
METS Modular Proximal Femur



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1.1 Product overview

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

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 amounts of resection, a range of different diameter collars to match the size of the resected bone and a range of stems to suit the intramedullary canal.

To complement the system, a range of modular metal and ceramic heads are also available. Individual components of the system are connected using interlocking taper junctions allowing quick and easy assembly.

1.2 Indications

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

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

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 proximal femoral replacement must consist of a trochanter section, a shaft with or without extension piece, a stem, a collar and a femoral head. The collar is not an optional item and must be used. Failure to do so may result in excessive subsidence of the prosthesis. A plain collar is provided if hydroxyapatite coating is not required.
- 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 prosthesis, which includes a set of trial components. All trial components are anodized blue to easily distinguish from implant components. In addition, the trial components can not be used in combination with implant components.
- The proximal femoral replacement must only be used with the specified femoral heads.
- The surgeon will need to select the correct acetabular cup supplied with the kit to match the chosen femoral head.
- This implant is produced from titanium alloy and therefore **under no circumstances should it be allowed to contact another stainless steel device since this would induce galvanic corrosion.**
- The trochanteric plate is to be used for hard tissue fixation only.

1.6 Components of the proximal femoral implant

Soft/Hard tissue attachment

An optional set of trochanters for hard tissue attachment only 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, with Ø3mm ligament holes. The only side specific component in the system. 32.5mm and 45mm head offsets for the small and standard sizes, respectively.

Collar

Ø27 to Ø36mm round titanium collars, in 3mm increments with hydroxyapatite coated stipples or smooth uncoated.

Cemented stem

Ø10 to Ø15mm curved titanium stems increasing in 1mm increment, 150mm in length, suitable for short to medium resection. Ø14 and Ø15mm straight titanium stems, 100mm in length, suitable for very long resection.



Femoral head
Ø28 and Ø32mm Cobalt Chromium heads with varying neck lengths.

Shaft

45 to 150mm long titanium shafts in 15mm increments. Also, a 120mm extension shaft to further increase the length capability giving a total range of 112mm to 337mm from the head centre to plateau.

Integral shaft stem component (not shown)

For short resections, <112mm. Available in 15mm and 30mm shaft lengths, in sizes: Ø27mm plateau with 150 x Ø11 > Ø7mm stem and Ø30mm plateau with 150 x Ø13 > Ø9mm stem.

2.1 Components of the trial implant

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

Trial collar
Ø27 to Ø36mm collars, in 3mm increments.



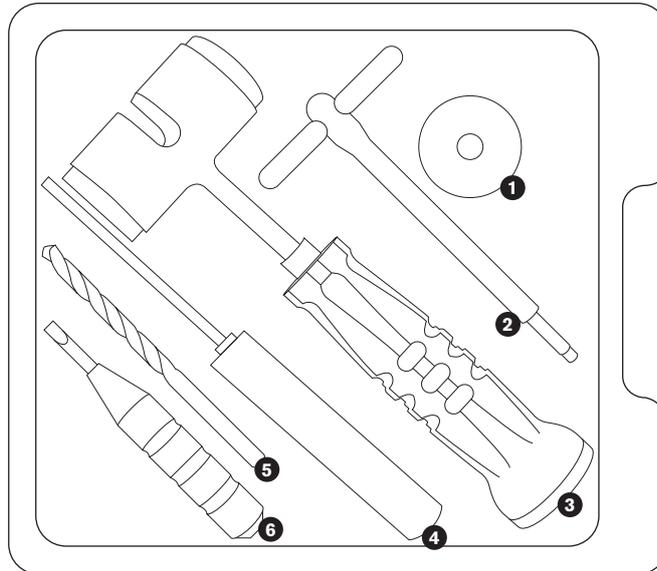
Trial femoral head
Ø28 and Ø32mm heads with varying neck lengths. Large trial heads ranging from Ø34 to Ø56mm are available on request.

Trial shaft
45 to 150mm principal shafts in 15mm increments with a 120mm long extension shaft.

Trial integral shaft stem component
For short resections. Two shaft lengths available, 15mm and 30mm. Stems 150 x Ø13 > Ø9 or 150 x Ø11 > Ø7

Trial stem
Ø10 to Ø15mm curved stems in 1mm increments and 150mm long. Ø14 and Ø15mm straight stems 100mm long.

2.2 Special instruments



- 1** Collar impactor
- 2** Hex key 4mm
- 3** Hammer (with soft ends)
- 4** Trial stem extractor
- 5** 6mm drill
- 6** Distraction tool

In addition to these instruments, it is anticipated that the theatre should make available a bone saw, a set of AO reamers from Ø11 to Ø17mm, appropriate cement application device and acetabular instrumentation.

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3.1 Pre-operative planning

It is important to assess the radiographs before the operation to establish the approximate size of the components required for each individual patient. This will help reduce the number of trials needed during surgery.

The following additional points may be considered during assessment:

- The neck offset (small or standard)
- Trochanteric attachment (with or without attachment)
- Collar type (with hydroxyapatite coating or plain)
- Availability of an acetabular component; this is not supplied as a part of this system and any acetabular cup with the same nominal internal diameter can be used.

3.2 Recommendations for component selection

— 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 either titanium or cobalt chromium wire as a suture. **Under no circumstances should stainless steel wire be used since this would induce galvanic corrosion.** Ligaments without bone should only be attached with the plate and screws.

— Shaft

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

— Stem

In order to optimize the implant fixation and strength, it is recommended that, where possible, a 150mm stem is used and the largest diameter is chosen whilst still allowing a minimum cement mantle of 1mm.

In selecting the shaft and stem components the surgeon needs to ensure that they are suitably sized to ensure that there is no risk of damage to the femoral epiphysis or the distal femur articular surface.

- For minimal resections (less than 112mm from the centre of the femoral head) all-in-one integral shaft stem components are available.

3.3 General points to consider when using trial components

- Except the collars, all trial components are assembled with a 'push & click' mechanism and the rotational orientation is controlled by an anti-rotation lug.
- The collar, which is unidirectional, is simply slid over the shaft and is held in position by the insertion of a stem.
- The trochanter is anatomical with a built-in 10° anteversion of the neck.
- 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 time to ensure optimal fit.

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

**3.4 Recommendations for assembly
of implant**

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

- Always assemble an implant fully before exposing it to the body's environment since contaminating the interlocking mechanism might impair the performance of the implant.
- Impact each junction as described in section 3.0 to provide optimum strength to the joint. This is important since each interface will experience large bending forces that would result in excessive wear and fretting if not correctly assembled.
- Care must be exercised when assembling components with hydroxyapatite coating, as it is brittle and can easily be damaged.

3.5 Bone preparation

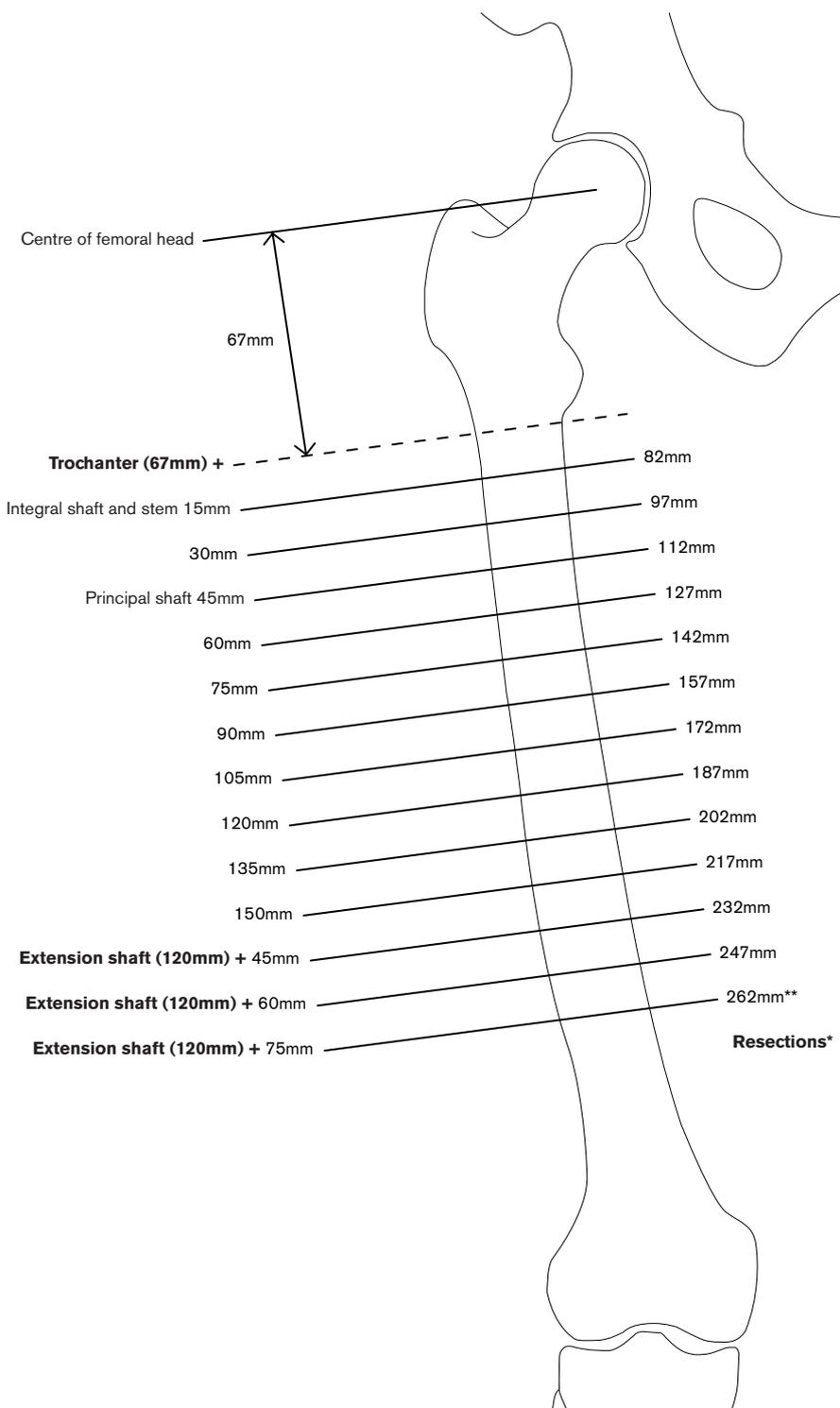
It should be noted that there is no prescribed order as to which bone (acetabulum or femur) is prepared first.

3.5.1 Acetabular preparation

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

3.5.2 Femoral resection levels

Please note that collar lengths are included in the resection values.



NB:*Resection levels are provided as guidance and a trial reduction should be performed to confirm satisfactory bone resection.

**Longer resection can be achieved by using the next principal shaft with the extension shaft.

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3.6 Short resections < 112mm

- For minimal resections less than 112mm, where the shortest shaft may not be suitable, the integral shaft stem construct may be used.
- Available in two shaft lengths of 15mm and 30mm, the integral shaft/stem construct is available with hydroxyapatite coated stipples, in sizes: Ø27mm plateau with 150mm long x Ø11mm stem or Ø30mm plateau with 150mm x Ø13mm stem.

3.6.1 Trial assembly and insertion

- Select the appropriate size and side trial trochanter component and integral shaft/stem construct to replace the resected length of the femur and assemble as described in section 3.3.
- The assembly sequence should be trial integral shaft/stem construct into trial trochanter component.
- Insert the trial proximal 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) and reduce the joint.
- If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the femur and repeat the trial.
- Once satisfied remove all the trial components and select the 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 6.



3.6.2 Implant assembly and insertion

- A Hold the integral shaft/stem construct with the spigot pointing upwards. Insert the trochanter component ensuring the alignment lug is properly engaged. With multiple sharp blows impact on the flat of the trochanter using the soft hammer provided as shown. This should lock the taper securely in place.
- The proximal femoral component is now assembled and ready for insertion.
- Cement the proximal femoral implant into the prepared canal ensuring 10° anteversion of the femoral neck and taking care not to get cement onto the hydroxyapatite coated collar if used.
- Ensure that the trunion and femoral head taper are clean and undamaged. Use the trial heads to assess femoral 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 bone 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 position it correctly over the detached trochanter/bone and 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:

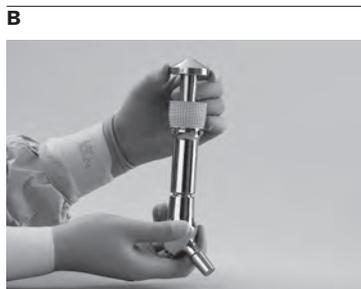
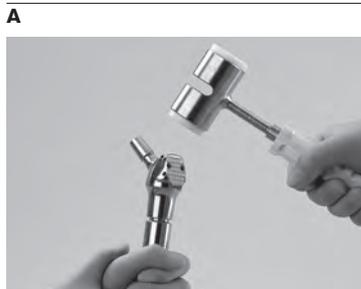
Trochanter / ligament thickness	
(mm)	Screw
3 to 9	Short – 23mm long
9 to 15	Medium – 29mm long
15 to 21	Long – 35mm long



**3.7 Resections between 112mm
and 217mm**

3.7.1 Trial assembly and insertion

- Select the appropriate size and side trial trochanter component, principal shaft, collar and stem to replace the resected length of the femur and assemble as described in section 3.3.
- The assembly sequence should be trial shaft into trial trochanter component, followed by the collar and then the stem respectively.
- Insert the trial proximal 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) and reduce the joint.
- If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the femur and repeat the trial.
- Once satisfied remove all the trial components and select the 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 6.



3.7.2 Implant assembly and insertion

A — Hold the principal shaft with the spigot pointing upwards and insert a trochanter ensuring the alignment lug is properly engaged. Impact on the flat of the trochanter as shown in the picture. Apply multiple sharp blows with the soft hammer provided to lock the taper together.

B — Place the selected collar onto the distal end of the shaft ensuring the the alignment lugs are correctly located. Place collar impactor over the collar. Impact with the soft ended hammer provided, applying multiple sharp blows. Take care not to damage the bore or hydroxyapatite coating.

C — Insert the appropriate stem, again ensuring the alignment lug is properly located and impact using multiple sharp blows with the hammer provided.

- The proximal femoral component is now assembled and ready for insertion.
- Cement the proximal femoral implant into the prepared canal ensuring 10° anteversion of the femoral neck and taking care not to get cement onto the hydroxyapatite coated collar if used.
- Ensure that the trunion and femoral head taper are clean and undamaged. Use the trial heads to assess femoral 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 position it correctly over the detached trochanter/ligaments and 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 / bone thickness (mm)	Screw
3 to 9	Short – 23mm long
9 to 15	Medium – 29mm long
15 to 21	Long – 35mm long



3.8 Resections > 217mm

3.8.1 Trial assembly and insertion

- Select the appropriate size and side trial trochanter component, extension shaft, principal shaft, collar and stem to replace the resected length of the femur and assemble as described in section 3.3.
- The assembly sequence should be extension shaft into trial trochanter component, followed by the principal shaft, the collar and then the stem respectively.
- Insert the trial proximal femoral assembly into the femur ensuring 10° anteversion of the femoral neck is correctly orientated.
- Select the appropriate colour coded trial femoral head (head size and offset) and reduce the joint.
- If the joint is too tight or too loose between shaft increments, it may be necessary to resect extra bone from the femur and repeat the trial.
- Once satisfied remove all the trial components and select the 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 6.



3.8.2 Implant assembly and insertion

- A** Hold the extension shaft with the spigot pointing upwards and insert a trochanter ensuring the alignment lug is properly engaged. Apply multiple sharp blows with the soft hammer provided on the flat surface of the trochanter to lock the taper together.
- B** Place the spigot of the principal shaft into the extension shaft and again ensuring the alignment lug is correctly engaged, apply multiple sharp blows to lock the taper together.
- C** Place the selected collar onto the distal end of the principal shaft ensuring the alignment lugs are correctly located. Place collar impactor over the collar and impact using the soft hammer. Take care not to damage the bore or hydroxyapatite coating.
- D** Insert the appropriate stem, again ensuring the alignment lug is properly located and impact using multiple sharp blows with the hammer provided.

- The proximal femoral component is now assembled and ready for insertion.
- Cement the proximal femoral implant into the prepared canal ensuring 10° anteversion of the femoral neck and taking care not to get cement onto the hydroxyapatite coated collar if used.
- Ensure that the trunion and femoral head taper are clean and undamaged. Use the trial heads to assess femoral 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 position it correctly over the detached trochanter/ligaments and 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 lavage, 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.

Multiple small anchoring holes can be drilled in the portions of the acetabulum to provide greater fixation and torsional resistance for the cement mantle.

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4.0 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 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/RSmlU			
	Standard	left		mstrc/LStdU			
	Standard	right		mstrc/RstdU			
Spiked	Small	left		mstrc/LSmlC			
HA coated	Small	right		mstrc/RSmlC			
	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			
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			
Extension shaft	120mm			msfext/120			
	Shaft						
Integral shaft & stems	L=15 D=27			msiss/15x27C			
Stippled	L=15 D=30			msiss/15x30C			
HA coated	L=30 D=27			msiss/30x27C			
	L=30 D=30			msiss/30x30C			
Collars							
Round	Ø27			mscol/R27S			
Smooth	Ø30			mscol/R30S			
Uncoated	Ø33			mscol/R33S			
	Ø36			mscol/R36S			
Collars							
Round	Ø27			mscol/R27C			
Stippled	Ø30			mscol/R30C			
HA coated	Ø33			mscol/R33C			
	Ø36			mscol/R36C			
Stems							
Curved, 150mm	Ø10>8.5mm			msstm/10x150			
	Ø11>9.5mm			msstm/11x150			
	Ø12>10.5mm			msstm/12x150			
	Ø13>11.5mm			msstm/13x150			
	Ø14>12.5mm			msstm/14x150			
	Ø15>13.5mm			msstm/15x150			
Straight, 100mm	Ø14>13.2mm			msstm/14x100H			
	Ø15>14.2mm			msstm/15x100H			
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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