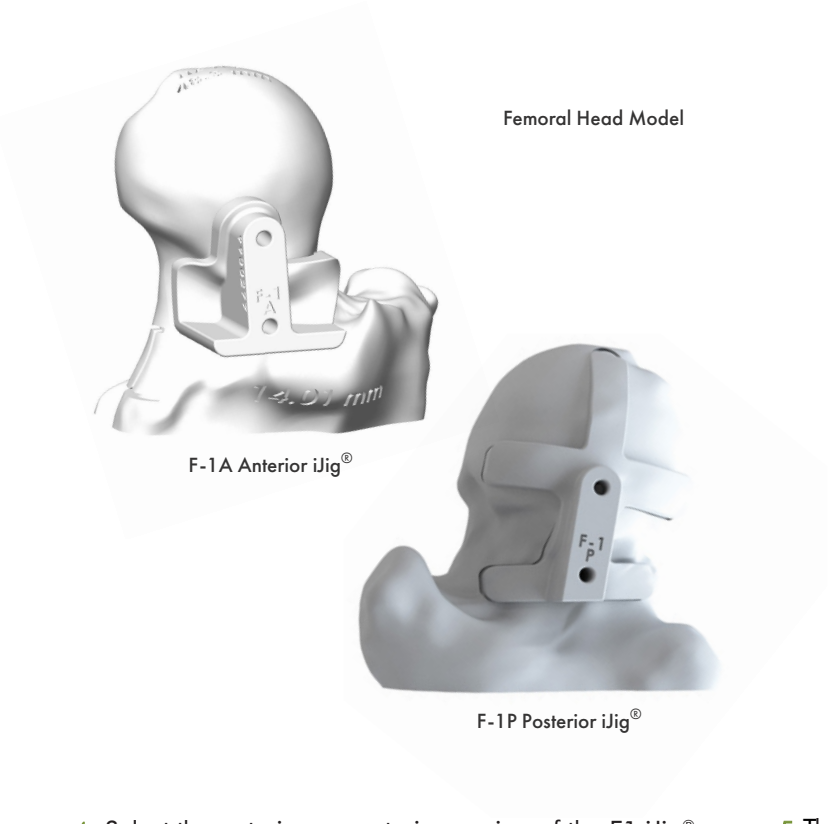
Conformis' Surgery-in-a-Box™ ordering option which includes, recommended standardized implants, personalized single use instruments (iJigs®) provided based on a surgeon approved, pre-operative surgical plan (iView®).

Step 1 EXPOSURE AND NECK RESECTION

1 The serial number is noted on the iView® and engraved on each iJig®. Before beginning the case, confirm that the serial number is correct and matches across all components.

2 The ACTERA™ Match or ACTERA™ HipRx™ total hip systems can be performed through either a posterior, anterior or lateral approach.

3 Adequately expose the acetabulum and proximal femur.



Femoral Head Model

F-1A Anterior iJig®

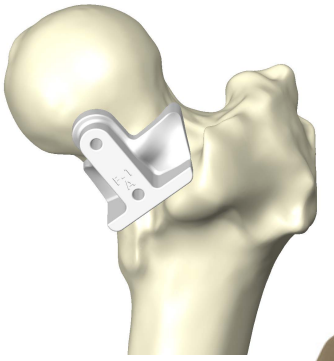
F-1P Posterior iJig®

4 Select the anterior or posterior version of the F1 iJig® corresponding to the surgical approach being used. The iJig® is marked "F-1 A" for the anterior approach, and "F-1 P" for the posterior approach. Note the femoral head model has the outline of both iJig® positions. Place the appropriate F1 iJig® on the femoral head model as a guide to demonstrate the patient's anatomy. Rotate the femur to expose the femoral neck for insertion and placement of the F1 iJig®.

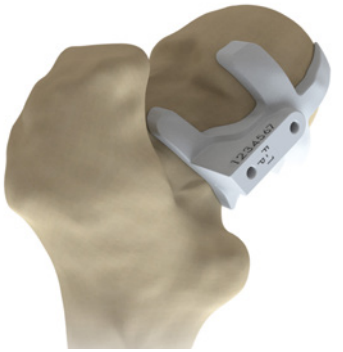
5 The contoured surface of the F1 iJig® matches the patient's femoral neck and will feel stable when it is in the correct position. Ensure all cartilage and soft tissue is removed as necessary to allow the iJig® to lay in direct apposition to bone. Adjust it on the neck until it is stable against the bone.

TECHNIQUE TIPS

- Internally and externally rotating the femur may help with insertion and location of the F1 iJig® in small incisions.
- Comparing the appearance in the patient to the markings on the femoral head model provides visual feedback.



F-1A Anterior iJig®

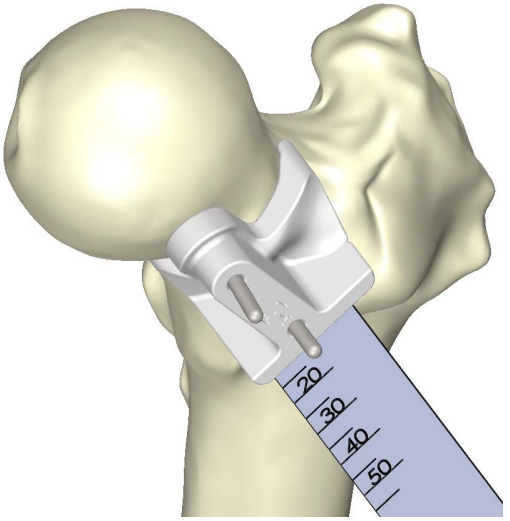


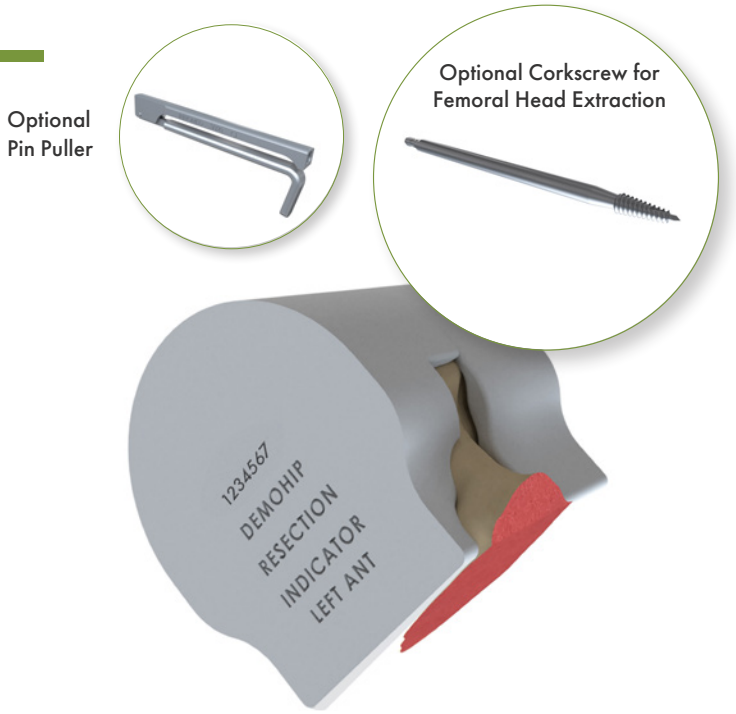
F-1P Posterior iJig®

6 Place two short 3 mm headless pins through the two divergent holes in the iJig®. The pins will lock the iJig® in place during resection of the femoral head. Verify that the iJig® is fully seated against the femoral neck.

TECHNIQUE TIPS

The F1 iJig® will not slide off over the pins, since they are divergent to keep it locked in place. At least one of the pins must be removed prior to removing the F1 iJig® after the resection is complete.





7 Using an oscillating or reciprocating saw, perform a femoral neck osteotomy by first cutting adjacent to the distal surface of the F1 iJig®. Perform a vertical

TECHNIQUE TIPS

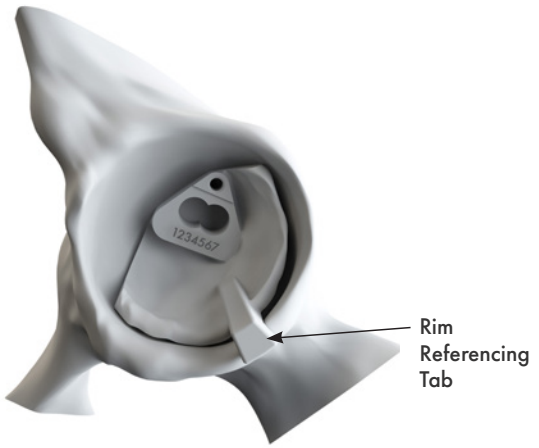
When making the neck resection, align the saw blade axis parallel to the inferior pin closest to the saw blade and flush against the bottom of the F1 iJig®.

8 Using the pin puller, remove the pins from the iJig® and remove the iJig® from the femoral neck. Remove the femoral head and neck from the incision. A corkscrew instrument is available to assist with femoral head removal. Once the femoral head is removed, place it into the Anterior and Posterior Resection Indicator Models and confirm intended neck resection in all planes. It is important the neck resection be flush with the face of the indicator for collared stems. A slightly divergent neck resection is allowable for non-collared stems.

TECHNIQUE TIPS

- If you wish to confirm head size, measure the diameter of the resected head with calipers. The measured head diameter should be approximately 4mm smaller than the Cup size on the iView®.
- Conformis' femoral broaches are female which allows for a femur first technique. If you prefer to perform femoral preparation next, advance to Step 4 on page 17.

Step 2 ACETABULAR PREPARATION



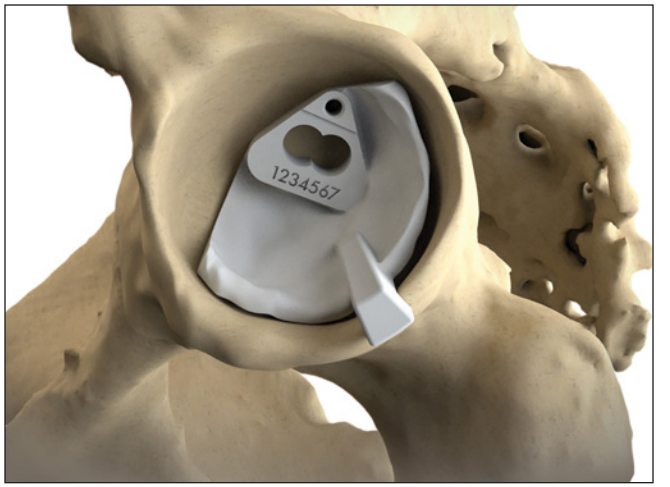
A-1 iJig® in Acetabulum
Bone Model

9 Place the A1 iJig® in the acetabular bone model to identify the location of the iJig® within the anatomy. Remove labrum, cartilage, and soft tissue as needed to ensure the iJig® seats directly on subchondral bone. Do not remove osteophytes from the rim of the acetabulum, as they are accounted for in the contour of the patient specific iJig® and may provide additional stability.

TECHNIQUE TIPS

- A full basket reamer (4mm smaller than final cup diameter) may be used with the straight reamer and ratcheting handles to manually scrape out cartilage from the acetabulum.
- In the case Conformis is unable to design acetabular jigs, the acetabulum should be prepared with standard full basket reamers using standard reaming protocol. The final reamer should be 2mm smaller than the cup size.
- In the case the surgeon does not utilize the acetabular jigs, proceed to Step 18.

CAUTION: If used aggressively, the full hemispherical acetabular reamer may invalidate the surgical plan. The ability to achieve the planned leg length and offset as well as acetabular cup position and orientation may be impacted.

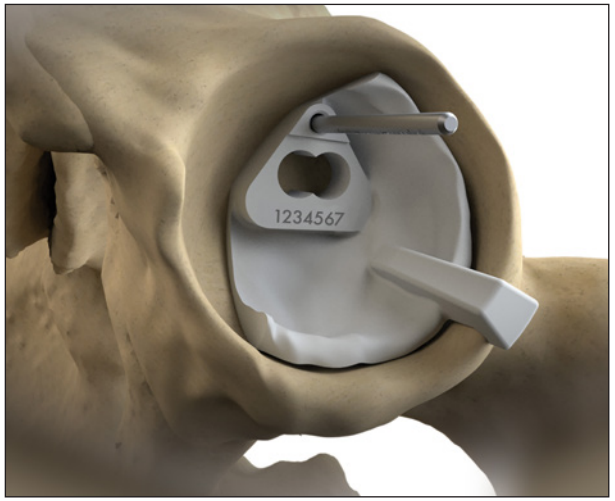


A-1 iJig® in Acetabulum

10 Place the A1 iJig® into the opening of the acetabulum. The rim-referencing tab of the iJig® will be oriented to reference the posterior edge of the rim by the transverse acetabular ligament. Insert the iJig® into the acetabulum and orient the iJig® within the socket until it has reached stable positioning. When in the correct position, the notch on the inferior edge should fit flush against acetabular edge.

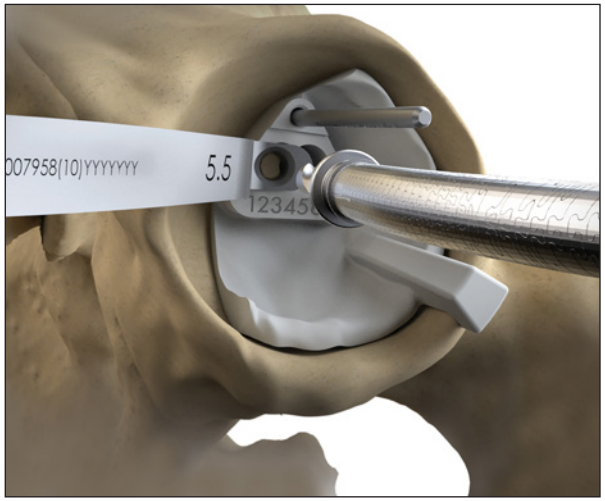
TECHNIQUE TIPS

- First place the A1 iJig® into the acetabular bone model. This gives a visual reference to placement of A1 in the patient's acetabulum. Bring the model close to the incision site for a visual confirmation of placement.
- Retention of osteophytes during placement of the A1 iJig® may provide additional stability as they are accounted for in the iJig® design.
- If osteophytes are removed from the rim prior to placement of the A1 iJig®, it will still seat at the correct location in the acetabulum.

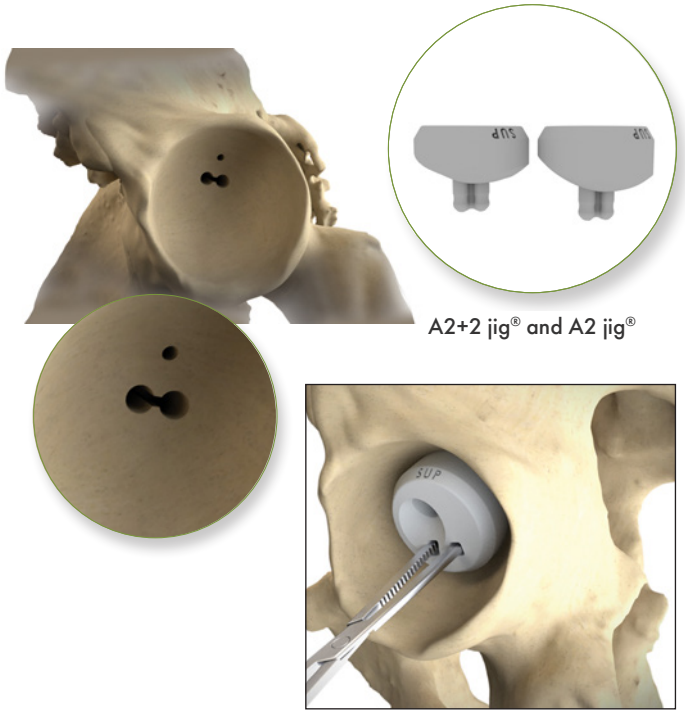


11 Use the short 3.5 mm flex drill and 3.5 mm end of the drill guide to drill through the smaller hole on the A1 iJig, and place a pin by hand to hold the A1 iJig® in place. The recommended depth of the hole from the top of the A1 iJig® as well as the depth of penetration into bone are stated on the surgical iView®. Use the depth gauge to assess whether the recommended drilling depth has been achieved.

CAUTION: Use caution to not drill through the medial wall of the pelvis.



12 Drill two pilot holes through the A1 iJig® using the 5.5 mm flexible drill bit and corresponding end of the double-ended drill guide. These two holes will be used for securing the pegs of the A2 iJig®. The A1 iJig® 5.5 mm holes have a built in depth stop.



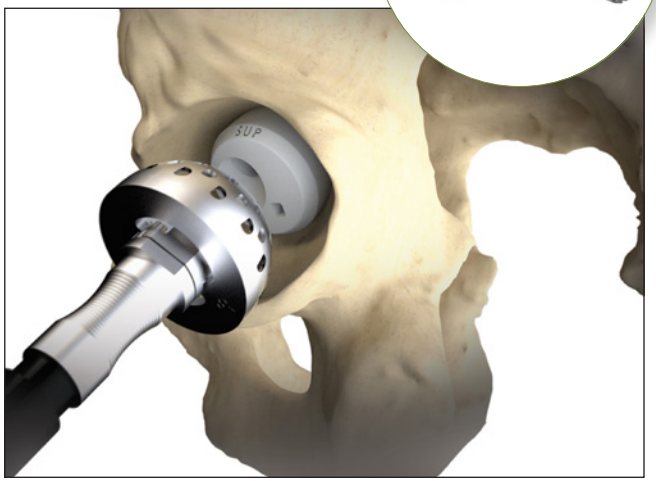
A2+2 jig® and A2 jig®

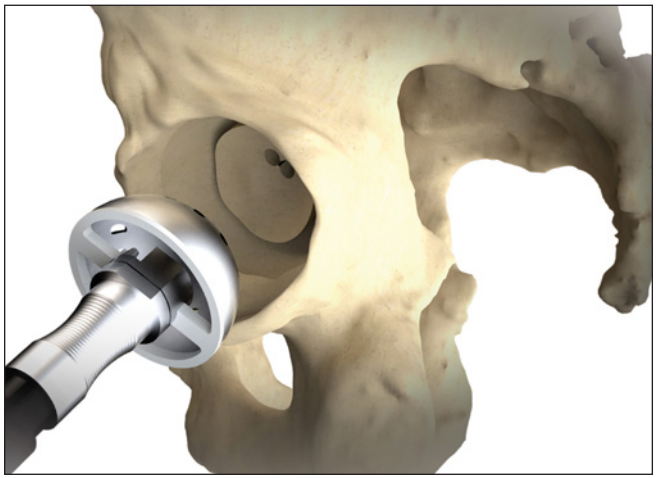
13 Remove the A1 iJig® and pin from the acetabulum. Inspect and ensure the bone bridge is removed between the 5.5mm drill holes. Choose one of the two A2 iJigs provided. One is designed to meet the plan (labeled "PLAN") for reamer depth, and the other (labeled "+2") deepens the reaming by an additional 2 mm. Insert the chosen A2 iJig® into the acetabulum, inserting the pegs on the back of the iJig® into the two drilled 5.5 mm holes. The two square holes on the iJig® can be grasped with a Kocher clamp to help aid with insertion. "SUP" is written on the superior side of the iJig® to help with proper alignment. Press to ensure the A2 iJig® is seated tightly and securely on the acetabulum floor. If desired, the A2 iJig® can be secured with a 3.5 mm screw using the 3.5 mm drill bit and drill guide.

TECHNIQUE TIP

Both A2 and A2+2 iJigs® reference bony anatomy within the acetabulum. Upon use of Stage 1 and Stage 2 reamers, the anatomical landmarks that help position these iJigs® will be removed. Do not use either A2 iJig® following this step, as this introduces the risk of over-reaming.

Optional Offset
Reamer Handle*





14 Because Conformis acetabular cups utilize a 2mm press fit, the appropriate reamer size is 2 mm smaller than the cup. Insert the Stage 1 acetabular reamer over the A2 iJig®. Ream until the handle is seated on top of the A2 iJig®. The A2 iJig® acts as a depth stop for the reamer.

Note: There is no need for consecutive size reaming. This system reams directly to size.

15 Remove the A2 iJig® using a Kocher or similar instrument.

16 Using the provided Stage 2 reamer that is 2 mm smaller than the planned cup size, ream away the remaining central bone that was previously covered by the A2 iJig® on the acetabular floor. The Stage 2 reaming process may leave loose tissue obscuring the triangular hole pattern. After reaming, ensure that all three holes in the triangular pattern are visible.

Note: After reaming is completed with the Stage 2 reamer, do not use the A2 iJig® again to guide the ream. The referencing will have been removed which results in a risk of over-reaming.

TECHNIQUE TIPS

- If the surgeon feels the need to medialize the cup further, standard reamers can be used.
- A full hemispherical acetabular reamer is available for use if the surgeon's medical judgment deems appropriate. However, the full hemispherical acetabular reamer is NOT intended for use with the acetabular iJigs®. The final reamer size should be 2 mm smaller than the planned cup size.

CAUTION: Use of the full hemispherical acetabular reamer may invalidate the surgical plan. The ability to achieve the planned leg length and offset as well as acetabular cup position and orientation may be impacted.

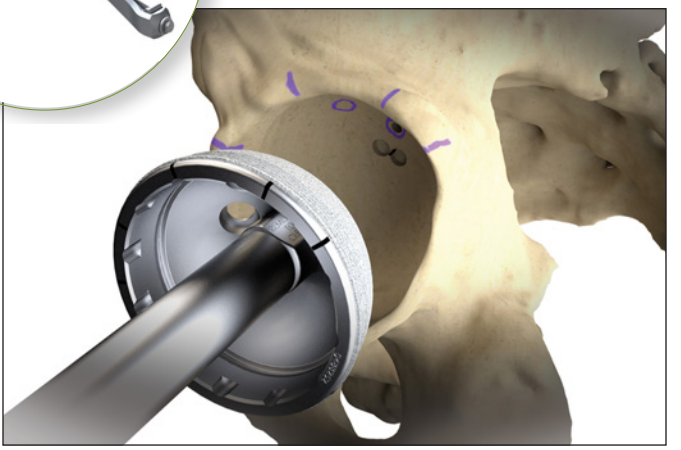
*For more information on this instrument please reference MK-03338-AA ENZTEC OFFSET REAMER DRIVER TECHNICAL GUIDE

Step 3 IMPLANT ACETABULAR CUP

17 The A3 cup-placement-iJig® sits in the two 5.5mm holes in the acetabulum, showing the final placement of the acetabular cup according to the surgical plan. This iJig® is intentionally undersized. Similar to the A1 iJig®, the A3 iJig® features a tab to reference the posterior rim of the notch. This iJig® has indentations around the rim that align with the laser marks around the rim of the cup. Use a marker or cautery device to mark the acetabulum at the aforementioned indentations. Additionally, there are 3 central holes representing the screw holes in the cup. The A3 iJig® provides the options to mark each screw hole position on the acetabular floor, or to outline the rim of the A3 iJig® on the acetabulum. These markings will help convey the planned position of the acetabular cup during implantation. Once position is marked, remove the iJig® and proceed with the cup insertion step.

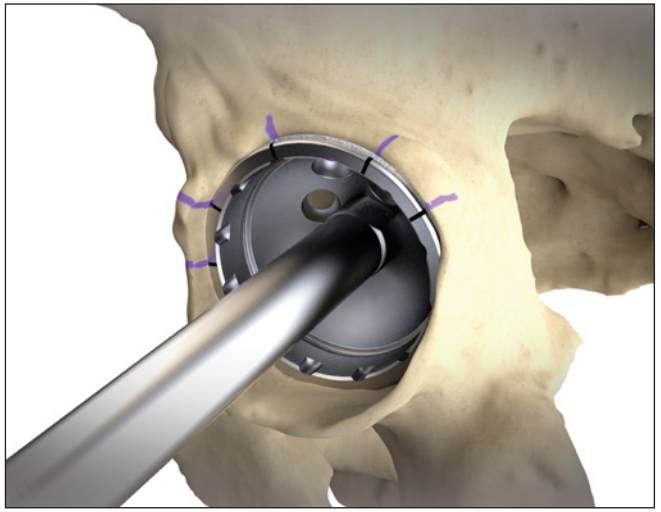
18 Attach the cup impactor tip onto the distal end of the cup impactor. Thread the cup impactor into the acetabular cup.
An optional offset cup impactor is also available.

Optional Offset
Cup Impactor*



19 Place the cup in the prepared acetabulum and rotate it until the laser marks on the rim of the cup are aligned with the acetabular rim and hole markings made in step 17.

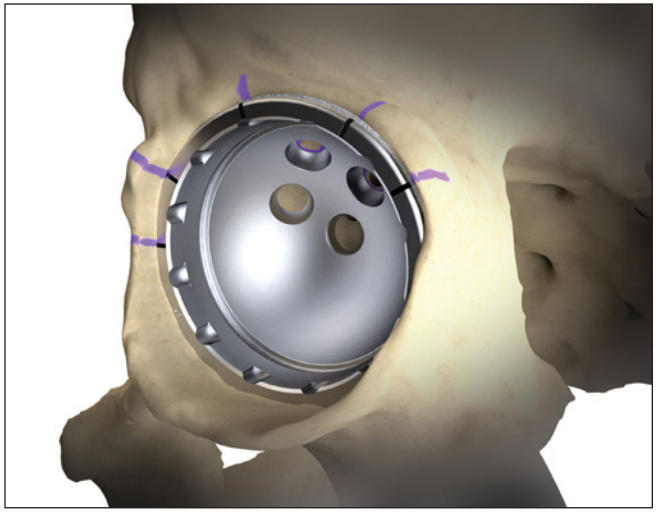
*For more information on this instrument please reference MK-03339-AA ENZTEC CLASSIC OFFSET CUP IMPACTOR+ TECHNICAL GUIDE



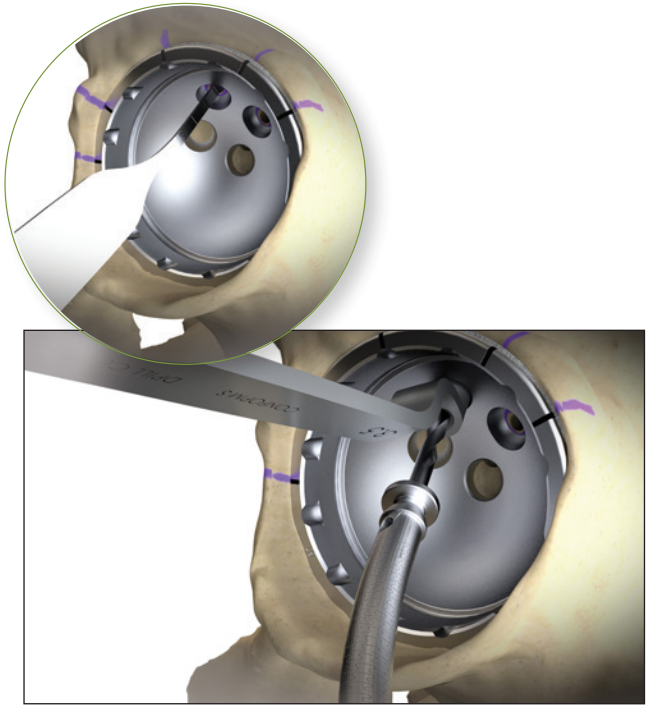
20 Impact with firm mallet blows until the cup is fully seated.

TECHNIQUE TIP

- Use the acetabular bone model with the cup simulator iJig® to visually confirm the cup placement in relation to the acetabular rim. This can be achieved by placing the iJig model assembly next to the incision to verify inclination and anteversion of the pre-operative plan.

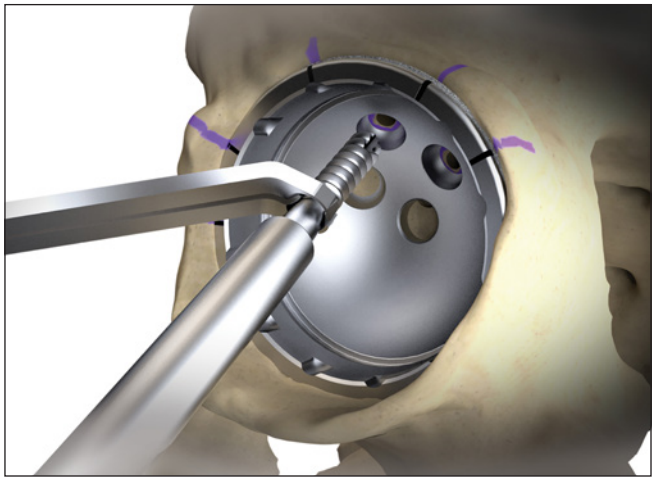


21 Unthread the impactor from the cup and remove it from the incision.



22 If use of screws is preferred, use the 3.5 mm flexible drill bit and drill guide (the short 3.5 mm drill for screws ≤ 25 mm, use the long 3.5 mm drill for screws > 25 mm length), to prepare pilot holes for the acetabular screws, using caution to not drill through the opposite cortex of the ilium. Use the depth gauge to measure the depth of each hole.

Note: The iView® plans for the two most posterior screw holes. Usage of the most anterior screw hole is not guided or planned and may be used at the surgeon's discretion.



23 Use the flexible or straight screwdriver, and screw holding forceps to place screws of appropriate lengths according to each measured hole depth, and drive until tight.

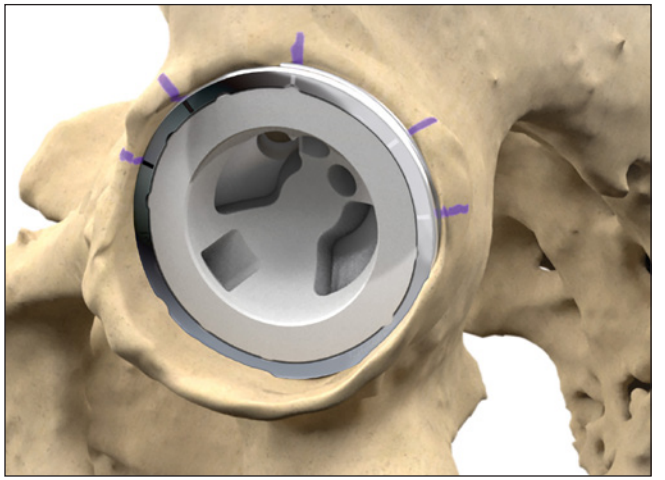
Note: Ensure that all screws are fully seated and are not protruding into the cup, as this could prevent the liner from locking.

- 6.5mm diameter, self-tapping cortical bone screws
- Available in lengths of 15-50mm in 5mm increments
- Drive feature: 3.5mm hex

TECHNIQUE TIP

- The screw lengths communicated in the iView® represent the longest screw that could be pre-operatively confirmed to safely sit within the ilium.

Caution: The planned positions and recommended maximum lengths of the acetabular fixation screws are determined based on the planned location and orientation of the cup. Repositioning or unintentional mis-positioning of the cup could alter the planned screw positions and the recommended maximum screw lengths provided may no longer reflect a safe length. Confirm intra-operatively, using standard surgical technique, that the acetabular fixation screws used reflect a safe length.

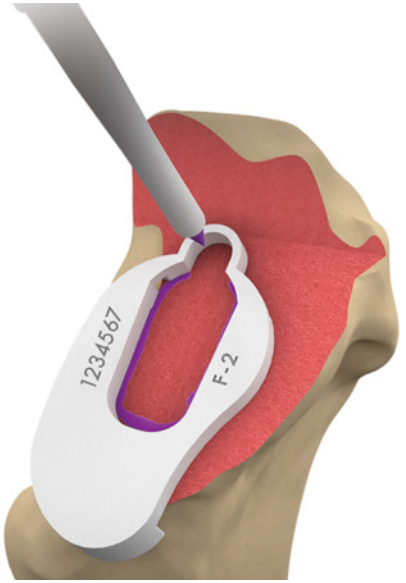


24 Place the trial liner in the acetabular cup. Reference Liner Compatibility page 28.

TECHNIQUE TIPS

- Remove surrounding excess osteophytes to minimize impingement risks.

Step 4 FEMORAL PREPARATION

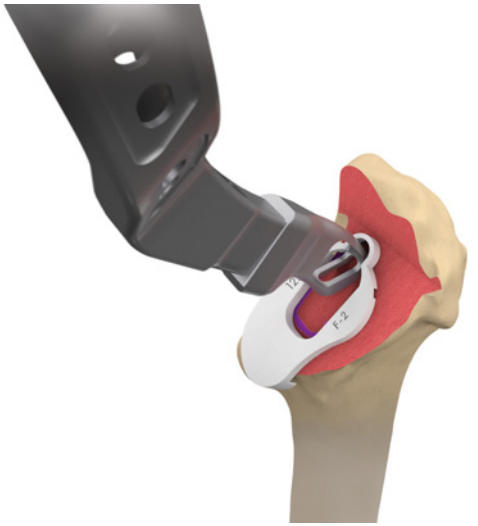


25 Place the F2 iJig® flush against the resected neck surface and against the remaining medial neck. The medial wall of the F2 iJig® overhangs the calcar and is contoured to match the patient's bone. Rotate the iJig® anteriorly and posteriorly until it is stable against the medial neck. It may be necessary to remove additional bone from the greater trochanter to allow proper iJig® placement.

Note: The most lateral portion of the F2 iJig® cutout indicates the planned lateral shoulder of the implant.

TECHNIQUE TIP

- Use a marking pen to draw the inner dimensions of the F2 iJig® onto the bone surface to be used as a reference.

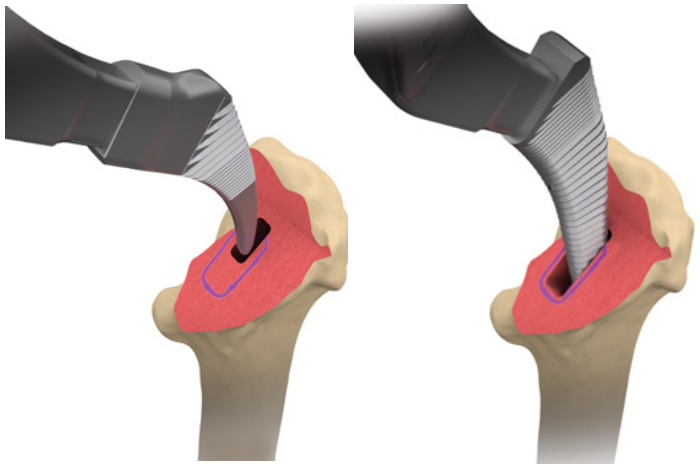


26 Use the box osteotome for initial entry into the canal where indicated by the lateral aspect of the F2 iJig®. This iJig® communicates placement of the femoral stem into the planned location and orientation. The medial side of the box osteotome and broaches should be assembled in alignment with the lever of the broach handles. Straight or Offset Broach Handles available.

Remove the F2 iJig® and set aside.

Offset Broach Handle

27 Use the canal finder and femoral rasp to further open the femoral canal, maintaining a neutral alignment with the canal axis to avoid a varus or valgus trajectory.



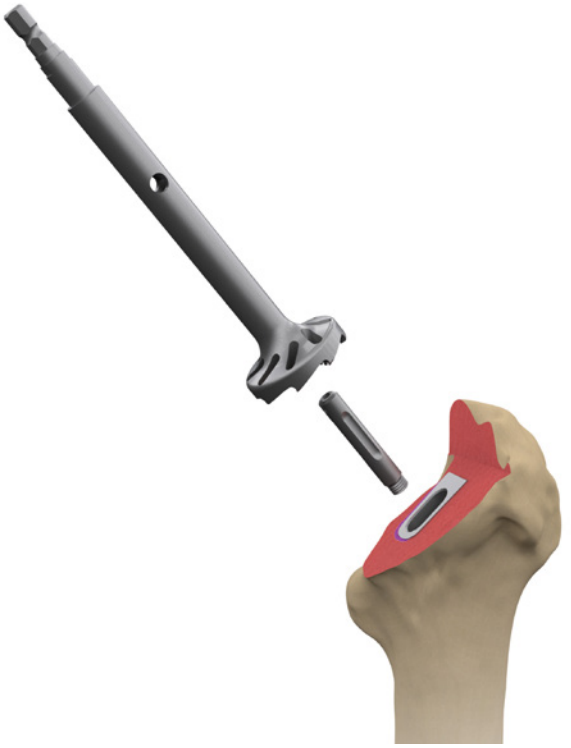
Starter broach Broach

28 Beginning with the smallest broach, progressively broach the femoral canal to the size determined during pre-operative planning. The medial side of the broach assembles parallel to the lever on the broach handle. Both straight or offset broach handles are available.

TECHNIQUE TIP

- The face of the broach corresponds to the resection level on the surgical plan; therefore, the broach should be impacted until the face is flush with the resection level.

29 The F2 iJig® can be reinserted and used to assess stem version after broaching. The lateral portion of the F2 iJig® can be snapped off for this step. When the broach is fully seated, the broach face will be flush with the resection plane.



30 If desired, a calcar planer is supplied to level the bone around the bone-broach interface. Screw the calcar planer post into the inserted broach. Place the calcar planer over the post and plane until the desired bone interface is obtained.

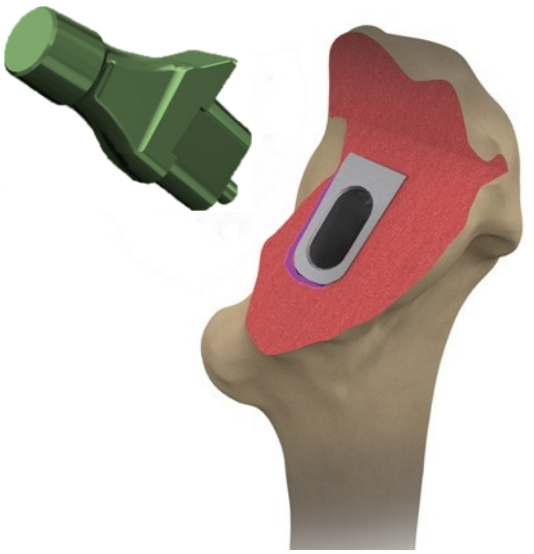
Drop-in calcar planer post also available.

Note: if you countersink the broach below the planned neck resection level and plane down, this will effectively shorten the leg by the depth of countersinking.

31 Leave the final broach size corresponding to the implant size in the femoral canal.

Step 5 TRIAL REDUCTION

32 If not already in place, position the trial liner into the cup.



33 Place the appropriate Trial Neck into the broach. For a patient specific, ACTERA™ HipRx™ plan, utilize the iJig® trial neck provided in the patient specific iJig® kit. An audible click or snap will be felt when in place.

For ACTERA™ Match plans, utilize the appropriately grouped and offset (STD / HIGH) trial neck provided in the reusable instrument tray.

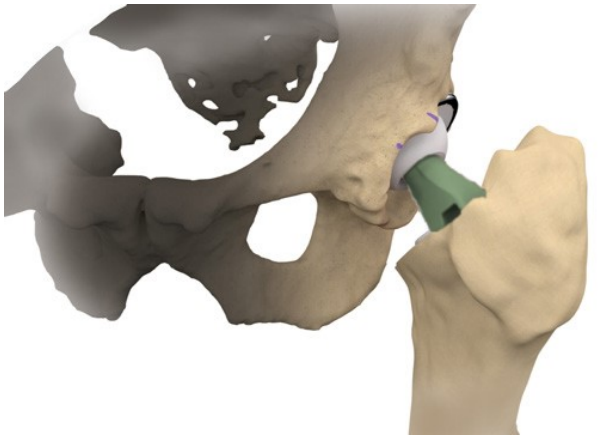
ACTERA™ Trial Neck Groupings:

A: Stem Size 0-3; STD & High Offset
B: Stem Size 4-6; STD & High Offset
C: Stem Size 7-9; STD & High Offset
D: Stem Size 10-12; STD & High Offset

Note: Trial Necks feature a small peg that sits in the threaded hole of the broach. This threaded hole is off-center so it will fit in only one direction.

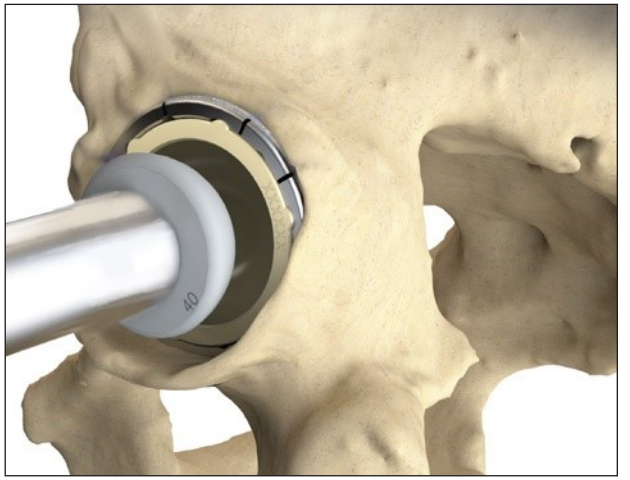
34 Place selected Trial Head onto the taper of the Trial Neck.

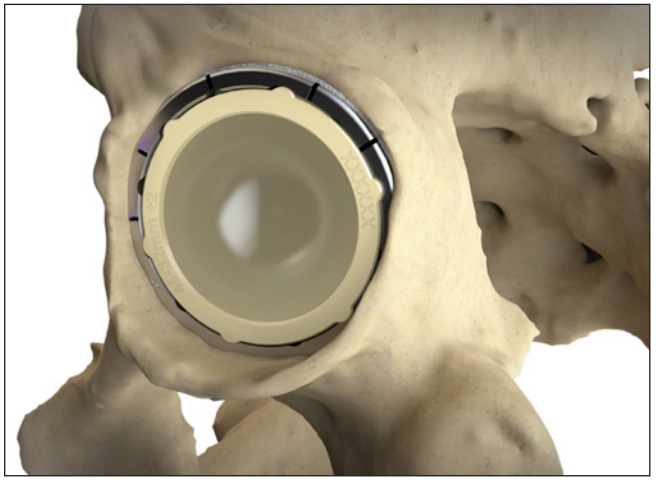
35 Reduce the hip.



36 Check leg length and stability through a full range of motion.

Step 6 FINAL IMPLANTATION



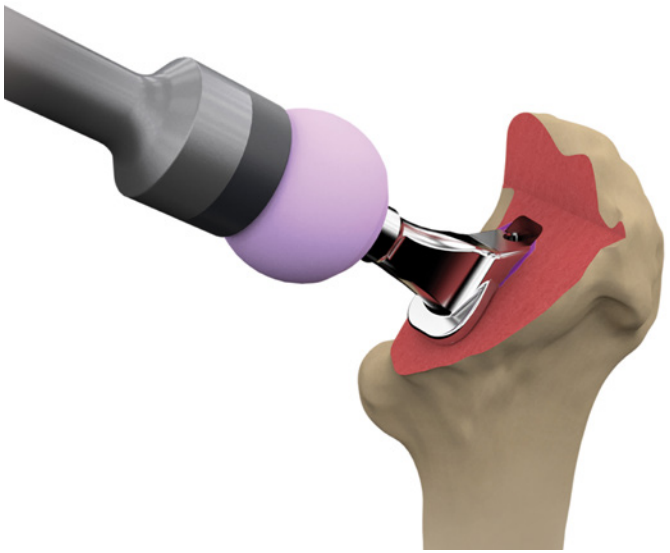


37 Remove all trials and the broach from the femoral canal.

38 Place the acetabular liner into the cup with the anti-rotation scallops aligned in the cup. Care must be taken that there is no soft tissue between the liner and cup, as this may prevent the liner from seating properly and locking into the cup. Seat it using the appropriately sized liner impactor tip with firm mallet blows in the direction of cup axis.

39 Confirm that the face of the liner is flush with the face of the cup to ensure that it is fully seated.

Note: + 0 and Standard Offset liners will sit flush with the face of the cup.
Lateralized liners will protrude beyond the edge of the cup. Reference Liner Compatibility and Thicknesses on pages 28 & 29 for more information.



Femoral Heads (12/14 taper)

BIOLOX® Delta Ceramic	CoCr Alloy
	
Zirconia-toughened alumina (BIOLOX® ***delta***) ceramic	Cobalt-Chrome Alloy: Co-28Cr-6Mo

Diameter	Offset				
	Short	Medium	Long	Extra Long	
28	-3.5	0	3.5	7	ONLY AVAILABLE IN CoCr
32	-4	0	4	7	
36	-4	0	4	8	
40	-4	0	4	8	ONLY AVAILABLE IN CERAMIC

40 Manually place the stem into the broached femoral canal. Using either the straight or offset impactor handle, set the impactor into the lateral shoulder of the femoral stem and impact along the axis of the stem until it is fully seated. The coating should sit level with where the face of the last broach sat.

Straight and Offset Inserters available.

41 If desired, place the Trial Head onto the stem taper and confirm the range of motion and leg length with the final implants. Remove the Trial Head.

42 Clean the taper of all blood and fat. Place the femoral head on the stem taper. Seat the taper using the head impactor and firm mallet blows in the direction of the neck axis.

TECHNIQUE TIPS

- Ensure that all mating surfaces are free of soft tissue, clean and dry prior to placing the liner inside the cup and impacting the head onto the stem.
- Lower impaction forces used to seat the head on the stem taper may contribute to fretting corrosion of CoCr heads at the taper interface. Therefore, it is important to firmly impact the head onto the stem taper.

43 Reduce the hip and do a final check of stability, range of motion and leg length.

44 Close the incision.

IMPLANT REMOVAL (OPTIONAL)

Should the femoral stem implant need to be removed after initial implantation, two modular stem extractor assemblies are available for implant extraction. A Straight Adaptor can be threaded into the lateral shoulder of the implant (intended for use with a posterior approach) OR an Offset Loop Adaptor, for offset access
(intended for use with a direct anterior approach), can be wrapped around the femoral neck of the implant before sliding the smaller slot under the trunnion. A mallet or slotted weight can be used against the strike plate to extract the implant.

Note: Use of the offset loop adaptor with the Extraction Handle may cause damage to the trunnion of the femoral stem and should be considered for use only if the stem won't be re-implanted.

Optional Stem Extractor with:

Straight Adaptor

Loop Adaptor

SURGICAL TECHNIQUE

WITHOUT IJIGS®

The following surgical steps instruct how to use the standardized ACTERA™ hip system implants:

ACTERA™ PRO

Conformis' ordering option which includes, pre-operative surgical planning (iView®) to estimate standard implant sizing and positioning

ACTERA™

Conformis' ordering option in which standard 2D templating is utilized at the surgeons discretion to estimate standard implant sizing and positioning

Exposure and Neck Resection

1. Adequately expose the acetabulum and proximal femur.

2. Using an oscillating or reciprocating saw, perform a femoral neck osteotomy. The recommended angle of resection is 45°. The resection of the neck can be performed with one or two cuts, depending on surgeon preference.

3. Remove the femoral head and neck from the incision.

Acetabular Preparation and Implantation

4. Make sure that the acetabulum is fully exposed and remove soft tissue to visualize the acetabular rim. Using standard full hemispherical reamers, progressively ream the acetabulum until bleeding subchondral bone is reached and the templated position has been achieved; progress until the reaming size is 2 mm smaller than the planned hemispherical cup size. Straight or Offset Acetabular Reamer Driver available. For instructions on how to assemble the Offset Reamer Driver please reference MK-03338.

5. The planned acetabular cup implant is then inserted with cup impactor. Use of C-Arm imaging can be used to monitor and adjust position and progressive seating of the prosthesis. Straight or Offset Cup Impactor available. For instructions on how to assemble the Offset Cup Impactor please reference MK-03339.

6. Following final seating of the acetabular shell, optional cancellous screw fixation may be accomplished, if desired. To insert screws, the drill and drill guide are used to drill single or multiple drill holes through the shell screw holes. The depth gauge is provided to determine the appropriate length of screw for each hole. Ensure each screw is fully seated with the screw heads counter sunk below the level of the inner surface of the shell implant to prevent impingement of the liner and ensure optimal liner seating within the shell implant. Sterile, single-use liner trials are available for use at surgeons request.

7. Select the appropriate acetabular liner for the Acetabular shell and planned head diameter. Ensure the inside surface of the implant shell is dry and cleared of any soft tissue debris and position the liner in the shell by hand. The liner is impacted by threading the liner impactor head onto the cup impactor. Seat the liner using the liner impactor with firm mallet blows in the direction of cup axis.

Femoral Preparation and Implantation

8. Use the box osteotome for initial entry into the canal in a posterolateral direction.
Use the canal finder to further open the femoral canal, maintaining a neutral alignment with the canal axis to avoid a varus or valgus trajectory. Optional use of the Femoral Rasp or Starter Broach may assist with preparing the femoral canal.

9. Beginning with the smallest broach, use the broach handle of choice to progressively broach the femoral canal until stability is obtained, which should agree to the size determined during pre-operative planning.

10. Leave the final broach size corresponding to the implant size in the femoral canal. If desired, use the calcar planar to plane the bone flush to the broach face.

11. Using the final broach, the surgeon has the option to trial the final construct with the desired trial neck and a trial femoral head. Place the trial neck into the broach and the trial head on the trial neck taper and reduce. Perform range of motion (ROM) and leg length measurements. Denote the selected neck offset, and the selected head size and length.

Using the markings on the trial neck, verify that the appropriate trial neck grouping is being used:

A: Stem Size 0-3; STD & High Offset B: Stem Size 4-6; STD & High Offset C: Stem Size 7-9; STD & High Offset D: Stem Size 10-12; STD & High Offset

12. Remove the broach from the femoral canal.

13. Manually place the stem into the broached femoral canal. Set the impactor into the lateral shoulder of the femoral stem and impact along the axis of the stem until it stops or desired level is reached.

Final Trialing

14. Place the trial head onto the stem taper and reduce. Perform range of motion (ROM) and leg length measurements. Denote selected head size and length.

Head Insertion

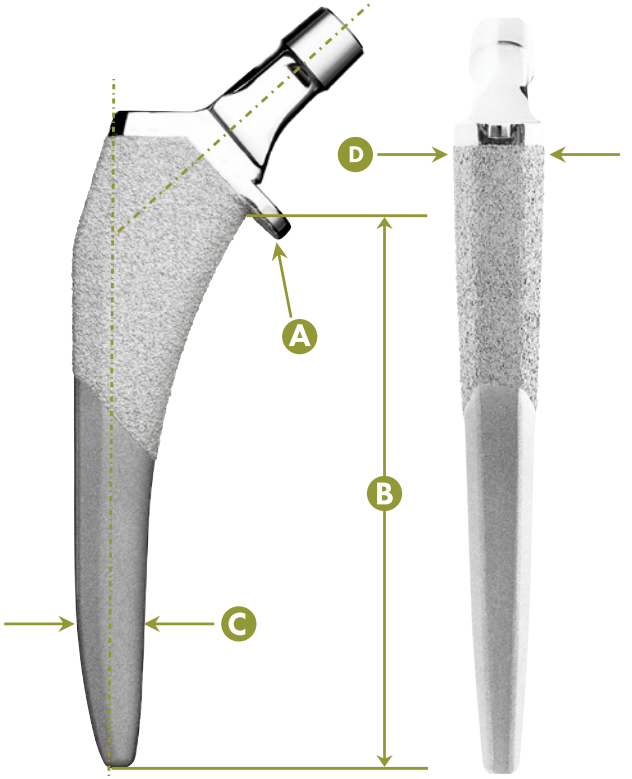
15. For final head insertion, clean and dry the stem taper carefully. Place the femoral head onto the taper and lightly tap it (especially if a ceramic head is used) using the head impactor. Ensure bearing surfaces are clean and finally reduce the hip.

IMPLANT SPECIFICATIONS AND INSTRUMENT TRAY LAYOUTS

ACTERA™ Specifications

Available in the following standardized options:

- 132° neck angle
- Neck lengths progressively increase with stem size
- Direct lateralization:
  - 6mm of direct lateralization offered with sizes 0–3 high offset options
- 8mm of direct lateralization with sizes 4–12 high offset options



Stem Dimensions

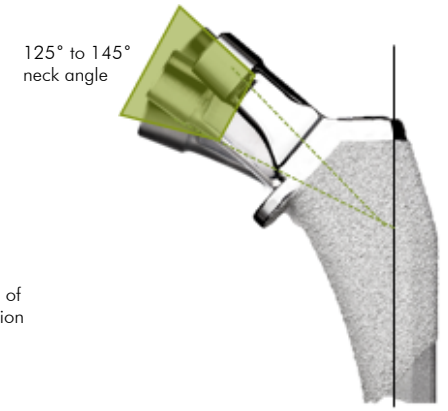
1mm added per size at A/P shoulder

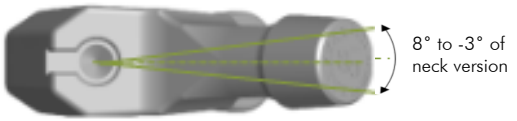
Size	A Collar Length	B Medial Stem Length	C Distal Width	D Proximal A/P Width at Shoulder **
0	7mm	95	8.0	12
1		97	8.5	13
2		99	9.5	14
3		101	10.5	15
4	8.5mm	103	11.0	16
5		105	12.0	17
6		107	13.0	18
7		109	13.5	19
8		111	14.5	20
9		113	15.5	21
10	10mm	115	16.5	22
11		117	17.5	23
12		119	18.0	24

All measurements in mm unless otherwise noted.
*Measured 25mm from distal tip **Includes coating thickness

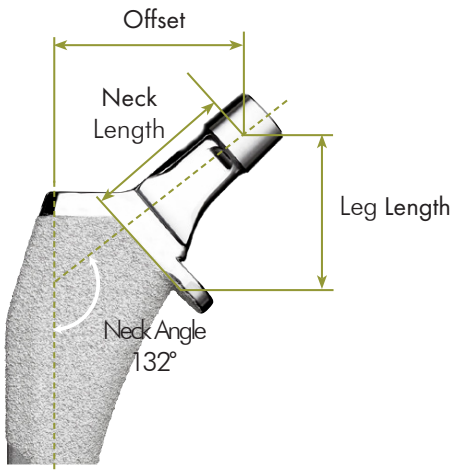
HipRx™ Design Range:

- 125° to 145° neck angle
- 29mm to 49mm neck length (progressive by size)
- 8° to -3° of neck version





Head Center Adjustment Chart



Size	Offset	Neck Length w/ +0 head	Offset				Leg Length			
			-4	0	+4	+8	-4	0	+4	+8
0	STANDARD	30	31.8	34.8	37.8	40.8	25.2	27.9	30.5	33.2
	HIGH	34.3	37.8	40.8	43.8	46.8				
1	STANDARD	30	32.6	35.6	38.5	41.5	25.2	27.9	30.5	33.2
	HIGH	34.3	38.6	41.6	44.5	47.5				
2	STANDARD	30	33.3	36.3	39.3	42.3	25.2	27.9	30.5	33.2
	HIGH	34.3	39.3	42.3	45.3	48.3				
3	STANDARD	30	33.3	36.3	39.3	42.2	25.9	28.6	31.2	33.9
	HIGH	34.3	39.3	42.3	45.3	48.2				
4	STANDARD	33	35.7	38.6	41.6	44.6	28.6	31.3	33.9	36.6
	HIGH	38.7	43.7	46.6	49.6	52.6				
5	STANDARD	33	36.4	39.4	42.4	45.3	28.6	31.3	33.9	36.6
	HIGH	38.7	44.4	47.4	50.4	53.3				
6	STANDARD	33	37.2	40.1	43.1	46.1	28.6	31.3	33.9	36.6
	HIGH	38.7	45.2	48.1	51.1	54.1				
7	STANDARD	36	39.4	42.4	45.4	48.3	31.3	34.0	36.7	39.3
	HIGH	41.7	47.4	50.4	53.4	56.3				
8	STANDARD	36	40.1	43.1	46.0	49.0	31.3	34.0	36.7	39.3
	HIGH	41.7	48.1	51.1	54.0	57.0				
9	STANDARD	36	40.7	43.7	46.7	49.6	31.3	34.0	36.7	39.3
	HIGH	41.7	48.7	51.7	54.7	57.6				
10	STANDARD	39	43.2	46.1	49.1	52.1	33.7	36.3	39.0	41.7
	HIGH	44.7	51.2	54.1	57.1	60.1				
11	STANDARD	39	43.8	46.7	49.7	52.7	33.7	36.3	39.0	41.7
	HIGH	44.7	51.8	54.7	57.7	60.7				
12	STANDARD	39	44.3	47.3	50.3	53.2	33.7	36.3	39.0	41.7
	HIGH	44.7	52.3	55.3	58.3	61.2				

CORDERA™ iPoly XE® Liner Compatibility

Neutral:
Available in sizes +0, standard (STD) and lateralized offsets.

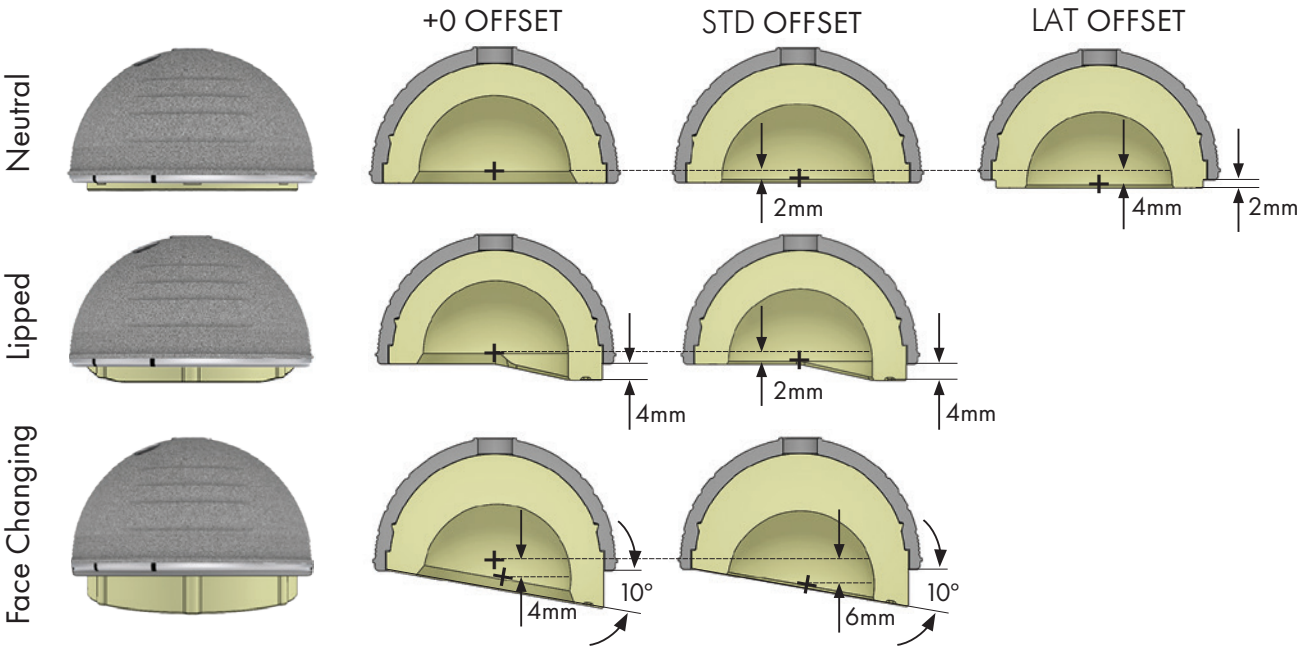
Lipped (4mm):
Available in +0 and STD offsets.

Face Changing (10 degree):
includes 4mm of additional lateralization compared to its neutral and lipped counterparts.

Liner Configurations										
			+0 Offset			STD Offset			Lateralized Offset	Head OD
Cup Size	Group	Liner ID	Neutral	Lipped	Face Changing	Neutral	Lipped	Face Changing	Neutral	
46-49	B	28	●	●	●					28
		32				●	●	●	●	32
50-53	C	32	●	●	●					32
		36				●	●	●	●	36
54-57	D	36				●	●	●	●	36
		40				●	●	●	●	40
58-63	E	36				●	●	●	●	36
		40				●	●	●	●	40
64-66	F	36				●	●	●	●	36
		40				●	●	●	●	40

Femoral Heads (12/14 taper)		Diameter	Offset				
BIOLOX® Delta Ceramic	CoCr Alloy		Short	Medium	Long	Extra Long	
		28	-3.5	0	3.5	7	ONLY AVAILABLE IN CoCr
		32	-4	0	4	7	
		36	-4	0	4	8	
		40	-4	0	4	8	ONLY AVAILABLE IN CERAMIC
Zirconia-toughened alumina (BIOLOX® ***delta***) ceramic	Cobalt-Chrome Alloy: Co-28Cr-6Mo						

CORDERA™ iPoly XE® Liner Specifications



Liner Thickness

Cup Size		46-49			50-53			54-57			58-63			64-66		
Group		B			C			D			E			F		
Head		28	32		32	36		36			36			36		
Offset		0	2	4	0	2	4	–	2	4	–	2	4	–	2	4
Liner Thickness	45°	5.6	5	6.3	5.6	5	6.3	–	7	8.3	–	7	8.3	–	12	13.3
	Apex	5.6	5.6	7.6	5.6	5.6	7.6	–	7.6	9.6	–	7.6	9.6	–	12.6	14.6
Ceramic Only																
Head								40			40			40		
Offset								–	2	4	–	2	4	–	2	4
Liner Thickness	45°							–	5	6.3	–	7	8.3	–	10	11.3
	Apex							–	5.6	7.6	–	7.6	9.6	–	10.6	12.6

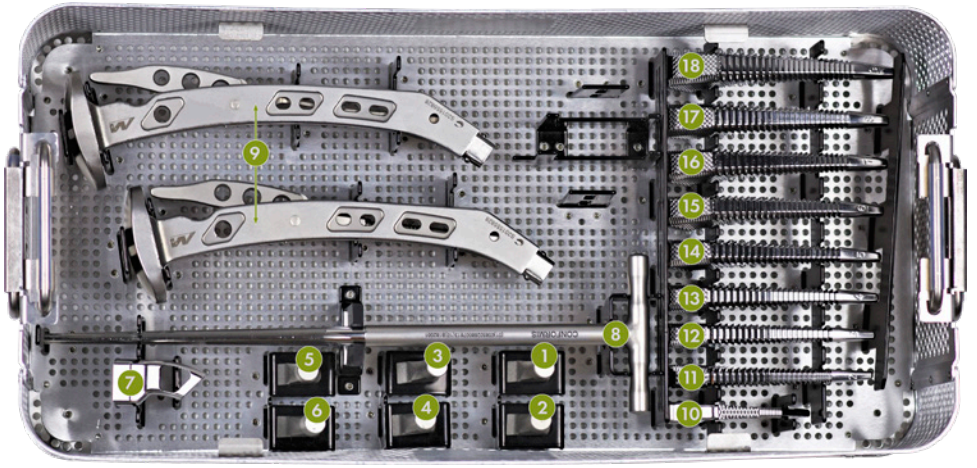
** Liners with +0 offsets are only available in Groups B & C to allow for 28 and 32 inner diameters*

ACTERA™ Femoral Instruments

X-RAY TEMPLATES 1080-669 – ACTERA™ Stem Acetates -115% Magnification Template

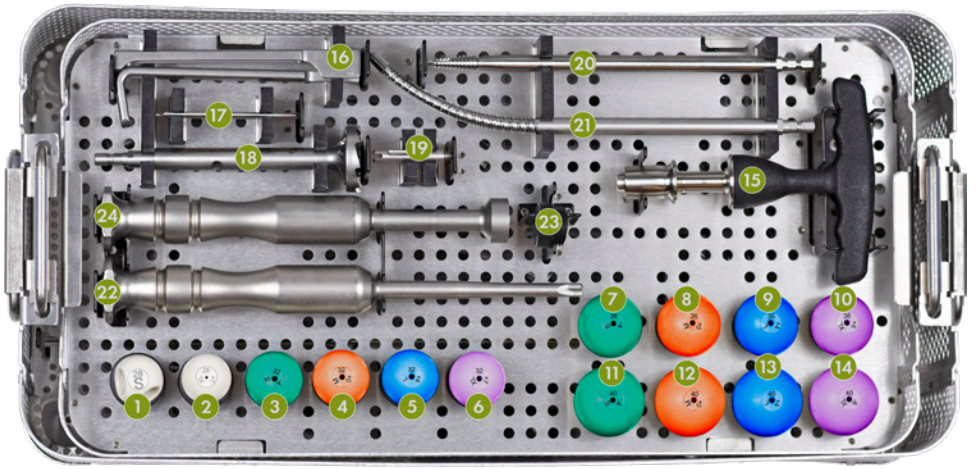
Digital templates available. Please contact your templating vendor.

ACTERA™ FEMORAL TRAY 1080-128 – BOTTOM TRAY



1. Trial Neck, Actera GRP A, Size 0-3 Standard
2. Trial Neck, Actera GRP A, Size 0-3 High Offset
3. Trial Neck, Actera GRP B, Size 4-6 Standard
4. Trial Neck, Actera GRP B, Size 4-6 High Offset
5. Trial Neck, Actera GRP C, Size 7-9 Standard
6. Trial Neck, Actera GRP C, Size 7-9 High Offset
7. Modular Box Osteotome
8. Femoral Tapered Reamer
9. Broach Handles, Neutral
10. Actera Starter Broach
11. Broach, Actera, Size 2
12. Broach, Actera, Size 3
13. Broach, Actera, Size 4
14. Broach, Actera, Size 5
15. Broach, Actera, Size 6
16. Broach, Actera, Size 7
17. Broach, Actera, Size 8
18. Broach, Actera, Size 9

ACTERA™ FEMORAL TRAY 1080-128 – TOP TRAY



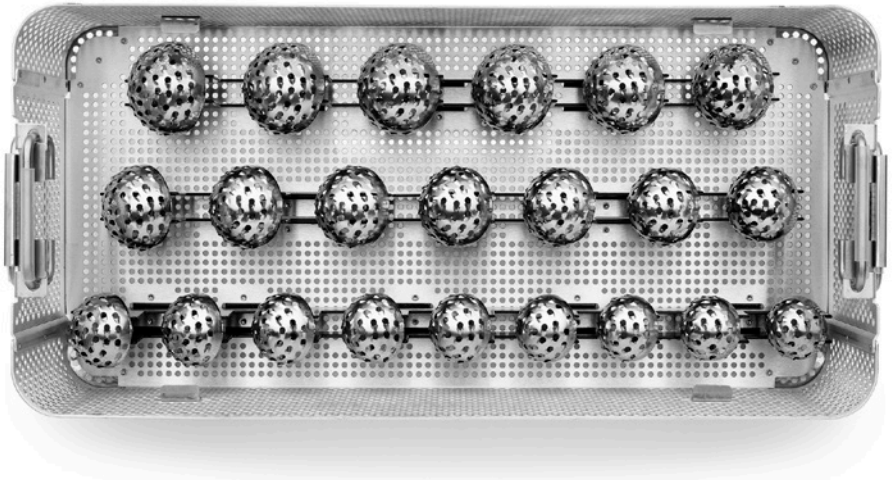
1. Ø28mm Universal
2. Ø28mm XL (+7)
3. Ø32mm SH (-4)
4. Ø32mm MD (0)
5. Ø32mm L (+4)
6. Ø32mm XL (+7)
7. Ø36mm SH (-4)
8. Ø36mm MD (0)
9. Ø36mm L (+4)
10. Ø36mm XL (+8)
11. Ø40mm SH (-4)
12. Ø40mm MD (0)
13. Ø40mm L (+4)
14. Ø40mm XL (+8)
15. T-Handle, Quick-Connect
16. Pin Puller
17. Steinmann Pins
18. Calcar Planer
19. Calcar Planer Adapter
20. Femoral Head Remover
21. Femoral Rasp, Quick-Connect
22. Femoral Stem Impactor
23. Femoral Head Impactor Tip
24. Femoral Head Impactor

CORDERA™ Acetabular Instruments

X-RAY TEMPLATES 1080-666 – CORDERA™ Cup Acetates -115% Magnification Template

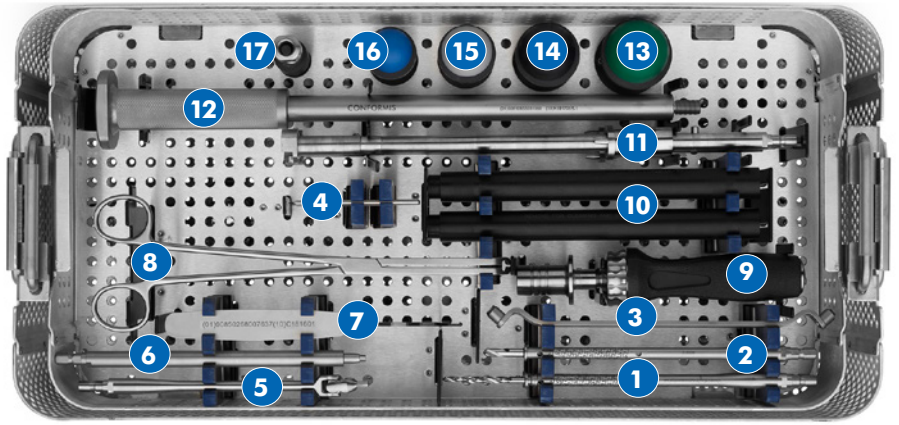
Digital templates available. Please contact your templating vendor.

CORDERA™ ACETABULAR, 1080-121 – Bottom tray



Full Basket Reamer Tray
Sizes 44–65

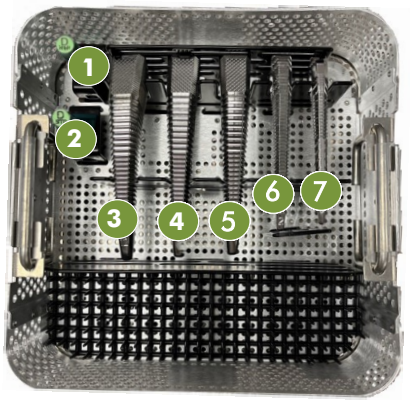
CORDERA™ ACETABULAR, 1080-121 – Top tray



1. Flexible Drills:
   3.5x35mm (above)
   3.5x50mm (below)
2. Flexible Drill, 5.5x25mm
3. Drill Guide — Double Ended
4. Steinmann Pins
5. U-Joint Driver
6. Rigid Driver
7. Depth Gauge
8. Screw Holding Forceps
9. Ratcheting Handle, Quick-Connect
10. Reamer Handle Sleeves
11. Reamer Handle Shaft
12. Cup Impactor
13. Liner Impactor, 40mm
14. Liner Impactor, 36mm
15. Liner Impactor, 32mm
16. Liner Impactor, 28mm
17. Cup Impactor Tip

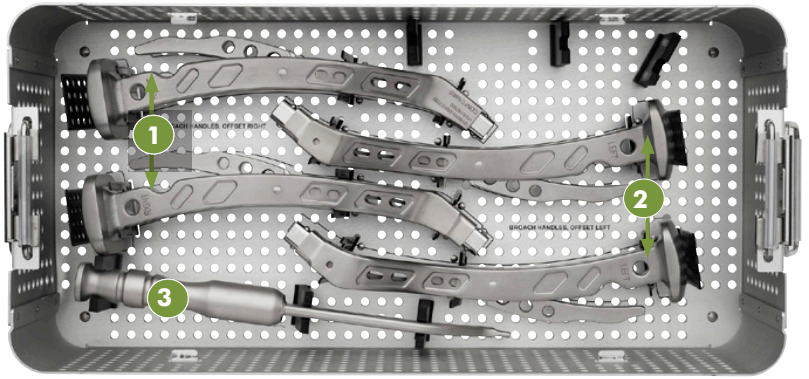
Optional Instruments

ACTERA OUTLIER FEMORAL 1080-129



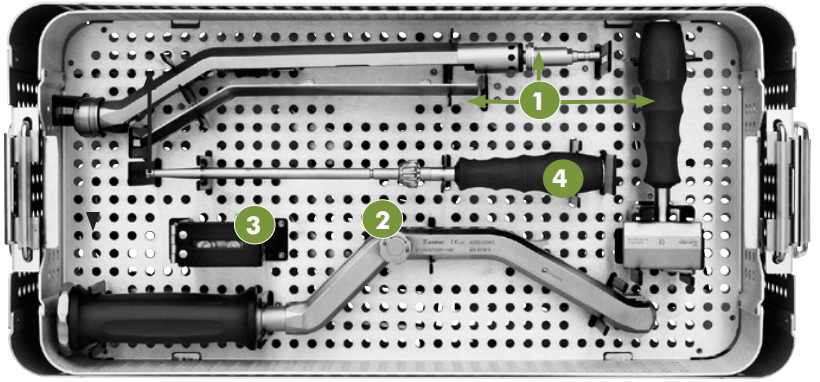
1. Trial Neck, Actera GRP D, Size 10-12 High
2. Trial Neck, Actera GRP D, Size 10-12 Standard
3. Broach, Actera, Size 12
4. Broach, Actera, Size 11
5. Broach, Actera, Size 10
6. Broach, Actera, Size 1
7. Broach, Actera, Size 0

OFFSET, 1080-114 – Bottom tray



1. Broach Handles, Offset Right
2. Broach Handles, Offset Left
3. Offset Stem Impactor

OFFSET, 1080-114 – Top tray



1. Offset Reamer Driver
2. Offset Cup Impactor
3. Offset Cup Impactor Trinket
4. Offset Cup Impactor Hex Driver

Intended Use

The Actera™ Hip System system may be designed from a patient's preoperative CT scan which must include certain necessary anatomic landmarks that are clearly identifiable. Total hip replacement using the ACTERA™ Hip System is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
- Treatment of non-displaced non-unions of the hip, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The ACTERA™ Hip System implants are intended for cementless fixation using an anterior, posterior or lateral surgical technique.

Warnings and Precautions

- Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
- Firmly seat the femoral head component to prevent loosening. Thoroughly clean and dry taper prior to attachment of the femoral head component to avoid crevice corrosion and improper seating.
- ACTERA™ Size 0 and Size 1 stems are only intended for patients weighing less than 170 pounds.
- See IFU on www.conformis.com/eifu for other warnings and precautions

Contraindications

The following conditions are contraindications for total hip replacement:

- Active or recent local or systemic infection.
- Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.
- Poor bone quality, such as osteoporosis, where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s).
- Charcot's or Paget's disease.
- Ceramic heads are contraindicated in revision surgery when the femoral stem is well fixed and is not being replaced.
- Poor quality femoral bone stock which may compromise the proximal fixation of the femoral stem.
- Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
- Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.
- Metal sensitivity

Magnetic Resonance (MR) Safety Information

The ACTERA™ Hip System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ACTERA™ Hip System in the MR environment is unknown. Scanning a patient who has a device may result in patient injury.

www.conformis.com

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Caution: Federal law restricts this device to sale by or on the order of a physician. Prior to use of a Conformis device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use. www.conformis.com/eifu.

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