eMP™

Evolution® Stemmed Tibia Instrumentation

SURGICAL TECHNIQUE

MicroPort Orthopedics

Full Function, Faster®

eMP™

Evolution®
Medial-Pivot Knee System

Distal Cut First Instrumentation
Surgical Technique

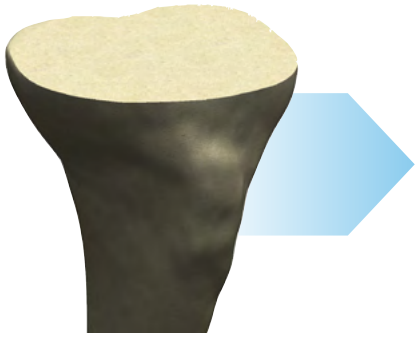
Table of Contents

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 and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. 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.

Please contact your local MicroPort representative for product availability.

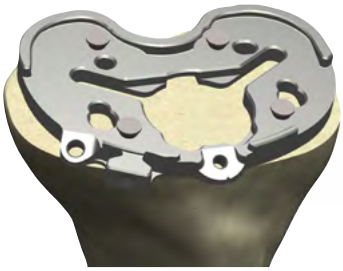
chapter 1

Streamlined Instrumentation for Stemmed Evolution® Primary Tibia Surgical Technique

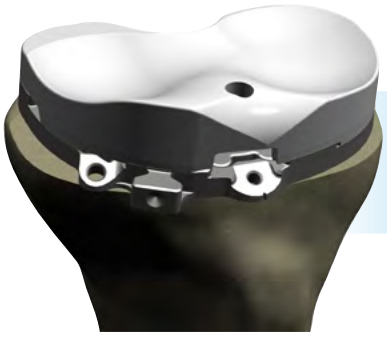


PROXIMAL RESECTION

SIZING



MARK THE TIBIAL BASE PLACEMENT



TRIAL REDUCTION

FINAL KEEL PUNCH

IMPLANT ASSEMBLY AND IMPLANTATION

KEEL PREPARATION

TRUNNION

INITIAL KEEL PUNCH

INSERT THE PASS THROUGH SCREW AT THE PROXIMAL END OF THE TIBIAL BASE

DEVICE DESCRIPTION

FEMORAL IMPLANT

- CS/CR and PS options offered in eight sizes, left and right
- Titanium Niobium Nitride (TiNbN) Coating to minimizes metal ions released
- 145° constant radius C-curve
- Anatomic, recessed patellar groove with bone conserving preparation and enhanced contact area
- Central pegs to minimize bone removal during downsizing

TIBIAL BASE IMPLANT
- Asymmetric for improved bone coverage
- 0° posterior slope relative to trunnion
- Enhanced locking mechanism
  o Angled 8° in direction of the incision approach (anterior-medial direction)

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

TIBIAL INSERT IMPLANT – PS
- Asymmetric to position mating femur more posterior
- Post and cam engagement around 80° of flexion due to high anterior lip
- 1-up, 1-down tibiofemoral sizing interchangeability
- Soft tissue friendly patellar tendon relief
- 15° permissible internal and external femoral rotation
- Same conformity as CR insert

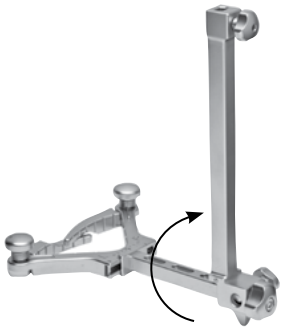


FIGURE 1

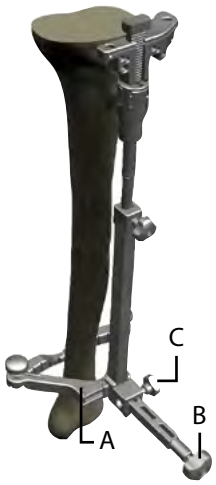


FIGURE 2

FIGURE 3

Tibial Preparation

The eMP™ tibial resection guides are designed for use with a 1.27 mm (.05") thick saw blade.

EXTRAMEDULLARY 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. A short proximal rod and a spiked proximal rod are also available. Attach the appropriate tibial resection guide to the proximal rod using the adjustment barrel |**FIGURE 2**.

NOTE: It is recommended to utilize the Evolution revision baseplate at a 0˚ posterior slope to avoid stem interference with the inner wall of the anterior cortex. A 0° EM resection guide is available in the Streamlined Instrumentation kit (E400KIT3).

For positioning, unlock the barrel by sliding the unlock button down and in to allow for height adjustment. Once the needed height is met, push in the lock button and spin the adjustment barrel to fine tune. 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 guide 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 2**

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**

When the vertical axis of the extramedullary tibial resection guide is parallel to the tibial axis, the tibial resection guide is set for 3° of posterior slope. For an anatomically sloped resection, place the dual reference gauge or a saw blade in the cutting slot 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.

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E210200L

E210200R

FIGURE 4

FIGURE 5

FIGURE 6

FIGURE 7

Depress the button on the tibial stylus to place it into one of the holes (medial or lateral) on the resection guide **|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 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 will be removed **|FIGURE 6**.

FIGURE 8

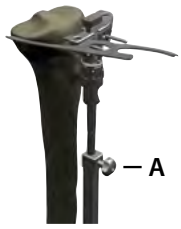

FIGURE 9

Varus/valgus angulation can be checked to the ankle using the external alignment guide **|FIGURE 7** or the external alignment guide with slope gauge **|FIGURE 8**. 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.

NOTE: It is recommended to utilize the Evolution revision baseplate at a 0˚ posterior slope to avoid stem interference with the inner wall of the anterior cortex. A 0° EM resection guide is available in the Streamlined Instrumentation kit (E400KIT3).

To remove the alignment guide, spin the adjustment barrel to release the resection guide. Loosen the knob at the top of the distal tower **|A IN FIGURE 9** and raise the proximal rod up to pull out from the guide. Remove the proximal rod and the ankle clamp. The spiked proximal rod is removed using the slaphammer and the extraction boss **|FIGURE 10**. The spiked proximal rod must be removed prior to making the tibial resection.

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 distal surface 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 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 11.**

FIGURE 10

FIGURE 11

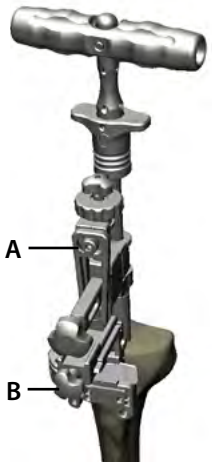

FIGURE 12

FIGURE 13

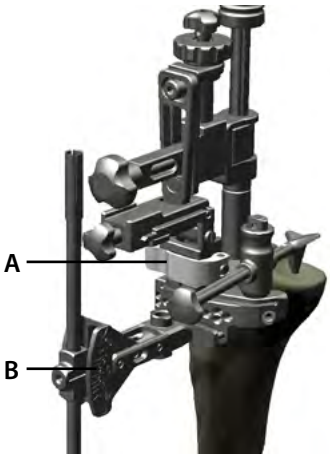

FIGURE 14

INTRAMEDULLARY TIBIAL RESECTION

NOTE: Some surgeons prefer the tibial resection guide and IM alignment guide to be pre-loaded on the IM rod before it is introduced into the tibial canal. After insertion, the T-handle is maintained on the IM rod 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 **|FIGURE 12**.

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. 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 **| A IN FIGURE 12**. Set the posterior slope using the posterior slope adjustment knob **| B IN FIGURE 12**. The resection guide is neutral and does not contribute any additional slope to the resection.

NOTE: It is recommended to utilize the Evolution revision baseplate at a 0˚ posterior slope to avoid stem interference with the inner wall of the anterior cortex.

Place the tibial stylus into the medial hole on the resection guide to set the desired level of tibial resection. Turn the tibial stylus knob to set the desired level of resection. The number in the upright position represents the resection depth **|A IN FIGURE 13.**

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 **|A IN FIGURE 14**. 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. With the alignment rod parallel to the tibia, posterior slope can be measured **|B IN FIGURE14**.

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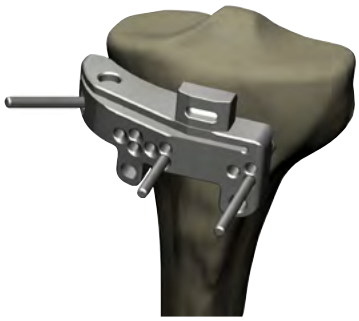

FIGURE 15

|**FIGURE 15**. Refer to |**FIGURE 16** for breakdown of IM Guide and for detail of the resection guide.

NOTE: Lubrication of the resection guide connection cam hinge is particularly important to maintenance of the mechanism. Regular lubrication with surgical-grade lubricant intended for heat sterilized medical instruments per cleaning instructions (document 150802) should be part of the routine instrument maintenance |A IN FIGURE 17

Flexion/Extension Blocks

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

Ensure the tibial resection guide is adjacent to the tibia and place a divergent pin. The flexion/extension gaps are measured following the femoral and tibial resections. With the knee flexed at 90°, insert the 10mm flexion block into the space between the posterior femoral resection and proximal tibial resection|**FIGURE 18**. If the 10mm spacer 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 10mm extension block into the space between the distal femoral resection and the proximal tibial resection |**FIGURE 19**.

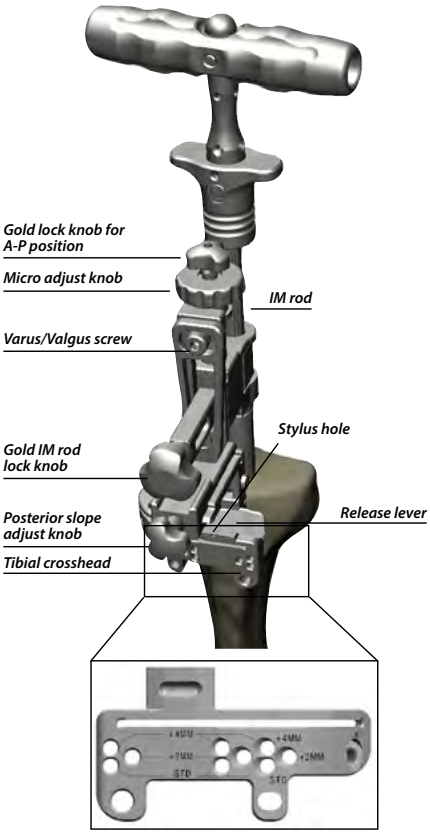

FIGURE 16

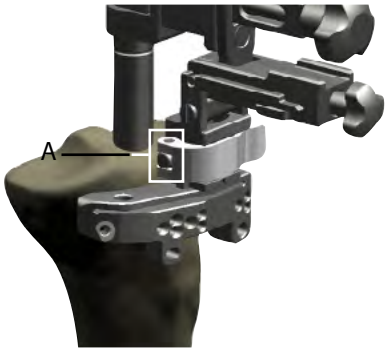

FIGURE 17

FIGURE 18

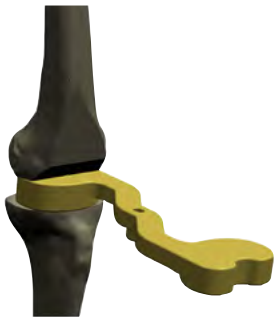

FIGURE 19

If the 10mm spacer 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.

PN E2101012

FLEXION \ EXTENSION	TIGHT	OK	LOOSE
TIGHT	Downsize poly insert Cut more tibia	Cut more posterior condyle (Resulting in smaller femoral componet)	Cut more posterior condyle (Resulting in smaller femoral componet)
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

FIGURE 20

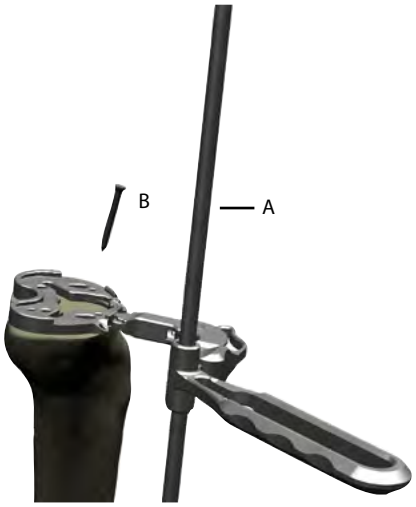

FIGURE 21

» ***Knee should be placed in 90° of flexion.***

Retractors and placement:

» ***Curved Single Prong Hohmann – on lateral tibia to cover patella and protect soft tissues***

» ***"Z" Retractor – on medial tibia to expose tibia and protect the medial collateral ligament***

» ***Cobb Elevator – subluxes tibia forward***

Refer to **|FIGURE 20** for more information on flexion/extension gaps.

Tibial Sizing

The eMP™ Knee System allows 1-up, 1-down interchangeability. (See Figure 30 for interchangeability information.) 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 21**. 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 21**.

NOTE: If using the spiked keel preparation tower you do not need to pin the base plate in place.

NOTE: The Odyssey Style trial base plates, E2301XXX, are NOT compatible with Leave-in Keels and can NOT be used with the Evolution Stemmed Tibia Instrumentation. Please ensure you are using the E2302XXX style base plates.

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PN E220100R

PN E220100L

PN E5101000

PN E5101001

FIGURE 22

FIGURE 23

FIGURE 24

Keel, Trunnion, and Stem Preparation

TRUNNION AND STEM 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 |**FIGURE 22**. Alternately, assemble the quick connect keel punch tower. Align the bottom tabs with the holes on the base plate and lock it into place by moving the tab on the front from right to left |**FIGURE 23**.

For the 25mm stem or for hard bone trunnion reaming is recommended. Ream with the long trunnion reamer until a full stop. This will clear for the trunnion and the 25mm stem. If using a 25mm stem than you can skip the stem preparation and move on to the Initial keel punch.

STEM PREPARATION

Insert the reamer sleeve into the keel tower |**FIGURE 24**. Ream with the 18mm Reamer through the sleeve to the proper depth marking. For a 25mm stem, ream to the first line |**A IN FIGURE 25**. For a 50mm stem ream to the second line |**B IN FIGURE 26**.

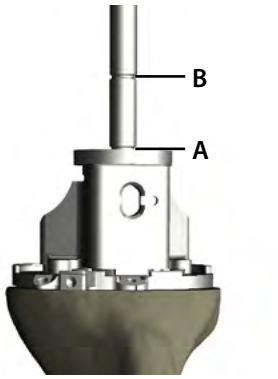

FIGURE 25

FIGURE 26

INITIAL KEEL PUNCH

Thread the appropriate trial stem into the initial leave in keel punch |**A IN FIGURE 26**. Assemble the construct to the keel punch handle by pulling back on the trigger mechanism |**B IN FIGURE 26** of the handle and inserting it into the opening on the punch |**FIGURE 26**. Impact the keel punch construct with strong mallet blows through the keel punch tower until the keel is fully seated. Use the window and laser marking to ensure the punch is fully seated |**A IN FIGURE 27**.

NOTE: Ensure you are utilizing the Evolution® MP Keel Leave-In Modular Handle, E2000001, with the Evolution® stemmed tibia keels.

Remove the keel punch handle by pulling back on the trigger mechanism. Remove the keel punch tower with the slaphammer and extraction boss |**FIGURE 28**. Leave the tibial base and keel punch in place |**FIGURE 29**. 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.

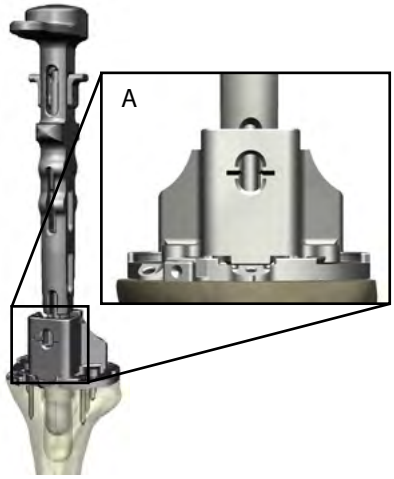

FIGURE 27

FIGURE 29

FIGURE 28

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PN E2005000, PN E2005036, PN E2005078

PN E23020XX

PN E2001020

PN K0002007

TRIAL REDUCTION

NOTE: The distal femur must also be prepped for trial reduction.

The Evolution® System allows for 1-up, 1-down interchangeability between the femur and tibia for all styles. Refer to the sizing chart above for size interchangeability, |**FIGURE 30**. Be aware of the size 2+, 6+, and 8+ tibial bases; these are required for the articular surface groupings built into this system.

Insert the trial tibial insert of the appropriate size and thickness onto the monolithic base trial |**FIGURE 31**.

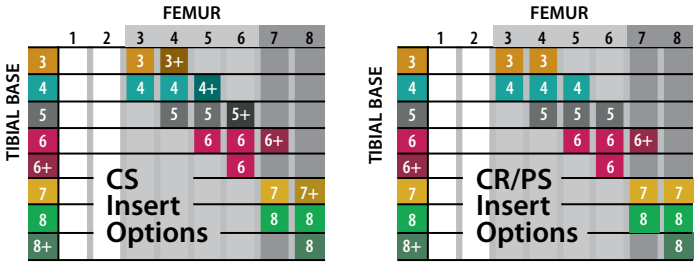

FIGURE 30

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 17, 20 and 24mm increments. Trial insert spacers work in conjunction with the size 14mm insert trials |**FIGURE 32**. Trial inserts may be assembled in conjunction with the final tibia base implant to allow the surgeon to continue to trial.

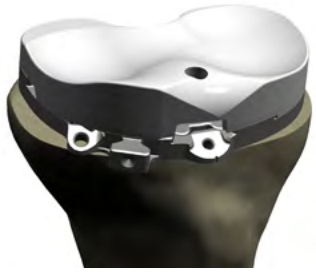

FIGURE 31

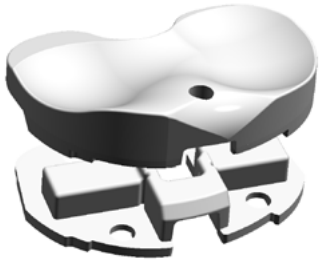

FIGURE 32

PN E3XXXXXX

PN E340XXXX

FIGURE 33

FIGURE 34

FIGURE 35

FIGURE 36

FINAL KEEL PUNCH

After the trial reduction is complete, remove the leave in keel with the keel punch handle and remove the trial base plate. Assemble the appropriate sized final keel punch with the keel punch handle by pulling back on the trigger mechanism **|A IN FIGURE 33**. If desired, the stem trial can also be threaded into the final keel punch **|B IN FIGURE 33**.

Using the previous keel punch hole as a guide impact the final keel punch until the top circle is flush with the resected surface of the tibia **|FIGURE 34**.

NOTE: the stem trial is optional with the final keel punch.

Final Implant Assembly and Implantation

NOTE: Due to the 3° internal rotation of the keel on the Evolution® primary base plate, the Evolution® revision modular keel needs to be assembled at 3° internal rotation.

IMPLANT ASSEMBLY

Place the Evolution® revision tibial base plate upside down on the proper side of the impaction platform, RIGHT for a right implant and LEFT for a left implant **|FIGURE 35**. Place the modular keel over the implant trunnion and internally rotate the keel to align the edge of the box on the keel with the center line on the tibial base. This will set the keel at 3° of internal rotation. **|FIGURE 36**. Impact the keel with the keel impactor with three firm blows **|FIGURE 37**. Insert the appropriate stem and impact with three strong blows. Insert the pass through screw in the proximal end of the tibial base implant and tighten with the 3.5 hex driver.

TIBIAL IMPLANTATION

The assembled tibial implant is then placed onto the tibia with the cementing technique chosen by the surgeon. The tibial holder driver may be used to seat the final implant. 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 37

FIGURE 38

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 are contoured to fit in the lock detail to help clear debris. Once the cement has cured, the appropriate Evolution® MP 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 medial and lateral dovetails. The 45° insert impactor may be utilized by placing the impactor tip in the anterior slot of the tibial insert at approximately a 45° angle to the tibial base. While maintaining this 45° angle, apply several strong mallet blows directing the insert posteriorly |**FIGURE 39**.

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 39

PN E3005111

PN E2001021

PN E2005101

Indications and Warnings

INDICATIONS

The Evolution® Revision Tibia 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® Revision System nonporous implants are for cemented use only.

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.

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.

Indications & Warnings

chapter 2

WARNINGS AND PRECAUTIONS

NEVER combine components made by different manufacturers.

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 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 bones 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 prosthesiseses. 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.

CAUTION: Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.

Accurate pre-operative templating requires good quality standardized radiographs of the appropriate anatomy.

CEMENTED APPLICATION

Use care to ensure complete support of all components of the prosthesis embedded in bone cement to prevent stress concentrations, which 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.

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, which may lead to early failure of the procedure.

ALIGNMENT OF COMPONENTS

Use care to restore the proper joint alignment and to balance ligamentous tension. Mal-alignment 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 reconstruction limitations 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.

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 these occurrences are unknown for these implants.

MicroPort Knee Systems have not been evaluated for safety and compatibility in the MR environment. MicroPort Knee Systems have not been tested for heating or migration in the MR environment. Since these devices have not been tested, MicroPort cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

Recommendations Regarding Device Fragments:

Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation

- If the device is damaged, retain it to assist with MicroPort's analysis of the event
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a) The material composition, 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

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 MRI and X-ray scatter in CT.

ADVERSE EFFECTS:

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. 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.

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.

FEMORAL, TIBIAL, AND PATELLAR COMPOENTS

To remove these components, small osteotomes, power saws, or other surgical instruments may be used to disrupt the bone-cement interface. Use caution to save remaining bone stock as well as to prevent fracture. 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. Use caution to avoid scratching or marring any component that is not intended to be removed.

MicroPort Orthopedics

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