eMP™

Evolution® BioFoam® Tibial System

For Cementless Tibial Fixation

Surgical Technique

MicroPort Orthopedics

Full Function, Faster®

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Package inserts can be found under:
Prescribing Information on ortho.microport.com

Please contact your local MicroPort Orthopedics representative for product availability.

TABLE OF CONTENTS

Chapter 1

PRODUCT INFORMATION

The eMP™ Knee System builds on the clinical history of the aMP™ Knee System design.

DEVICE DESCRIPTION

Tibial Base Implant

- Offered in nonporous and BioFoam® options
- Asymmetric for improved bone coverage
- Enhanced locking mechanism
  - Angled 8° in direction of the incision approach (anterior-medial direction)
  - Lower insertion loads while maintaining strong disassociation loads
- Stem and keel configured for less-invasive surgery

Tibial Insert Implant - CS

- Asymmetric to position mating femur more posterior
- 1-up interchangeability with plus size insert options
- 1-down interchangeability with standard insert
- Soft tissue friendly patellar tendon relief
- 15° of permissible femoral rotation

Tibial Insert Implant - CR

- Asymmetric to position mating femur more posterior
- PCL soft tissue relief angled in the direction of PCL pull
- 1-up, 1-down tibiofemoral sizing interchangeability
- Soft tissue friendly patellar tendon relief
- 15° of permissible femoral rotation

Chapter 2

SURGERY PREPARATION

NOTE: The following chapters only illustrate the tibial preparation and implantation. For femoral preparation and patellar preparation, please refer to the Evolution® Primary Knee System Surgical Technique (009787).

Size specific component part numbers are represented with X's throughout this surgical technique.

A 1.3mm (.05") thick saw blade is recommended for resections.

9.5mm (3/8") diameter drill (E5001002)

T-handle (E5001001) and IM rod (E5001003) with valgus module (E1101001, E1100357, E1000010)

Ensure proper resection guide is set at appropriate valgus angle and the bushing is rotated with the correct side designation (left or right) facing up.

Dual reference "angel wing" gauge (E5001006)

3.5mm hex screwdriver (E5001005)

Slaphammer (E5002001) with attached extraction boss E5002002)

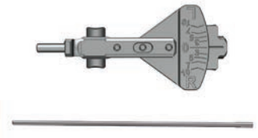
Extramedullary tibial alignment guide (E2102001), standard proximal rod (E2102002), adjustment barrel (E2102006), tibial resection crosshead (K004007L or K004007R), and stylus (E2100210)

(IM guide [E2101012] not pictured)

Tibial base trials (E2302XXX), trial base handle (E2001020), and anchoring pins (K0002007)

Keel punch tower (E2004028)

Keel punch (E2005XXX) and handle (E2000001)



External alignment guide with slope gauge (E5101000) and drop rod (E5101001)

Chapter 3

SURGICAL TECHNIQUE

TIBIAL RESECTION

NOTE: The eMP™ tibial resection guides are designed for use with a 1.3mm (.05") thick saw blade.

Extramedullary (EM) Tibial Resection

Assemble the extramedullary tibial resection guide by erecting the distal tower portion of the ankle clamp | **FIGURE 1** and inserting the standard proximal rod with the adjustment barrel into the distal tower. The adjustment barrel should have the smallest portion towards the top of the rod and the larger portion towards the bottom. A short proximal rod and a spiked proximal rod are also available. Attach the appropriate tibial resection crosshead to the proximal rod using the adjustment barrel | **FIGURE 2.** Unlock the barrel by sliding the unlock button down and in to allow for height adjustment.

Once the needed height is found, push in the lock button and spin the adjustment barrel to fine tune the position. The distance between each line on the short, standard, and spiked proximal rod is 2mm. Place the ankle clamp around the ankle and position the tibial resection crosshead close to the tibia by sliding the distal tower toward the shaft of the tibia. The varus/valgus alignment of the extramedullary guide may be adjusted to match the tibial axis by using the left – right adjustment feature on the ankle clamp | **A IN FIGURE 1**. Tighten the large distal knob to secure its position | **B IN FIGURE 2**.

If the spiked proximal rod is used, place the longer (posterior) spike into the center of the proximal tibia, adjust the internal-external rotation of the guide, then drive both spikes into the tibia with a mallet | **FIGURE 3**.

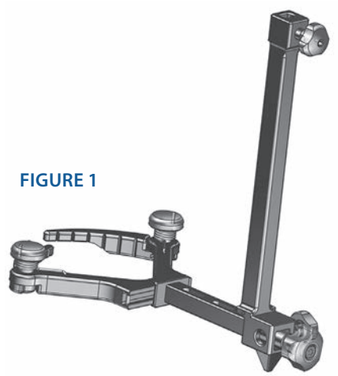


FIGURE 1

FIGURE 2

FIGURE 3

P/N E2102001

P/N E2102002

P/N E2102005

P/N E2102006

P/N E2102013

P/N K004007L

P/N K004007R

When the vertical axis of the extramedullary tibial resection guide is parallel to the tibial axis, the tibial resection crosshead will create 3° of posterior slope. For an anatomically sloped resection, place the dual reference gauge or a saw blade in the cutting slot, next to the tibia, and adjust the long axis of the EM guide by loosening the ankle screw on the right side of the ankle clamp and pulling the distal end of the guide away from the ankle | **C iN FIGURE 2**. Adjust the guide until the cutting slot angle matches the anatomic slope of the tibia. Depress the button on the tibial stylus to place it into one of the holes (medial or lateral) on the resection crosshead | **FIGURE 4**.

Generally, the stylus is set to resect 2mm from the most deficient side and/or 10mm from the most prominent. The stylus can also be rotated to take 4mm of bone. The number on the knob in the upright position represents the resection depth | **A IN FIGURE 5**. Pin the resection guide to the proximal tibia through the "STD" holes using headless pins. The dual reference gauge may also be used to check how much bone is to be removed | **FIGURE 6**.

To remove the alignment guide, spin the adjustment barrel to release the resection crosshead. Loosen the knob at the top of the distal tower | **A IN FIGURE 6** and raise the proximal rod up to pull out from the crosshead. Remove the proximal rod and the ankle clamp. The spiked proximal rod is removed using the slaphammer and the extraction boss.

The spiked proximal rod must be removed prior to making the tibial resection | **FIGURE 7.**

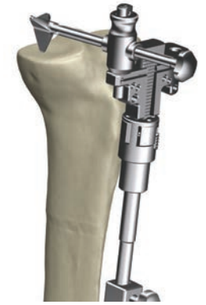


FIGURE 4

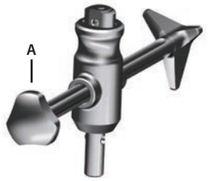


FIGURE 5

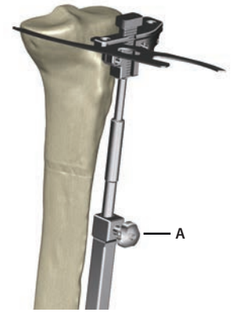


FIGURE 6

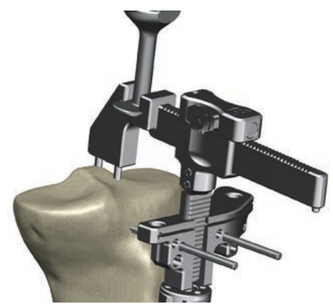


FIGURE 7

P/N E2100210

Varus/valgus angulation can be checked to the ankle using the external alignment guide | **FIGURE 8** or the external alignment guide with slope gauge | **A IN FIGURE 9**. If using the external alignment guide with slope gauge, slope can be approximated by aligning the alignment rod parallel to the shaft of the tibia | **FIGURE 9**.

Once the resection guide is detached from the EM guide, it can be moved distally 2mm if headless pins are used. The top surface of the resection guide can also be used to resect the tibia and is 4 mm proximal to the cut level of the captured slot. Use of a divergent pin is recommended to prevent the resection block from vibrating off the pins during resections. In the absence of a divergent pin, a kocher clamp can be clipped to the pin to provide stability.

To fold the distal tower of the ankle clamp, fully loosen the large distal knob. Hold the left – right adjustment portion to the ankle clamp, slide the distal tower toward the large knob, and fold the distal tower | **FIGURE 10**.

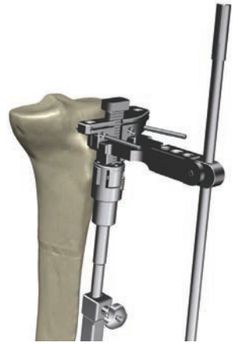


FIGURE 8

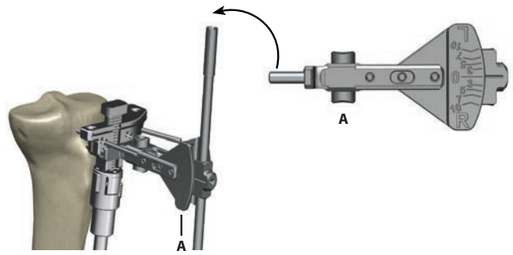


FIGURE 9

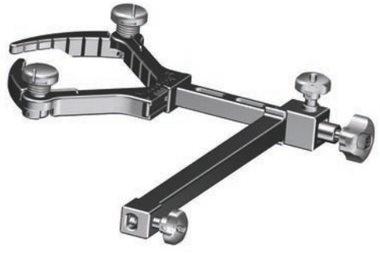


FIGURE 10

P/N E5101002

P/N E5101000

P/N E5101001

Intramedullary (IM) Tibial Resection

EFFICIENCY SUGGESTION: Some surgeons prefer the tibial crosshead (E220100L or E220100R) and IM alignment guide (E2101012) to be pre-loaded on the IM rod (E5001003) before it is introduced into the tibial canal. After insertion, the T-handle (E5001001) is maintained on the IM rod (E5001003) for easier rod removal.

The 3/8" (9.5 mm) drill bit is used to penetrate the proximal tibia just posterior to the tibial ACL attachment. Insert the fluted IM reamer/rod into the tibial canal, constantly turning the T-handle.

Irrigate and aspirate several times to reduce the chance of a fat embolus. The IM rod with assembled IM guide should be inserted to at least the mid isthmus | **FIGURE 11**. Turn the gold anterior lock knob to secure the guide to the IM reamer/rod. Use the varus/valgus screw to set the desired varus/valgus angle with the 3.5mm hex driver. Set the posterior slope using the posterior slope adjustment knob. The crosshead resection guide is neutral and does not contribute any additional slope to the resection.

Place the tibial stylus into the medial hole on the resection guide to set the desired level of tibial resection | **FIGURE 12**. Turn the tibial stylus knob to set the desired level of resection. The number in the upright position on the knob represents the resection depth | **A IN FIGURE 12**.

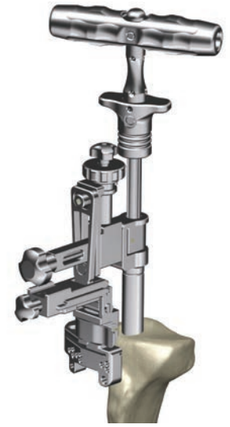


FIGURE 11

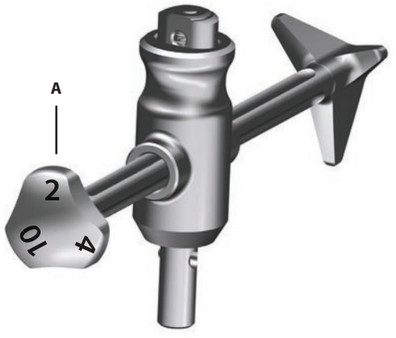


FIGURE 12

P/N E2101012

P/N E2100210

P/N E220100L

P/N E220100R

Generally the stylus is set to resect 2mm from the most deficient side and/ or 10mm from the most prominent. Pin the resection guide to the proximal tibia through the "STD" holes. Using the release lever, release the resection guide from the intramedullary alignment guide. The rest of the alignment guide assembly will remain connected to the IM rod and can be removed all at once by pulling up on the T-handle. Varus/valgus angulation can be checked to the ankle using the external alignment guide with slope gauge and alignment rod| **FIGURE 13**. With the alignment rod parallel to the tibia, posterior slope can be measured.

Ensure the tibial resection guide is adjacent to the tibia and place a divergent pin | **FIGURE 14**

NOTE: Lubrication of the crosshead connection cam hinge is particularly important to maintenance of the mechanism. Regular lubrication with surgical-grade lubricant intended for heat sterilized medical instruments per MicroPort Orthopedics cleaning instructions should be part of the routine instrument maintenance | **FIGURE 15**.

FIGURE 13

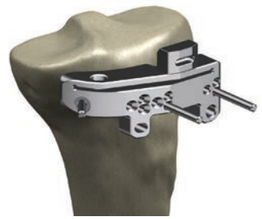


FIGURE 14

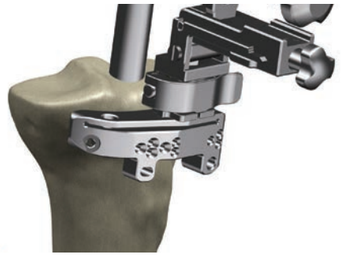
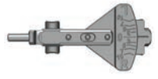


FIGURE 15



P/N E5101001

P/N E5101001

FLEXION/EXTENSION BLOCKS

NOTE: Flexion/Extension blocks are not part of the standard kit. They can be ordered under kit # MP30FKT1 or E200KT20.

The flexion/extension gaps are measured following the femoral and tibial resections. With the knee flexed at 90°, insert the flexion side of the 10mm block with the corresponding femoral size into the space between the posterior femoral resection and proximal tibial resection | **FIGURE 16**. If the flexion side of the 10mm block does not fit in flexion, additional tibial resection or a smaller femoral size may be needed. After the flexion gap has been determined, place the leg in extension. Insert the extension side of the 10mm block into the space between the distal femoral resection and the proximal tibial resection | **FIGURE 17**. If the extension side of the 10mm block does not fit, additional distal femoral bone resection may be required to achieve full extension. The spacer blocks indicate the thickness of the appropriate tibial insert and are available for all insert thicknesses. The thickness of the femoral condyles, tibial base, and tibial insert are built into the spacer block thickness.

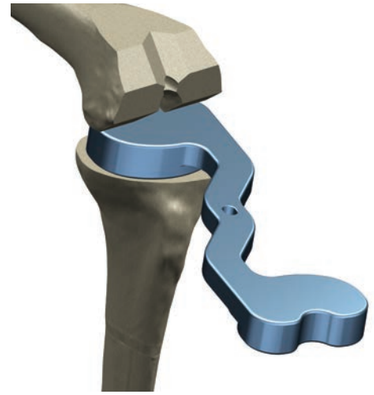


FIGURE 16

FIGURE 17

EXTENSION

FLEXION	TIGHT	OK	LOOSE
TIGHT	Downsize poly insert Cut more tibia	Cut more posterior condyle (Resulting in smaller femoral component)	Cut more posterior condyle (Resulting in smaller femoral component)
OK	Recut distal femur	No adjustment necessary	Cut more posterior slope and use thicker poly
LOOSE	Recut distal femur and use thicker poly (If necessary)	Change may not be necessary. Ball-in-socket design accommodates for slight laxity in flexion If necessary, recut distal femur and use thicker poly	Change may not be necessary. Ball-in-socket design accommodates for slight laxity in flexion Use thicker poly

P/N E50010XX

TIBIAL SIZING, AND KEEL PREPARATION

NOTE: Make sure cement free reamers, towers, and keels all match to their respective sizes.

The eMP™ Knee System allows 1-up, 1-down interchangeability. (See page 18 for interchangeability information.)

NOTE: Evolution® keels are compatible with Evolution® BioFoam® Ttibial Bases of the same size or larger.

Assemble the appropriate trial tibial base to the trial base handle and place it against the proximal tibial surface. The alignment rod can be inserted through the handle to check alignment to the ankle **| A IN FIGURE 18**. Align the base (generally to the medial one-third of the tibial tubercle). The base may be pinned to the tibia using short headed anchoring pins through the holes with vertical lines **| B IN FIGURE 18.**

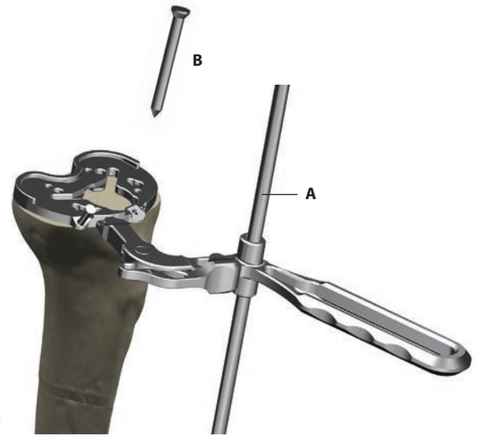


FIGURE 18

Implanting Evolution® Keel Preparation

Align the four spikes on the keel punch tower with the corresponding holes on the trial base and impact the guide with a mallet until the guide is seated on the surface of the trial base. In the event of hard tibial bone, before punching, prepare the entry hole for the tibial stem using the 15mm (1/2") cement free reamer. Separate reamers are available for sizes 1, 2 and sizes 2+ through 8+ . For the size 2+ through 8+ cement free reamer, ream to the first line on the reamer for a size 2+, 3 or 4 base, to the second line for a 5 or 6 base, and to the third line for a 6+, 7, 8 or 8+ base **| FIGURE 19**.

NOTE: Incorrectly using cemented reamers instead of cement free reamers may lead to poor fit and tibial loosening.

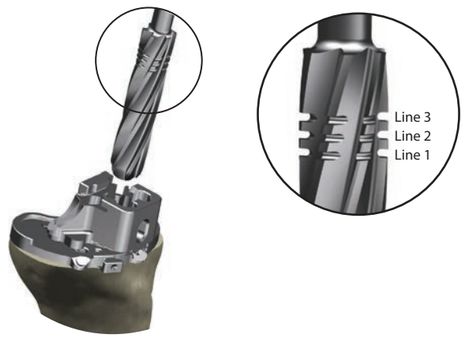


FIGURE 19

P/N E23020XX

P/N E2001020

P/N K0002007

P/N E2004028

P/N E2001238

P/N E2001138

For leave-in keel punches, assemble the appropriate size keel punch to the keel punch handle by pulling back on the trigger mechanism of the handle and inserting it into the opening on the punch **| FIGURE 20.** The keel punch handle is impacted with a mallet until fully seated and the bottom edge of the handle aligns with the top of the keel tower **| FIGURE 21**.

The handle is released from the punch by pulling back on the handle's trigger mechanism. The keel punch tower is removed with the slaphammer and the extraction boss **| FIGURE 22** or hook **| FIGURE 23**, leaving the tibial base and keel punch **| FIGURE 24**. If desired, the lines on the anterior portion of the trial bases can be marked to aid with alignment of the final tibial base implant.

FIGURE 20

FIGURE 21

FIGURE 22

FIGURE 23

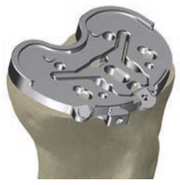


FIGURE 24

P/N E2005XXX

P/N E2000001

P/N E5002003

PATELLA PREPARATION

Choose the appropriate patella resection depth stylus. The 6mm and 8mm resection depth gauge come standard in the patella kit. Attach the resection depth gauge to the top of the resection guide **| A IN FIGURE 25.** Position the resection guide) jaws parallel to the articular margin and securely clamp the guide to the bone; ensuring the gauge is contacting the apex of the articular surface **| FIGURE 26.** Remove the gauge and make the patellar resection.

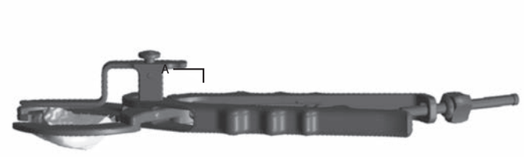


FIGURE 25

FIGURE 26

PN E4202002

PN E4202001

PN E4202000

NOTE: The Metal Backed Patella implants and instrumentation are only available in the United States.

Attach the single peg, tri-peg, or appropriate sized metal backed patella drill guide to the patellar clamp **| A IN FIGURE 27.** The single peg and tri-peg drill guides have grooves on their surfaces indicating the patellar diameter options. The single peg, tri-peg or odyssey drill bit with stop is used to prepare the peg holes. There are no trial drill is used to prepare the peg hole(s). The single peg and tri-peg patella componets have the same peg position between sizes and can be easily changed during trial reduction.
The metal backed patella can be implanted using the parallel patellar clamp and implant seater. The single peg or tri-peg patellar implants can be implanted and held in place while the cement cures using the parallel patellar clamp and implant seater **| FIGURE 28.**

NOTE: There is no trial for the metal backed patella option.

FIGURE 27

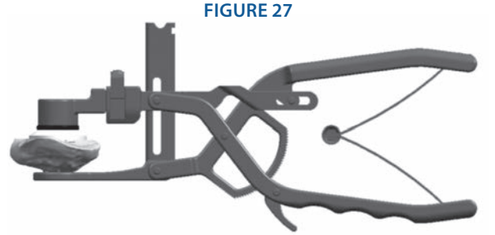


FIGURE 28

PN E00311xx

PN K0031104

PN K0031103

PN E4001015

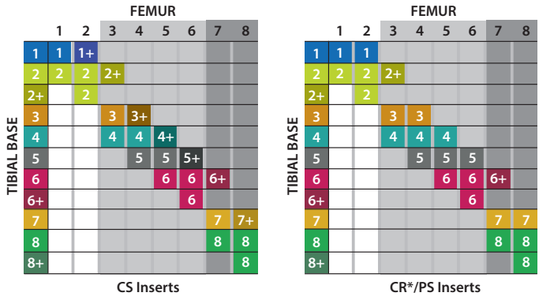
PN K0001017

PN E4001035

PN E4001008

TRIAL REDUCTION AND IMPLANT INSERTION

The eMP™ system allows for 1-up, 1-down interchangeability between the femur and tibia for all styles. Refer to the sizing chart below for size interchangeability and see the implant specification charts at the end of this surgical technique for a more detailed look at the options available for use . Be aware of the size 2+, 6+, and 8+ tibial bases; these are required for the articular surface groupings built into this system.



TRIAL REDUCTION

CS/CR Trial Reduction

Place the appropriate size CS/CR femoral trial patella cap on the femoral trial | **FIGURE 29**. Insert the trial tibial insert of the appropriate size and thickness onto the trial base and complete the trial reduction | **FIGURE 30**.

NOTE: When assembling the tibial insert trial, slightly angle the insert trial with some posterior slope during insertion to clear the anterior lip of the trial base.

To achieve an insert trial with a thickness of more than 14mm, use the trial insert spacers which make 17mm, 20mm and 24mm increments. Trial insert spacers work in conjunction with the size 14mm insert trials | **FIGURE 31**. Trial inserts may be assembled in conjunction with the final tibia base implant to allow the surgeon to continue to trial.

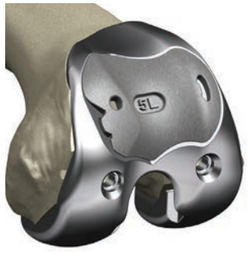


FIGURE 29

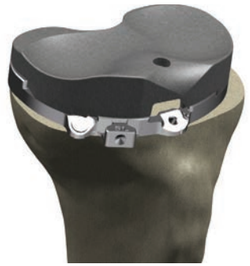


FIGURE 30

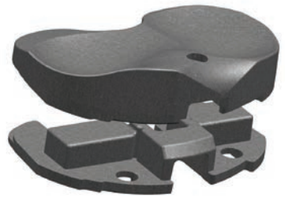


FIGURE 31

P/N E13050XX

P/N E3XXXXXX

P/N E340XXXX

P/N ETPKNXXX

After the trial reduction is complete, remove the femoral trial, along with the femoral trial pins, with the slaphammer by sliding the extraction boss into the slot between the femoral condyles| **FIGURE 32.** During removal, keep one hand on the trial to control its extraction.

2MM RECUT GUIDE, 2˚ POSTERIOR SLOPE RECUT GUIDE, AND 2˚ VARUS/VALGUS RECUT GUIDE

These guides are generally employed to alter the proximal tibial resection. The holes on all guides are convergent and do not correlate to the holes on the distal femoral or proximal tibial resection guides. To position the guides, place the wings on the resected surface with the resection slot touching the edge of the surface. Pin the guide while applying downward pressure on the surface to prevent it from rising up during pinning | **FIGURE 33.**

FIGURE 32

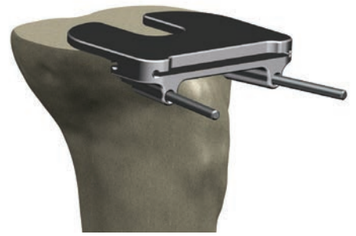


FIGURE 33

P/N E2201002

P/N E2201020

P/N E2201010

FINAL TIBAL IMPLANT AND INSERT IMPLANTATION

NOTE: The recommended order for implantation is left to the discretion of the orthopaedic surgeon.

Care should be taken when handling the tibial bases. The locking mechanism on the proximal surface of the tibial base may contain sharp edges that could puncture surgical gloves.

The proper size tibial base is chosen and assembled by impacting the stem onto the Morse taper of the base. Care should be taken to align the anterior tab and key. After ensuring the base is placed on a rigid surface during assembly the stem is impacted with three or five strong blows from a mallet | **FIGURE 34**.

IMPORTANT NOTE: To assemble, do not cushion the mallet or base with any materials. The base should be placed directly on a firm surface, while the end of the stem is directly struck with the head of the mallet an odd number of times.

The tibial holder driver may be used to seat the final tibial implant | **FIGURE 35**. To engage the tibial holder driver, depress and engage the locking mechanism with the front of the tibial base implant. The tibial finishing impactor may be used to fully impact the tibial implant | **FIGURE 36**.

Screw Hole Preparation and Screw Fixation

To prepare for the bone screws, each hole is drilled using the fixed-angle drill guide and a 3.2mm (1/8") drill bit. The posterolateral screw is angled toward the midline of the tibial to avoid the peroneal nerve. If the screws are to be angled outward, care should be taken when drilling through the cortical bone. To avoid damage to surrounding soft tissue, do not plunge the drill bit through the cortex. The screw depth gauge is utilized to approximate the screw lengths to be used. For bi-cortical screw fixation, the inside "hook" is used to grasp the cortical bone. Additionally, trans-cortical screws can be measured by placing the end of the gauge into the bottom of the hole. The screw length is determined by reading the increments off the end of the gauge and the appropriate length screw is chosen. A 3.5mm hex screwdriver is used to advance and fully seat the cancellous screws into the base.

FIGURE 34

FIGURE 35

FIGURE 36

P/N E2001021

P/N E20051X1

TIBIAL INSERT SEATING

Ensure the posterior and peripheral captures of the tibial base implant are completely clear of soft tissue and bone. If these captures are not clear, the tibial insert will not be able to seat. The tips of the dual reference "angel wing" gauge (E5001006) are contoured to fit in the lock detail to help clear debris.

Once the tibial base is fully seated, the appropriate tibial insert may be locked into place. Initial seating is accomplished by pushing the insert as far posterior as possible with hand pressure, paying special attention to engage the central dovetail and posterior captures of the tibial base. For final seating of the insert, the 45° insert impactor is utilized by placing the impactor tip in the anterior slot of the tibial insert. The impactor handle should be at an angle slightly greater than 45° | **FIGURE 34**. While maintaining this 45° angle relative to the tibial base, apply several strong mallet blows directing the insert posteriorly. After the anterior edge of the insert has been pushed past the anterior capture of the tibial base, it will automatically drop behind the anterior capture and the insert face will be flush against the surface of the tibial base.

If implanting the Evolution® Medial-Pivot PS insert, initial seating of the insert is performed with the knee in flexion, but final insertion is easier if the knee is in extension.

FIGURE 37

EXPLANT INFORMATION

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Femur, Tibia and Patella Components

To remove the components, small osteotomes, power saws, or other surgical instruments may be used to disrupt the bone-cement interface and bone ingrowth into porous coating. Once the components have been removed, rongeurs or small osteotomes as well as other surgical instruments may be used to remove the remaining cement.

Insert Replacement

A narrow osteotome may be inserted into the anterior region of the insert to facilitate removal. A hemostat may be used to remove the insert once it is no longer locked to the tibial base. Care must be taken not to scratch or mar any component that is not intended to be removed.

P/N E3005111

Chapter 5

ADDENDUM

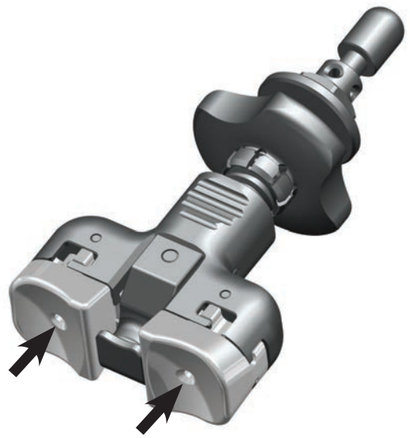


FIGURE 38

REPLACEABLE PLASTIC IMPACTION SURFACES

The femoral finishing impactor , tibial finishing impactor, CS/CR holder driver, PS holder driver, and tibial holder driver have replaceable plastic impaction surfaces. All can be disassembled by inserting a pin in each hole in the impaction surface and depressing the locking mechanism | **FIGURE 38**. Slide each impactor pad to the side and pull up to remove.

PN E1005102 or PN 1005212

PN E2005102 or PN E2005212

PN 1005104 or PN E1005114

PN 1005108 or PN 1005118

PN E2001022

P/N E10051X3

P/N E10051X7

Chapter 6

ORDERING INFORMATION

EBFRKITA Evolution® BioFoam®

With Screwholes, Right

Catalog No.	Description	Size
ETPSB2PR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 2+ Right
ETPSB3SR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 3 Right
ETPSB4SR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 4 Right
ETPSB5SR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 5 Right
ETPSB6SR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 6 Right
ETPSB6PR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 6+ Right
ETPSB7SR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 7 Right
ETPSB8SR	Evolution® BioFoam® Tibial Base w/Screwholes	Size 8 Right

EBFRKITB Evolution® BioFoam®

Without Screwholes, Right

Catalog No.	Description	Size
ETPLB2PR	Evolution® BioFoam® Tibial Base Screwless	Size 2+ Right
ETPLB3SR	Evolution® BioFoam® Tibial Base Screwless	Size 3 Right
ETPLB4SR	Evolution® BioFoam® Tibial Base Screwless	Size 4 Right
ETPLB5SR	Evolution® BioFoam® Tibial Base Screwless	Size 5 Right
ETPLB6SR	Evolution® BioFoam® Tibial Base Screwless	Size 6 Right
ETPLB6PR	Evolution® BioFoam® Tibial Base Screwless	Size 6+ Right
ETPLB7SR	Evolution® BioFoam® Tibial Base Screwless	Size 7 Right
ETPLB8SR	Evolution® BioFoam® Tibial Base Screwless	Size 8 Right

EBFLKITA Evolution® BioFoam®

With Screwholes, Left

Catalog No.	Description	Size
ETPSB2PL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 2+ Left
ETPSB3SL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 3 Left
ETPSB4SL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 4 Left
ETPSB5SL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 5 Left
ETPSB6SL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 6 Left
ETPSB6PL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 6+ Left
ETPSB7SL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 7 Left
ETPSB8SL	Evolution® BioFoam® Tibial Base w/Screwholes	Size 8 Left

EBFLKITB Evolution® BioFoam®

Without Screwholes, Left

Catalog No.	Description	Size
ETPLB2PL	Evolution® BioFoam® Tibial Base Screwless	Size 2+ Left
ETPLB3SL	Evolution® BioFoam® Tibial Base Screwless	Size 3 Left
ETPLB4SL	Evolution® BioFoam® Tibial Base Screwless	Size 4 Left
ETPLB5SL	Evolution® BioFoam® Tibial Base Screwless	Size 5 Left
ETPLB6SL	Evolution® BioFoam® Tibial Base Screwless	Size 6 Left
ETPLB6PL	Evolution® BioFoam® Tibial Base Screwless	Size 6+ Left
ETPLB7SL	Evolution® BioFoam® Tibial Base Screwless	Size 7 Left
ETPLB8SL	Evolution® BioFoam® Tibial Base Screwless	Size 8 Left

EKPFKITA Evolution® Primary Keel Kit

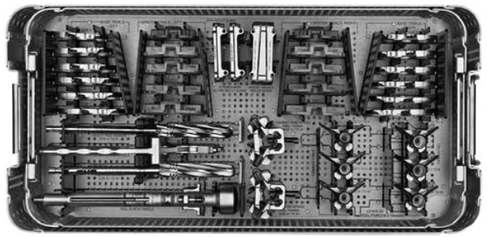
Catalog No.	Description	Size
ETPK1534	Evolution® Porous Keel Primary 15mm	Size 2+/3/4
ETPK1556	Evolution® Porous Keel Primary 15mm	Size 5/6
ETPK1578	Evolution® Porous Keel Primary 15mm	Size 6+/7/8/8+

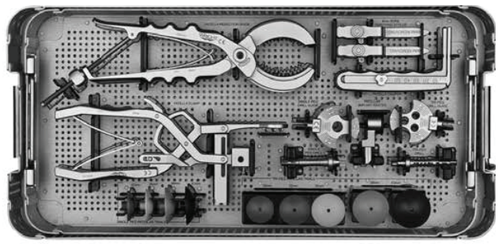
Advance® Metal Backed Patella

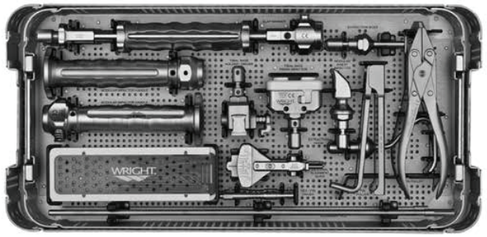
Catalog No.	Description	Size
KPON29MB	Advance® Onlay Metal Backed Patella	Size 29mm
KPON32MB	Advance® Onlay Metal Backed Patella	Size 32mm
KPON35MB	Advance® Onlay Metal Backed Patella	Size 35mm
KPON38MB	Advance® Onlay Metal Backed Patella	Size 38mm

Chapter 7

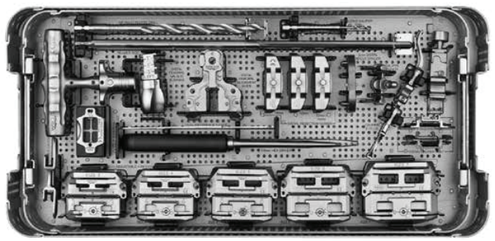
INSTRUMENT KIT ORDERING INFORMATION



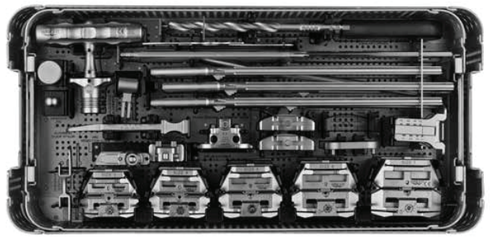




E200KT10 - EVOLUTION® Core Instruments

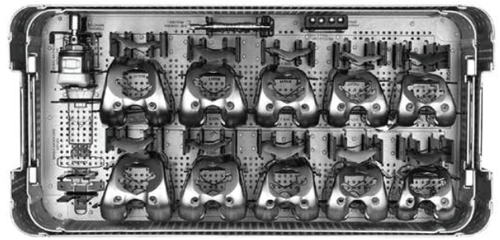


E200KIT1 - EVOLUTION® DCF Instruments

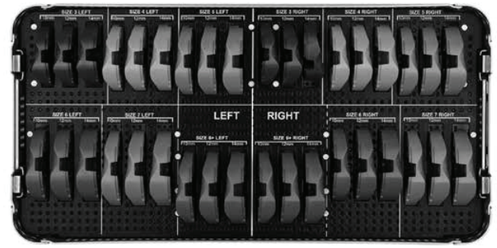


E200KT40 - EVOLUTION® ARC Instruments

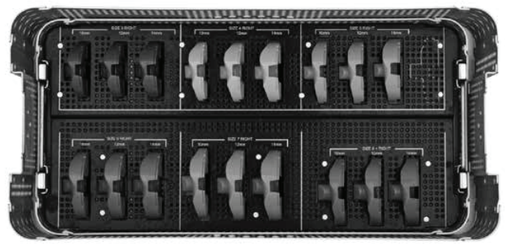
E200KIT7 - CS Insert Trials

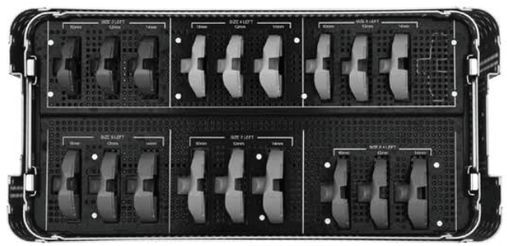


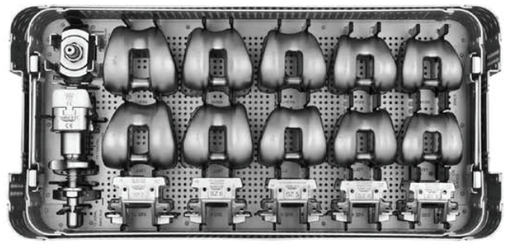
E200KT29 - CS/CR Femoral Trials



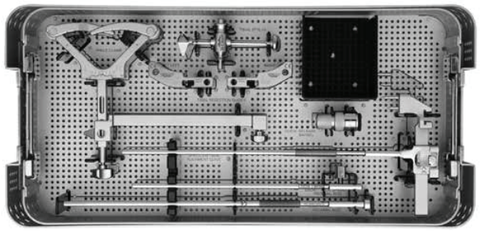
E200KIT6 - CR Insert Trials



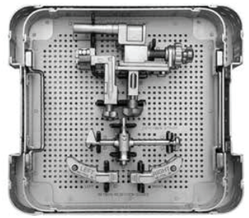




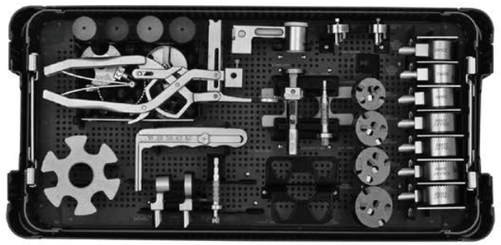
E200KT30 - PS Femoral/Insert Trials



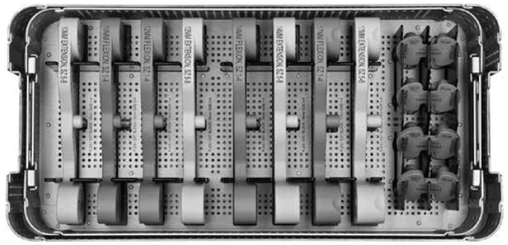
E200KIT3 - eMP™ EM Tibial Guide Kit



E200KIT4 - eMP™ IM Tibial Guide Kit



K100KT75 - ADVANCE® Patella Reaming Kit

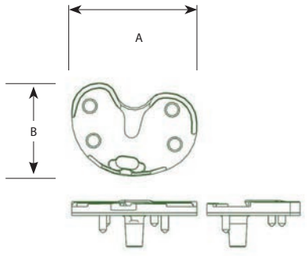


E200KT20 - Flexion/Extension Blocks

E200KT23 - 20mm and 24mm Trials (CS and PS)

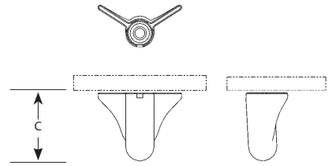
Chapter 8

IMPLANT DIMENSIONS



eMP™
MP BioFoam® Tibial Base Plate
ETPSB (X) (S/P) (L/R)
ETPLB (X) (S/P) (L/R)

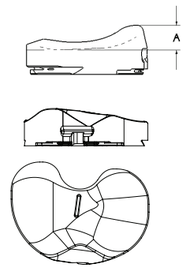
Size	A	B
2+	62	46
3	62	46
4	66	49
5	70	52
6	74	55
6+	78	58
7	78	58
8	82	61



eMP™
Primary Keel - 15mm

Implant	C
ETPK1512	31
ETPK1534	34
ETPK1556	38
ETPK1578	41

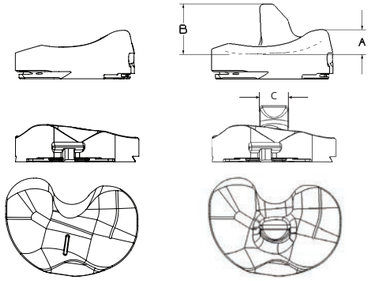
Dimensions are in mm



eMP™ CS Insert
Available Thicknesses
10, 12, 14, 17, 20, 24mm

CS	A
1	11
1+	11
2	11
2+	11
3	11
3+	11
4	11
4+	11
5	11
5+	11
6	11
6+	11
7	11
7+	11
8	12

Dimensions are in mm



eMP™ CR Insert
Available Thicknesses
10, 12, 14, 17mm

eMP™ CR Insert
Available Thicknesses
10, 12, 14, 17, 20, 24mm

CR/PS	A	B	C
1	9	19	14
2	9	19	14
2+	9	20	16
3	9	20	16
4	9	20	16
5	9	21	16
6	10	22	16
6+	10	23	19
7	10	23	19
8	11	24	19

Dimensions are in mm

Chapter 9

INDICATIONS AND WARNINGS

INDICATIONS

The eMP™ Knee System is 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.

The Evolution® BioFoam® Tibial System implants are for use without bone cement.

CONTRAINDICATIONS

Patients should be warned of these contraindications. Contraindications include:

1. Overt infection;
2. Distant foci of infections (which may cause hematogeneous 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 (eg. 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.

IMPORTANT Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions for use package insert is available on the website listed.

WARNINGS AND PRECAUTIONS

NEVER combine components made by different manufacturers.

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.

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 (eg. 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.

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

Non-Cemented Application

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

Modular Components

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

Alignment of Components

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

POSTOPERATIVE PRECAUTIONS

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

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

Periodic 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. 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.

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 intraoperatively due to the use of bone cement;
6. Damage to blood vessels or hematoma;
7. Periarticular calcification or ossification, with or without impediment to joint mobility;
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.

MicroPort Orthopedics

Full Function, Faster®

MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN USA 38002
866 872 0211

ortho.microport.com

EC REP

MicroPort Scientific Coop. U. A.
Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands
+31 20 545 01 00

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