METS SMILES
Total Knee Replacement
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**Surgical Procedure**

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1.1 Product overview
The SMILES knee system is designed as a modular system that can be used to replace diseased or deficient bone around the knee joint. The SMILES knee has three tibial options in two sizes; rotating hinge polyethylene tibia suitable for routine cases, rotating hinge metal cased tibia with short and long stems suitable for extra-articular resection or difficult revisions and a fixed hinge tibia with short and long stems suitable for knees with marked instability or gross deformity.

1.2 Indications
— 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 osteopathy, arthrodensis or previous joint replacement.
— Ligament deficiencies
— Tumor resections
— Revision of previously failed total joint arthroplasty.
— Trauma
— The fixed hinge tibial component is intended for limb salvage procedures requiring radical resection of bone and soft tissue.

The METS® Smiles Knee Total replacement is for cemented use only.

The METS® Smiles Knee Total replacement and its components are for single use only.

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 tibial bone stock.
— 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 SMILES knee replacement must consist of one femoral component (small or standard) pre assembled with bushes and one tibial component pre assembled with bumper pad, an axle and a circlip.
— The implant components are for SINGLE USE only and must not be re-used.
— A set of instruments is provided to assist prosthesis assembly, which includes a set of metal trial components. The trial components are anodised blue to easily distinguish them from implant components.
— In addition, the trial components cannot be used in conjunction with implant components.
— This implant is produced from titanium and CoCrMo alloys and therefore under no circumstances must it be allowed to come into contact with a stainless steel device as this would induce galvanic corrosion.
1.6 Components of the SMILES Knee

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

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

**Femoral component**
Cobalt-chromium-molybdenum femoral component with a titanium stem. Anatomical 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.

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

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

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

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

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

**Tibial plateau plates**
Optional titanium 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 implants

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

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

**Femoral component**
Small and standard sizes in left and right versions.

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

**Trial tibial plateau plates**
Plateau plates (not shown) in 5, 10, 15 and 20mm thickness for use with rotating hinge metal cased or fixed hinge tibial components in both sizes.

**Rotating hinge metal cased tibia**
Stem length 140 and 180mm in both standard and small sizes.

**Rotating hinge polyethylene tibia**
Stem length 114mm for standard and 105mm small size.

**Fixed hinge tibia**
Stem length 140 and 180mm in both standard and small sizes.
2.0 Trial components and instrument overview

2.2 SMILES Knee dimensions

2.2.1 Femoral component

Small: 54mm  
Standard: 60mm

2.2.2 Tibial component

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

Small: 62mm  
Standard: 68mm

Small: 40.5mm  
Standard: 45mm

Tibial plateau

Anterior
2.0 Trial components and instrument overview

2.3 Components of the trial implants

Layer 1
1. Femoral plateau plate, small 20mm
2. Femoral plateau plate, small 15mm
3. Femoral plateau plate, small 10mm
4. Femoral plateau plate, small 5mm
5. Femoral plateau plate, standard 20mm
6. Femoral plateau plate, standard 15mm
7. Femoral plateau plate, standard 10mm
8. Femoral plateau plate, standard 5mm
9. Trial axle
10. Trial femoral knee, right/small
11. Trial femoral knee, left/small
12. Trial femoral knee, right/standard
13. Trial femoral knee, left/standard
14. Tibial plateau plate, small 20mm
15. Tibial plateau plate, small 15mm
16. Tibial plateau plate, small 10mm
17. Tibial plateau plate, small 5mm
18. Tibial plateau plate, standard 20mm
19. Tibial plateau plate, standard 15mm
20. Tibial plateau plate, standard 10mm
21. Tibial plateau plate, standard 5mm

Layer 2
22. Tibial metal case, small/long
23. Tibial metal case, standard/long
24. Tibial metal case, small/short
25. Tibial metal case, standard/short
26. Tibial fixed hinge, small/long
27. Tibial fixed hinge, standard/long
28. Tibial fixed hinge, small/short
29. Tibial fixed hinge, standard/short
30. Tibial poly, small
31. Tibial poly, standard
2.4 Special instruments

Layer 1
1. Hammer (with soft ends)
2. Circlip pliers
3. General impactor
4. Pins (x2)
5. Tibial bearing impactor, standard
6. Positioning plate with holes, small
7. Positioning plate with slot, small
8. Positioning plate with holes, standard
9. Positioning plate with slot, standard
10. Tibial bearing impactor, small

Layer 2
11. Tibial reamer metal casing, standard
12. Tibial reamer: Poly standard
13. Tibial reamer: Poly small
14. Tibial reamer metal casing, small
15. AR lug drill
16. Bush reamer, small
17. Bush compressor, standard
18. Tibial reamer: Fixed hinge
19. Bush compressor, small
20. Bush compressor nut
22. Osteotome
2.5 Jig tray

Layer 1
1. Femoral cutting block, standard
2. Femoral cutting block, small
3. Drill guide
4. Drill Ø8mm
5. Drill Ø10mm
6. Drill Ø2.5mm
7. Bone Pins x 7
8. Pliers
9. Distal cutting guide
10. Distal cutting guide bolt
11. Distal cutting guide slider
12. Distal cutting IM rod
13. Distal cutting guide plate
14. Tibial cutting guide rod
15. Tibial cutting guide prong
16. Tibial cutting guide rest

In addition to these tools, the operating theatre should provide a bone saw, a set of flexible 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.
3.1 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 (Standard or Small)
— 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 femoral and/or tibial plateau plates (for cases where there is extra articular resection)

3.2 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
  A rotating hinge polyethylene tibial component should only be used where the surgeon believes that a metal base plate is not required. 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 components should be considered where there is marked instability of the joint.

— Plateau Plates
  For extra articular restrictions, femoral and tibial plateau plates can be used. Only one femoral and one tibial plateau plate can be used if required. The size of the plate corresponds to the size of the knee components (femoral component and tibial component), chosen.

3.3 General points to note when using trial components

— There is a single sized axle for the trial components, thus it can be used for both small and standard size knees. The axle 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 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 tibial components represent only the size and shape of the actual tibial construct and therefore do not rotate.
— 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.
3.4 Bone preparation

It should be noted that there is no prescribed order as to which bone (the femur or the tibia) is prepared first. Before femoral preparation, the size of the SMILES knee must be chosen as appropriate for the patient’s knee.

3.5 Tibial resection levels

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

- Resect the tibial plateau 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. (See figure 3.5).

- Based on the type of tibial component 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.

- For a rotating hinge polyethylene tibial component use the plate with slots.

- For rotating hinge metal cased and fixed hinge tibias, use the plate with holes.
3.0 Operation instructions and guidelines

Total Knee Replacement

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 12mm flexible reamer.

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

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

3.7 Femoral cutting guide 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 resting in the patella track of the bone, 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 back edge of drill guide and that the patella rest is approximately in line with the femoral canal.

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 stop located on the drill.

   — Remove the guide.

   — Using Ø8mm drill, deepen the hole ensuring the drill follows the intramedullary canal of the femur to the depth marked on the drill.
3.0 Operation instructions and guidelines

Insert the IM rod into the distal cutting guide for right or left femur – making sure left/right mark aligned with arrow – and lock it in position using the locking screw located in front of the distal cutting guide. The relevant marking should be proximal when inserting the rod into the guide.

Assemble distal cutting guide, guide slider, distal cutting guide slider bolt and the distal cutting plate. Using the chart below, adjust the guide slider for the amount of femoral resection measured from the femoral condyles and secure it by tightening the locking screw positioned above it.

Note:
These dimensions are for guidance only. Due to degeneration and laxity of the knee, more bone may need to be trimmed if necessary.
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 back edge of the cutting guide. Secure the cutting plate in place using the bone pins provided.
Unscrew the slider bolt and remove the
distal cutting guide, leaving the distal
cutting plate securely in position.

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.
Twist the block so that the sloping
face is parallel with the posterior
condyles. Secure the block into position
using bone pins provided.

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

Remove the block using the pliers
provided and using flexible reamers,
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.
3.8 Trial assembly and insertion

- Select the required size and type of trial tibial mono-block and insert into the tibial canal.
- Select and insert the appropriate size femoral component.
- Join the two components together by inserting the trial axle ensuring that it is correctly seated before performing a trial reduction.
- Once satisfied, remove all trial components and select the corresponding implant components.

3.9 Implant assembly and insertion

3.9.1 The femoral component

- Cement the required femoral component into the femoral canal, ensuring the correct orientation is achieved.
- Impact using the general impactor.

3.9.2 Femoral plateau plates

- Optional femoral plateau plates are available in 5, 10, 15 and 20mm thicknesses for both small and standard sizes.
- 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.
- If femoral plateau plates are required, they should be cemented onto the femoral component first and then the femoral component should be inserted into the patient, as described in 3.9.1.

3.10 The tibial component

- Remove the inner tibial bearing component from the specific tibial casing chosen.

A

- 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 and for the rotating hinged metal cased tibial arrangement, cement the outer metal tibial casing.
- Impact using the appropriate impactor. For rotating hinge polyethylene, impact using the plastic impactor; and for the rotating hinged metal cased, impact using the general impactor.
- Once cemented securely in place, insert the tibial bearing components into the cemented tibia.
- For the fixed hinge tibial arrangement, cement the component into the canal and impact using the general impactor.
3.11 Tibial plateau plates
— Optional tibial plateau plates are available in 5, 10, 15 and 20mm thickness for use with the rotating hinge metal cased or fixed hinge tibial components.
— Using a small amount of bone cement, secure the plateau plate onto the tibial component by sliding it over the tibial stem until the anti-rotation lugs on the tibial component are located within the holes in the tibial plateau plate.
— The tibial component can then be inserted as described in section 3.10.
— It should be noted that only one tibial plateau plate can be used, multiple plates cannot be stacked onto one another.

3.12 Insertion of the axle and circlip
— 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 femoral component.
— Check to ensure the axle head is correctly seated inside the recess and that it is not trapped within the circlip groove.
— Secure the axle by inserting the circlip, so that it is seated inside the circlip groove as described in section 3.13.
3.13 Use of circlip pliers

- Locate the circlip onto the circlip pliers.

- 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 in the pictures below.

- A correctly inserted circlip is shown with the jaws of the circlip pliers in the correct position.

- This picture shows an incorrectly inserted circlip. This will not function and the circlip requires reinserting. (Rotating 180°).

- 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 circlip 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.

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

#### 4.0 Parts and order references

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| Standard 15mm          |  |  | mktp/Std15 |
| Standard 20mm          |  |  | mktp/Std20 |