ELEOS™
Limb Salvage System

Surgical Technique: ELEOS™ Proximal Tibial Replacement

Featuring BioGrip® Modular Collars with Nano HA Treatment

The ELEOS™ 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™ System provides the surgeon the ability to meet a variety of patient needs.

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Precision Orthopaedic Oncology

- ELEOS™ Limb Salvage Solutions
- My3D® Personalized Solutions
- GenVie™ Regenerative Biologics

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ELEOS™
Limb Salvage System

Proximal Tibial Replacement

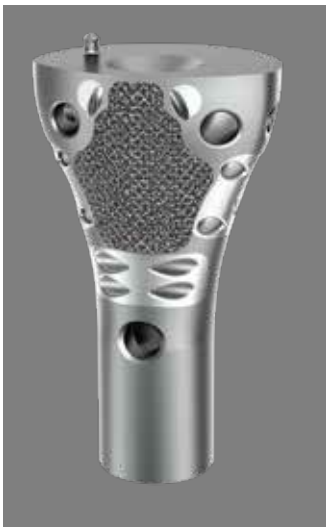
Construct overview

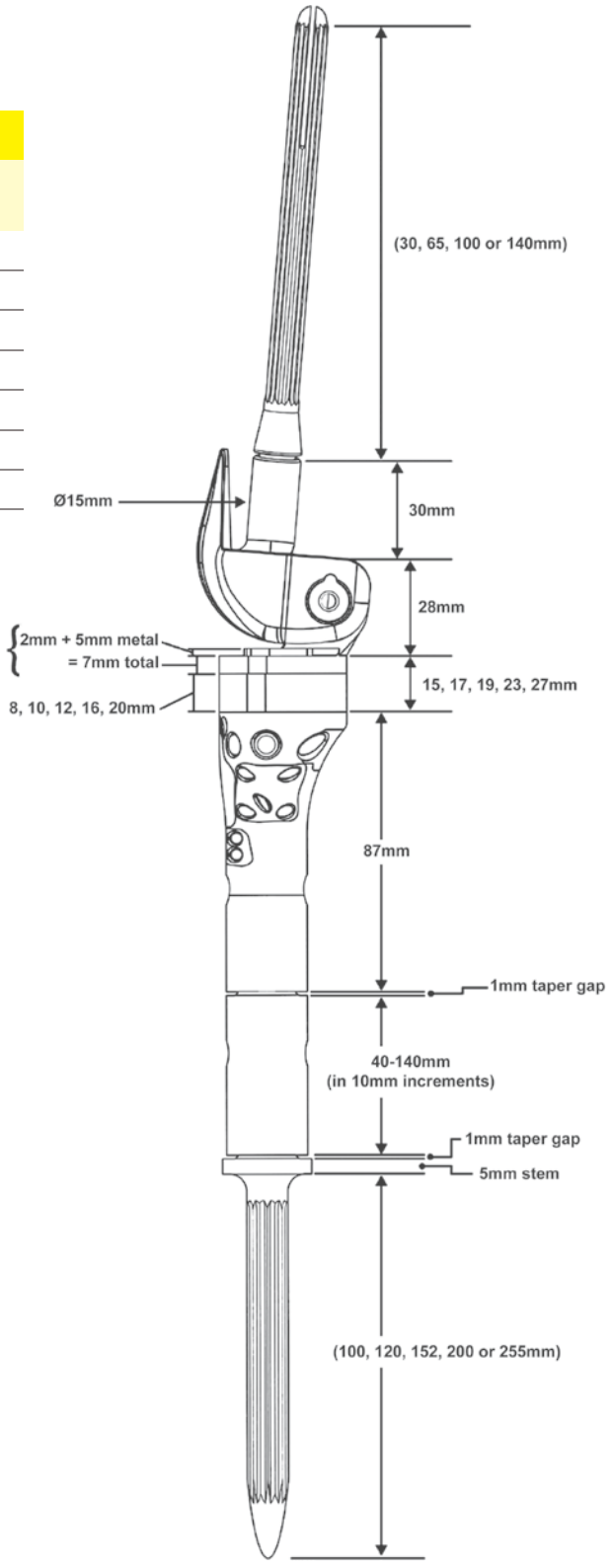
Standard Proximal Tibia

Table 1.

Proximal Tibial Resection Standard Lengths[1]

Proximal Tibia	Taper Gap	Midsections	Taper Gap	Stem Collar	Poly + Hinge[2]	Overall Resection
87mm	1mm	None	None	5mm	15mm	108mm
87mm	1mm	40mm	1mm	5mm	15mm	149mm
87mm	1mm	50mm	1mm	5mm	15mm	159mm
87mm	1mm	60mm	1mm	5mm	15mm	169mm
87mm	1mm	70mm	1mm	5mm	15mm	179mm
87mm	1mm	90mm	1mm	5mm	15mm	199mm
87mm	1mm	110mm	1mm	5mm	15mm	219mm
87mm	1mm	140mm	1mm	5mm	15mm	249mm





1. Resection lengths can also total 189, 209, 229, and 239mm when certain midsections are coupled together. An additional 1mm should be considered for the taper gap between the midsection and segmental stem
2. Assumes a minimum 8mm poly spacer – resection length will increase according to size of poly spacer

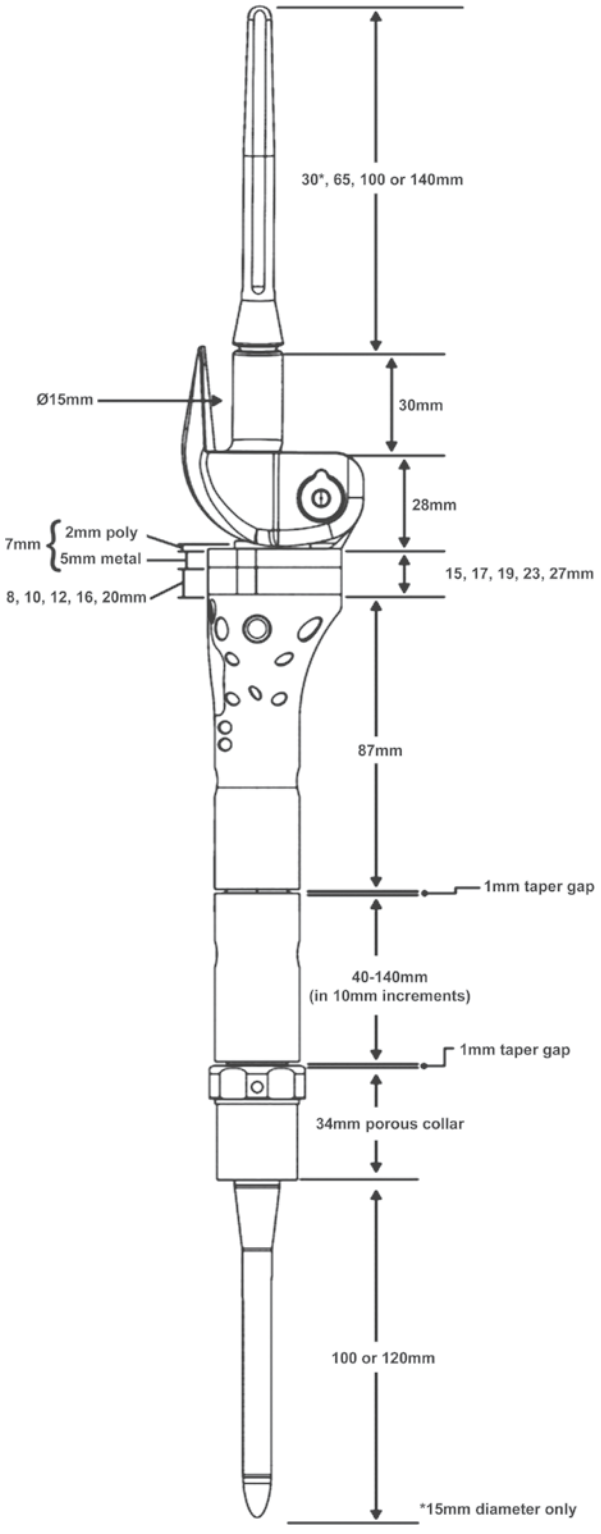
Construct overview

Proximal Tibia with BioGrip® Porous Collar

Table 2.

Proximal Tibia Resection Lengths with Modular Porous Collar[1]

Proximal Tibia	Taper Gap	Midsections	Taper Gap	BioGrip® Collar	Poly + Hinge[2]	Overall Resection
87mm	1mm	None	None	34mm	15mm	137mm
87mm	1mm	40mm	1mm	34mm	15mm	178mm
87mm	1mm	50mm	1mm	34mm	15mm	188mm
87mm	1mm	60mm	1mm	34mm	15mm	198mm
87mm	1mm	70mm	1mm	34mm	15mm	208mm
87mm	1mm	90mm	1mm	34mm	15mm	228mm
87mm	1mm	110mm	1mm	34mm	15mm	248mm
87mm	1mm	140mm	1mm	34mm	15mm	278mm



1. Resection lengths can also total 218, 238, 258, and 268mm when certain midsections are coupled together.Assumes a minimum 8mm poly spacer – resection length will increase according to size of poly spacer
2. An additional 1mm should be considered for the taper gap between the midsection and segmental stem

Set configurations

Please refer to document CORP 06.05.21 ELEOS™ Proximal Tibia with BioGrip® Set Configurations for a full listing of implant and instrument set requirements, images, and part listings.

Component overview

The ELEOS™ Proximal Tibia System consists of up to nine components that create a proximal tibial replacement: Stem Extension, Resurfacing Femur, Axial Pin, Tibial Polyethylene Spacer, Tibial Hinge Component, Proximal Tibia Component, Optional Midsection, Optional Modular Porous Collar, and Segmental Stem. Additional midsections can be added if more length is required.

Stem extensions

The Resurfacing Femur accepts cemented or canal filling Stem Extensions in a variety of lengths and diameters. | Table 3

Table 3.

Stem Extensions – Cemented				
Stem	Description	Length	Diameter	Collar
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

Resurfacing femur

The Resurfacing Femur features a deepened patellar groove and a 5° valgus angle to assist in the restoration of patello-femoral kinematics, reduction of patellar subluxation and promotion of normal loading patterns. Internal/external rotation of the hinge can be controlled with a component that has a stop set for +/- 15° or a hinge component without a stop can be used. The Resurfacing Femur is available in three sizes for intraoperative flexibility. | Table 4

Table 4.

Resurfacing Femur and Axial Pin	
Part #	Description
RF-L002E-01M	Resurfacing Femur, Size 2, Left 60MM M/L
RF-L003E-01M	Resurfacing Femur, Size 3, Left 65MM M/L
RF-L004E-01M	Resurfacing Femur, Size 4, Left 70MM M/L
RF-R002E-01M	Resurfacing Femur, Size 2, Right 60MM M/L
RF-R003E-01M	Resurfacing Femur, Size 3, Right 65MM M/L
RF-R004E-01M	Resurfacing Femur, Size 4, Right 70MM M/L
RF-TSCRW-01M	Resurfacing Femur Tapered Screw
25002112E	Resurfacing Femur Axial Pin, Size 2
25002113E	Resurfacing Femur Axial Pin, Size 3
25002114E	Resurfacing Femur Axial Pin, Size 4

Component overview

Tibial spacer & hinge

The Tibial Poly Spacer is available in 8mm, 10m, 12mm, 16mm and 20mm thicknesses. The Tibial Hinge component is available both with and without a rotational stop that is set to +/- 15° of rotation. | Table 5

Table 5.

Tibial Poly Spacer and Hinge[1]	
Part #	Description
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 w/ rotational stop (one size)
THSMWOS01M	Tibial Hinge w/o rotational stop (one size)

1 - Note the following for revision scenarios:

Any ELEOS or Guardian procedures prior to September 2021 that require revision and replacement of the Resurfacing Femur component are required to have the Tibial Hinge component replaced. The replacement Tibial Hinge Component must be either THSMWRS01M or THSMWOS01M.

Proximal Tibial Implant with BioGrip® Technology

The Proximal Tibial Implant with BioGrip® Porous Technology comes in one size - with an 87mm resection. The implant is 3D printed with a porous titanium anterior surface designed to support soft tissue ingrowth and with suture holes that allow soft tissue anchoring in the desired anatomical directions. | Table 6

Table 6.

Proximal Tibial Component	
Part #	Description
PT-20000-02M	Proximal Tibia Implant

Midsections

Seven lengths of optional Male/Female Midsection components are interchangeable with all ELEOS systems to allow for precise length determination intraoperatively. Lengths ranging from 40-70mm in 10mm increments in addition to 90mm, 110mm, and 140mm sizes to accommodate bone resection. | Table 7

Table 7.

Femoral Bone Resection – Midsections	
Part #	Component
25001040E	40mm
25001050E	50mm
25001060E	60mm
25001070E	70mm
25001090E	90mm
25001110E	110mm
25001140E	140mm

Component overview

Segmental stems

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. Segmental Stems are available in a variety of lengths and diameters in both cemented and canal filling options. Modular Collar Segmental Stems are straight and fluted only | Table 8

Table 8.

Segmental Stems – Cemented			
Stem	Description	Length	Stem Diameter (mm)/ Collar Diameter (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

Modular Collar Segmental Stems				
Stem	Description	Length	Diameter	Porous Collar
HR-30001-03M	Modular Collar Locking Ring and Impactor Tip	N/A	N/A	ALL
HC-09100-03M	Modular Collar Stem, Cemented, Fluted	100mm	9mm	24/28mm
HC-10100-03M	Modular Collar Stem, Cemented, Fluted	100mm	10mm	24/28mm
HC-11120-03M	Modular Collar Stem, Cemented, Fluted	120mm	11mm	24/28mm
HC-13120-03M	Modular Collar Stem, Cemented, Fluted	120mm	13mm	24/28/32/36/40mm
HC-15120-03M	Modular Collar Stem, Cemented, Fluted	120mm	15mm	32/36/40mm
HC-17120-03M	Modular Collar Stem, Cemented, Fluted	120mm	17mm	32/36/40mm

Modular Collars – BioGrip® Porous with Nano HA

Modular BioGrip® Porous Collars have a 3D printed porous structure and nano HA treatment designed to support bone in-growth and anchoring. BioGrip® collars are round in shape and 34mm in overall height (including the lockingring). BioGrip® collars come in diameters ranging from 24mm to 40mm, in 4mm increments. All collars are used with a Locking Ring and single-use Impactor Tip as shown in Table 9. Modular collars are used with modular collar segmental stems listed in Table 8.

Table 9.

Modular Porous and Solid Body Collars					
Collar	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

Surgical technique steps

Femoral preparation

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

Femoral reaming

1. Initiate an opening in the femoral canal with the Starter Drill Bit 3/8 inch. The entry point is placed medial and anterior to the anteromedial corner of the intercondylar notch. | Figure 1

Note: Hand reaming may be appropriate to avoid a thin femoral cortex that could result in a fracture. Care should be taken if reaming with power.

2. Utilize the cylindrical reamer to continue preparing the femoral canal for the stem extension.

3. If the femoral resection has been completed, ream to the appropriate depth of the femoral construct (shown in Figure 2 in red).

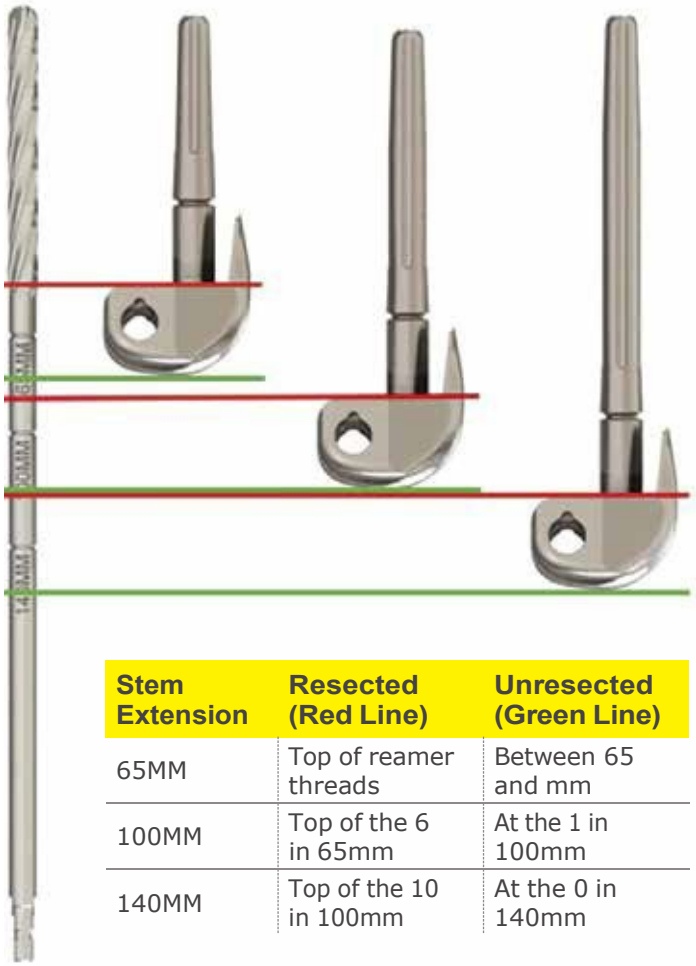
4. If the femoral resection has not been completed, ream approximately 20mm beyond that distance (shown in Figure 2 in green) to account for the appropriate full depth of the femoral component.

5. Consider an additional 20mm to account for the placement of a cement restrictor in the proximal end of the prepared femoral canal.

6. When desired reaming is complete, ensure the Reamer provides a stable construct for additional femoral preparation.

Figure 1

Figure 2



Stem Extension	Resected (Red Line)	Unresected (Green Line)
65MM	Top of reamer threads	Between 65 and mm
100MM	Top of the 6 in 65mm	At the 1 in 100mm
140MM	Top of the 10 in 100mm	At the 0 in 140mm

Surgical technique steps

Note: The Stem Extension diameters from Table 3 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.

7. Make sure to ream in an elliptical fashion with the first few reamers to ensure the distal bone does not dictate the path of the reamer.

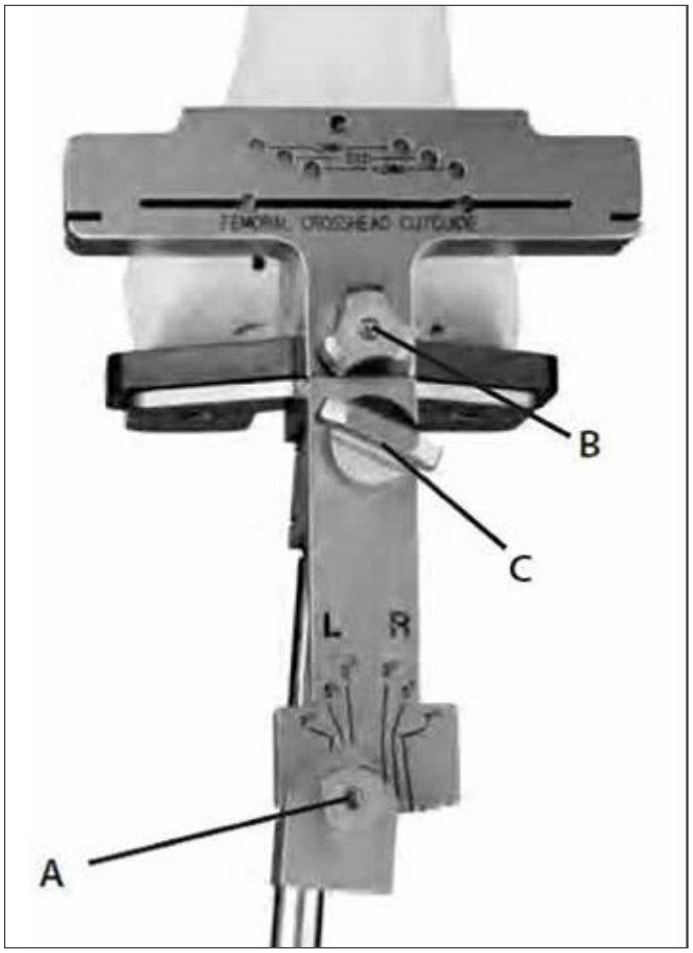
Caution: During the reaming process, the intramedullary canal of the femur should be repeatedly irrigated and aspirated to reduce the chance of fat emboli.

8. With desired reaming complete, ensure the Reamer provides a stable construct for additional femoral preparation.

Distal femoral alignment

1. The Valgus Angle Alignment Guide should be set at 5° (left or right) to match the 5° valgus orientation of the Resurfacing Femur. Set the valgus angle to 5° and tighten the small thumb screw A shown in Figure 3. Attach the Distal Femoral Resection Guide by fully seating it to the Valgus Angle Alignment Guide and tighten the small screw by hand or with a screwdriver B shown in Figure 3. Slide the entire construct over the fixed Cylindrical Reamer and lock the guide to the reamer by tightening the large thumb screw after the guide touches the most prominent condyle surface from the joint line C shown in Figure 3.

Figure 3



Surgical technique steps

Distal femoral resection

Note: All femoral resection slots are designed for use with a .050" (1.3mm) thick saw blade. The distal femoral resection depth can be adjusted using the 9mm spacer between the platform of the Valgus Angle Alignment Guide and the most proximal condyle if a femoral component was removed in a revision situation. | Figure 4

1. The 9mm Femoral Distal Spacer accounts for the distal thickness of a primary femoral implant that was removed. Once assembled, the spacer will provide a 28mm resection along the most prominent condyle surface from the joint line.

2. A secondary check is available by referencing the small slots on the Distal Femoral Resection Guide. By matching the position of these slots to the transepicondylar axis, a theoretical placement of the original joint line is indicated. | Figure 5

Caution: Placing the Valgus Angle Alignment Guide paddles (Figure 5), or the 9mm spacer if present, flush against the resected distal surface will result in a 28mm distal resection from the joint line (where the paddles touch the femur).

3. With the guide properly positioned, pin the Distal Femoral Resection Guide by placing 1/8" (3.2mm) Headless Fixation Pins or Drill Bits into the holes marked "STD" A shown in Figure 6. The distal femoral resection can be performed with or without the Reamer and Valgus Angle Alignment Guide in place. If the guide is left, take caution to avoid the IM reamer while making the resection. To remove the guide, loosen both thumb screws B shown in Figure 6 and disengage the Valgus Angle Alignment Guide from the Distal Femoral Resection Guide. Utilize the Quick Disconnect T-handle to remove the reamer. A distal resection is performed through the resection slot C shown in Figure 6.

4. After the resection is complete, remove the Distal Femoral Resection Guide and pins from the bone.

Figure 4

Figure 5

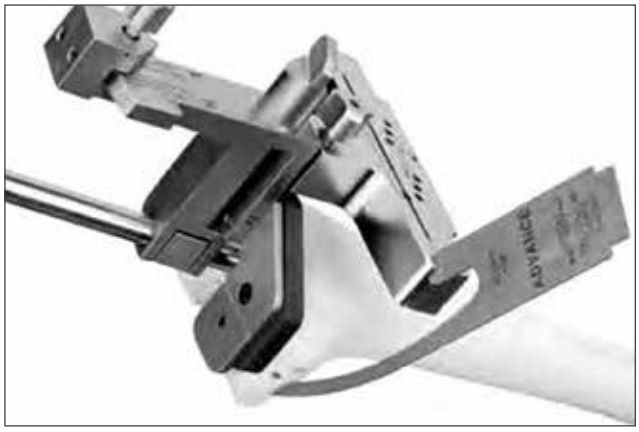
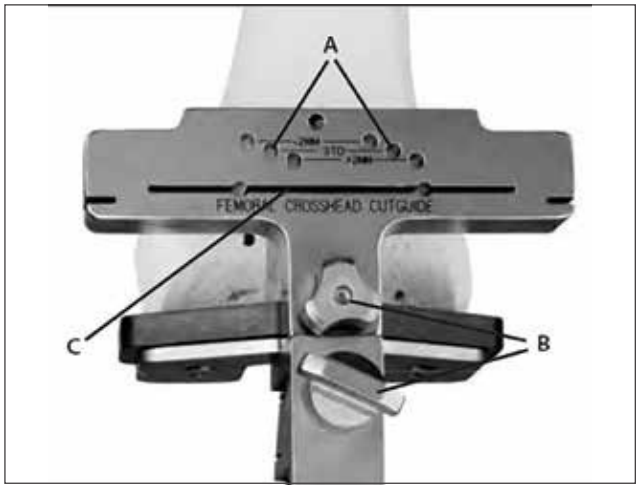


Figure 6



Surgical technique steps

Femoral sizing

Femoral implant sizing can be approximated by one of the following methods:

1. Use of trial femoral components
2. Pre-operative radiographic evaluation of both knees.

Anterior and posterior resections

If the Cylindrical Reamer was removed to make the distal resection, the Reamer needs to be inserted again to accommodate attachment of the Femoral A/P Resection Guide.

1. Select the Femoral A/P Resection Guide corresponding to the size Resurfacing Femur previously determined. Assemble the 5° IM Revision Angle Locator with the correct "Left" or "Right" marking facing the arrow on the Femoral A/P Resection Guide A shown in Figure 7 and place the entire assembly over the fixed Cylindrical Reamer. Two laser marks on the face of the block indicate the M-L width of the Resurfacing Femur for a final check of femoral sizing B shown in Figure 7.
2. External rotation can be set by referencing either the medial and lateral epicondyles (transepicondylar axis) or A/P axis of the femur (perpendicular plane to the patella groove). After rotation is established, fully seat the A/P resection guide on the distal femoral resection.
3. Tighten the thumbscrew C shown in Figure 7 and stabilize the block using fixation pins on the medial and lateral sides of the block. The fixation holes can be predrilled with a 1/8 inch Drill Bit. Femoral resections are performed through the anterior and posterior resection slots. The anterior femoral resection is 6° divergent to the posterior resection.

Resurfacing femur trialing

Assemble the appropriate size Trial Stem Extension to the Trial Resurfacing Femur. Using the Femoral Impactor, impact the Trial Resurfacing Femur onto the prepared bone. | Figure 8

Figure 7

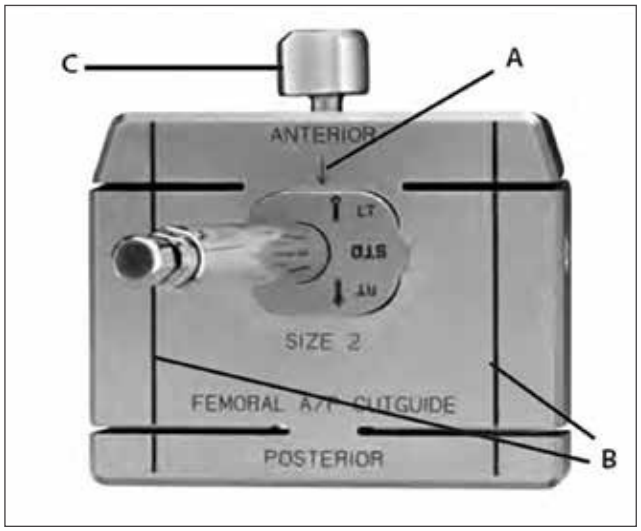


Figure 8

Surgical technique steps

Tibial preparation

Tibial resection

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

1. Determine the amount of tibial bone to be resected while noting x-ray magnification. Resect the minimal amount of bone that conforms to implant availability. The amount of bone to be resected is determined by clinical evaluation. To determine the midsection and stem to use, consult Tables 1 and 2 (Page 4-5). Refer to the resection measurement tables on pages 4 and 5 for different options.

2. Using an available ruler or the trial construct needed, measure the level of resection from the proximal tibia. Mark the level of resection. | Figure 9

3. Resect the proximal tibia at the marked location, making a transverse cut. | Figure 10

Figure 9

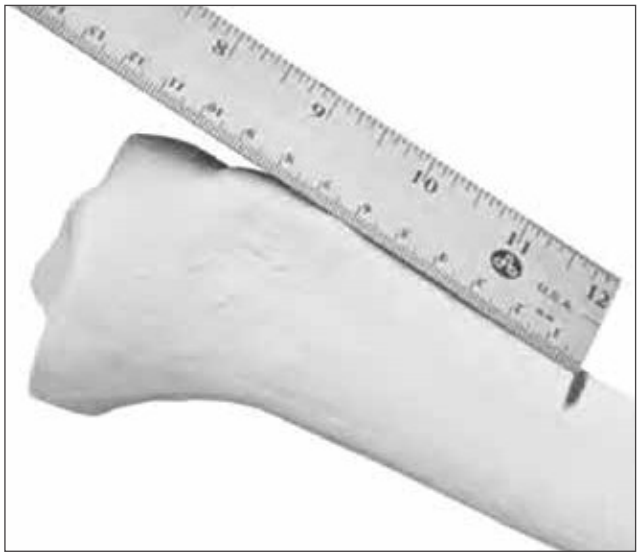
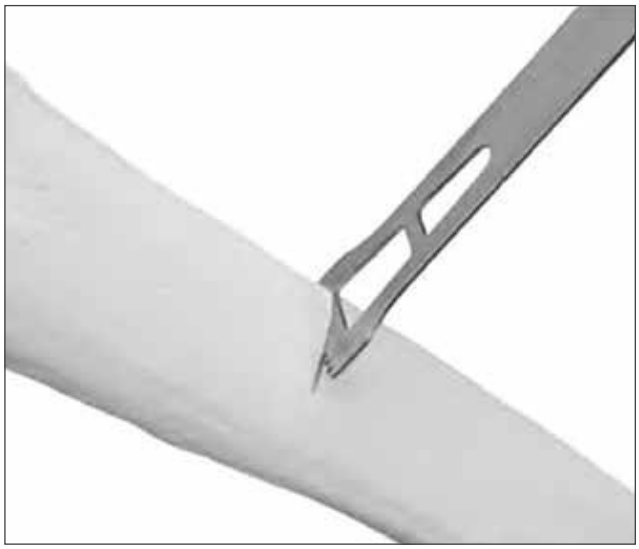


Figure 10



Surgical technique steps

Tibial reaming and planing for segmental stems and modular collar stems

1. Based on preoperative planning, it is suggested to 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. Ream the (tibial) canal using Reamer Trials by inserting to the full 120mm depth (100mm depth in the case of 9mm and 10mm Reamer Trials) to face ream the resection area ensuring collar contact on the cortices. | Figure 11

2. If a bowed stem is chosen, a set of flexible reamers can be used from the hospital's general surgical OR instrumentation. 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. | Table 10

Table 10.

Bowed Stem Planers		
Part Number	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

Figure 11

Surgical technique steps

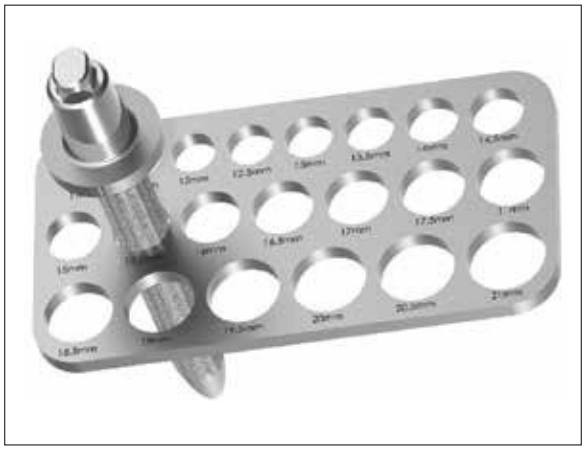
3 Select a stem diameter that corresponds to the appropriate cement mantle or canal filling fit based on clinical evaluation. | Table 8

- Note: Use the Reamer Trial Adapter shown in Figure 12 with both Reamer Trials and Bowed Stem Planers 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 bothreaming and subsequent trialing.
- Note: The Segmental Cemented Stem diameters from Table 8 are 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.
- Caution: The Segmental Canal Filling Stem diameters from Table 8 are 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 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. Additional reaming may be performed to achieve the desired press fit based on this information and based on the patient's bone quality. | Figure 13
- 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.

4 If a straight stem (100mm or 120mm) is planned to be utilized, this final diameter Reamer Trial is disconnected from the Reamer Trial Adapter and should be left in the distal femoral canal as it also functions as the stem trial.

Figure 12

Figure 13



Surgical technique steps

Trialing

Reamer trial assembly

1. Assemble the Trial Proximal Tibia and any necessary Trial Midsections to the in-situ Reamer Trial to reproduce the appropriate resection 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 14

Bowed trial assembly

1. Assemble the Trial Proximal Tibia and any necessary Trial Midsections to the Bowed Trial Stem to reproduce the appropriate resection length.

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

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 15

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

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

4. Assemble the Trial Proximal Tibia construct with the Trial Tibial Poly Spacer, Trial Tibial Hinge Component and Trial Axial Pin. | Figures 16-17

Figure 14

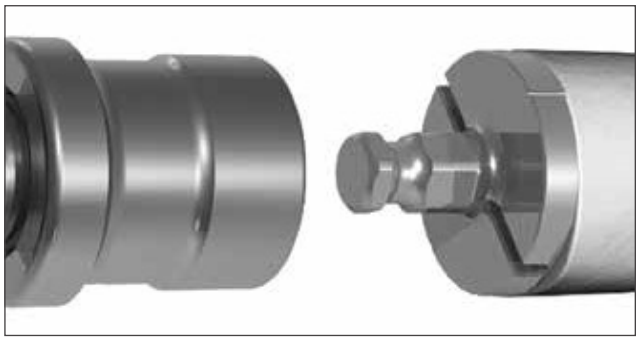
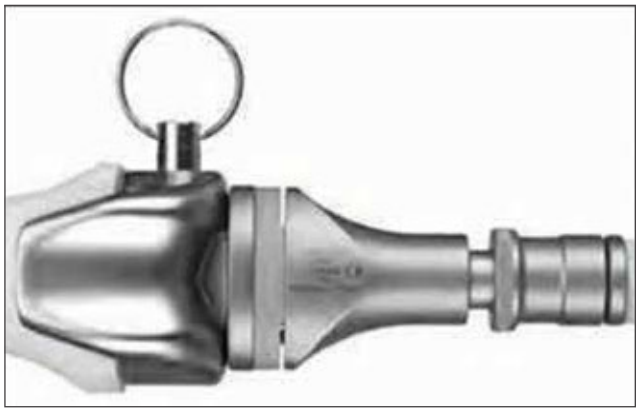


Figure 15

Figure 16

Figure 17



Surgical technique steps

Optional Step

Trial assembly with modular BioGrip® porous collar

1. BioGrip® 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 BioGrip® Proximal Tibia Trial, BioGrip® Collar Height Trial, and any necessary Trial Midsections to the in-situ Reamer Trial to reproduce the appropriate leg length. | 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, aligning the tab with the slot, then release

3. Utilize the face planer and appropriate size pilot point to fine plane the resection area at the resection level if needed to ensure the Collar will seat flush on the cortices.

   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 Stem Guide. Proceed to face ream the remaining bone to desired state. | Figure 3

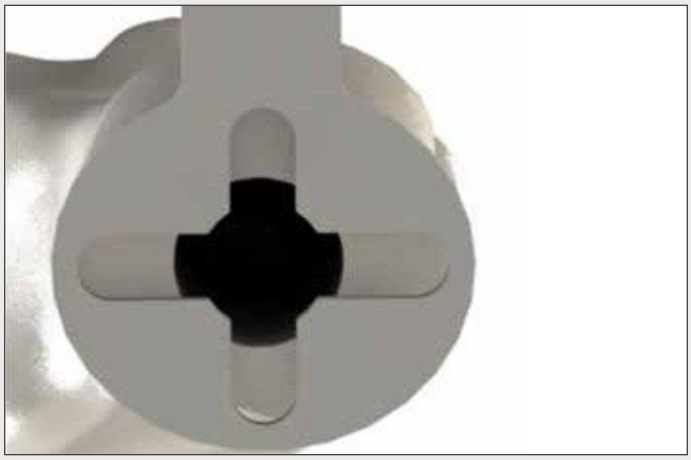
Note: Collar size and geometry can be rechecked by overlaying a Collar Trial Gauge on the resection level visually centered on the canal. | Figure 4

Optional Step: Figure 1

Optional Step: Figure 2

Optional Step: Figure 3

Optional Step: Figure 4



Surgical technique steps

Trial reduction

Perform a trial reduction. If the soft tissues require adjustment, minor changes can be accomplished by selecting alternate Tibial Poly Spacers. More significant adjustments may require changing the resection level and midsections.

- Note: Final tibial rotation can be set by marking the bone to match up with the stem match mark.
- Note: To reproduce tibial rotation, the Reamer Trial can be rotated counter-clockwise within the canal to achieve desired rotation utilizing the T-Handle attached to the Reamer Trial Adapter or with the Proximal Tibia 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.

Component assembly

Femoral component

1. Place the Resurfacing Femur and Stem Extension in the Femoral Assembly Platform using the Trial Axial Pin and assemble with five hard mallet blows using the Stem Assembly Impactor. | Figure 18

- 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.
- Note: Utilize the match mark on the Stem Extension so that the slot accommodates the bow of the femur.
- Note: Recommend using 2lb mallet from the hospital's general surgical OR instrumentation.
- Note: Make sure to remove the protective cap on the tip of the Stem Extension before assembly.

Figure 18

Surgical technique steps

Optional Step

Resurfacing Femur 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.

   Manually insert the Resurfacing Femur Tapered Screw into the Resurfacing Femur chamber. Using the driver, hand tighten the Resurfacing Femur Tapered Screw into the threads of the assembled Stem Extension. **| Optional Step: Figure 1**

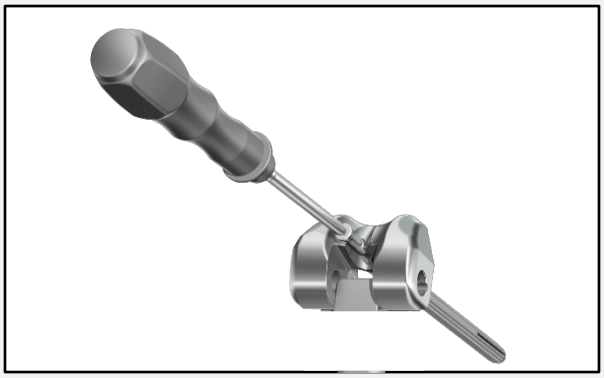
   Remove the Extension Driver from the Resurfacing Femur.

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

3. Ensure that the Resurfacing Femur is fully seated against the surface of the instrument with the white counter rotation block located between the condyles. **| 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 Resurfacing Femur and the Resurfacing Femur assembly from the Counter Torque Instrument.



Optional Step: Figure 1

Optional Step: Figure 2

Optional Step: Figure 3

Optional Step: Figure 4

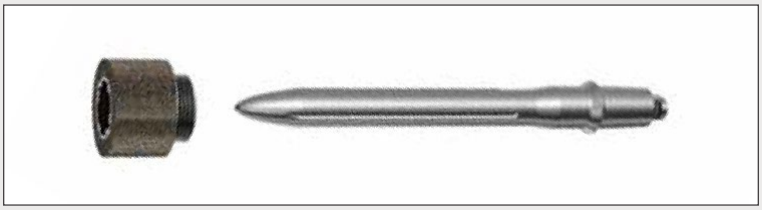
Surgical technique steps

Optional Step

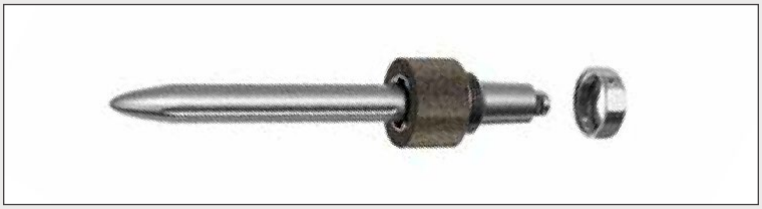
Modular BioGrip® collar/stem assembly

1. Assemble the collar over the intermedullary shaft of the modular 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 modular 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
4. Insert the Counter-Torque Socket into the Assembly Tower base hole. | Figure 4
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

Optional Step: Figure 1



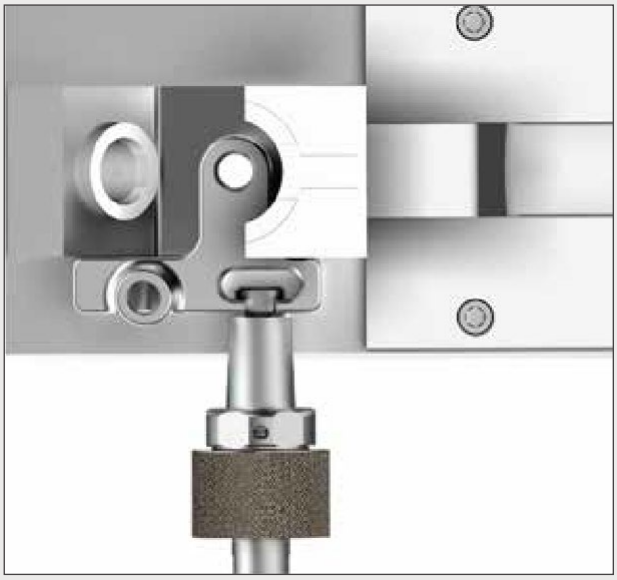
Optional Step: Figure 2



Optional Step: Figure 3

Optional Step: Figure 4

Optional Step: Figure 5



Surgical technique steps

Optional Step

Modular BioGrip® collar/stem assembly (cont.)

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

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 peening 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.

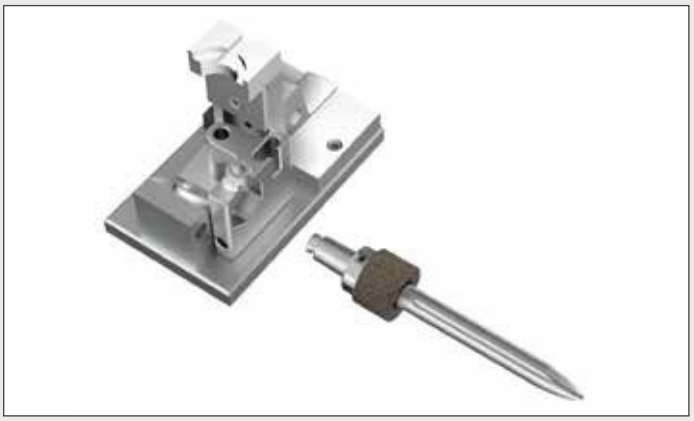
12. Thread a single-use Impactor Tip on the Collar Impactor. | Figure 10

Optional Step: Figure 6

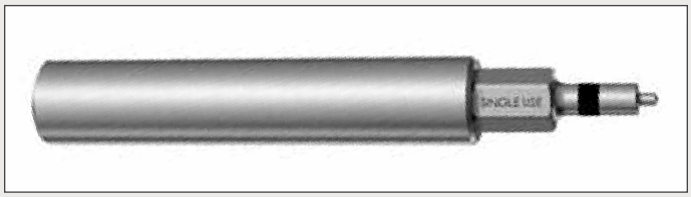
Optional Step: Figure 7

Optional Step: Figure 8

Optional Step: Figure 9



Optional Step: Figure 10



Surgical technique steps

Optional Step

Modular BioGrip® collar/stem assembly (cont.)

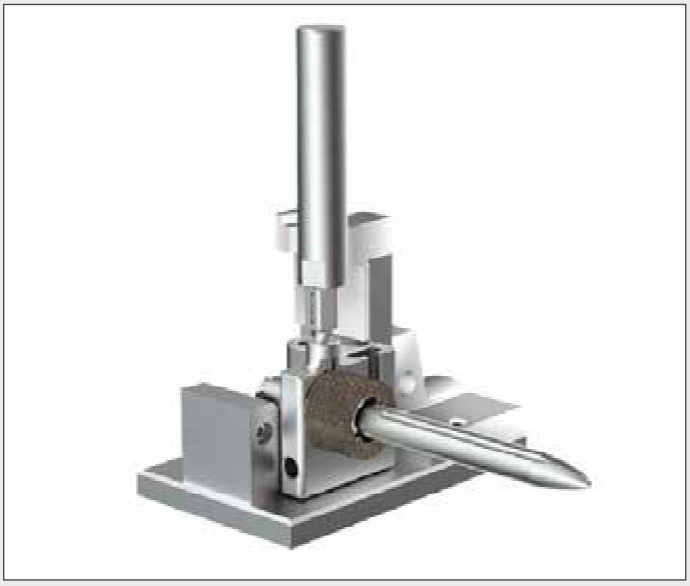
13 Insert the Impactor Tip into the guide ring of the Counter-Torque Socket, ensuring that the black ring on the tip is no longer visible (it is covered by the guide ring). | Figure 11

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

15 Remove the stem-collar-locking ring assembly from the hex socket of the Counter-Torque Socket. Proceed to the standard surgical technique step for standard impaction to the implant and/or optional midsections.

Optional Step: Figure 11



Optional Step: Figure 12

Surgical technique steps

Tibial component

1. Place the Proximal Tibia on the Tibial Baseplate Assembly Platform. Assemble the Segmental Stem and Midsection, if needed, onto the Proximal Tibia using five hard mallet blows with the Stem Assembly Impactor directly on the tip of the stem. If a midsection is used, assemble each individually and impact with 5 hard mallet blows followed by the segmental stem last. | Figure 19

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.

Figure 19

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

Femoral component

1. Place the resurfacing femur Stem Extension in the femoral canal. Guide and impact the Resurfacing Femur into the canal with the Femoral Impactor until the implant is seated. | Figure 20
2. Remove excess cement. Final position of the implant should be maintained until the cement cures.

Tibial component

1. Place the Proximal Tibia and Tibial Polyethylene Spacer into the canal using the Tibial Impactor. | Figure 21

- Caution: Care should be taken to maintain the final components in the appropriate position until the cement has set fully.
- Note: Align the stem match mark to the marking on bone made earlier to obtain proper rotational alignment as planned for during trialing.

Figure 20

Figure 21

Figure 22

Surgical technique steps

Tibial hinge assembly

1. Insert the tibial portion of the Tibial Hinge Component assembly into the tibia. | Figure 22
2. Align the Resurfacing Femur with the Tibial Hinge. | Figure 23
3. Insert the Axial Pin using the Axial Pin Inserter/ Extractor instrument. | Figures 24-28
4. The Resurfacing Femur Axial Pin can be inserted either on the medial or lateral side. The Axial Pin key must fall into the corresponding pocket in the Resurfacing Femur. Make sure the axial pin is flush with the side of the femoral component. | Figure 27

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 23

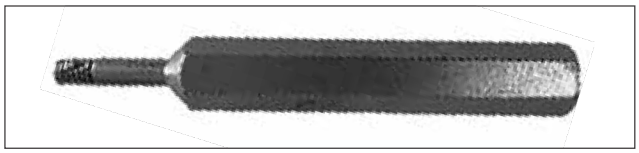
Figure 24

Figure 25

Figure 26

Figure 27

Figure 28



Surgical technique steps

Optional Step

Patella 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

The Resurfacing Patella Resection Guide can be used with or without Resection Depth Gauges or Minimum Thickness Gauges as shown in Figure 29. When used without gauges, the Resection Guide is positioned at the desired level of resection.

1. 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.

2. 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.

Figure 29

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 11

Table 11.

Resurfacing Patella, All-Poly, Tri-Peg			
Part Number	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

Surgical technique steps

Optional Step

Patella reconstruction (cont.)

3. 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 30

- 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.

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

5. Once the patella surface is prepared, mix cement, wash and dry the bone, pressurize the cement, and insert 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 30

Suture Technique

1. Using a heavy non-absorbable suture and a straight needle, advance through the anterior superior-inferior hole of the implant from inferior to superior (Point A to Point B for a left knee shown). Leave approximately 100mm of suture at point A. (See Figure 31)
2. Utilizing a locked stitch, starting anteriorly and underneath on the deep side of the patellar tendon, sew a few locked stitches medially from distal to proximal exiting out the superficial side of the tissue proximally. Then sew a few locked stitches laterally from proximal to distal exiting on the deep side of the tissue distally. *Note: the direction* (See Figure 32)

Figure 31

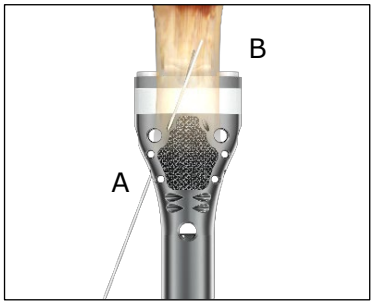
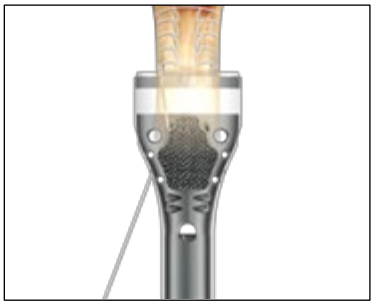
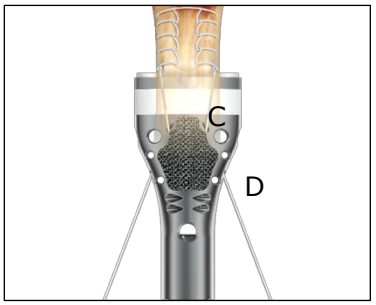


Figure 32



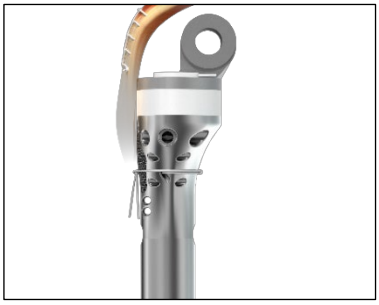
3. Advance the suture through the lateral superior-inferior hole of the implant from superior to the implant from superior to inferior (Point C to Point D). (See Figure 33)

Figure 33



4. Position the knee at approximately 20 degrees of flexion. Tension suture to approximate the patellar tendon to the implant. At about the level of the most proximal A/P suture hole, wrap sutures and tie posteriorly around the implant (having flexed the knee at 20 degrees would provide access). Then wrap back anteriorly and tie suture again around the patellar tendon on the anterior side of the implant. An absorbable hemostat can be inserted between the implant and the suture to protect the suture from the BioGrip surface, if necessary. (See Figure 34)
5. If possible, use the most proximal A/P hole to tie down the patellar tendon. If a medial gastrocnemius muscle flap is utilized, use the A/P holes to tie the muscle flap to the implant. Tie the muscle flap to the patellar tendon, remaining soft tissues of the extensor mechanism, and other fascia to close the joint capsule and ensure that none of the implant is left exposed.

Figure 34



Surgical technique steps

Component disassembly

To disengage the ELEOS 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 components separate as shown in Figures 35 and 36. Support the implant during disassembly. Alternatively, 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 as shown in Figures 37 and 38. Again, support the implant during disassembly.

Figure 35

Figure 36

Figure 37

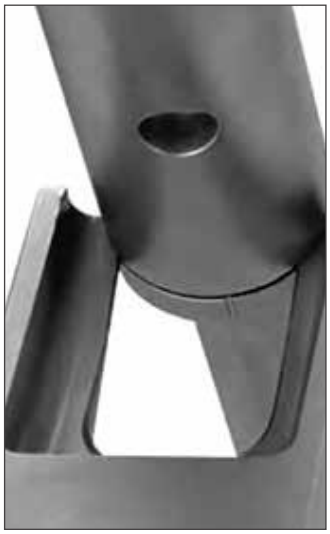


Figure 38

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 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.

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