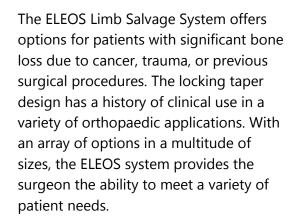
ELEOS[™] Limb Salvage System

Surgical Technique Proximal Femoral Replacement







ELEOS Limb Salvage System PROXIMAL FEMORAL REPLACEMENT

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for informational purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience and patient condition. Prior to the use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instruction for use are available on www.onkossurgical.com/ELEOS/IFU.

PRODUCT DESCRIPTION

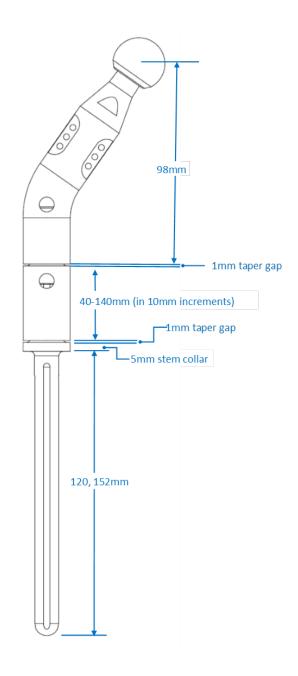
The ELEOS Proximal Femoral System consists of four components: the Proximal Femur, Optional Midsection, Segmental Stem, and a Femoral Head.

The ELEOS Proximal Femur (25000001E) offers total bone replacement of 104mm to 244mm when measured from the center of a +0mm Femoral Head | **TABLE 1.**

Table 1. FEMORAL BONE RESECTION

Part Number	Component	Resection
25000001E	Proximal Femur	98mm*
N/A	Stem Collar	5mm +1mm taper gap = 104mm
	Midsections	
25001040E	40mm	145mm
25001050E	50mm	155mm
25001060E	60mm	165mm
25001070E	70mm	175mm
25001090E	90mm	195mm
25001110E	110mm	215mm
25001140E	140mm	245mm
*With +0 head		

Seven lengths of optional Midsection (25001(XX)0E) components are interchangeable with all ELEOS systems to allow for precise length determination intraoperatively. Lengths ranging from 40-140mm accommodate bone resection in 10mm increments. Midsections are also available with male tapers on both ends enabling the implantation of a Total Femoral Replacement by combining the ELEOS Proximal and Distal Femur components (refer to the ELEOS Total Femoral Replacement surgical technique).



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 (152mm only) and have plasma spray on the stem to enhance initial fixation | **TABLE 2**.

Table 2.

Segmental Stems – Cemented				
Stem	Description	Length	Diameter	Collar
250000(XX)E	Straight Cylindrical, Fluted, Titanium	152mm	11, 13mm	25mm
2500CC(XX)E	Straight Cylindrical, Fluted, Titanium	152mm	15, 17mm	32mm
SPSEB0(XX)E	Bowed, Cylindrical, Fluted, Titanium	152mm	11, 13, 15, 17mm	25mm
250040(XX)E	Straight, Cylindrical, Fluted, Cobalt Chrome	120mm	9, 11, 13mm	25mm
Segmental St	tems – Canal Filling			
SPSE00(XX)E	Straight, Cylindrical, Splined, Slotted, Titanium w/ Plasma Spray 2/3	152mm	12, 14, 16, 18mm	25mm
2500CP(XX)E	Straight, Cylindrical, Splined, Slotted, Titanium w/ Plasma Spray 2/3	152mm	12, 14, 16mm	32mm
2500BP(XX)E	Bowed, Cylindrical, Splined, Slotted, Titanium w/ Plasma Spray 2/3	152mm	12, 14, 16, 18, 20, 22mm	32mm
2500SP(XX)E	Straight, Cylindrical, Splined, Full Plasma Spray, Titanium	120mm	12, 14, 16mm	25mm
2500SP(XX)E	Straight, Cylindrical, Splined, Full Plasma Spray, Titanium	120mm	18, 20, 22mm	32mm

^{*}Tapers down 2mm

Cobalt chrome Femoral Heads (260(X)00(XX)E) are available in 22.25mm, 28mm, 32mm and 36mm diameters | **TABLE 3** and are compatible with MicroPort Orthopedics' Gladiator Bipolar, and Lineage Acetabular Systems. Refer to the ELEOS Limb Salvage System Instructions for Use for compatibility information.

NOTE | MicroPort Orthopedics ceramic femoral heads in 28, 32, and 36mm diameters are compatible with the ELEOS System if a ceramic head is indicated.

Table 3.

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Ø HEAD	MATERIAL	-3.5mm	0mm	+3.5mm	+7mm	+10.5mm
22.25mm	Co-Cr		Χ	Χ		
28mm	Co-Cr	Χ	Χ	Χ	Χ	Χ
32mm	Co-Cr	Χ	Χ	Χ	Χ	_
36mm	Co-Cr	X	X	X	Х	

SURGICAL TECHNIQUE STEPS

FEMORAL PREPARATION

FEMORAL RESECTION

To assure restoration of leg length, measure several points of reference between the pelvis and an area distal to the proposed resection area.

A Proximal Femoral Resection Template is available. The amount of bone to be resected is determined by clinical evaluation. To determine the midsection and stem to use consult | **TABLE 1.**

CAUTION | Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively. Accurate preoperative 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 Proximal Femoral Resection Template, mark the level of the femoral resection by approximating the center of the femoral head with the hole in the template | **FIGURE 1.** Note the indicated femoral segment length on the template. Resect the proximal femur at the marked location, making a transverse cut | **FIGURE 2.**



Figure 1.



Figure 2.

ACETABULAR PREPARATION

Use a compatible acetabular system and prepare the acetabulum with standard technique.

NOTE | ELEOS is compatible with MicroPort Orthopedics' Gladiator, Bipolar, and Lineage Acetabular Systems. Refer to the ELEOS Limb Salvage System Instructions for Use for Compatibility information.

FEMORAL REAMING

Ream the femoral canal using Cylindrical Reamers if a cylindrical stem is to be implanted. Ream to a depth of 120mm or 152mm depending on the segmented stem | **FIGURE 3**. If a bowed stem is chosen, a set of flexible reamers can be used from general surgical instrumentation. Select a stem diameter that corresponds to the appropriate cement mantle based on clinical evaluation. | **Table 2**.



Figure 3.

NOTE | The Segmental Stem diameters are equal to reamer diameters when determining the appropriate Cylindrical Reamer size for the desired 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 markings on the Reamer account for the additional material of the Resurfacing Femur (implant thickness and boss length). Therefore, a 65mm mark corresponds to an actual depth of 115mm, and a 100mm mark corresponds to an actual depth of 150mm length, and a 140mm mark to a depth of 190mm.

FEMORAL PLANING Utilize the appropriate the resection level. | FIGURE 1

Utilize the appropriate Resection Planers to plane the resection area at the resection level. **| FIGURE 4.** Use the Resection Planer closest in diameter to the diameter of the intramedullary canal at the resection level.



Figure 4.

TRIALING

TRIAL ASSEMBLY

Assemble appropriate trials including the Trial Proximal Femur, the Trial Segmental Stem, the Trial Femoral Head, and any Trial Midsections necessary to reproduce the appropriate leg length. To assemble the Trial Midsection to the Trial Segmental Stem, 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 5**. Place the femoral trial construct into femoral canal.

NOTE | When assembling a Bowed Trial Stem, ensure that the Bow is in alignment with the curve of the bone.



Figure 5.

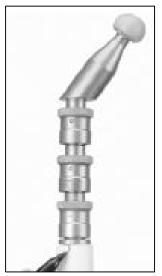


Figure 6.

TRIAL REDUCTION

Perform a trial reduction. Determine anteversion using the groove on the Trial Stem and the linea aspera as reference points. Mark the resection level with the anteversion position by the notch on the segmental stem trial. **| FIGURE 6.** This will mark the position for the final implant.

Note | If the soft tissues are excessively tight, utilize a shorter trial femoral head or resect additional bone from the femur as necessary. If the tissues are excessively loose, evaluate a longer Trial Femoral Head or utilize a longer midsection component.

Evaluate leg length and tension to ensure sufficient stability to prevent postoperative dislocation.

COMPONENT ASSEMBLY

On the back table, assemble the Proximal Femur on to a Trial Femoral Head on the Femoral Assembly Platform. Then assemble any optional Midsections to the Proximal Femur and Trial Femoral Head assembly with five hard mallet blows using the Midsection Assembly Impactor | **FIGURE 7.**



Figure 7.

Place the Segmental Stem in the Proximal Femur/Midsection/Femoral Head component, or in the Proximal Femur if no Midsection was used, and assemble with five hard mallet blows using the Stem Assembly Impactor | FIGURE 8.



Figure 8.

PREPARATION OF CEMENT

Cement mixing begins and the femoral canal is cleaned using pulsating lavage and then dried with a femoral sponge or tampon. If desired, a cement restrictor (plug) can be placed in the canal. Cement is then injected in a pressurized retrograde fashion.

COMPONENT INSERTION

FEMORAL COMPONENT

Place the assembled implant in the femoral canal, aligning the anteversion mark on the stem with the anteversion mark on the femur | **FIGURE 9.**



Figure 9.



Guide and impact the stem into the canal with the Proximal Femoral Impactor until the stem is seated at the resected plane | **FIGURE 10**. Remove excess cement. Proper position of the implant should be maintained until the cement cures.

Figure 10.



FEMORAL HEAD ASSEMBLY

A final trial reduction may be performed with the 22.25mm, 28mm, 32mm or 36mm Trial Femoral Heads to insure precise soft tissue balancing.

Remove the Trial Femoral Head from the implant. The taper of the femoral Segmental Stem should be cleaned and dried of any liquid or foreign materials. The Femoral Head is selected and placed on the femoral stem taper using a slight turning motion. Final seating of the Femoral Head is accomplished by impacting the Femoral Head Impactor with five final mallet blows | **FIGURE 11**.

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 the components separate | FIGURES 12 AND 13.

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 | FIGURES 14 AND 15. Again, support the implant during disassembly.









Figure 12.

Figure 13.

Figure 14.

Figure 15.

EXPLANTATION INFORMATION

In a revision case, when Segmental Stem explantation is required, use the Stem Extractor Attachment and attach to the Slap Hammer Extraction Handle to remove the stem.

IMPLANTS

FEMORAL HEADS

PART NUMBER	DESCRIPTION	SIZE	
26010002E	FEMORAL HEAD, +0MM TAPER	22.25MM	
26010003E	FEMORAL HEAD, +3.5MM TAPER	22.25MM	
26012801E	FEMORAL HEAD, -3.5MM TAPER	28MM	
26012802E	FEMORAL HEAD, +0MM TAPER	28MM	
26012803E	FEMORAL HEAD, +3.5MM TAPER	28MM	
26012804E	FEMORAL HEAD, +7MM TAPER	28MM	
26012805E	FEMORAL HEAD, +10.5MM TAPER	28MM	
26010007E	FEMORAL HEAD, -3.5MM TAPER	32MM	
26010008E	FEMORAL HEAD, 0MM TAPER	32MM	
26010009E	FEMORAL HEAD, +3.5MM TAPER	32MM	
26010010E	FEMORAL HEAD, +7MM TAPER	32MM	
26000025E	FEMORAL HEAD, SUPER FINISH, -3.5MM TAPER	36MM	
26000026E	FEMORAL HEAD, SUPER FINISH, +0MM TAPER	36MM	
26000027E	FEMORAL HEAD, SUPER FINISH, +3.5MM TAPER	36MM	
26000028E	FEMORAL HEAD, SUPER FINISH, +7MM TAPER	36MM	

PROXIMAL FEMUR

PART NUMBER	DESCRIPTION	SIZE
25000001E	ELEOS PROXIMAL FEMUR	98MM RESECTION

MALE-FEMALE MIDSECTIONS

PART NUMBER	DESCRIPTION	SIZE
25001040E	ELEOS MALE-FEMALE MIDSECTION	40MM
25001050E	ELEOS MALE-FEMALE MIDSECTION	50MM
25001060E	ELEOS MALE-FEMALE MIDSECTION	60MM
25001070E	ELEOS MALE-FEMALE MIDSECTION	70MM
25001090E	ELEOS MALE-FEMALE MIDSECTION	90MM
25001110E	ELEOS MALE-FEMALE MIDSECTION	110MM
25001140E	ELEOS MALE-FEMALE MIDSECTION	140MM

SEGMENTAL STEMS (CEMENTED)

PART NUMBER	DESCRIPTION	SIZE
25004009E	ELEOS SEGMENTAL STEM	9MM X 120MM
25004011E	ELEOS SEGMENTAL STEM	11MM X 120MM
25004013E	ELEOS SEGMENTAL STEM	13MM X 120MM
25000011E	ELEOS SEGMENTAL STEM	11MM X 152MM
25000013E	ELEOS SEGMENTAL STEM	13MM X 152MM
2500CC15E	ELEOS SEGMENTAL STEM	15MM X 152MM
2500CC17E	ELEOS SEGMENTAL STEM	17MM X 152MM
SPSEB011E	ELEOS SEGMENTAL STEM	11MM X 152MM
SPSEB013E	ELEOS SEGMENTAL STEM	13MM X 152MM
SPSEB015E	ELEOS SEGMENTAL STEM	15MM X 152MM
SPSEB017E	ELEOS SEGMENTAL STEM	17MM X 152MM

SEGMENTAL STEMS (CANAL FILLING)

PART NUMBER	DESCRIPTION	SIZE
2500SP12E	ELEOS SEGMENTAL STEM	12MM X 120MM
2500SP14E	ELEOS SEGMENTAL STEM	14MM X 120MM
2500SP16E	ELEOS SEGMENTAL STEM	16MM X 120MM
2500SP18E	ELEOS SEGMENTAL STEM	18MM X 120MM
2500SP20E	ELEOS SEGMENTAL STEM	20MM X 120MM
2500SP22E	ELEOS SEGMENTAL STEM	22MM X 120MM
2500BP12E	ELEOS SEGMENTAL STEM	12MM X 152MM
2500BP14E	ELEOS SEGMENTAL STEM	14MM X 152MM
2500BP16E	ELEOS SEGMENTAL STEM	16MM X 152MM
2500BP18E	ELEOS SEGMENTAL STEM	18MM X 152MM
2500BP20E	ELEOS SEGMENTAL STEM	20MM X 152MM
2500BP22E	ELEOS SEGMENTAL STEM	22MM X 152MM
2500CP12E	ELEOS SEGMENTAL STEM	12MM X 152MM
2500CP14E	ELEOS SEGMENTAL STEM	14MM X 152MM
2500CP16E	ELEOS SEGMENTAL STEM	16MM X 152MM
SPSE0002E	ELEOS SEGMENTAL STEM	12MM X 152MM
SPSE0003E	ELEOS SEGMENTAL STEM	14MM X 152MM
SPSE0004E	ELEOS SEGMENTAL STEM	16MM X 152MM
SPSE0005E	ELEOS SEGMENTAL STEM	18MM X 152MM

INSTRUMENTS

REAMERS

PART NUMBER	DESCRIPTION	SIZE
K0051010E	CYLINDRICAL REAMER	10MM
K0050510E	CYLINDRICAL REAMER	10.5MM
K0051011E	CYLINDRICAL REAMER	11MM
K0050511E	CYLINDRICAL REAMER	11.5MM
K0051012E	CYLINDRICAL REAMER	12MM
K0050512E	CYLINDRICAL REAMER	12.5MM
K0051013E	CYLINDRICAL REAMER	13MM
K0050513E	CYLINDRICAL REAMER	13.5MM
K0051014E	CYLINDRICAL REAMER	14MM
K0050514E	CYLINDRICAL REAMER	14.5MM
K0051015E	CYLINDRICAL REAMER	15MM
K0050515E	CYLINDRICAL REAMER	15.5MM
K0051016E	CYLINDRICAL REAMER	16MM
K0050516E	CYLINDRICAL REAMER	16.5MM
K0051017E	CYLINDRICAL REAMER	17MM
K0050517E	CYLINDRICAL REAMER	17.5MM
K0051018E	CYLINDRICAL REAMER	18MM
K0050518E	CYLINDRICAL REAMER	18.5MM
K0051019E	CYLINDRICAL REAMER	19MM
K0050519E	CYLINDRICAL REAMER	19.5MM
K0051020E	CYLINDRICAL REAMER	20MM
K0050520E	CYLINDRICAL REAMER	20.5MM
K0051021E	CYLINDRICAL REAMER	21MM
K0050521E	CYLINDRICAL REAMER	21.5MM
K0051022E	CYLINDRICAL REAMER	22MM
K0050522E	CYLINDRICAL REAMER	22.5MM
K0051023E	CYLINDRICAL REAMER	23MM
K0051116E	STABILIZING COLLET	16MM
K0051118E	STABILIZING COLLET	18MM
K0051120E	STABILIZING COLLET	20MM
K0051122E	STABILIZING COLLET	22MM
K0051124E	STABILIZING COLLET	24MM
001-03-00001	REAMERS (TRAY 1)	
001-03-00016	TRAY LID STANDARD	

ASSEMBLY/DISASSEMBLY INSTRUMENTS

PART NUMBER	DESCRIPTION	SIZE
18041000E	SLAP HAMMER EXTRACTOR HANDLE	
25100008E	TIBIAL BASEPLATE ASSEMBLY PLATFORM	
25107000E	TAPER DISASSEMBLY TOOL	
25107001E	TAPER DISASSEMBLY FORK	
25107101E	FEMORAL ASSEMBLY PLATFORM	
25107500E	MIDSECTION ASSEMBLY IMPACTOR	
25107501E	STEM ASSEMBLY IMPACTOR	
25107600E	FEMORAL IMPACTOR	
25107601E	DISTAL FEMORAL EXTRACTOR	
25107602E	TIBIAL IMPACTOR	
001-03-00002	ASSEMBLY/DISASSEMBLY INSTRUMENTS (TRAY 2)	
001-03-00016	TRAY LID STANDARD	

SEGMENTAL STEM TRIALS

PART NUMBER	DESCRIPTION	SIZE
25100011E	TRIAL SEGMENTAL STEM	11MM X 152MM
25100013E	TRIAL SEGMENTAL STEM	13MM X 152MM
25100015E	TRIAL SEGMENTAL STEM	15MM X 152MM
25100017E	TRIAL SEGMENTAL STEM	17MM X 152MM
SPSETB11E	TRIAL SEGMENTAL STEM	11MM X 152MM
SPSETB13E	TRIAL SEGMENTAL STEM	13MM X 152MM
SPSETB15E	TRIAL SEGMENTAL STEM	15MM X 152MM
SPSETB17E	TRIAL SEGMENTAL STEM	17MM X 152MM
25104009E	TRIAL SEGMENTAL STEM	9MM X 120MM
25104011E	TRIAL SEGMENTAL STEM	11MM X 120MM
25104013E	TRIAL SEGMENTAL STEM	13MM X 120MM
25107400E	STEM EXTRACTOR ATTACHMENT	
25107201E	UNIVERSAL RESECTION PLANER	
25107207E	RESECTION PLANER	7MM
25107209E	RESECTION PLANER	9MM
25107211E	RESECTION PLANER	11MM
20040110E	PILOT POINT #10	
20040111E	PILOT POINT #11	
20040112E	PILOT POINT #12	
20040113E	PILOT POINT #13	
20040114E	PILOT POINT #14	
20040115E	PILOT POINT #15	
001-03-00003	SEGMENTAL STEM TRIALS (TRAY 3)	
001-03-00016	TRAY LID STANDARD	

PROXIMAL/DISTAL FEMORAL SEGMENTAL TRIALS

PART NUMBER	DESCRIPTION	SIZE	
18052205E	TRIAL FEMORAL HEAD 22MM		
18052206E	TRIAL FEMORAL HEAD 22MM		
18056050E	TRIAL FEMORAL HEAD	28MM	
18056051E	TRIAL FEMORAL HEAD	28MM	
18056052E	TRIAL FEMORAL HEAD	28MM	
18056053E	TRIAL FEMORAL HEAD	28MM	
18056054E	TRIAL FEMORAL HEAD	28MM	
18056007E	TRIAL FEMORAL HEAD	32MM	
18056008E	TRIAL FEMORAL HEAD	32MM	
18056009E	TRIAL FEMORAL HEAD 32MM		
18056010E	TRIAL FEMORAL HEAD	32MM	
18056020E	TRIAL FEMORAL HEAD 36MM		
18056021E	TRIAL FEMORAL HEAD 36MM		
18056022E	TRIAL FEMORAL HEAD 36MM		
18056023E	TRIAL FEMORAL HEAD	36MM	
18080279E	PROXIMAL FEMUR IMPACTOR		
18810211E	UNIVERSAL IMPACTOR		
25100001E	TRIAL PROXIMAL FEMUR		
25100003E	TRIAL DISTAL FEMUR		
25100005E	TRIAL DISTAL FEMUR		
25100040E	TRIAL MALE-FEMALE MIDSECTION	40MM	
25100050E	TRIAL MALE-FEMALE MIDSECTION 50MM		
25100060E	TRIAL MALE-FEMALE MIDSECTION 60MM		
25100070E	TRIAL MALE-FEMALE MIDSECTION 70MM		
25100090E	TRIAL MALE-FEMALE MIDSECTION 90MM		
25100110E	TRIAL MALE-FEMALE MIDSECTION 110MM		
25100140E	TRIAL MALE-FEMALE MIDSECTION	140MM	
25102113E	TRIAL AXIAL PIN		
25107502E	PROXIMAL FEMORAL RESECTION TEMPLATE		
25107504E	DISTAL FEMORAL RESECTION TEMPLATE		
001-03-00004	PROXIMAL DISTAL FEMORAL SEGMENTAL TRIALS (TRAY 4)		
001-03-00016	TRAY LID STANDARD		

X-RAY TEMPLATES

PART NUMBER	DESCRIPTION	SIZE
G015XRGSE	X-RAY TEMPLATES	

The ELEOS Limb Salvage System is compatible with the following MicroPort Orthopedics systems trademarked by MicroPort: Guardian, Advance, Gladiator, Lineage, and Transcend.

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ELSS PF.12.13.16 v0

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