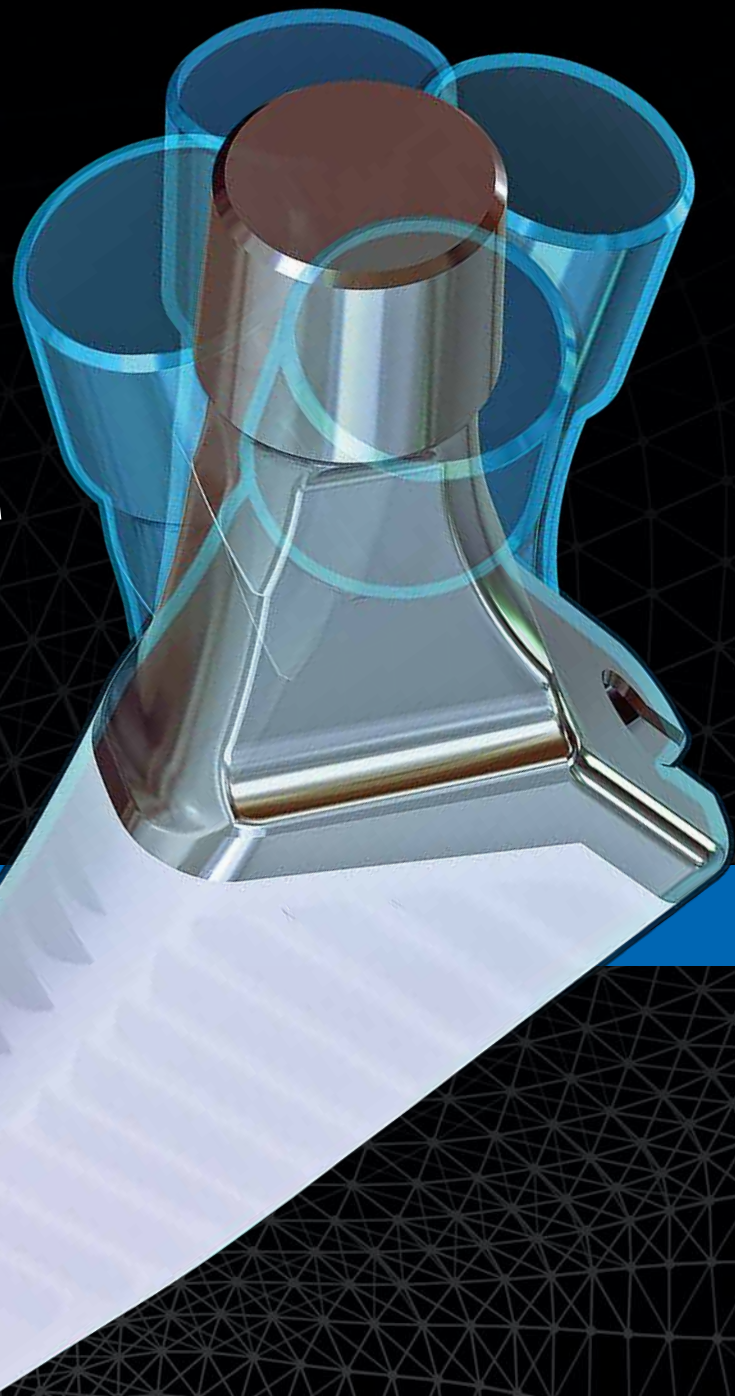
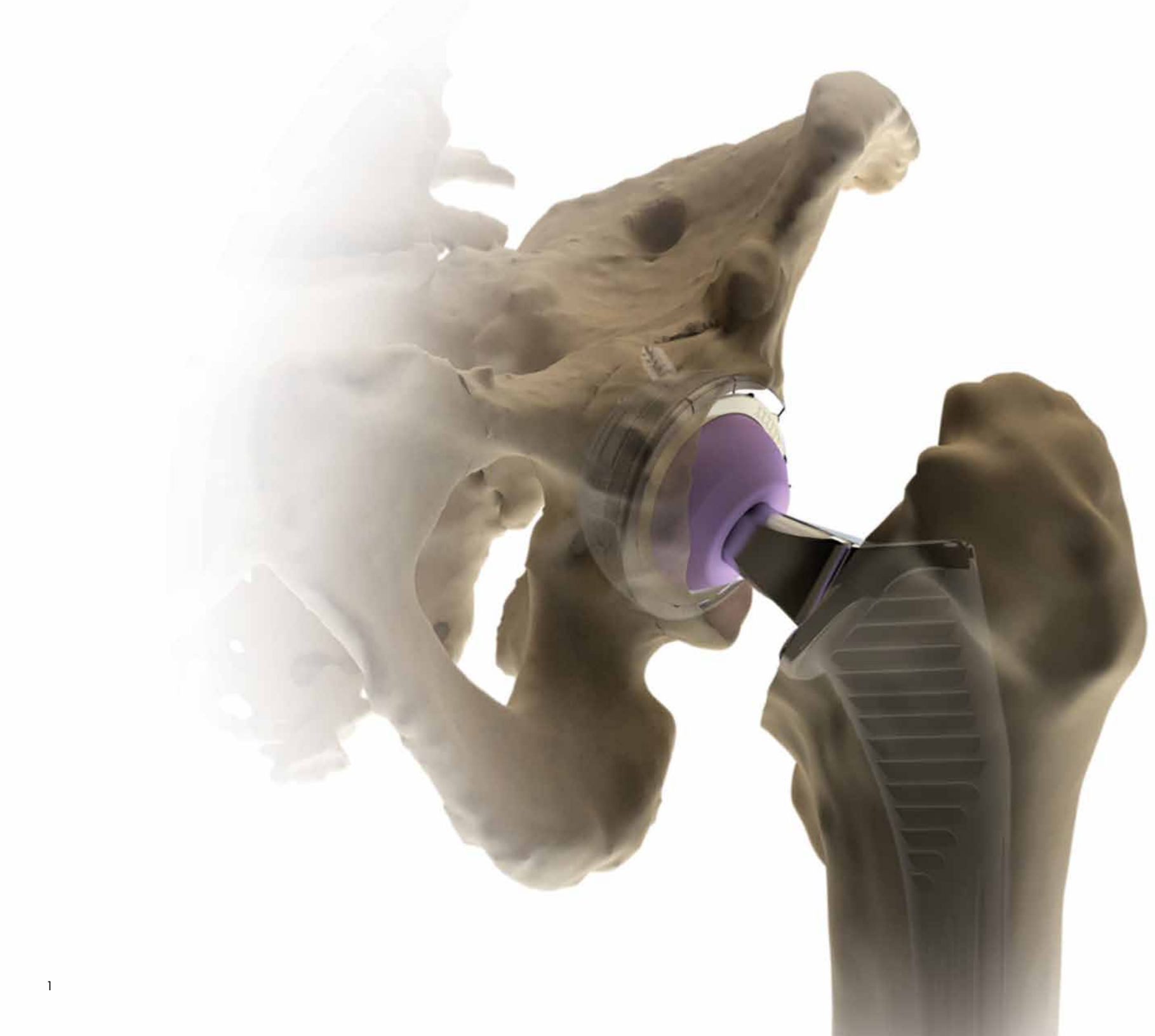
CONFORMIS®
FORM · FIT · FUNCTION

CORDERA™ Hip Rx™

SURGICAL TECHNIQUE GUIDE

Patient Specific Total Hip Replacement System





Introduction

The Cordera™ HipRx™ system is a patient-specific cementless total hip replacement system that includes personalized implants and disposable instrumentation. The product design incorporates an anatomically based reconstruction approach for the treatment of severe pain and/or disability of a hip damaged by osteoarthritis or trauma. By utilizing proprietary iFit® image-to-implant® technology and data from a patient's CT scan, implants are personalized for each patient. The accompanying patient-specific, disposable iJig® instrumentation is employed in this surgical technique guide.

Surgeon Design Team

The Cordera™ HipRx™ Surgical Technique was developed in collaboration with:

Scott Ball, MD
University of California at San Diego,
Department of Orthopedic Surgery,
San Diego, CA

Wolfgang Fitz, MD
Brigham and Women's Hospital,
Boston, MA

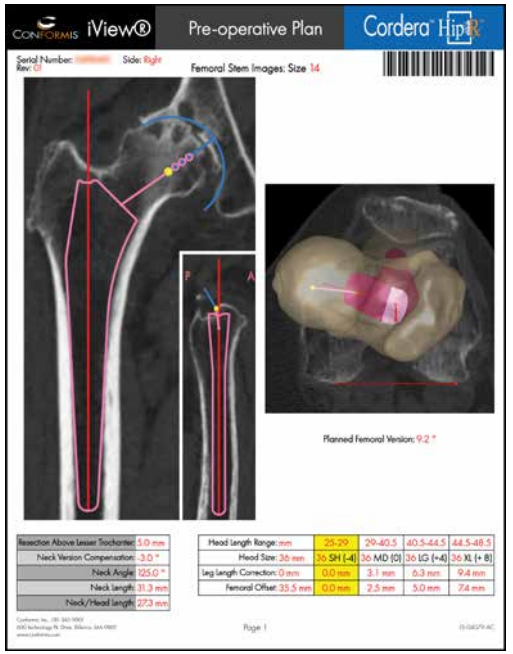
Derek Johnson, MD
Centura Orthopedics and Spine,
Parker, CO

Will Kurtz, MD
Tennessee Orthopedic Association,
Nashville, TN

Greg Martin, MD
Personalized Orthopedics of the Palm Beaches,
Boynton Beach, FL

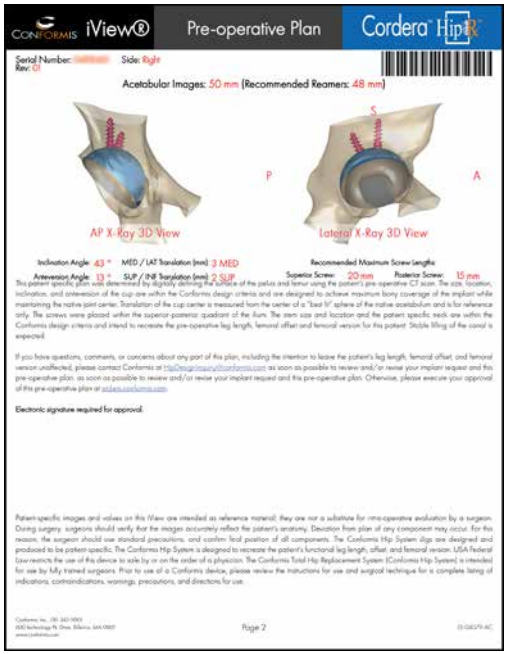
Robert Tait, MD
Orthopaedic Institute of Henderson,
Henderson, NV

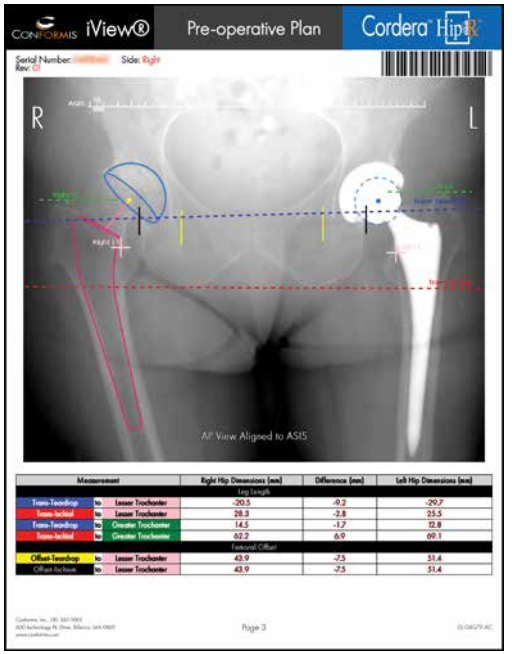
Pre-operative Image Review



Pre-operative planning images compiled in a report 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.





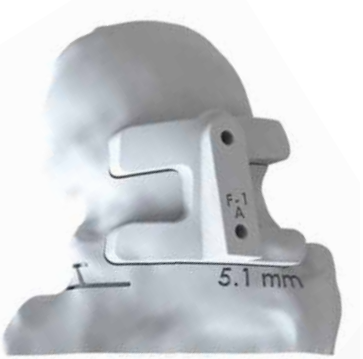
hip

Step 1 EXPOSURE AND NECK RESECTION

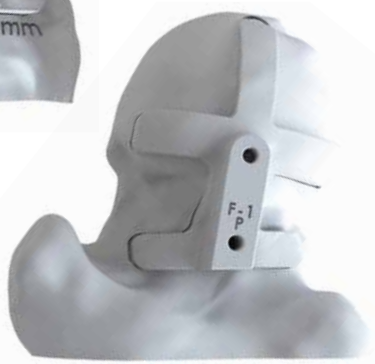
1 The serial number is noted on the iView®, laser marked on the stem, and engraved on each iJig®. Before beginning the case, confirm that the serial number is correct and matches across all components.

2 Utilizing the Cordera™ HipRx™ system, total hip replacement surgery can be performed through either a posterior or anterior approach.

3 Adequately expose the acetabulum and proximal femur.



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.

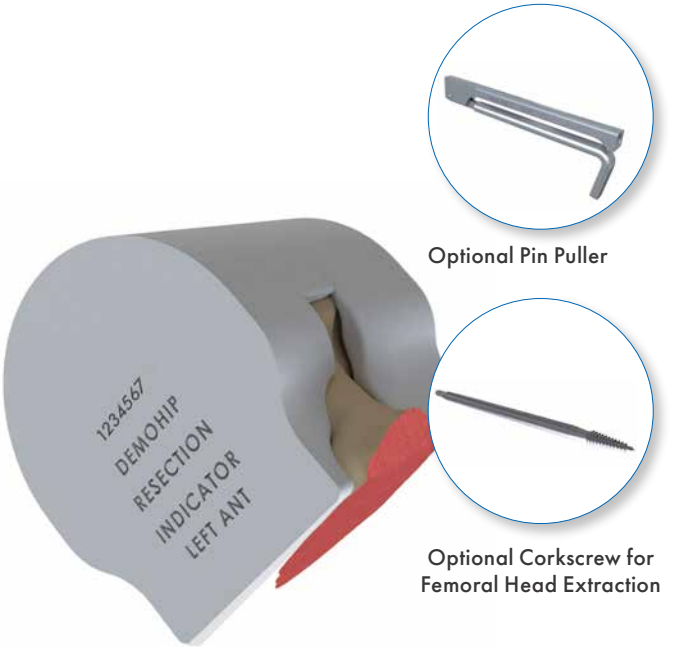
F-1A Anterior iJig®

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 TIP

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.



Optional Pin Puller

Optional Corkscrew for Femoral Head Extraction

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 cut, if needed, with the saw or an osteotome.

TECHNIQUE TIP

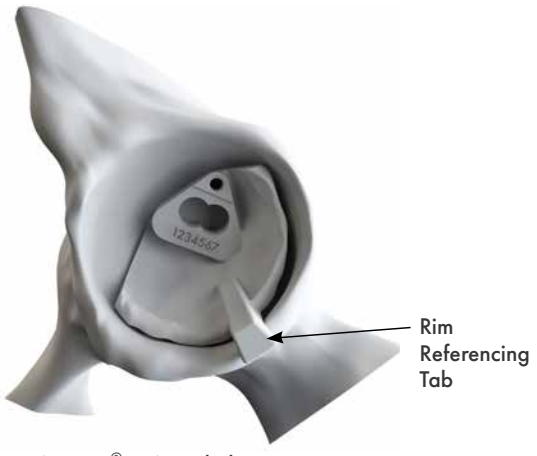
When making the neck resection, align the saw blade axis parallel to the inferior pin closest to the saw blade and flush against the bottom of the F1 iJig®.

8 Remove the pins from the iJig® and remove the iJig® from the femoral neck. An optional pin puller for removing pins is available with the system. 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 in between 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

- The resected head may not fit tightly in the Anterior and Posterior Resection Indicator model. This is due to the model being designed to subchondral bone. For a closer fit, remove any remaining cartilage and soft tissue. Use it as a guide only for the level of the neck resection.
- 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®.

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.

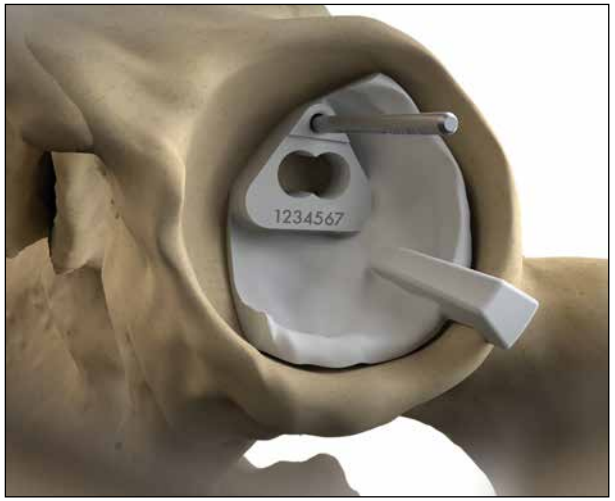
CAUTION: If used aggressively, the full hemispherical acetabular reamer may invalidate the Cordera™ HipRx™ surgical plan. The ability to achieve the planned leg length and offset as well as acetabular cup position and orientation may be impacted.

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.

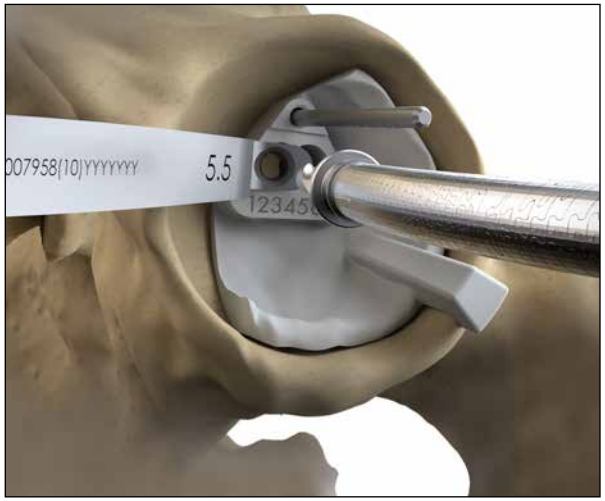
TECHNIQUE TIPS

- 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.

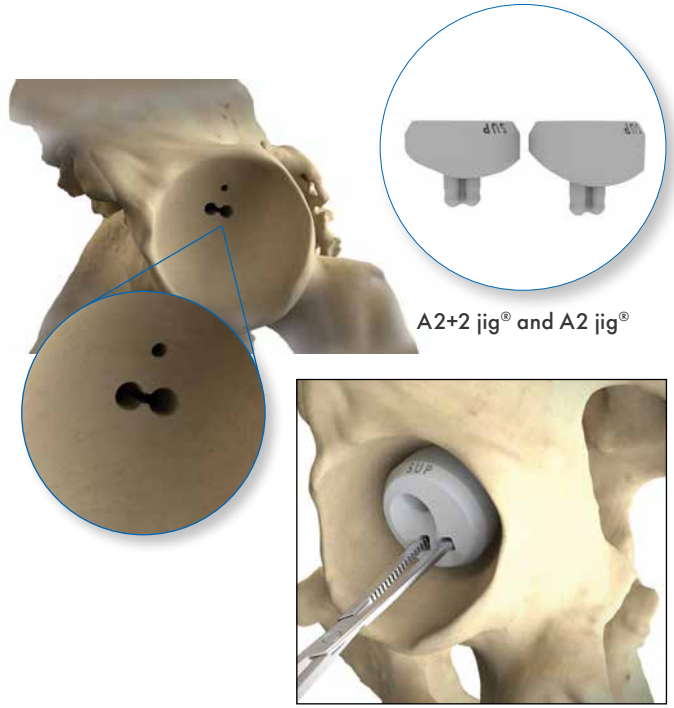


11 Use the short 3.5 mm flex drill and 3.5 mm end of the drill guide to drill through the smaller hole on the A1 iJig®, and place a pin by hand to hold the A1 iJig® in place. The recommended depth of the hole from the top of the A1 iJig® as well as the depth of penetration into bone are stated on the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



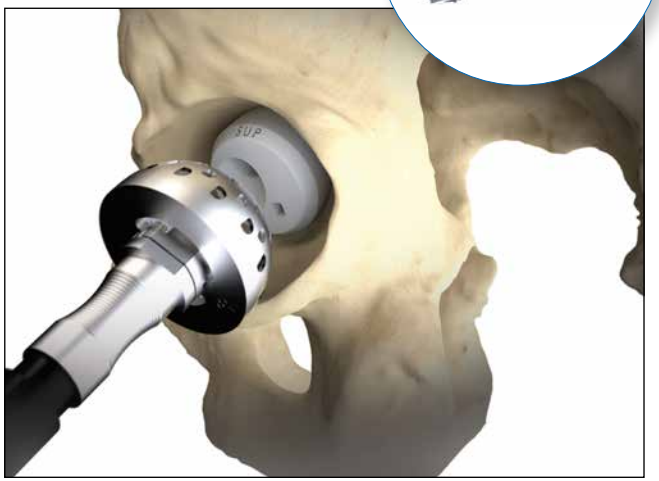
A2+2 jig® and A2 jig®

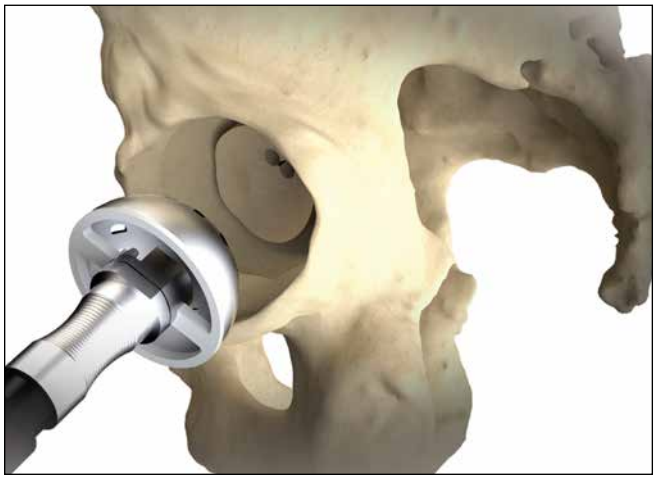
13 Remove the A1 iJig® and pin from the acetabulum. Inspect and ensure the bone bridge is removed between the 5.5mm drill holes. Choose one of the two A2 iJig®s provided. One is designed to meet the plan (labeled "PLAN") for reamer depth, and the other (labeled "+2") deepens the reaming by an additional 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(R) 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 Conformis acetabular cups utilize a 2mm press fit. As a result 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.

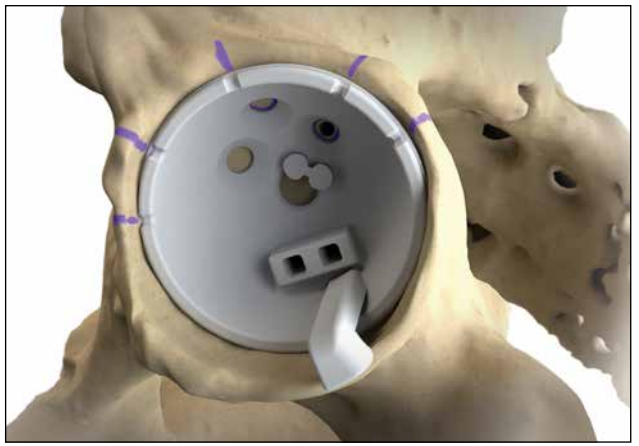
TECHNIQUE TIPS

- 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 Cordera™ HipRx™ acetabular iJigs®. The final reamer size should be 2 mm smaller than the planned cup size.

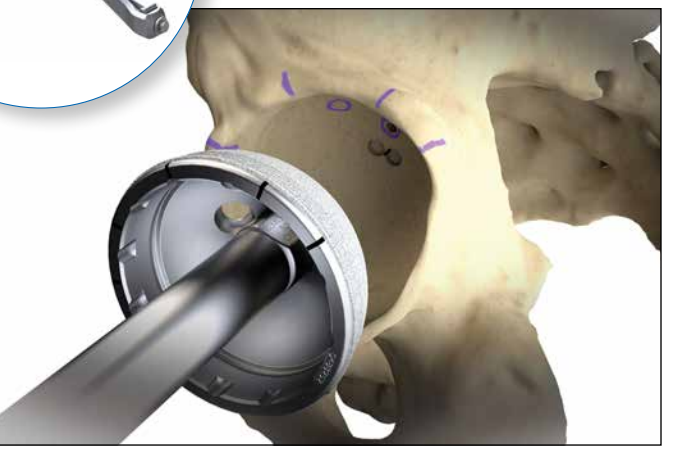
CAUTION: Use of the full hemispherical acetabular reamer may invalidate the a™ HipRx™ surgical plan. The ability to achieve the planned leg length and offset as well as acetabular cup position and orientation may be impacted.

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

Step 3 IMPLANT ACETABULAR CUP



Optional Offset
Cup Impactor*

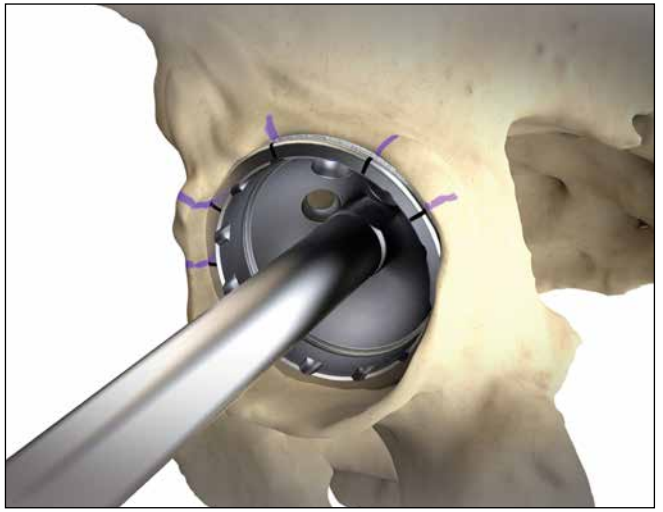


17 The A3 cup-placement-iJig® sits in the two 5.5mm holes in the acetabulum, showing the final placement of the acetabular cup according to the surgical plan. This iJig® is intentionally undersized. Similar to the A1 iJig®, the A3 iJig® features a tab to reference the posterior rim of the notch. This 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 If using a straight cup impactor, attach the cup impactor tip onto the distal end of the cup impactor. An Optional Offset Cup Impactor is also available.

19 Place the cup in the exposure and rotate it until the laser marks on the rim of the cup are aligned with the marks previously made on the acetabular rim and screw holes.

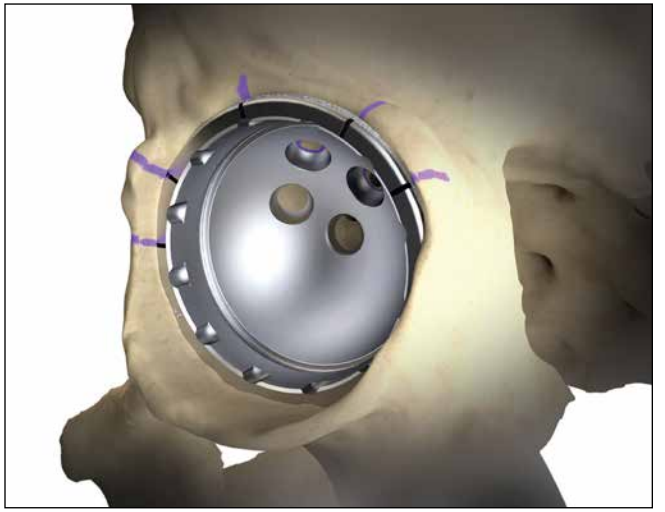
*For more information on this instrument please reference MK-03339-AA ENZTEC CLASSIC OFFSET CUP IMPACTOR+ TECHNICAL GUIDE



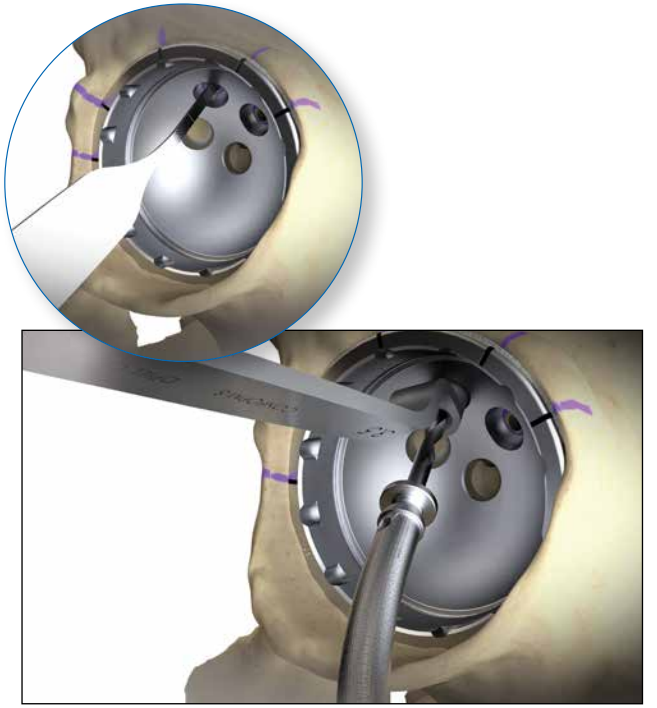
20 Use the acetabular bone model with the cup simulation iJig(R) to visually confirm the cup placement in relation to the acetabular rim. This can be achieved by placing the iJig(R) model assembly next to the incision to verify inclination and anteversion of the pre-operative plan.

TECHNIQUE TIP

- Use the acetabular bone model with the cup simulation 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.

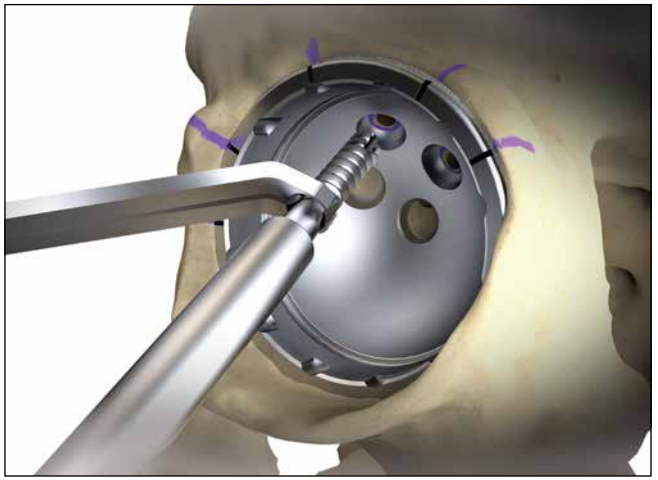


21 Unthread the impactor from the cup and remove it from the incision.



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.



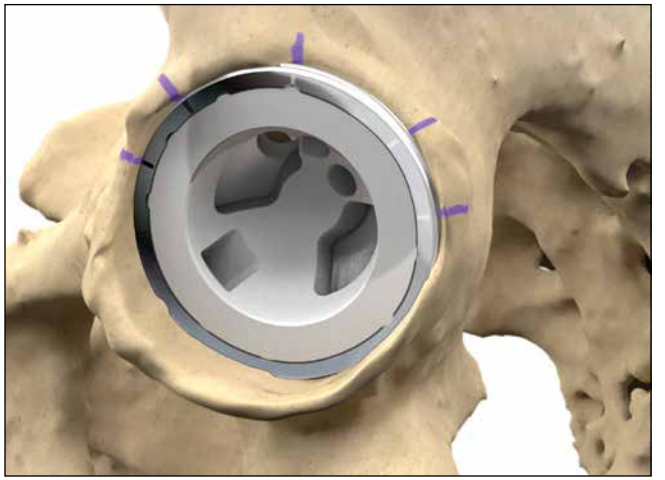
23 Use the flexible or straight screwdriver with screw holding forceps to place screws of appropriate lengths according to each measured hole depth, and drive until tight.

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

TECHNIQUE TIPS

- 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 mispositioning 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.

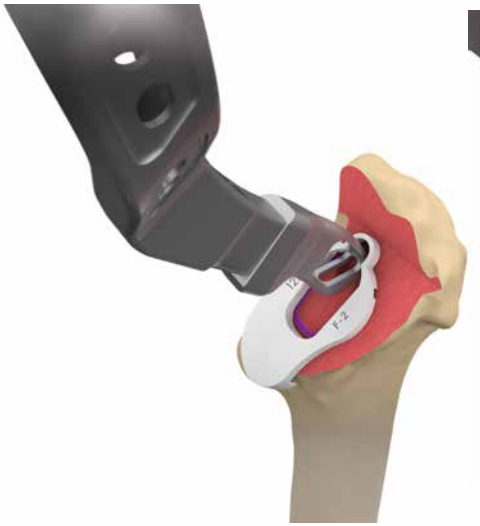
Step 4 FEMORAL PREPARATION

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.

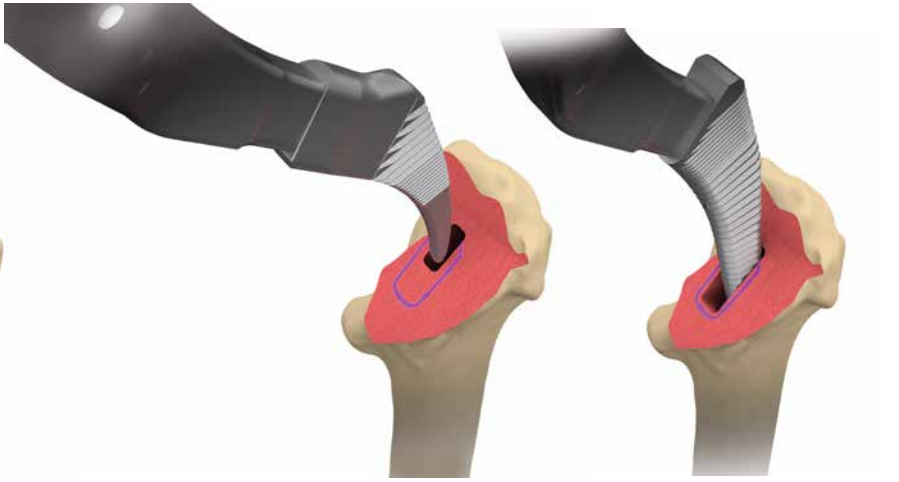
TECHNIQUE TIP

- 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. Remove the F2 iJig® and set aside.

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.

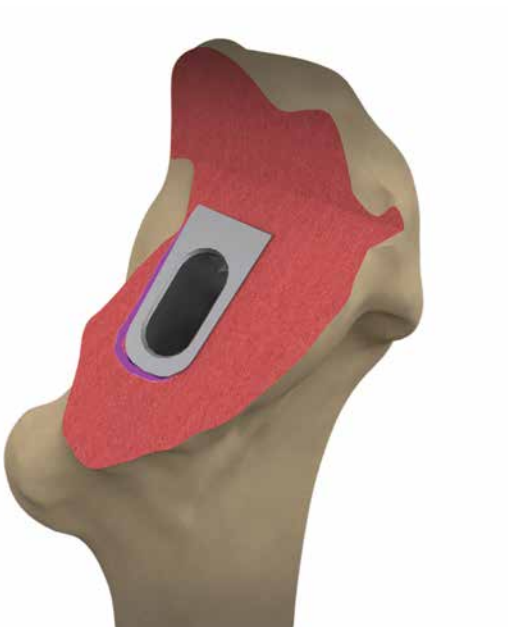
TECHNIQUE TIPS

- The face of the broach corresponds to the resection level; therefore, the broach should be impacted until the face is flush with the resection level.
- Note that the broaches compact cancellous bone in all areas except the proximal lateral side of broach. In this area a diamond tooth pattern is used so that the broaches can be used as a rasp to lateralize the femur.

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.

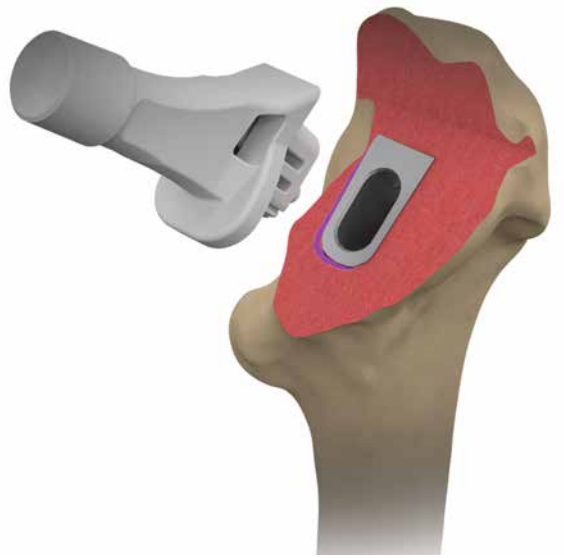
30 If desired, a calcar planer is supplied to level the bone around the bone-broach interface. Screw the calcar planer post into the inserted broach. Place the calcar planer over the post and plane until the desired bone interface is obtained.

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

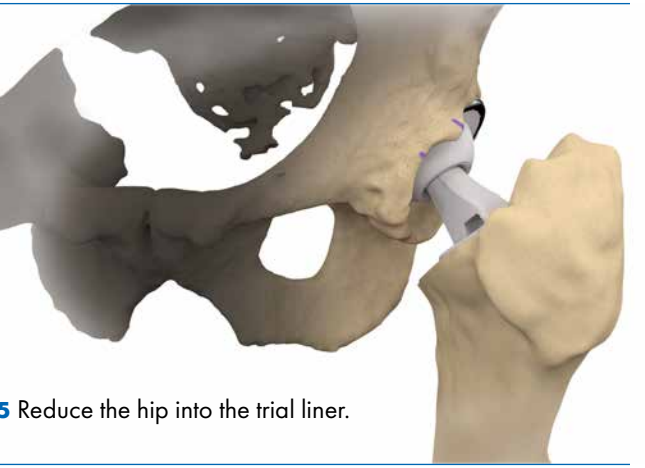


32 If not already in place, position the trial liner into the cup.

33 Place the patient-specific trial neck into the broach (an audible click or snap may be felt when in place).

Note: The trial neck features 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.

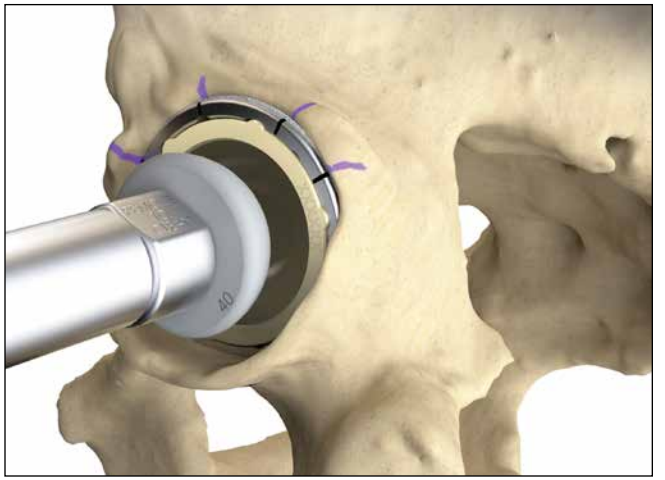
34 Place the planned trial head onto the taper of the trial neck.

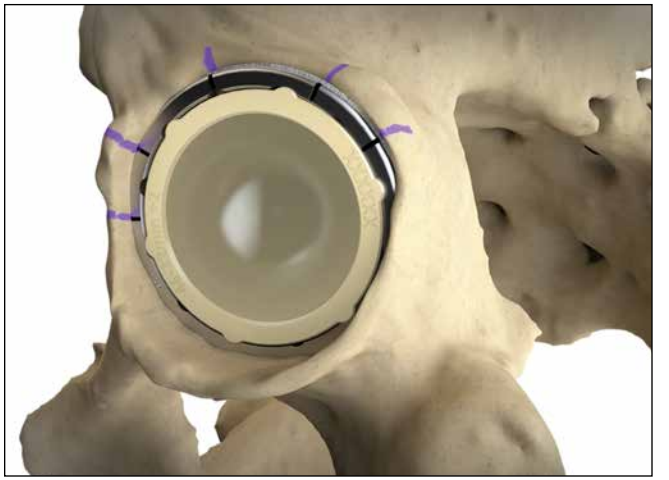


35 Reduce the hip into the trial liner.

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

Step 6 FINAL IMPLANTATION





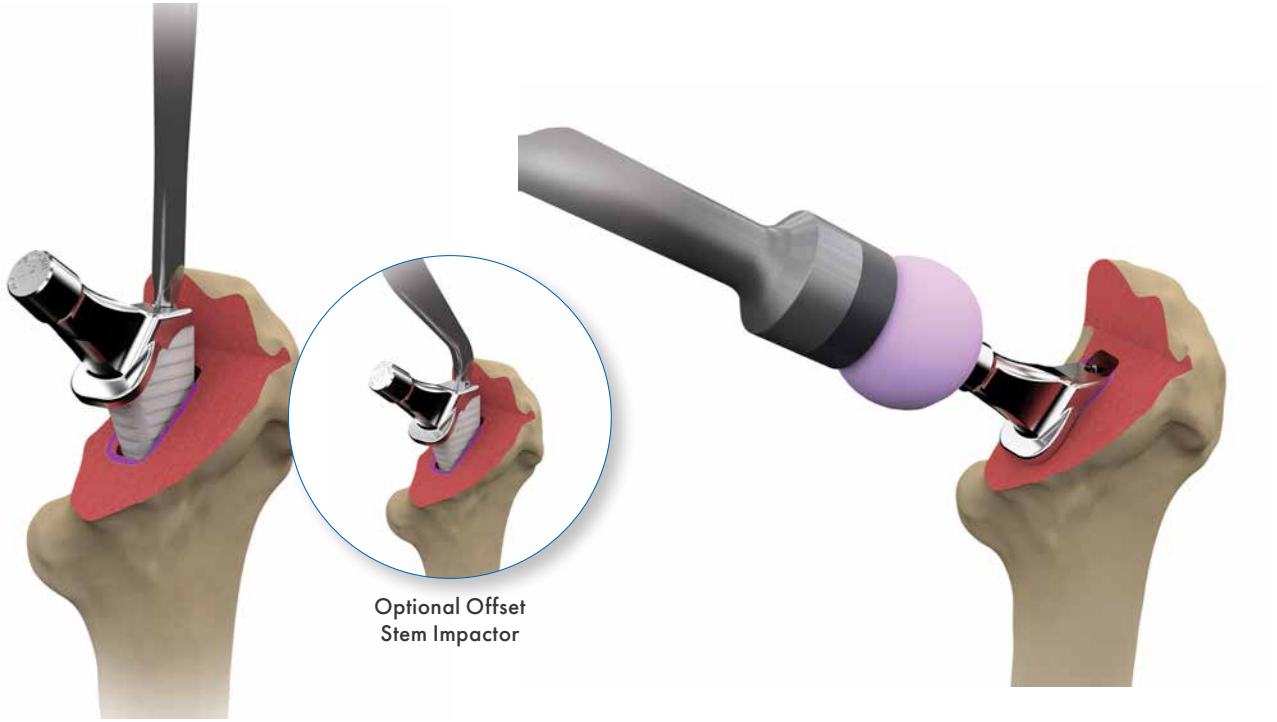
37 Remove all trials and the broach from the femoral canal. Do not irrigate or dry the femoral canal, as this will help to preserve the compacted cancellous bone.

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 +2 neutral liners will sit flush with the face of the cup. +4 liners, will protrude beyond the edge of the cup. Reference Liner Compatibility and Thicknesses on pages 19 & 20 for more information.



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 HA coating should sit level with the femoral neck resection.

41 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.

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

43 Close the incision.

OPTIONAL STEM EXTRACTION:

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 extractor, 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.

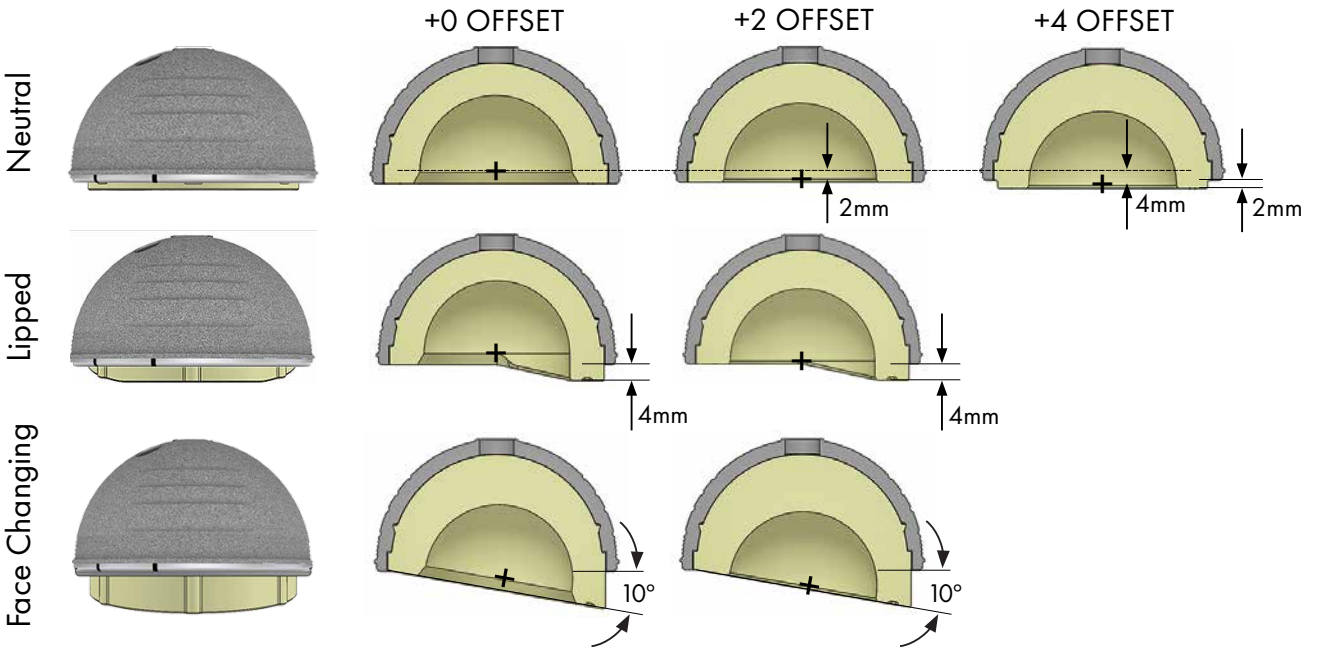
NOTE: Use of the offset loop adaptor with the Extraction Handle may cause damage to the trunnion of the femoral stem and should be considered for use only if the stem won't be re-implanted.

Liner Compatibility and Thicknesses

Standard:
The case is planned to a +2 liner. Also available in sizes 0 and +4 mm.

Lipped (4mm):
The lip style liner supplied in 0 and +2 mm.

Face Changing (10 degree):
The FC liner supplied in 0 and +2 mm.



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	0	2	4	0	2	4	0	2	4
Liner Thickness	45°	5.6	5	6.3	5.6	5	6.3	5.6	7	8.3	5.6	7	8.3	10.6	12	13.3
	Apex	5.6	5.6	7.6	5.6	5.6	7.6	5.6	7.6	9.6	5.6	7.6	9.6	10.6	12.6	14.6

Ceramic Only

Head		40			40			40					
Offset		–	2	4	0	2	4	0	2	4			
Liner Thickness	45°	–	5	6.3	5.6	7	8.3	8.6	10	11.3			
	Apex	–	5.6	7.6	5.6	7.6	9.6	8.6	10.6	12.6			

Conformis plans all cases using a default +2mm neutral liner. An alternative liner may be used at the surgeon's discretion.

Liner Configurations

Cup Size	Group	Liner ID	+0 Offset			+2 Offset			+4 Offset	Head OD
			Neutral	4mm Lipped	10° Face Changing	Neutral	4mm Lipped	10° 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)

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

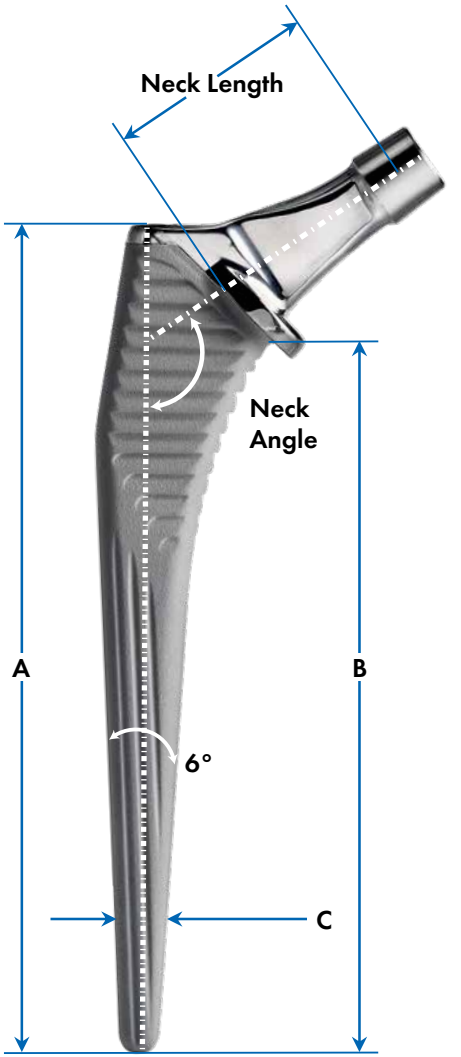
Leg Length & Offset Calculations

Neck Angle	Offset	Liners			Heads			
		+0	+2 (PLAN)	+4	-4	+0 (PLAN)	+4	+8
127°	Leg Length Δ	-1.2	0	+1.2	-2.4	0	+2.4	+4.8
	Medial/Lateral Offset Δ	-1.6	0	+1.6	-3.2	0	+3.2	+6.4
132°	Leg Length Δ	-1.3	0	+1.3	-2.7	0	+2.7	+5.4
	Medial/Lateral Offset Δ	-1.5	0	+1.5	-3.0	0	+3.0	+5.9

Patient-Specific Stem Dimensions

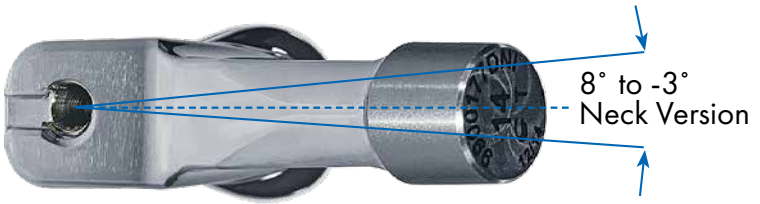
Cordera™HipRx™ features a patient-specific femoral neck that is planned in conjunction with the acetabular cup to match the patient's unique anatomy. Utilizing Image-to-Implant® technology, the Cordera™HipRx™ system offers a comprehensive range of neck angle, length, and version options.

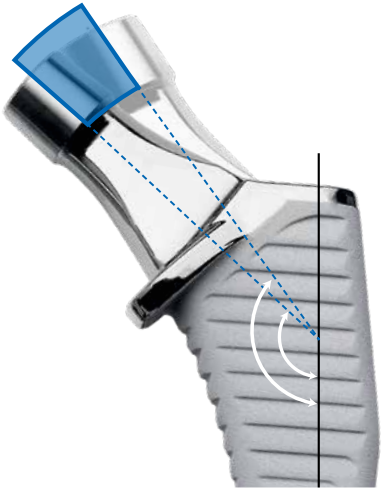
Size	Lateral Stem Length (A)	Medial Stem Length (B)	Distal M/L Width* (C)	Proximal A/P Width at Shoulder	Distal A/P Width*
10	137	118	7.6	14.2	8.6
11	142	123	8.5	14.8	9.1
12	147	129	9.5	15.3	9.5
13	152	133	10.2	16.1	9.5
14	157	138	11.5	16.4	9.5
15	162	144	12.5	16.6	9.4
16	167	148	13.4	16.9	9.4



Patient-Specific Design Range**

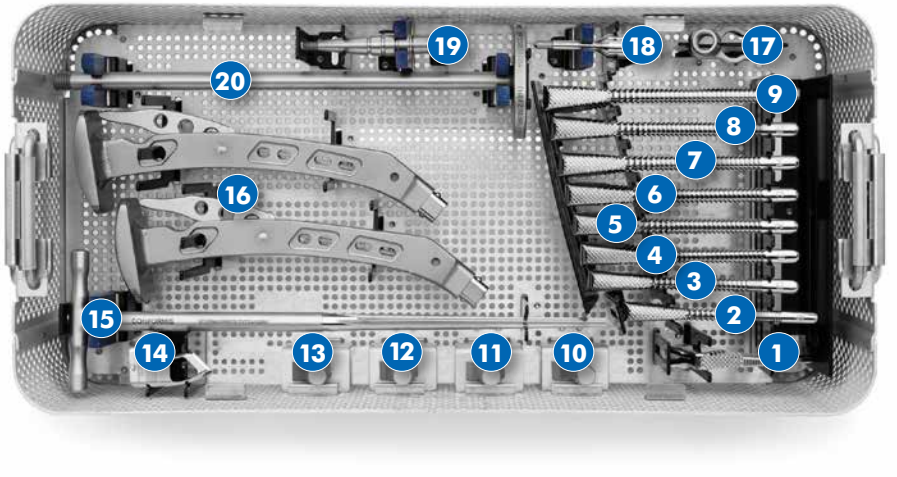
- 125° to 145° neck angle
- 29mm to 40.5mm neck length
- 8° to -3° of neck version





Instrumentation

FEMORAL, 1080-122 – Bottom tray

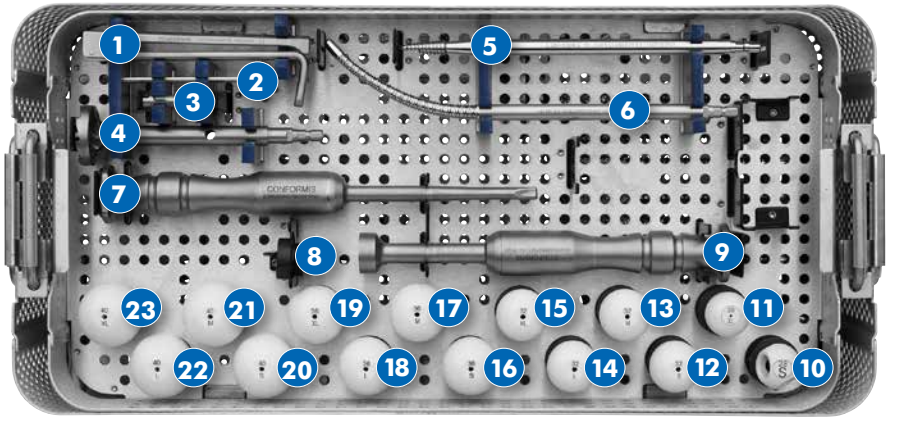


1. **Starter Broach**

Femoral Broaches:

2. **Size 9**
3. **Size 10**
4. **Size 11**
5. **Size 12**
6. **Size 13**
7. **Size 14**
8. **Size 15**
9. **Size 16**
10. **127°, 29.0mm Trial Neck**
11. **127°, 36.5mm Trial Neck**
12. **132°, 29.0mm Trial Neck**
13. **132°, 36.5mm Trial Neck**
14. **Modular Box Osteotome**
15. **Femoral Tapered Reamer**
16. **Broach Handles, Neutral**
17. **Stem Extractor, Loop Adapter**
18. **Stem Extractor, Threaded Adapter**
19. **Stem Extractor Handle**
20. **Stem Extractor Handle Extension**

FEMORAL, 1080-122 – Top tray



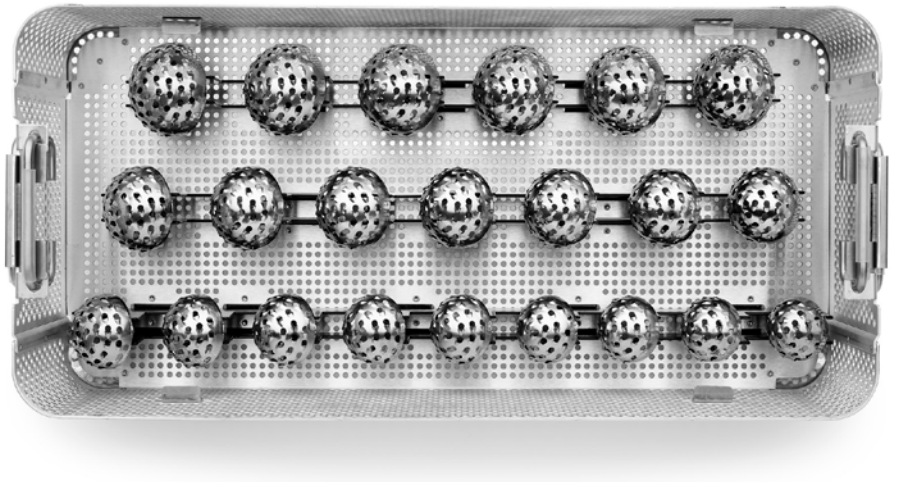
1. **Pin Puller**
2. **Steinman Pins**
3. **Calcar Planer Adaptor**
4. **Calcar Planer**
5. **Femoral Head Remover**
6. **Femoral Rasp**
7. **Femoral Stem Impactor**
8. **Femoral Head Impactor Tip**
9. **Femoral Head Impactor**
10. **Ø28mm Universal**
11. **Ø28mm XL (+7)**
12. **Ø32mm SH (-4)**
13. **Ø32mm MD (0)**

Femoral Head Trials:

14. **Ø32mm L (+4)**
15. **Ø32mm XL (+8)**
16. **Ø36mm SH (-4)**
17. **Ø36mm MD (0)**
18. **Ø36mm L (+4)**
19. **Ø36mm XL (+8)**
20. **Ø40mm SH (-4)**
21. **Ø40mm MD (0)**
22. **Ø40mm L (+4)**
23. **Ø40mm XL (+8)**

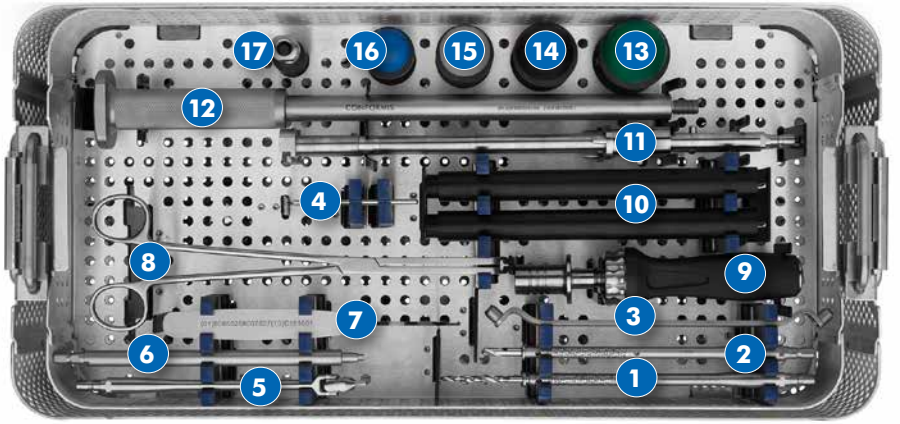
Instrumentation

ACETABULAR, 1080-121 – Bottom tray



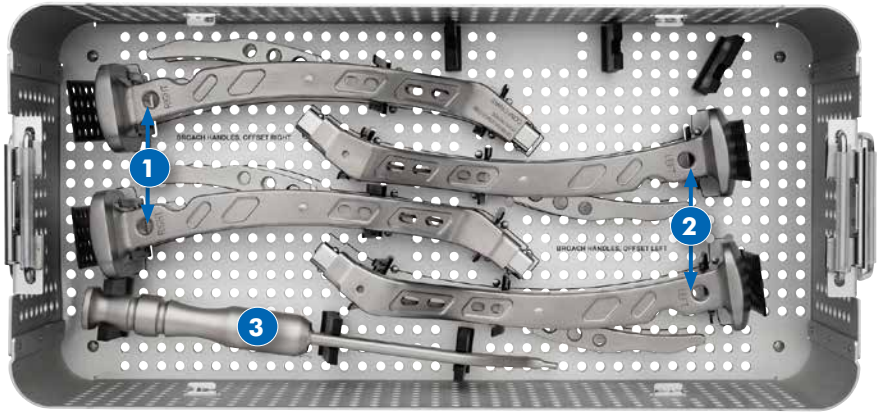
Full Basket Reamer Tray
Sizes 44–65

ACETABULAR, 1080-121 – Top tray



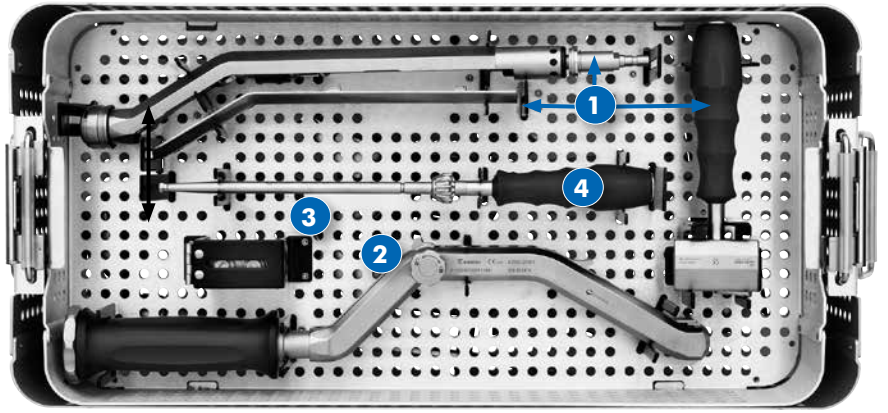
1. **Flexible Drills:**
   3.5x35mm (above)
   3.5x50mm (below)
2. **Flexible Drill, 5.5x25mm**
3. **Drill Guide — Double Ended**
4. **Steinman Pins**
5. **U-Joint Driver**
6. **Rigid Driver**
7. **Depth Gauge**
8. **Screw Holding Forceps**
9. **Ratcheting Handle, Quick-Connect**
10. **Reamer Handle 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**

AUXILIARY, 1080-114 – Bottom tray



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

AUXILIARY, 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 Cordera™ HipRx™ system is designed from a patient's pre-operative CT scan which must include certain necessary anatomic landmarks that are clearly identifiable. Total hip replacement using the Cordera™ HipRx™ 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 Cordera™ HipRx™ system includes standard hip replacement components and if selected, may use patient-specific single-use instrumentation.

Cordera™ HipRx™ implants are intended for cementless fixation using an anterior or posterior surgical technique.

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

Cordera™ HipRx™ 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 Cordera™ HipRx™ in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

NOTES

conformis.com

Conformis, Inc.
600 Technology Park Drive, 4th Floor
Billerica, MA 01821
Phone: 781-345-9001
Fax: 781-345-0147

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.

MK-03337-AA