MicroPort Orthopedics

REPIPHYSIS® LIMB SALVAGE SYSTEM

150800-0

For additional information please contact the manufacturer or local distributor.

MicroPort Orthopedics Inc.
5677 Airline Rd
Arlington, TN 38002
U.S.A.

℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

REPIPHYSIS® LIMB SALVAGE SYSTEM (150800-0)

OUTLINE

I. GENERAL PRODUCT INFORMATION

Through the advancement of the REPIPHYSIS® Limb Salvage System, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal and plastic materials and that any limb salvage system, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human bone/joint.

In using limb salvage prostheses, the surgeon should be aware of the following:

- **Correct selection of the prosthesis is important.** The potential for success in limb salvage surgery is increased by selection of the proper size, shape, and design of the prosthesis. Limb salvage 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.
- **In selecting patients for limb salvage surgery, the following factors can be critical to the eventual success of the procedure:**

  1. **Patient's weight.** An overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. An average weight patient performing high impact activities may also produce high loads on the prosthesis, which can lead to failure of the prosthesis. Therefore, the patient should be strongly cautioned against performing any activity that may increase the force applied to the prosthesis and the surgeon should consider the patients current weight and activity level as well as the ability of the patient to follow post-operative instructions regarding activity level.

     Because of the nature of the REPIPHYSIS® Total Femur and REPIPHYSIS® Proximal Femur, the weight of the patient is extremely important. Patients weighing over 67 lbs (30 kg) should be strongly cautioned against receiving either the REPIPHYSIS® Total or Proximal Femur.

2. **Patient's occupation or activity.** If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
3. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. INDICATIONS

REPIPHYSIS® Distal Femur and Proximal Tibia are indicated for cemented procedures where radical resection and replacement of the distal femur and/or proximal tibia is required with the following conditions:

1) patients suffering from severe arthropathy of the hip/ knee that does not respond to any conservative therapy or better alternative surgical treatment;
2) surgical intervention for severe trauma, revision hip/ knee arthroplasties, and/or oncology indications;
3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors).

The REPIPHYSIS® Proximal Femur and REPIPHYSIS® Total Femur are indicated for cemented procedures where radical resection and replacement of the proximal or total femur is required in skeletally immature patients (weighing up to 67 lbs/30 kg) with osteosarcoma.

Limb salvage devices are intended for cement use only.

B. CONTRAINDICATIONS

Absolute 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) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/ or inadequate abductor strength), poor bone stock, or poor skin coverage around the knee joint that would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

1) uncooperative patient or patient with 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 or cause bone loss;
4) osteomalacia; and
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

C. POTENTIAL COMPLICATIONS

Improper selection, placement, positioning, or fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component. The surgeon must be thoroughly familiar with the prosthesis, instruments, and surgical procedure prior to performing surgery. 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.

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although MicroPort Orthopedics Inc. cannot recommend a particular surgical technique suitable for all patients, a surgical technique is available for surgeon reference. Medical procedures for optimal utilization of the prosthesis should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following limbsalvage arthroplasty may be reduced by:

1. Consistent use of prophylactic antibiotics.
2. Utilizing a laminar flow clean air system.
3. Having all operating room personnel, including observers, properly attired.
4. Protecting instruments from airborne contamination.
5. Impermeable draping.

Metal Components. Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to evaluate these questions have not produced convincing evidence of such phenomenon.

Cemented Application. Care is to be taken to assure 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 prosthesis. 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.

Materials. The limb salvage components are manufactured from a variety of materials that include cobalt-chromium-molybdenum alloy, titanium alloy, ceramic, medical grade silicone adhesive, and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM standards. Other components that have been self-certified through biocompatibility and mechanical testing include PEEK and polyacetyl.

Prosthetic Components. Do not mix limb salvage components of different prosthetic systems, or from different manufacturers. Be aware that mixing certain sizes of the same prosthetic system may be inadvisable. 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.

D. PRECAUTIONS

1. 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.

2. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses, and follow the instructions of the physician with respect to follow-up care and treatment. The patient should be closely monitored if a change at the operative site has been detected. The possibility of deterioration of the joint should be evaluated and possible revision surgery considered.
3. 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.
4. Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Do not mix instruments from different manufacturers. 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.
5. Preoperative templates should be used to assure proper sizing of prostheses.
6. 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

- Use medical devices in accordance with their labeled indications and MicroPort Orthopedics's instructions for use, especially during insertion and removal.
- Inspect devices **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.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with MicroPort Orthopedics's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
  a. The material composition of the fragment (if known);
  b. The size of the fragment (if known);
  c. The location of the fragment;
  d. The potential mechanisms for injury, e.g., migration, infection;
  e. 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.

E. ADVERSE EFFECTS

1. Wear of the polyethylene articulating surfaces of the tibial bushing has been reported following limb salvage surgery about the knee. Higher rates of wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components. Wear can lead to the

increased presence of particulate debris in the joint with associated histological reaction to that debris.

2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate matter. Particulate matter is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles can also be generated by third-body wear. Osteolysis can lead to pain, swelling, and future complications necessitating the removal and replacement of prosthetic components. See **Important Physician Information Section** below for more information.
3. Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in cellular reactions involving lymphocytes, macrophages, and fibroblasts.
4. Peripheral neuropathies have been reported following knee joint surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma.
5. Dislocation and subluxation of prosthetic components can result from improper positioning and/or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
6. Prosthetic components can loosen or migrate due to trauma or loss of fixation.
7. Infection can lead to failure of the joint replacement.
8. While rare, fracture of the component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
9. Soft tissue imbalance can cause excessive wear and/or failure of the implant.
10. Intraoperative fracture of the femur, tibia, or patella can occur while preparing the bone sites and/or seating the components.
11. Allergic reactions to the prosthetic component materials can occur.

Intraoperative and early postoperative complications can include:

1) femoral, tibial, or patellar bone or component fracture;
2) damage to blood vessels;
3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
4) a sudden drop in blood pressure intra-operatively due to the use of bone cement;
5) varus-valgus deformity;
6) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
7) hematoma;
8) delayed would healing; and
9) 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.

Late postoperative complications can include:

1) patellar fracture as a result of excess tension, trauma, or inadvertent intraoperative weakening;
2) aggravated problems of the affected limb or contralateral extremity by leg length discrepancy;
3) periarticular calcification or ossification, with or without impediment to joint mobility;
4) inadequate range of motion due to improper selection or positioning of components, impingement, and periarticular calcification;

5) late or early loosening, change in position of the components, wear, and bending or cracking of one or more prosthetic components represent potential adverse effects; and

6) bone fractures, dislocation, subluxation, flexion contracture, decreased range of motion, or lengthening or shortening of the leg have all been reported in association with knee replacement.

Important Physician Information

Bone resorption can occur as a natural consequence of knee joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to prosthesis loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, ultra high molecular weight polyethylene (UHMWPE), and ceramic. Regarding the etiology, it has been hypothesized that particulate debris generated by articulation of the components of a prosthesis migrate into the synovial cavity and the bone-prosthesis interface, where they recruit macrophages and stimulate phagocytic action. The cellular response is probably related to the size, distribution, and amount of particulate debris (rate of debris generation). The phagocytic action has been demonstrated in vitro to induce release of cytokines and cellular mediators (IL-1, 2, IL-6, PGE2, TNF3). These mediators have been shown to modulate osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomena and potential ways to reduce its occurrence.

Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions that are progressive may necessitate replacement of the prosthetic component(s).

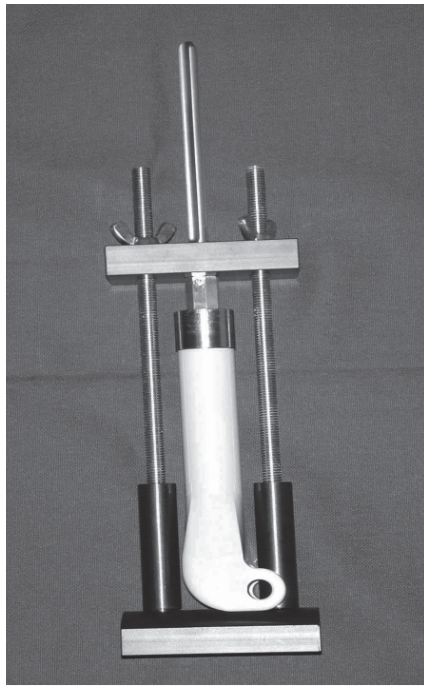
F. HANDLING AND STERILIZATION

REPIPHYSIS® Limb Salvage System is supplied non-sterile, only the tibial bushings have 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 accepted sterile technique, only after 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 product is for single use only. The REPIPHYSIS® Limb Salvage System should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded. While it may appear undamaged, microscopic imperfections may exist that would reduce the service life of the prosthesis.

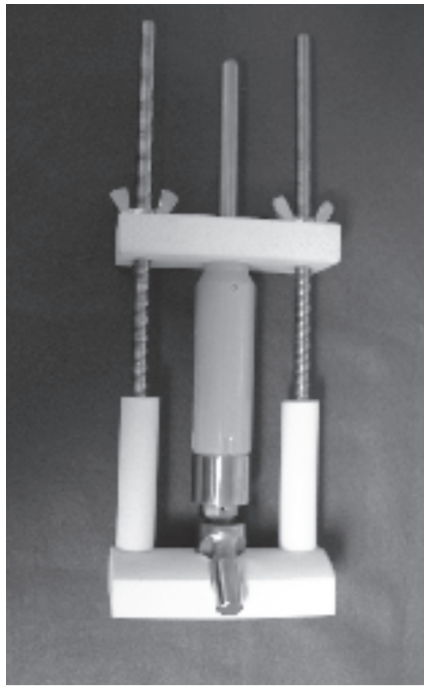
MicroPort Orthopedics validated the steam sterilization parameters for REPIPHYSIS® Limb Salvage System according to the requirements of ANSI/AAMI/ISO 11134-1993, Sterilization of Health Care Products- Requirements for Validation and Routine Control – Industrial Moist Heat Sterilization. The following sterilization recommendation has been developed for the REPIPHYSIS® Limb Salvage System using specific equipment for a SAL of 10-6 and may vary depending on processing conditions, wrapping materials, or equipment. The cycle and conditions must be demonstrated to produce sterility in your environment. If sterilization/ resterilization of the metal component(s) is required, proceed accordingly.

1. Place the device in the sterilization frame prior to sterilization. Place the selected implant component in the sterilization frame as shown. Make sure the wing nuts are snug and not too tight. The entire assembly will be autoclaved.

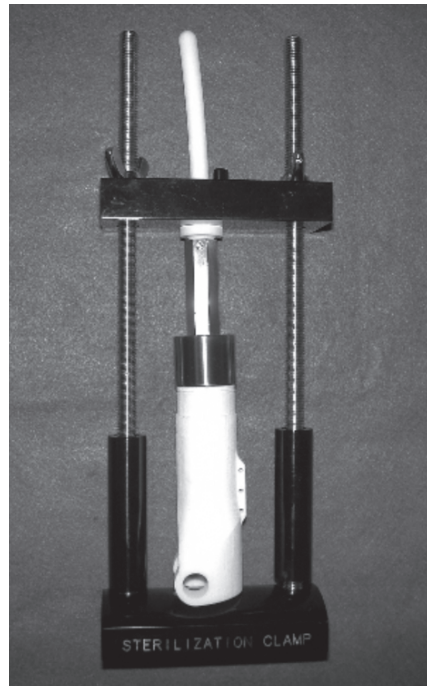


A. Distal Femur

B. Total Femur



C. Proximal Femur



D. Proximal Tibia

2. Wrap the component in central supply room (CSR) type non-woven medical grade wrapping material or place in a sealed sterilization pouch. If using the 270°F (132°C) pulsing vacuum cycle, the component may be placed on a standard mesh sterilization tray.
3. Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Steam	Pulsing Vacuum	270-275°F (132-135°C)	40 minutes

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

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

THIS PRODUCT IS FOR CEMENTED USE ONLY IN THE U.S.