ELEOS™ and ELEOS™ with NanoCept® Technology Limb Salvage System

℞ ONLY

Printed in U.S.A.

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following symbols comply with ISO 15223-1, "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied". The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Title; Description
	Consult instructions for use; indicates the need for the user to consult the instructions for use
	Batch code; indicates the manufacturer's batch code so that the batch or lot can be identified
	Manufacturer; indicates the medical device manufacturer
	Date of Manufacture; indicates the date when the medical device was manufactured
	Catalog number; indicates the manufacturer's catalogue number so that the medical device can be identified
	Sterilized using irradiation; indicates a medical device that has been sterilized using irradiation
	Sterilized using ethylene oxide; indicates a medical device that has been sterilized using ethylene oxide
	Do not re-use/single use; indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Use-by date; indicates the date after which the medical device is not to be used
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if the product sterile barrier system or its packaging is compromised; indicates a medical device that should not be used if the package has been damaged or opened
	Non-sterile; indicates a medical device that has not been subjected to a sterilization process

Symbol	Title; Description
	Caution; Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Temperature limit; indicates the temperature limits to which the medical device can be safely exposed
	Keep dry; indicates a medical device that needs to be protected from moisture
	Keep away from sunlight; indicates a medical device that needs protection from light sources.
	Do not re-sterilize; indicates that a device should not be re-sterilized after it once has been sterilized.

Abbreviation	Material
CoCr	Cobalt Chrome Alloy
HA	Hydroxyapatite
SS	Stainless Steel
Ti	Titanium
Ti6Al4V	Titanium Alloy
UHMWPE	Ultra High Molecular Weight Polyethylene
MDPB	12-Methacryloyloxydodecyl Pryidinium Bromide

Device Description

The Onkos Surgical ELEOS and ELEOS with NanoCept Technology Limb Salvage System consists of components that are used in the reconstruction of the lower limb. The reconstruction applications are proximal femur, distal femur, total femur, proximal tibia, and hinged knee. The ELEOS and ELEOS with NanoCept Technology Limb Salvage components are femoral head, proximal femur, mid-section, stem, distal femur, tibial hinge component, axial pin, tibial poly spacer, tibial baseplate, male-male mid-section, resurfacing femur, proximal tibia, patella, stem extension, modular collar, tibial wedges and augments. Instrumentation is provided non-sterile in surgical trays which are to be re-processed per validated instructions.

	RECONSTRUCTION APPLICATIONS				
Components	Proximal Femur	Distal Femur	Total Femur	Proximal Tibia	Hinged Knee
Femoral head	✓		✓		
Proximal Femur	✓		✓		
Mid-Section[4]	✓	✓	✓	✓	
Segmental Stem	✓	✓		✓	
Modular Collar[1, 3]	✓	✓		✓	
Distal Femur		✓	✓		
Tibial Hinge Component		✓	✓	✓	✓
Axial Pin		✓	✓	✓	✓
Tibial Poly Spacer		✓	✓	✓	✓
Tibial Baseplate[2]		✓	✓		✓
Male-Male Mid-Section[4]			✓		
Resurfacing Femur[2]				✓	✓
Proximal Tibia[1]				✓	
Patella[3]		✓	✓	✓	✓
Wedges and Augments[3]		✓	✓		✓
Stem Extensions[3]		✓	✓	✓	✓

1 – Bolded components are offered with BioGrip® porous technology. Porous modular collars are offered with HA treatment.

2 – The Resurfacing Femur and Tibial Baseplate have the option for addition of a tapered screw between the respective component and a stem extension. The surgeon shall use their medical judgement to determine if the additional fixation is necessary based on factors such as patient bone quality, joint stability, and pathology.

3 – These implants are optional for each procedure. The surgeon shall use their medical judgement to determine if these implants are necessary based on factors such as patient bone quality, joint stability, and pathology.

4 – These implants are also available with NanoCept antibacterial (MDPB) coating technology.

The implants are single use devices.

A. INDICATIONS

ELEOS and ELEOS with NanoCept Technology Limb Salvage System Hip Components:
Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia;
2) Inflammatory degenerative joint disease such as rheumatoid arthritis;
3) Correction of functional deformity
4) Revision procedures where other treatments or devices have failed; and,
5) Treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

1) Patients suffering from severe arthropathy of the hip that does not respond to any conservative therapy or better alternative surgical treatment;
2) Surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications.
3) Metastatic diseases

ELEOS and ELEOS with NanoCept Technology Limb Salvage System Knee Components:
Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) Inflammatory degenerative joint disease including rheumatoid arthritis;
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and
5) Treatment of fractures that are unmanageable using other techniques.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal tibia is required with the following conditions:

1) Patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2) Surgical intervention for severe trauma, revision knee arthroplasties, and/or Oncology indications.
3) Metastatic diseases

The ELEOS with NanoCept Technology MDPB coating, where applied, is intended to reduce bacterial contamination prior to implantation resulting from deposition in the operating room on the surface of the device components. The clinical impact associated with the MDPB coating, including prevention of infection or reduction of infection risk in patients, has not been evaluated in human clinical trials. The MDPB coating is not intended to treat existing infections and does not act within or on the body.

The subject device is for prescription use only.

B. CONTRAINDICATIONS

Patients should be warned of these contraindications. **Contraindications include:**

1) overt infection;
2) distant foci of infections (which may cause hematogenous spread to the implant site);
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
4) skeletally immature patients (patients less than 21 years of age at the time of surgery);
5) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
6) inflammatory degenerative joint disease;
7) neuropathic joints;
8) hepatitis or HIV infection;
9) obesity where obesity is defined as a Body Mass Index (BMI) of 30.0 or higher;
10) female of child bearing age, for whom a negative pregnancy test is not obtained; and
11) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

Use with stainless steel bone screws is contraindicated. Inflammatory arthritis is contraindicated for patellofemoral resurfacing.

C. WARNINGS

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

The device coating is not intended for the treatment of existing infections or prevention of future infections in patients. The potential clinical impact of bacterial reduction from the ELEOS with NanoCept Technology coating, including prevention of infection or reduction of infection risk in patients, has not been evaluated in human clinical studies.

In-vitro bacterial reduction testing data was provided to support the stated indications for use for ELEOS with NanoCept Technology parts, with the following noted limitations: The testing was performed using MDPB-coated test coupons and components of the final finished device assembly (but not the complete final finished device assembly), under certain simulated use operating room conditions but not in an actual operating room, and only a portion of the final device assembly is coated with MDPB. Therefore, it is uncertain if the final finished device assembly will achieve similar bacterial reduction effect in the operating room.

The potential biological effects or the potential impact on the effectiveness of the MDPB coating from exposure of MDPB-coated devices to Isopropyl Alcohol (IPA) are not known.

D. PRECAUTIONS

<u>Preoperative Precautions</u>

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments and surgical procedure prior to performing surgery. The surgeon should contact Onkos Surgical for product-specific surgical techniques.

Patient selection should consider the following factors, which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Patients with high activity levels, poor bone quality, or heavyweight patients may not be candidates for a narrower femoral implant. Any joint replacement system, including the implant/bone interface, cannot be expected to withstand activity levels and loads as would normal healthy bone and will not be as strong, reliable, or durable as a natural human joint. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Additional conditions presenting increased risk of failure include:

1) uncooperative patient or patient with mental or neurologic disorders, incapable of following instructions;
2) marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3) metabolic disorders that may impair bone formation;
4) osteomalacia;
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).
6) conditions that could impair or impede healing (e.g., alcohol or drug abuse, decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);
7) pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

Intraoperative Precautions

While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

Inspect device **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.

Correct selection of the prosthesis is important. The potential for success in knee joint replacement is increased by selection of the proper size, shape, and design of the prostheses. Knee join prostheses require careful seating and adequate bone support. Smaller sized implants are intended for patients with small bone and normally slight weight. Such components could be

inappropriate for other patients. Surgeons are encouraged to use their best medical judgement when choosing the proper implant size regardless of the endosteal area of the bone.

Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

X-ray templates are used to estimate the size of the product to be used. The anatomy of the patient ultimately determines the size of the product for an individual patient. The extent of bone preparation is determined intraoperatively by reaming and/or broaching starting at the smallest size and continuing until bleeding cancellous bone is reached. Trial prostheses should be used to evaluate the position of the final implant and the joint range of motion. The final size of the implant selected during surgery may differ from the size originally planned during preoperative assessment or the combination chosen during preliminary trialing.

Cemented Application. Care is to be taken to ensure complete support of all components of the prosthesis embedded in bone cement to prevent stress concentrations that may lead to failure of the device or cement mantle. Complete cleaning including complete removal of bone chips, bone cement fragments, and metallic debris, prior to closure of the prosthetic site is critical to prevent accelerated wear of the articular surfaces of the prosthesis.

Non-Cemented Application. Adequate fixation at the time of surgery is critical to the success of the procedure. The femoral/tibial components must press fit in the femur/tibia, which necessitates precise operative technique and the use of specified instruments. Intraoperative fracture of the femur/tibia can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

Modular Components. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components that could compromise the locking action of the components. Surgical debris must be cleaned from components before assembly since debris may inhibit the proper fit and interfere with the locking mechanisms of modular components that may lead to early failure of the procedure.

Alignment of Components. Care should be taken to restore the proper joint alignment and to balance ligamentous tension. Malalignment of the joint can cause excessive wear, loosening of the prosthesis, and pain leading to premature revision of one or more of the prosthetic components.

Postoperative Precautions

The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic components. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone. Periodic post-operative x-rays are

recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.

Recommendations Regarding Device Fragments

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of un-retrieved device fragments including the following information:
    a. The material composition, size, and location of the fragment (if known);
    b. The potential mechanisms for injury, e.g., migration, infection;
    c. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

MRI Safety Information

The ELEOS and ELEOS with NanoCept Technology Limb Salvage System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ELEOS and ELEOS with NanoCept Technology Limb Salvage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

E. ADVERSE EFFECTS can include:

1) Osteolysis (progressive bone resorption). Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication.
2) Particulate generation leading to increased wear rates necessitating early revision. Soft tissue imbalance leading to excessive wear;
3) Allergic reactions to materials; metal sensitivity that may lead to histological reactions; or reactions to wear debris that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL).
4) Delayed wound healing; Deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required.
5) A sudden drop in blood pressure intra-operatively due to the use of bone cement;
6) Damage to blood vessels or hematoma;
7) Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
8) Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
9) Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
10) Periarticular calcification or ossification, with or without impediment to joint mobility;
11) Varus-valgus deformity;
12) Traumatic arthrosis of the knee from intraoperative positioning of the extremity;

13) Inadequate range of motion due to improper selection or positioning of components, periarticular calcification, flexion contracture; or femora impingement
14) Femoral, tibial or patellar bone or component fracture intraoperatively or postoperatively; fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
15) Undesirable shortening or lengthening of the limb;
16) Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;
17) Pain.
18) Fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight;
19) Trochanteric non-union due to inadequate reattachment and or early weight bearing;
20) Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;
21) Femoral or acetabular perforation or fracture; femoral fracture while seating the device; femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;

F. HANDLING AND STERILIZATION

Implants

Implants are sterilized by gamma radiation or ethylene oxide. The immediate package label should be consulted for specific method of sterilization. Irradiated implants have been exposed to a minimum 25 and a maximum 40 kilograys (kGy) of gamma radiation.

This product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product. This is particularly important in handling porous coated and HA prostheses. Do not allow porous surfaces or HA surfaces to come in contact with cloth or other fiber releasing materials.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

A prosthesis should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Onkos Surgical does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

Pyrogenicity was assessed using the LAL test which identified an acceptable endotoxin limit. Testing to monitor pyrogens will be performed using periodic testing.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- You must NEVER steam sterilize/re-sterilize ceramic, HA, calcium sulfate, plastic, antibacterial coated, and/or metal/plastic implants.

Instruments

Instruments are reusable and provided non-sterile and must be steam sterilized prior to surgical use. The system must be cleaned prior to sterilization. Clean and inspect all instruments within the tray to ensure they are suitable for use. Refer to Section H on Re-Processing Instructions for recommended cleaning instructions.

The sterilization trays shall be wrapped using FDA cleared sterilization wrap and steam sterilized using Moist Heat Sterilization per ANSI/AAMI ST-79.

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270˚F (132˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20 minutes (minimum, in chamber)

G. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

H. INSTRUMENT RE-PROCESSING INSTRUCTIONS

RE-PROCESSING INSTRUCTIONS

1. **Surgical Points of Use**

   - After use remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a tray of distilled water or cover with damp towels.
   - Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning. If cleaning must be delayed, place groups of instruments in a covered container with cold water or an appropriate detergent or enzymatic solutions to delay drying.
   - Clean all instruments, as recommended in Section 4, whether or not they were used or inadvertently contacted with blood or saline solution.

2. **Containment and Transportation to Processing Area**

   - Used instruments must be transported to the central sterile in closed or covered containers to prevent unnecessary contamination risk.

3. **Preparation Before Cleaning**

   - Symbols or specific instructions etched on instruments or instruments trays and cases should be strictly followed.
   - Where applicable, multi-component instruments should be disassembled for appropriate cleaning.
   - All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Neutral cleaning agents with a pH between 7-9 are recommended. Softened tap water may be used to prepare cleaning agents. Use of recommend temperature ranges is important for optional performance of cleaning agents.
   - Those items with mating surfaces, i.e. ratchets, hinges, serrations, lumens, blind holes, etc. must be manually cleaned to remove all visible debris from the items.

4. **Manual or Manual/Automatic Cleaning Process:**

4a. Manual Cleaning/Disinfection Procedure

Step 1	Completely submerge instruments in enzyme solution (temp. 35-40ºC) and soak for a minimum of 15 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard to clean areas. Brush all cannula with nylon brush to ensure the inner diameters are clean. Refer to Table 1 for a specific size nylon brush to be used with each cannulated part.
Step 2	Remove the device from the enzyme solution and rinse in tap water (temp. 35-40ºC) for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 3	Place prepared cleaning agents in a sonication unit. Completely submerge device in neutral cleaning solution (pH between 7-9) and sonicate for 10 minutes.
Step 4	Rinse instrument in purified water (temp. 35-40ºC) for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.

Step 5	Remove visible moisture from the instrument with a clean, absorbent and non-shedding wipe. Flush lumens, holes and other difficult to reach areas with alcohol and/or spray with clean, compressed air.

4b. Manual/Automatic Washer/Disinfector Cycle Procedure

Step 1	Manual pre-cleaning is mandatory. Refer to 4a.
Step 2	Run the automatic wash cycle. (An automatic cleaning process may involve a washer-sterilizer, a washer-sanitizer/disinfector, ultrasonic cleaner. There are many difference types of automatic washer systems, each with their own unique instructions that must be followed. Follow the manufacturer's recommendations for proper cleaning and selections of cleaning solutions. Be aware that loading patterns, water temperature and pH of cleaning solutions may change the effectiveness of the equipment.)
Step 3	Check instruments for visible soil. Repeat cleaning if soil is visible and re-inspect.

Table 1: Nylon Brush Sizes

Cannula Size Range	Nylon Brush
.040- .053"	**4.0Fr x 400mm**
.054-.066"	**5.0Fr x 360mm**
.067 -.079"	**6.0Fr x 360mm**
.080 -.092"	**7.0Fr x 360mm**
.093-.105"	**8.0Fr x 360mm**
.106-.118"	**9.0Fr x 360mm**
.119-.131"	**10.0Fr x 360mm**
.159-.170"	**13.0Fr x 360mm**

*Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches recommended.

5. Inspection, Functional Testing & Maintenance

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the actuation of moving parts (e.g. hinges, connectors, sliding parts, triggers, etc.) to ensure smooth operation throughout the intended range of motion.
- Where instruments form part of a larger assembly, check that devices assemble readily with mating components.
- Prepare all instruments in proper case and tray configuration (if applicable) to prepare for steam sterilization.

Note: Onkos Surgical does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

6. Steam Sterilization

Steam auto-clave (moist heat) sterilization using a pre-vacuum cycle is recommended. Autoclaves should comply with the requirements of, and be validated and maintained in accordance with ANSI/AAMI ST-79.

Onkos Surgical has validated an autoclave cycle for sterilization of complete re-usable instrument cases/trays. Onkos Surgical trays are only validated for use with Onkos Surgical implants and instruments. Instruments shall be sterilized in the assembled state as stored on the tray. Onkos Surgical trays should be double wrapped according to AAMI/CSR technique. Do not stack trays during sterilization.

The process parameters shown below are validated and recommended by Onkos Surgical for sterilization.

Method:	**Moist Heat Sterilization per ANSI/AAMI ST-79**
Sterilizer Type:	**Pre-Vacuum**
Exposure Time	**4 minutes**
Minimum Temperature:	**132ºC (270ºF)**
Minimum Dry Time	**20 minutes (minimum, in chamber)**

After sterilization, remove the component from its wrapping using accepted sterile technique with powder free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

Note: These recommendations are consistent with AAMI ST-79 table 5 guidelines and have been validated for use with Onkos Surgical devices and trays. Due to variations in health care user environments and equipment, it remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves sterility. This requires validation and monitoring of the process. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

7. Storage

- After sterilization, re-usable instruments should be stored in the sterilization wrap in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized re-usable instruments before use should be defined by each health care facility.
- Reusable devices may be stored between cleaning and sterilization and therefore the devices shall be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments.

I. COMPATIBILITY

The ELEOS Limb Salvage System is compatible with the MicroPort Orthopedics GUARDIAN® Limb Salvage System. ELEOS implants with BioGrip porous surfaces and with NanoCept Technology are interchangeable with the ELEOS Limb Salvage System. In addition, ELEOS is compatible with the MicroPort Gladiator Bipolar and Lineage Acetabular Systems. The ELEOS (Morse taper) femoral head is identical to the SLT (Morse taper) MicroPort metal and ceramic SLT femoral heads; they may be used interchangeably. Therefore, the ELEOS proximal femur is compatible with MicroPort Orthopedics SLT taper femoral heads (Lineage, Transcend) therefore, by way of the same femoral head taper and specification, may mate with both MicroPort Gladiator and Lineage Acetabular Systems. Please refer to the compatibility table located in Appendix A.

J. PRODUCT-SPECIFIC WARNINGS AND PRECAUTIONS

NEVER combine these metals in NON-ARTICULATING contact surfaces:

- Stainless steel (excluding the stainless steel described in ISO 5832-9)/cobalt chrome alloy
- Stainless steel (excluding the stainless steel described ISO 5832-9)/titanium alloy.
- Stainless steel (excluding the stainless steel described ISO 5832-9)/unalloyed titanium.

Do not attempt to seat the implant beyond the envelope of femoral bone preparation. Forcing to seat the implant beyond the prepared femoral bone may increase the chance of bone fracture. In some cases, a portion of the proximal body with or without coating may be visible above the proximal resection level.

The smaller sized femoral implants are intended for patients with narrower intramedullary femoral canals. The geometry of these implants is reduced to accommodate the anatomy of the narrower intramedullary femoral canal, which also decreases the fatigue-strength and load-bearing characteristics of the implant.

Modular Components (Femoral Head and Stems, and Proximal Body)

Scratching of femoral heads and proximal and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Prior to assembly, surgical debris must be cleaned from the interior of the female seat of the proximal body to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body **must** be clean and dry before assembly.

Please refer to the corresponding surgical technique and Appendix A for allowable device combinations.

Stems with the SLT Taper should only be used in combination with femoral heads with the SLT Taper. Cobalt chrome femoral heads with the SLT Taper are designed for use with cobalt-chromium-molybdenum, and titanium alloys stems.

MANUFACTURER:

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Appendix A: Femoral Head Compatibility

				MicroPort Lineage Liners																						
		Part numbers		364528X1	364528X2	364528X3	364528X4	364128X1	364128X2	364128X3	364128X4	364532X2	364532X3	364532X4	364132X2	364132X3	364132X4	364536X3	364536X4	364136X3	364136X4	7100-2846	7200-3252	7300-3258	7300-3658	7400-3664
			Description	28MM 15DG CROSSLINKED POLY LINER	28MM 15DG CROSSLINKED POLY LINER	28MM 15DG CROSSLINKED POLY LINER	28MM 15DG CROSSLINKED POLY LINER	28MM 0DG CROSSLINKED POLY LINER	28MM 0DG ROSSLINKED POLY LINER	28MM 0DG CROSSLINKED POLY LINER	28MM 0DG CROSSLINKED POLY LINER	32MM 15DG CROSSLINKED POLY LINER	32MM 15DG CROSSLINKED POLY LINER	32MM 15DG CROSSLINKED POLY LINER	32MM 0DG CROSSLINKED POLY LINER	32MM 0DG CROSSLINKED POLY LINER	32MM 0DG CROSSLINKED POLY LINER	36MM 15DG STD	36MM 15DG STD	36MM 0DG STD	36MM 0DG STD	Ceramic Liner 28mm ID	Ceramic Liner 32mm ID	Ceramic Liner 32mm ID	Ceramic Liner 36mm ID	Ceramic Liner 36mm ID
Femoral Heads	**ELEOS Part Numbers**	26010002E	22.25MM +0MM																							
		26010003E	22.25MM +3.5MM																							
		26012801E	28MM -3.5MM	x	x	x	x	x	x	x	x															
		26012802E	28MM +0MM	x	x	x	x	x	x	x	x															
		26012803E	28MM +3.5MM	x	x	x	x	x	x	x	x															
		26012804E	28MM +7MM	x	x	x	x	x	x	x	x															
		26012805E	28MM +10.5MM	x	x	x	x	x	x	x	x															
		26010007E	32MM -3.5MM									x	x	x	x	x	x									
		26010008E	32MM +0MM									x	x	x	x	x	x									
		26010009E	32MM +3.5MM									x	x	x	x	x	x									
		26010010E	32MM +7MM									x	x	x	x	x	x									
		26000017E	SUPER FINISH, 28MM -3.5MM	x	x	x	x	x	x	x	x															
		26000018E	SUPER FINISH, 28MM +0MM	x	x	x	x	x	x	x	x															
		26000019E	SUPER FINISH, 28MM +3.5MM	x	x	x	x	x	x	x	x															
		26000020E	SUPER FINISH, 28MM +7MM	x	x	x	x	x	x	x	x															
		26000021E	SUPER FINISH, 32MM -3.5MM									x	x	x	x	x	x									
		26000022E	SUPER FINISH, 32MM +0MM									x	x	x	x	x	x									
		26000023E	SUPER FINISH, 32MM +3.5MM									x	x	x	x	x	x									
		26000024E	SUPER FINISH, 32MM +7MM									x	x	x	x	x	x									
		26000025E	SUPER FINISH, 36MM -3.5MM															x	x	x	x					
		26000026E	SUPER FINISH, 36MM +0MM															x	x	x	x					
		26000027E	SUPER FINISH, 36MM +3.5MM															x	x	x	x					
		26000028E	SUPER FINISH, 36MM +7MM															x	x	x	x					

				MicroPort Orthopedic Gladiator Implants																															
		Part numbers		GLBP2236	GLBP2237	GLBP2238	GLBP2239	GLBP2240	GLBP2241	GLBP2842	GLBP2843	GLBP2844	GLBP2845	GLBP3246	GLBP3247	GLBP3248	GLBP3249	GLBP3650	GLBP3651	GLBP3652	GLBP3653	GLBP3654	GLBP3655	GLBP3656	GLBP3657	GLBP3658	GLBP3659	GLBP3660	GLBP3661	GLBP3662	GLBP3663	GLBP3664	GLBP3665
			Description	36MM OD X 22MM ID	37MM OD X 22MM ID	38MM OD X 22MM ID	39MM OD X 22MM ID	40MM OD X 22MM ID	41MM OD X 22MM ID	42MM OD X 28MM ID	43MM OD X 28MM ID	44MM OD X 28MM ID	45MM OD X 28MM ID	46MM OD X 32MM ID	47MM OD X 32MM ID	48MM OD X 32MM ID	49MM OD X 32MM ID	50MM OD X 36MM ID	51MM OD X 36MM ID	52MM OD X 36MM ID	53MM OD X 36MM ID	54MM OD X 36MM ID	55MM OD X 36MM ID	56MM OD X 36MM ID	57MM OD X 36MM ID	58MM OD X 36MM ID	59MM OD X 36MM ID	60MM OD X 36MM ID	61MM OD X 36MM ID	62MM OD X 36MM ID	63MM OD X 36MM ID	64MM OD X 36MM ID	65MM OD X 36MM ID
Femoral Heads	**ELEOS Part Numbers**	26010002E	22.25MM +0MM	x	x	x	x	x	x																								
		26010003E	22.25MM +3.5MM	x	x	x	x	x	x																								
		26012801E	28MM -3.5MM							x	x	x	x																				
		26012802E	28MM +0MM							x	x	x	x																				
		26012803E	28MM +3.5MM							x	x	x	x																				
		26012804E	28MM +7MM							x	x	x	x																				
		26012805E	28MM +10.5MM							x	x	x	x																				
		26010007E	32MM -3.5MM											x	x	x	x																
		26010008E	32MM +0MM											x	x	x	x																
		26010009E	32MM +3.5MM											x	x	x	x																
		26010010E	32MM +7MM											x	x	x	x																
		26000017E	SUPER FINISH, 28MM -3.5MM							x	x	x	x																				
		26000018E	SUPER FINISH, 28MM +0MM							x	x	x	x																				
		26000019E	SUPER FINISH, 28MM +3.5MM							x	x	x	x																				
		26000020E	SUPER FINISH, 28MM +7MM							x	x	x	x																				
		26000021E	SUPER FINISH, 32MM -3.5MM											x	x	x	x																
		26000022E	SUPER FINISH, 32MM +0MM											x	x	x	x																
		26000023E	SUPER FINISH, 32MM +3.5MM											x	x	x	x																
		26000024E	SUPER FINISH, 32MM +7MM											x	x	x	x																
		26000025E	SUPER FINISH, 36MM -3.5MM															x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		26000026E	SUPER FINISH, 36MM +0MM															x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		26000027E	SUPER FINISH, 36MM +3.5MM															x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		26000028E	SUPER FINISH, 36MM +7MM															x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

ELEOS Proximal Femurs:
Are compatible with these MicroPort Femoral Heads

		Part numbers	Description
Femoral Heads	**MicroPort Part Numbers**	26010002	22.25MM +0MM
		26010003	22.25MM +3.5MM
		26012801	28MM -3.5MM
		26012802	28MM +0MM
		26012803	28MM +3.5MM
		26012804	28MM +7MM
		26012805	28MM +10.5MM
		26010007	32MM -3.5MM
		26010008	32MM +0MM
		26010009	32MM +3.5MM
		26010010	32MM +7MM
		26000017	SUPER FINISH, 28MM -3.5MM
		26000018	SUPER FINISH, 28MM +0MM
		26000019	SUPER FINISH, 28MM +3.5MM
		26000020	SUPER FINISH, 28MM +7MM
		26000021	SUPER FINISH, 32MM -3.5MM
		26000022	SUPER FINISH, 32MM +0MM
		26000023	SUPER FINISH, 32MM +3.5MM
		26000024	SUPER FINISH, 32MM +7MM
		26000025	SUPER FINISH, 36MM -3.5MM
		26000026	SUPER FINISH, 36MM +0MM
		26000027	SUPER FINISH, 36MM +3.5MM
		26000028	SUPER FINISH, 36MM +7MM