JTS Non-Invasive Extendible Distal Femoral Replacement

Surgical Technique:
Rotating Hinged Polyethylene Tibia Option

973.264.5400

onkossurgical.com

Precision Orthopaedic Oncology

- ELEOS™ Limb Salvage Solutions
- My3D® Personalized Solutions
- GenVie® Regenerative Biologics

1 IMPLANT DESCRIPTION & INDICATIONS

1.1 Implant Description:

The Onkos JTS Extendible Distal Femoral implant is manufactured in accordance with an approved prescription for a named patient. It **MUST NOT** be used for any other patient.

The patient name is detailed in the operation drawing supplied with the implant.

Before commencing surgery please refer to packaging insert for complete product information, including contraindications, warnings, precautions, and possible adverse effects/complications. Packaging Inserts are also available from Onkos Surgical.

1.2 Implant Intended Use/Indications For Use:

The JTS Extendible Distal Femoral Implant is indicated for limb sparing procedures in pediatric (between the ages of 2 and 21) cases where radical resection and replacement of the distal femur is required with the following conditions:

- Patients suffering from severe arthropathy of the distal femur that do not respond to any conservative therapy or better alternative surgical treatment
- Surgical intervention for severe trauma, revision arthroplasties, failed previous prostheses and/or oncology indications; and malignant diseases (e.g. osteogenic sarcoma)

The JTS Extendible Distal Femoral Implant and its components are for single use only

1.3 Contraindications:

Absolute contra-indications include:

- Infection and sepsis

Relative contra-indications include:

- Long delay between manufacturing and insertion of a patient specific implant may result in significant mismatch due to possible changes in bone geometry
- Inadequate or incomplete soft tissue coverage
- Uncooperative or unwilling patient or patient unable to follow instructions
- Foreign body sensitivity. Where materials sensitivity occurs seek advice with respect to testing
- Obesity
- Vascular disorder, neuromuscular disorders or muscular dystrophy
- Compromised patella

1.4 Patient Selection:

Factors to be considered:

- Resection of neoplastic or diseased bone
- At risk from pathological fracture
- Pain relief and improved function
- Ability of patient to willingly follow instructions and undergo rehabilitation

The JTS Extendible Distal Femoral Implant is available for use with the following tibial configuration options:

- Passive rotating hinge tibia
- Rotating hinge – polyethylene tibia
- Metal cased tibia
- Fixed hinge tibia

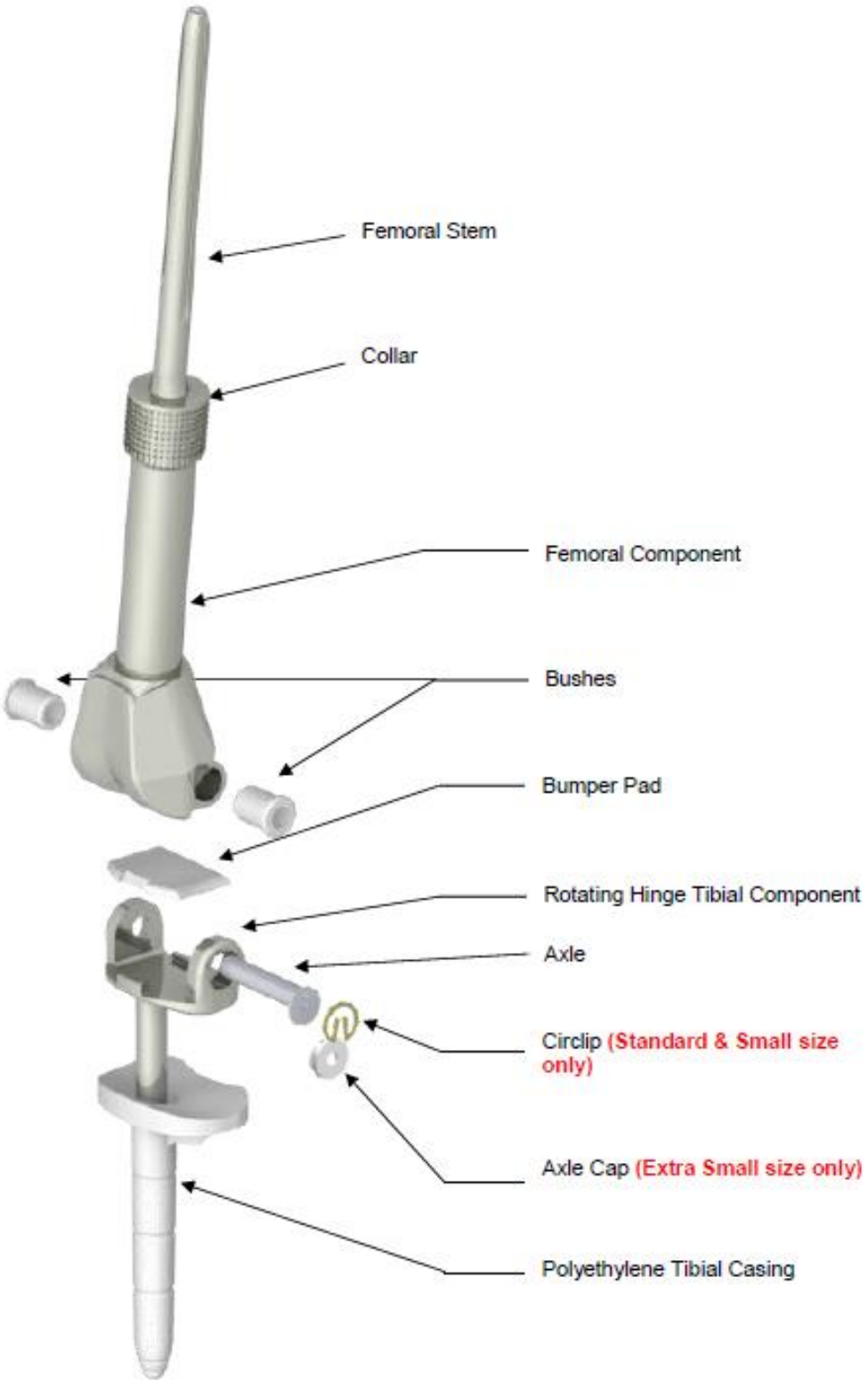
The rotating hinge polyethylene tibial option is suitable for routine cases, the rotating hinge metal cased tibial option is suitable for extra-articular resection or difficult revisions and the fixed hinge tibial option is suitable for knees with marked instability or gross deformity.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution and use by or on the order of a physician. THIS PRODUCT IS FOR CEMENTED USE ONLY IN THE U.S

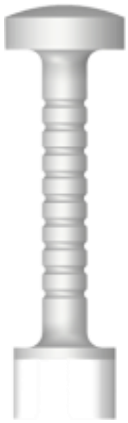
RXonly

ONKOS SURGICAL

2 EXPLODED VIEW



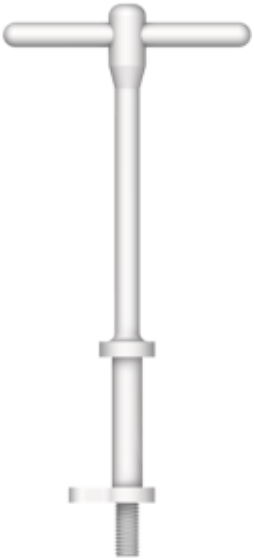
3 INSTRUMENTS



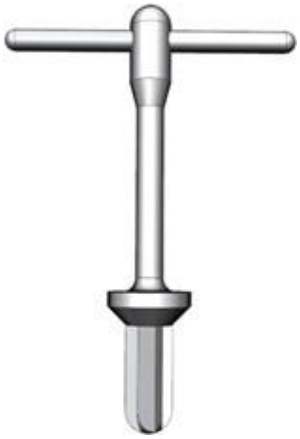
General Impactor

Anti-Rotation Lug Drill

Hole Cutting Guide



Bush Compressor



Fixed Hinge Tibial Reamer

Circlip Pliers **(Standard & Small size only)**

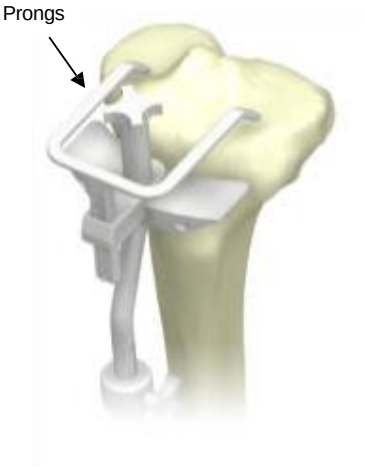
Axle-Cap Introducer **(Extra Small size only)**

Hammer

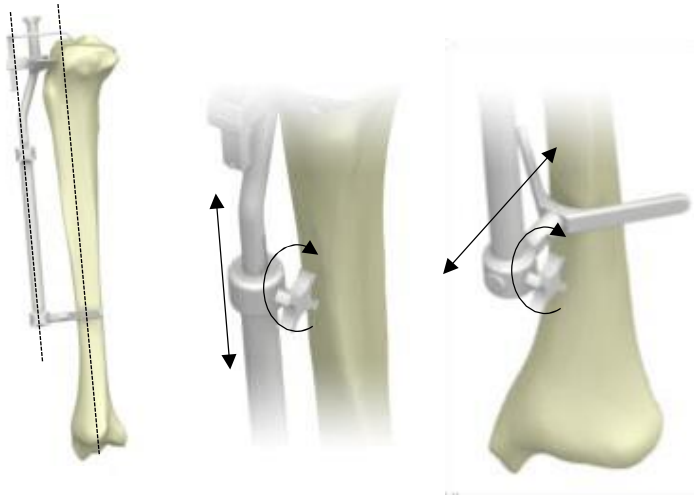
Tibial Hole Cutting Guide Pins

Tibial Cutting Guide

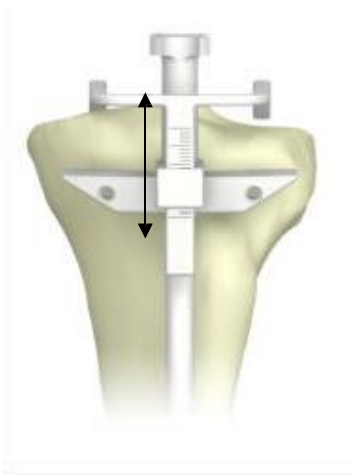
4 TIBIA PREPARATION



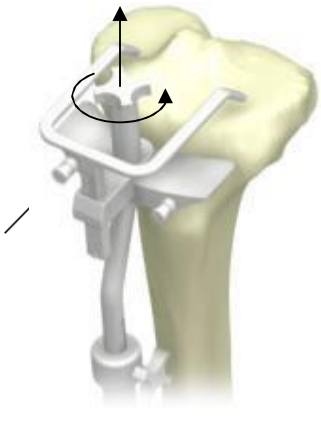
Adjust prongs of tibial cutting guide to sit on the plateau of the tibia



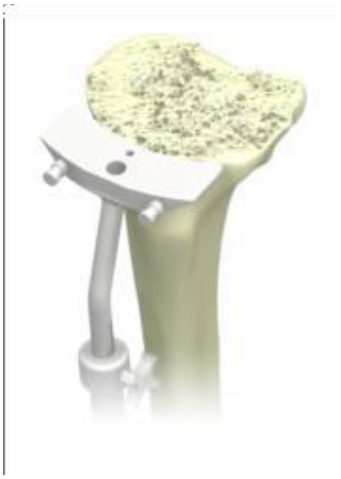
Align cutting guide to be parallel with tibia and secure adjustments using locking screws



Adjust the reference cutting face to match the depth indicated on the operation drawing

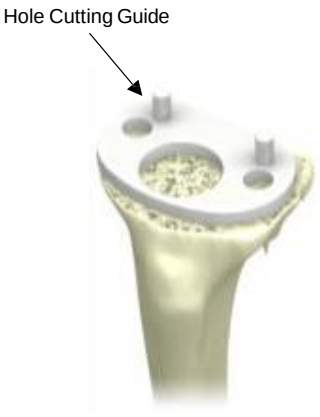


Secure the reference cutting face using bone pins and remove prong assembly

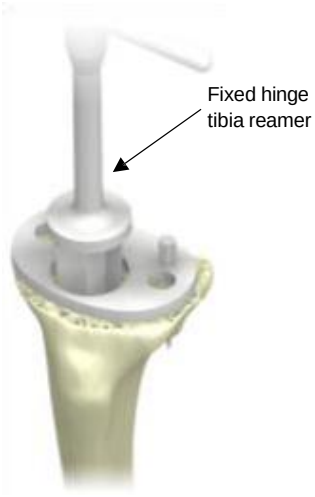


Trim tibial plateau in line with plane of reference cutting face

5 TIBIAL INSERTION

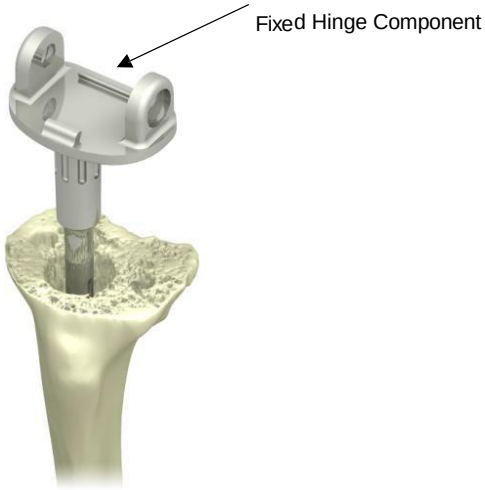


Secure cutting guide with pins, aligning straight edge with posterior of tibia



Ream tibial canal using fixed hinge tibia reamer

Use AR Lug drill to make two 10mm deep holes as indicated by cutting guide



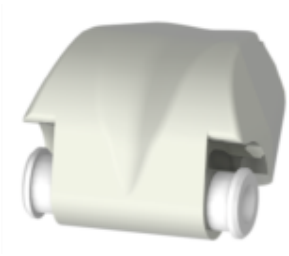
Remove cutting guide and cement in fixed hinge tibia

Note: If optional plateau plate is to be used, it should be cemented with a thin layer of cement to the underside of the tibial component prior to impacting tibial component into tibia

6 BUMPER PAD & BUSHES

Insert bumper pad, aligning curved anterior edge under anterior rail of tibial component

Use general impactor to clip posterior edge of bumper pad into place

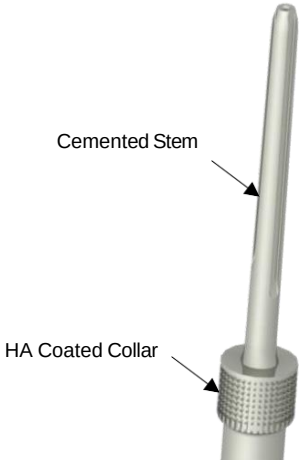


On the femoral component, insert bushes into either end as far as possible

If not seated fully, use bush compressor to fully seat the bushes

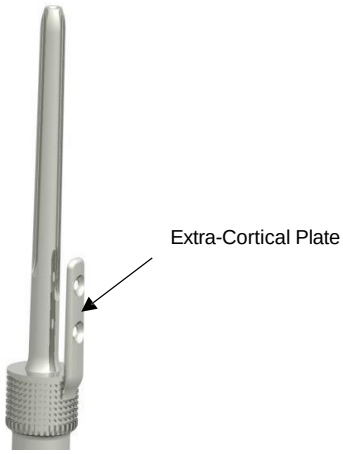
Slide in from one side and screw in nut until bushes are fully seated

7 FEMORAL INSERTION



When cementing the femoral component into the femur, ensure that no cement adheres to the HA coated collar. Failure to do so may result in poor bony ingrowth.

It is advised to use a cement restrictor where possible.

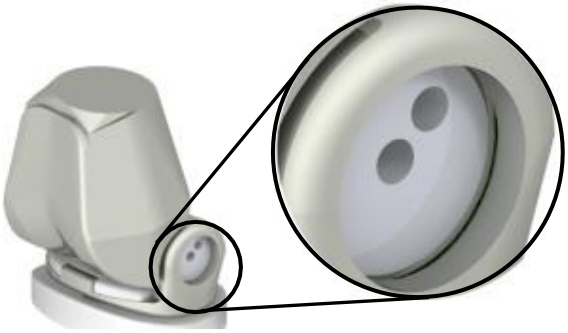


If the femoral component has an extra-cortical plate incorporated into the shaft, implant grade titanium alloy Ø4.5mm cortical bone screws of appropriate length (selected by the surgeon) may be used in the screw holes.

8 AXLE INSERTION

Align femoral and tibial component. Insert axle from either side

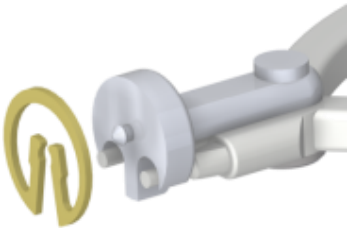
Using pointed implement, rotate axle to ensure offset head fits into recess within tibial component



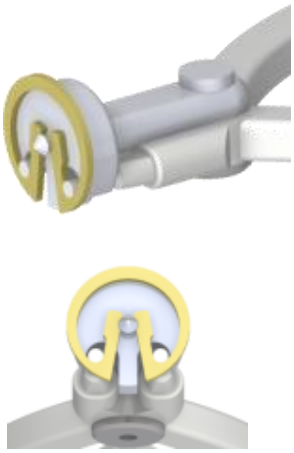
Ensure offset head is seated within recess and not trapped in circlip groove

9 CIRCLIP INSERTION

(Standard & Small Size Only)



Align opening of circlip with prongs of circlip pliers



Push circlip onto pliers, locating central locating pin into centre of circlip. Ensure prongs of pliers are oriented as shown

Engage circlip by approaching at an angle, from same side as axle insertion

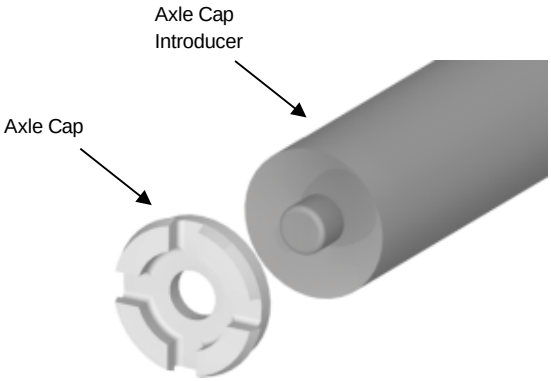
Squeeze the circlip pliers to close the circlip. Insert circular edge within groove in tibial component

Straighten out to engage circlip into groove

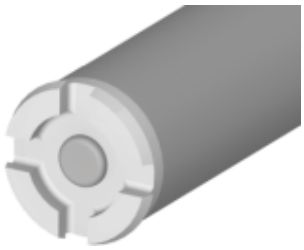
Once within groove, release grip on pliers to secure circlip within groove. Rotate circlip within groove, to ensure correct fit.

10 AXLE CAP INSERTION

(Extra Small Size Only)



Orientate axle cap with flanges away from axle cap introducer

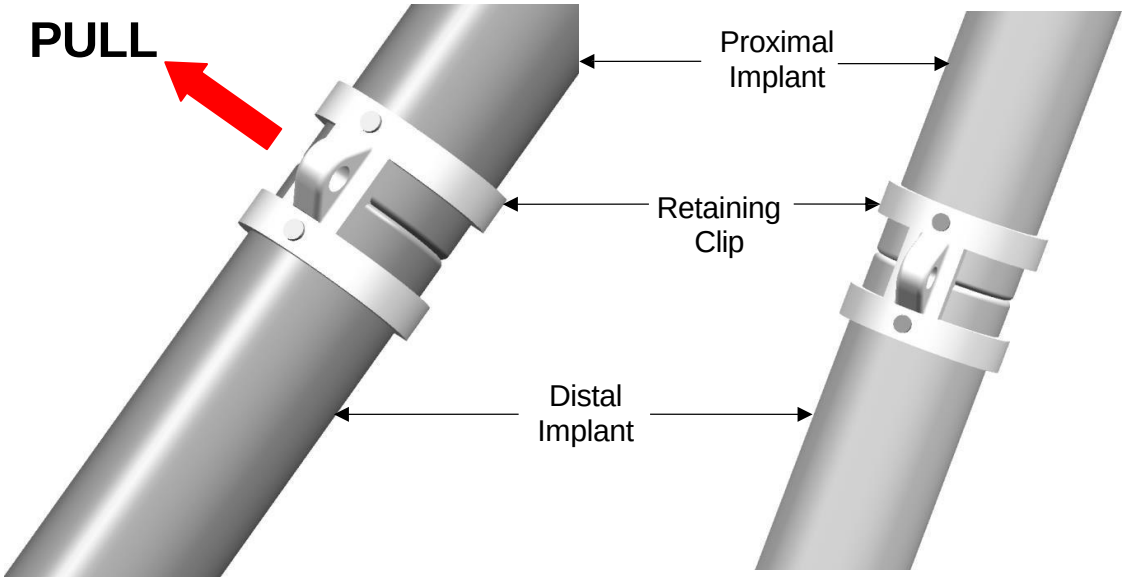


Press axle cap firmly onto introducer

Insert axle cap by approaching from same side which axle was inserted

Press in fully until flanges click into groove on tibial component

11 GROWER CLIP REMOVAL



Once implant has been fully inserted and secured with axle and circlip, or axle and axle-cap, remove retaining clip located on the femoral component. Failure to do so will result in malfunction of the device and may lead to future surgical intervention.

Warnings, Precautions, Adverse Effects and Possible Complications

The JTS Extendible Distal Femoral Implant is manufactured in accordance with an approved prescription for a named patient. It must not be used for any other patient.

The JTS Extendible Distal Femoral Implant is supplied sterilized and must not be steam sterilized. Contact Onkos Surgical for advice.

The JTS Extendible Distal Femoral Implant is MRI UNSAFE and neither the implant nor a patient with an implant in place must be taken into an MRI environment.

If the packaging of parts marked sterile has been compromised or is damaged do not use.

Do not steam sterilize the JTS Extendible Distal Femoral Implant as this will damage the internal magnet and it will not extend.

Once implant has been fully inserted and secured with axle and circlip or axle and axle-cap, remove retaining clip located on the femoral component. Failure to do so will result in malfunction of the device and may lead to future surgical intervention.

All polyethylene components are supplied sterile and must not be re-sterilized if the sterility of the component has been compromised an alternative sterile component must be used

The JTS Extendible Distal Femoral Implant must not be used with products from other manufacturers. Different manufacturers have different tolerances and therefore a mismatch could lead to failure of the implant.

If cortical bone screws are to be used to fix the extra-cortical plate in place, these must be of a suitable size to fit through the plate (nominally ø4.5mm) and made from implant grade titanium.

The JTS Extendible Distal Femoral Implant is for Single Use Only.

An operation instruction supplied with the implant contains patient specific information to aid the implantation

The operation technique instruction must be read prior to carrying out any surgical procedure.

The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment. The patient should be closely monitored if a change at the operative site has been detected. The possibility of deterioration of the joint should be evaluated and possible revision surgery considered.

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.

Hitting or dropping the JTS Extendible Distal Femoral Implant can result in demagnetizing the magnets in the growing section which will result in being unable to grow the implant.

Particular care and attention should be taken with respect to all bearing surfaces, tapers and ceramic coated surfaces.

If the HA coating is contaminated or damaged do not try to clean. Remove from use and contact Onkos Surgical for advice.

Warnings, Precautions, Adverse Effects and Possible Complications

The HA coated components are not to be cemented in place.

Improper use or mishandling of the components can result in damage to one or more of the components reducing the in- service life of the implant.

For any items that are supplied sterile check to ensure that they are still within their shelf life prior to use.

If there is more than six months between supply of the JTS Extendible Distal Femoral Implant and the implantation, further scans must be produced and reviewed against the design by Onkos Surgical as this could result in a possible mis-match due to changes in bone geometry.

If revision of the implant is required, this should be carried out by a suitably qualified person. There are no special techniques required for the revision of a JTS Extendible Distal Femoral Implant. The revision procedure would use the same surgical procedure and tooling required for implantation

Before any action is taken to grow the JTS Extendible Distal Femoral Implant, the JTS Drive Unit operations manual must be read and understood

Specialized instruments are required to assemble and disassemble the components. Using other instruments may damage the components. Instruments can become damaged or may even fracture after repeated use or if used with excessive force. Instruments should be inspected prior to surgery and not used if damaged or worn excessively

Before any action is taken to grow the JTS Extendible Distal Femoral Implant, the operation Drawing must be consulted as this gives details of the direction of magnetic field rotation for each individual implant.

CT scans obtained with a metal implant inside the patient do produce artefacts and therefore tissue definition in the adjacent area is compromised and this must be taken into account when reviewing any results.

Warnings, Precautions, Adverse Effects and Possible Complications

Possible adverse effects:

There is a range of potential adverse reactions; these may include:

- Patient sensitivity to implant materials which may ultimately require removal of the device
- Infection which may require temporary or permanent removal of the device
- Discoloration of the adjacent tissues may occur Fretting between metal parts is possible under certain circumstances

Intraoperative and early postoperative complications:

These may include:

- Temporary or permanent nerve damage
- Damage to blood vessels
- Hematoma
- Cardiovascular disorders
- Pulmonary embolism
- Myocardial infarction or venous thrombosis
- Delayed wound healing
- Infection
- Loosening
- Varus and valgus deformity
- Dislocation

Late postoperative complications:

These may include:

- Loosening
- Bone resorption
- Bone fracture
- Fatigue fracture of metal components
- Wear of components due to misalignment or excessive loading
- Inadequate range of movement
- Infection
- Metal sensitivity or allergic reaction

Onkos Surgical
77 East Halsey Road
Parsippany, NJ USA 07054
+1-973-264-5400
www.onkossurgical.com

JTS US DFPRPT ST 06.09.23 v0