MicroPort Orthopedics

MICROPORT HIP SYSTEMS
150803-6

The following languages are included in this packet:

English (en) Español (es)

For additional languages, visit our website **www.ortho.microport.com/ifus**

For additional information and translations please contact the manufacturer or local distributor.

CE 0086*

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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ELECTRONIC IFU NOTICE

EN	**English** Additional translations of this package insert are available in electronic form on MicroPort Orthopedics' website and can be accessed by visiting www.ortho.microport.com/ifus. A web browser with a PDF viewer is required to access the electronic package inserts. Printed translations of the package insert can be requested at no additional cost by contacting MicroPort Orthopedics' Customer Service department at +1 901-290-5290 or +1 901-354-8134.
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SCH	**简体中文** 本插页的其他翻译以电子形式在 MicroPort Orthopedics 的网站上提供，并可通过访问 www.ortho.microport.com/ifus 进行访问。若要访问电子插页，需要使用具有 PDF 阅读器的 Web 浏览器。 如需本插页的打印版翻译，可以通过联系 MicroPort Orthopaedics 的客户服务部门 +1 901-290-5290 或 +1 901-354-8134 免费索取。
DA	**Dansk** Yderligere oversættelser af dette pakkeindlæg findes i elektronisk form på MicroPorts Orthopedics' webside og kan ses ved at besøge www.ortho.microport.com/ifus. Der kræves en webbrowser med en pdf-fremviser for at kunne se de elektroniske pakkeindlæg. Trykte oversættelser af pakkeindlægget kan bestilles uden yderligere omkostninger ved at kontakte MicroPort Orthopedics' kundeservice på +1 901-290-5290 eller +1 901-354-8134.
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NL	**Nederlands** Aanvullende vertalingen van de bijsluiter zijn beschikbaar in elektronische vorm op de website van MicroPort Orthopedic en zijn toegankelijk via: www.ortho.microport.com/ifus. Er is een webbrowser met een PDF-viewer vereist om toegang te krijgen tot de elektronische bijsluiters. Gedrukte vertalingen in papiervorm van de bijsluiter kunnen zonder extra kosten worden aangevraagd bij de klantenservice van MicroPort Orthopedics, telefoonnummer: +1 901-290-5290 of +1 901-354-8134.
CS	**Čeština** Další překlady této příbalové informace jsou k dispozici v elektronické formě na webových stránkách společnosti MicroPort Orthopedics. Máte-li o ně zájem, navštivte www.ortho.microport.com/ifus. Pro zpřístupnění příbalových informací v elektronické podobě je nutný webový prohlížeč s PDF prohlížečem. Tištěné překlady příbalové informace si lze bezplatně vyžádat v Oddělení zákaznických služeb společnosti MicroPort Orthopedics na telefonním čísle +1 901-290-5290 nebo +1 901-354-8134.
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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

HIP SYSTEM
(150803-6)

OUTLINE

HIP GENERAL INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbols Glossary. (Can also be found at www.ortho.microport.com/ifus)		
Symbol	**Title [Additional Explanation]; Reference Number/ Standard#**	**Explanatory Text from Standard**
LOT	Batch code; 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue number; 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Do not re-use; 5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Symbols Glossary. (Can also be found at www.ortho.microport.com/ifus)		
Symbol	**Title [Additional Explanation]; Reference Number/ Standard#**	**Explanatory Text from Standard**
	Caution [consult warnings or precautions]; 5.4.4	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.
	Consult instructions for use [operating instructions]; 5.4.3	Indicates the need for the user to consult the instructions for use [operating instructions].
	Consult instructions for use [electronic IFU] [Where applicable, refer to http://www.ortho.microport.com/ifus or call +1 901-290-5290, for an urgent request call +1 901-354-8134, to obtain instructions for use.]; 5.4.3 A.15	Indicates that the instructions for use [warnings or precautions] are available in an electronic format.
	Use-by date; 5.1.4	Indicates the date after which the medical device is not to be used.
	Temperature limit; 5.3.7	Indicates the temperature limits to which the device can be safely exposed.
	Keep dry; 5.3.4	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight; 5.3.2	Indicates a medical device that needs protection from light sources.
	Date of manufacture; 5.1.3	Indicates the date when the medical device was manufactured.
	Manufacturer; 5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
EC REP	Authorized Representative in the European Community; 5.1.2	Indicates the authorized representative in the European Community.
STERILE	Sterile; 5.2.1	Indicates a medical device that has been subjected to a sterilization process.
STERILE EO	Sterilized using ethylene oxide; 5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
STERILE R	Sterilized using radiation; 5.2.4	Indicates a medical device that has been sterilized using irradiation.

Symbols Glossary. (Can also be found at www.ortho.microport.com/ifus)		
Symbol	**Title [Additional Explanation]; Reference Number/ Standard#**	**Explanatory Text from Standard**
	Do not resterilize; 5.2.6	Indicates a medical device that is not to be resterilized.
	Non-sterile; 5.2.7	Indicates a medical device that has not been subjected to a sterilization process.
℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician; 21 CFR 801.15(c)(1)(i)F; 21 CFR 801.109 – U.S. *Code of Federal Regulations Title 21, Part 801 Labeling*	Use of this device is not safe except under the supervision of a practitioner licensed by law to direct the use of such device.
	MR Conditional; ASTM F2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* (FDA Designation Number 8-349).	Indicates an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. If applicable, conditions can be found within the package insert or at www.ortho.microport.com/ifus.
	Do not use if package is damaged; 5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
CE	CE marking; 93/42/EEC *European Union Medical Devices Directive, Annex XII CE Marking of Conformity*	Indicates that the device fulfills the provisions of the European Medical Devices Directive.

#Unless otherwise noted, all symbols are sourced from ISO 15223-1 *Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements* (FDA Designation Number 5-117, 5-118)

Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
Al_2O_3	Alumina
ZrO_2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
PDLLA	Poly D, L-Lactic Acid
PDMS	Silicone 55D

DESCRIPTION

MicroPort Orthopedics Inc. (MicroPort) has a variety of hip joint replacement prostheses. The components for these systems include an acetabular shell, acetabular liner, fixation screws, femoral head, femoral stem, modular neck and a proximal body. These components can be utilized in a variety of configurations to assemble the final construct. Only components from MicroPort should be used to prevent mismatch or misalignment of components, with exception of bearing couples involving a MicroPort head and ATF dual mobility acetabular liner insert or ATF Exclusif acetabular shell (not available in U.S. or Canada).

The femoral, acetabular, and cement restrictor components are manufactured from a variety of materials which include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, alumina ceramic (Biolox Forte diameters 28-36mm; and "Conserve® Total BCH® Femoral Head" diameters 38-54mm), Alumina Matrix Composite ceramic (Biolox Delta), hydroxyapatite, polymethylmethacrylate (PMMA), Poly D,L-Lactic Acid (PDLLA), silicone (PDMS) 55D, stainless steel and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards, or internal standards. See Table 1.

The implants are single use only devices.

A. GENERAL PRECAUTIONS

Preoperative Precautions

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 MicroPort 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 conditions which can affect patient's ability or willingness to follow 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) conditions that could impair or impede healing (e.g., alcohol or drug abuse, decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition);
6) 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

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.

Inspect instruments **prior to use** for items that may cause unacceptable functional deterioration that exceeds the instrument's use life.

- Damage during shipment or storage.
- Visual cues such as worn surfaces, dull edges, corrosion, pitting, cracking, or discoloration.
- Difficulty to move, lock, or mate pieces.

Inspect implant 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.

If condition of a device is found to be unacceptable, the surgeon should contact the manufacturer using the contact information located at the beginning of this package insert under "ELECTRONIC IFU NOTICE" to receive instructions for returning the device to the manufacturer for investigation.

Correct selection of the prosthesis is extremely important. 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 procedure. 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. The PMMA Distal Centralizers are intended for use as part of a cemented total hip arthroplasty.

Non-Cemented Application. Adequate fixation at the time of surgery is critical to the success of the procedure. Uncemented femoral stems and acetabular shells must press fit into the host bone, which necessitates precise operative technique and the use of specified instruments. Bone stock must be adequate to support the device.

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. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses and possible loosening, fracture and/or wear, and follow the instructions of the physician with respect to follow-up care and treatment. 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 unretrieved 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.

MR Safety Information

MR Conditionality, if applicable, is determined by experimental testing and is denoted on a product's immediate package labeling by the MR Conditional symbol defined in the Table 1 legend above. Once an unevaluated component is added to the system, the entire system becomes unevaluated. There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

MicroPort Hip Systems that do not possess the symbol for MR Conditionality on the package label have not been evaluated for safety and compatibility in the MR environment. MicroPort devices that do not possess the MR Conditional symbol on the package label have not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

MicroPort Hip Systems that do possess the symbol for MR Conditionality on the package label have been experimentally tested in the following conditions. All CE marked hip devices have been tested for safety in an MR environment.

Non-clinical testing has demonstrated that items bearing the symbol for MR Conditionality on the package label are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions.

- Static magnetic field of 1.5-Tesla and 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning
- Normal Operating Mode of operation for the MR system
- Under the scan conditions defined above, devices bearing the symbol for MR Conditionality are expected to produce a maximum temperature rise of 11.7°C at 1.5-Tesla/64-MHz and 5.8°C at 3.0-Tesla/128-MHz after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the assembled MicroPort Hip device extends approximately 50-mm from the device assembly when imaged with a gradient echo pulse sequence and a 3.0-Tesla MRI system.

B. ADVERSE EFFECTS for total hip arthroplasty implants 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) Particulates leading to increased wear rates necessitating early revision.
3) Allergic reactions to materials; metal sensitivity; 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) 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;
10) Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
11) Periarticular calcification or ossification, with or without impediment to joint mobility;
12) Trochanteric non-union due to inadequate reattachment and or early weight bearing;

13) Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening;

14) Traumatic arthrosis of the knee from intraoperative positioning of the extremity;

15) Inadequate range of motion due to improper selection or positioning of components, by femoral impingement, and periarticular calcification;

16) 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;

17) Undesirable shortening or lengthening of the limb;

18) Aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency;

19) Pain.

C. 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 45 kiloGrays of gamma radiation.

Unless supplied non-sterile, 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 coated 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 resterilized or reused after contact with body tissues or fluids, but rather should be discarded. MicroPort does not take any responsibility for the use of implants resterilized after contact with body tissues or fluids.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- Do not sterilize femoral prostheses with ceramic femoral heads seated on the stem, as sterilization may cause undetectable material damage.
- You must **NEVER** steam sterilize ceramic, HA, plastic, and/or metal/plastic implants. If in the operating room, steam sterilization of the metal implant(s) is required, steam sterilize as described below.

<u>Sterilization</u>

The minimum recommended steam sterilization conditions are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

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

3. 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.

These recommendations are consistent with ANSI/AAMI ST79: 2017 Table 5 guidelines[1] and have been developed and validated using specific equipment. Variations in process parameters or equipment may compromise the sterility assurance level.

For additional information regarding instruments, see MicroPort's Cleaning and Handling of MicroPort Instruments.

D. 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.

HIP FEMORAL SYSTEM

E. INDICATIONS

Intended Use

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and the hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

(European Union only) PROFEMUR® R Revision hip system is not intended for use in primary arthroplasty.

(European Union only) PROFEMUR® GLADIATOR® Cemented hip stem is not intended for use in revision arthroplasty.

Limb Salvage System is 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;

1 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2017)

2) surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications;

3) metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors).

Ultime Hip Stem (not available in the U.S. or Canada) is indicated for the following conditions:

1) revision after stem loosening in cases of proximal bone loss (Paprosky grade III and IV);

2) peri-prosthetic femoral fractures; and,

3) major bone loss due to tumor cases or revision of previous massive prosthesis.

F. 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 (patient is 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) neuropathic joints;

7) hepatitis or HIV infection;

8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

G. 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.

Other **Modular Components** (Femoral Head and Stems, Modular Necks and Proximal Body). Always follow the recommended surgical technique. Failure to adhere to the advised assembly instructions may have potential to increase risk of fretting corrosion, fatigue fracture or disassociation of the product. Prior to assembly, surgical debris and fluid must be cleaned from the interior of the female seat 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. Impact according to the recommended surgical technique. Scratching of femoral heads, modular necks 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. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem, as sterilization may cause undetectable ceramic damage. Please refer to the section below named Hip Bearing System for specific warnings and precautions regarding ceramic femoral heads.

Please refer to the corresponding surgical technique and package labels for allowable device combinations.

Stems and modular necks with the MicroPort 12/14 SLT Taper should only be used in combination with femoral heads with the MicroPort 12/14 SLT Taper. Cobalt chrome femoral heads with the MicroPort 12/14 SLT Taper are designed for use with cobalt-chromium-molybdenum, titanium alloy and ISO 5832-9 stainless steel (not available in the U.S. or Canada) femoral components with the MicroPort 12/14 SLT Taper.

The neck/body component or neck/femoral stem should be changed only when clinically necessary. Refer to proper neck extraction technique in the surgical technique.

PROFEMUR® A^{M} Stems. (Not available in the U.S. or Canada)

- PROFEMUR® AM Size 1 stems are only intended for patients weighing less than 60kg.
- 15° Varus Modular Necks, both Long and Short, are not for use with the PROFEMUR® AM Size 1 and Size 2 Stems

Modular Necks

- Higher than normal rates of early failure of the long offset PROFEMUR® Titanium Modular Necks have been observed for heavyweight (>230 lbs) patients. This should be considered in patient selection when using a titanium modular neck. Other patient selection factors such as activity level cannot be dismissed as potential factors in these failures. Alternative devices, such as cobalt chrome modular necks and monoblock hip stems, may also be considered for these patients.
- Neck sizes designed with flexibility to choose between Anteverted/Retroverted orientation, when used in anatomic retroversion (retroverted beyond the coronal plane), may potentially result in unintended mechanical load distribution that may have potential to influence stress and fracture of the product.
- Modular femoral necks manufactured from cobalt chrome alloy may potentially present an increased risk, as compared to titanium, to elicit a tissue reaction in some patients from the cobalt chrome material.
- Cobalt Chrome Modular Necks are not for use with the following devices:
    - Alumina (Biolox Forte) “Ceramic Femoral Head” (size 28mm Long)
    - PROFEMUR® E Size 0 hip stem
- **PROFEMUR® Preserve Stems** are only intended for use with cobalt chrome modular necks.
- In the United States, **ONLY** the following stems are cleared to be used with both options of titanium or cobalt chrome modular necks:
    - PROFEMUR® R Stem
    - PROFEMUR® Z Grit Blast Stem
    - PROFEMUR® RENAISSANCE® Stem
    - PROFEMUR® LX Revision Stem
    - PROFEMUR® TL Stem
        - o All other stems are cleared for use with cobalt chrome modular necks only.

Neck Sleeves must only be used with femoral stems and necks having the MicroPort 12/14 SLT Taper.

Ultime Hip Stem. (Not available in the U.S. or Canada) Success depends on proximal bone reconstruction and correct distal fixation (as also explained within the device surgical technique):

- In the case of massive proximal bone loss it is recommended to provide perfect metaphyseal stability to the implant and achieve optimal bone reconstruction, by means of grafting and/or bone substitute.
- To avoid damaging the first proximal hole, it is recommended to avoid drilling or fixating this hole before having drilled and fixed the other distal holes, to prevent jeopardizing its functionality.
- At the moment of the closure, metallic monofilament cerclages are recommended to allow solid fixation of the flap on the implant.

- Progressive weight-bearing must begin only in the presence of good proximal femoral reconstruction (partial loading with crutches).

HIP BEARING SYSTEM

H. INDICATIONS

Intended Use

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed.

Rough grit blast surfaces and the hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

CONSERVE® shells are intended only for uncemented arthroplasty, with the exception of those shells possessing screw holes for additional screw fixation, which may be used in either cemented or uncemented arthroplasty (Not available in U.S.).

PROCOTYL® C UHMWPE shells are intended only for cemented arthroplasty (Not available in U.S. or Canada).

PROCOTYL® DM, E, L, O, W and Z shells are intended only for uncemented arthroplasty (Some designs are not available in U.S. or Canada).

LINEAGE® and DYNASTY® modular shells with porous metal bead coating are intended only for uncemented arthroplasty.

PRIME shells are intended only for uncemented arthroplasty.

(European Union Only) BIOLOX® delta Option Heads are not intended for use in primary hip arthroplasty.

The size 50 and 54mm alumina ceramic "CONSERVE® Total BCH® Femoral Heads" are only intended for patients with giganticism or malunion of the acetabulum, and/or revision.

Note: The CONSERVE® Femoral Resurfacing Component/Head is not cleared for use with an acetabular component in the U.S.

Note: Cobalt chrome femoral heads with the MicroPort 12/14 SLT Taper are designed to articulate with UHMWPE bearings only.

CONSERVE® Metal-on-Metal Hip Replacement Shells (Not available in U.S.) are indicated for primary use only in Total Resurfacing procedures with the CONSERVE® or CONSERVE® A-CLASS® Femoral Resurfacing Component.

(Canada Only) CONSERVE® Plus and CONSERVE® A-CLASS Total Resurfacing Systems are technically demanding surgeries. Therefore, they should only be performed by surgeons having previous experience with more than 50 total hip resurfacing surgeries.

CONSERVE® Femoral Resurfacing Component/Head is indicated for use in resurfacing of the femoral head for reduction or relief of pain and/or improved hip function in skeletally mature, patients with non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.

Hemi Unipolar Head is indicated for use in hemiarthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients, for replacement of the femoral head of the hip joint due to degenerative bone disease, trauma, non-union, or avascular necrosis.

Bipolar Hip System is indicated for the following conditions:

1) Pathological fractures of the femoral neck;
2) Non-union of femoral neck fractures;
3) Aseptic necrosis of the femoral head and neck; and,
4) Primary pathology in the young involving the femoral head but with a non deformed acetabulum.

I. 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 (patient is 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) neuropathic joints;
7) hepatitis or HIV infection;
8) neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

Additional contraindications for the "CONSERVE® Femoral Resurfacing Component/Head" include:

1) inflammatory degenerative joint disease;
2) severe osteopenia.

Additional contraindications for a metal-on-metal bearing include (Not available in U.S.)**:**

1) Patients with known moderate to severe renal insufficiency;
2) Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.

(Canada Only; Not available in U.S.**) CONSERVE® Plus and CONSERVE® A-CLASS Total Resurfacing Systems** are contraindicated for female patients UNLESS they require heads ≥50mm and there is no evidence of dysplasia.

J. PRODUCT-SPECIFIC WARNINGS AND PRECAUTIONS

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.

Please refer to the corresponding surgical technique and package labels for allowable device combinations.

NEVER combine modular or hard bearing components made by different manufacturers, with the following exceptions.

- Bearing couples involving one of the following MicroPort heads and a polyethylene dual mobility acetabular liner insert manufactured by ATF (not available in U.S. or Canada).

26010002 (22.25 M)	26012801 (28mm S)	PHA04402 (28mm S)
PPT07034 (22.25 L)	26012802 (28mm M)	PHA04404 (28mm M)
26000017 (28mm S)	26012803 (28mm L)	PHA04406 (28mm L)
26000018 (28mm M)		
26000019 (28mm L)		

- Bearing couples involving one of the following MicroPort heads and an Exclusif acetabular shell manufactured by ATF (not available in U.S. or Canada).

PHA04408 (32mm S)	PHA04414 (36mm S)
PHA04410 (32mm M)	PHA04416 (36mm M)
PHA04412 (32mm L)	PHA04418 (36mm L)
PHA04413 (32mm XL)	PHA04419 (36mm XL)

Skirted (hooded/collared) femoral heads are not intended for use with ATF dual mobility acetabular liner inserts.

Metal/metal (Not available in U.S.) and ceramic/ceramic articulating combinations should only combine bearing components from a single manufacturer to ensure the two components possess compatible manufacturing tolerances. [In the U.S., the only approved ceramic/ceramic[2] combination is the alumina (Biolox Forte) "LINEAGE® Ceramic Liners" in assembly with the corresponding 28-36mm diameter alumina (Biolox Forte) "Ceramic Femoral Head".]

The **cross-linked "DYNASTY® A-CLASS® Poly Liners"** are designed to articulate with the following ceramic femoral heads:

- Alumina "Ceramic Femoral Head" (Biolox Forte diameters 28-36mm)
- Alumina "CONSERVE® Total BCH® Femoral Head" (diameter range 38-54mm)
- Alumina Matrix Composite "Biolox Delta Femoral Head" (diameter range 28-40mm)
- Alumina Matrix Composite "Delta Option Head" (diameter range 28-44mm)

The **cross-linked " PRIME A-CLASS®" and "E-CLASS™ Poly (UHMWPE) Liners"** are designed to articulate with the following ceramic femoral heads:

- Alumina "Ceramic Femoral Head" (Biolox Forte diameters 28-36mm)
- Alumina "CONSERVE® Total BCH® Femoral Head" (diameter range 40-44mm)
- Alumina Matrix Composite "Biolox Delta Femoral Head" (diameter range 28-40mm)
- Alumina Matrix Composite "Delta Option Head" (diameter range 28-44mm)

Additionally, the Alumina "Ceramic Femoral Head" (Biolox Forte) are designed to articulate with "LINEAGE® DURAMER®" and "LINEAGE® A-CLASS®" UHMWPE polyethylene acetabular liners (diameters 28-36mm).

2 Please see the additional package insert addressing ceramic-on-ceramic articulation.

Outside the U.S., **alumina ceramic (Biolox Forte) acetabular liners** are designed for use with the following Biolox ceramic femoral heads:

- Alumina "Ceramic Femoral Head"
- Alumina "Biolox Forte Femoral Head"
- Alumina Matrix Composite Ceramic Heads: "Biolox Delta Femoral Head"
- Alumina Matrix Composite "Delta Option Head" (diameter range 28-44mm)

Outside the U.S., **Alumina Matrix Composite (Biolox Delta) acetabular liners** are designed for use with the following ceramic femoral heads (manufactured by CeramTec and packaged by MicroPort):

- Alumina Matrix Composite Ceramic Heads: "Biolox Delta Femoral Head"
- Alumina Matrix Composite "Delta Option Head" (diameter range 28-44mm)

Ceramic femoral heads and acetabular liners[2] should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

A ceramic **"Delta Option Head"** and a titanium **"Delta Option Sleeve"** must always be used together. "Delta Option Sleeves": PHA044SH (Short), PHA044MD (Medium), PHA044LG (Long), or PHA044XL (X-Long)

Fracture of ceramic components is a serious complication. Special care must be taken with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Only use a plastic tip to introduce the ceramic devices. Impact according to the recommended surgical technique. Patients should be advised to report unusual noise and/or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components. Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement. Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures. Surgeons are advised to carefully consider all available implant options on an individual basis. It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

Acetabular Fixation Screws. Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner.

o Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.

In order to prevent mismatch of tapers:

- Modular liners from MicroPort Orthopedics Inc must be used only with shell components of the same system from MicroPort.

Exceptions to this rule are:

- LINEAGE® UHMWPE liners can also be used in Orion, EHS, and Procotyl E, W and Z shells (Some designs are not available in U.S. or Canada).
- all MicroPort 18° taper liner components can be used with MicroPort 18° modular acetabular shells.

The **cross-linked "DYNASTY® A-CLASS® Poly Liners"** are to be used with ceramic heads or the following metal heads (Some designs are not available in U.S.):

o "LINEAGE®/TRANSCEND® Femoral Head" SuperFinished CoCr with the SLT taper

o "CONSERVE® BFH® Head" with the SLT taper

- o "CONSERVE® A-CLASS® BFH® Head" with the SLT taper
- o "CONSERVE® Total A-CLASS® Femoral Head" with the SLT taper

The **cross-linked "PRIME A-CLASS®" and "E-CLASS™ Poly Liners"** are to be used with ceramic heads or the following metal heads (Some designs are not available in U.S.):

- o "Femoral Head" CoCr with the SLT taper
- o "LINEAGE®/TRANSCEND® Femoral Head" SuperFinished CoCr with the SLT taper
- o "CONSERVE® BFH® Head" with the SLT taper
- o "CONSERVE® A-CLASS® BFH® Head" with the SLT taper
- o "CONSERVE® Total A-CLASS® Femoral Head" with the SLT taper

(Canada Only; Not available in U.S.**) CONSERVE® Metal-on-Metal Hip Replacement Shells**. Proper positioning of the acetabular component is imperative. Care is to be used to ensure that the acetabular cup is placed so that the anteversion angle is within ±10° of 15°.

Conditions presenting increased risk of failure for the **CONSERVE® and CONSERVE® A-CLASS® Femoral Resurfacing Component/Head** include:

1) significant leg length discrepancy; and,
2) presence of multiple cysts in the femoral head.

(Canada Only) Suboptimal conditions for a **CONSERVE® and CONSERVE® A-CLASS® Femoral Resurfacing Component/Head** bearing include:

1) Males ≥ 60 years of age;
2) Femoral Head size < 48mm;
3) ASA grade > 2.

CONSERVE® Shells.

In international markets (shells are not available in the U.S.), the use of the CONSERVE® family of shells ("CONSERVE® Thick Shells", "CONSERVE® Thin Shells", "CONSERVE® Spiked Shells", "CONSERVE® SUPER-FIX® Shells", "CONSERVE® QUADRA-FIX® Shells", and "CONSERVE® HA Shells") are only intended for use with the "CONSERVE® Femoral Resurfacing Components/Heads" and "CONSERVE® A-CLASS® Femoral Resurfacing Heads".

The **"CONSERVE® Total Neck Sleeves"** are only indicated for use with the alumina "CONSERVE® Total BCH® Femoral Heads" or the following metal "CONSERVE® Total A-CLASS® Femoral Heads". These femoral heads are indicated for mandatory use with these modular neck sleeves. Neck sleeves must only be used with femoral stems and necks having the MicroPort 12/14 SLT Taper.

Metal "CONSERVE® Total A-CLASS® Femoral Head Femoral Heads" for mandatory use with **"CONSERVE® Total Neck Sleeves"**:

38AC3600	38AC4400	38AC5200
38AC3800	38AC4600	38AC5400
38AC4000	38AC4800	38AC5600
38AC4200	38AC5000	

The size 28mm Long Neck **alumina (Biolox Forte) "Ceramic Femoral Heads"** are indicated for use only with titanium alloy femoral stems. All other sizes of the alumina (Biolox Forte) "Ceramic Femoral Heads" and all sizes of the Alumina Matrix Composite Heads ("Delta Option Heads" that are used with "Delta Option Sleeves", and the "Biolox Delta Femoral Head") are indicated for use with titanium alloy, cobalt chrome, or MicroPort stainless steel (not available in the U.S. or Canada) femoral stems.

Bipolar cups should not be used in combination with skirted (hooded/collared) femoral heads. Once a removal key has been used to disassociate a head from a bipolar cup, the head must be replaced with a new implant to avoid potential scratch damage.

The cobalt-chromium-molybdenum, (ISO 5832-9) stainless steel, and the titanium femoral components with the Orthomet taper are designed for use with the **Orthomet taper femoral heads**, fabricated from cobalt-chromium-molybdenum alloy as indicated above:

Orthomet Taper Cobalt Chrome Femoral Heads:

- "Femoral Head" OMET Taper SuperFinished CoCr
- "Hemi Head" OMET Taper CoCr

These stems can also be used with the following **Zirconia Ceramic Femoral Heads** (not available in the U.S.): "Orthomet Taper Ceramic Femoral Heads"; "Femoral Head OMET Taper Zr."