ELEOS™ and ELEOS™ with NanoCept™ Technology

Limb Salvage System

Surgical Technique: Distal Femoral Replacement

Featuring BioGrip® Modular Collars with Nano HA Treatment

The ELEOS™ and ELEOS™ with NanoCept™ Technology Limb Salvage System offers options for patients with significant bone loss due to cancer, trauma, or previous surgical procedures. The locking taper design has a history of clinical use in a variety of orthopaedic applications. With an array of options in a multitude of sizes, the ELEOS™ and ELEOS™ with NanoCept™ Technology system provides the surgeon the ability to meet a variety of patient needs.

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Precision Orthopaedic Oncology

- ELEOS™ Limb Salvage Solutions
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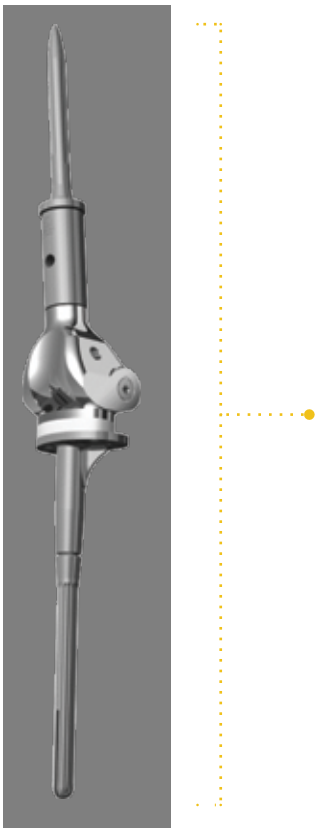
Distal Femoral Replacement

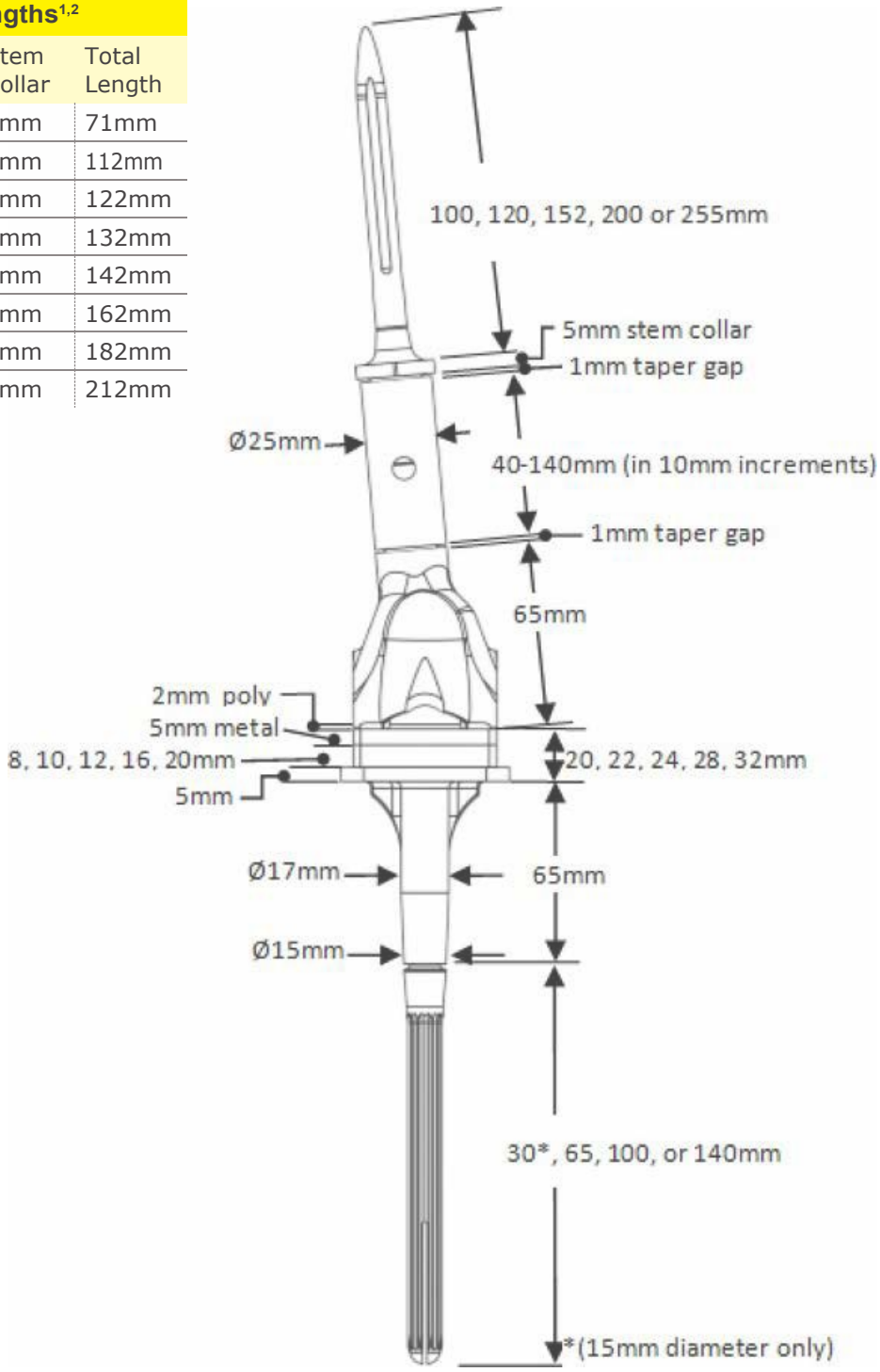
Construct overview

Standard Distal Femur

Table 1.

Standard Distal Femoral Resection Lengths[1,2]					
Distal Femur	Taper Gap	Midsections	Taper Gap	Stem Collar	Total Length
65mm	1mm	None	N/A	5mm	71mm
65mm	1mm	40mm	1mm	5mm	112mm
65mm	1mm	50mm	1mm	5mm	122mm
65mm	1mm	60mm	1mm	5mm	132mm
65mm	1mm	70mm	1mm	5mm	142mm
65mm	1mm	90mm	1mm	5mm	162mm
65mm	1mm	110mm	1mm	5mm	182mm
65mm	1mm	140mm	1mm	5mm	212mm





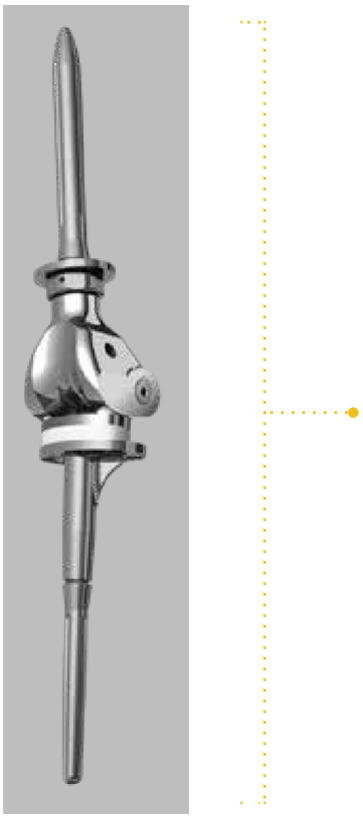
1. Two 40mm Midsections are available to achieve desired resection lengths in 10mm increments.
2. The 20mm Tibial Resection is with an 8mm polyethylene spacer and the thickness of the Tibial Hinge Component (5mm metal and 2mm poly). The actual resection may be less depending on joint line positioning and ligament compliance.

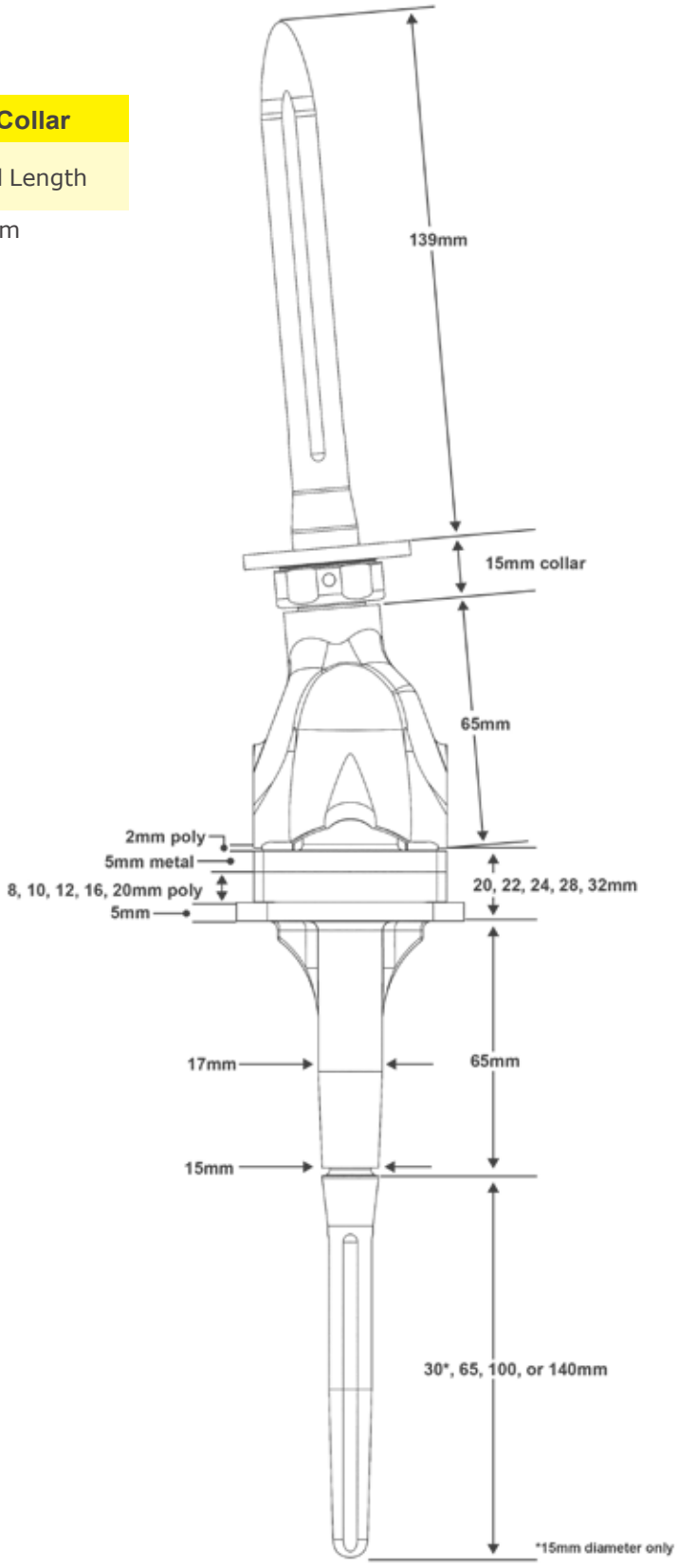
Construct overview

Distal Femur with Reduced Resection Collar

Table 2.

Distal Femur Resection With Reduced Resection Collar			
Distal Femur	Taper Gap	Reduced Resection Collar	Total Length
65mm	1mm	15mm	81mm



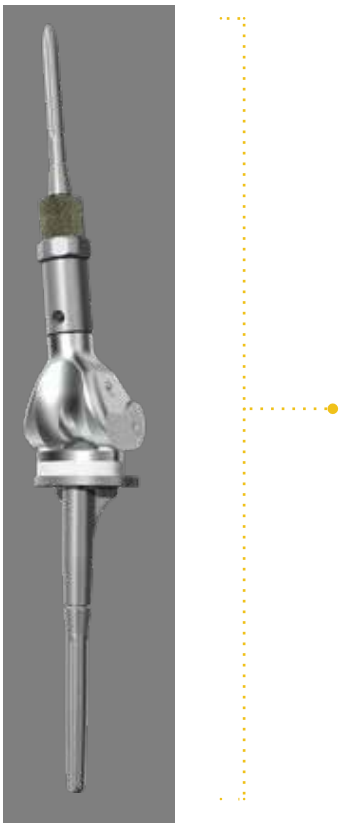


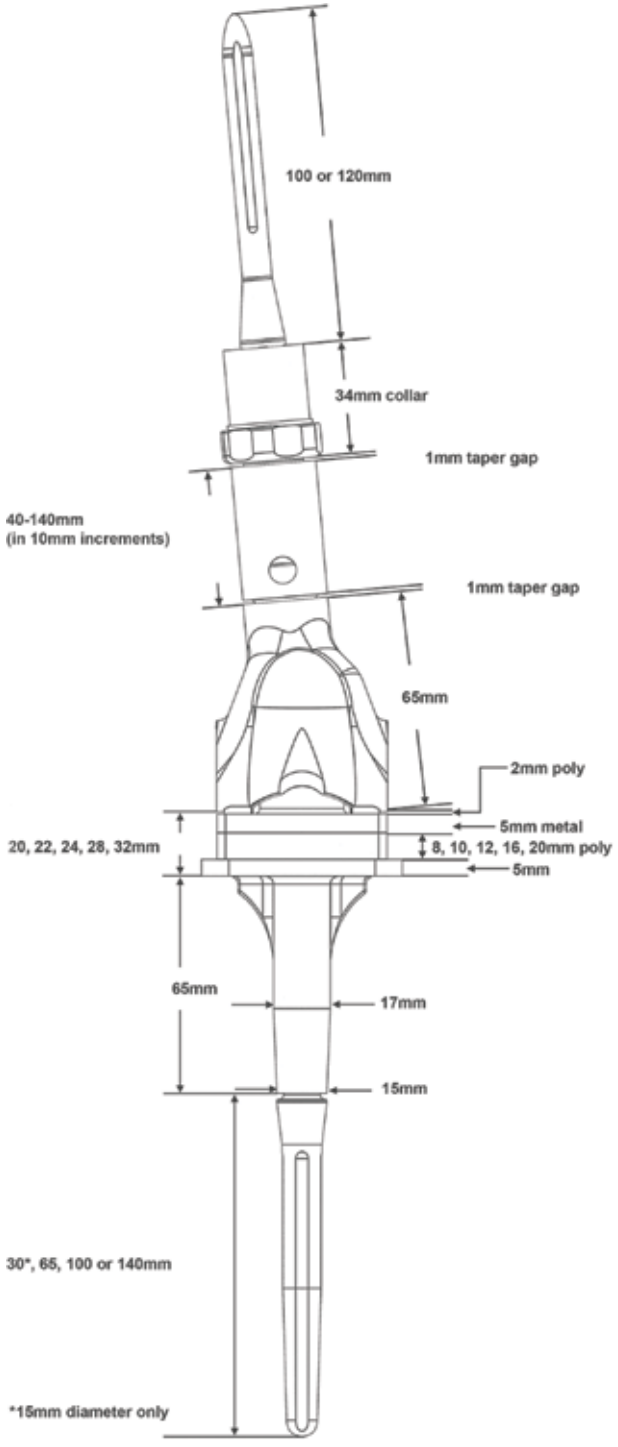
Construct overview

Distal Femur with BioGrip® Porous Collar

Table 3.

Distal Femoral Resection Lengths With BioGrip® Porous Collar[1,2]					
Distal Femur	Taper Gap	Midsections	Taper Gap	Collar Height	Total Length
65mm	1mm	None	None	34mm	100mm
65mm	1mm	40mm	1mm	34mm	141mm
65mm	1mm	50mm	1mm	34mm	151mm
65mm	1mm	60mm	1mm	34mm	161mm
65mm	1mm	70mm	1mm	34mm	171mm
65mm	1mm	90mm	1mm	34mm	191mm
65mm	1mm	110mm	1mm	34mm	211mm
65mm	1mm	140mm	1mm	34mm	241mm





1. Two 40mm Midsections are available to achieve desired resection lengths in 10mm increments.
2. The 20mm Tibial Resection is with an 8mm polyethylene spacer and the thickness of the Tibial Hinge Component (5mm metal and 2mm poly). The actual resection may be less depending on joint line positioning and ligament compliance.

Set configurations

Please refer to document CORP 06.03.21 for a full listing of implant and instrument set requirements, images, and parts.

Component description

The ELEOS™ and ELEOS™ with NanoCept™ Technology Distal Femoral System consists of up to ten components that create a distal femur; the SegmentalStem, Optional Modular Collar, Optional Midsection, Distal Femoral Component, Tibial Hinge Component, Axial Pin, Tibial Baseplate, Tibial Polyethylene Spacer, Optional Tapered Screw, and Optional Stem Extension. The ELEOS™ with NanoCept™ Technology antibacterial coated system provides the Optional Midsection with 12-methacryloyloxydodecyl pyridinium bromide (MDPB), an antibacterial coating.

Note: A Cemented Resurfacing Patella and Block Augments are available if needed.

Segmental stems

Segmental Stems are available in a variety of diameters and lengths in both cemented and canal filling options. Cemented Stems provide flutes to enhance mechanical interlock of bone cement. Canal Filling Stems are splined and slotted (bowed only) and have plasma spray to enhance initial fixation. Modular Collar Segmental Stems are straight and with cemented flutes only. | Table 4

Table 4.

Segmental Stems – Cemented					
Part #	Description	Length	Stem Dia (mm)/ Collar Dia (mm)		
CS-XX100-03M	Straight, Cylindrical, Fluted, Cobalt Chrome	100mm	9/24, 10/24		
CS-XX120-03M	Straight, Cylindrical, Fluted, Cobalt Chrome	120mm	11/28, 13/28, 15/32, 17/36		
CB-XX152-03M	Bowed, Cylindrical, Fluted, Titanium	152mm	11/28, 13/28, 15/32, 17/36		
CB-XX200-03M	Bowed, Cylindrical, Fluted, Titanium	200mm	11/28, 13/28, 15/32, 17/36		
CB-11255-03M	Bowed, Cylindrical, Fluted, Titanium	255mm	11/32		
Segmental Stems – Canal Filling					
FS-XX120-03M	Straight, Cylindrical, Splined, Full Plasma Spray, Titanium	120mm	11/28, 12/28, 13/28, 14/32, 15/32, 16/36, 17/36, 18/36, 19/36, 20/36, 21/36		
FB-XX152-03M	Bowed Cylindrical, Splined, 2/3 Plasma Spray, Slotted, Titanium	152mm	11/28, 12/28, 13/28, 14/32, 15/32, 16/36, 17/36, 18/36, 19/36, 20/36, 21/36		
Segmental Stems – Modular Collar					
Part #	Description	Diameter	Length	Porous Collar	Solid Collar
HR-30001-03M	Modular Collar Locking Ring and Impactor Tip	N/A	N/A	ALL	ALL
HC-09100-03M	Modular Collar Stem, Cemented, Fluted	9mm	100mm	24/28mm	N/A
HC-10100-03M	Modular Collar Stem, Cemented, Fluted	10mm	100mm	24/28mm	N/A
HC-11120-03M	Modular Collar Stem, Cemented, Fluted	11mm	120mm	24/28mm	N/A
HC-13120-03M	Modular Collar Stem, Cemented, Fluted	13mm	120mm	24/28/32/ 36/40mm	36x40mm 40x44mm
HC-15120-03M	Modular Collar Stem, Cemented, Fluted	15mm	120mm	32/36/40mm	36x40mm 40x44mm
HC-17120-03M	Modular Collar Stem, Cemented, Fluted	17mm	120mm	32/36/40mm	36x40mm 40x44mm

Component description

Modular Collars – BioGrip® Porous with Nano HA and Reduced Resection

Modular BioGrip® Porous Collars have a 3D printed porous structure and nano HA treatment to support bone in-growth and anchoring. BioGrip® collars are round in shape and 34mm in overall height. BioGrip® collars come in diameters ranging from 24mm to 40mm, in 4mm increments. Reduced Resection Collars are oval in shape and have a solid body that provides a wide surface area for metaphyseal contact in the distal femur. Reduced Resection Collars are 15mm in overall height (including the locking ring) and have oval footprints of 36mm x 40mm and 40mm x 44mm. All modular collars are used with a Locking Ring and single-use Impactor Tip. | Table 5

Table 5.

Modular Collars – BioGrip® Porous With Nano HA And Reduced Resection					
Part #	Description	Shape	Height	Width	Stems
PB-2400R-03M	Modular Porous BioGrip® HA Collar	Round	34mm	24mm	9/10/11/13mm
PB-2800R-03M	Modular Porous BioGrip® HA Collar	Round	34mm	28mm	9/10/11/13mm
PB-3200R-03M	Modular Porous BioGrip® HA Collar	Round	34mm	32mm	13/15/17mm
PB-3600R-03M	Modular Porous BioGrip® HA Collar	Round	34mm	36mm	13/15/17mm
PB-4000R-03M	Modular Porous BioGrip® HA Collar	Round	34mm	40mm	13/15/17mm
SB-3640V-03M	Modular Reduced Resection Collar	Oval	15mm	36 x 40mm	13/15/17mm
SB-4044V-03M	Modular Reduced Resection Collar	Oval	15mm	40 x 44mm	13/15/17mm

Optional midsections

Seven lengths of optional Midsection components are interchangeable with all ELEOS™ and ELEOS™ with NanoCept™ Technology systems to allow for precise length determination intraoperatively. Lengths range from 40-140mm to accommodate bone resections in various increments. Various configurations of Male/Female Midsections can be coupled to produce the desired resection and overall construct length. | Table 6

Table 6.

Male/Female Midsections	
Part #	Description
25001040E	40mm
25001050E	50mm
25001060E	60mm
25001070E	70mm
25001090E	90mm
25001110E	110mm
25001140E	140mm
Male/Female Midsections with NanoCept™ Antibacterial Coating	
Part #	Description
AM-MS-040MF	40mm, Antibacterial Coated
AM-MS-050MF	50mm, Antibacterial Coated
AM-MS-060MF	60mm, Antibacterial Coated
AM-MS-070MF	70mm, Antibacterial Coated

Component description

Distal femur and axial pin

The Distal Femur features a deepened patellar groove and a 5° valgus angle to assist in the restoration of patellofemoral kinematics, reduction of patellar subluxation and promotion of normal loading patterns. Implant details shown in the below table. | Table 7

Table 7.

Distal Femur And Axial Pins		
Part #	Description	Size
25000007E	Distal Femur Left, Segmental	65mm
25000009E	Distal Femur Right, Segmental	65mm
25002111E	Distal Femur Axial Pin	One Size

Tibial spacer and hinge

The Polyethylene Tibial Spacer is available in 8, 10, 12, 16 and 20mm thicknesses. The Tibial Hinge component is available both with and without a +/- 15° rotational stop. | Table 8

Table 8.

Polyethylene Tibial Spacer And Hinge		
Part #	Description	Size
25001208E	Tibial Poly Spacer	8mm
25001210E	Tibial Poly Spacer	10mm
25001212E	Tibial Poly Spacer	12mm
25001216E	Tibial Poly Spacer	16mm
25001220E	Tibial Poly Spacer	20mm
THSMWRS01M	Tibial Hinge with Rotational Stop	One size
THSMWOS01M	Tibial Hinge without Rotational Stop	One size

Tibial baseplate

The Tibial Baseplate is available in five sizes for optimal tibial coverage. | Table 9

Table 9.

Tibial Baseplate And Tapered Screw		
Part #	Description	Size
TB-2201E-01M	Tibial Baseplate Size 1	60mm M/L
TB-2202E-01M	Tibial Baseplate Size 2	65mm M/L
TB-2203E-01M	Tibial Baseplate Size 3	70mm M/L
TB-2204E-01M	Tibial Baseplate Size 4	75mm M/L
TB-2205E-01M	Tibial Baseplate Size 5	80mm M/L
TB-TSCRW-01M	Tibial Baseplate Tapered Screw	-
KSC01500E	Modular Tibial Base Stem Cap	N/A

Component description

Tibial block augments

The Tibial Baseplate also accepts optional Block Augments that can be placed on the medial or lateral compartment to address specific patient bone deficiencies. The augments are available in three thicknesses (5, 10 and 15mm) and are size-specific to the tibial tray used. | Table 10

Table 10.

Tibial Block Augments		
Part #	Description	Size
KTAGB(XXX)E	Tibial Block Augment	(1, 2, 3, 4, 5) X (5, 10, 15mm)

Stem extensions

Stem Extensions are available in lengths ranging from 30-140mm in either cemented or canal filling options. | Table 11

Table 11.

Stem Extensions – Cemented				
Part #	Description	Length	Diameter	Collar
KSC01530E	Straight Cylindrical, Fluted, Titanium (bullet tip)	30mm	15mm	None
KSC0(XX)65E	Straight Cylindrical, Fluted, Titanium	65mm	10, 12, 14, 16mm	None
KSC(XX)100E	Straight Cylindrical, Fluted, Titanium	100mm	10, 12, 14, 16, 18mm	None
Stem Extensions – Canal Filling				
KSP(XX)100E	Straight, Cylindrical, Splined, Slotted, Titanium	100mm	11, 12, 13, 14, 15, 16, 17, 18, 19, 21mm	None
KSP(XX)140E	Straight, Cylindrical, Splined, Slotted, Titanium	140mm	11, 12, 13, 14, 15, 16, 17, 18, 19, 21mm	None

Surgical technique steps

Femoral preparation

Femoral resection

Preoperatively assess the amount of femoral and tibial bone to be resected. The amount of bone to be resected is determined by clinical evaluation.

- Note: Following tumor resection, it is surgeon preference if the femoral resection or tibial resection is done first.

- Caution: Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively. Accurate pre-operative planning requires good quality standardized radiographs of the appropriate anatomy.

- Caution: A full femoral x-ray and/or 3-dimensional image or MRI must be reviewed prior to surgery to ensure adequate bone stock is available for resection and proper reaming.

Using the Distal Femoral Resection Template, measure the level of resection from the distal end of the medial condyle.

If using a modular collar, use the Distal Femur Resection Template provided in the Collar Instrument Tray as it includes resection markings that include the modular Reduced Resection Collar and BioGrip® Porous Collar.

1. Mark the level of resection determined during templating as seen in Figure 1. Consult the resection measurement tables on Pages 4-6 of this document for additional reference.

2. Resect the distal femur at the marked location, making a transverse cut as shown in Figure 2.

Figure 1

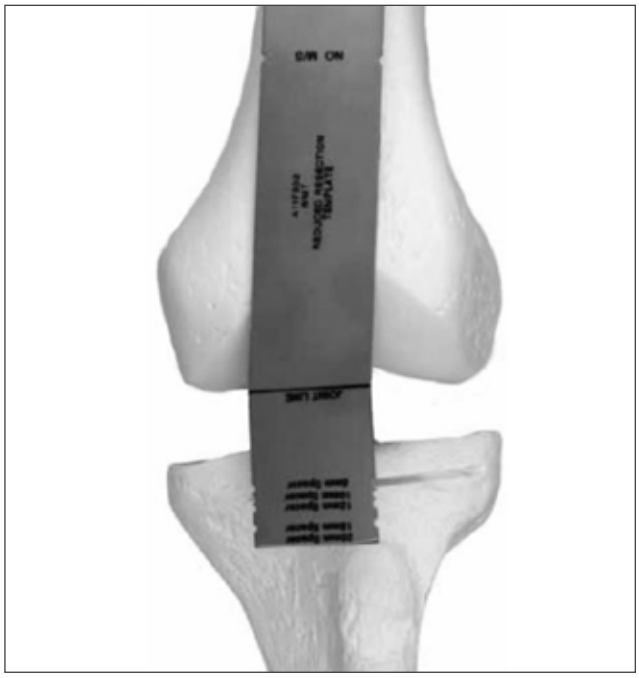
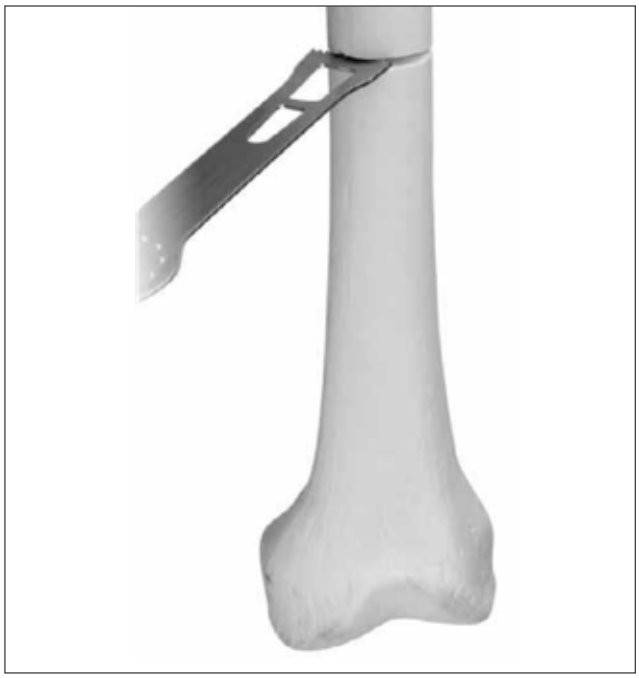


Figure 2



Surgical technique steps

Femoral reaming and planing – straight segmental stems and modular collar segmental stems

Important: If using a standard segmental stem or modular BioGrip® porous collar, use the standard Reamer Trial instruments for canal reaming, planing, and trialing. If using a Reduced Resection Collar, use the Reduced Resection Reamer Trials provided in the Collar Instrument Tray.

Start by using a Reamer Trial at least 2 millimeters less than the assessed canal diameter. Progressively ream in 1/2mm or 1mm increments until cortical chatter is achieved. If using a Reduced Resection Collar where the smallest diameter stem is 13mm, you can progressively ream the canal from 11mm to 13mm using a straight Cylindrical Reamer, taking care to ream to the 100mm depth marking on that instrument. Ream the (femoral) canal using Reamer Trials by inserting to the full depth to face ream the resection area ensuring collar contact on the cortices | Figure 3. Select a stem diameter that corresponds to the appropriate cement mantle or canal filling fit based on clinical evaluation.

- Note: Use the Reamer Trial Adapter | Figure 4 with Reamer Trials to ream under power. To assemble the Reamer Trial Adapter, lift the sliding portion of the quick connect mechanism of the adapter, engage the post, aligning the hexagon, then release. The T-Handle can also be used with the Reamer Trial Adapter for manual reaming. The Reamer Trials are used for both reaming and subsequent trialing.
- Note: The segmental stem diameters from Table 4are equal to Reamer Trial diameters. When determining the appropriate Reamer Trial size for the desired cement mantle, the difference will represent the cement mantle. For instance, reaming to a 13mm diameter will provide a line-to-line fit with a 13mm stem. Reaming to a 14mm will provide a 0.5mm cement mantle per side, while reaming to 15mm will provide a 1mm cement mantle per side.
- Note: The Segmental Canal Filling Stem diameters from Table 4are larger by 0.5mm than the packaged stem size due to the addition of the plasma spray. When determining the appropriate Reamer Trial size for the desired press fit, the difference between the Reamer Trial size and the stem size will represent the press fit. For instance, reaming to a 12.5mm diameter will provide a 1mm press fit with a 13mm stem. A 13mm Reamer Trial will provide a 0.5mm press fit and a 13.5mm Reamer Trial will provide a line-to-line fit.
- Caution: Canal filling stems require appropriate clinical evaluation for sizing. Use of a canal filling stem may increase the risk of fracture during implantation. Intraoperative fluoroscopy during reaming and implantation will decrease this risk. Depending on patient bone quality, the canal may require reaming to the same diameter as the actual stem implant diameter.
- Caution: Canal filling stems are 0.5mm larger in diameter than the corresponding diameter reamer trials. As with any plasma spray process, there may be slight variations to the overall diameter. Canal filling stems should be inserted through the various holes of the Ring Gauge to measure the actual stem implant diameter of the chosen stem. Additional reaming may be performed to achieve the desired press fit based on this information and the patient's bone quality shown in Figure 5.
- Note: Cerclage wire can be used at the surgeon's discretion to address stresses in the bone that are inherent during the implantation of canal filling stems.

Figure 3

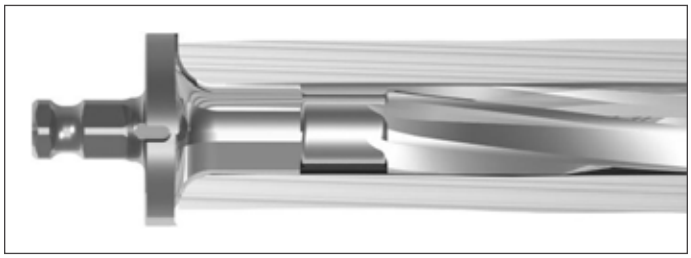
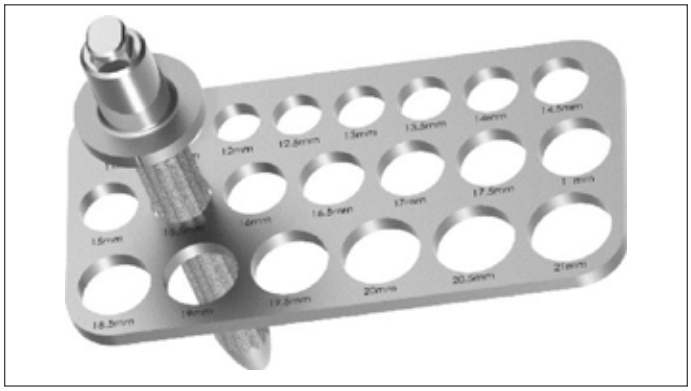


Figure 4

Figure 5



Surgical technique steps

Femoral reaming and planing – bowed segmental stems

If a bowed stem is chosen, a set of flexible reamers can be used from the hospital's general surgical OR instrumentation. Based on preoperative planning, it is suggested to start by using a flexible reamer at least 2 millimeters less than the assessed canal diameter. Progressively ream in 1/2mm or 1mm increments until cortical chatter is achieved. Follow the flexible reamer with the appropriate size Bowed Stem Planer, based on chosen stem diameter, to face ream the resection area and prepare for the stem taper geometry ensuring collar contact on the cortices and mates with the proximal femur. | Table 12

- Caution: It is important to use the Bowed Stem Planer that matches the desired stem to be implanted. This will assure that the correct proximal geometry is prepared in the bone to match the implanted stem.
- Note: Use the Reamer Trial Adapter shown in Figure 6 with Bowed Planer to ream under power. To assemble the Reamer Trial Adapter, lift the sliding portion of the quick connect mechanism of the adapter, engage the post, aligning the hexagon, then release.

Figure 6

Table 12.

Bowed Stem Planers		
Part #	Description	Use with Bowed Stem Diameters
BP-1113S-03N	Bowed Planer Small	11mm-13mm
BP-1417M-03N	Bowed Planer Medium	14mm-17mm
BP-1821L-03N	Bowed Planer Large	18mm-21mm

Select a stem diameter that corresponds to the appropriate cement mantle or canal filling fit based on clinical evaluation. Table 4. (Page 7)

- Note: The bowed trials diameters are line to line with the marked size. For example, a 12mm bowed stem trial is 12mm actual outside diameter.
- Note: The Segmental Cemented Stem diameters from Table 4 are equal to bowed stem trial diameters. When determining the appropriate bowed stem trial size for the desired cement mantle, the difference will represent the cement mantle. For instance, reaming to a 13mm diameter will provide a line-to-line fit with a 13mm stem. Reaming to a 14mm will provide a 0.5mm cement mantle per side, while reaming to 15mm will provide a 1mm cement mantle per side.
- Note: The Bowed Segmental Canal Filling Stem diameters from Table 4 are larger by 0.5mm than the packaged stem size due to the addition of the plasma spray. When determining the appropriate Bowed Segmental Stem Trial for the desired press fit, the difference between the Bowed Segmental Stem Trial size and the Bowed Segmental Canal Filling Stem size will represent the press fit. For instance, reaming to a 12.5mm diameter will provide a 1mm press fit with a 13mm stem. A 13mm Reamer Trial will provide a 0.5mm press fit and a 13.5mm Reamer Trial will provide a line-to-line fit.

Surgical technique steps

- Caution: Canal filling stems require appropriate clinical evaluation for sizing. Use of a canal filling stem may increase the risk of fracture during implantation. Intraoperative fluoroscopy during reaming and implantation will decrease this risk. Depending on patient bone quality, the canal may require reaming to the same diameter as the actual stem implant diameter.
- Caution: Bowed Segmental Canal Filling Stem Canal filling stems are 0.5mm larger in diameter than the corresponding diameter reamer trials. As with any plasma spray process, there may be slight variations to the overall diameter. The canal filling stems should be inserted through the various holes of the Ring Gauge to measure the actual stem implant diameter of the chosen stem similar to that shown in Figure 5. Additional reaming may be performed to achieve the desired press fit based on this information and based on the patient's bone quality.
- Note: Due to the bow of the stem, the Bowed Segmental Canal Filling Stem may not insert fully to the collar in the Ring Gauge. The size of the plasma spray can be assessed when the stem is inserted partially prior to reaching the bow.
- Note: Cerclage wire can be used at the surgeon's discretion to address stresses in the bone that are inherent during the implantation of canal filling stems.

Surgical technique steps

Tibial preparation

Resect the tibia using the provided Intramedullary (IM) Resurfacing Instrumentation. Consider that the Tibial Components (Tibial Baseplate, Tibial Polyethylene Spacer, and Tibial Hinge Component) will add 20mm of length when using an 8mm spacer; confirm that enough tibial bone is removed.

Note: The ELEOS™ Tibial implants are designed for a perpendicular tibial base orientation to the IM canal. Hence, IM instrumentation helps ensure a neutral resection.

Tibial reaming

1. Initiate an opening in the proximal tibia with the 3/8 in. Starter Drill Bit. The opening shouldbe slightly posterior to the anterior cruciate ligament tibial attachment.
2. Attach the Quick Disconnect T-handleto the 11 in. Reamer/IM Rod.
3. Ream to establish the anatomical axis of the proximal tibia and to allow for the assembly of the IM Tibial Alignment Guide. | Figure 7
4. Drill to approximately 1 to 1.5 inches in depth.
5. Toggle the drill to increase the opening diameter. Remove the T-Handle quick connect,leaving the reamer shaft/IM Rod in the bone.

Note: If using a Stem Extension, continue reaming with consecutive larger reamer diameters until thedesired canal diameter is achieved. This is ideally done after making the tibial resection.

Caution: Hand reaming is recommended when a patient has poor bone quality.

Figure 7

Surgical technique steps

Tibial resection

1. Preassemble the IM Tibial Alignment guide and IM Tibial Resection guide on the back table. Remove the Quick Disconnect T-Handle from the 11 inch Reamer/IM Rod.

2. Slide the IM Tibial Alignment and Resection Guide Assembly onto the 11 inch Reamer/IM Rod until the bottom surface of the guide rests against the tibial surface. | Figure 8

3. Turn the locking screw to lock the guide to the 11 inch Reamer/IM Rod A shown in Figure 8. The Depth Stylus and/or Dual Reference Gauge (also known as crab claw/angel wing) can be used to set the proximal/distal position of the IM Tibial Resection guide to the desired level of tibial resection B shown in Figure 8. The Depth Stylus can be set to measure a depth of resection of 2mm or 10mm.

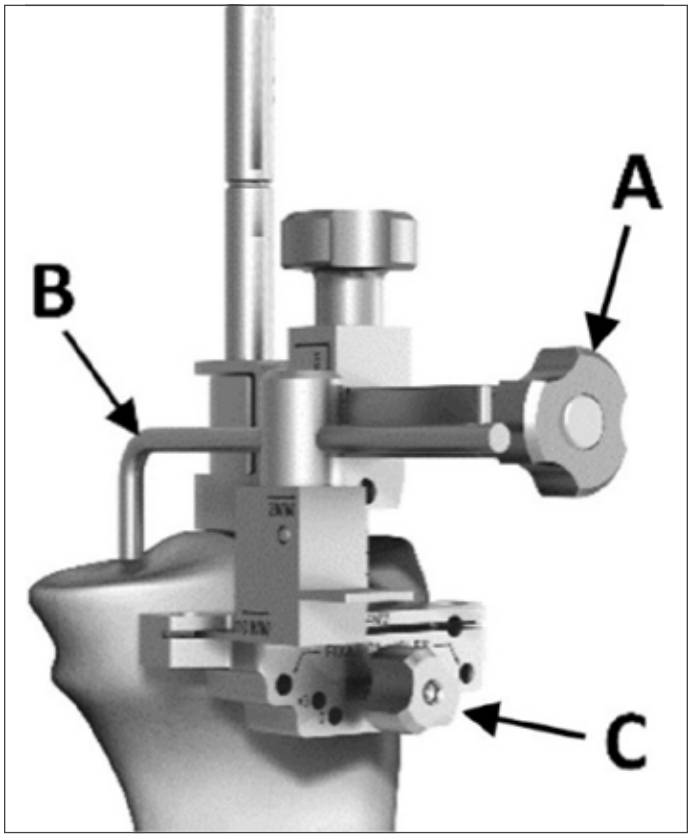
Note: The IM Tibial Resection Guide can be moved an additional 3mm down if the initial pin is placed in the "0" hole to get the desired resection level. Due to patient specific anatomy or pathology, greater resection may be required to accommodate the hinge component. The Distal Femoral Resection Template may aid in identifying the tibial resection and minimize the need for additional resections. The required resection can be verified by template measurement per Figure 1 (Page 11).

4. After desired resection level is achieved, tighten the knob on the IM Tibial Resection Guide C shown in Figure 8. Pin the IM Tibial Resection Guide to the proximal tibia.

5. After the desired alignment is achieved and pins are in place, loosen the locking screw shown in Figure 8 and knob on the IM Tibial Resection Guide C shown in Figure 8. Remove the top of the IM Tibial Alignment Guide leaving the IM Tibial Resection Guide pinned into the tibia.

6. Make the tibial resection and remove the IM Tibial Resection Guide.

Figure 8



Surgical technique steps

Optional Tibial stem extension

1. Stem Extensions are available in either canal-filling or cemented options shown in Table 11. If a Stem Extension is to be used, continue reaming with consecutive larger reamer diameters until the desired diameter.

2. Utilize the cylindrical reamer to continue preparing the tibial canal for the Stem Extension.

3. If the tibial resection has been completed, ream to the appropriate depth of the tibial construct (shown in Figure 9 in red).

4. If the tibial resection has not been completed, ream approximately 20mm beyond that distance (shown in Figure 9 in green) to account for the tibial baseplate tray, general poly spacer, and tibial hinge component.

   - Note: Consider an additional 20mm to account for the placement of a cement restrictor in the distal end of the prepared tibial canal.

5. When desired reaming is complete, ensure that the Reamer provides a stable construct for additional tibial preparation.

   - Caution: Hand reaming may be appropriate to avoid thinning the tibial cortex which could result in a fracture.

   - Note: The Stem Extension diameters from Table 11 are equal to Reamer diameters. When determining the appropriate Cylindrical Reamer size for the desired cement mantle, the difference will represent the cement mantle. For instance, reaming to a 13mm diameter will provide a line-to-line fit with a 13mm stem. Reaming to a 14mm will provide a 0.5mm cement mantle per side, while reaming to 15mm will provide a 1mm cement mantle per side. When determining the appropriate Cylindrical Reamer size for the canal filling stems, the difference will represent the fit. For instance, reaming to a 13mm diameter will provide a line-to-line fit with a 13mm stem, while reaming to 12mm will provide a 1mm press fit.

Figure 9

Stem Extension	Resected (Red Line)	Unresected (Green Line)
30mm	Top of reamer threads	Between 65mm letters
65mm	Top of 65mm etching	Between 100mm letters
100mm	Top of 100mm etching	Between 140mm letters
140mm	Top of 140mm etching	20mm past top of 140mm

Surgical technique steps

Tibial baseplate preparation

1. Select the Trial Tibial Baseplate Template that provides the optimal proximal tibial bone coverage. | Figure 10

Note: If Augments are used, see "Block Augments (optional)" on Page 32 and attach the appropriate size and thickness Trial Augment to the Trial Tibial Baseplate Template.

2. Place the Trial Tibial Baseplate Template on the proximal tibia.

Note: To ensure optimal Trial Tibial Baseplate Template sizing and location, the template may be initially placed over the Cylindrical Reamer. Slide the Trial Tibial Base Handle/Drill Guide over the reamer until it interfaces with the template, centering the template on the tibial canal (Figure 11). Change the template size if required to optimize proximal tibial bone coverage.

3. Once size and alignment are confirmed, pin the Trial Tibial Baseplate Template to the proximal tibia using Tibial Fixation Pins. After pinning, remove the reamer and attach the Trial Tibial Base Handle/Drill Guide and External Check Rod to the Trial Tibial Baseplate Template. | Figure 12

Note: Align the distal end of the External Check Rod with the second toe.

4. Remove the Tibial Baseplate Handle and External Check Rod.

5. Loosely attach the Keel Punch Guide Handle to the Keel Punch Guide. Align the pegs on the bottom of the Keel Punch Guide to the center holes in the Trial Tibial Baseplate Template A as shown in Figure 10.

6. Secure the Keel Punch Guide to the Trial Tibial Baseplate by turning the knurled handle, ensuring that the Keel Punch Guide Handle is in the correct orientation (refer to A in Figure 13).

Figure 10

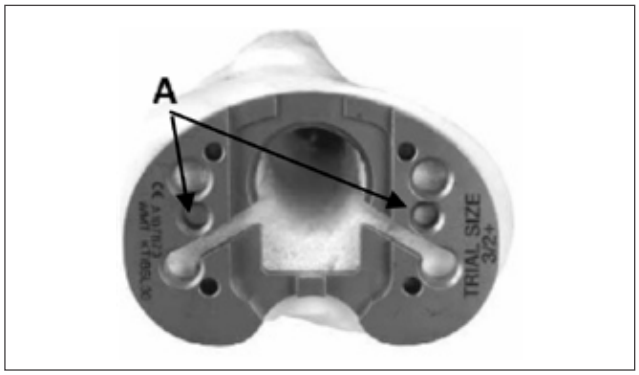


Figure 11

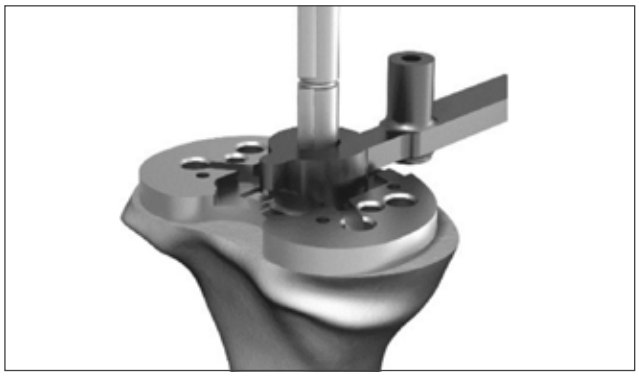


Figure 12

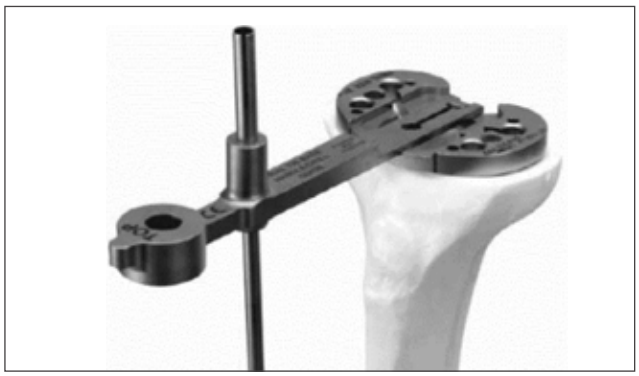
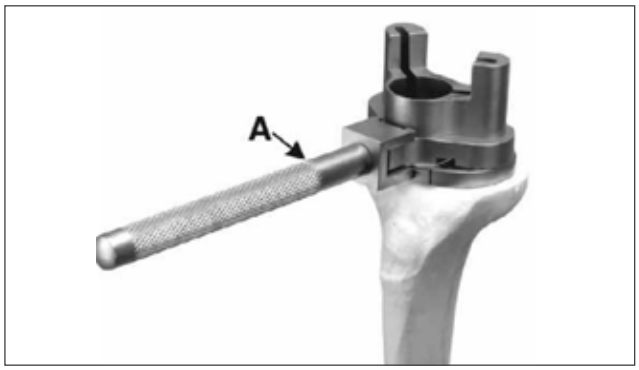


Figure 13



Surgical technique steps

Tibial baseplate reaming

1. Align the Press Fit Reamer Guide or Cemented Reamer Guide through the Keel Punch Guide A | Figure 14. If a thin cement mantle is preferred, utilize the Press Fit Reamer Guide and Press Fit Reamer; if a thicker cement mantle is preferred, use the Cemented Reamer Guide and Cemented Reamer.

Note: The Press Fit Reamer Guide and Reamer provide a 0.5mm overall undersize fit. The Cemented Reamer Guide and Reamer provide a 0.5mm per side cement mantle.

2. Using the appropriate reamer, ream until no teeth are visible above the Reamer Guide. | Figure 14

Note: Make certain that the Tibial Baseplate Template stays flush to the resection surface during the reaming and punching steps.

3. Remove the Reamer Guide from Keel Punch Guide.

Tibial baseplate keel punch

1. Using the Keel Punch Impactor and the Press Fit or Cemented Keel Punch, slide the punch through the guide until the punch is fully seated | Figure 15 and Figure 16. If Stem Extension reaming was performed, attach appropriate size Trial Stem Extension to the chosen Keel Punch.

2. Disassemble and remove all tibial preparation instruments. Use the Pin Puller to remove fixation pins.

Figure 14

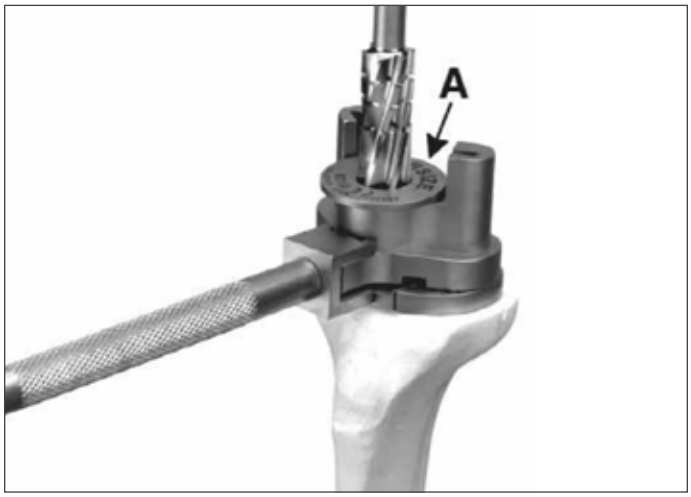


Figure 15

Figure 16

Surgical technique steps

Trialing

Reamer trial assembly

1. Assemble the Trial Distal Femur and any necessary Trial Midsections to the in-situ Reamer Trial to reproduce the appropriate resected length.

Note: To reproduce the appropriate resection length within 10mm increments, two 40mm Trial Midsections are available in the instrumentation tray.

2. To assemble the Trial Midsections to the Reamer Trials, lift the sliding portion of the quick connect mechanism of the trial component, engage the post, aligning the tab with the slot, then release. | Figure 17

Bowed trial assembly

1. Assemble the Trial Distal Femur and any necessary Trial Midsections to the Bowed Trial Stem to reproduce the appropriate resected length.

Note: When assembling a Bowed Trial Stem, ensure that the bow is in alignment with the curve of the bone.

Note: To reproduce the appropriate resected length within 10mm increments, two 40mm Trial Midsections are available in the instrumentation tray.

2. To assemble the Trial Midsections to the Bowed Stem Trials, lift the sliding portion of the quick connect mechanism of the trial component, engage the post, aligning the tab with the slot, then release. | Figure 18

3. After assembly, insert the femoral trial construct into the femoral canal.

Caution: If the construct is difficult to insert into the femoral canal, replace the Bowed Stem Trial with the next smallest size until insertion is feasible.

Figure 17

Figure 18

Surgical technique steps

Optional Step

Trialing with Modular Collars

1. If using a Modular BioGrip® Porous Collar, determine the optimal collar size and geometry by overlaying the Collar Trial Gauge with the in-situ Reamer Trial. | Figure 1

2. Assemble the Distal Femur Trial, BioGrip® Collar Height Trial, and any necessary Trial Midsections to the in-situ Reamer Trial. | Figure 2

Note: To reproduce the appropriate leg length within 10mm increments, two 40mm Trial Midsections are available in the instrumentation tray.

To assemble the Trial Midsections to the BioGrip® Collar Height Trial, lift the sliding portion of the quick connect mechanism of the trial component, engage the post, aligningthe tab with the slot, then release.

3. If additional face reaming is desired prior to final Trial Reduction, remove the in-situ reamer trial by turning it counter-clockwise. Assemble the Face Planer with the appropriate diameter Modular Guide Stem. Proceed to face plane the remaining bone to desired state. | Figure 3

4. Remove the Face Planer and Guide Stem and replace with the desired diameter Reamer Trial to perform final Trial Reduction.

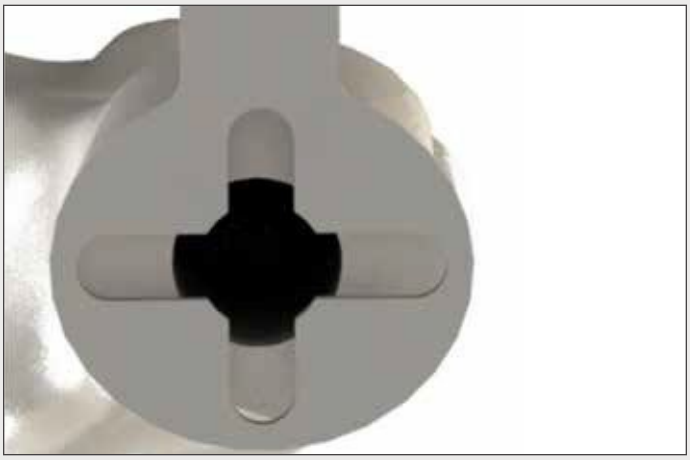
Note: Collar size and geometry can be rechecked by overlaying a Collar Trial Gauge on the resection level visually centered on the canal. | Figure 4

Optional Step: Figure 1

Optional Step: Figure 2

Optional Step: Figure 3

Optional Step: Figure 4



Surgical technique steps

Tibial trial assembly

1. Assemble the Trial Tibial Baseplate, Trial Stem Extension (optional), Trial Tibial Poly Spacer and Trial Tibial Hinge Component according to previously determined sizes chosen. | Figure 19
2. Insert the trial tibial component assembly into the tibia. | Figure 20
3. Reduce the trial femoral construct onto the trial hinge component. Next, insert the Trial Axial Pin to attach the Trial Distal Femur to the Trial Tibial Hinge Component to secure the construct for trial reduction. | Figure 21

Note: The Trial Axial Pin can be inserted from the medial or lateral side. | Figure 22

Trial reduction

1. Perform a trial reduction. Align the tibial trial components in the planned expected rotation. The tibia and soft tissue will determine the subsequent proper femoral rotation alignment.
2. To ensure proper patella-femoral tracking is achieved, mark or re-mark the rotational position on the bone from the notch on the collar of the Reamer Trial at the resection level based on the interface with the trial hinge component after trial reduction is performed. This will mark the position for the final implant. If the overall leg length requires adjustment or soft tissue tensioning, minor changes can be accomplished by selecting alternate poly spacers. More significant adjustments may require altering the choice of midsection lengths and/or changing the resection level.

Caution: To avoid malrotation of the tibial components, align the tibial components first and set the femoral rotation based off the planned expected tibial rotation. If previously marked, the linea aspera can be used as a secondary check reference for rotational alignment of the distal femur using the notch on the collar of the Reamer Trial. | Figure 23

Note: To reproduce femoral rotation, the Reamer Trial can be rotated counter-clockwise within the canal to achieve desired femoral rotation utilizing the T-Handle attached to the Reamer Trial Adapter or with the Distal Femur Trial itself. To assemble the Reamer Trial Adapter, lift the sliding portion of the quick connect mechanism of the adapter, engage the post, aligning the hexagon, then release.

Figure 19

Figure 20

Figure 21

Figure 22

Figure 23

Surgical technique steps

Optional Step: Modular BioGrip® Collar + Stem

How to Assemble Modular BioGrip® Collar + Stem (required to be implanted together)

1. Assemble the collar over the intermedullary shaft of the hybrid stem, starting distally and sliding up the stem proximally. Confirm the taper of the collar threads matches the taper of the stem shaft. | Figure 1
2. Assemble the locking ring over the proximal end of the hybrid stem in preparation for threading to the collar. | Figure 2
3. Hand-tighten the locking ring while holding the collar in a firm fingertip grip. | Figure 3

   Note: For the Reduced Resection Collar, make sure that the implant oval is oriented perpendicular to the stem boss. The oval should be oriented lengthwise in relation to the narrow orientation of the stem boss.
4. Insert the Counter-Torque Socket into the Assembly Tower base hole. | Figure 4

Figure 1

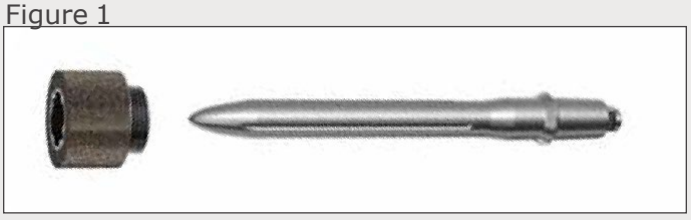
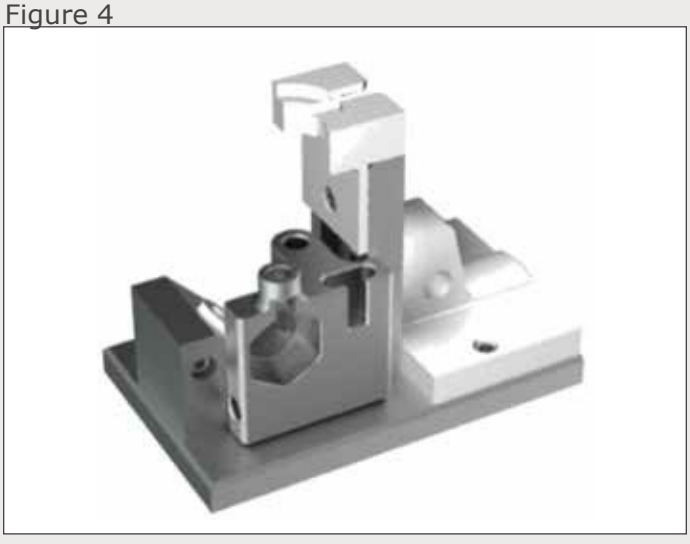


Figure 2

Figure 3

Figure 4



Surgical technique steps

Optional Step: Modular BioGrip® Collar + Stem

How to Assemble Modular BioGrip® Collar + Stem (required to be implanted together)

5. Align the T-shaped anti-rotation boss of the stem with the matching T-slot of the Counter-Torque Socket. Insert the hand-tightened stem-collar-locking ring assembly into the Counter-Torque Socket. | Figure 5

6. Slide the open socket of the Torque Wrench on the hex of the locking ring ensuring the handle of the Torque Wrench is fully seated. | Figure 6

7. Insert the Counter-Torque Handle into the indicated hole of the Counter-Torque Socket facing the user. | Figure 7

8. In a scissor motion, apply force on the Torque Wrench handle in the direction of the "Tightening" arrow on the upper surface of the Counter-Torque Socket until the handle shaft reaches a minimum of 35Nm on the Torque Wrench scale indicator. | Figure 8

Figure 5

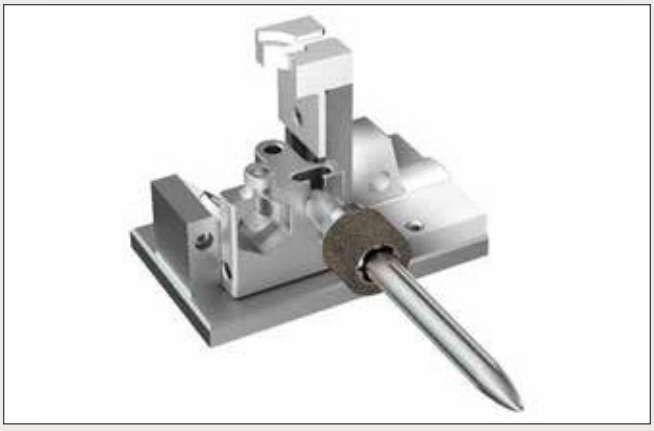


Figure 6

Figure 7

Figure 8

Surgical technique steps

Optional Step: Modular BioGrip® Collar + Stem

How to Assemble Modular BioGrip® Collar + Stem (required to be implanted together)

9. Remove the Torque Wrench and stem-collar-locking ring assembly from the socket.

10. Rotate the stem-collar locking ring assembly until the Locking Ring Impactor Hole is aligned vertically up. | Figure 9

11. Insert the stem-collar-locking ring assembly in the hex socket of the Counter-Torque Socket, ensuring the peening hole is visible through the guide ring of the Counter-Torque Socket.

12. Thread a single-use Impactor Tip on the Collar Impactor. | Figure 10

Figure 9

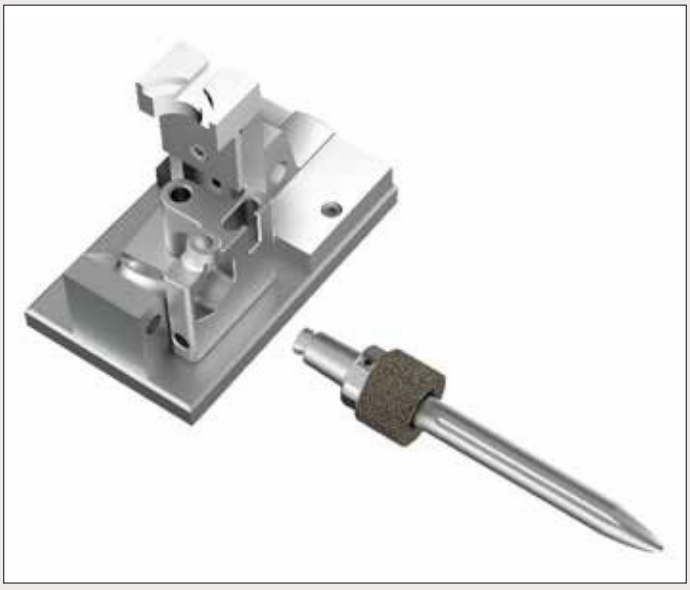


Figure 10

Surgical technique steps

Optional Step: Modular BioGrip® Collar + Stem

How to Assemble Modular BioGrip® Collar + Stem (required to be implanted together)

13 Insert the Impactor Tip into the guide ring of the Counter-Torque Socket, ensuring that the black ring on the tip is no longer visible (it is covered by the guide ring). | Figure 11

This indicates the tip is fully seated on the collar thread prior to impaction. The shaft of the stem can be gently pulled on to test that the Impactor Tip is fully seated on the collar thread through the Locking Ring peening hole.

14 While firmly holding the Collar Impactor, firmly strike the impactor with the surgical mallet five times. | Figure 12

Figure 11

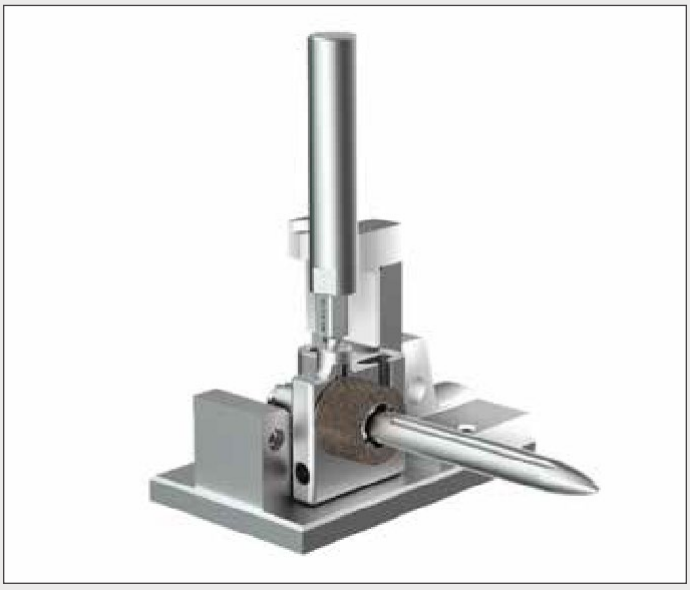


Figure 12

Surgical technique steps

Component assembly

Femoral component

1. If a Midsection is to be used, assemble the Distal Femur and Midsection. Place the Distal Femur and Midsection in the Femoral Assembly Platform using the Trial Axial Pin, and assemble with five hard mallet blows using the Midsection Assembly Impactor. Repeat for each midsection used. | Figure 24

2. Place the Segmental Stem into the Midsection Component or into the Distal Femur if no Midsection was used and assemble with five hard mallet blows using the Stem Assembly Impactor. | Figure 25

Caution: Mallet assembly must be performed over or near the support legs of a rigid back table and not on an unstable surface such as the mayo stand. Ensure the components are free from debris and dry prior to assembly. If required, wipe/dry components with a sterile lap sponge. If using antibacterial coated components, do not wipe with isopropyl alcohol.

Note: Recommend using 2lb mallet from the hospital's general surgical OR instrumentation.

Tibial component

1. If not using a Stem Extension, insert the Poly Plug included in the Tibial Baseplate package into the distal taper. Alternatively, a Modular Tibial Base Stem Cap (KSC01500E) can be inserted and impacted using the instructions for a Stem Extension. This will prevent cement from extruding into the implant during insertion.
   If using a Stem Extension, place the Tibial Baseplate on the Tibial Baseplate Assembly Platform. A marking on the anterior portion of the Tibial Baseplate boss provides a reference to align the slot of the Stem Extension when a canal filling stem is indicated. | Figure 27

Note: The slot on the Stem Extension B shown in Figure 27 should align with the marking on the Tibial Baseplate boss A shown in Figure 27.

2. Assemble the Stem Extension onto the Tibial Baseplate using five hard mallet blows directly on the tip of the Stem Extension with the Stem Assembly Impactor. | Figure 26

Note: Make sure to remove the protective cap on the tip of the Stem Extension before assembly.

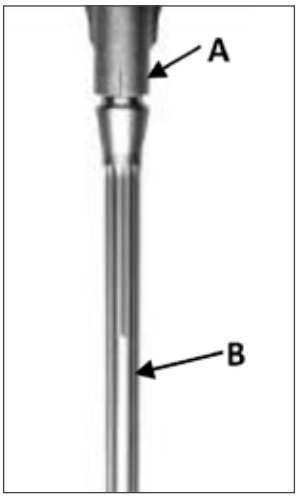
If augments are to be used, see "BlockAugments (Optional)."

Figure 24

Figure 25

Figure 26

Figure 27



Surgical technique steps

Optional Step

Tibial Baseplate Tapered Screw

1. Assemble the Extension Driver shaft to the Screwdriver Handle.

   Note: Confirm that the proper Tapered Screw has been selected. The Tibial Baseplate Tapered Screw is 16.5mm in length and the Resurfacing Femur Tapered Screw is 25.5mm in length. They are not cross-compatible.

   Insert the Tibial Baseplate Tapered Screw into the Tibial Baseplate chamber. Using the driver, hand tighten the Tibial Baseplate Tapered Screw into the threads of the assembled Stem Extension. **| Optional Step: Figure 1**

   Remove the Extension Driver from the Tibial Baseplate.

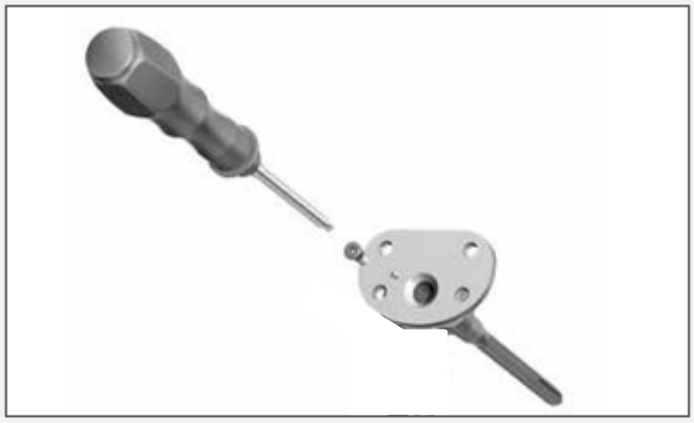
2. Assemble the second Extension Driver Shaft to the Torque Wrench. Insert the Tibial Baseplate and Stem Extension into the Counter Torque Instrument by sliding the stem extension into the Tibial Baseplate side of the Counter Torque Instrument. **| Optional Step: Figure 2.**

3. Ensure the Tibial Baseplate keel is aligned with the slots in the Counter Torque Wrench and that the Tibial Baseplate is fully seated against the surface. **| Optional Step: Figure 3**

4. Insert the assembled Torque Wrench and Extension Driver shaft into the chamber until it engages with the head of the screw. Turn until the Torque Wrench clicks (8 Nm) indicating that the tightening torque has been reached **| Optional Step: Figure 4**

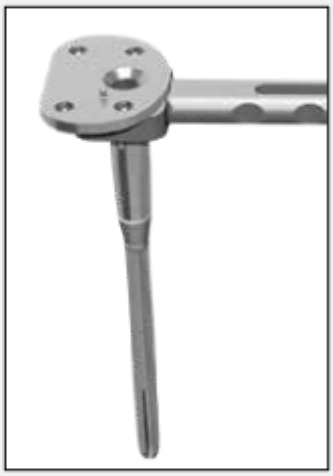
5. Remove the Torque Wrench from the Tibial Baseplate and the Tibial Baseplate assembly from the Counter Torque Instrument.

   Note: If using Tibial Augments, see "Block Augments (Optional) on page 32.



Optional Step: Figure 1

Optional Step: Figure 2



Optional Step: Figure 3

Optional Step: Figure 4

Surgical technique steps

Cement preparation

Begin the cement mixing process. Clean the femoral and tibial canals using pulsating lavage and then dry with a sponge or surgical cloth. If desired, place a cement restrictor into the canal. Inject cement into the canal in a pressurized retrograde fashion.

Component insertion

Tibial component

If a cementation for both femoral and tibial components is chosen by the surgeon, the tibia is best done first, followed by the femur. The femoral component requires stable positioning in order to avoid rotation as the cement cures. The tibial component is more stable during polymerization.

1. Place the Tibial Baseplate and Tibial Poly Spacer into the canal using the Tibial Impactor | Figure 28. Care should be taken to anchor the final components in the appropriate position until the cement has fully set.

Caution: If a Stem Extension is not used, ensure that the Tibial Baseplate Poly Plug or Modular Tibial Base Stem Cap is firmly in place prior to insertion.

Femoral component

1. Place the assembled implant in the femoral canal, aligning the mark on the stem with the mark on the femur previously made | Figure 29. Guide and impact the stem into the canal with the Femoral Impactor until the stem is fully seated at the resected plane | Figure 30. Remove excess cement. Proper position of the implant should be maintained until the cement cures.

Figure 28

Figure 29

Figure 30

Surgical technique steps

Tibial hinge assembly

1. Insert the Tibial Hinge Component into the Tibial Poly Space. | Figure 31
2. Align the Distal Femur with the Tibial Hinge Component. | Figure 32
3. Insert the Distal Femur Axial Pin using the Axial Pin Inserter/Extractor Instrument | Figure 33 thru Figure 37.
4. The Distal Femur Axial Pin can be inserted either on the medial or lateral side. The Axial Pin key must fall into the corresponding keyway in the femoral component. Make sure the Axial Pin is flush with the side of the Distal Femur. | Figure 36

Note: To help align the components, the Trial Axial Pin can be inserted part way into the opposite side of the final Axial Pin insertion. Then insert the Axial Pin into the other end and advance the pin forward, ejecting the Trial Axial Pin. Engage the Axial Pin until it is flush on both sides of the Distal Femur.

Figure 31

Figure 32

Figure 33

Figure 34

Figure 35

Figure 36

Figure 37

Surgical technique steps

Optional

Patellar reconstruction

Patella resurfacing is determined based on medical judgment of the clinical situation. If severe degeneration or arthritis is present on the articular surface of the patella, resurfacing may be indicated. If the patella is otherwise normal, such as in a tumor case, and has not been removed for malignant considerations, it may be acceptable to resurface the patella or to leave it in its natural state.

Resurfacing patella

1. The Resurfacing Patella Resection Guide can be used with or without Resection Depth Gauges or Minimum Thickness Gauges | Figure 38. When used without gauges, the Resection Guide is positioned at the desired level of resection.

2. Securely clamp the jaws into the patella and resect the patellar bone. For a calibrated resection, the appropriate Resection Depth Gauge corresponding to the implant thickness should be attached to the top of the resection guide with the lock screw. Position the resection guide jaws parallel to the articular margin and securely clamp the guide to the bone, assuring the gauge is contacting the apex of the articular surface. The gauge can be removed to increase visibility. Resurfacing Patella Minimum Thickness Gauges are available for preservation of 10mm or 15mm bone stock. Use of the Minimum Thickness Gauge is based on intraoperative assessment of bone quality and thickness. | Table 13

The Resurfacing Peg Drill Guide is used to size the patella and prepare holes in the bone for the implant pegs. Attach the Resurfacing Peg Drill Guide to the Patella Clamp. The Drill Guide has grooves on the surface indicating the patella diameter options. The Resurfacing Patella Peg Drill is used to prepare the peg holes. | Figure 39

- Note: The Resurfacing Patella have the same peg patterns between sizes and can be easily changed during trial reduction.
- Note: A Patella/Femoral Head Sizing Caliper is available for assessment of thickness.

3. Remove the Resurfacing Patella Drill Guide from the Patella Clamp and insert the Patella Clamp Seater in its place.

4. Once the patella surface is prepared, mix cement, wash and dry the bone, pressurize the cement, and insert the patella pegs into the prepared holes. Use the Patella Clamp with the Patella Clamp Seater attached to fully seat the Patella. Remove residual cement and keep the Patella Clamp in place until cement is cured.

Figure 38

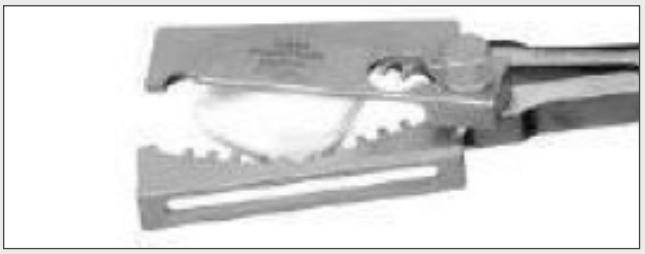


Table 13.

Resurfacing Patella, All-Poly, Tri-Peg			
Part #	Description	Diameter	Thickness
KPONTP29E	ELEOS™ Resurfacing Patella	29mm	8mm
KPONTP32E	ELEOS™ Resurfacing Patella	32mm	8mm
KPONTP35E	ELEOS™ Resurfacing Patella	35mm	8mm
KPONTP38E	ELEOS™ Resurfacing Patella	38mm	10mm
KPONTP41E	ELEOS™ Resurfacing Patella	41mm	11mm

Figure 39

Surgical technique steps

Optional

Tibial block augments

1. During the tibial resection step of the surgical technique, if Block Augments are necessary, begin by making a proximal "clean-up" resection along the most prominent condyle through the 0mm resection slot marked "STD" in the Revision Block Augment Resection Guide (Refer to A in Figure 40).

Note: The Revision Block Augment Resection Guide is available in a right and left-hand version.

2. If block augmentation is needed, the Revision Block Augment Resection Guide provides resection slots for the 5mm, 10mm, and 15mm (Refer to B in Figure 40).

3. These Augments can be placed independently on the medial or lateral side of the tibia.

4. During tibial baseplate preparation, if an Augment is to be used, attach the appropriate size Block Augment to the Trial Tibial Baseplate Template and proceed with tibial preparation, as specified in Figure 41.

5. During component assembly, attach the Augment by aligning the three centering pegs on the Tibial Augment with the three recessed areas of the Tibial Baseplate.

6. Using the packaged screws, assemble the augments through the Tibial Baseplate. Plastic starter handles are provided with each augment screw and should be removed once the screw is tightened. | Figure 42

7. A final tightening of the Augment should be completed with a standard 3.5mm hex head screwdriver.

Figure 40

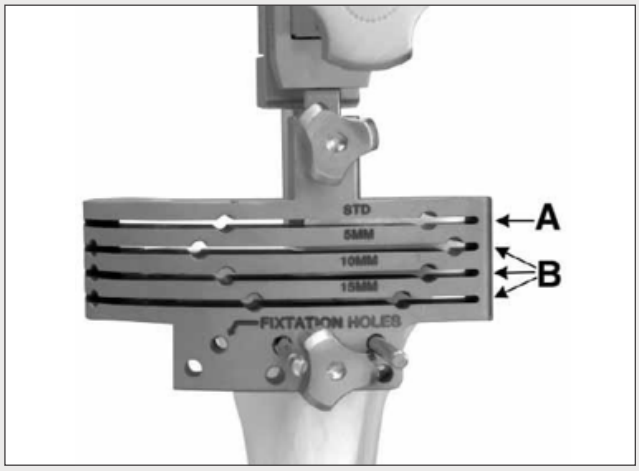


Figure 41

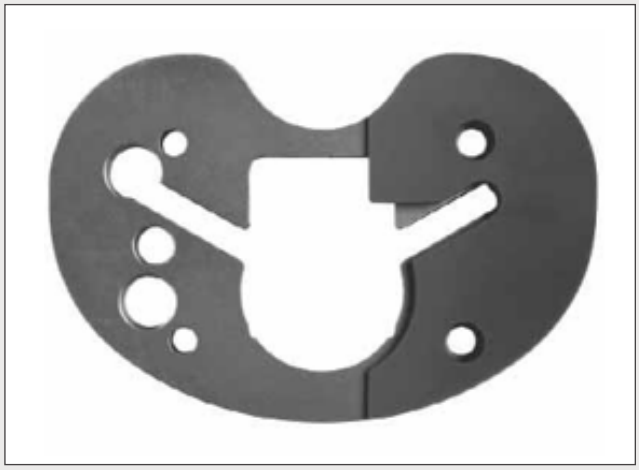


Figure 42

Component disassembly

To disengage the ELEOS™ and ELEOS™ with NanoCept™ Technology tapers, insert the Taper Disassembly Tool into the hole on the side of the implant.Strike the end of the tool with a mallet until the components separate. | Figures 43 and 44

Support the implant during disassembly. Alternatively, or in concert with disassembly tools, insert the Taper Disassembly Fork around the outside of the implant, below the seam between the two components to be disassembled. Strike the end of the fork to disengage the tapers shown in Figures 45 and 46. Again, support the implant during disassembly.

Figure 43

Figure 44

Figure 45

Figure 46

Explantation information

In a revision case, when Segmental Stem explantation is required, use the Stem Extractor Attachment and attach to the Slap Hammer Extractor Handle to remove the stem. To disengage Stem Extensions, use the Stem Implant Extractor-Adaptor. Assemble it to the Slap Hammer Pin Extractor. Next, thread the full assembly to the Stem Extension that needs to be removed. A trephine from the hospital's general surgical OR instrumentation can also be used to remove the stem by placing the trephine over the stem to ream the interface between the stem and the bone.

Contact us to learn more:
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