
METS Modular Total Femur



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1.1 Product overview

The METS total femoral replacement system is designed as a modular system that can be used to replace diseased or deficient bone in the femur. The system also allows the conversion of the Proximal and Distal femoral systems into a Total femur using a link shaft. The system consists of a variety of different trochanter sections, anatomical in shape, with provisions for trochanteric attachment, a range of shafts in 15mm increments to suit differing lengths of resection, a link shaft available in two lengths of 165mm and 225mm, and a SMILES Knee.

Individual components of the femoral shaft are connected using interlocking taper junctions allowing quick and easy assembly. The SMILES Knee has three tibial options in two sizes; rotating hinge polyethylene tibia suitable for routine cases rotating hinge metal casing tibia with short and long stems suitable for extra-articular resections or difficult revisions and a fixed hinge tibia with short and long stems suitable for knees with marked instability or gross deformity. For very special cases, the modular system can be used in conjunction with custom-made components to provide an off the shelf solution.

1.2 Indications

- Limb salvage procedures where radical resection and replacement of the bone is required
- Painful and disabled joint resulting from avascular necrosis osteoarthritis, rheumatoid arthritis or traumatic arthritis
- Correction of varus, valgus or post traumatic deformity
- Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
- Ligament deficiencies
- Tumour resections
- Revision of previously failed total joint arthroplasty
- Trauma
- Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques

1.3 Absolute contra-indications

- Existing 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
- Compromised patella

1.5 Capabilities and restrictions of use

- The components are designed and manufactured and are 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 total femoral replacement must consist of a trochanter section with a suitable head, a link and principal shaft, a femoral component with bushes, an axle and a circlip, and one of the three optional tibial assemblies with a bumper pad.
- 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.
- A set of instruments is provided to assist assembly of the prosthesis, which includes a set of trial components. Some trial components are colored to easily distinguish from implant components. Trochanters, collars and trial shafts and trial tibial components are anodized blue. Trial femoral components however are not anodized.
- 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 come into contact with any stainless steel devices, as this will induce galvanic corrosion.**

The surgeon will need to select the correct acetabular cup supplied with the kit to match the chosen femoral head

- The trochanteric plate is to be used for hard tissue fixation only.

1.6 Components of the modular total femur

Femoral head

Ø28 and Ø32mm Cobalt Chromium heads with varying neck lengths (It is recommended that Ø22mm femoral heads should not be used due to neck impingement and increased risk of dislocation). Ceramic heads and large hemi heads in sizes Ø34 – Ø56mm are available on special request.

Link shaft

165 and 225mm curved titanium link shafts with male fittings at both ends.

Principal shaft

45 to 150mm titanium shafts in 15mm increments.

Soft/Hard tissue attachment

An optional set of trochanters with soft/hard tissue attachment either using a plate and two screws or using a titanium or cobalt chromium wire.

Trochanter

67mm long titanium trochanters measured from the head centre to plateau. Side specific with the option of using a ligament attachment and available with two head offsets 32.5 and 45mm.

Femoral component

A cobalt-chromium-molybdenum femoral component anatomical for left and right sides available in two sizes. small and standard.

Axle, Bushes and Circlip

A cobalt-chromium-molybdenum axle, a pair of UHMWPE bushes available in both sizes and a titanium circlip.

Bumper pad

An UHMWPE bumper available in both sizes providing a secondary bearing surface and a soft hyperextension stop.

SMILES Knee

Knee components are available in small and standard sizes with three different types of tibial arrangements.



Rotating hinge metal cased tibia
A UHMWPE tibial bearing with a Co-Cr-Mo tibial component and titanium casing. Stem length 140mm and 180mm.



Rotating hinge polyethylene tibia
A Co-Cr-Mo tibial component with UHMWPE tibial bearing. Stem length 105mm for Small and 114mm for Standard knee.



Fixed hinge tibia
A Co-Cr-Mo tibial component. Stem length 140mm and 180mm.

Tibial plateau plates
Optional tibial plateau plates (not shown) are available in 5, 10, 15 and 20mm thickness for use with rotating hinge metal cased or fixed hinge tibial components.

2.1 Components of the trial implant

Link shaft
165 and 225mm in length, with male fittings at both ends.

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

Trial axle

Trial tibial mono-blocks
Represents each of the three tibial assemblies.



Rotating hinge metal cased tibia
Stem length 140 and 180mm in both Small and Standard sizes.



Rotating hinge polyethylene tibia
Stem length 105mm for Small and 114mm for Standard size.



Fixed hinge tibia
Stem length 140 and 180mm in both Small and Standard sizes.

Trial femoral head
28 and 32mm diameter heads with varying neck lengths. Large trial heads ranging from 34 to 56mm are available on request.

Trial trochanter
67mm long trochanters measured from the head centre to plateau. Small and Standard in left-hand and right-hand versions.

Trial principal shaft
45 to 150mm principal shafts in 15mm increments.

Tibial plateau plates (not shown) are available in 5, 10, 15 and 20mm thicknesses for use with rotating hinge metal casing or fixed hinge tibial components.

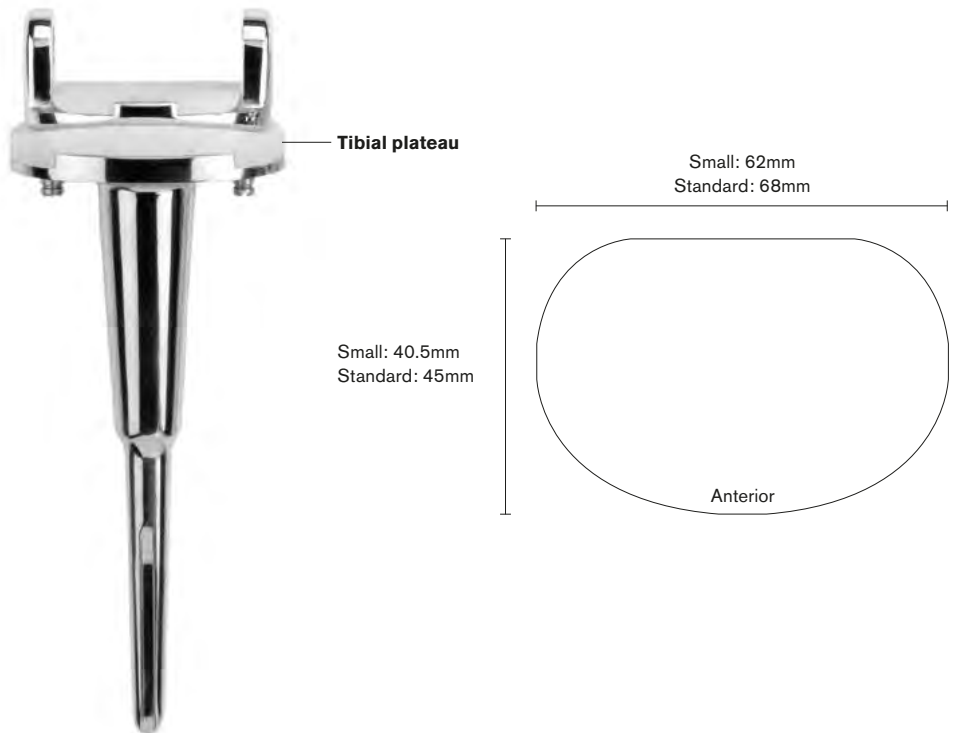
2.2 SMILES Knee dimensions

2.2.1 Femoral component

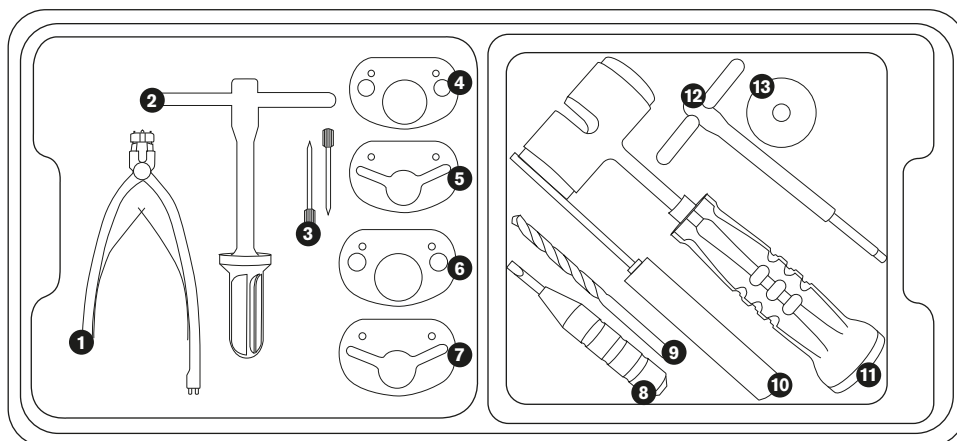


2.2.2 Tibial component

(Metal cased rotating hinge tibial component shown, but plateau dimensions are the same for all three tibial options)

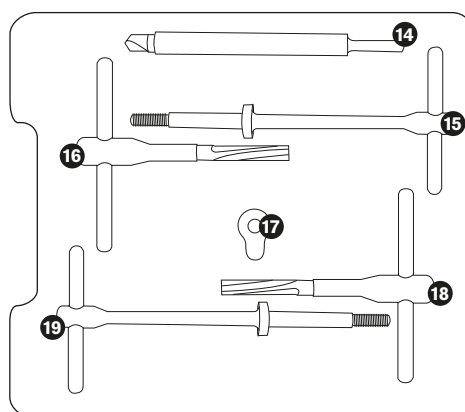


2.3 Special instruments



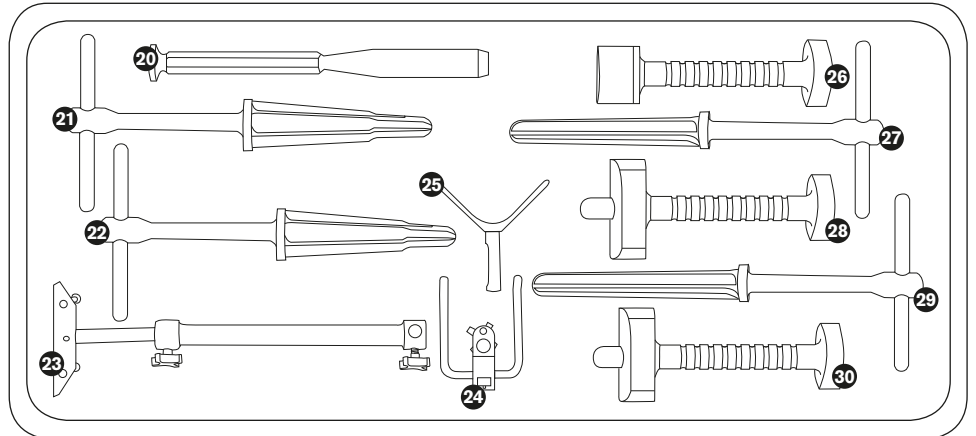
Layer 1

- 1 Circlip pliers
- 2 Tibial reamer: Fixed hinge
- 3 Pins (x2)
- 4 Positioning plates with holes, Small
- 5 Positioning plates with slot, Small
- 6 Positioning plates with holes, Standard
- 7 Positioning plates with slot, Standard
- 8 Distraction Tool
- 9 6mm Drill
- 10 Trial Stem Extractor
- 11 Hammer (with soft ends)
- 12 Allen/Hex Key 4mm
- 13 Collar Impactor



Layer 2

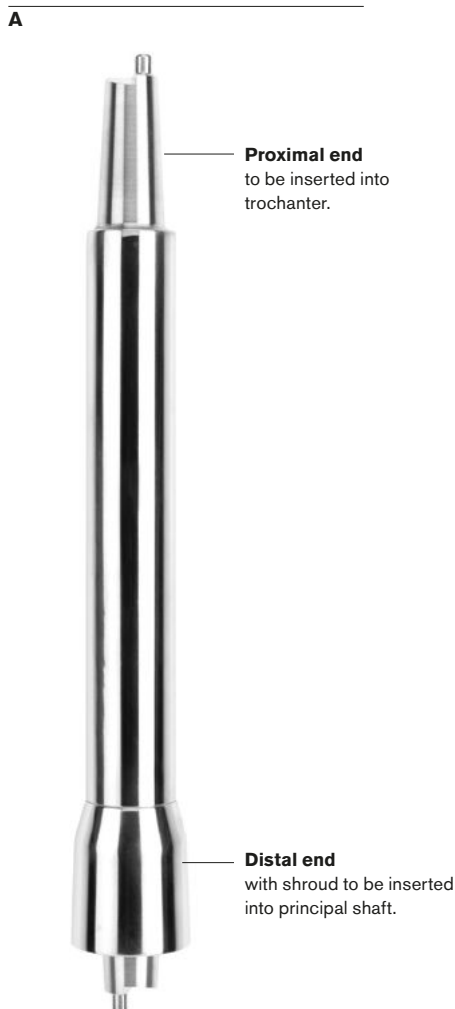
- 14 A R Lug drill
- 15 Bush compressor, Small
- 16 Bush reamer, Small
- 17 Compressor nut
- 18 Bush reamer, Standard
- 19 Bush compressor, Standard



Layer 3

- 20** Osteotome
- 21** Tibial reamer metal casing, Standard
- 22** Tibial reamer metal casing, Small
- 23** Tibial cutting guide
- 24** Tibial cutting guide
- 25** Tibial cutting guide
- 26** General impactor
- 27** Tibial reamer: Poly Small
- 28** Tibial bearing impactor, Standard
- 29** Tibial reamer: Poly Standard
- 30** Tibial bearing impactor, Small

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



3.1 Link Components

- There are two link shafts available in lengths 165mm and 225mm. The link components have male fittings at both ends. On the distal end of the link shafts, the male fitting has a shroud. It is this end that is matched with the female end of the principal shaft of the distal femoral implant. The proximal end of the link shaft should be mated with the trochanter. It should be noted that the link shaft should be placed proximally into the femur so the curve of the link shaft matches the natural curvature of the femoral bone.

3.2 Pre-operative planning

It is important to assess the radiographs in order to establish the approximate size of the components required. This will help reduce the number of trials needed during surgery. The following addition points may be considered during assessment:

- The neck offset (Small or Standard)
- Trochanter (with or without attachment)
- Link shaft length
- Principal shaft length
- Knee size (Small or Standard)
- Choice of tibial component (rotating hinge polyethylene, rotating hinge metal cased or fixed hinge)
- Length of tibial component (Short or Long. This only applies to rotating hinge metal cased and fixed hinge tibial components)
- Use of Plateau Plates (for rotating hinge metal cased and fixed hinge tibial components only.)

3.3 Recommendations for component selection

3.3.1 Trochanter

Ligaments incorporated with bone should ideally be attached to the trochanter using the plate and the screws provided.

Alternatively, they can be attached using cobalt chromium wire as a suture.

Under no circumstances should stainless steel wire be used as this will induce galvanic corrosion.

Ligaments without bone should only be attached with the plate and screw.

3.3.2 Shafts

The prosthetic construct should consist of one link shaft and one principal shaft only. More than one principal shaft must not be used.

Shaft selections for varying length total femurs can be determined from the tables below. The “length of femoral implant” values correspond to femoral length taken from centre of the femoral head to the medial femoral condyle.

Small Sized SMILES Knee

Rotating Hinge	Fixed Hinge	Principal shaft lengths	
		To be used with 165mm link shaft	To be used with 225mm link shaft
Length of Femoral implant (mm)	Length of femoral implant (mm)		
345	338	45	
360	353	60	
375	368	75	
390	383	90	
405	398		45
420	413		60
435	428		75
450	443		90
465	458		105
480	473		120
495	488		135
510	503		150

Standard Sized SMILES Knee

Rotating Hinge	Fixed Hinge	Principal shaft lengths	
		To be used with 165mm link shaft	To be used with 225mm link shaft
Length of Femoral implant (mm)	Length of femoral implant (mm)		
352	345	45	
367	360	60	
382	375	75	
397	390	90	
412	405		45
427	420		60
442	435		75
457	450		90
472	465		105
487	480		120
502	495		135
517	510		150

Please note: The table provided is a guide only. The implant lengths are in 15mm increments. Please use the trial components provided to ascertain the correct length of implant required.

3.3.3 Tibial components

Ideally, a Rotating hinge polyethylene tibial component is recommended for cases where tibial cortical bone is strong as in most primaries and some revision cases. Rotating hinge metal cased tibial components are more suited for revision cases where the knee has reduced stability and/or where tibial plateau plates are required to maintain the joint line, for instance extra-articular resection. Fixed hinged tibial components should be considered where there is marked instability of the joint.

3.4 General points to consider when using the trial components

- Choose appropriate size trial trochanter, link shaft, principal shaft, knee size and type of tibial component.
- Only the femoral component and trochanter are anatomical, the rest of the components are not. There is a built-in 10° anteversion of the neck on the trochanters.
- When inserting the trial prosthesis and acetabular component, please ensure 10° anteversion of the femoral neck is orientated correctly. Select the appropriate color-coded trial femoral head (head size and offset).
- There is only one size axle for the trial components, which can be used for both small and standard sized knees and 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 volume of actual implant components and therefore, during trial reduction, they should provide an indication of the degree of soft tissue coverage and the function of the device. Alternative sized components can be chosen at any point to ensure the optimal fit.
- The trial tibial components represent only the size and shape of the actual tibial construct and therefore do not rotate.

**3.5 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 contamination of the interlocking mechanism, which can impair the performance of the implant.
- Impact each junction as described in section 3.7 in order to provide optimum strength to the joint. This is important since each interface will experience large bending forces that can 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.
- As the tibial canal preparation will vary according to the type of tibial component selected, it is advised that the correct trial tibial component is chosen i.e. rotating hinge polyethylene, rotating hinge metal cased or fixed hinge before any preparation of the tibia is undertaken.

3.5.1 Bone Preparation

It should be noted that there is no prescribed order as to which bone (the acetabulum or tibia) is prepared first.

3.5.2 Tibial Resection Levels

Rotating hinge polyethylene

Rotating hinge metal cased

Fixed hinge

Note:
These dimensions are for guidance only.
Due to degeneration and laxity of the knee,
more bone may need to be trimmed if
necessary.

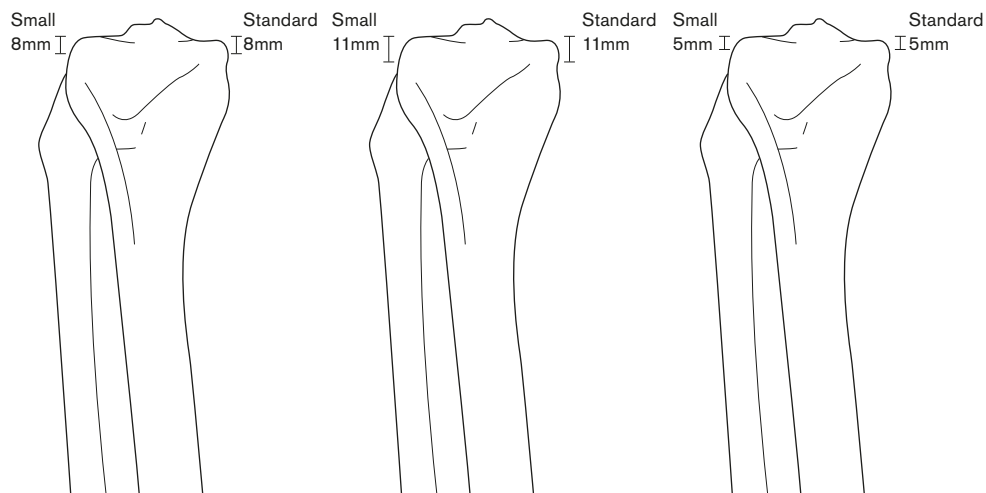




Plate with slots
for rotating hinge polyethylene tibia



Plate with holes
for rotating hinge metal cased and fixed
hinge tibial components.

3.5.3 Tibial preparation

- A** Resect the top of the tibia using the tibial cutting guide provided. Adjust the prongs of the tibial guide so that they sit into the condyles of the tibia. It is recommended that 8mm is resected for rotating hinge polyethylene tibial components, 11mm resection for rotating hinge metal cased tibias and 5mm resection for fixed hinge tibial components.
- B** Based on the type of tibial composition to be used, place a tibial positioning plate onto the cut surface of the tibia ensuring the straight edge of the plate is on the posterior side. Also, since the straight edge of the plate corresponds to the axis of the knee joint, rotate it so that the foot is correctly orientated before fixing it using the pins provided.
- C** For a rotating hinge polyethylene tibial component use, the plate with slots.
- D** For rotating hinge metal cased and fixed hinge tibias, use the plate with holes.

E



E Ream the tibial canal through the central hole using the appropriate reamer (specific for the type of tibial component chosen).

— For the rotating hinge metal cased and the fixed hinge tibial components, in addition to the proximal reamer and if required, ream the distal canal to a depth of 140mm for short stems and 180mm for the long stems using a Ø12mm flexible reamer.

F For rotating hinge polyethylene tibial component, use the osteotome to cut the slots to a depth of 8 to 10mm.

G For rotating hinge metal cased and fixed hinge tibial components, use the Ø10mm drill piece to cut 10mm deep holes for the anti-rotational lugs.

3.5.4 Acetabular preparation

Prepare acetabulum in accordance with the instructions provided in the surgical planning guide.

F



The tibia is now prepared

G





3.6 Trial Assembly and insertion

- Select the required size and type of trial tibial mono-block and insert into the tibial canal.
- Select appropriate size femoral component, link and principal shaft and trochanter component to replace the length of the femur and assemble them as described in the section 3.4.
- The assembly sequence should be femoral component onto the principal shaft followed by the link shaft onto the principal shaft followed by the trochanter.
- Insert the femoral assembly into the femur ensuring 10° anteversion of the femoral neck is correctly orientated.
- Select the appropriate color coded trial femoral head (head size and offset).
- Join the two components together by insertion of the trial axle ensuring that it is correctly seated before performing a trial reduction. Replace trial construct as required until satisfactory assembly is produced.
- Once satisfied, remove all trial components and select corresponding implant components.



A



3.7 Implant assembly

A Holding the principal shaft so that the male end is facing upwards, insert the femoral component onto the shaft ensuring the alignment lug is properly engaged and impact onto the flat of the femoral component by applying multiple sharp blows using the soft hammer provided.

B Next, holding the link shaft with the shrouded male end pointing upwards, insert the principal shaft/femoral component assembly, again ensuring the correct orientation of the alignment lug and impact onto the flat of the femoral component, again with multiple sharp blows.

B



C Holding the implant assembly with the exposed male end of the link shaft facing upwards, insert the trochanter and impact onto the flat of the trochanter with multiple sharp blows.

C



The total femoral implant is now ready for insertion.



3.8 Implant insertion

- Remove the outer tibial component from the specific tibial assembly chosen.
- For the rotating hinge arrangements, cement the appropriate tibial component into the tibial canal, i.e. for rotating hinge polyethylene assembly, cement the long plastic tibial component. For the rotating hinged metal cased tibial arrangement, cement the outer metal tibial casing.

— Impact using the plastic impactor.

— Once cemented securely in place, reposition the tibial bearing components into the cemented tibial casing.

— For the Fixed hinge tibial arrangement, simply cement the component into the canal and impact using the general impactor.

— Ensuring 10° anteversion of the femoral neck, insert the total femoral implant into the leg.

— Ensure that the trunion and femoral head taper are clean and damage free. Use the trial heads to assess the femoral head neck length. Finally place the selected femoral head firmly onto the trochanter trunion.

— If the option of trochanter attachment is used, once the joint is reduced, stretch detached trochanter/ligaments and centralise over the spikes. If a wire is to be used for fixation, push the tissues securely into the spikes of the trochanter and secure using the cobalt chromium wire provided. For this, a series of holes are provided in the clamp region.

Under no circumstances should stainless steel wire be used since this would induce galvanic corrosion.

— If a bolted plate is to be used for fixation, using the trochanter plate as a drill guide positioned correctly over the detached trochanter/ligaments, drill two 6mm holes. With the plate in position, insert two appropriate length screws and tighten them over the spikes using the key provided. To select an appropriate length screw, use the following guide:

Trochanter / ligament thickness	
(mm)	Screw
3 to 9	Short – 23mm long
9 to 15	Medium – 29mm long
15 to 21	Long – 35mm long

3.9 Acetabular preparation

Select the suitable correct acetabular cup depending upon head size and patient requirements as per list below

Acetabular Cup	
ID/OD in mm	Reference code
28-46mm	ACNC 28-46
28-48mm	ACNC 28-48
28-50mm	ACNC 28-50
28-52mm	ACNC 28-52
28-55mm	ACNC 28-54
28-56mm	ACNC 28-56
32-48mm	ACNC 32-48
32-50mm	ACNC 32-50
32-52mm	ACNC 32-52
32-54mm	ACNC 32-54
32-56mm	ACNC 32-56

After the skin incision and fully exposure the rim of the acetabulum, ensure that all the osteophytes around the acetabulum are removed, a progressively acetabular reamer (cheese-grater type device) is used to create a perfect hemispherical bone socket, finished with the final reamer which is 2mm larger than the external shape of the selected acetabular cup. The reamer should be held steadily with even pressure in the same direction in which the cup will be implanted. Multiple small anchoring holes can be drilled in the portions of the acetabulum to provide greater fixation and torsional resistance for the cement mantle.

Prior to introducing the bone cement, the reamed acetabulum should be lavaged, cleaned and dried. The bone cement can then be mixed and packed into the acetabulum. Using a cement compressor to hold acetabular cup in position with sustained and firm pressure until cement is set and solid. Any extruded cement from the periphery of the compressor should be removed and cleaned. The position of the cup should normally be aimed at inclination of 40 ± 10 degrees and anteversion of 15 ± 10 degrees.

A



B



C



3.10 Insertion of the Axle and circlip

- A** — 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.

- B** — 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 femoral component.

- C** — Check to ensure the axle head is correctly sitting 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 3.10.

A



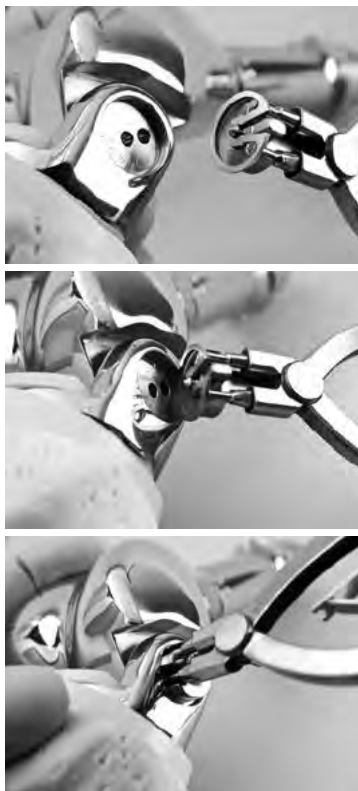
B - Correct



C - Incorrect



D



E

















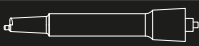



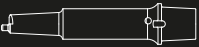












































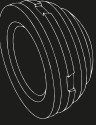


3.11 Use of circlip pliers

- A** — The circlip and the 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.
- 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** — The circlip is best inserted into the knee by holding the circlip at an angle, then placing the circular part of the circlip into the groove in the tibial component and then straightening and pushing the circlip into position as shown.
- Release circlip pliers 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.

3.12 Disassembly of prosthesis

During revision surgery, it may be necessary to disassemble the implant, which is achieved by inserting a distraction tool through the anterior hole on the shaft and impacting it 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.**

Trochanters						
Smooth	Small	left		mstrc/LSmlU		
Uncoated	Small	right		mstrc/RSmIU		
	Standard	left		mstrc/LStdU		
	Standard	right		mstrc/RStdU		
Spiked	Small	left		mstrc/LSmlC		
HA coated	Small	right		mstrc/RSmIC		
	Standard	left		mstrc/LStdC		
	Standard	right		mstrc/RStdC		
Trochanter plate				msfpte		
Trochanter screws	Short			msfscw/Short		
	Medium			msfscw/Medium		
	Long			msfscw/Long		
Trochanter Reattachment wire	0.6m			mstrw		
Total femoral link components	165mm			mstfl/165		
	225mm			mstfl/225		
Principal shafts	45mm			msfshft/45		
	60mm			msfshft/60		
	75mm			msfshft/75		
	90mm			msfshft/90		
	105mm			msfshft/105		
	120mm			msfshft/120		
	135mm			msfshft/135		
	150mm			msfshft/150		
Femoral knees	Small	Left		mkfe/LSm		
	Small	Right		mkfe/RSm		
	Standard	Left		mkfe/LStd		
	Standard	Right		mkfe/RStd		
Tibial: rotating hinges Polyethylene	Small			mkrhp/Sm		
	Standard			mkrhp/Std		
Tibial: rotating hinges Metal casing	Small	Short Stem		mkrhm/SmSt		
	Standard	Short Stem		mkrhm/StdSt		
	Small	Long Stem		mkrhm/SmLg		
	Standard	Long Stem		mkrhm/StdLg		
Tibial: fixed hinges	Small	Short Stem		mkfh/SmSt		
	Standard	Short Stem		mkfh/StdSt		
	Small	Long Stem		mkfh/SmLg		
	Standard	Long Stem		mkfh/StdLg		
Tibial: plateau plates						
Small	Sml 5mm			mktp/Sm5		
	Sml 10mm			mktp/Sm10		
	Sml 15mm			mktp/Sm15		
	Sml 20mm			mktp/Sm20		
Standard	Std 5mm			mktp/Std5		
	Std 10mm			mktp/Std10		
	Std 15mm			mktp/Std15		
	Std 20mm			mktp/Std20		
CoCr femoral heads	Ø28mm	-3.5mm		msfmh/cc28-3.5		
	Ø28mm	0mm		msfmh/cc28-0		
	Ø28mm	+3.5mm		msfmh/cc28+3.5		
	Ø28mm	+7mm		msfmh/cc28+7		
	Ø28mm	+10.5mm		msfmh/cc28+10.5		
	Ø32mm	-4mm		msfmh/cc32-4		
	Ø32mm	0mm		msfmh/cc32-0		
	Ø32mm	+4mm		msfmh/cc32+4		
	Ø32mm	+8mm		msfmh/cc32+8		
Acetabular Cup	28-46mm			ACNC 28-46		
	28-48mm			ACNC 28-48		
	28-50mm			ACNC 28-50		
	28-52mm			ACNC 28-52		
	28-54mm			ACNC 28-54		
	28-56mm			ACNC 28-56		
	32-48mm			ACNC 32-48		
	32-50mm			ACNC 32-50		
	32-52mm			ACNC 32-52		
	32-54mm			ACNC 32-54		
	32-56mm			ACNC 32-56		



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