

---

# METS™ Modular Proximal Femur





# Contents

<b>1.0</b>	<b>Device information</b>	<b>2 — 3</b>
	1.1 Product overview	
	1.2 Indications	
	1.3 Absolute contra-indications	
	1.4 Relative contra-indications	
	1.5 Capabilities and restrictions of use	
	1.6 Components of the METS Modular Proximal Femur implant	
<b>2.0</b>	<b>Trial components and instrumentation overview</b>	<b>4 — 5</b>
	2.1 Components of the trial implant	
	2.2 Special instruments	
<b>3.0</b>	<b>Operation instructions and guidelines</b>	<b>6 — 13</b>
	3.1 Pre-operative planning	
	3.2 Recommendations for component selection	
	3.3 General points to consider when using trial components	
	3.4 Recommendations for assembly of implant	
	3.5 Bone preparation	
	3.5.1 Acetabular preparation	
	3.5.2 Femoral resection levels	
	3.6 Short resections < 112mm	
	3.6.1 Trial assembly and insertion	
	3.6.2 Implant assembly and insertion	
	3.7 Resections between 112mm and 217mm	
	3.7.1 Trial assembly and insertion	
	3.7.2 Implant assembly and insertion	
	3.8 Resections > 217mm	
	3.8.1 Trial assembly and insertion	
	3.8.2 Implant assembly and insertion	
	3.9 Disassembly of prosthesis	
<b>4.0</b>	<b>Parts and order references</b>	<b>15</b>

This publication sets forth detailed recommended procedures for using the depicted devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

### 1.1 Product overview

The METS Modular Proximal Femur 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 Cobalt Chrome (CoCr) alloy, heads are also available. Individual components of the system are connected using interlocking taper junctions allowing quick and easy assembly.

### 1.2 Indications

- Limb salvage procedures where radical resection and replacement of the bone is required
- Tumour resections
- Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
- Revision of previously failed total joint arthroplasty

### 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

- 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.

- It is the responsibility of the surgeon to make available an appropriate acetabular system to match the selected specified femoral head. The SIW Modular Femoral Heads are compatible with Stryker Exeter X3™ RimFit Cups.
- With the exception of the acetabular component, 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 Femur replacement must consist of either a trochanter component, integral shaft and stem and femoral head, or a trochanter component, a principal shaft with or without extension shaft, a stem, a collar and a femoral head. Failure to use a collared device 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.
- Do not use if package is damaged.
- A set of instruments is provided to assist assembly of prosthesis, which includes a set of trial components. The trial components cannot be used in combination with implant components, with the exception of the trial femoral heads.
- This implant is manufactured from titanium and CoCr alloys and therefore **under no circumstances should it be allowed to contact another stainless steel implantable device since this may induce galvanic corrosion.**
- *The METS Modular Proximal Femur and its components are for single use only*
- *The METS Modular Proximal Femur 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 Modular Proximal Femur System has not been evaluated for safety and compatibility in the MR environment
- The METS Modular Proximal Femur System has not been tested for heating or migration in the MR environment

## 1.6 Components of the METS Modular Proximal Femur implant

### Tissue attachment

An optional set of trochanters for bone block 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 distal end of trochanter component, with Ø3mm holes for ligament attachment. The only side specific component in the system, with 10° anteversion built in. 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 long resection.



### Femoral head

Ø28 and Ø32mm Cobalt Chromium heads with varying neck lengths available as standard.

Ø22mm CoCr heads and CoCr hemi-arthroplasty femoral heads ranging from Ø34mm to Ø56mm, are available on special request. Although it has been identified in literature\* that larger femoral heads may have a reduced risk of impingement and dislocation, there may still be a clinical need for smaller heads (Ø22mm).

### 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 prosthesis/bone interface.

### Integral shaft stem component (not shown)

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

\*

1. Chandrasekar, CR *et al.* 2009. Modular endoprosthetic replacement for tumours of the proximal femur. *J Bone Joint Surg [Br]* 2009;91-B:108-12.
2. Ashford, RU *et al.* 2009. Proximal femoral replacements for metastatic bone disease: financial implications for sarcoma units. *International Orthopaedics (SICOT)*. DOI 10.1007/s00264-009-0838-6

2.1 Components of the trial implant

**Trial trochanter**

67mm long trochanters measured from the head centre to distal end of trochanter component. Small and standard sizes in left-hand and right-hand versions, with 10° anteversion built in.

**Trial collar**

Ø27 to Ø36mm collars, in 3mm increments.



**Trial femoral head**

Ø28 and Ø32mm heads with varying neck lengths. If Ø22mm and large femoral heads are requested, appropriately sized trial heads will also be supplied.

**Trial shaft**

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

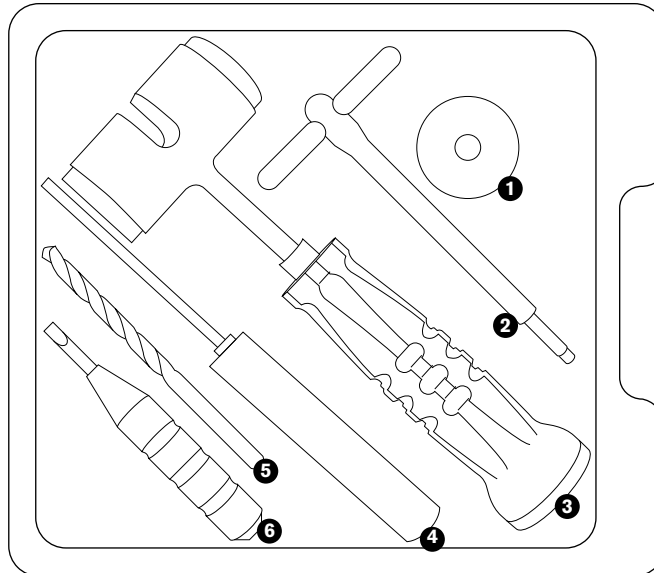
**Trial integral shaft stem component (not shown)**

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

**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** 4mm Allen Key
- 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 flexible reamers from Ø8 to Ø17mm, appropriate cement application device and acetabular instrumentation together with an acetabular system.

A



### 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 an 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 may induce galvanic corrosion.**

#### — 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 optimise 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.

- 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.

- 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 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 3.6.2 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 be exercised when assembling components with hydroxyapatite coating, as it is brittle and can easily be damaged.

### **3.5 Bone preparation**

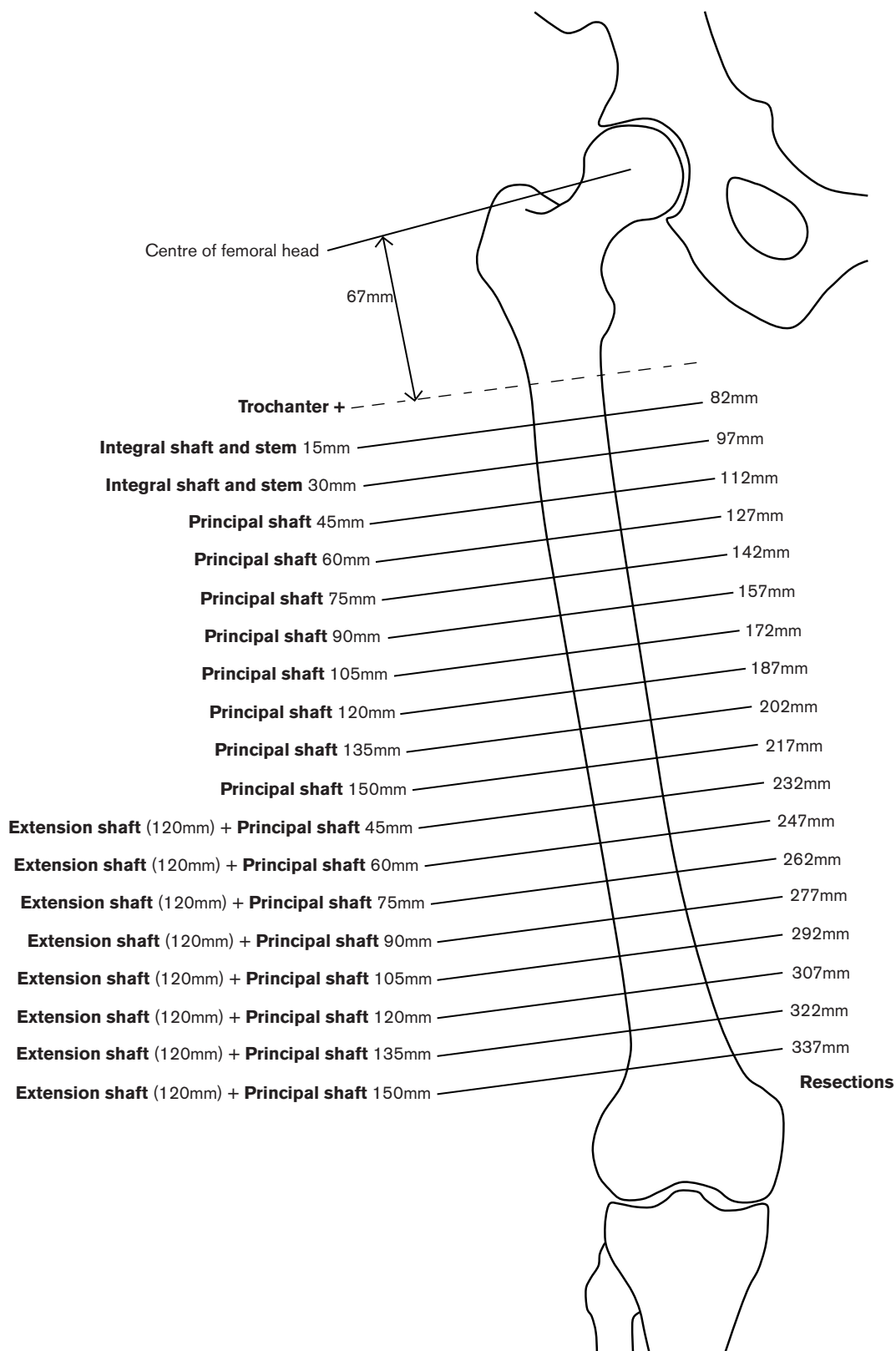
It should be noted that there is no prescribed order as to which bone (acetabulum or femur) is prepared first.

#### **3.5.1 Acetabular preparation**

- Prepare the acetabulum using the chosen acetabular reconstruction system.

**3.5.2 Femoral resection levels**

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



A



### 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 has an integral hydroxyapatite collar, in sizes: Ø27mm collar with 150mm long x Ø11mm stem or Ø30mm collar 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 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/or go up a shaft size, 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**

- 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 taking into account the built-in 10° anteversion of the femoral neck and taking care not to get cement onto the hydroxyapatite coated collar if used.
- Ensure that the trunnion and femoral head taper are clean and undamaged. Use the trial heads to assess femoral neck length. Finally impact the selected femoral head firmly onto the trochanter trunnion.
- If the option of trochanter attachment is used, once the joint is reduced, bring the detached trochanteric bone block down and centralise over the spikes.
- If a wire is to be used for fixation, push the trochanteric bone block securely onto the spikes of the trochanter component 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 may 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 trochanteric bone block 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:

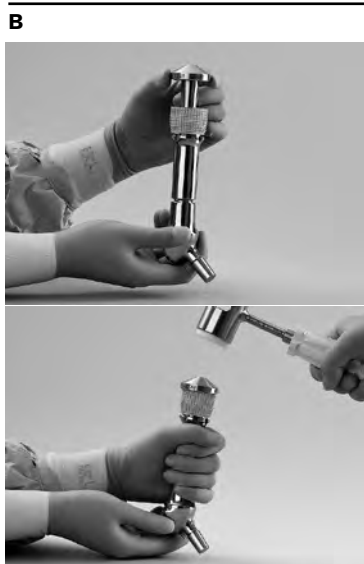
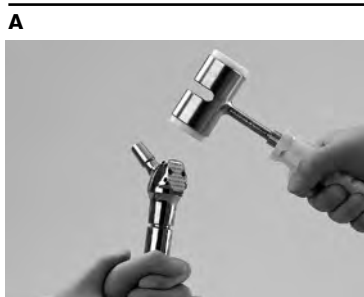
<b>Trochanteric bone block thickness (mm)</b>	<b>Screw</b>
3 to 9	Short – 23mm long
9 to 15	Medium – 29mm long
15 to 21	Long – 35mm long



**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. This picture shows the implant not the trial.
- 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 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/or go up a shaft size, 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**

- Hold the principal shaft with the spigot pointing upwards and insert into 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.
- A**
- Place the selected collar onto the distal end of the shaft ensuring 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.
- B**
- Insert the appropriate stem, again ensuring the alignment lug is properly located and impact using multiple sharp blows with the hammer provided.
- C**

- The proximal femoral component is now assembled and ready for insertion.
- Cement the proximal femoral implant into the prepared canal taking into account the built-in 10° anteversion of the femoral neck and taking care not to get cement onto the hydroxyapatite coated collar if used.
- Ensure that the trunnion and femoral head taper are clean and undamaged. Use the trial heads to assess femoral neck length. Finally, impact the selected femoral head onto the trochanter trunnion.
- If the option of trochanter attachment is used, once the joint is reduced, bring the detached trochanteric bone block down and centralise over the spikes.
- If a wire is to be used for fixation, push the trochanteric bone block securely onto the spikes of the trochanter component 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 may 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 trochanteric bone block 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:

<b>Trochanteric bone block thickness</b>	
<b>(mm)</b>	<b>Screw</b>
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. This picture shows the implant not the trial.
- 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 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/or go up a shaft size, 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 taking into account the built-in 10° anteversion of the femoral neck and taking care not to get cement onto the hydroxyapatite coated collar if used.
  - Ensure that the trunnion 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 trunnion.
  - If the option of trochanter attachment is used, once the joint is reduced, bring the detached trochanteric bone block down and centralise over the spikes.
  - If a wire is to be used for fixation, push the trochanteric bone block securely onto the spikes of the trochanter component 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 may 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 trochanteric bone block 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:

---
































































<b>Trochanteric bone block thickness (mm)</b>	<b>Screw</b>
3 to 9	Short – 23mm long
9 to 15	Medium – 29mm long
15 to 21	Long – 35mm long

A



### 3.9 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.**

<b>Trochanters</b>							
<b>Smooth Uncoated</b>	Small	left		mstrc/LSmlU			
	Small	right		mstrc/RStdU			
	Standard	left		mstrc/LStdU			
	Standard	right		mstrc/RStdU			
<b>Spiked HA coated</b>	Small	left		mstrc/LSmlC			
	Small	right		mstrc/RStdC			
	Standard	left		mstrc/LStdC			
	Standard	right		mstrc/RStdC			
<b>Trochanter plate</b>				msfpte			
<b>Trochanter screws</b>	Short			msfscw/Short			
	Medium			msfscw/Medium			
	Long			msfscw/Long			
<b>Trochanter Reattachment wire</b>	0.6m			mccw1.1/0.6			
<b>Principal shafts</b>	45mm			msfshft/45			
	60mm			msfshft/60			
	75mm			msfshft/75			
	90mm			msfshft/90			
	105mm			msfshft/105			
	120mm			msfshft/120			
	135mm			msfshft/135			
	150mm			msfshft/150			
<b>Extension shaft</b>	120mm			msfsext/120			
<b>Integral shaft &amp; stems (with integral stippled HA coated collar)</b>	Shaft L = 15 D = 27			msiss/15x27C			
	L = 15 D = 30			msiss/15x30C			
	L = 30 D = 27			msiss/30x27C			
	L = 30 D = 30			msiss/30x30C			
<b>Collars Round</b>	Ø27			mocol/R27S			
<b>Smooth</b>	Ø30			mocol/R30S			
<b>Uncoated</b>	Ø33			mocol/R33S			
	Ø36			mocol/R36S			
<b>Collars Round</b>	Ø27			mocol/R27C			
<b>Stippled</b>	Ø30			mocol/R30C			
<b>HA coated</b>	Ø33			mocol/R33C			
	Ø36			mocol/R36C			
<b>Stems Curved, 150mm</b>	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			
<b>Straight, 100mm</b>	Ø14 > 13.2mm			msstm/14x100			
	Ø15 > 14.2mm			msstm/15x100			
<b>CoCr femoral heads</b>	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			
<b>CoCr Ø22mm femoral heads</b>						Available on special request	
<b>CoCr hemi-arthroplasty femoral heads Ø34 - 56mm in 2mm increments</b>						Available on special request	









Stanmore Implants is a fully owned subsidiary of Stryker Corporation.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stanmore Implants does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stanmore Implants product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stanmore Implants product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stanmore Implants products in your area.

The products depicted are CE marked in accordance with applicable EU Regulations and Directives.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: METS, Stryker. All other trademarks are trademarks of their respective owners or holders.

QL537 English ROW Issue 1 ©2020 Stanmore Implants Worldwide Ltd.

No reproduction, even partial is permitted without prior written authorisation from Stanmore Implants Worldwide Ltd.



**Stanmore Implants  
Worldwide Ltd**  
210 Centennial Avenue  
Centennial Park Elstree  
WD6 3SJ  
United Kingdom

---

T +44 (0) 20 8238 6500  
F +44 (0) 20 8953 0617

---