Stanmore Implants

METS™ Modular Proximal Tibia

Contents

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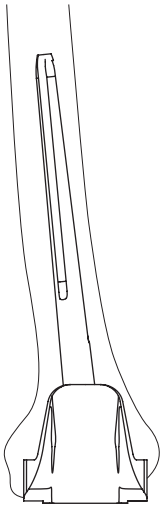

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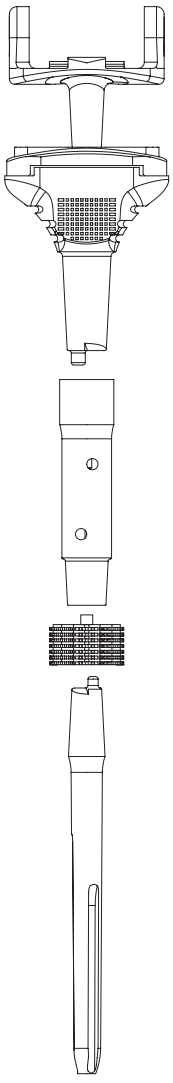

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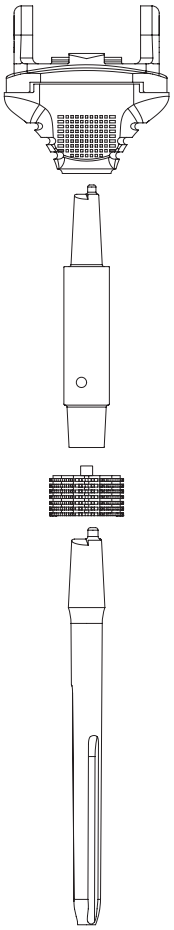

Basic overview

A — For femoral preparation, please refer to section 2.5, 2.6 and 2.7.

The METS proximal tibial system is available with the option of two different proximal tibial components:

B — Rotating hinge configuration which is covered in Section 3.

C — Fixed hinge configuration which is covered in Section 4.

1.1 Product overview

The METS proximal tibial replacement system is designed as a modular system that can be used to replace diseased or deficient bone in the proximal tibia.

The system consists of a SMILES knee, a proximal tibial component, a range of shafts in 15mm increments to suit differing lengths of resection, a range of hydroxyapatite coated collars of different diameters to match the size of the resected bone and a range of cemented stems to fit the intramedullary canal.

Individual components of the tibial shaft are connected using interlocking taper junctions allowing quick and easy assembly. The SMILES knee comes with the option of two different proximal tibial components; a rotating hinge and a fixed hinge, both suitable for primary and revision bone tumour cases.

1.2 Indications

— Tumour resections

1.3 Absolute contra-indications

— Infection and sepsis.

1.4 Relative contra-indications

— 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 disorders, neuromuscular disorders or muscular dystrophy
— Inadequate bone stock.

1.5 Capabilities and restrictions of use

— Before using the device, read the instructions for use leaflet provided with the device in the product packaging
— The components are designed and manufactured to be assembled and used only in the manner specified. Any deviation from this may reduce the in-service life of the prosthesis.
— Mixing with unspecified components either from Stanmore Implants or from other manufacturers is not permitted since it may lead to mal-alignment, inadequate assembly, excessive wear and premature failure.
— A fully assembled METS Modular Proximal Tibial replacement must consist of a proximal tibia assembly (rotating hinge or fixed hinge) with bumper, a femoral component with bushes, an axle and a circlip, and either an integral shaft/stem construct or a principal shaft with or without an extension shaft, a collar, and a stem.
— Femoral and Tibial sizes cannot be mixed. A small femoral component must be used with a small tibial component and a standard femoral component must be used with a standard tibial component.
— Failure to use a collared device may result in excessive subsidence of the prosthesis.
— Should the interlocking surfaces of any of the implant components become damaged, they must not be used.
— The implant components are for SINGLE USE only and they must not be re-used.
— Do not use if package is damaged
— A set of instruments is provided to assist assembly of prosthesis, which includes a set of metal trial components. The trial components are coloured to easily distinguish from implant components. Trials are titanium and anodised blue, while trial femoral components are silver and blue.
— In addition, the trial components cannot be used in combination with implant components.
— This implant is produced from titanium and CoCrMo alloys and therefore **under no circumstances should it be allowed to contact a stainless steel device since this may induce galvanic corrosion.**

- The METS Proximal Tibial system and its components are for single use only
- The METS Proximal Tibial system and its components are for cemented use only

— When cementing components into the bone, it is recommended that a high viscosity bone cement is used.
— The METS Proximal Tibial system has not been evaluated for safety and compatibility in the MR environment.
— METS Proximal Tibial system has not been tested for heating or migration in the MR environment.

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2.1 Pre-operative Planning

It is important to assess the radiographs before the operation to establish approximate size of the components required for the patient. This will help reduce the number of trial components used during surgery. The following points should be considered during assessment:

- The size of the knee (small or standard).
- Choice of tibial component (rotating hinge or fixed hinge).
- An Integral shaft/stem contruct for shorter resections or Principal shaft length, and additional option of extension shaft. for longer resections.
- Stem length and diameter.

2.2 Recommendations for component selection

Size of femoral knee component

Where possible, a standard sized knee component should be used if the bone and surrounding soft tissues can accommodate it. For smaller patients, a small sized femoral knee can be used.

Tibial components

Ideally, a rotating hinge proximal tibial replacement is recommended for cases where there is good muscle function and stability of the joint.

Fixed hinged proximal tibial replacements should be considered where there is marked rotational instability of the joint and the soft tissues have been sacrificed.

Shaft

The prosthetic construct should only have one principal shaft with an extension shaft if required. More than one principal shaft must not be used.

Stem

In order to optimise the implant fixation and strength, it is recommended that the largest stem diameter be chosen whilst still maintaining a minimum of 1mm cement mantle. Where thicker cortex is present, consider reaming the canal to accommodate the largest possible stem.

2.3 General points to note when using trial components

- Except the collars, trial shafts and stems are assembled with a “push and click” mechanism where the rotational orientation is controlled by an anti-rotation lug.
- The trial collar, which is unidirectional, is simply slid over the shaft and is held in position by the insertion of a stem
- There is only one size axle for the trial components, which can be used for both small and standard size knees and it can be inserted from either side. It should be noted that a circlip is not required for the trial components.
- The trial components are designed to give a representation of the physical size of the actual implant component, and therefore, during trial reduction, they should provide an indication of the degree of soft tissue coverage and the function of the device.
- The trial proximal tibial components represent only the size and shape of the actual tibial construct and therefore do not rotate.

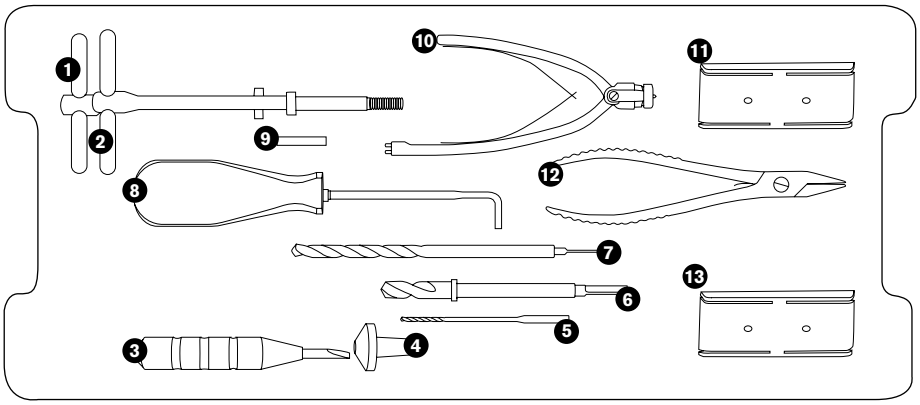
A During removal of the trial implant, if the stem should become lodged in the canal and left behind, use the trial stem extractor to remove it.

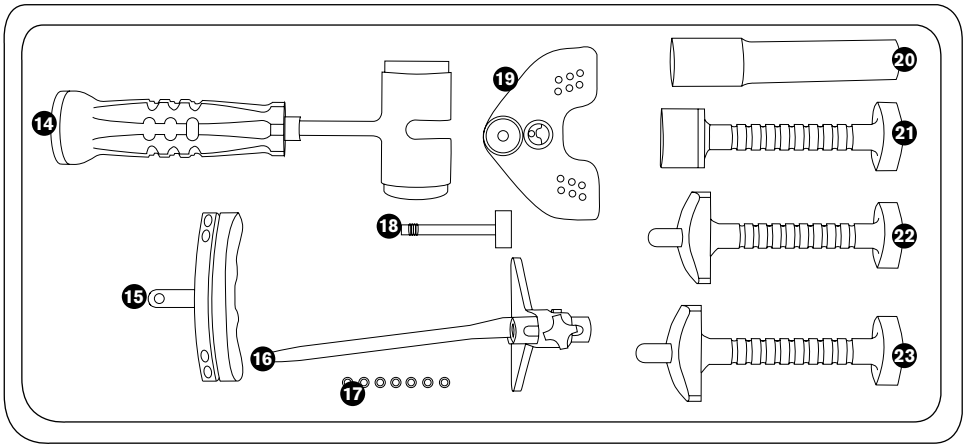
2.4 Recommendations for assembly of implant

It is recommended that the following points be considered during assembly of an implant:

- Always fully assemble an implant before exposing it to the body’s environment; failure to do so may result in contaminating the interlocking mechanism, which can impair the performance of the implant.
- Impact each junction as described in sections 3.5.2 or 4.5.2 in order to provide optimum strength to the joint. This is important since each interface may experience large bending forces that may result in excessive wear and fretting if not correctly assembled.
- Care must also be exercised when assembling components with hydroxyapatite coating, as it is brittle and can easily be damaged.

2.5 Special Instruments



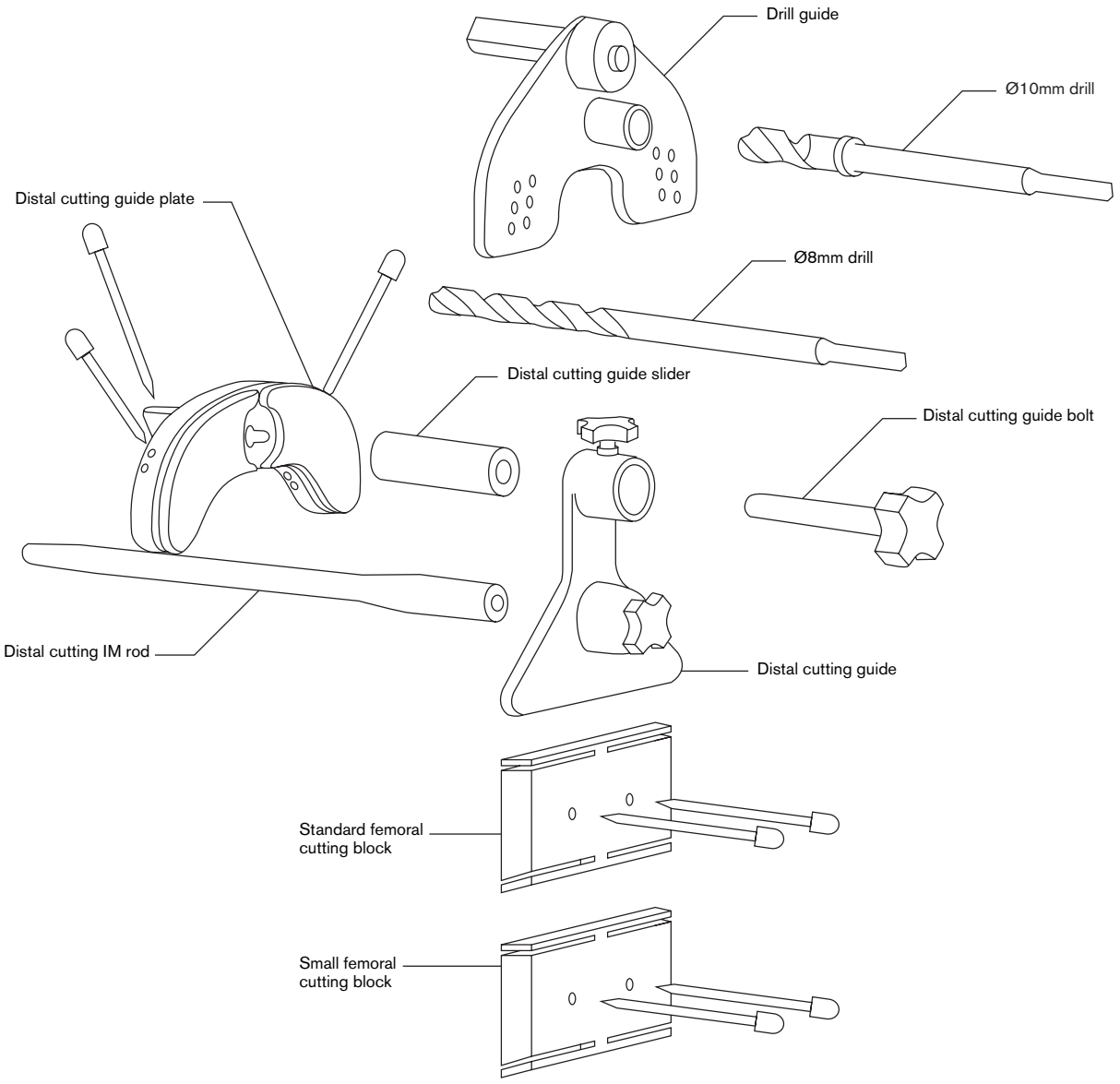


1 Bush compressor standard
2 Bush compressor small
3 Distraction tool
4 Collar impacter small
5 Drill Ø2.5mm
6 Drill Ø10mm
7 Drill Ø8mm
8 Stem extractor
9 Bush compressor nut
10 Circlip pliers
11 Femoral cutting block standard
12 Pliers
13 Femoral cutting block small
14 Hammer
15 Distal cutting guide: plate
16 Distal cutting guide with im rod and slider
17 Bone pins x 7
18 Distal cutting guide: slider bolt
19 Drill guide
20 Collar impactor integral
21 General impactor
22 Plastic bearing impactor small
23 Plastic bearing impactor standard

In addition to these tools, it is anticipated that the operating theatre should make available a bone saw (maximum thickness 1.48mm), a set of reamers, and an appropriate cement application device

2.6 Femoral cutting guide

In addition to these instruments, it is anticipated that the operating theatre should make available a bone saw, flexible reamers and an appropriate cement application device.



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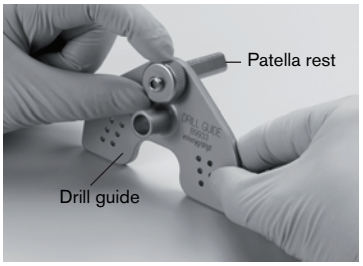

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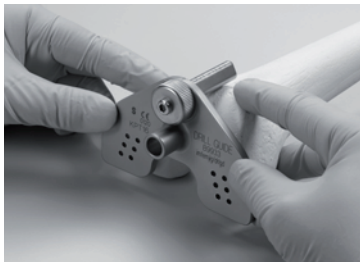

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2.7 Femoral cutting guide assembly and bone preparation

A Rotate the patella rest on the drill guide until the correct size SMILES knee mark is aligned with the arrow on the top of the guide.

B Place the drill guide on the condyles of the femur.

C With the patella rest in the trochlea, rotate the drill guide in the sagittal plane and about the long axis of the bone so that the posterior condyles are aligned with the posterior edge the drill guide.

D Use the Ø2.5mm drill to prepare pin holes, impact the bone pins to secure drill guide in place.

E Using the Ø10mm drill, drill through the guide into the inter-condylar notch to the depth indicated by the drill stop.

— Remove the guide.

— Using Ø8mm drill, deepen the hole ensuring the drill follows the intramedullary canal of the femur until the intramedullary canal is penetrated.

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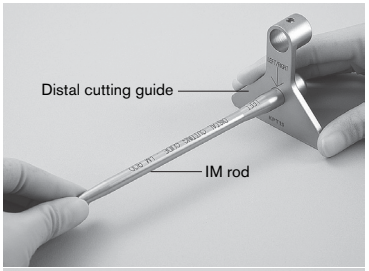

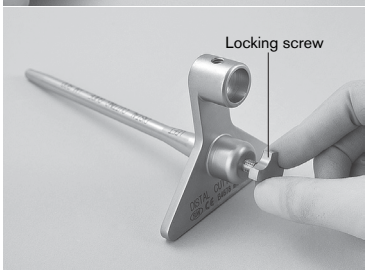

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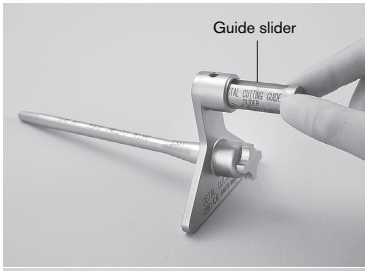

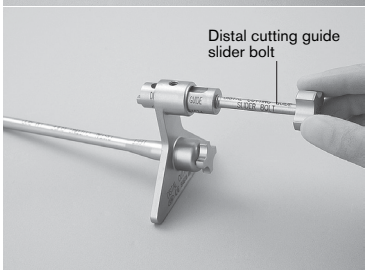

F Assemble the Distal cutting guide by first inserting the IM rod ensuring that the left/right mark is aligned with the arrow on the Distal cutting guide, as this provides a 6° valgus angle for Left or Right sides.

– Lock the IM rod into position using the locking screw located in front of the distal cutting guide.

G Continue to assemble the distal cutting guide by inserting the slider, with the threaded hole facing distally, and secure in place with locking screw. Then insert slider bolt, screwing in until fully inserted. Attach distal cutting plate by screwing into distal cutting guide slider bolt.

Size of SMILES Knee	Slider reading
Small	22mm
Standard	24mm

Note:
These dimensions are for guidance only. More or less bone may need to be resected if necessary.

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Insert IM rod into the previously drilled hole in the femur. Push the rod in as far as it can go, ensure that at least one of the femoral condyles is making contact with the distal cutting guide and then rotate the guide along the long axis of the femur to align the posterior condyles with the posterior edge of the cutting guide. Secure the cutting plate in place using the bone pins provided.

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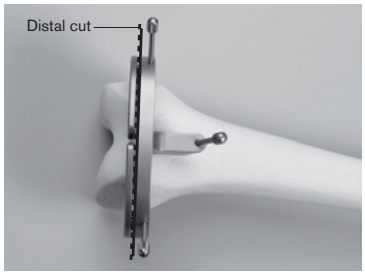

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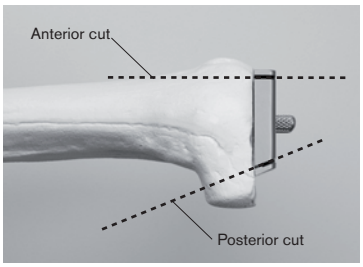


— Unscrew the slider bolt and remove the distal cutting guide assembly, leaving the distal cutting plate securely in position. I

— Perform the distal cut using an oscillating saw within the slot on the distal cutting plate, and then remove the cutting plate.

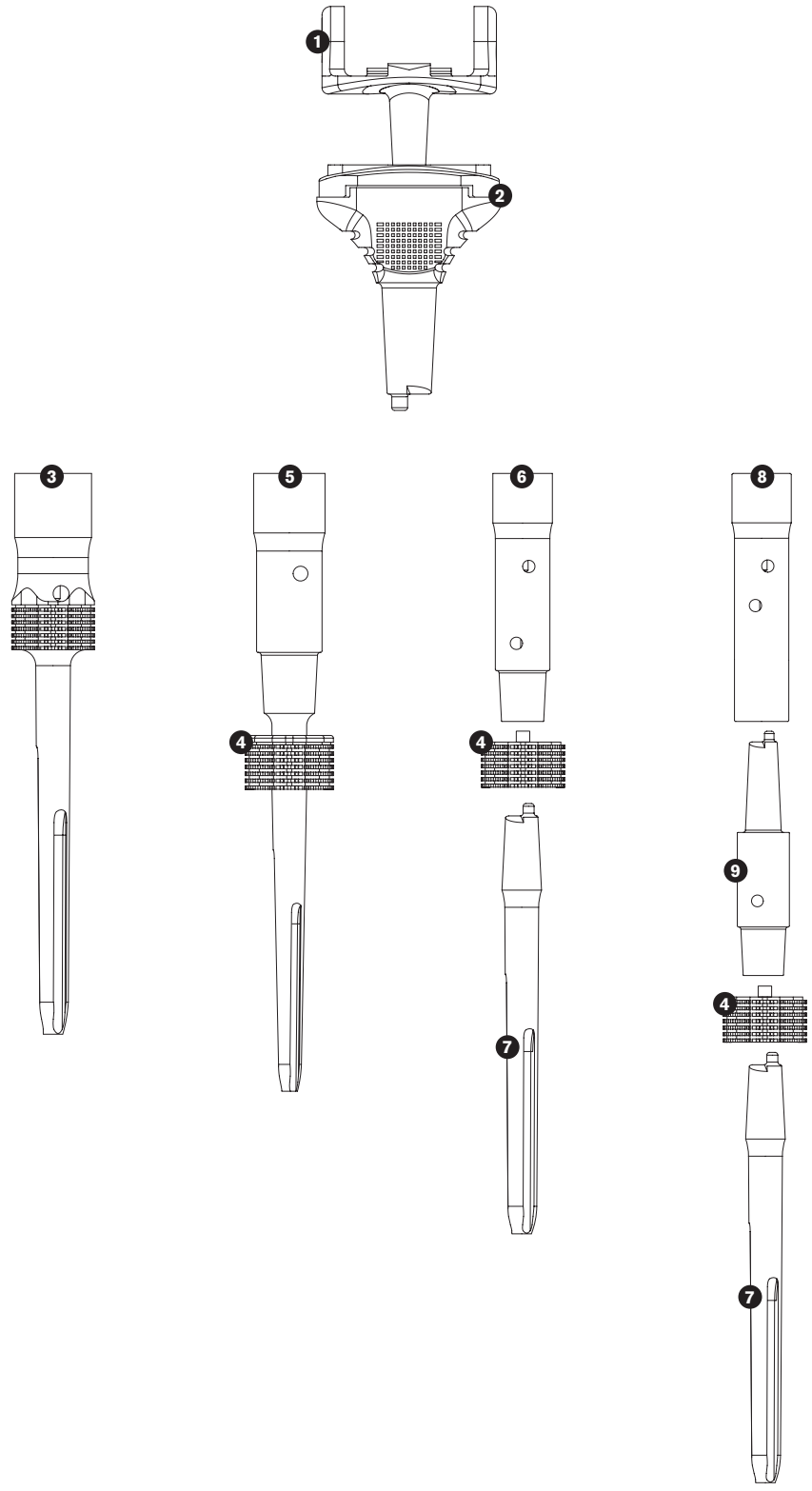
— Place an appropriate size (small or standard) femoral cutting block on the resected end of femur ensuring that the centralising peg is located in the previously drilled hole and that the sloping face is orientated posteriorly. Rotate the block to the desired orientation. Secure the block into position using bone pins provided. J

— Using the oscillating bone saw, trim the anterior condyles using the anterior slot of the block and posterior condyles using the posterior slot of the block.

— Remove the block using the pliers provided and ream the femoral canal to a depth of 140mm and to a diameter approximately 1mm bigger than the femoral stem. (Ø13mm for small size and Ø14mm for standard size).

— The femur is now prepared. Insert the chosen trial femoral component to establish cuts are correctly produced. If not, trim the bone as required.

1 Rotating hinge tibial component small and standard
2 Rotating hinge proximal tibial component small and standard
3 Integral collar/shaft/stem x1 (HA coated)
4 HA collars x5 sizes
5 Integral shaft/stem x1
6 Rotating hinge prinicpal shafts x3 lengths
7 IM stems x5 diameters
8 Rotating hinge extension shafts x1 length
9 Fixed hinge principal shafts x5 lengths



3.1 Components of the rotating hinged proximal tibial implant

Femoral plateau plates
Optional femoral plateau plates (not shown) are available in 5, 10, 15 and 20mm thicknesses for both small and standard sizes.

Rotating hinge proximal tibial component
A titanium proximal tibial component with UHMWPE tibial bearing and a CoCrMo tibial component. In small and standard sizes, with HA coated patella tendon reattachment mechanism or smooth uncoated. Packaged as two individual assemblies:

- Rotating hinge proximal tibial component and UHMWPE bearing.
- Rotating hinge CoCrMo tibial component and UHMWPE bumper pad.

Femoral component
Cobalt-chromium-molybdenum femoral component with a titanium stem. Anatomical (with 6° valgus angle) for left and right sides. Available in small and standard sizes, with 140mm long femoral curved stem Ø13mm for standard components and Ø12mm for small components.

Axle, bushes and circlip
A cobalt-chromium-molybdenum axle, a pair of UHMWPE bushes and a titanium circlip. (Packaged with the femoral component).

Bumper
An UHMWPE bumper available in both sizes providing a secondary bearing surface and a soft hyperextension stop, preassembled within the tibial component.

Shaft
85 to 115mm long titanium shafts in 15mm increments.

- A 85mm long extension shaft to further increase the length capability.
- For very short resections, integral shafts / stems are available in two lengths 55mm available with Hydroxyapatite coating and 70mm for use with a Hydroxyapatite coated Collar.

Collar
Ø20, Ø23, Ø26, Ø29 and Ø32mm HA coated titanium collars.

Cemented stem
Ø9 to Ø13mm straight titanium stems in 1mm increments and 120mm long.

3.2 Trial components of the rotating hinged proximal tibia

Femoral plateau plates
Trial femoral plateau plates (not shown) in 5, 10, 15 and 20mm thicknesses for both small and standard sizes.

Trial femoral component
Small and standard sizes in left hand and right hand versions.

Trial axle
One size axle that can fit both small and standard components and can be inserted from either side of the knee.

Trial rotating hinge proximal tibial component
Trial proximal tibial component in small and standard sizes.

Trial shaft
85 to 115mm trial shafts in 15mm increments with an 85mm long trial extension shaft and 55 and 70mm long trial integral shaft/stem constructs.

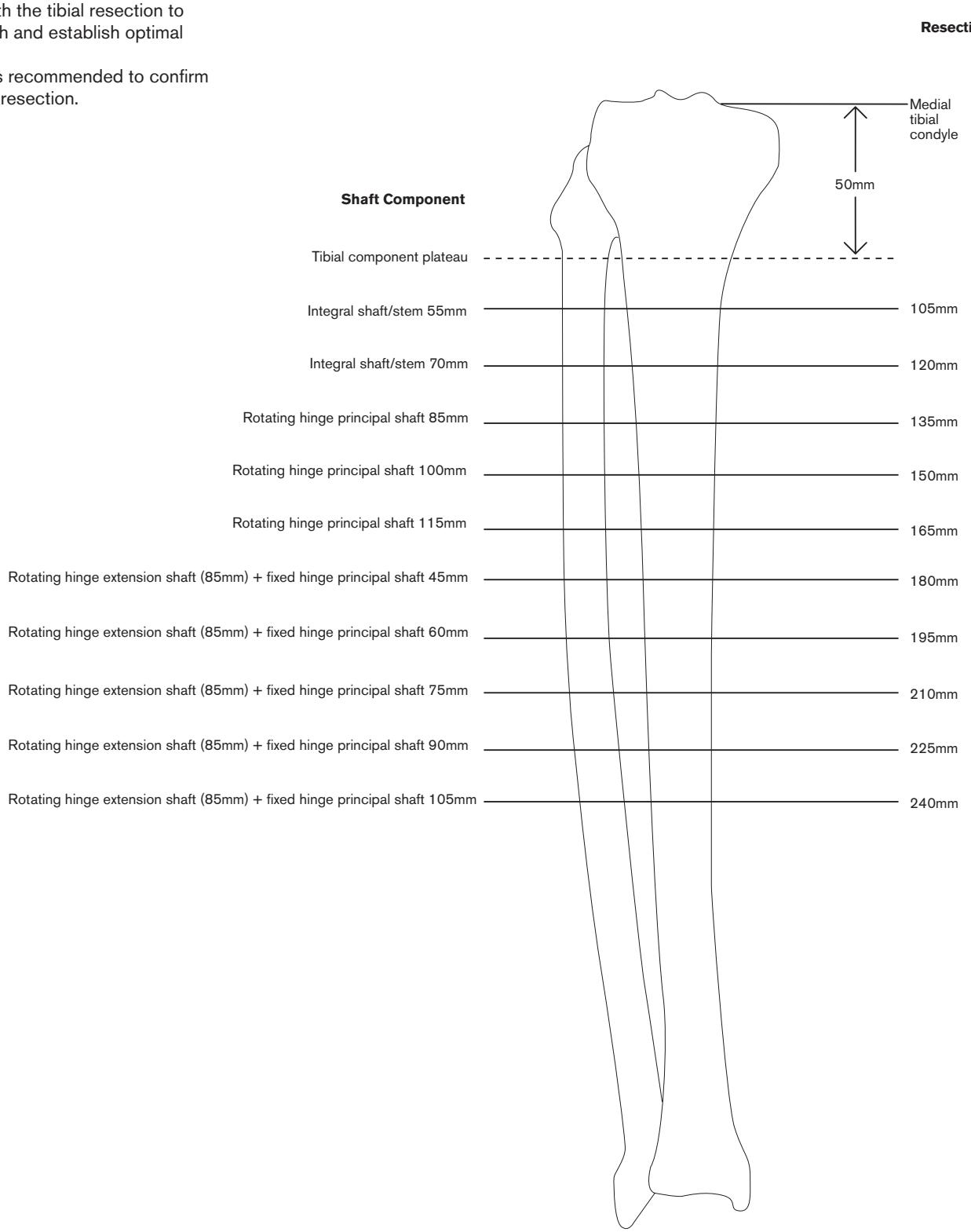
Trial collars
Ø20mm to Ø32mm trial collars.

Trial stem
Ø9 to Ø13mm straight stems in 1mm increments, 120mm long.

3.3 Tibia resection levels: Rotating hinge proximal tibia

It should be noted collar lengths are included in the resection values.

The length of the femoral resection must be considered with the tibial resection to recreate leg length and establish optimal patellar tracking.
A trial reduction is recommended to confirm satisfactory bone resection.



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3.4 Tibial preparation

— Resect the tibial bone to the level required
— Further trimming may be required when selecting the trial components. Please refer to section 3.3 as a guide.
— Ream the tibial canal using an appropriate sized reamer to a depth of 120mm and to the required diameter to accommodate the tibial stem, leaving a minimum of 1mm for the cement mantle.

3.5 Short resections < 120mm

— For very short resections integral shaft/stem constructs are available in two shaft lengths 55mm and 70mm with a 120mm straight tibial stem Ø10mm.

— A The 55mm integral shaft/stem construct has a fixed collar diameter of 26mm and is available hydroxyapatite coated.

— B The 70mm integral shaft/stem construct must be used with a hydroxyapatite coated collar.

3.5.1 Trial assembly and insertion

— Select the required size and side of the trial femoral component and insert into the prepared femur.
— Select the appropriate size proximal tibial component and integral shaft/stem construct to replace the resected length of the tibia and assemble them as described in section 2.2. The assembly sequence should be tibial component onto the shaft/stem construct followed by the collar if using the 70mm integral construct.
— Insert the tibial assembly into the tibia.
— Join the trial femoral component to the tibial assembly by fully inserting the trial axle, and perform a trial reduction. Exchange trial components as required.
— If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the tibia and repeat the trial.
— Once satisfied, remove all trial components and select corresponding implant components.
— During removal of the trial implant, if the stem should become lodged within the canal and left behind, the trial stem extractor should be used to remove it as shown on Page 5.

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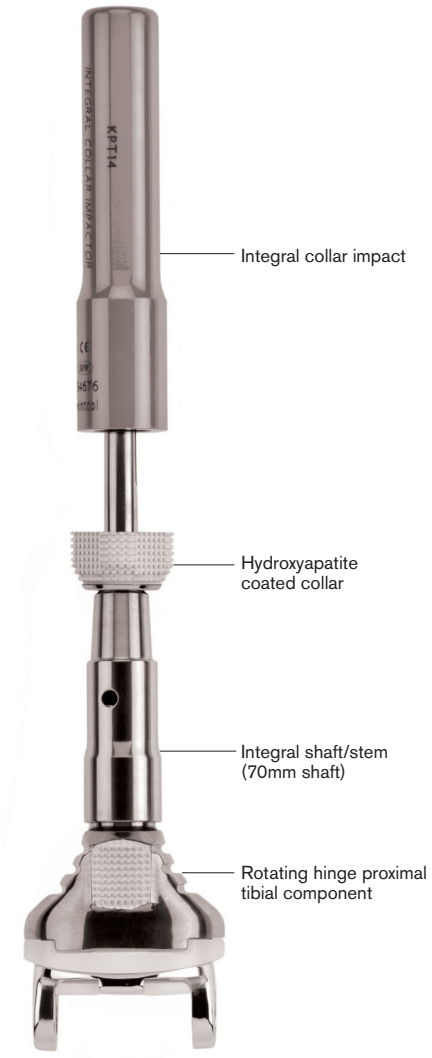

3.5.2 Implant assembly and insertion

A Holding the proximal tibial component with the spigot pointing upwards, insert the integral shaft/stem construct ensuring that the alignment lug is properly engaged. Place the integral collar impactor over the stem and apply multiple sharp blows using the soft hammer provided to lock the taper securely in place.

70mm integral shaft/stem construct only

B Slide the selected collar over the stem of the assembled integral shaft/stem construct ensuring the alignments lugs are properly engaged.

C Place the integral collar impactor over thestem and using the soft ended hammer, apply multiple sharp blows, taking care not to damage the hydroxyapatite coating.

The proximal tibial component is now assembled and ready for insertion.

- Insert the proximal tibial component into the tibial canal and cement it securely into place using the polyethylene bearing impactor and the soft ended hammer provided, ensuring desired rotational alignment.
- Insert the rotating hinge tibial component into the UHMWPE tibial bearing.
- Proceed to section 5.0

3.6 Resections > 120mm

3.6.1 Trial assembly and insertion

- Select the required size and side of the trial femoral component and insert into the prepared femur. This picture shows the implant not the trial.
- Select the corresponding size proximal tibial component, shaft, collar and stem to replace the resected length of the tibia and assemble them as described in section 2.2. The assembly sequence should be tibial component onto the shaft followed by collar and then stem respectively.
- Insert the trial tibial assembly into the tibia.
- Join the trial femoral and tibial components together by fully inserting the trial axle and perform a trial reduction. Exchange trial components as required until satisfactory assembly is produced.
- If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the tibia and repeat the trial.
- Once satisfied, remove all trial components and select corresponding implant components.
- During removal of the trial implant, if the stem should become lodged within the canal and left behind, the trial stem extractor should be used to remove it as shown on Page 5.

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3.6.2 Implant assembly and insertion

3.6.3 The proximal tibial component

A Place the proximal tibial component with the spigot pointing upwards; insert the principal shaft ensuring that the alignment lug is properly engaged. Holding the collar impactor over the shaft apply multiple sharp blows using the soft hammer provided, to lock the taper securely in place.

B Place the selected collar onto the distal end of the shaft ensuring once again the alignment lugs are correctly aligned. Holding the collar impactor over the collar, impact with multiple sharp hammer blows as shown opposite, taking care not to damage the bore or hydroxyapatite coating.

C Finally, insert the appropriate sized stem, ensuring the alignment lug is correctly located and impact with multiple sharp blows on the end of the stem.

— The proximal tibial component is now assembled and ready for insertion.
— Insert the proximal tibial component into the tibial canal and cement securely into place ensuring desired rotational alignment. Impact the stem using the polyethylene bearing impactor and soft ended hammer provided.
— Insert the rotating hinge tibial component into the UHMWPE tibial bearing.
— Proceed to Section 5.0

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3.7 Extensive resections > 165mm

A — For resections greater than 165mm, the use of an extension shaft is required. The rotating hinged extension shaft is 85mm long and **must be used with the fixed hinge principal shafts.**

3.7.1 Trial assembly and insertion

- Select the required size and side of the trial femoral component and insert into the prepared femur. This picture shows the implant, not the trial.
- Select appropriate size proximal tibial component, extension shaft, fixed hinge principal shaft, collar and stem to replace the resected length of the tibia and assemble them as described in the sections 2.2. The assembly sequence should be tibial component onto extension shaft, then the fixed hinge principal shaft followed by collar and then stem respectively. Insert the trial tibia assembly into the tibia.
- Join the trial femoral and tibial components together by fully inserting the trial axle and perform a trial reduction. Exchange trial components as required until satisfactory assembly isproduced.
- If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the tibia and repeat the trial.
- Once satisfied, remove all trial components and select corresponding implant components.
- During removal of the trial implant, if the stem should become lodged within the canal and left behind, the trial stem extractor should be used to remove it as shown on Page 5.

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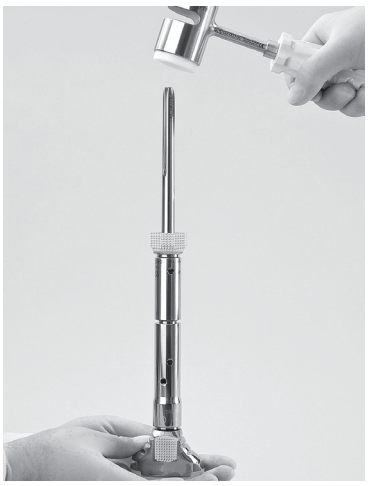


3.7.2 Implant assembly and insertion

3.7.3 The proximal tibial component

A Holding the proximal tibial component with the spigot pointing upwards with two hands, insert the rotating hinge extension shaft ensuring the alignment lug is properly engaged. Holding the collar impactor over the extension shaft apply multiple sharp blows.

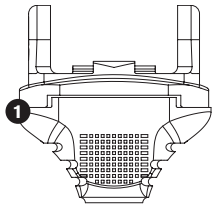
B Insert the spigot of the required fixed hinge principal shaft into the bore of the extension shaft again ensuring that the alignment lug is properly engaged. Place the collar impactor over the principal shaft and apply multiple sharp blows using the soft hammer provided, to the taper securely in place.

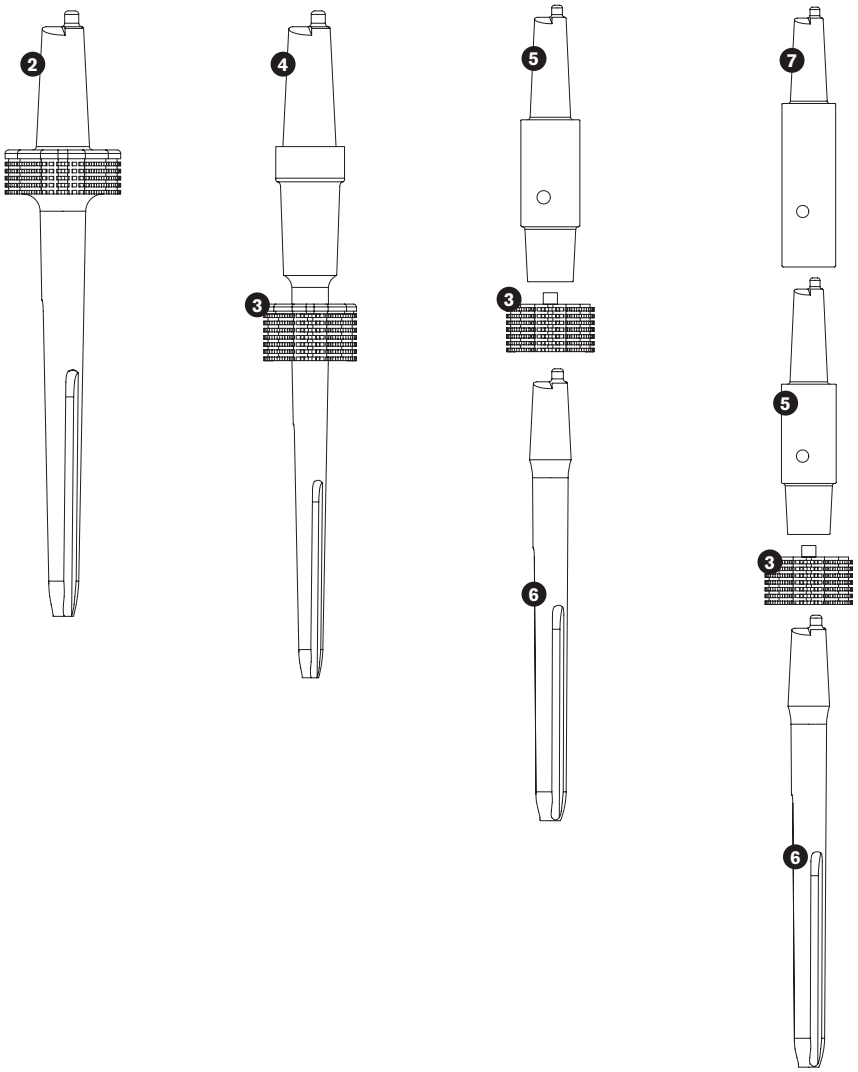
C Place the selected collar onto the distal end of the principal shaft ensuring once again the alignment lugs are properly aligned. Holding the collar impactor over the collar, impact using multiple sharp hammer blows as shown, taking care not to damage the bore or hydroxyapatite coating.

D Finally, insert the appropriate sized stem, ensuring the alignment lug is correctly located and impact with multiple sharp blows on the end of the stem. The proximal tibial component is now assembled and ready for insertion.

— Insert the proximal tibial component into the tibial canal and cement securely into place ensuring correct rotational alignment. Impact using the polyethylene bearing impactor and soft ended hammer provided.
— Insert the rotating hinge tibial component into the UHMWPE tibial bearing.
— Proceed to Section 5.0

1 Fixed hinge proximal tibial small and standard
2 Integral collar/shaft/stem x1 (HA coated)
3 HA collars x5 sizes
4 Integral shaft/stem x1
5 Fixed hinge principal shafts x5 shafts
6 IM stems x5 diameters
7 Fixed hinge extension shafts x1





4.1 Components of the fixed hinged proximal tibial implant

Femoral plateau plates
Optional femoral plateau plates (not shown) are available in 5, 10, 15 and 20mm thicknesses for both small and standard sizes.

Fixed hinged proximal tibial component
A CoCrMo proximal tibial component. In small and standard sizes with HA coated patella tendon reattachment mechanism or smooth uncoated.

Femoral component
Cobalt-chromium-molybdenum femoral component with a titanium stem. Anatomical (with 6° valgus angle) for left and right sides. Available in small and standard sizes, with 140mm long femoral curved stem Ø13mm for standard components and Ø12mm for small components.

Axle, bushes and circlip
A cobalt-chromium-molybdenum axle, a pair of UHMWPE bushes and a titanium circlip. (Packaged with femoral components)

Bumper
An UHMWPE bumper available in both sizes providing a secondary bearing surface and a soft hyperextension stop, preassembled within the tibial component.

Shaft
45 to 105mm long titanium shafts in 15mm increments.

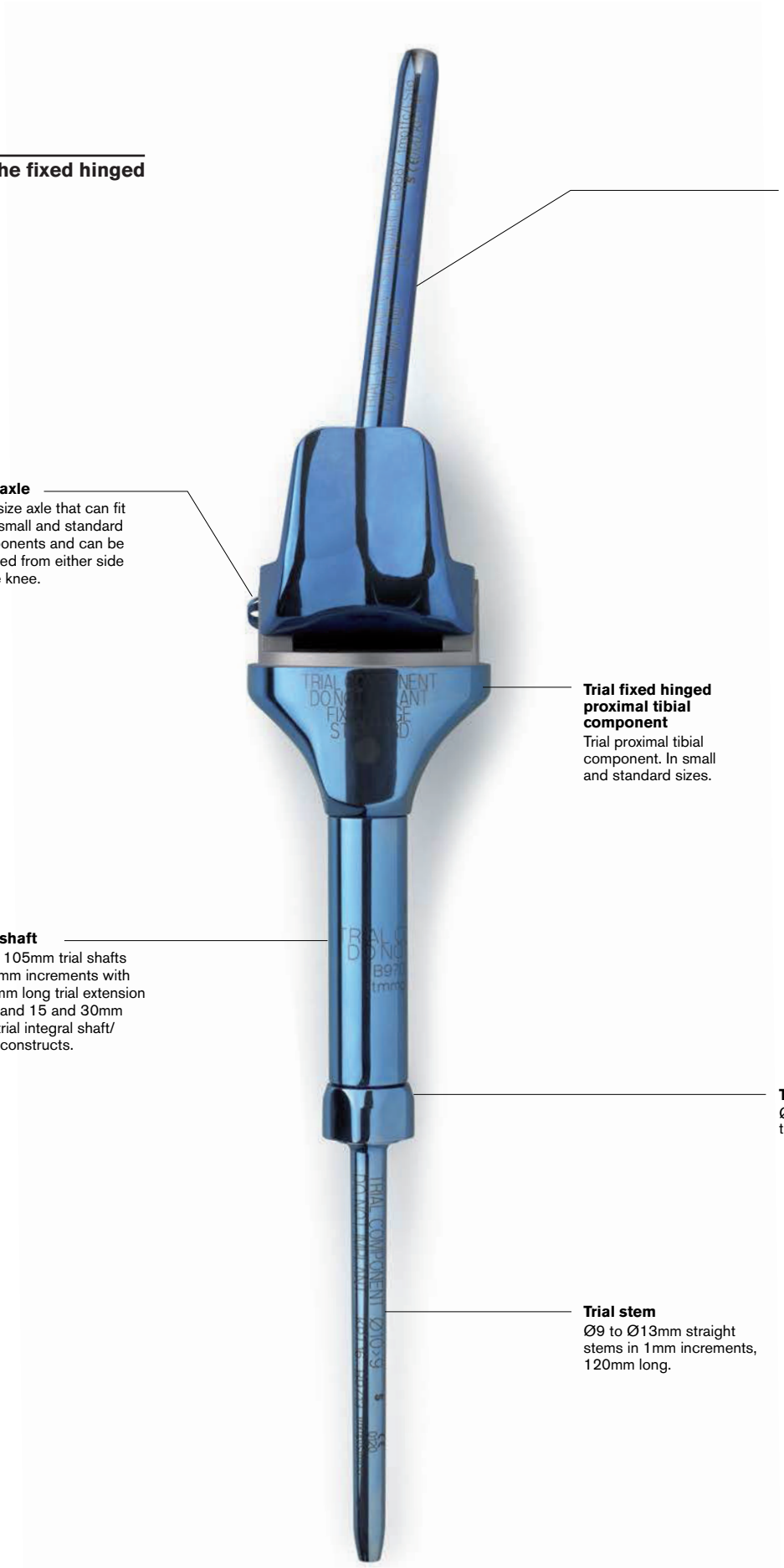
- A 75mm extension shaft to further increase the length capability.
- For very small resections, integral shafts/stems are available in two lengths 15mm available with Hydroxyapatite coating and 30mm for use with a Hydroxyapatite coated Collar.

Collar
Ø20, Ø23, Ø26, Ø29 and Ø32mm HA coated titanium collars.

Cemented stem
Ø9 to Ø13mm straight titanium stems in 1mm increments and 120mm length.

4.2 Trial components of the fixed hinged proximal tibia

Femoral plateau plates
Trial femoral plateau plates (not shown) in 5, 10, 15 and 20mm thicknesses for both small and standard sizes.



Trial femoral component
Small and standard sizes in left hand and right hand versions.

Trial axle
One size axle that can fit both small and standard components and can be inserted from either side of the knee.

Trial fixed hinged proximal tibial component
Trial proximal tibial component. In small and standard sizes.

Trial shaft
45 to 105mm trial shafts in 15mm increments with a 75mm long trial extension shaft and 15 and 30mm long trial integral shaft/ stem constructs.

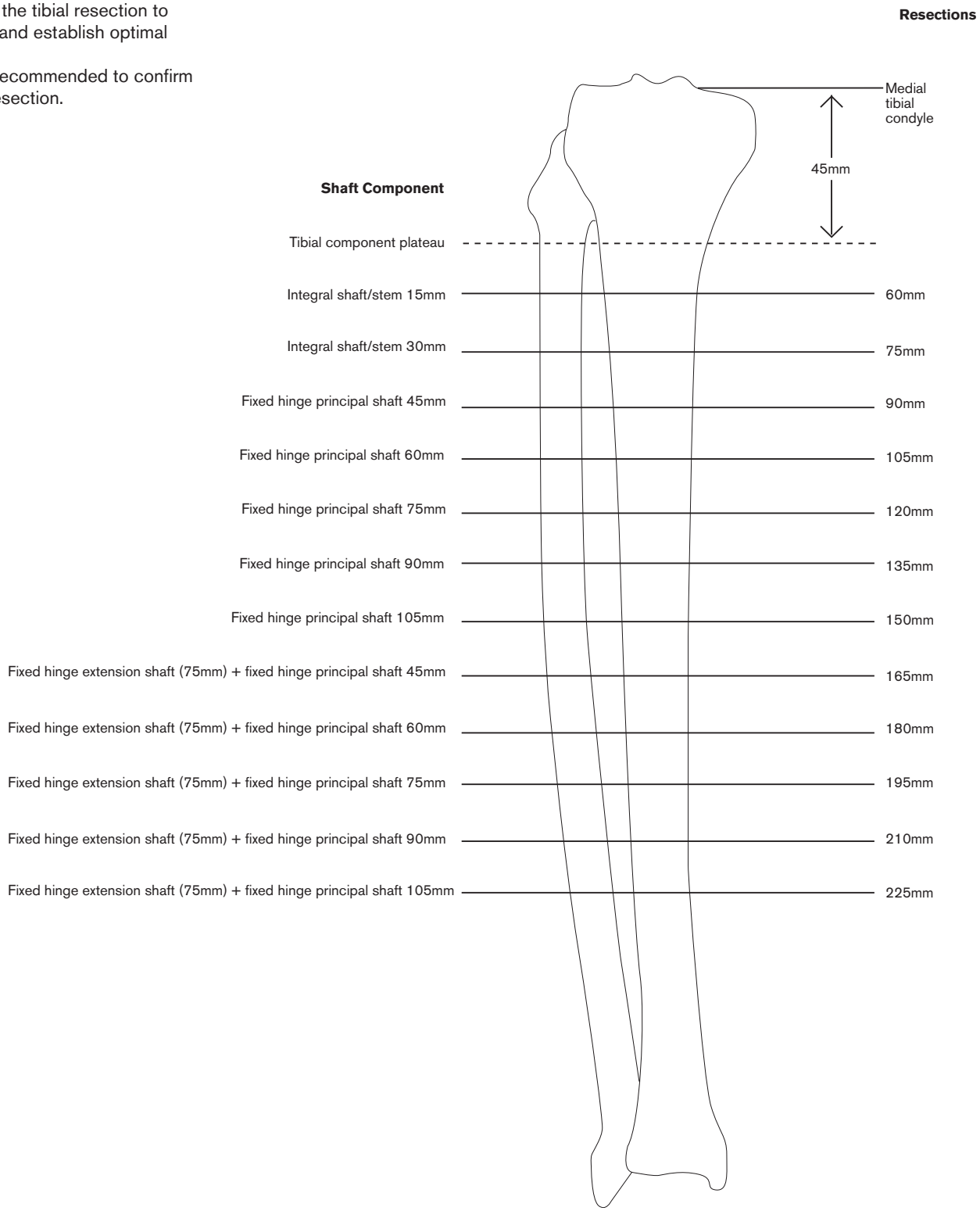
Trial collar
Ø20mm to Ø32mm trial collars.

Trial stem
Ø9 to Ø13mm straight stems in 1mm increments, 120mm long.

4.3 Tibial resection levels: fixed hinge proximal tibia

It should be noted that collar lengths are included in the resection values.

The length of the femoral resection must be considered with the tibial resection to recreate leg length and establish optimal patellar tracking.
A trial reduction is recommended to confirm satisfactory bone resection.



A

B

4.4 Tibial preparation

— Resect the tibial bone to the level required.
— Further trimming may be required when selecting the trial components. Please refer to section 4.3 as a guide.
— Ream the tibial canal using an appropriate sized flexible reamer to a depth of 120mm and to the required diameter to accommodate the tibial stem, leaving a minimum of 1mm for the cement mantle.

4.5 Short resections < 75mm

— For very short resections integral shaft/stem constructs are available in two shaft lengths 15mm and 30mm with a 120mm straight tibial stem Ø12mm.

— The 15mm integral shaft/stem construct has a fixed collar diameter of 33mm and is hydroxyapatite coated.

— The 30mm integral shaft/stem construct must be used with a hydroxyapatite collar.

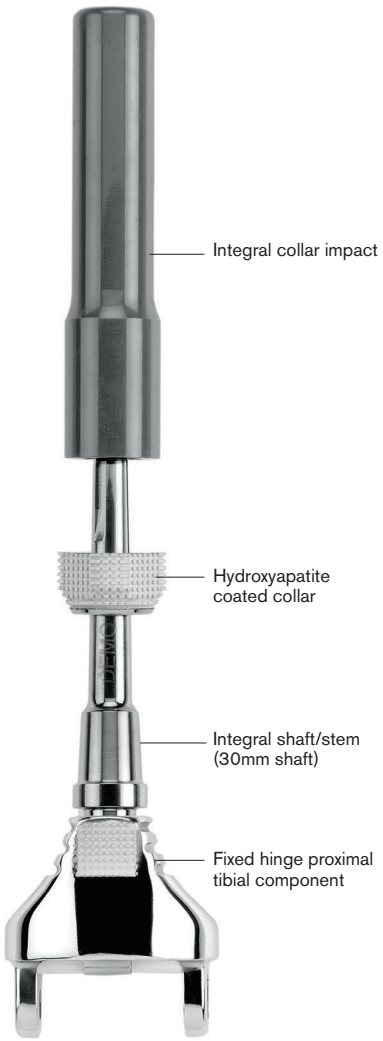
4.5.1 Trial assembly and insertion

— Select the required size and side of trial femoral component and insert into the prepared femur.
— Select appropriate size proximal tibial component and integral shaft/stem construct to replace the resected length of the tibia and assemble them as described in section 2.2. The assembly sequence should be tibial component onto the shaft stem/stem construct followed by the collar if using the 30mm integral construct. Insert the tibial assembly into the tibia.
— Insert the tibial assembly into the tibia.
— Join the trial femoral component to the tibial assembly by fully inserting the trial axle, and perform a trial reduction. Exchange trial components as required.
— If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the tibia and repeat the trial.
— Once satisfied, remove all trial components and select corresponding implant components.
— During removal of the trial implant, if the stem should become lodged within the canal and left behind, the trial stem extractor should be used to remove it as shown on Page 5.

A

C

B



4.5.2 Implant assembly and insertion

A Holding the proximal tibial component with the bore pointing upwards, insert the integral shaft/stem construct ensuring that the alignment lug is properly engaged. Place the integral collar impactor over the stem and apply multiple sharp blows using the soft hammer provided to lock the taper securely in place.

30mm integral shaft stem construct only

B To assemble the collar slide the selected collar over the stem of the assembled integral shaft/stem construct ensuring the alignments lugs are correctly engaged and the correct orientation is achieved.

C Place the integral collar impactor over the stem and using the soft ended hammer, apply multiple sharp blows taking care not to damage the hydroxyapatite coating.

The proximal tibial component is now assembled and ready for insertion.

— Using the general impactor and soft ended hammer provided, insert the proximal tibial component into the tibial canal and cement securely into place, ensuring desired rotational alignment.

— Proceed to section 5.0

A

4.6 Resections > 75mm

4.6.1 Trial assembly and insertion

A — Select the required size and side of trial femoral component and insert into the prepared femur. This picture shows the implant, not the trial.

— Select corresponding size proximal tibial component, shaft, collar and stem to replace the resected length of the tibia and assemble them as described in section 2.2. The assembly sequence should be tibial component onto the shaft followed by the collar and then the stem respectively.

— Insert the trial tibial assembly into the tibia.

— Join the trial femoral and tibial two components together by inserting the trial axle and perform a trial reduction.

— If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the tibia and repeat the trial.

— Once satisfied, remove all trial components and select corresponding implant components.

— During removal of the trial implant, if the stem should become lodged within the canal and left behind, the trial stem extractor should be used to remove it as shown on Page 5.

A

B

C

4.6.2 Implant assembly and insertion

4.6.2.1 The proximal tibial component

A — Hold the proximal tibial component with the bore pointing upwards. Insert the spigot of the required principal shaft ensuring that the alignment lug is properly engaged. Place the collar impactor into the bore on the shaft and apply multiple sharp blows using the soft hammer provided, to lock the taper securely in place.

B — Place the selected collar onto the distal end of the shaft ensuring once again the alignment lugs are correctly aligned. Holding the collar impactor over the collar, impact with multiple sharp hammer blows as shown, taking care not to damage the bore or hydroxyapatite coating.

C — Finally, insert the appropriate sized stem, ensuring the alignment lug is correctly located and impact with multiple sharp hammer blows on the end of the stem.

— The proximal tibial component is now assembled and ready for insertion.

— Using the general impactor and soft ended hammer provided, insert the proximal tibial component into the tibial canal and cement securely into place, ensuring correct rotational alignment.

— Proceed to section 5.0

A

4.7 Extensive resections > 120mm

A For resection greater than 120mm, the use of an extension shaft is required. The extension shaft is 75mm long and must be used with a principal shaft.

4.7.1 Trial assembly and insertion

- Select the required size and side of trial femoral component and insert into the prepared femur. This picture shows the implant, not the trial.
- Select appropriate size proximal tibial component, extension shaft, principal shaft, collar and stem to replace the resected length of the tibia and assemble them as described in the section 2.2. The assembly sequence should be tibial component onto the extension shaft, then the principal shaft followed by the collar and then the stem respectively.
- Insert the trial tibial assembly into the tibia.
- Join the trial femoral and tibial components together by inserting the trial axle and perform a trial reduction.
- If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the tibia and repeat the trial.
- Once satisfied, remove all trial components and select corresponding implant components.
- During removal of the trial implant, if the stem should become lodged within the canal and left behind, the trial stem extractor should be used to remove it as shown on Page 5.

A

B

C

D

4.7.2 Implant assembly and insertion

4.7.2.1 The proximal tibial component

A Holding the proximal tibial component with the bore pointing upwards insert the spigot of the fixed hinge extension shaft ensuring the alignment lug is properly engaged. Holding the collar impactor over the bore of the extension shaft impact with multiple sharp hammer blows.

B Insert the spigot of the required fixed hinge principal shaft into the bore of the extension shaft again ensuring that the alignment lug is properly engaged. Place the collar impactor into the bore of the principal shaft and apply multiple sharp hammer blows to lock the taper securely in place.

C Place the selected collar onto the distal end of the shaft ensuring once again the alignment lugs are correctly aligned. Holding the collar impactor over the collar, impact using multiple sharp hammer blows as shown taking care not to damage the bore or hydroxyapatite coating.

D Finally, insert the appropriate sized stem, ensuring the alignment lug is correctly located and impact with multiple sharp blows on the end of the stem.

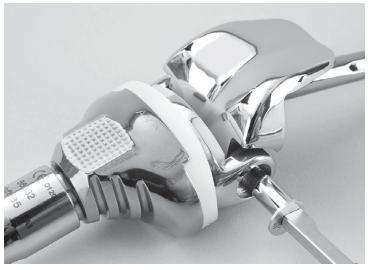
— The proximal tibial component is now assembled and ready for insertion.

— Using the general impactor and soft ended hammer provided, insert the proximal tibial component into the tibial canal and cement securely into place, ensuring correct rotational alignment.

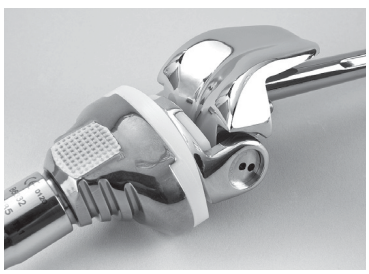
— Proceed to section 5.0

A

B



C



5.0 The femoral component

— Cement the required femoral component into the femoral canal, ensuring the correct orientation is achieved.

— Impact using the general impactor.

5.1 Femoral plateau plates

— Optional femoral plateau plates are available in 5, 10 15 and 20mm thicknesses for both small and standard sizes.

— A Using a small amount of bone cement, secure the plateau plate onto the femoral component by sliding it over the femoral stem until the anti-rotation lugs on the femoral component are located within the holes in the femoral plateau plate.

It should be noted that only one femoral plateau plate can be used. Multiple plates cannot be stacked onto one another.

5.2 Insertion of the axle and circlip

5.2.1 Insertion of axle

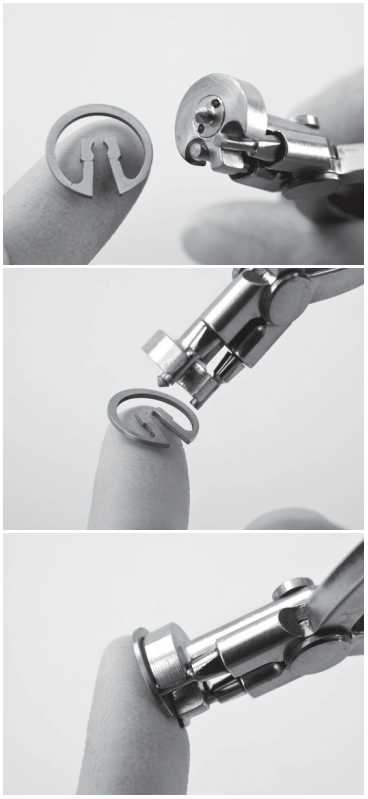
— B Align the femoral and tibial components and insert the axle into position as shown. It should be noted that the axle can be inserted from either side of the knee joint.

— Using the pronged end of the circlip pliers handle, push the axle in place. If required, rotate the axle to engage the axle head into the offset recess in the tibial component.

— C Check to ensure the axle head is correctly seated inside the recess and that it is not trapped within the circlip groove.

— The axle is secured by inserting the circlip as described in section 5.2.2

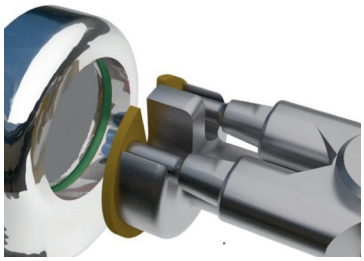
A



B – Correct

C – Incorrect

D



E

5.2.2 Use of circlip pliers

A The circlip and the circlip pliers are designed to clip together for ease of use. The best way to place the circlip onto the pliers is by holding the circlip on your finger tip and then pushing the pliers into it ensuring the central pin locates in the centre of the circlip and the two moving jaws are either side of the central strips of the circlip as shown in the pictures below.

B A correctly inserted circlip is shown on the left with the jaws of the circlip pliers in the correct position.

C This picture on the left shows an incorrectly inserted circlip. This would not function and the circlip needs reinserting. (Requires rotating 180°)

D Squeeze handle of circlip pliers to close the circlip, and push circlip into groove (shown in green)

— Release handle of circlip pliers to open the circlip within the groove and pull circlip pliers to unclip from the circlip. and pull to unclip from the circlip.

E Ensure that the circlip is seated inside the groove in the tibial component and then, using a pointed implement, rotate it to ensure it turns inside the groove. Rotation of the circlip ensures the circlip is fully engaged in the groove.

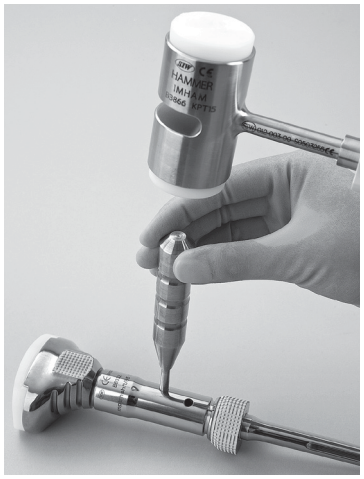
— Separately package components are available if required. See section 6.0

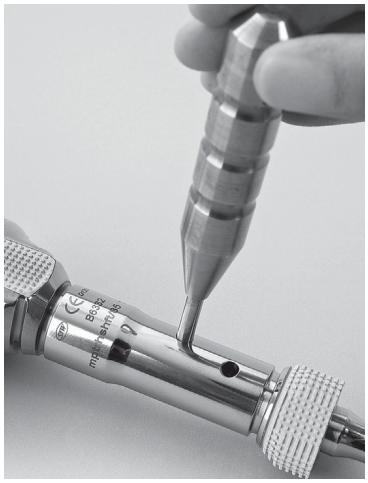
5.3 Disassembly

A — During revision surgery, it may be necessary to disassemble the implant. This is achieved by inserting the distraction tool into the anterior hole of the shaft and impacting with a hammer.

— The distraction tool has a flat, which should locate on the end of the inner spigot. Parts are for SINGLE USE only and cannot be reused.

A

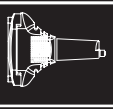
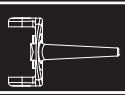


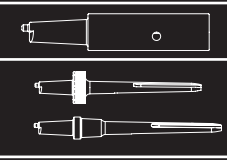


Femoral knee				
Components	Small	Left		mptfc/LSm
	Small	Right		mptfc/RSm
	Standard	Left		mptfc/LStd
	Standard	Right		mptfc/RStd
Proximal tibia				
Fixed hinge	Small			mptfh/SmU
Plain uncoated	Standard			mptfh/StdU
Fixed hinge	Small			mptfh/SmC
With reattachment	Standard			mptfh/StdC
HA coated				
Rotating hinge	Small			mptrh/SmU
Plain uncoated	Standard			mptrh/StdU
Rotating hinge	Small			mptrh/SmC
With reattachment	Standard			mptrh/StdC
HA coated				
Tibial components				
Rotating hinge	Small			mktsc/Sm
	Standard			mktsc/Std
Tibial shafts				
Fixed hinge	45mm			mptfhshft/45
	60mm			mptfhshft/60
	75mm			mptfhshft/75
	90mm			mptfhshft/90
	105mm			mptfhshft/105
Tibial extension shaft				
Fixed hinge	75mm			mptfhext/75
Integral shaft & stems	Shaft	Stem		
Fixed hinge	L = 15 D = 33	L=120 D=10>9		mptfhiss/15C
	L = 30 D = 33	L=120 D=10>9		mptrhiss/30N
Tibial shafts				
Rotating hinge	85mm			mptrhshft/85
	100mm			mptrhshft/100
	115mm			mptrhshft/115
Tibial extension shaft				
Rotating hinge	85mm			mptrhext/85
Integral shafts & stems	Shaft	Stem		
Rotating hinge	L = 55 D = 26	L=120 D=10>9.5		mptrhiss/55C
	L = 55 D = 26	L=120 D=10>9.5		mptrhiss/70N
Tibial collars				
HA coated	Ø20			mptcol/20C
	Ø23			mptcol/23C
	Ø26			mptcol/26C
	Ø29			mptcol/29C
	Ø32			mptcol/32C
Tibial stems				
	Ø9 > 8mm			mptstm/9
	Ø10 > 9mm			mptstm/10
	Ø11 > 10mm			mptstm/11
	Ø12 > 11mm			mptstm/12
	Ø13 > 12mm			mptstm/13
Femoral plateau plates	Small	5mm		mkfp/Sm5
	Small	10mm		mkfp/Sm10
	Small	15mm		mkfp/Sm15
	Small	20mm		mkfp/Sm20
	Standard	5mm		mkfp/Std5
	Standard	10mm		mkfp/Std10
	Standard	15mm		mkfp/Std15
	Standard	20mm		mkfp/Std20

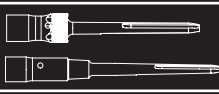











Other components available in small and standard sizes	Axle, Circlip, Bumper pad, Bushes and Tibial Bearing also available in Small and Standard sizes packaged separately

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