Conformis ® Hip System Surgical Technique Guide

Patient Specific Total Hip Replacement System

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Introduction

The Conformis® Hip 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 Conformis® Hip System Surgical Technique was developed in collaboration with:

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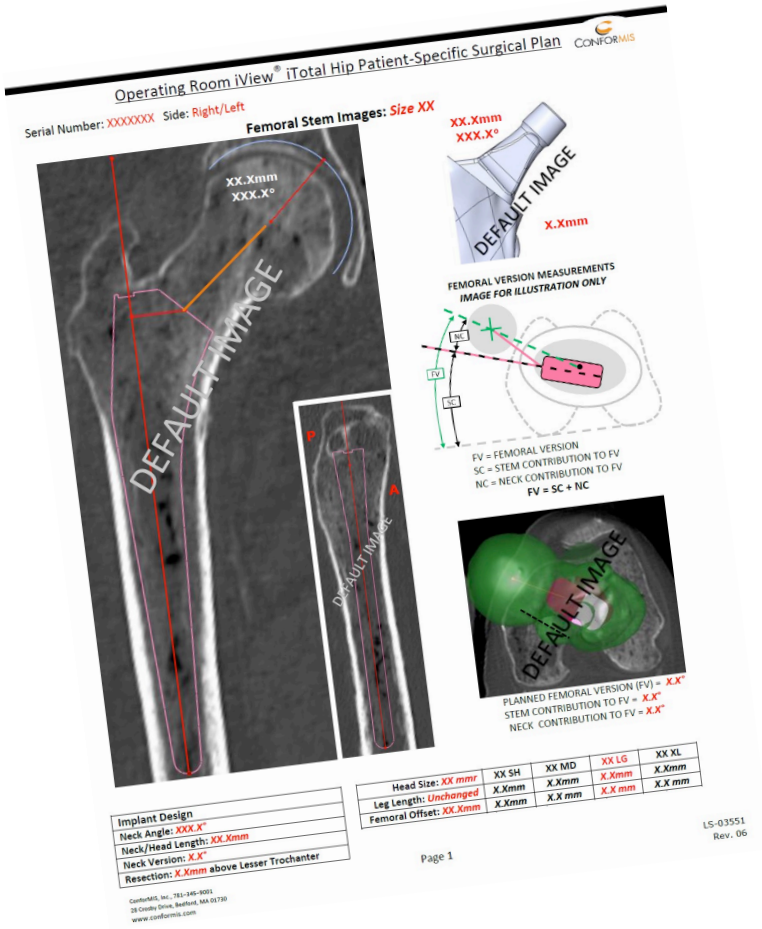
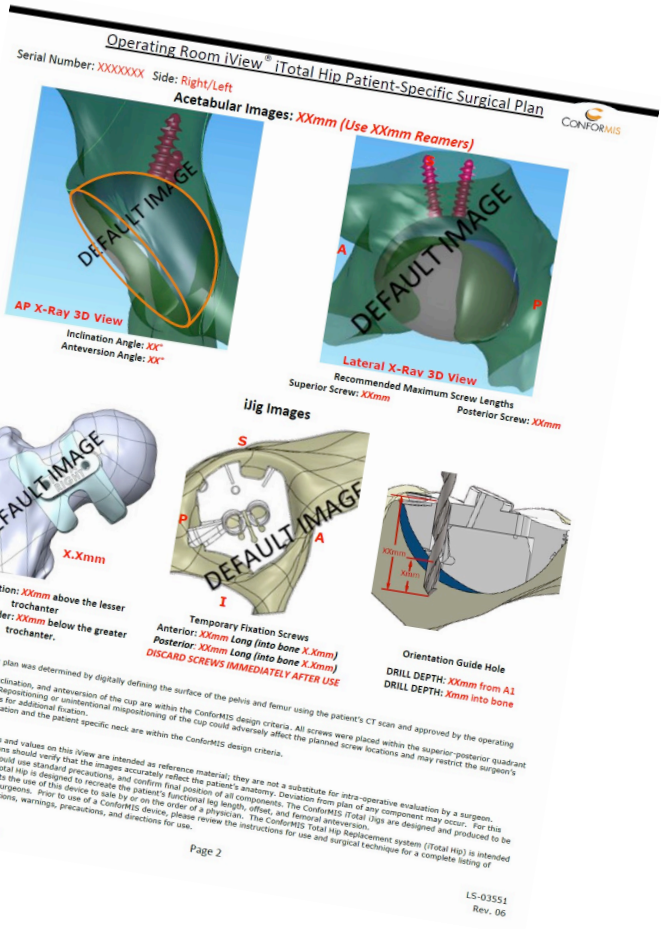
Pre-operative Image Review

iView® patient-specific planning images are included with each implant and are also available preoperatively from Conformis. 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.





Exposure and Neck Resection

1. The serial number is noted on the iView, laser marked on the stem and cup, and engraved on each iJig. Before beginning the case, confirm that the serial number is correct and matches across all components.
2. Utilizing the Conformis® Hip System, total hip replacement surgery can be performed through either a posterior or anterior approach.
3. Adequately expose the acetabulum and proximal femur.

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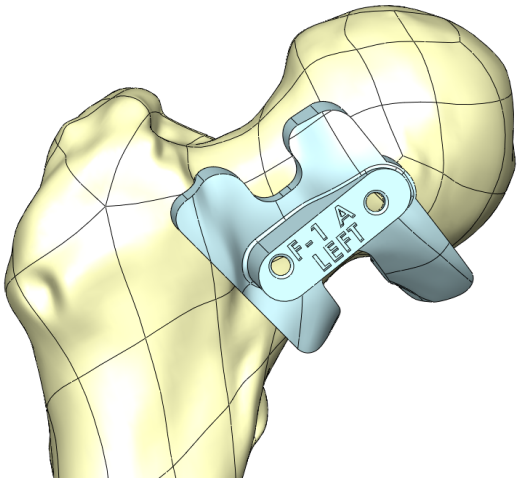
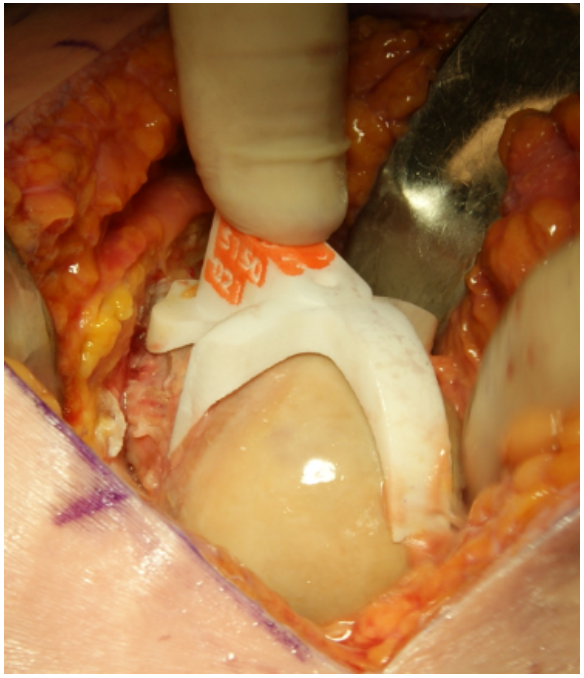
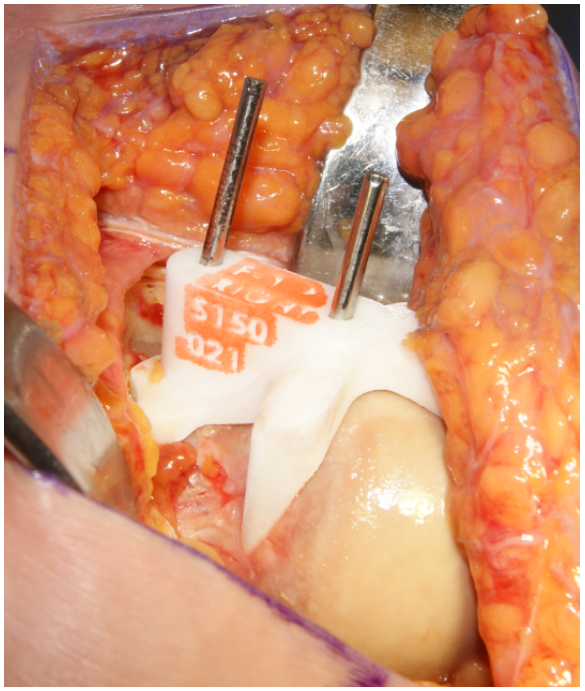
4. Select the anterior or posterior version of the F1 jig corresponding to the surgical approach being used. The jigs are marked “F-1 A” for the anterior approach, and “F-1 P” for the posterior approach. Rotate the femur to expose the femoral neck for insertion of the F1 jig.



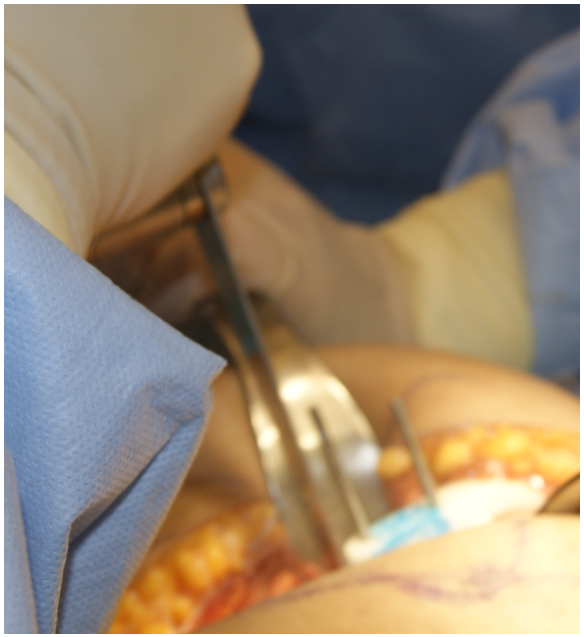
5. The contoured surface of the F1 jig matches the patient’s femoral neck and will feel stable when it is in the correct position. Push the jig against the femoral neck. Slide it around the neck until it is stable against the bone. Verify that the edges of the jig are in direct apposition to bone.



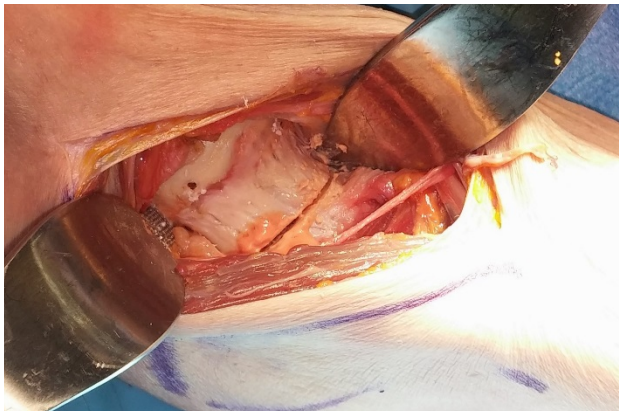
6. Place two short 3 mm headless pins through the two divergent holes in the jig. The pins will lock it in place during resection of the femoral head. Verify that the jig is fully seated against the femoral neck.



7. Using an oscillating or reciprocating saw, perform a femoral neck osteotomy by first cutting adjacent to the distal surface of the F1 jig, parallel to the nearest pin. Complete the osteotomy by using an osteotome on the superior neck.



8. Using the pin puller, remove the pins from the jig and remove the jig from the femoral neck. Remove the femoral head and neck from the incision.

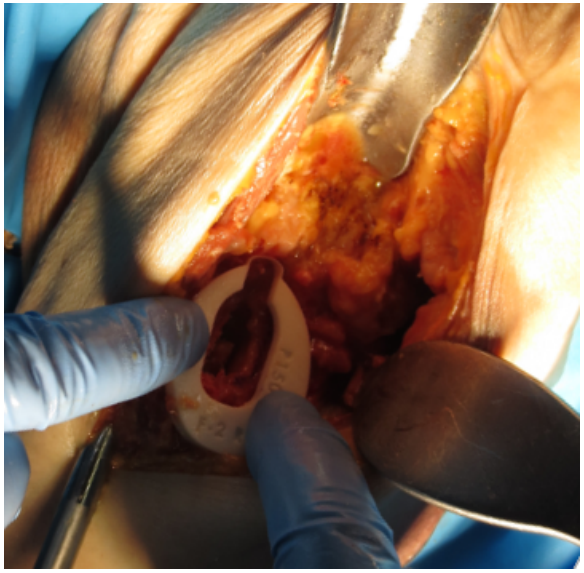


Technique Tips

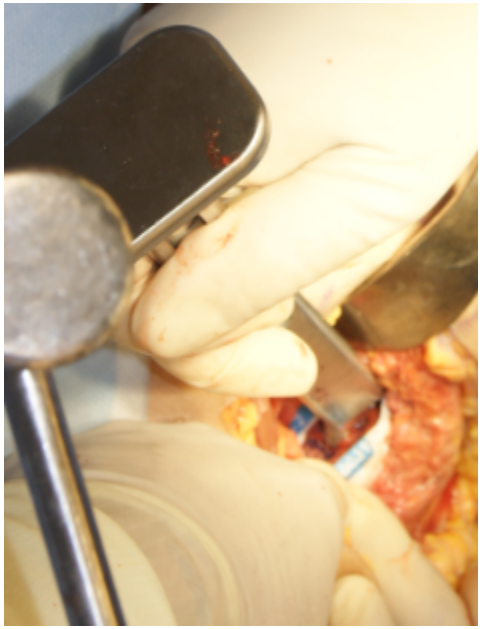
- *Internally and externally rotating the femur may help with insertion and location of the F1 jig in small incisions.*
- *The F1 jig will not slide off over the pins, since they are divergent to keep it locked in place. At least one of the pins must be removed prior to removing the F1 jig after the resection is complete.*
- *Two different F1 jigs are provided with each case. One for the anterior approach (marked "F-1 A"), which references the anterior femoral neck. Another one for the posterior approach (marked "F-1 P") which references the posterior femoral neck. Use of the version corresponding to the approach being utilized is necessary.*

Femoral Preparation

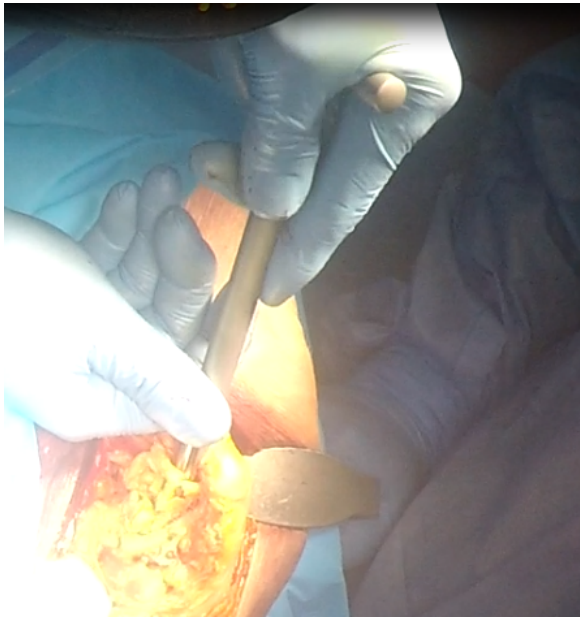
1. Place the F2 jig flush against the resected neck surface and against the remaining medial neck. The medial wall of the F2 jig overhangs the calcar and is contoured to match the patient's bone. Rotate the jig anteriorly and posteriorly until it is stable against the medial neck. It may be necessary to remove additional bone from the greater trochanter to allow proper jig placement. Note: The most lateral portion of the F2 jig cutout indicates the planned lateral shoulder of the implant.



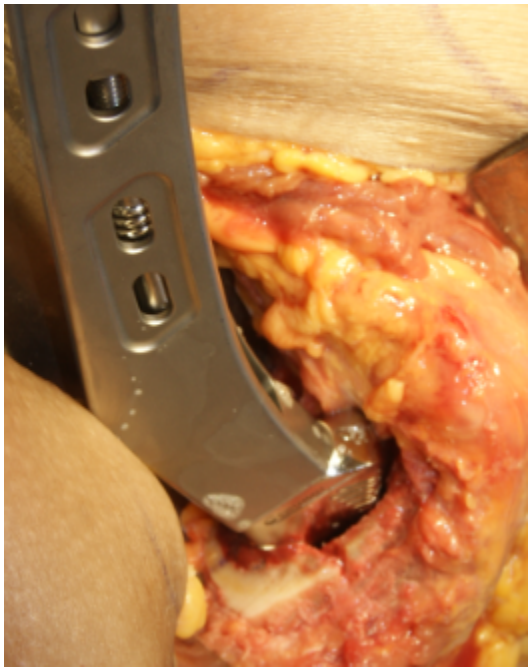
2. Use the box osteotome for initial entry into the canal where indicated by the lateral aspect of the F2 jig. This jig communicates placement of the femoral stem into the planned location and orientation. Remove the F2 jig and set aside.



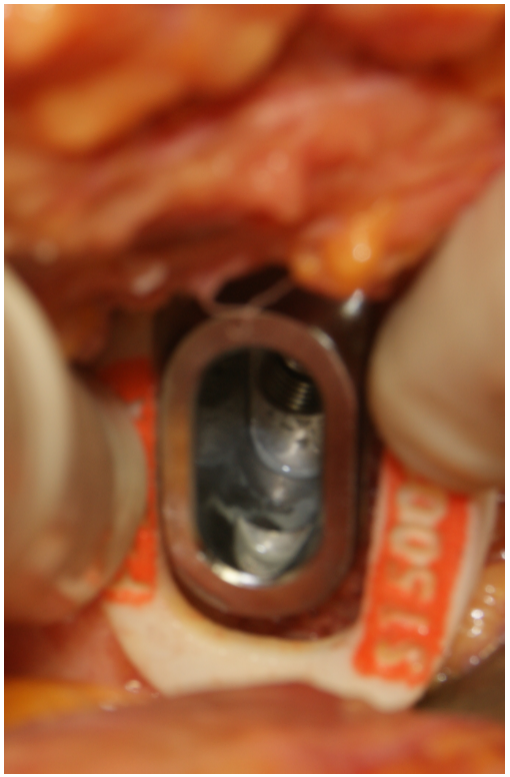
3. Use the canal finder to further open the femoral canal, maintaining a neutral alignment with the canal axis to avoid a varus or valgus trajectory.



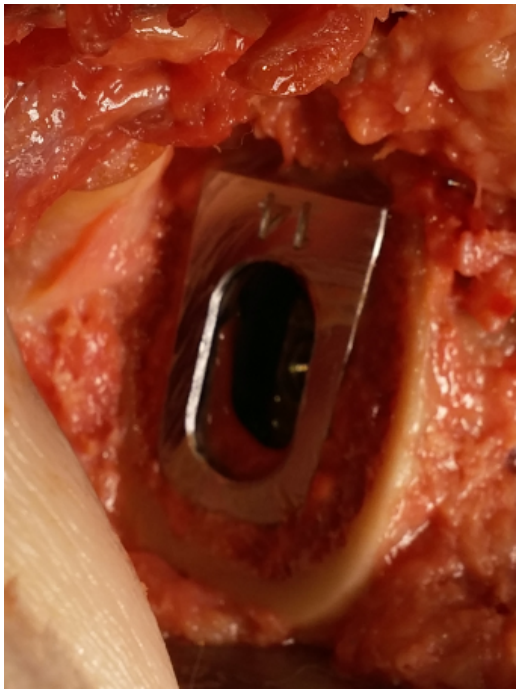
4. Beginning with the smallest broach, progressively broach the femoral canal to the size determined during pre-operative planning.



5. The F2 jig can be used to assess stem version after broaching. The lateral portion of the F2 jig can be snapped off for this step.



6. Leave the final broach size corresponding to the implant size in the femoral canal. Using a retractor to move the femur out of the way, expose the acetabulum.

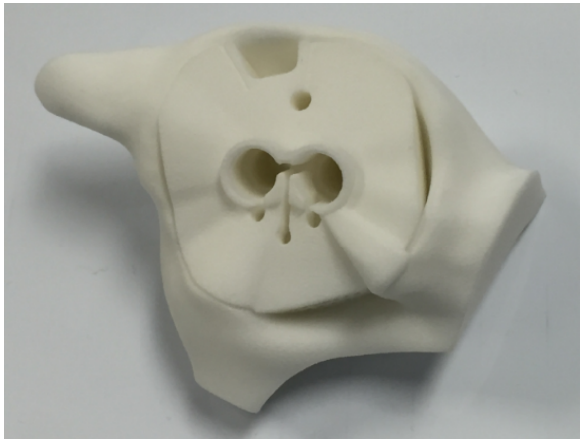


Technique Tips

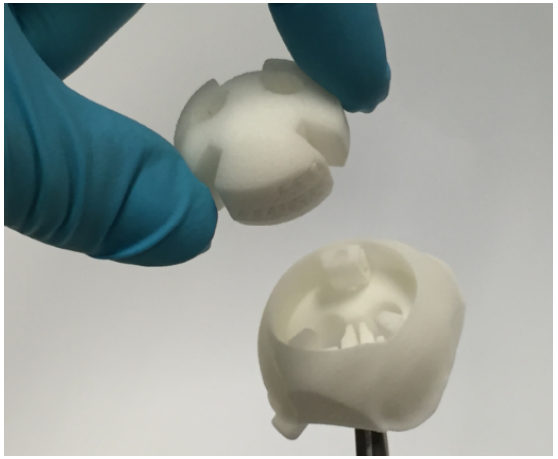
- *The face of the broach corresponds to the resection level, therefore the broach should be impacted until the face is flush with the resection level. See image.*
- *Note that the broaches compact cancellous bone in all areas except the proximal lateral side of broach. In this area a diamond tooth pattern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

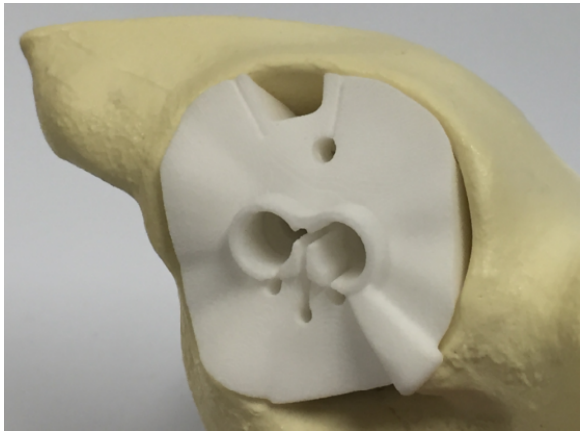
Acetabular Preparation

1. Remove the labrum and clean out the acetabular fossa and remaining cartilage. Do not remove osteophytes from the rim of the acetabulum, as they are accounted for in the contour of the patient specific jig and may provide additional stability.
   A 3D model of the acetabulum is provided for reference and can be used outside the incision to confirm proper seating of the jigs.



2. Assemble the A2 jig inside the A1 jig and place the construct in the opening of the acetabulum. The grooved lines on the face of the A1 jig should be pointing superior/posteriorly. Push the jig into the acetabulum and orient the jig within the socket until it has reached stable positioning. When in the correct position, the contoured perimeter of the A1 jig will closely follow the acetabular rim.





Technique Tips

- *Retention of osteophytes during placement of the A1 jig may provide additional stability as they are accounted for in the jig design.*
- *If osteophytes are removed from the rim prior to placement of the A1 jig, it will still seat at the correct location in the acetabulum.*

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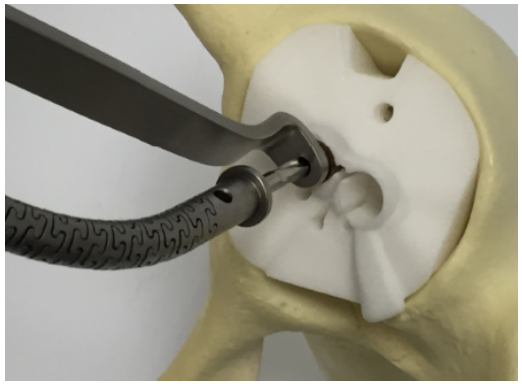
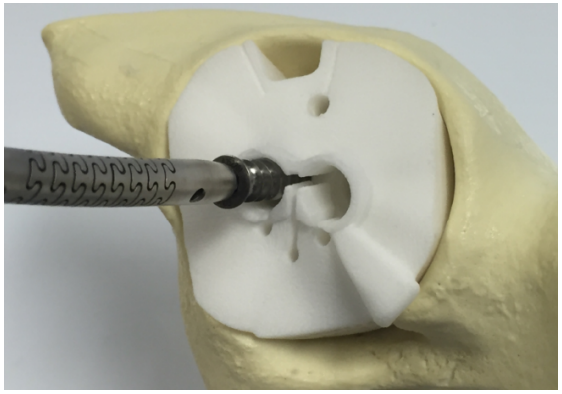
3. Use the flexible drill and drill guide through the A1 A2 jig construct to create a pilot hole for the temporary fixation screw. The pilot hole need only penetrate the cortical wall of the acetabulum immediately adjacent to the A1/A2 Jig. ***Use caution to not drill through the medial wall of the pelvis as the drill bit is extended.***

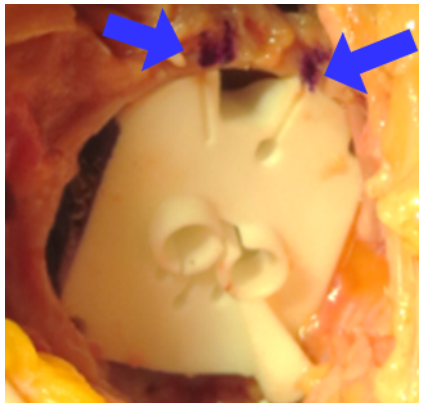


4. Use the flexible or rigid driver to advance the temporary fixation screw through the A1 jig to anchor the A2 jig to the acetabulum beneath. Do not overtighten the screw. Repeat steps 3 & 4 for the second screw.

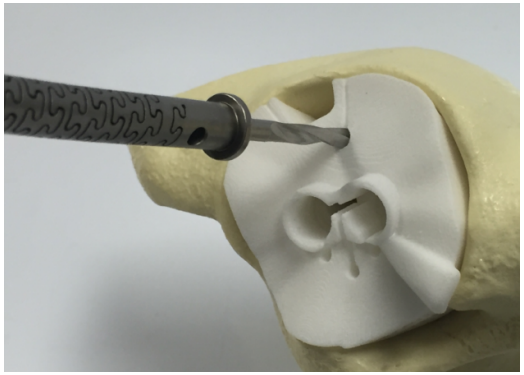


Caution: The planned positions and recommended lengths of the temporary fixation screws are determined based on the planned location and orientation of the A1/A2 jig construct. Repositioning or unintentional mispositioning of the A1/A2 construct could alter the planned screw positions and the recommended screw lengths provided may no longer reflect a safe length. Confirm intra-operatively, using standard surgical technique, that the temporary fixation screws used reflect a safe length.

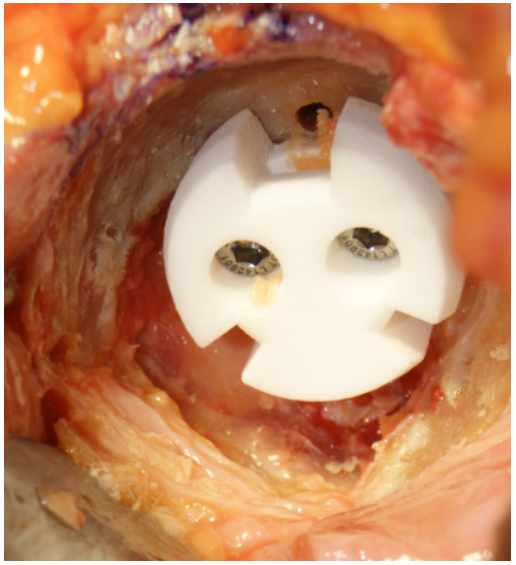
5. Mark the rim of the acetabulum at the superior/posterior grooved lines in the jig. These lines will be used to orient the patient specific acetabular cup.



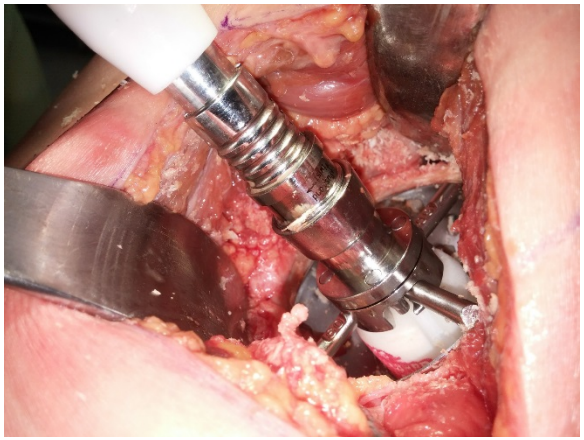
6. Use the flexible drill through the third guide hole in the A1 jig to drill the orientation guide hole, which will be referenced by the impaction guide during cup implantation. The recommended depth of the hole from the top of the A1 jig as well as the depth of penetration into bone are stated on the OR iView. Use the depth gauge to assess whether the recommended drilling depth has been achieved. ***Use caution to not drill through the medial wall of the pelvis as the drill bit is extended***.



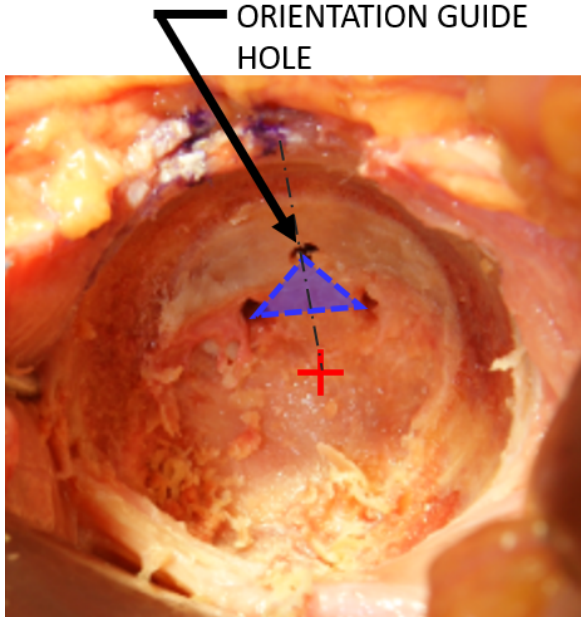
7. Pull the A1 jig straight out of the acetabulum, leaving the anchored A2 jig in place on the floor of the acetabulum. Use the depth gauge to assess if the depth of drilling into the bone matches that recommended on the OR iView. If the depth of drilling into the bone is less than recommended the A1 jig should be placed back over the A2 jig and the additional necessary drilling performed. ***Caution: If the depth of drilling of the orientation hole is too shallow there is the potential for the hole to be obliterated during reaming thus leaving no means by which to orient the acetabular cup.***



8. Using the provided stage 1 acetabular reamer that is 2 mm smaller than the planned cup size, ream the acetabulum over the A2 jig. Ream until the handle is seated on top of the A2 jig. Note: there is no need for consecutive size reaming.

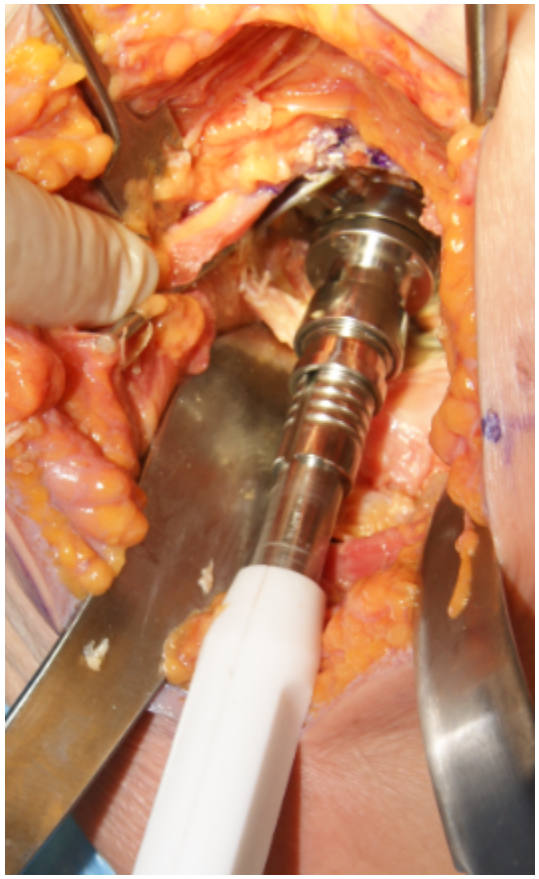


9. Use the flexible or rigid driver to remove the screws from the A2 jig. Dispose of both temporary fixation screws – they should not be used a second time. Remove the A2 jig with a Kocher.

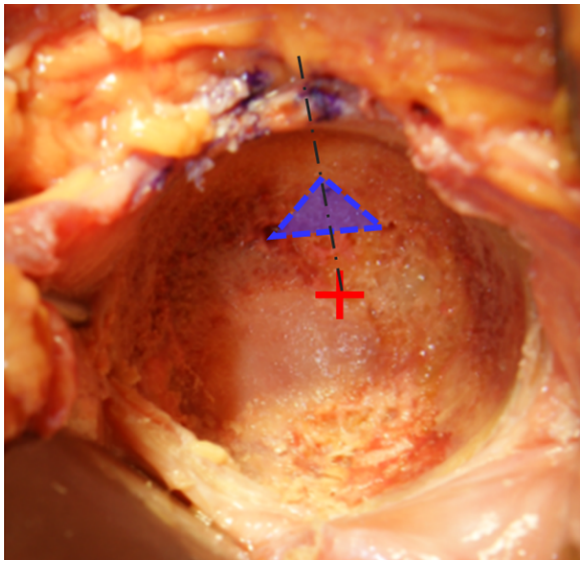


Once the A2 jig is removed, a triangular hole pattern will be visible. Note the hole pattern and its orientation. The hole pattern will be a triangle with its base near the center of the acetabulum and its peak pointing toward the posterior rim mark made previously. The hole at the triangle's peak is the orientation guide hole used during cup impaction.

10. Using the provided stage 2 reamer that is 2 mm smaller than the planned cup size, ream away the remaining bone that was under the A2 jig in the acetabular floor.



11. 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.



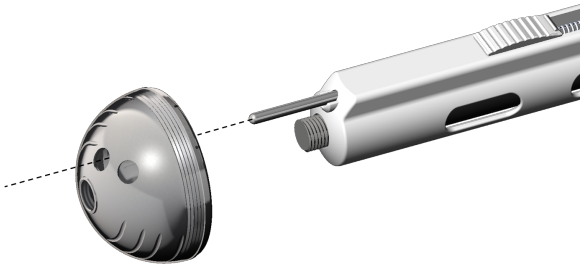
Identifying the Orientation Guide Hole:
The hole at the triangle's peak, pointing toward the posterior rim mark, is the orientation guide hole used during cup impaction.

Technique Tips

- *A full hemispherical acetabular reamer is available for use if the surgeon's medical judgement deems appropriate. However, the full hemispherical acetabular reamer is NOT intended for use with the Conformis® Hip System acetabular iJigs.*
- ***CAUTION**: Use of the full hemispherical acetabular reamer may invalidate the Conformis® Hip System surgical plan. The ability to achieve the planned leg length and offset as well as acetabular cup position and orientation may be impacted.*

Implant Acetabular Cup

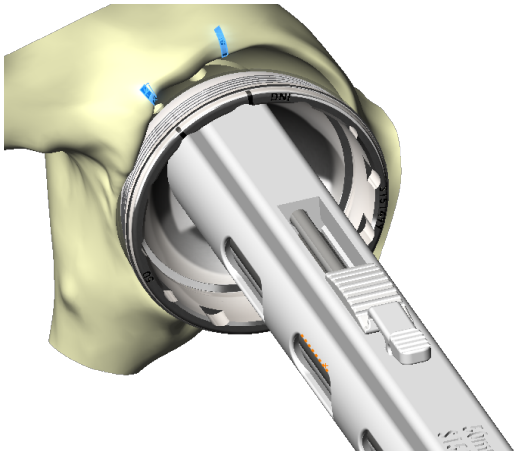
1. Slide the orientation guide over the cup impactor. Align the guide's tip with the posterior screw hole in the patient specific acetabular cup and thread the cup impactor into the apex hole in the cup. NOTE: The cup impactor will only assemble to the cup when the orientation guide tip is engaged in the posterior screw hole of the cup.



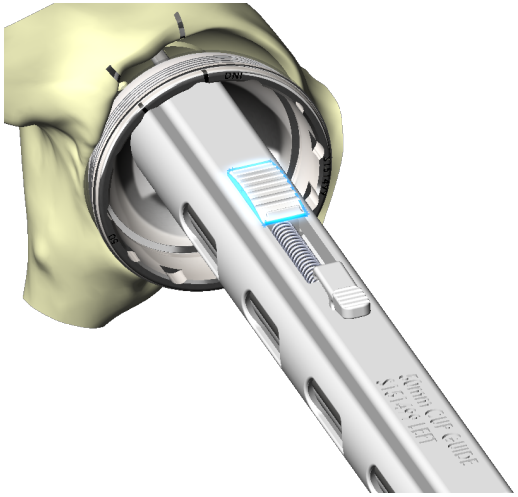
***NOTE**: The posterior hole of the cup will always be closest to the apex hole, in both right and left cups.*

RIGHT CUP *LEFT CUP*

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



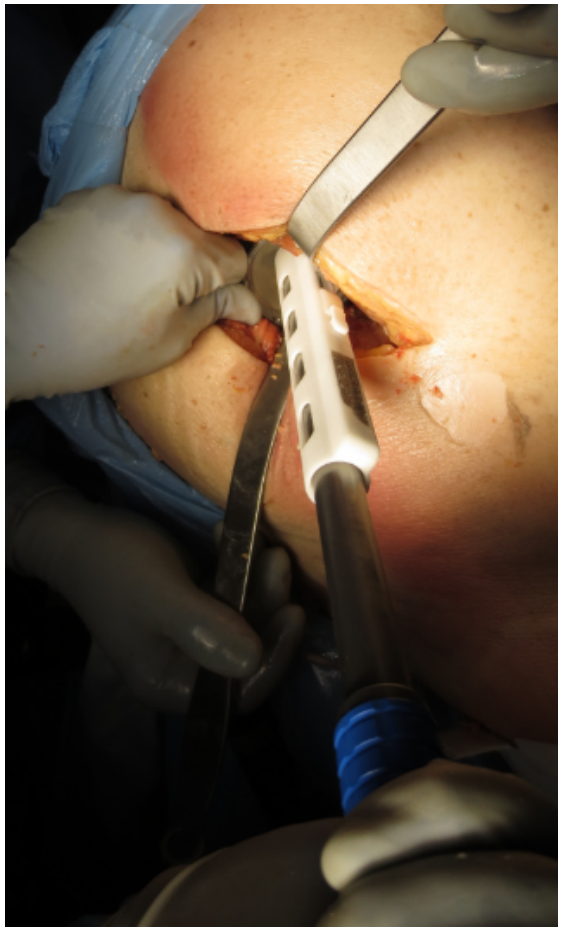
3. Orient the cup impactor so that the spring loaded pin in the orientation guide deploys into the guide hole drilled in the acetabular floor. The slider on the orientation guide will advance 5-10 mm, but may not advance completely.



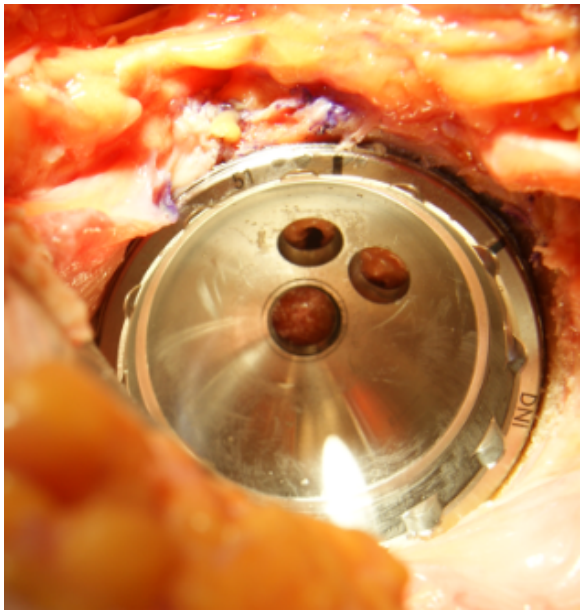
Technique Tips

The 3D model of the acetabulum and cup in its planned position can be used outside the incision to compare against the plan.

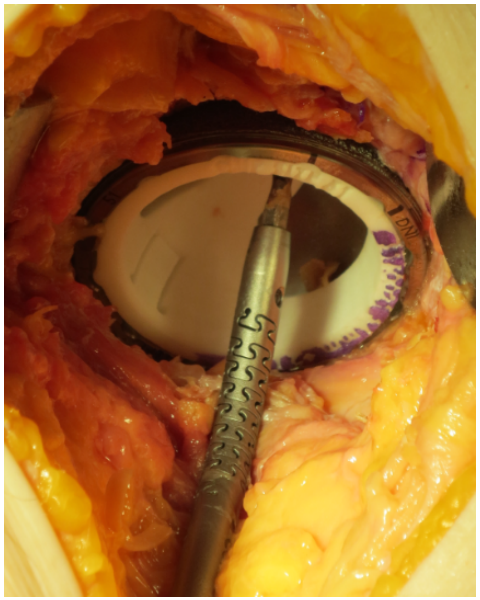
4. Impact with firm mallet blows until the cup is fully seated.



5. Unthread the impactor from the cup and remove it from the incision. Confirm that that the guide hole is visible and roughly centered in the screw hole of the cup.



6. Place the trial liner in the acetabular cup, ensuring the drill guide holes are aligned with the screw holes in the cup. Use the flexible drill through the trial liner guide holes to prepare pilot holes for the acetabular screws, again using caution to not drill through the opposite cortex of the ilium. Remove the trial liner and use the depth gauge to measure the depth of each hole.



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.*

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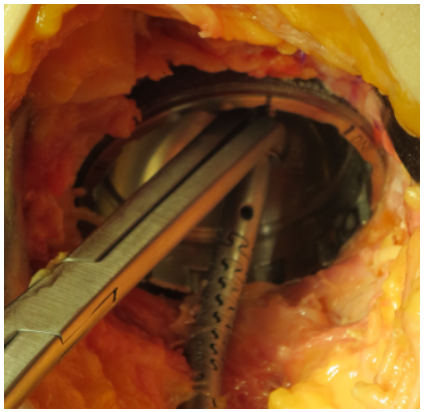
Caution: The planned positions and recommended maximum lengths of the acetabular fixation screws are determined based on the planned location and orientation of the cup. Repositioning or unintentional mis-positioning of the cup could alter the planned screw positions and the recommended maximum screw 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.

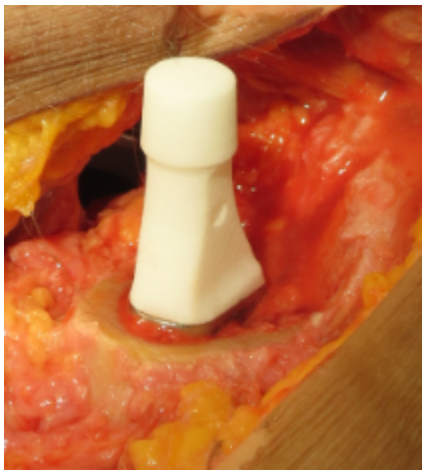
7. Use the flexible driver and screw holding forceps to place screws of appropriate lengths according to each measured hole depth, and drive until tight.



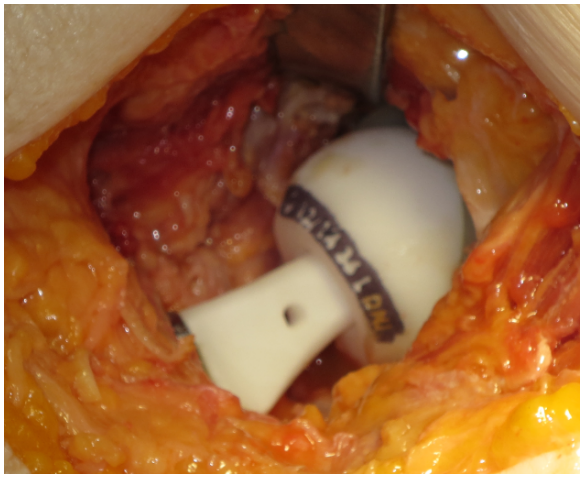
NOTE:
Ensure that all screws are fully seated and are not protruding into the cup, as this could prevent the liner from locking.

Trial Reduction

1. Place the trial liner into the cup
2. Place the patient specific trial neck into the broach.

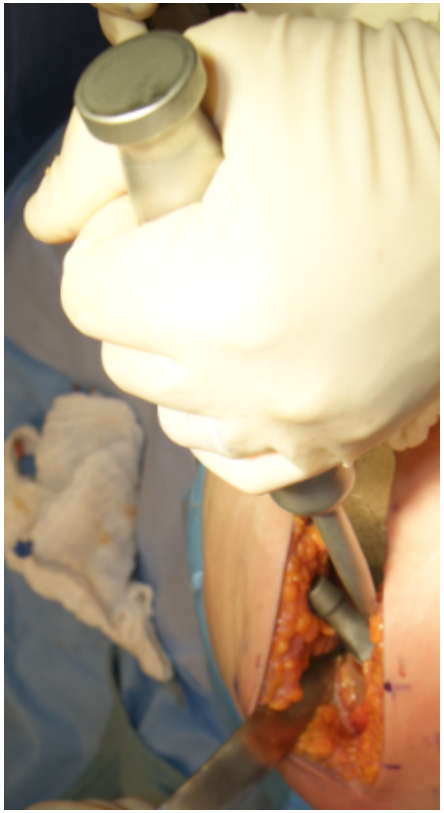


3. Place the trial head onto the taper of the trial neck.
4. Reduce the hip into the trial liner.
5. Check leg length and stability through a full ROM.

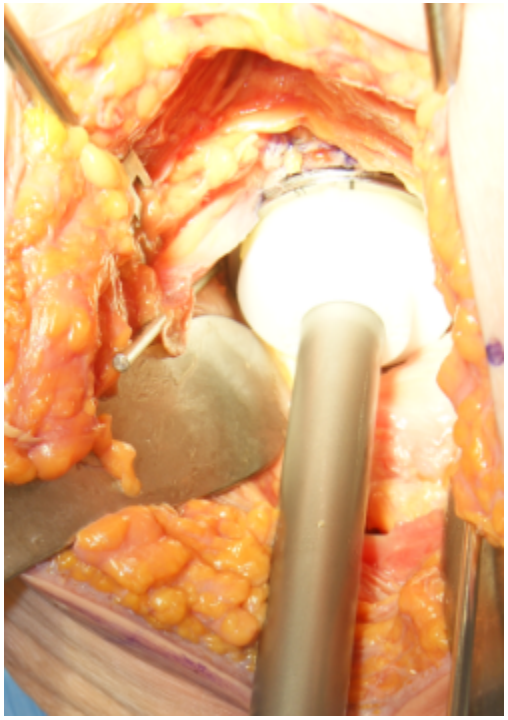


Final Implantation

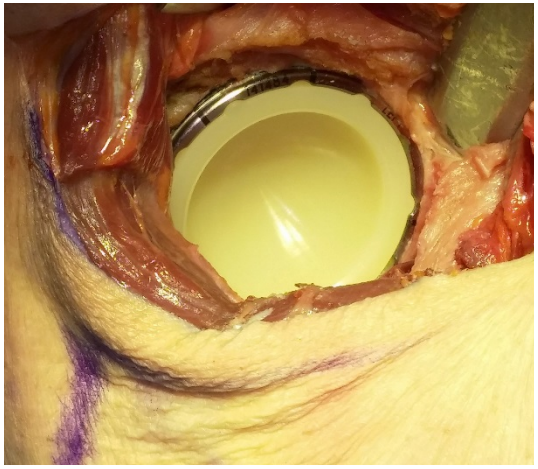
1. Remove all trials and the broach from the femoral canal. Note: Do not irrigate or dry the femoral canal. This will help to preserve the compacted cancellous bone.
2. Manually place the stem into the broached femoral canal. Set the stem impactor into the lateral shoulder of the femoral stem and impact along the axis of the stem until it is fully seated. The HA coating should sit level with the femoral neck resection.



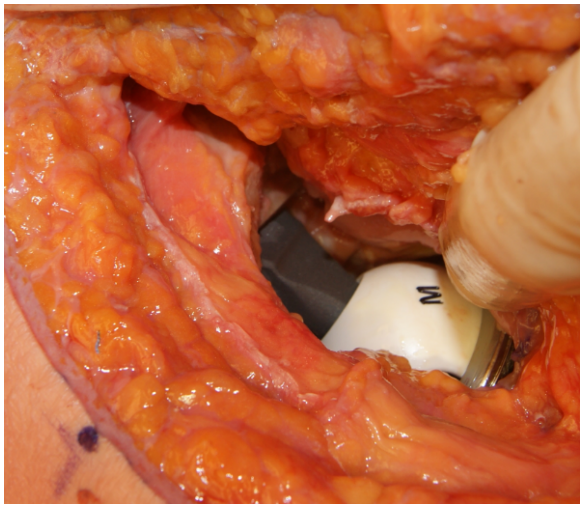
3. Place the acetabular liner into the cup with the anti-rotation scallops aligned in the cup. Care must be taken that there is no soft tissue between the liner and cup, as this may prevent the liner from seating properly and locking into the cup. Seat it using the liner impactor with firm mallet blows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



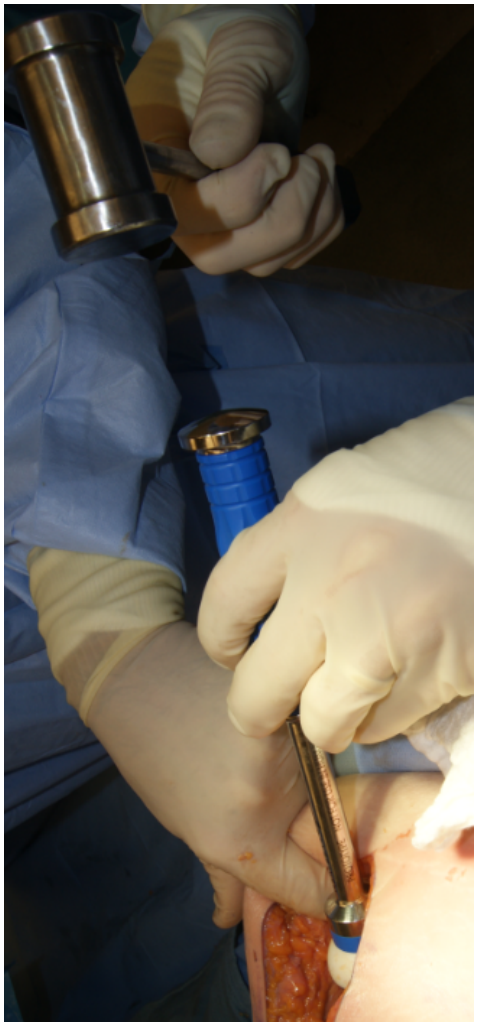
4. Confirm that the face of the liner is flush with the face of the cup to ensure that it is fully seated.



5. Replace the trial head onto the stem taper and confirm the ROM and leg length with the final implants.



6. 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.

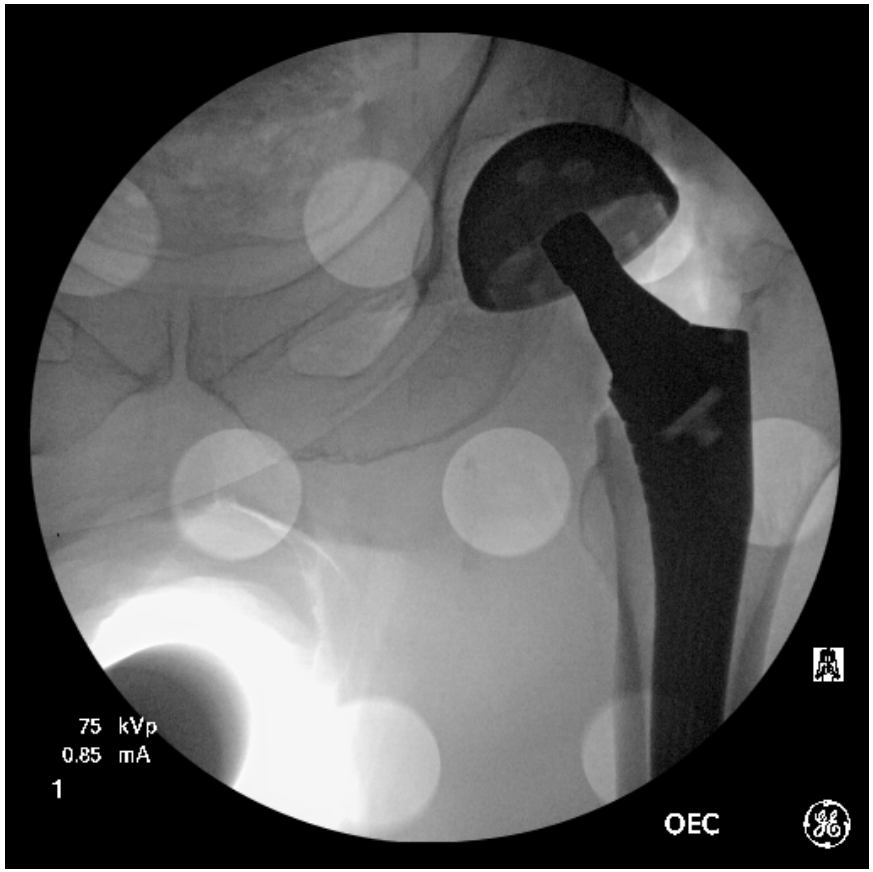


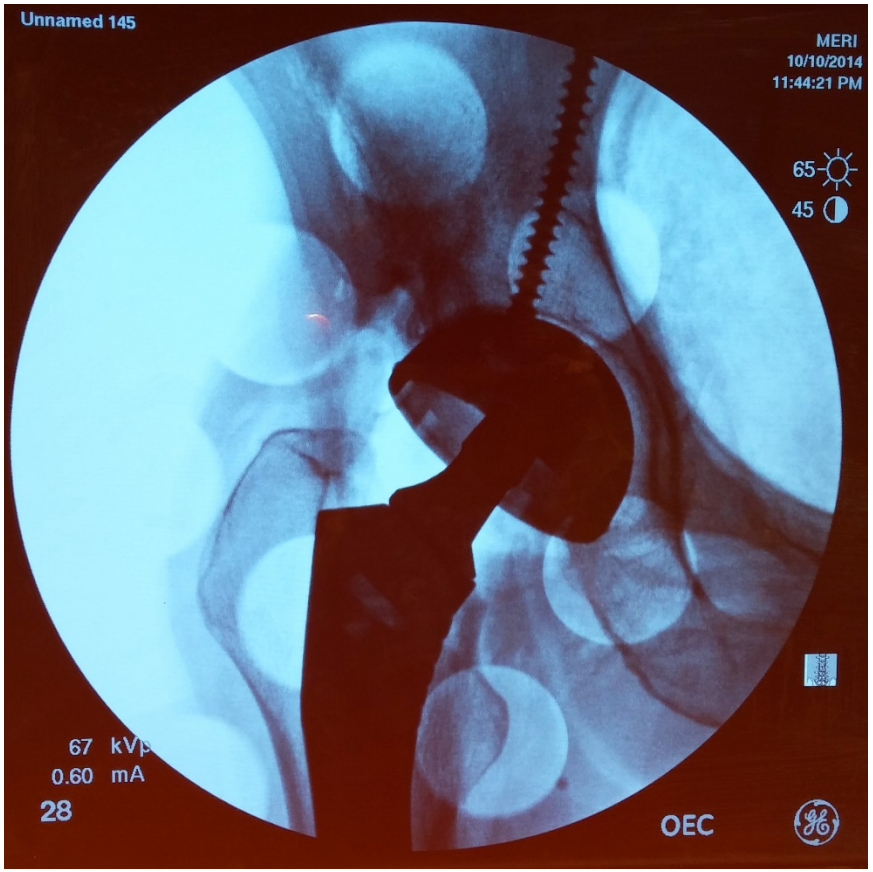
7. Reduce the hip and do a final check of stability, ROM and leg length.
8. Close the incision.

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 very important to firmly impact the head onto the stem taper.*

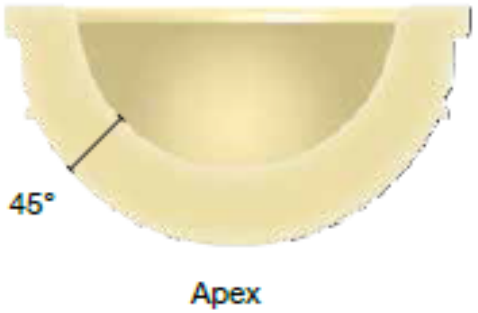
Post-Operative X-Rays





Liner Compatibility and Thicknesses

Cup	Cup	46-49 mm			50-53 mm			54-57 mm			58-63 mm			64-66 mm		
	Group	B			C			D			E			F		
Liner	Head	28	32		32	36		36			36			36		
	Offset	+0	+2	+4	+0	+2	+4	+0	+2	+4	+0	+2	+4	+0	+2	+4
Thickness	45°	5.6	5.0	6.3	5.6	5.0	6.3	5.6	7.0	8.3	7.6	9.0	10.3	10.6	12.0	13.3
	Apex	5.6	5.6	7.6	5.6	5.6	7.6	5.6	7.6	9.6	7.6	9.6	11.6	10.6	12.6	14.6
Liner	Head							Ceramic Only	40		40			40		
	Offset								+2	+4	+0	+2	+4	+0	+2	+4
Thickness	45°								5.0	6.3	5.6	7.0	8.3	8.6	10.0	11.3
	Apex								5.6	7.6	5.6	7.6	9.6	8.6	10.6	12.6



Head Options

Femoral Heads		Diameter	Short	Medium	Long	X-Long
	CoCr Heads	28 mm	✓	✓	✓	✓
		32 mm	✓	✓	✓	✓
		36 mm	✓	✓	✓	✓
	Delta Heads	28 mm	✓	✓	✓	
		32 mm	✓	✓	✓	✓
		36 mm	✓	✓	✓	✓
		40 mm	✓	✓	✓	✓

Intended Use

The Conformis® Hip 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 Conformis® 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 fractures, 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 Conformis® Hip System includes standard hip replacement components as well as the following patient specific components: femoral neck, acetabular cup, single use instrumentation.

The Conformis® Hip System implants are intended for cementless fixation using an anterior or posterior surgical approach.

Contraindications

The following conditions are contraindications for total hip replacement:

1. Active local or systemic infection
2. Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.
3. 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).
4. Charcot's or Paget's disease.
5. Ceramic heads are contraindicated in revision surgery when the femoral stem is well fixed and is not being replaced.
6. Poor quality femoral bone stock which may compromise the proximal fixation of the femoral stem.
7. Any disease, ligamentous or severe muscle laxity or inadequate soft tissue coverage which may compromise the normal healing process or function of the implant.
8. Pathological conditions, neuromuscular disorders or mental conditions whereby the risks associated with these conditions outweigh the benefits to be derived.
9. Metal sensitivity

Magnetic Resonance (MR) Safety Information

The Conformis® 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 Conformis® Hip System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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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.

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