



ACTERA™ HIP SYSTEM

Surgical Technique Guide

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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.

Surgeon Design Team

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

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Pre-operative Image Review

Determination of Leg Length Discrepancy

Perform a clinical evaluation in conjunction with a radiographic analysis 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. 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

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.

Step 1

EXPOSURE AND NECK RESECTION

1 Adequately expose the acetabulum and proximal femur.

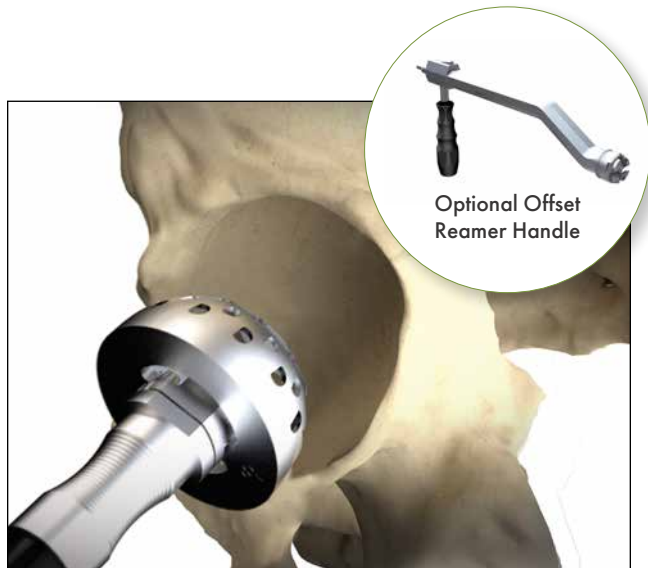
2 Using an oscillating or reciprocating saw, perform a femoral neck osteotomy. The recommended angle of resection is 45° at the templated distance from the lesser trochanter. The resection of the neck can be performed with one or two cuts, depending on surgeon preference.



Optional Corkscrew for
Femoral Head Extraction

3 Remove the femoral head and neck from the incision. A corkscrew instrument is available to assist with femoral head removal.

Step 2 ACETABULAR PREP 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 and drivers, 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. Cordera™ acetabular cups utilize a 2mm pressfit.

Straight or Offset Acetabular Reamer Driver available. For instructions on how to assemble the Offset Reamer Driver please reference MK-03338.

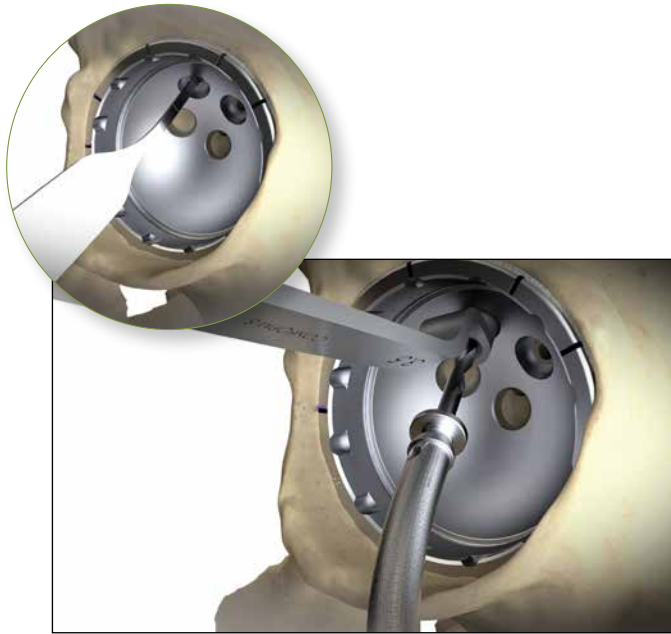
- 5** Assemble the cup impactor and Cordera™ Cup Implant.

If utilizing the straight cup impactor, thread the cup impactor tip onto the distal end of the cup, prior to threading on the cup.

Straight or Offset Cup Impactor available. For instructions on how to assemble the Offset Cup Impactor please reference MK-03339.

- 6** Impact with firm mallet blows until the cup is fully seated. C- Arm imaging can be used to monitor and adjust position and progressive seating of the prosthesis.
- 7** Unthread the impactor from the cup and remove it from the incision.

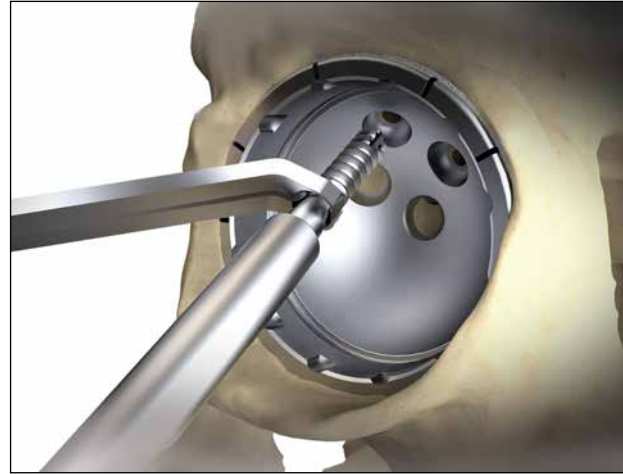
ACETABULAR PREP AND IMPLANTATION



- 8 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 \leq 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.

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



- 9 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.

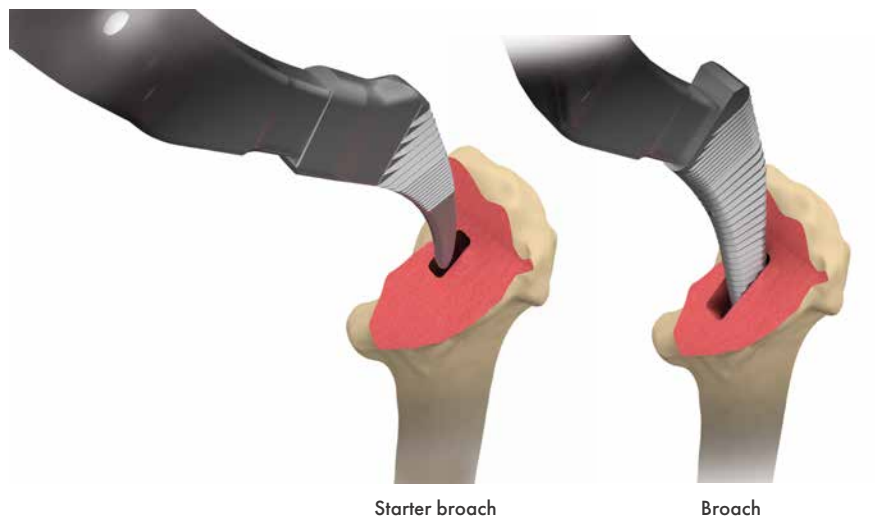


- 10 Place the appropriate grouped trial liner in the acetabular cup.

NOTE:

Liner compatibility chart available at end of surgical technique to determine appropriate grouping.

Step 3 FEMORAL PREPARATION



11 Use the box osteotome assembled with a broach handle of choice for initial entry into the canal in a posterolateral direction. The medial side of the box osteotome and broaches should be assembled in alignment with the lever of the broach handles.

TECHNIQUE TIPS

Using a rongeur to remove posterolateral cortical bone at the piriformis fossa can help reduce the risk of undersizing or malpositioning of the stem.

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

12 Beginning with the smallest broach, progressively broach the femoral canal to the size determined during pre-operative planning. Images above reference the straight broach handles. Straight or Offset Broach Handles available.



13 If desired, a calcar planer is supplied to shape 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.

FEMORAL PREPARATION



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

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



16 Place the appropriate Trial Neck into the broach (an audible click or snap will 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.

Trial Neck Grouping:

A: Stem Size 2-3; STD & High Offset

B: Stem Size 4-6; STD & High Offset

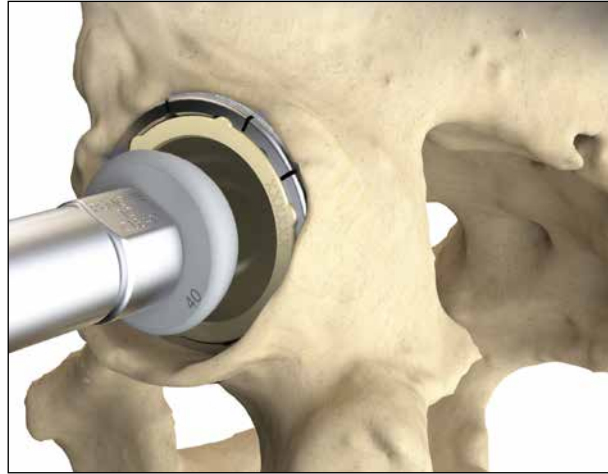
C: Stem Size 7-9; STD & High Offset



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

18 Reduce the hip.

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

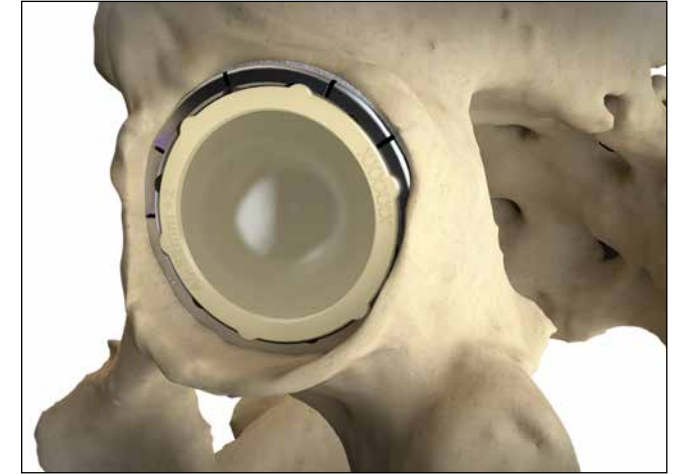


20 Remove all trials and the broach from the femoral canal.

NOTE:

Do not irrigate or dry the femoral canal, as this will help to preserve the compacted cancellous bone.

21 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.



22 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 16 & 17 for more information.



- 23** 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 where the face of the last broach sat.



Straight and Offset Inserters available.

- 24** 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.

- 25** 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.**

| 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 |

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

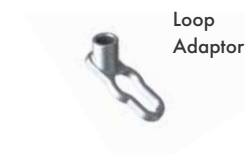
- 27** Close the incision.

Step 6 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 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:

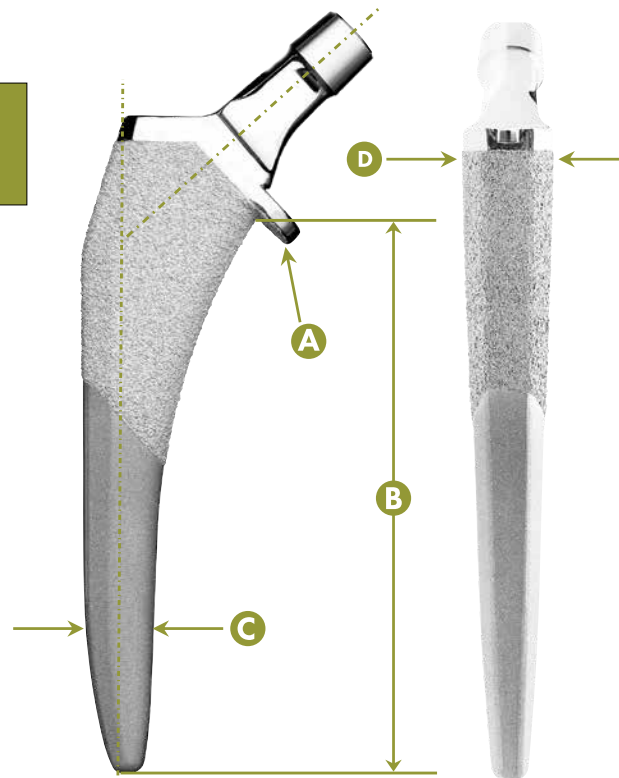
Use of the offset loop adaptor with the Extraction Handle may cause damage to the trunnion of the femoral stem and should be considered for use only if the stem won't be re-implanted.



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 2–3 high offset options
 - 8mm of direct lateralization with sizes 4–9 high offset options



Stem Dimensions

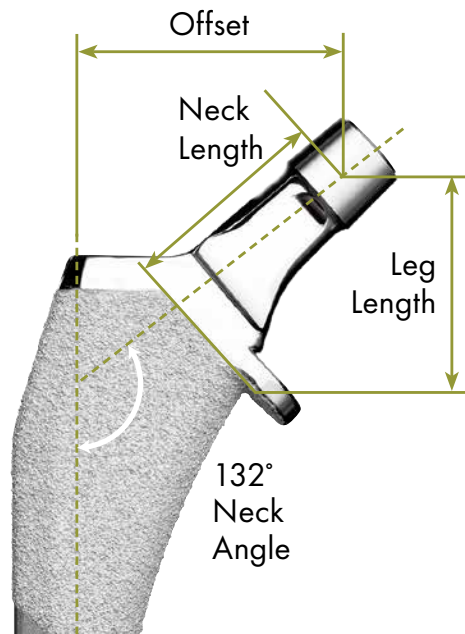
1mm added per size at A/P shoulder

| Size | A Collar Length | B Medial Stem Length | C Distal Width* | D Proximal A/P Width at Shoulder** |
|------|--------------------|-------------------------|--------------------|---------------------------------------|
| 2 | 7mm | 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 |

All measurements in mm unless otherwise noted.

*Measured 25mm from distal tip **Includes coating thickness

Head Center Adjustment Chart





| Size | Offset | Neck Length w/ +0 head | Offset | | | | Leg Length | | | |
|------|----------|---------------------------|--------|------|------|------|------------|------|------|------|
| | | | -4 | 0 | +4 | +8 | -4 | 0 | +4 | +8 |
| 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 | | | | |

Liner Compatibility and Thickness

The face changing liner includes 4mm of additional lateralization compared to its neutral and lipped counterparts.

| 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) | | Diameter | Offset | | | | |
|--|---|----------|--------|--------|------|------------|---------------------------|
| BIOLOX® Delta Ceramic | CoCr Alloy | | Short | Medium | Long | Extra Long | |
|  <p>Zirconia-toughened alumina (BIOLOX® <i>delta</i>) ceramic</p> |  <p>Cobalt-Chrome Alloy: Co-28Cr-6Mo</p> | 28 | -3.5 | 0 | 3.5 | 7 | ONLY AVAILABLE IN CoCr |
| | | 32 | -4 | 0 | 4 | 7 | |
| | | 36 | -4 | 0 | 4 | 8 | ONLY AVAILABLE IN CERAMIC |
| | | 40 | -4 | 0 | 4 | 8 | |

Liner Compatibility and Thicknesses

Neutral:

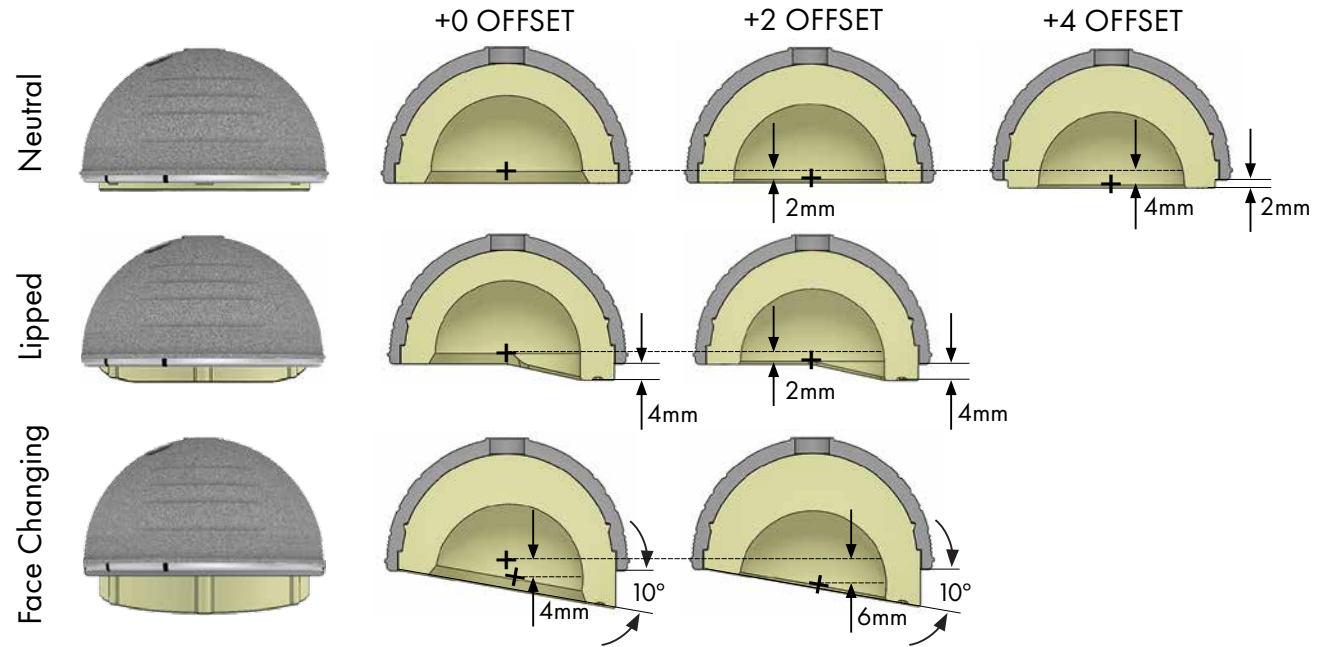
Available in sizes 0, +2, and +4 mm.

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.



| Cup Size | | 46-49 | | | 50-53 | | | 54-57 | | | 58-63 | | | 64-66 | | |
|-----------------|--------|-------|-----|-----|-------|-----|-----|-------|-----|-----|-------|-----|-----|-------|------|------|
| | | B | | | C | | | D | | | E | | | F | | |
| Liner Thickness | Head | 28 | 32 | 32 | 36 | 36 | 36 | 36 | 36 | 36 | 36 | 36 | 36 | 36 | 36 | |
| | Offset | 0 | 2 | 4 | 0 | 2 | 4 | 0 | 2 | 4 | 0 | 2 | 4 | 0 | 2 | 4 |
| | 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 | | | 40 | | | 40 | | |
| | Offset | - | | | - | | | - | | | - | | | - | | |
| | 45° | - | | | - | | | - | | | - | | | - | | |
| | Apex | - | | | - | | | - | | | - | | | - | | |

Actera™ Femoral Instruments

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

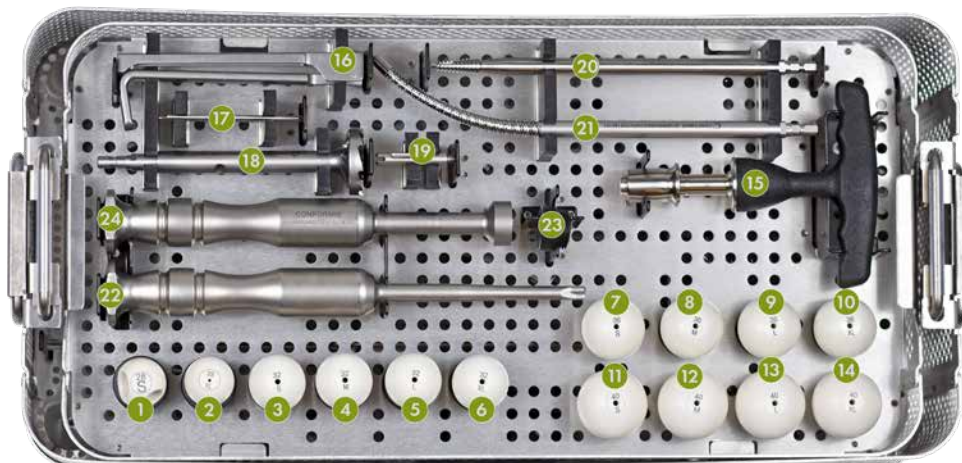
Digital templates available. Please contact your templating vendor.

ACTERA™ FEMORAL TRAY 1080-128 – BOTTOM TRAY



1. Trial Neck, Actera, Size 02-03 Standard
2. Trial Neck, Actera, Size 02-03 High Offset
3. Trial Neck, Actera, Size 04-05-06 Standard
4. Trial Neck, Actera, Size 04-05-06 High Offset
5. Trial Neck, Actera, Size 07-08-09 Standard
6. Trial Neck, Actera, Size 07-08-09 High Offset
7. Modular Box Osteotome
8. Femoral Tapered Reamer
9. Broach Handles, Neutral
10. Actera Starter Broach
11. Broach, Actera, Size 02
12. Broach, Actera, Size 03
13. Broach, Actera, Size 04
14. Broach, Actera, Size 05
15. Broach, Actera, Size 06
16. Broach, Actera, Size 07
17. Broach, Actera, Size 08
18. Broach, Actera, Size 09

ACTERA™ FEMORAL TRAY 1080-128 – TOP TRAY



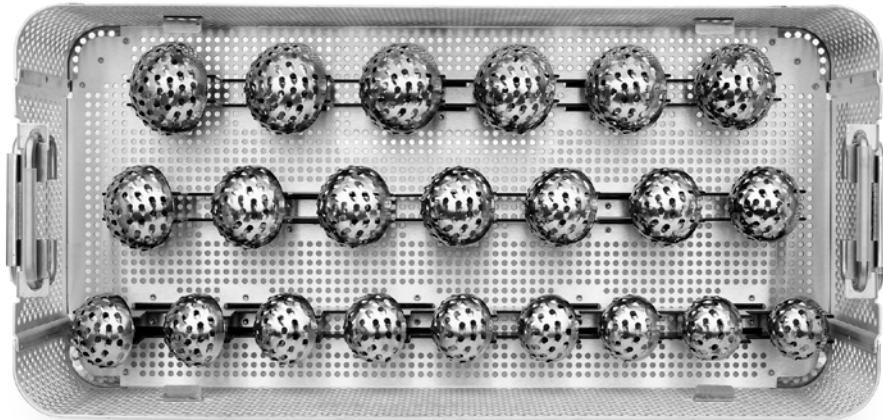
1. Ø28mm Universal
2. Ø28mm XL (+7)
3. Ø32mm SH (-4)
4. Ø32mm MD (0)
5. Ø32mm L (+4)
6. Ø32mm XL (+8)
7. Ø36mm SH (-4)
8. Ø36mm MD (0)
9. Ø36mm L (+4)
10. Ø36mm XL (+8)
11. Ø40mm SH (-4)
12. Ø40mm MD (0)
13. Ø40mm L (+4)
14. Ø40mm XL (+8)
15. T-Handle, Quick-Connect
16. Pin Puller
17. Steinman Pins
18. 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

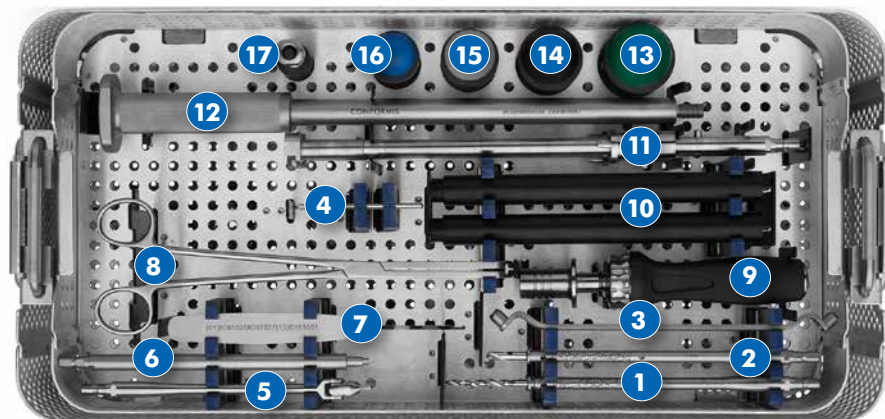
Digital templates available. Please contact your templating vendor.

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. 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

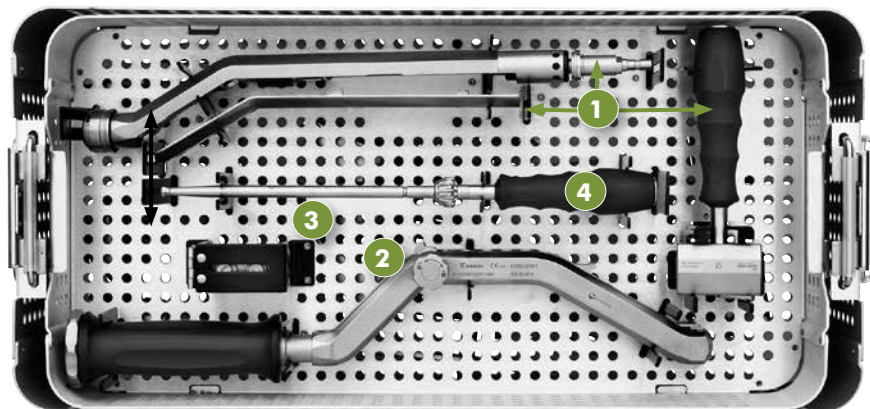
Auxillary Instruments

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

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.

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.



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MK-03340 AA 9.22