

Proximal Tibia Replacement

Surgical Technique:
Rotating Hinged Option



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onkossurgical.com

Precision Orthopaedic Oncology

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



1 IMPLANT DESCRIPTION & INDICATIONS

1.1 Implant Description:

Onkos Surgical Patient Specific Devices are manufactured in accordance with an approved prescription for a named patient. They **MUST NOT** be used for any other patient.

The patient name is detailed in the operation drawing supplied with the device/s.

The planned resection levels are indicated on 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:

Patient Specific Implants are indicated for limb sparing and skeletal restorative procedures 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).

Onkos Surgical Patient Specific Devices and their components are for single use only.

1.3 Indications:

- Primary bone tumors
- Secondary tumors arising in bone
- Non-neoplastic conditions affecting the shafts of long bone
- Failed joint replacements
- Failed massive replacements

Onkos Surgical Patient Specific Devices are indicated for cemented and cementless procedures where radical resection and replacement of the distal femur is required.

1.4 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.

1.5 Patient Selection:

Factors to be considered:

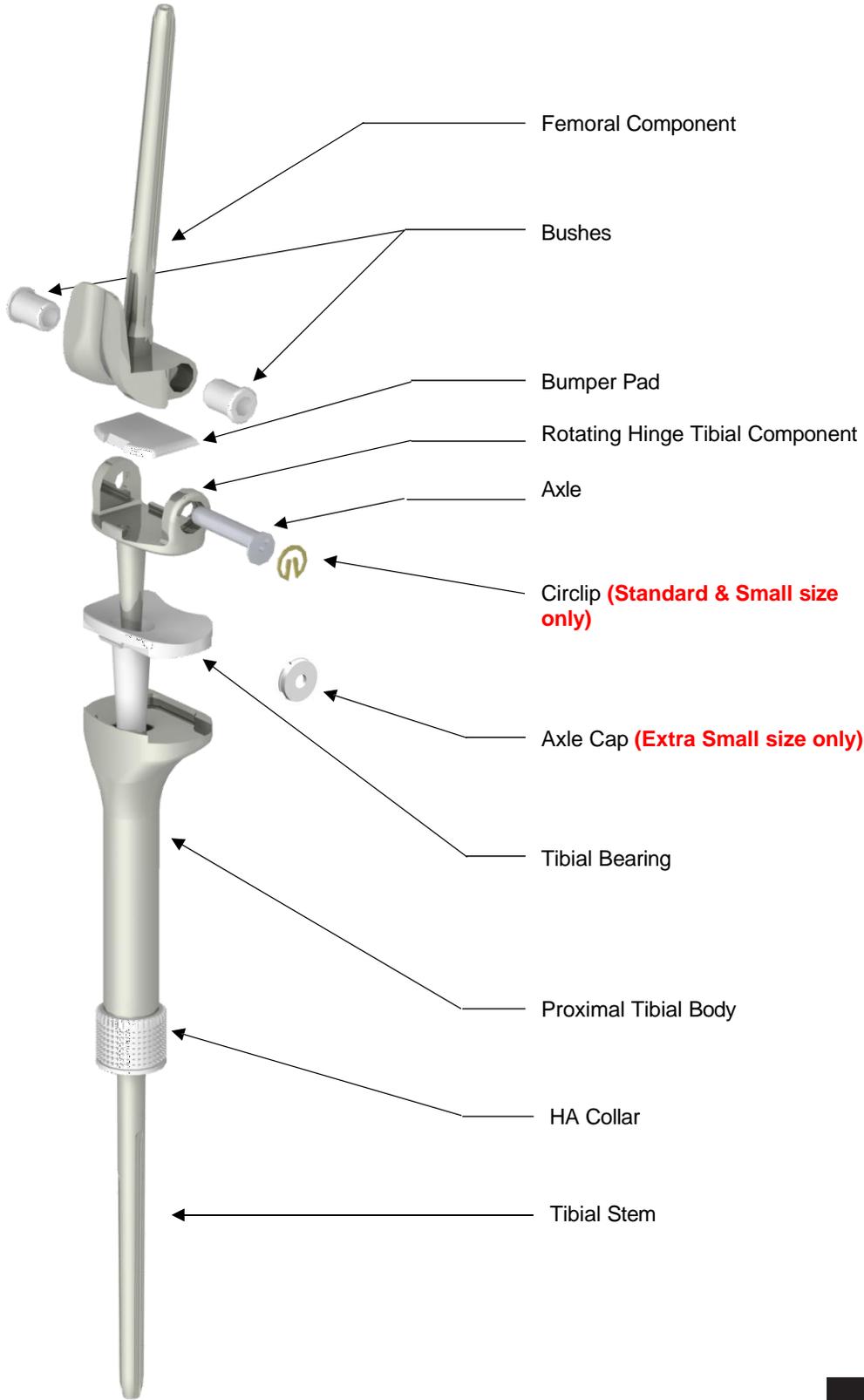
- Resection of neoplastic or diseased bone
- At risk from pathological fracture
- Pain relief and improved function
- Ability of patient to willingly follow instructions and undergo rehabilitation

Onkos Surgical Patient Specific Devices are available for use with the following tibial configuration options:

- Rotating hinge
- Fixed hinge tibia

The rotating hinge tibial option is suitable for routine cases. The fixed hinge tibial option is suitable for knees with marked instability.

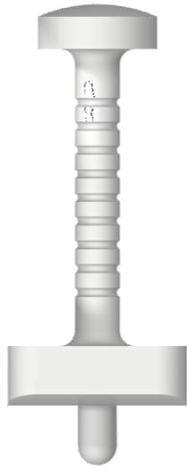
2 EXPLODED VIEW



3 INSTRUMENTS



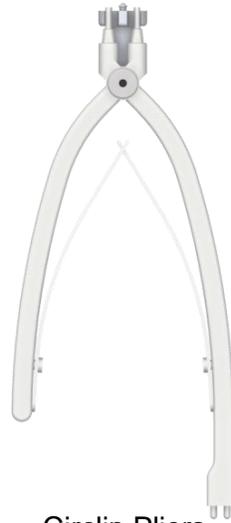
General Impactor



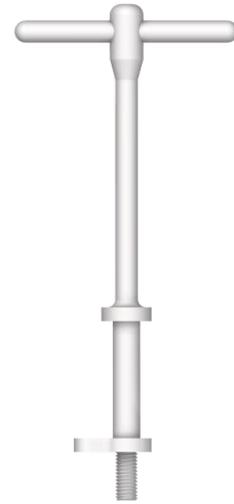
Plastic Impactor



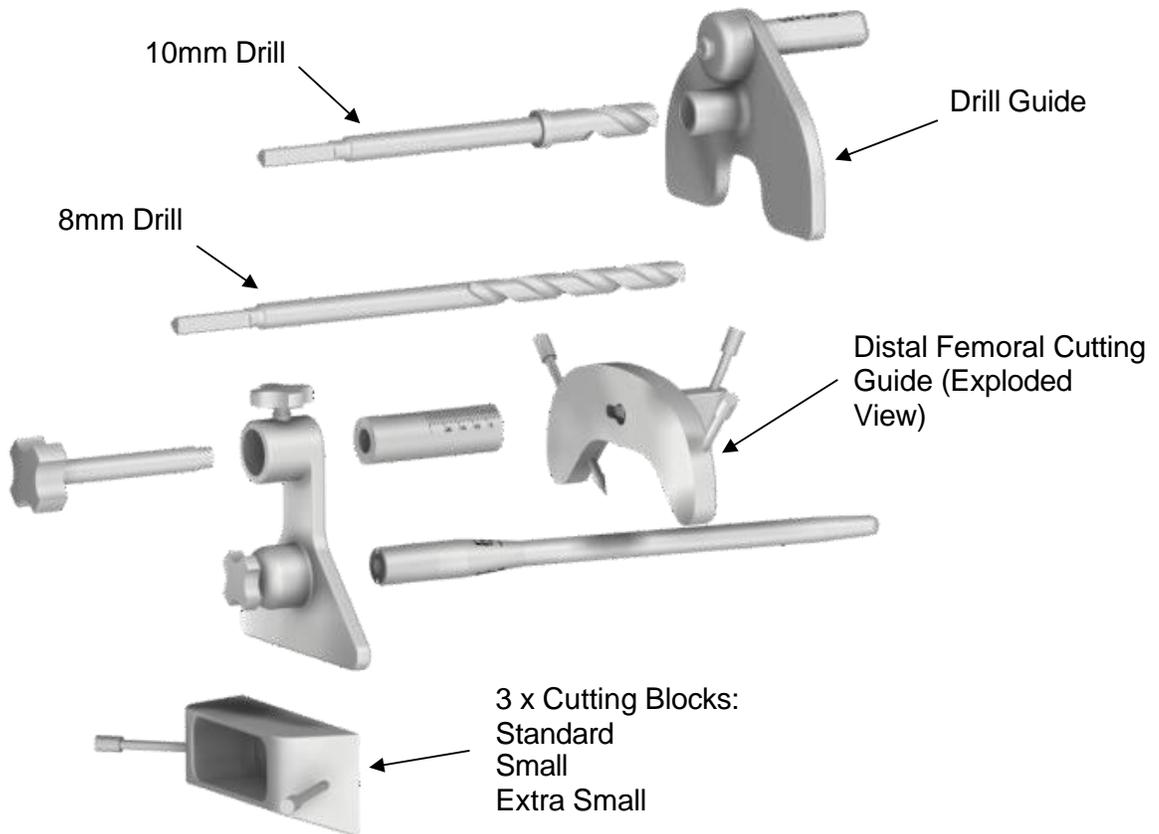
Axle-Cap Introducer
(Extra-small size only)



Circlip Pliers
(Standard & Small sizes only)



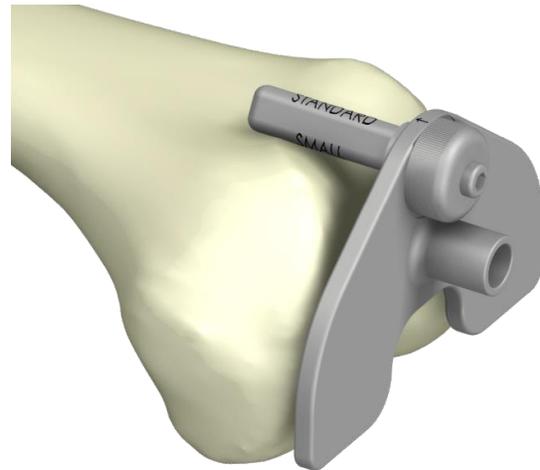
Bush Compressor



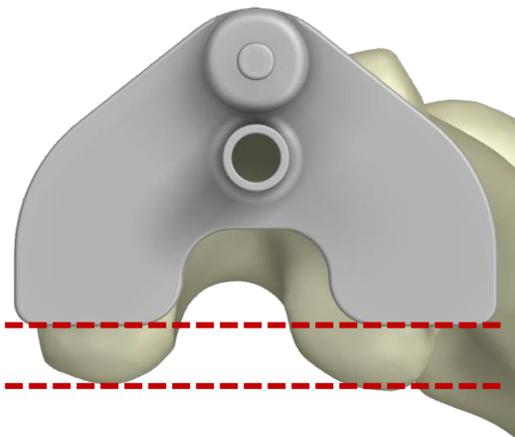
4 FEMUR PREPARATION



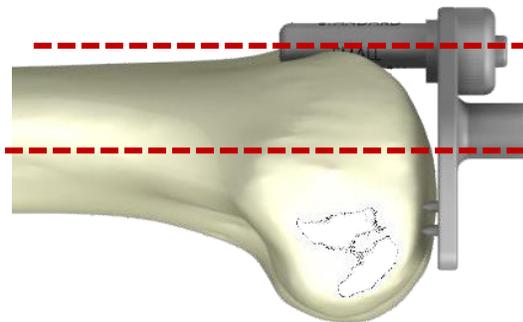
Rotate patella groove rest on drill guide to align required size indication with arrow on top of guide



Place drill guide on condyles of femur, with patella groove rest locating in patella track

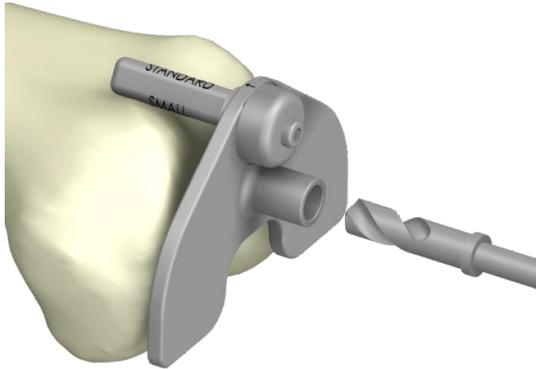


Align posterior of drill guide with posterior of femoral condyles

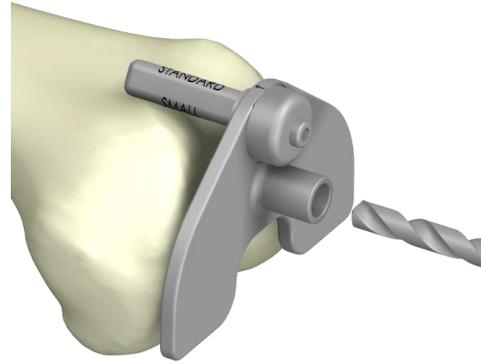


Align patella groove rest to be approximately in line with femoral canal. Once aligned tap to allow spikes to bite into condyles

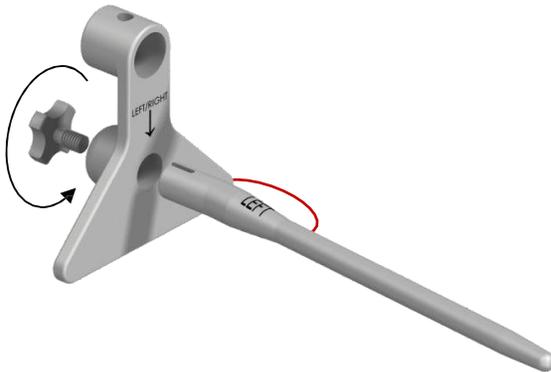
4 FEMUR PREPARATION



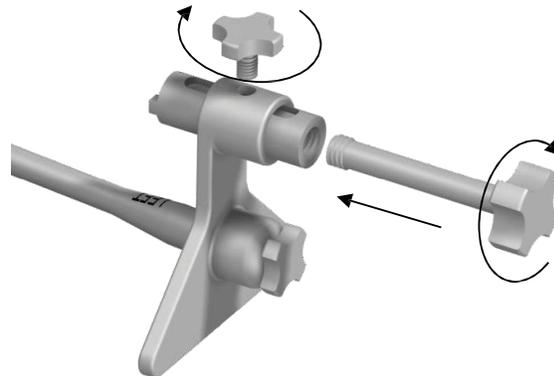
Use Ø10mm drill to depth indicated by drill stop



Use Ø8mm drill to extend depth of hole until intermedullary canal is penetrated.

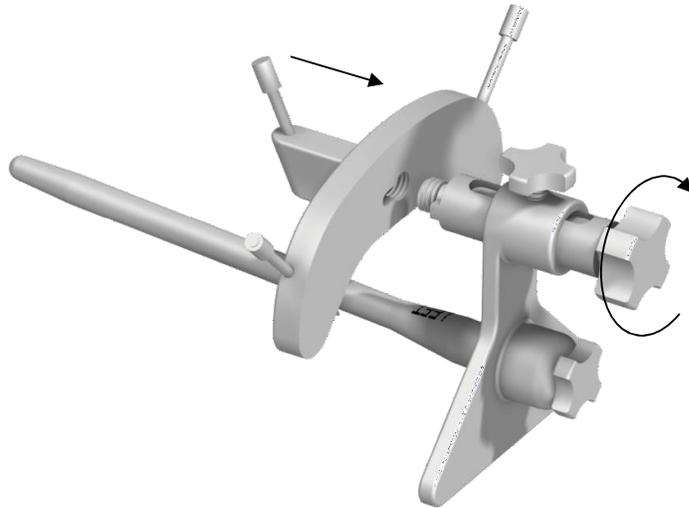


Assemble distal cutting guide by first inserting IM rod, making sure correct side is aligned with arrow. Screw into place with locking screw

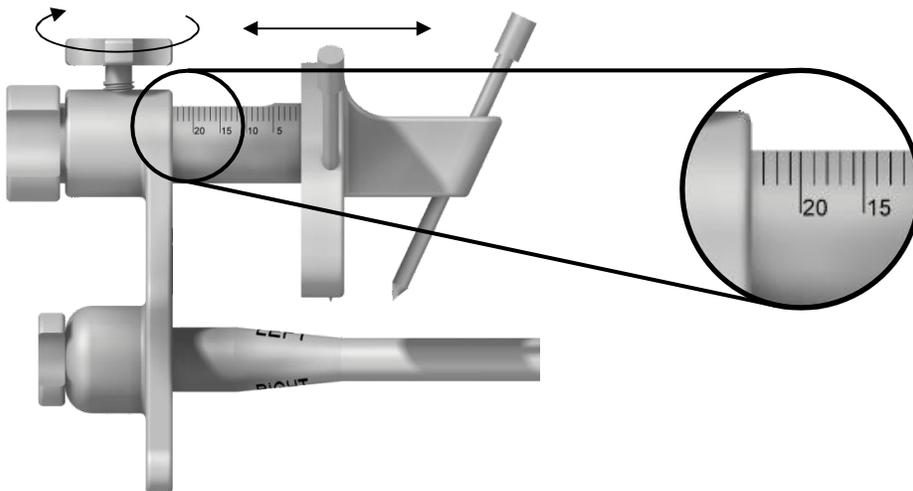


Insert slider and secure in place with locking screw, followed by slider bolt, screwing in until fully inserted.

4 FEMUR PREPARATION



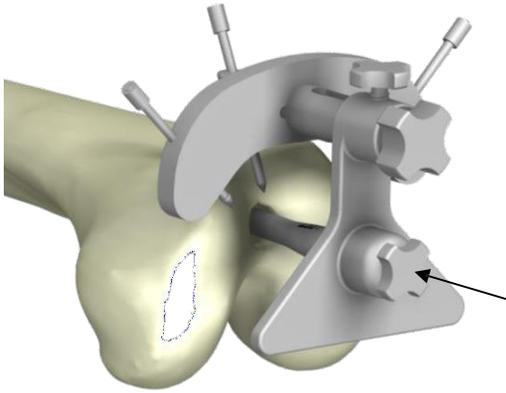
Attach distal cutting plate by screwing into distal cutting guide slider bolt



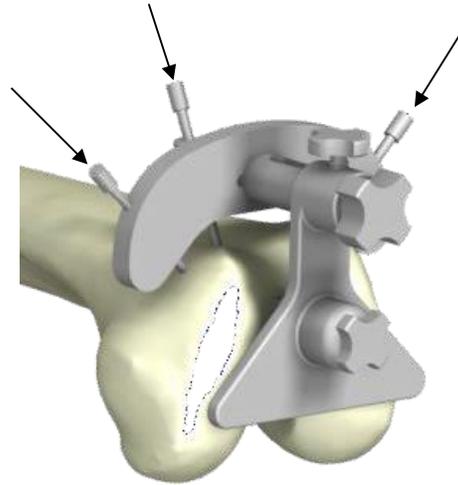
Adjust slider to depth required and secure in place with locking screw

The depth is indicated on the operation drawing

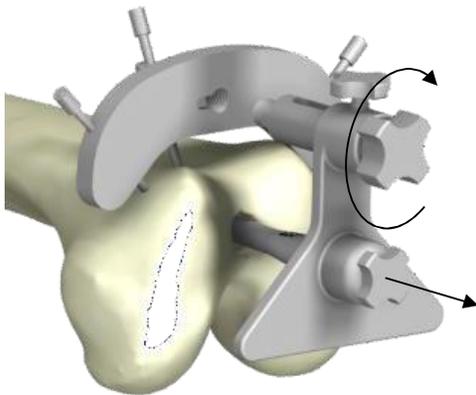
4 FEMUR PREPARATION



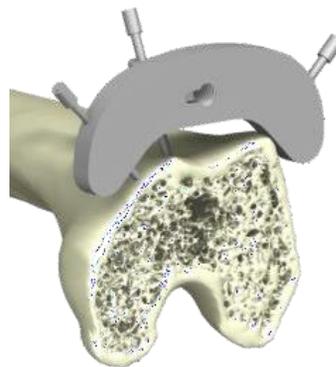
Insert IM rod of assembled guide into femur fully



Secure in place using pins on cutting plate

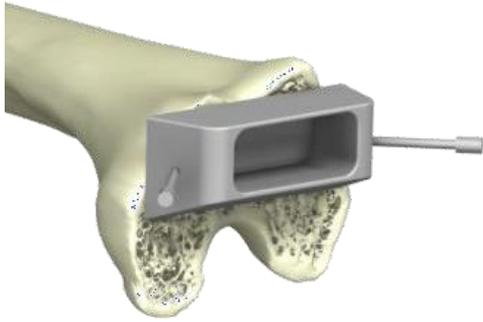


Unscrew slider bolt and slide out rod sub-assembly

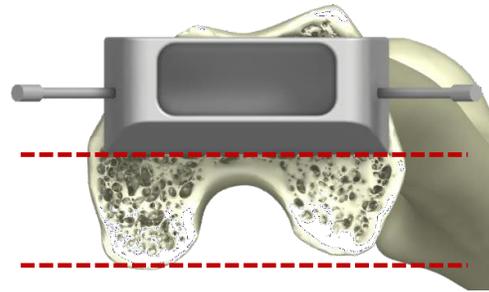


Trim condyles in line with cutting plate

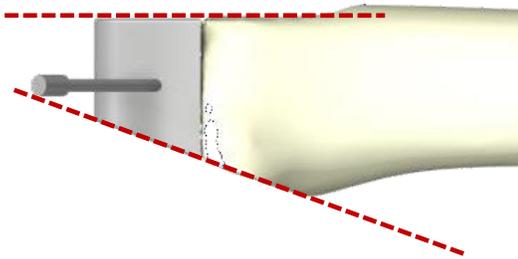
4 FEMUR PREPARATION



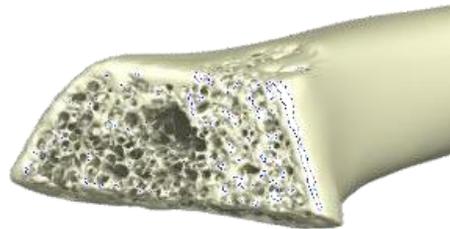
Remove cutting plate and attach appropriate cutting block with sloping face oriented posteriorly



Rotate to align bottom edge with posterior of condyles. Secure in place using pins



Trim femur in line with anterior and posterior planes of cutting block

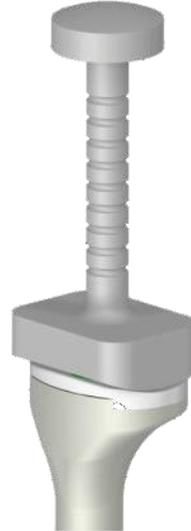


Prepared femur

5 TIBIAL ASSEMBLY



Insert tibial bearing into proximal tibial component



Secure in place using plastic impactor



Insert tibial rotating hinge component into tibial bearing, aligning curved anterior edge with anterior of proximal tibial implant



6 BUMPER PAD & BUSHES



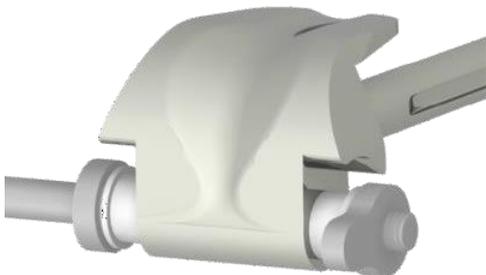
Insert bumper pad, aligning curve and anterior edge under anterior rail of tibial component



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

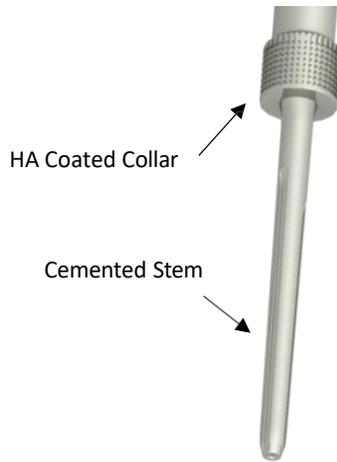


If not seated fully, use bush compressor to fully seat the bushes



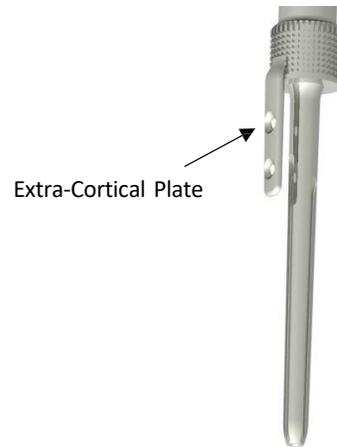
Slide in from one side and screw in nut until bushes are fully seated

7 TIBIAL INSERTION



When cementing the tibial component into the tibia, 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 tibial 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.

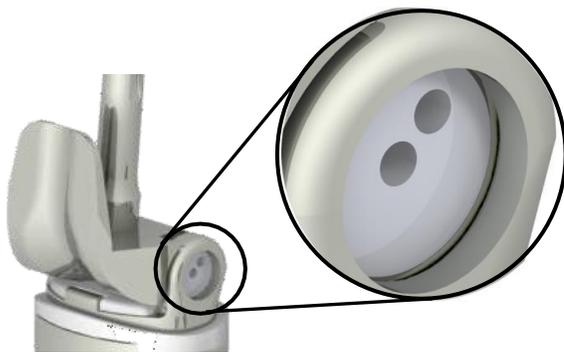
8 AXLE INSERTION



Align femoral and tibial component.
Insert axle from either side



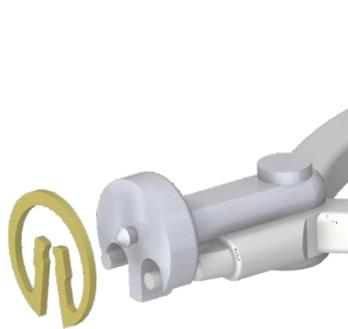
Using pointed implement, rotate axle
to ensure offset head fits into recess
within tibial component



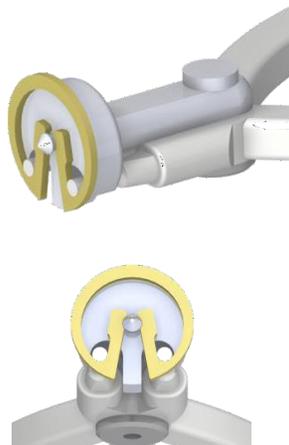
Ensure offset head is seated within recess and not
trapped in circlip groove

9 CIRCLIP INSERTION

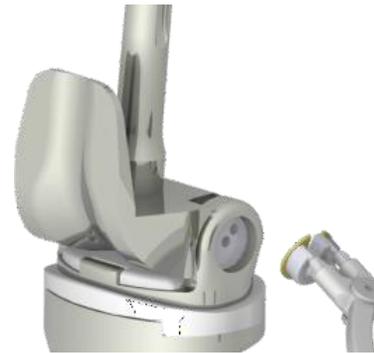
(Standard & Small Size Only)



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



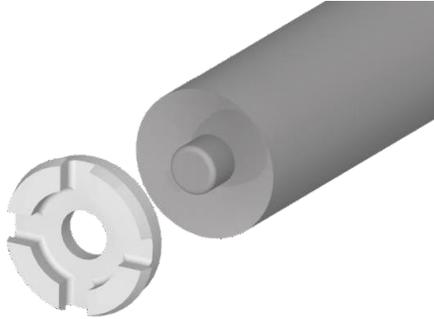
Straighten out to engage circlip into groove



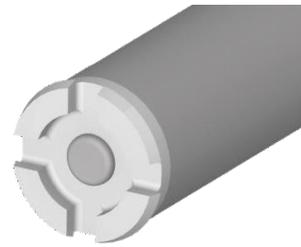
Once within groove, release grip on pliers to secure circlip within groove. Rotate circlip within groove, to ensure correct fit

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



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