MICROPORT KNEE SYSTEMS

150806-1

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.
TK	**Türkçe** Bu paket ekinin ilave tercümeleri, MicroPort Orthopedics'in websitesinde elektronik formatta mevcuttur ve www.ortho.microport.com/ifus sayfasından ulaşılabilir. Elektronik paket eklerine erişebilmek için PDF görüntüleyicili bir web tarayıcısı gereklidir. Paket ekinin basılmış tercümeleri, +1 901-290-5290 veya +1 901-354-8134 nolu telefonlardan MicroPort Orthopedics Müşteri Hizmetleri departmanı ile temasa geçilerek ücretsiz talep edilebilir.
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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.
LT	**Lietuvių k.** Šio pakuotės lapelio vertimai kitomis kalbomis elektroniniu formatu pateikti „MicroPort Orthopedics“ interneto svetainėje. Juos galima peržiūrėti apsilankius www.ortho.microport.com/ifus. Norint peržiūrėti elektroninius pakuotės lapelius reikia interneto naršyklės su PDF peržiūros programa. Jeigu pageidaujate gauti nemokamą spausdintinį pakuotės lapelio vertimą, kreipkitės į „MicroPort Orthopedics“ klientų aptarnavimo skyrių telefonais +1 901--290--5290 arba +1 901-354-8134.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

MICROPORT KNEE SYSTEMS (150806-1)

OUTLINE

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**
	Batch code; 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	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.
	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.

Symbols Glossary. (Can also be found at www.ortho.microport.com/ifus)		
Symbol	**Title [Additional Explanation]; Reference Number/ Standard#**	**Explanatory Text from Standard**
	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.
	Authorized Representative in the European Community; 5.1.2	Indicates the authorized representative in the European Community.
	Sterile; 5.2.1	Indicates a medical device that has been subjected to a sterilization process.
	Sterilized using ethylene oxide; 5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
	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 15223-1:2016 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)

DESCRIPTION

MicroPort Orthopedics Inc. has a variety of knee joint replacement prostheses. The components for these systems include femoral, tibial and patellar components, and accessories. Modular keel prostheses offered in the ADVANCE® BIOFOAM® and EVOLUTION® BIOFOAM® tibial systems may be used interchangeably in both systems. Modular keel prostheses offered in the EVOLUTION® Revision Tibial System are designed for use with EVOLUTION® Revision tibia bases only. Only components from MicroPort should be used to prevent mismatch or misalignment of components.

The femoral, tibial and patellar components are manufactured from a variety of materials that include cobalt-chromium-molybdenum alloy, titanium alloy, unalloyed titanium, stainless steel, polymethylmethacrylate (PMMA), and ultra high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards. The component material is provided on the outside carton label. Device size compatibility is indicated in the relevant surgical technique.

Porous coated cobalt-chromium and titanium components feature a porous coating of cobalt-chromium beads and unalloyed titanium beads, respectively. The porous coating which is applied to BIOFOAM® Tibial Base is manufactured from commercially pure titanium. Hydroxylapatite (HA) coatings are supplied either on grit-blasted or porous surfaces for non-cemented applications only.

The implants are single-use only devices.

A. INDICATIONS

Total Knee Systems

MicroPort Total Knee Systems are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1) noninflammatory 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 treatment of fractures that are unmanageable using other techniques.

Non-porous MicroPort total knee replacement implants are for cemented use only.

Porous coated MicroPort total knee replacement implants, including **ADVANCE® BIOFOAM® Tibial System** and **EVOLUTION® BIOFOAM® Tibial System** implants, are for use without bone cement.

Limb salvage system is also indicated for 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 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 (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors).

Unicondylar and Patellofemoral Resurfacing Knee Systems

Note: The FPV Patellofemoral Resurfacing Knee System is not cleared for use in the U.S. and Canada.

MicroPort unicondylar and patellofemoral resurfacing knee systems are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) correction of functional deformity;
3) revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

Unicondylar knee systems are indicated for patients with unicompartmental joint disease secondary to the above indications with or without valgus, varus, or flexion deformities where all ligaments are intact.

The **EVOLUTION® Unicondylar Knee System** (not licensed for sale in Canada) is for cemented 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;

5) 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 joint that would make the procedure unjustifiable.

Use with stainless steel bone screws is contraindicated.

Inflammatory arthritis is contraindicated for unicondylar knee arthroplasty and 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.

NEVER combine components made by different manufacturers.

D. 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. Additional 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;

4) osteomalacia;

5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency, and/or malnutrition).

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.

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 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 important. The potential for success in knee joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Knee joint 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 judgment when choosing the proper implant size regardless of the endosteal area of the bone.

Preoperative templates and trial prostheses should also be used to assure proper sizing of prostheses. Use only with mating prosthetic components of appropriate size. Mismatching of components could impede component articulation, leading to wear and possible failure of the component and also contribute to joint laxity.

The **FPV Patellofemoral Resurfacing Knee System** is not for use in combination with any other knee system.

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.

Fixation Screws. Fixation screws, when used, should be fully seated to ensure stable fixation and to avoid interference with proper seating of components.

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 postoperative 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 Conditional, 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 Knee Systems that do not possess the MR Conditional symbol on the package label have not been evaluated for safety and compatibility in the MR environment. MicroPort Knee Systems 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 Knee Systems that do possess the MR Conditional symbol on the package label have been experimentally tested in the following conditions. Non-clinical testing has demonstrated that items bearing the MR Conditional symbol 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
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2W/kg for patient landmarks above the acetabulum and <0.5W/kg for patient landmarks below the acetabulum.
- Normal Operating Mode of operation for the MR system
- The effect of local RF transmit coils have not been tested and are not recommended in the area of the implant.

Under the scan conditions defined above, the MicroPort knee devices bearing the symbol for MR Conditionality are expected to produce a maximum temperature rise of 10.9°C at 1.5 Tesla/64 MHz and 5.4°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 Knee device extends approximately 50 mm from the device assembly when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system. In non-clinical testing, the image artifact caused by the assembled MicroPort Knee device extends approximately 50-mm from the device assembly when imaged with a gradient echo pulse sequence and a 3.0-Tesla MRI system.

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;

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;

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.

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 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.

HANDLING AND STERILIZATION WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.
- You must NEVER steam sterilize/resterilize 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.

Sterilization

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.

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.

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