Restor RH
ROTATING HINGE Modular Resection Prosthesis

Rotating Hinge Modular Resection Prosthesis

Surgical Technique Guide

ADLER®

Adler Healthcare Pvt. Ltd. would like to thank the following surgeons for their contribution to this surgical technique:

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Adler Healthcare Pvt. Ltd. would like to thank
Tata Memorial Hospital Orthopaedic Oncology Service
as a development partner in RESTOR^{RH} prosthesis.

RESTOR[RH]

Rotating Hinge Modular Resection Prosthesis

Surgical Technique Guide

Contemporary limb salvage surgery aims to compensate the loss of surgically resected diseased bone and soft tissue with reconstructions that retain limb function. Limb salvage surgery using ''mega-prostheses'', so named due to the large segments of bone usually replaced, offer patient benefits in restoring structural and skeletal stability while retaining functional joint mobility .

restor® (Resection of Tumour and Optimal Reconstruction) Modular Resection Prosthesis is a cemented, modular system that enables reconstruction following limb salvage surgery, provides a clinically demonstrated and cost-effective solution to patients who could benefit from limb salvage surgery following tumours of:

- Proximal, Distal & Total Femur
- Proximal Tibia
- Diaphyseal regions of the Femur/Humerus
- Proximal, Distal and Total Humerus

The restor[RH] (Rotating Hinge) system, now added to the RESTOR family, is designed to extend implant longevity in patients undergoing limb salvage surgery for bone tumours around the knee or in patients undergoing revision of conventional joint replacement prosthesis with extensive bone loss through the rotating hinge design that minimizes torsional stresses on the implant construct.

Indications for Use

- Primary malignant bone tumours,
- Metastatic bone tumors.
- Benign bone tumors (where intra-lesional methods may be unsuitable).
- Revision of conventional joint replacement prosthesis with extensive bone loss.

Careful preoperative planning and precise surgical technique form the basis required to achieve optimal results with the RESTOR system. Operating surgeons must consider different factors in order to minimize the risk of postoperative complications, such as the anatomical stress situation, available soft tissue support of the components planned. It is usually advisable to implant the RESTOR system only in patients with fully grown skeletal structures.

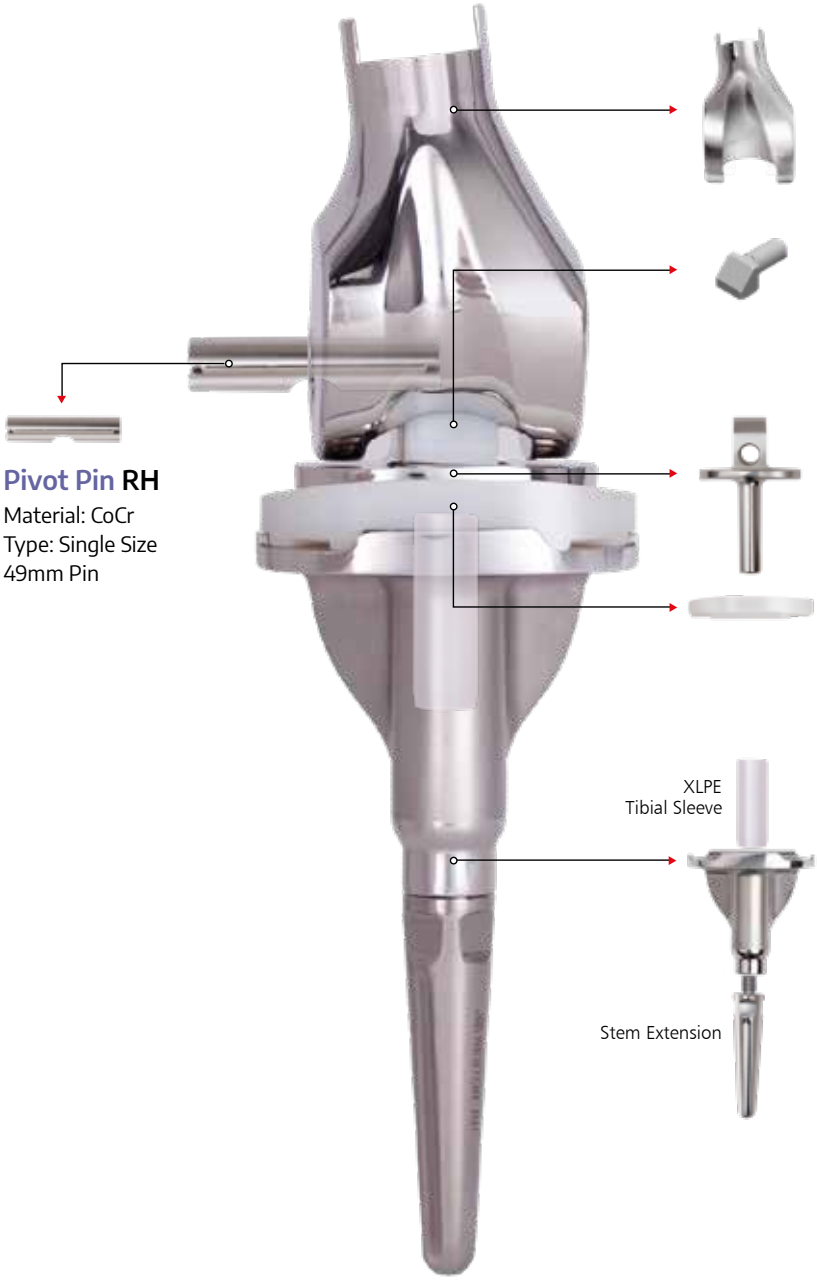
Contra-Indications for Use

- Bacterial infections.
- Defects in soft tissues caused by irradiation and expected bone growth.
- Anatomical conditions which do not allow for an adequate implant size.
- Anatomical conditions that would not maintain sufficient bony support for the implant.
- Insufficient blood supply caused by prior surgeries or vessels affected by alcohol abuse or due to other factors.
- Mental or other neurological conditions that could affect the patient's capability to follow restrictions in activity.
- Any conditions that could cause extreme stress on the implanted components such as multiple arthropathies, myopathies etc.
- Sensitivity to Implant materials.
- Marked osteoporosis or poor bone stock.
- History of general or local infections.
- Severe deformities leading to impaired fixation or improper positioning of the implant.
- Allergic reactions to implant materials (e.g., bone cement, metal, polyethylene).

THE SYSTEM

Distal Femoral Replacement

An Overview



Pivot Pin RH
Material: CoCr
Type: Single Size
49mm Pin

RESTOR^{RH}
Femur FR - Left /Right
Material: CoCr with XLPE Bushes
AP-45mm ; ML-45mm
2 Bushes + Pivot Pin in the sterile package

RESTOR^{RH}
Bumper FR - 3°
Material: UHMWPE

RESTOR^{RH}
Rotating Component
Material: CoCr
AP-28mm ; ML-52mm
Common to both sizes of Tibia FR

RESTOR^{RH}
Tibial Insert FR - Small/Standard, 8mm, 13mm, 16mm
Material: XLPE

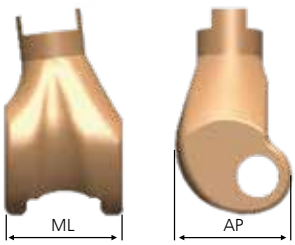
	Small	Standard
AP	30mm	36mm
ML	60mm	65mm

RESTOR^{RH}
Tibia FR
Keel Baseplate - Small/Standard
Material: CoCr

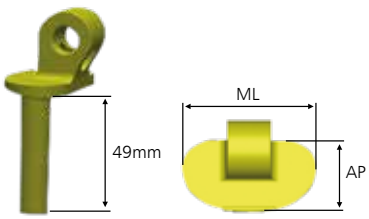
	Small	Standard
AP	35mm	41mm
ML	60mm	65mm

Pre-assembled XLPE Tibial Sleeve and Stem Extension.

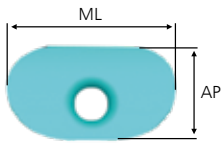
Measure	Freedom/Constraint
Femoral Valgus Angle	7°
Hyperextension	3°
Rotation	15°
Maximum Flexion	147.5°-Standard Tibia 153.7°-Small Tibia



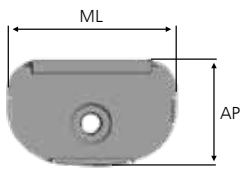
RESTOR^{RH} Femur FR - Left /Right



RESTOR^{RH} Rotating Component



RESTOR^{RH} Tibial Insert FR
Small/Standard



RESTOR^{RH} Tibia FR
Keel Baseplate, Small/Standard

Illustrations not to scale. Specifications subject to change without notice

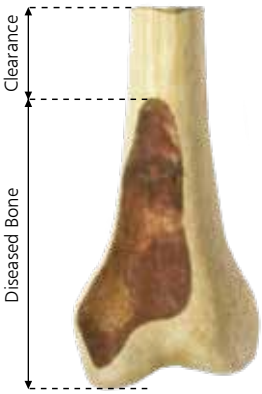
RESTOR[RH]

Distal Femoral Replacement

Abbreviated Technique

Femur

Measure,Mark & Resect



Ream for Stem & Insert Restrictor

Conical Reamer for Stem-Collar Junction

Tibia

Position Jig & Resect

Size & Drill

Ream for Stem Taper

Broach for Stem Keel

RESTOR[RH]

Distal Femoral Replacement

Abbreviated Technique - contd.

Trial

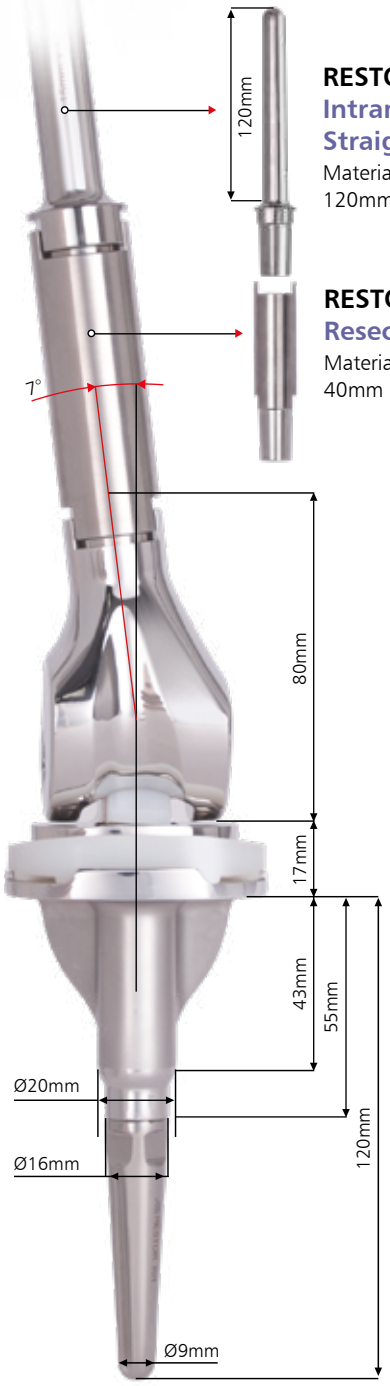
Implant

RESTOR[RH]

Distal Femoral Replacement

Resection Planning

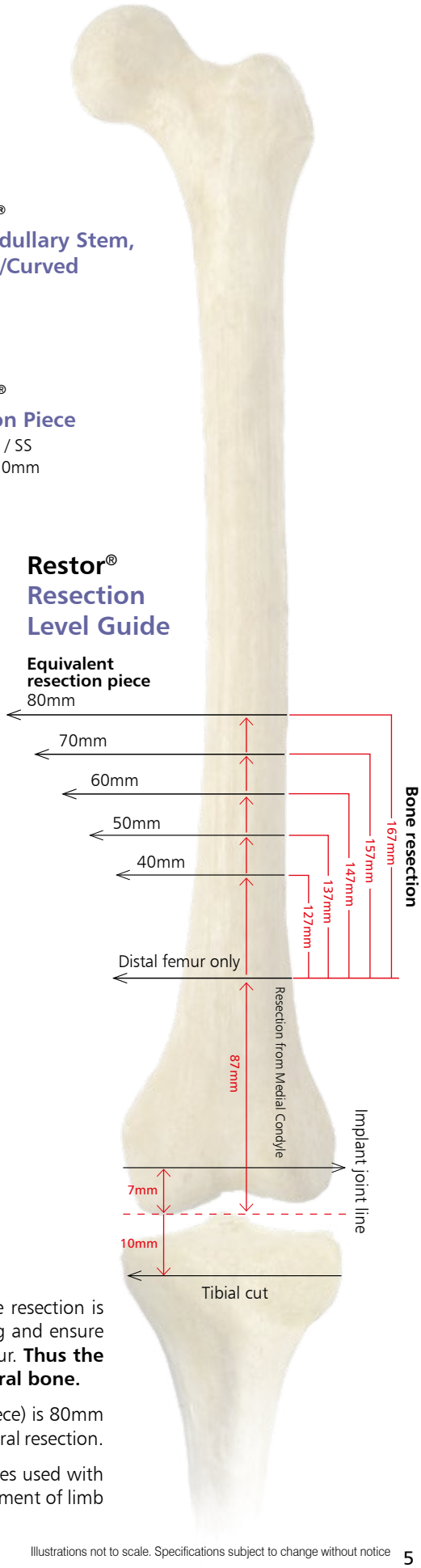
Femur FR
Trial Prosthesis Construct



RESTOR®
Intramedullary Stem, Straight/Curved
Material: Ti
120mm

RESTOR®
Resection Piece
Material: Ti / SS
40mm - 220mm

Restor® Resection Level Guide



The minimum Tibial construct is 17mm. To minimise undue excision of the tibia, the resection is recommended at 10mm from the medial plateau. To avoid postoperative lengthening and ensure correct limb length, the extra 7mm of bone resection required is taken from the femur. **Thus the final femoral implant construct will be 7mm shorter than the resected femoral bone.**

The length of the distal femoral component alone (without an additional resection piece) is 80mm (70mm for the distal femur + 10mm stem collar). This will require an 87mm distal femoral resection.

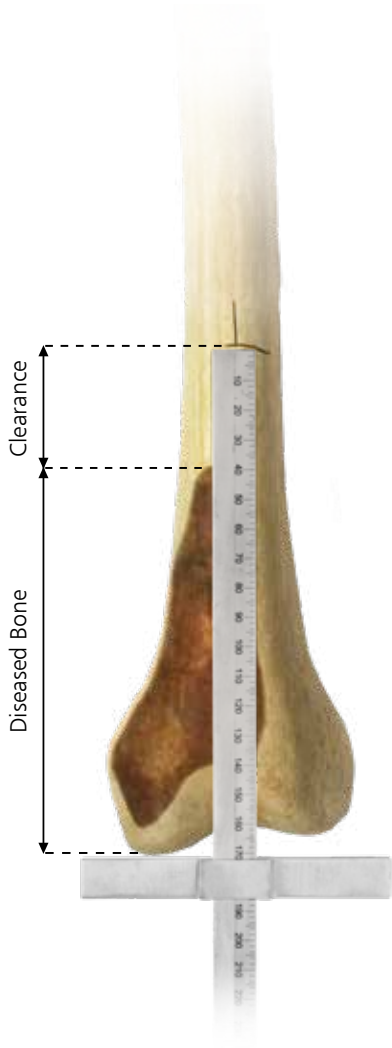
Suggested femoral cuts are correlated with the lengths of the available resection pieces used with an 8mm tibial insert. Alternatively, 13mm or 16mm inserts can be used for finer adjustment of limb length, if required.

RESTOR[RH]

Distal Femoral Replacement

Measuring & Marking Resection

- Use RESTOR™ Right Angle Measuring Scale from medial condyle to determine the level at which resection is to be done.
- Mark this level on the bone. Considering the construct size options (shown on resection level guide) and adequate clearance of diseased bone.
- To ensure correct rotational positioning of the femoral implant, make a longitudinal mark to identify the correct anterior reference line of the femur with respect to the anatomically correct position of the intercondylar notch, as this position may not be easily evident after the resection.
- This would not be an accurate reference point if there is a pathological fracture preoperatively.
- This longitudinal mark should finally align with a corresponding longitudinal anterior rotation mark (laser marked) on the implant stem.

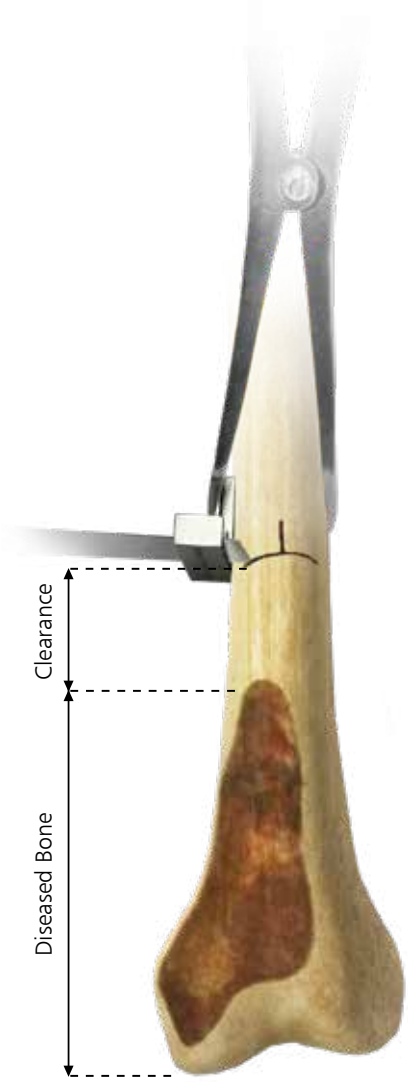


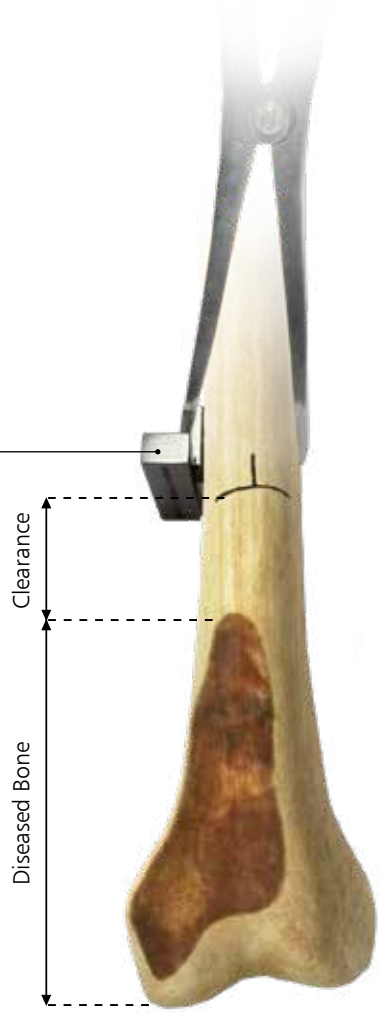
RESTOR[RH]

Distal Femoral Replacement

Tumor Resection

- Use Jig C3900.021 or make a freehand cut to carry out the perpendicular resection at the pre-decided and marked level on the femur.





- A bone clamp/reduction clamp (not supplied with the RESTOR™ instrument set) may be used to clamp the jig to bone.
- Resection of the bone may be carried out using a standard orthopaedic power saw.

NOTE:

This resection cut needs to be perpendicular to anatomical axis of the femur. A non-perpendicular resection cut may result in inadequate fixation of the I.M. stem and would result in high stresses on the stem - collar junction.

RESTOR[RH]

Distal Femoral Replacement

Femoral Stem Preparation - Reaming

- Ream the femoral canal using reamers (not provided with the RESTOR™ instrument set)
- The diameter of the intramedullary,120mm stem to be finally selected for placement into the femoral canal will depend on the last size of reamer used with adequate over reaming carried out to accommodate cementing, considering a minimum 1mm cement mantle around the stem.

- Insert a cement restrictor to a depth of 2-3 cm more than the selected stem, using the Cement Restrictor Inserter *H0102.12*.

RESTOR® Straight, Intramedullary Stem, Trial

Code No.	Ø (mm)
Length 120 mm	
C1601.0109	09
C1601.0110	10
C1601.0111	11
C1601.0112	12
C1601.0113	13
C1601.0115	15
C1601.0117	17

RESTOR® Curved, Intramedullary Stem, Trial

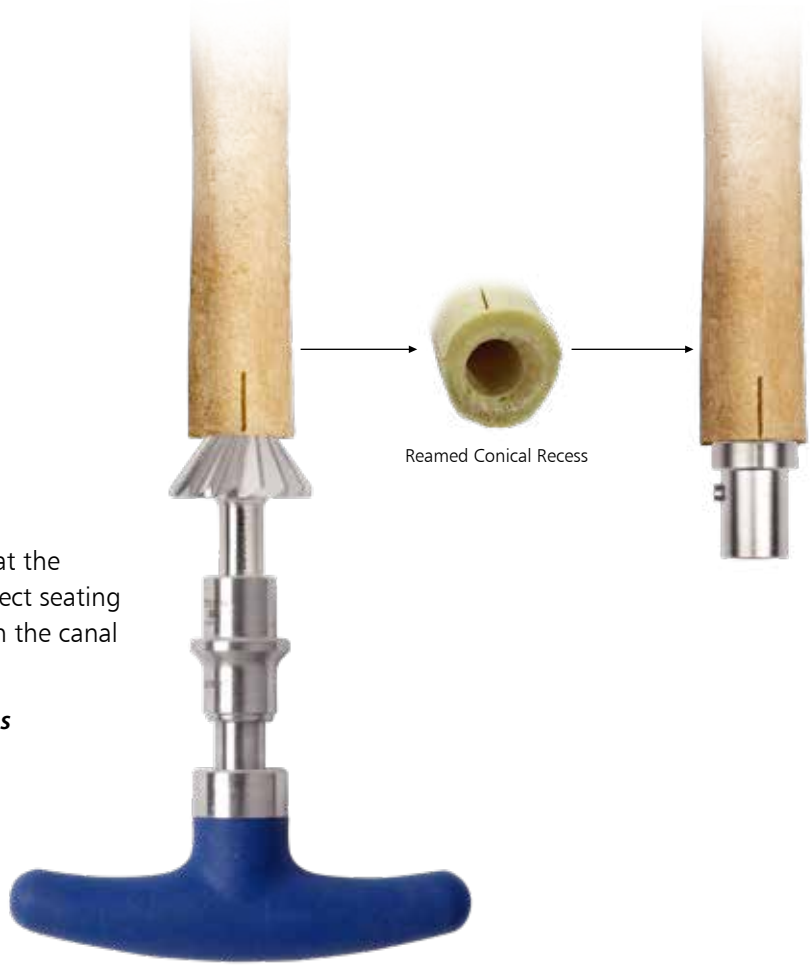
Code No.	Ø (mm)
Length 120 mm	
C1601.0209	09
C1601.0210	10
C1601.0211	11
C1601.0212	12
C1601.0213	13
C1601.0215	15
C1601.0217	17

RESTOR[RH]

Distal Femoral Replacement

Femoral Stem Preparation - Conical Ream

- Assemble the RESTOR™ Conical Reamer, Modular C3900.1401 and select appropriate RESTOR™ Conical Reamer Centralizer (9,10 or 11mm).



- Create a conical recess in the bone at the level of the resection to enable correct seating of the filleted intramedullary stem in the canal at the stem-collar junction.

Avoid over-reaming the conical recess

NOTE:

Not using the conical reamer with centraliser could lead to an incorrectly seated intramedullary stem and may lead to higher stresses on the stem-collar junction.

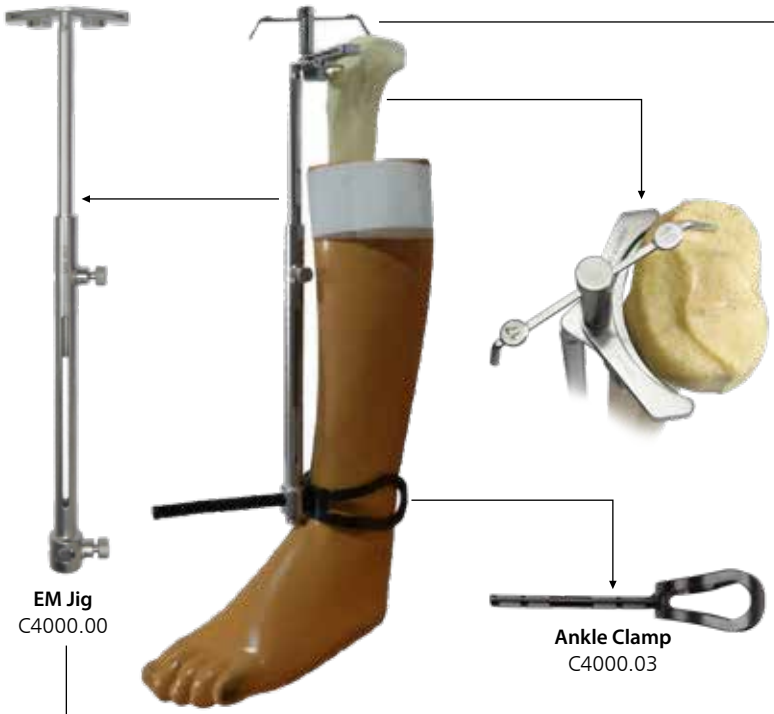
Check appropriate circumferential seating of the trial stem on bone after conical reaming, else you may need to revise the cut to ensure appropriate seating.

RESTOR[RH]

Distal Femoral Replacement

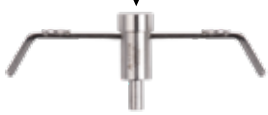
Tibia Base Preparation - Resurfacing Resection

- Use the Extra medullary Jig (EM) C4000.00 for tibia component positioning.



EM Jig
C4000.00

Ankle Clamp
C4000.03



Restor[RH] Stylus
C4000.02

FH Stylus
C4000.01

- The10/17mm tibia stylus is attached to the tibia cutting guide. It is used to determine the minimal resection of the proximal tibia from the lowest point on the medial condyle.

- The **standard technique** is to split the required resection (17mm) with a **10 mm** tibia cut and a 7mm additional femoral resection (Refer to the 'Measured Resection Length' of this technique guide).
- To enable a standard tibia cut place the stylus with the longer arm (10mm) on the lowest point of the medial tibia plateau.
- Pin the Cutting block & take the tibia cut with a 1.35 mm or thinner saw blade (surgical saw blades not included in the Restor[RH] Instrument Set).

NOTE:

The EM Jig is positioned parallel to the tibia shin and as close to the limb as possible. Ensure cut is perpendicular to the anatomical axis (horizontal).

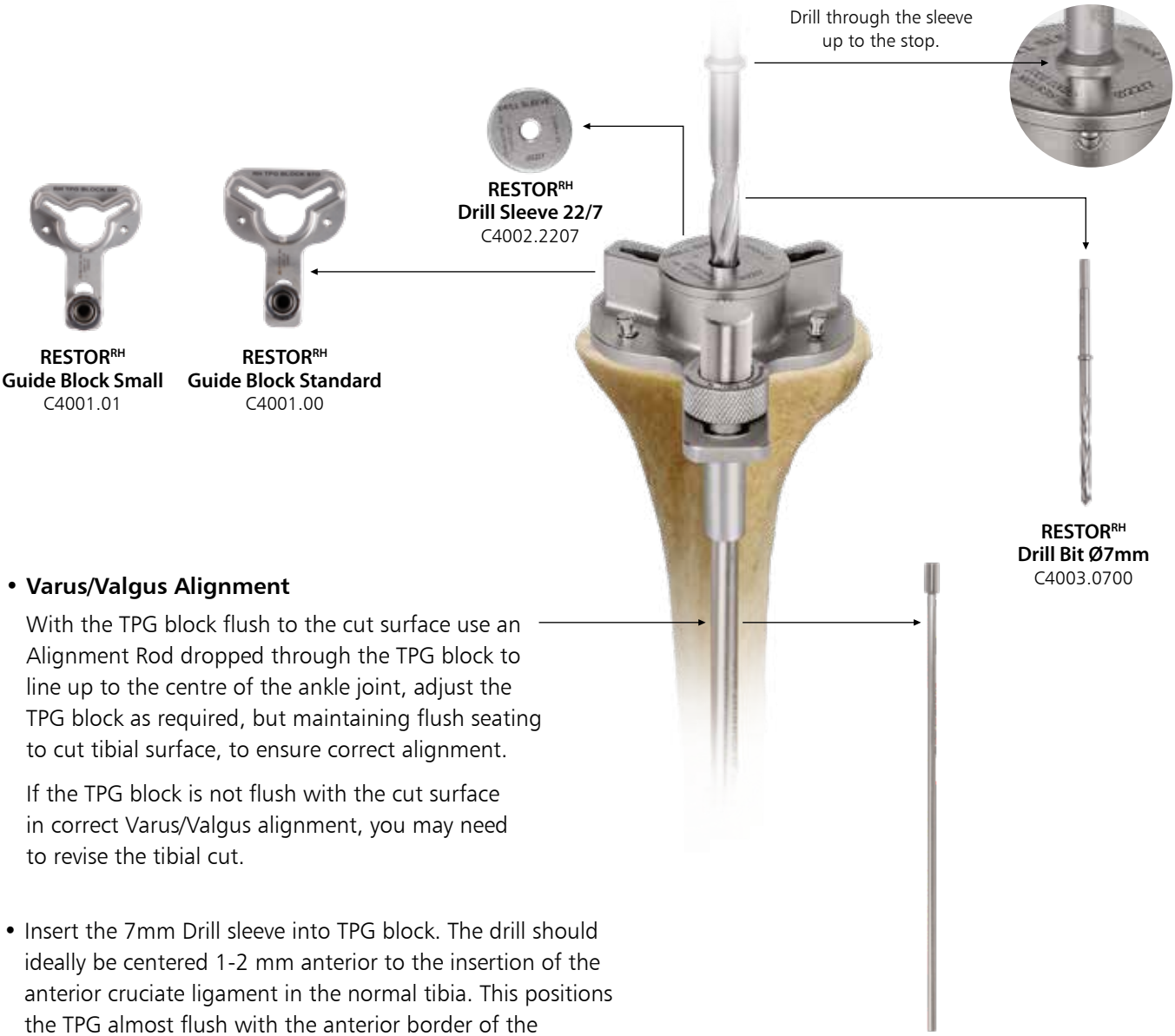
Caution must be exercised to prevent damage to the posterior neuro-vascular bundle while making the proximal tibial cut.

RESTOR[RH]

Distal Femoral Replacement

Tibia Base Preparation - Sizing & Stem Preparation

- Select the appropriate size (Standard or Small) TPG (Tibia Prep Guide) block.
- Using the blocks as tibia sizers, assess coverage on the tibia plateau.
- Pin the selected TPG block to the tibia plateau using short headed pins provided. Ensure the TPG block is in the correct rotation, parallel to the posterior cortical border of the resected tibia surface.



- **Varus/Valgus Alignment**

  With the TPG block flush to the cut surface use an Alignment Rod dropped through the TPG block to line up to the centre of the ankle joint, adjust the TPG block as required, but maintaining flush seating to cut tibial surface, to ensure correct alignment.

  If the TPG block is not flush with the cut surface in correct Varus/Valgus alignment, you may need to revise the tibial cut.

- Insert the 7mm Drill sleeve into TPG block. The drill should ideally be centered 1-2 mm anterior to the insertion of the anterior cruciate ligament in the normal tibia. This positions the TPG almost flush with the anterior border of the cut surface. Drill through the sleeve using Drill bit 7.0 up to the stop. Remove the drill sleeve, leaving the TPG block in place.

RESTOR[RH]

Distal Femoral Replacement

Tibia Base Preparation - Final Stem & Keel Preparation

- With the TPG block still pinned in place use the Taper Reamer to prepare the tibia for the Tibial Component.

Ream through the TPG block up to the stop.

Ensure that the Taper Reamer remains perpendicular to the cut tibial surface during reaming.

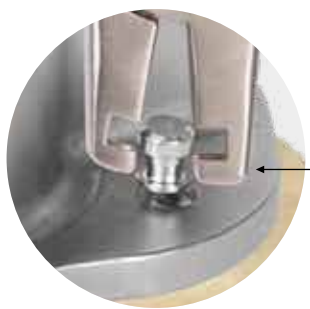
RESTOR[RH]
Taper Reamer
C4011.00

RESTOR[RH]
Impaction/
Extraction Coupler
C4005.02

RESTOR[RH]
Keel Broach Small
C4005.01

RESTOR[RH]
Keel Broach Std.
C4005.00

- Connect the appropriate size, Standard or Small, Keel Broach to Impaction Handle and prepare the tibia for tibial Keel Baseplate, through the TPG block.
- A slotted mallet is provided for in-out-in broaching technique.



Remove the two pins using Pin Extractor (C3900.1102).

The TPG block can now be removed.

RESTOR[RH]

Distal Femoral Replacement

Trial Implant Assembly

Tibia

- Screw in the tibia Trial Stem to the Trial Tibia Baseplate (standard or small)

Q. C. Handle
C4012.00

RESTOR[RH] Tibia Punch
C4013.03

RESTOR[RH] Insert Small, 16mm, 13mm, 8mm
C1606.0616, C1606.0613, C1606.0608

RESTOR[RH] Baseplate, Small
C1606.0201

RESTOR[RH] Rotating Component
C1606.04

RESTOR[RH] Insert Std. 16mm, 13mm, 8mm
C1606.0516, C1606.0513, C1606.0508

RESTOR[RH] Baseplate, Standard
C1606.0200

Tibial Stem, Trial
C1606.0200.065

- Attach Tibia Punch to the modular QC Handle & impact the assembled trial baseplate into prepared tibia.
- Ensure the trial tibia baseplate remains flush to the cut surface of the tibia.
- Slide in the selected trial tibia insert (8,13 or16mm)
- Drop the trial rotating component (Anterior Marked) on to and through the trial insert.

RESTOR[RH]

Distal Femoral Replacement

Trial Implant Assembly - Contd.

Femur

- Select the appropriate RH Left/Right Femoral Component Trial.
- Select appropriate Resection piece Trial (depending on the resection length) and appropriate Curved/Straight Intramedullary Stem Trial depending on the pre-decided intramedullary stem diameter.
- The stem used for femur resection surgery is curved to account for the anterior femoral curvature where required. (*this may not always be the case & in certain situations the surgeon may find it appropriate to use a straight stem)
- Align the previously marked anterior femur with the lasermarked trial stem to ensure correct rotational alignment.

NOTE:

The Trial Components do not have a Morse Taper lock and are designed for easy insertion and removal into each other.

REMINDER:

The trial femoral construct and subsequent final femoral implant construct is 7mm shorter than the actual resected femoral bone, provided, the standard tibia resection technique is followed (Page No. 5).

RESTOR[RH]

Distal Femoral Replacement

Trial Implant Reduction

- Build the Pivot Pin Inserter, Pivot Pin Aligner and RESTOR™ RH Pivot Pin Trial as shown (provided in the RESTOR Trial Case)
- The Pivot Pin Inserter Assembly is inserted through both the Femur RH Trial and Tibia RH Trial via the rotating component.
- The Pivot Pin Aligner and Inserter handle are unscrewed, by hand,from the Pivot Pin trial, leaving the trial in place.
- Align the pivot pin and push the Anterior bumper, by hand, till it touches the rotating component face.

RESTOR[RH] Pivot Pin Inserter
C4009.00

RESTOR[RH] Pivot Pin FR Trial
C1606.09

RESTOR[RH] Pivot Pin Aligner
C4008.00

- Check the length of the limb and ensure appropriate rotational alignment of the implants.
- Check the patella tracking through a trial range of motion.

Removal of anterior bumper
The cylindrical section of the bumper projecting posteriorly should be pushed towards the anterior side to enable quick disassembly.

RESTOR[RH]

Distal Femoral Replacement

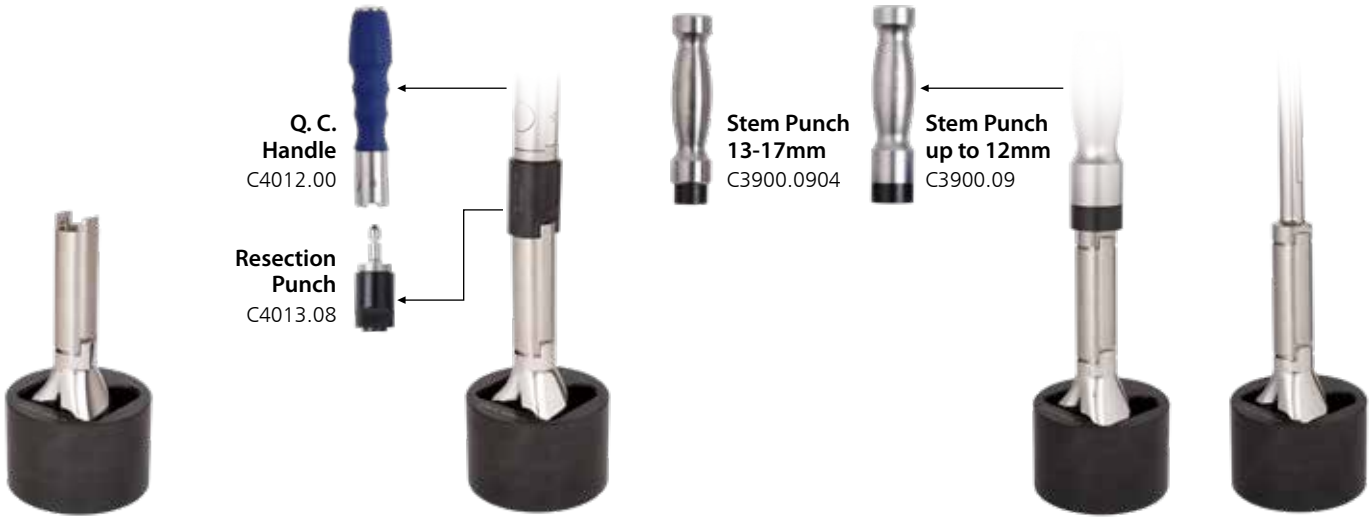
Distal Femoral Implant Assembly

- The femoral and tibial components are assembled prior to mixing cement.
- Ensure all taper surfaces are cleaned & dry before assembly.
- Use the Base for Femur FR Assembly to assemble the modular prosthesis components. It holds the femur component while enabling impaction and assembly of the resection piece and the I.M stem - one after the other.

NOTE:

You will always find a small gap of about 1 mm between the assembled modular components. This is normal and further hammering should not be attempted to close this gap as component damage or instrument damage may result.

Base For Femur FR Assembly, RESTOR[RH]
C4006.00



- The Modular Q.C.Handle is used with the Resection Piece Adaptor for impacting the resection piece to the femur and a separate Modular Stem Impactor is provided for Impacting the stem to the resection piece or femur directly (if no resection piece is required).

- If the assembled modular components need to be dis-assembled for any reason, the Wedge Fork supplied with the instrumentation may be inserted into the gap between the components and impacted to cause separation of the assembled modular components.

Wedge Fork
C3900.13

NOTE:

When using a curved intramedullary stem, the surgeon must ensure correct orientation of the bow to match the anterior bow of the femur prior to impacting the femoral implant assembly.

RESTOR[RH]

Distal Femoral Replacement

RESTOR™ Rotating Hinge Final Implantation

- Cement is inserted into the tibial canal.
- Cement is also applied circumferentially on the stem of the tibia including the flutes & baseplate to ensure adequate cement coverage at the implant/bone interface.
- Impact Final RESTOR RH Tibia with the Modular Tibia Punch attachment
- Remove excess cement.

Q. C. Handle
C4012.00

RESTOR[RH] Tibia Punch
C4013.03

RH Femur FR Punch
C4013.02

Q. C. Handle
C4012.00

- A cement restrictor should be used.
- Cement is injected into the femoral canal using a cement syringe.
- Cement is also applied circumferentially on the stem including the flutes to ensure adequate cement coverage at the implant/bone interface.
- Use previously made alignment mark on the bone to align with the laser marked line on the stem collar.
- The femoral component is impacted into place using the Modular Femoral Punch attachment
- Remove excess cement.

RESTOR[RH]

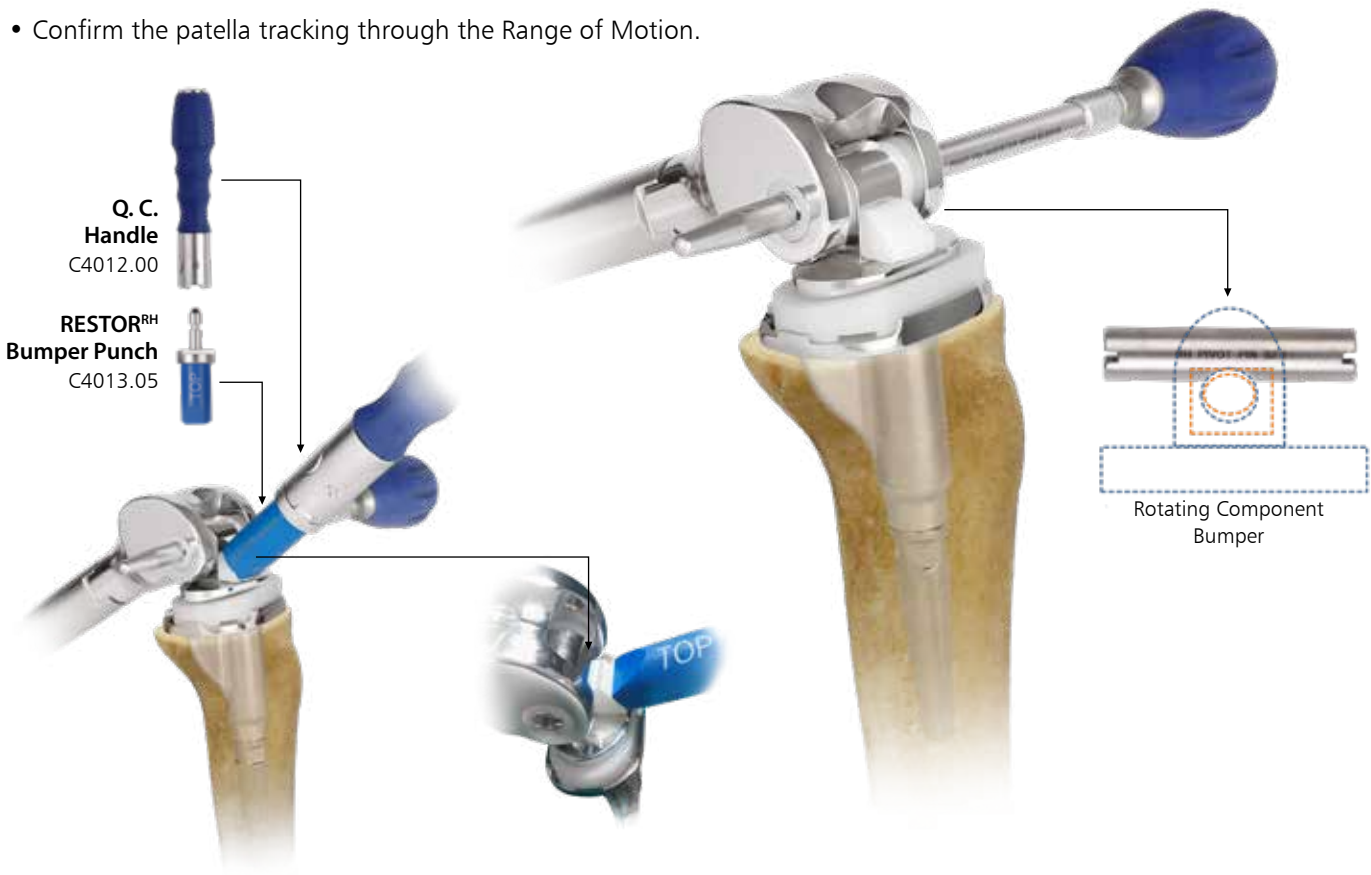
Distal Femoral Replacement

RESTOR™ Rotating Hinge Final Implantation

- Select and Insert the appropriate Tibia poly insert (8,13or16mm) Use the modular RH Tibia Insert Punch on Quick Connect(Q.C)Handle to Impact the poly insert into the locking mechanism (note the punch is marked TOP for correct orientation during impaction).

- Insert the CoCr Rotating Component into the tibia insert
- Assemble the CoCr pivot pin to pivot pin inserter, in the same way as with the trial pivot pin.

- Align the pivot pin (see image) and Impact the anterior bumper. Use the Modular RH Bumper Punch on Quick Connect Handle to impact the bumper.
- Disassemble the pivot pin inserter, leaving the pivot pin in place
- Confirm the length of the limb and appropriate rotational alignment of the implants.
- Confirm the patella tracking through the Range of Motion.



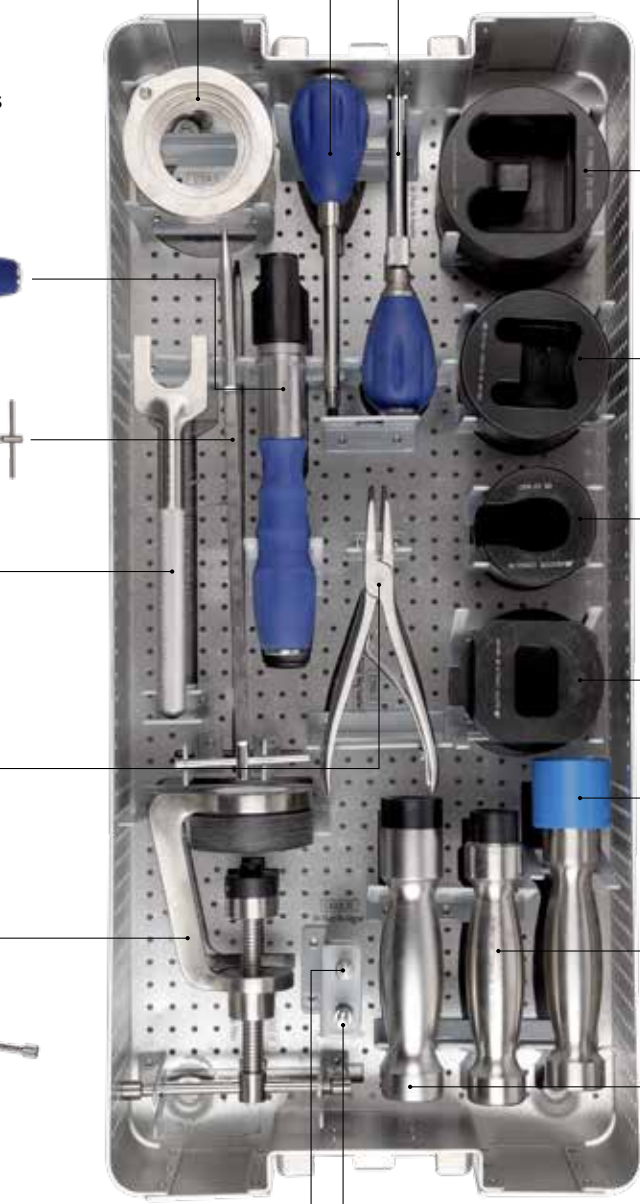
NOTE:

The punch is marked 'TOP' for correct orientation during impaction.

RESTOR[RH]

Instrument Set

Assembly/Disassembly, Rotating Hinge



FH Pivot Pin Inserter
C3900.03

RESTOR[RH] Pivot Pin Inserter
C4009.00

Head Gauge Set
for hip prosthesis
C1304.10

Q. C. Handle
C4012.00

Resection Punch
C4013.08

Restrictor Inserter
H0102.12

Wedge Fork
C3900.13

FH Ret. Ring Inserter
C3900.11

ModuLoc®
Bipolar Cup Press
for hip prosthesis
H0103.10

Base For Femur FR
Assembly, RESTOR[RH]
C4006.00

Base For Femur FR
Assembly, FH
C3901.09

Base For Trochanteric
Component Assembly
for hip prosthesis
C3902.19

Base For Tibia TR
Assembly, FH
C3902.14

Cup Impactor for hip prosthesis
H0102.15

Stem Punch 13-17mm
C3900.0904

Stem Punch up to 12mm
C3900.09

FH Pivot Pin Aligner
C3901.0411

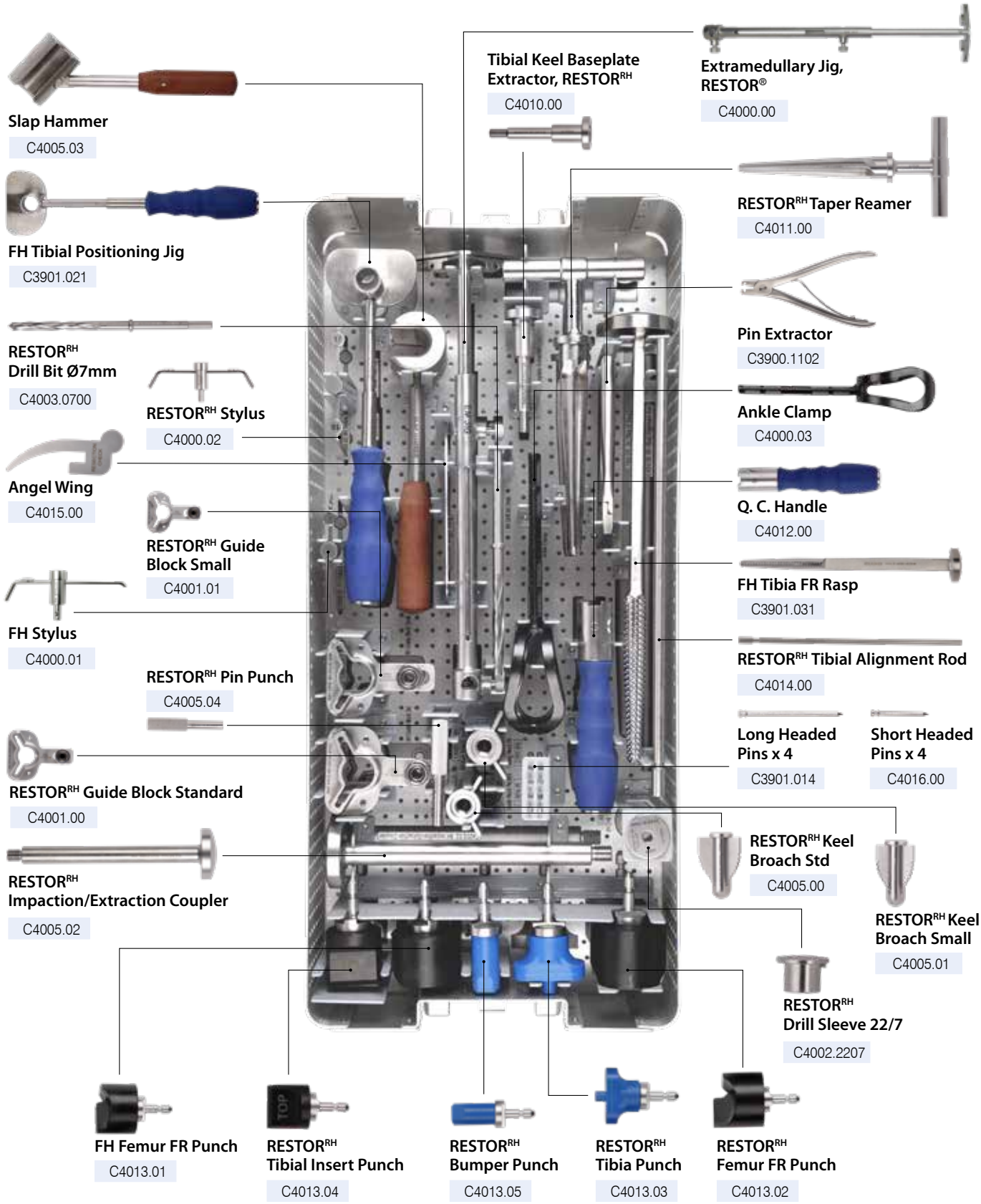
RESTOR[RH] Pivot Pin Aligner
C4008.00

Illustrations not to scale. Specifications subject to change without notice

RESTOR[RH]

Instrument Set

Instruments for Distal Femur



Slap Hammer
C4005.03

FH Tibial Positioning Jig
C3901.021

RESTOR[RH] Drill Bit Ø7mm
C4003.0700

RESTOR[RH] Stylus
C4000.02

Angel Wing
C4015.00

RESTOR[RH] Guide Block Small
C4001.01

FH Stylus
C4000.01

RESTOR[RH] Pin Punch
C4005.04

RESTOR[RH] Guide Block Standard
C4001.00

RESTOR[RH] Impaction/Extraction Coupler
C4005.02

Tibial Keel Baseplate Extractor, RESTOR[RH]
C4010.00

Extramedullary Jig, RESTOR®
C4000.00

RESTOR[RH] Taper Reamer
C4011.00

Pin Extractor
C3900.1102

Ankle Clamp
C4000.03

Q. C. Handle
C4012.00

FH Tibia FR Rasp
C3901.031

RESTOR[RH] Tibial Alignment Rod
C4014.00

Long Headed Pins x 4
C3901.014

Short Headed Pins x 4
C4016.00

RESTOR[RH] Keel Broach Std
C4005.00

RESTOR[RH] Keel Broach Small
C4005.01

RESTOR[RH] Drill Sleeve 22/7
C4002.2207

FH Femur FR Punch
C4013.01

RESTOR[RH] Tibial Insert Punch
C4013.04

RESTOR[RH] Bumper Punch
C4013.05

RESTOR[RH] Tibia Punch
C4013.03

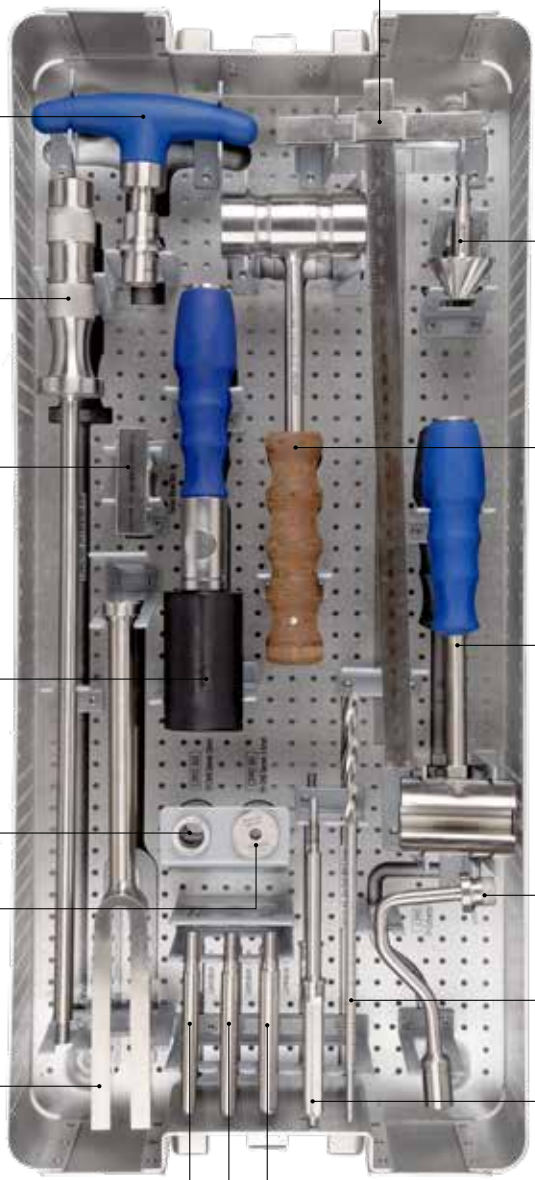
RESTOR[RH] Femur FR Punch
C4013.02

Illustrations not to scale. Specifications subject to change without notice

RESTOR[RH]

Instrument Set

Common Instruments, Rotating Hinge



Q. C. 'T' Handle
J0147.03

FH Extraction Rod
C3900.1001

Jig For Perpendicular Resection, RESTOR®
C3900.021

Q. C. Handle
C4012.00

FH Tibial Punch
C4013.07

FH Drill Sleeve Ø 13mm
C3902.062

FH Drill Sleeve Ø 5.5mm
C3902.061

FH Slotted Hammer
C3902.17

Right Angle Measuring Scale - Telescopic for RESTOR® Prosthesis
C3900.011

RESTOR® Conical Reamer, Modular
C3900.1401

Hammer With Fibre Handle, RESTOR®
C3902.18

Implant Extraction Hammer, RESTOR®
C3900.1002

Extractor Hook Assembly, RESTOR®
C3901.10

FH Drill Bit Ø 5.5mm
I0522.55

FH Pivot Pin Cutter
C3902.081

Centralizer, Ø 9mm
C3900.1403

Centralizer, Ø 10mm
C3900.1405

Centralizer, Ø 11mm
C3900.1404

RESTOR[RH]

Instrument Set

Trial Resection Pieces and IM Stems, Rotating Hinge

RESTOR®
Resection Piece,Trial
Bottom Tray

40mm

Code No.	Length (mm)
C1601.0304	40
C1601.0305	50
C1601.0306	60
C1601.0307	70
C1601.0308	80
C1601.0309	90
C1601.0310	100
C1601.0311	110
C1601.0312	120
C1601.0313	130
C1601.0314	140
C1601.0315	150
C1601.0316	160
C1601.0317	170
C1601.0318	180
C1601.0319	190
C1601.0320	200
C1601.0321	210
C1601.0322	220

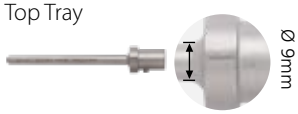
220mm

HA Collar Stem Spacer
C1601.0140

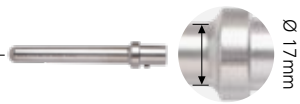
RESTOR® Resection Coupler, Trial

Length 180mm
C1604.0180

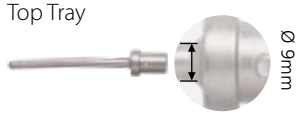
RESTOR® Straight, Intramedullary Stem, Trial
Top Tray



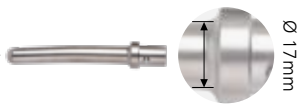
Code No.	Ø (mm)
Length 120 mm	
C1601.0109	09
C1601.0110	10
C1601.0111	11
C1601.0112	12
C1601.0113	13
C1601.0115	15
C1601.0117	17



RESTOR® Curved, Intramedullary Stem, Trial
Top Tray



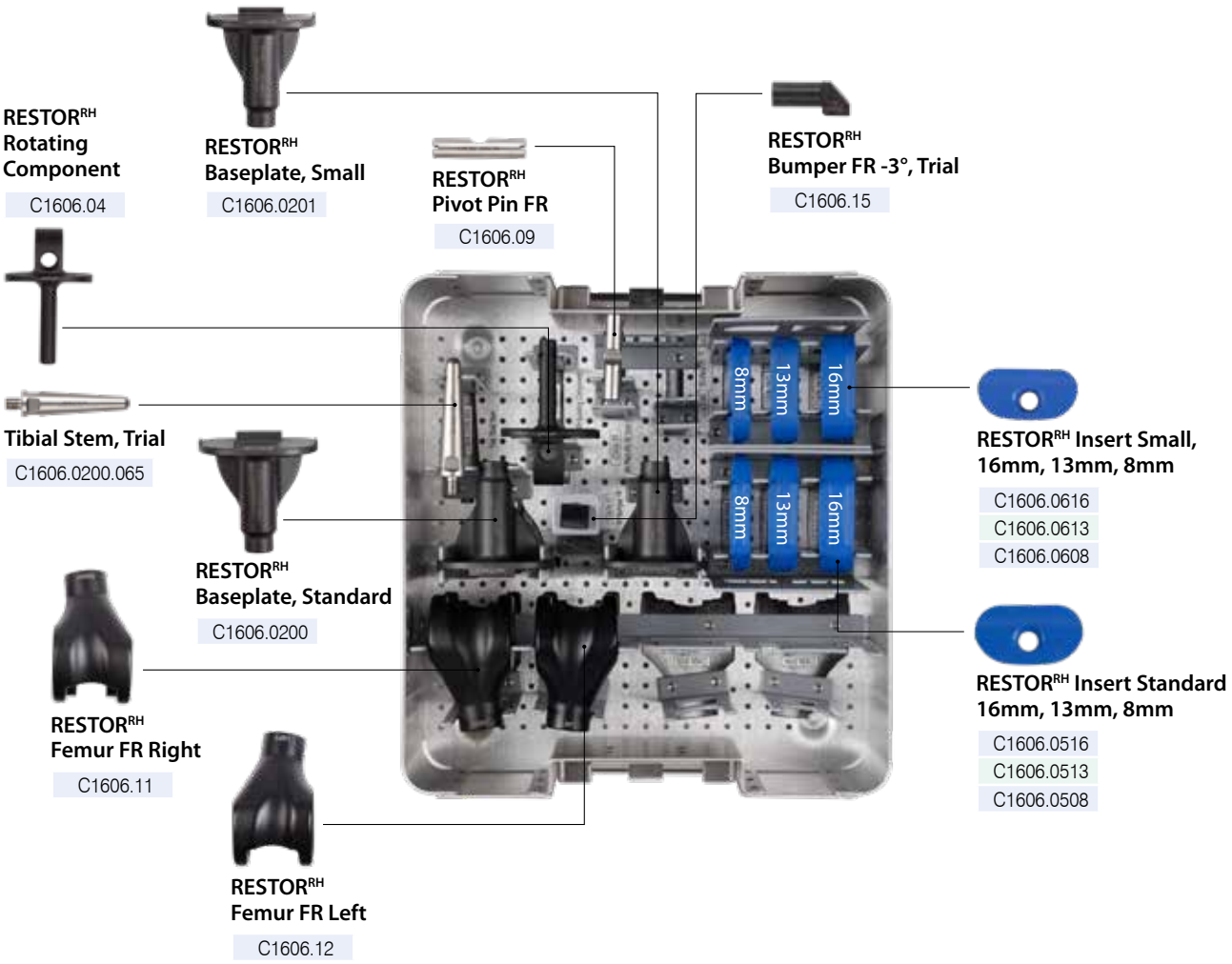
Code No.	Ø (mm)
Len.120 mm	
C1601.0209	09
C1601.0210	10
C1601.0211	11
C1601.0212	12
C1601.0213	13
C1601.0215	15
C1601.0217	17



RESTOR[RH]

Instrument Set

Trial Implants, Rotating Hinge



RESTOR[RH]

Implants

Rotating Hinge

RESTOR® Straight, Intramedullary Stem, Ti

Length 120 mm	Ø (mm)
A1601.0109	09
A1601.0110	10
A1601.0111	11
A1601.0112	12
A1601.0113	13
A1601.0115	15
A1601.0117	17

RESTOR® Curved, Intramedullary Stem, Ti

Length 120 mm	Ø (mm)
A1601.0209	09
A1601.0210	10
A1601.0211	11
A1601.0212	12
A1601.0213	13
A1601.0215	15
A1601.0217	17

RESTOR® Resection Piece - SS/Ti

S.Steel	Titanium	Length (mm)
A1601.0304	A1601.1304	40
A1601.0305	A1601.1305	50
A1601.0306	A1601.1306	60
A1601.0307	A1601.1307	70
A1601.0308	A1601.1308	80
A1601. 0309	A1601.1309	90
A1601.0310	A1601.1310	100
A1601.0311	A1601.1311	110
A1601.0312	A1601.1312	120
A1601.0313	A1601.1313	130
A1601.0314	A1601.1314	140
A1601.0315	A1601.1315	150
A1601.0316	A1601.1316	160
A1601.0317	A1601.1317	170
A1601.0318	A1601.1318	180
A1601.0319	A1601.1319	190
A1601.0320	A1601.1320	200
A1601.0321	A1601.1321	210
A1601.0322	A1601.1322	220

RESTOR[RH] Femur FR - CoCr, Left with XLPE Bushes & Pivot Pin

A1606.0102

RESTOR[RH] Femur FR - CoCr, Right with XLPE Bushes & Pivot Pin

A1606.0101

RESTOR[RH] Pivot Pin FR

A1606.09

RESTOR[RH] Femoral Bush FR pair

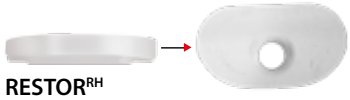
A1606.08

RESTOR[RH] Bumper FR - 3°

A1606.11

RESTOR[RH] Rotating Component

A1606.04



RESTOR[RH] XLPE Tibial Insert FR Standard - 8mm, 13mm, 16mm

A1606.0508
A1606.0513
A1606.0516

RESTOR[RH] XLPE Tibial Insert FR Small - 8mm, 13mm, 16mm

A1606.0608
A1606.0613
A1606.0616

RESTOR[RH] Tibial Sleeve FR

A1606.10

RESTOR[RH] Tibia FR Keel Baseplate, Small Assembly consisting of Tibial Sleeve A1606.10 and Tibial Stem 65mm A1606.0200.065

A1606.0201

RESTOR[RH] Tibia FR Keel Baseplate, Standard Assembly consisting of Tibial Sleeve A1606.10 and Tibial Stem 65mm A1606.0200.065

A1606.0200

Tibial Stem 65mm

A1606.0200.065

Illustrations not to scale. Specifications subject to change without notice

Important Medical Information

Purpose

The RESTOR® system is designed to Restore structural skeletal stability and enable functional joint mobility in patients undergoing limb salvage surgery for bone tumors or in patients undergoing revision of a conventional joint replacement prosthesis with extensive bone loss.

Patient selection criteria for use of the RESTOR® system must be carefully observed and must respect the following criteria:

1. Patients whose anatomic features allow for implant dimensions adequate to withstand expected loading and degree of activity.
2. Patients who are willing and able to respect their physician's directions, particularly with regard to the necessary stress reduction on the implant, either partially or totally in the immediate post-operative period, if indicated.

The largest possible diameter of intramedullary stem should be selected from the RESTOR® system, particularly for obese patients. Patients must be cautioned about the consequences of participation in sports or any other activity that could cause excessive loading or strain on the implanted components.

System Description and Materials

RESTOR® is a modular system with components that can be selected either pre-operatively or intra-operatively.

RESTOR® implants consist of cast cobalt-chromium-molybdenum alloy (ISO 5832-4), wrought titanium-aluminium-vanadium alloy Ti_6Al_4V ELI (ISO 5832-3), stainless steel AISI 316L, Hi Nitrogen Stainless Steel (ISO 5832-9) or Stainless Steel 316LVM (ISO 5832-1). PE components are made from UHMWPE (ISO 5834-2). Adler Healthcare warrants that these devices are fabricated from the material specifications defined herein. No other warranties, either expressed or implied, are made.

RESTOR® system components are strictly single-use devices.

Indications, Contraindications and possible Adverse Effects

Indications

The use of modular prosthesis is frequently the consequence of resection of a bone tumor. Other indications could include revision of a conventional joint replacement prosthesis with extensive bone loss.

Careful preoperative planning and precise surgical technique form the basis required to achieve optimal results with the RESTOR® system. Operating surgeons must consider different factors in order to minimize the risk of postoperative complications, such as the anatomical stress situation, available soft tissue support and alignment of the components planned. It is preferable to implant the RESTOR® system only in patients with fully grown skeletal structures.

The RESTOR® system can enable quick Restoration of function and considerably improve the quality of life of the patient. However, at no stage must the primary goal of achieving oncological clearance be compromised in the attempt to Restore function.

Contraindications

Primary contraindications include bacterial infections, poor quality soft tissue cover and defects in soft tissues caused by irradiation. Other contraindications would include:

1. Anatomical conditions which do not allow for an adequate implant size.
2. Anatomical conditions that would not maintain sufficient bony support for the implant.
3. Insufficient blood supply caused by prior surgeries or vessels affected by alcohol abuse or due to other factors.
4. Mental or other neurological conditions that could affect the patients capability to follow restrictions in activity. Such conditions would include but would not be restricted to drug abuse, mental illness, senility and general neurological limitations.
5. Any conditions that could cause extreme stress on the implanted components such as polyarthropathies, myopathies etc.

Contraindications may, in many cases, be of a relative nature rather than an absolute contraindication. Hence, contraindications must be carefully considered with respect to the complete status of the patient as well as the comparative prognosis of alternative therapies.

Possible Adverse Effects

1. Loosening, distortion or fracture of one or more components of the device. Usually, these effects are likely to be caused by one or more of the factors listed as contraindications.
2. Migration, subluxation or rotation of the implant, flexion contractures, reduction in mobility, increase or decrease in leg length and bone wear.
3. Acute postoperative wound infection and severe sepsis.
4. Postoperative fractures of the tibia, femur, patella, humerus or ulna.
5. Cardiovascular disorders, wound haematoma, venous thromboses, pulmonary embolisms.
6. Tissue reactions such as phagocytal reactions, foreign body reactions or myositis ossificans.

Warnings and Precautions

The possibility of implant loosening, bending, fissure and/or breakage and other complications can greatly increase if the following instructions and warnings are not considered and followed:

Preoperative:

1. In every surgery, all implant sizes must be available. Before insertion, implant components must be carefully checked to ensure absence of damage during preoperative handling and to confirm correct size selection.
2. Implant components must be handled with great care at all times. Cutting, bending, denting or scratching of the implant surfaces can considerably reduce stability and resistance to fatigue and wear. Even defects that are not easily visible could lead to stress conditions within the implant that could lead to premature failure on dynamic loading.
3. If preoperative planning and analysis indicates that the available modular components may not suit the patient, the use of a customized implant is necessary.
4. Allergies and other reactions to implanted materials should be considered and tested for if indicated to enable preoperative exclusion.
5. **Instruments used to introduce the implant must be compatible with the implant components and hence must necessarily belong to the RESTOR® system.**
6. The operating surgeon must be sufficiently familiar with principles and operative techniques related to the surgery being performed as well as the recommended surgical technique and instrumentation for this system and its proper use. A description of the surgical technique with this system is available with the manufacturer.

Intraoperative

1. Adequate and durable component support achieved through proper cementation technique and/or bone graft and correct component size selection are critical for optimal results.
2. Repositioning of implant components during the phase of cement hardening must be avoided.
3. The operating surgeons must avoid excessive limb lengthening in order to prevent neurovascular complications.
4. It is extremely important to achieve correct axial and rotational alignment of the implant. Not doing so could lead to subluxation, dislocation and/or breakage of implant components. Particular attention should be paid to curved intramedullary stems which may rotate while being inserted leading to incorrect alignment.
5. Revision surgeries following a preceding primary surgery could be extremely demanding. Common mistakes during revision surgeries include incorrect surgical access, insufficient identification and mobilization of bony structures, insufficient removal of ectophytic bone material or imprecise positioning of the components. Extreme blood loss and postoperative instability are possible consequences. Overall, longer operating times, risk of pulmonary embolism and wound haematoma, increased blood loss are factors that must be taken into consideration in cases of revision surgery.
6. The tapered interlocking surfaces of modular components must be thoroughly cleaned and dried before assembly with the corresponding mating component. Any unremoved particle present on the surface could cause extreme friction and wear and may be responsible for premature failure.
7. Modular components once assembled must not be disassembled and re-used due to microscopic surface changes during the assembly process.

Postoperative

1. Postoperative instructions and warnings by the physician and patient care in the postoperative period are of great importance. External support to the operated limb in the immediate postoperative period to enhance the healing process is recommended in some cases.
2. Postoperative therapy should support the process of healing and prevent the leg from being submitted to excessive stresses.
3. Caution must be exercised in carrying out active and passive movements.
4. Patients should be repeatedly reminded of the need to modify their activity levels as recommended by the physician.

Special Note to Users

Implant components that have been implanted and removed must never be re-used even if they appear undamaged due to the high risk of fatigue failure due to internally accumulated material stresses.

Packaging and labeling

RESTOR® implant components are supplied pre-sterile in double packaging packed into outer boxes. Sterilisation is carried out gamma irradiation / ethylene oxide gas using validated sterilisation parameters and processes. Packaging must be carefully checked for perforation or other damage prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery.

Metallic components may be re-sterilised using steam or ethylene oxide sterilization process.

Re-sterilization of PE components is not permitted.

Further information

For further information concerning the use of this system, please check with Adler® customer service at the addresses given overleaf or email ***info@adler-healthcare.com***.

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AHPLXI.2024.20.a