



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 skeletal stability while retaining functional joint mobility and is acknowledged as the standard of care in the treatment of bone tumours.

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 **restorRH** (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.

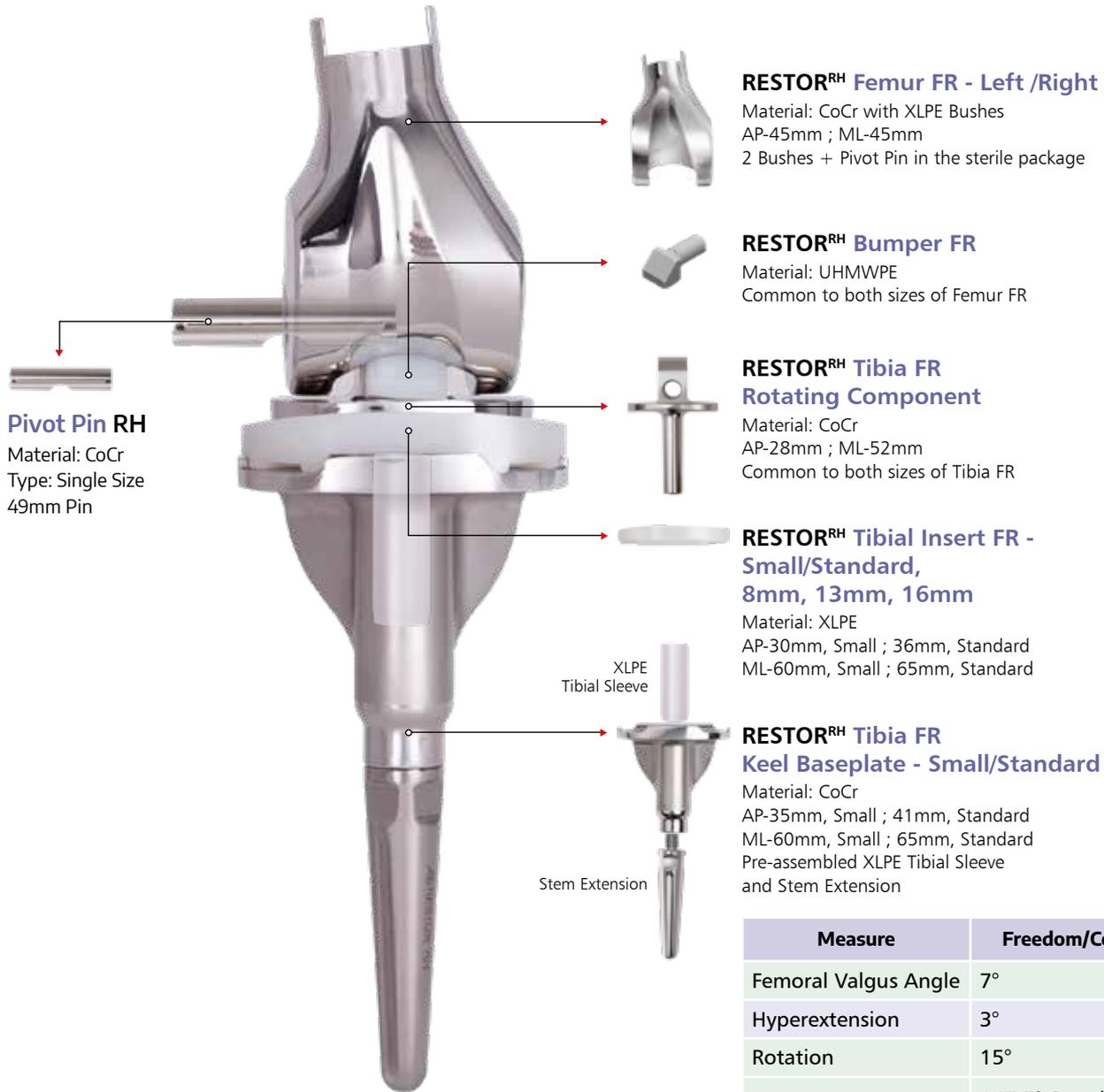
Careful preoperative planning and precise surgical technique form the basis required to achieve optimal results with the RESTOR system. Operating surgeons must consider different factors in order to minimize the risk of postoperative complications, such as the anatomical stress situation, available soft tissue support and alignment 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 multi plearthropathies, 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[®] Femur FR - Left /Right
Material: CoCr with XLPE Bushes
AP-45mm ; ML-45mm
2 Bushes + Pivot Pin in the sterile package

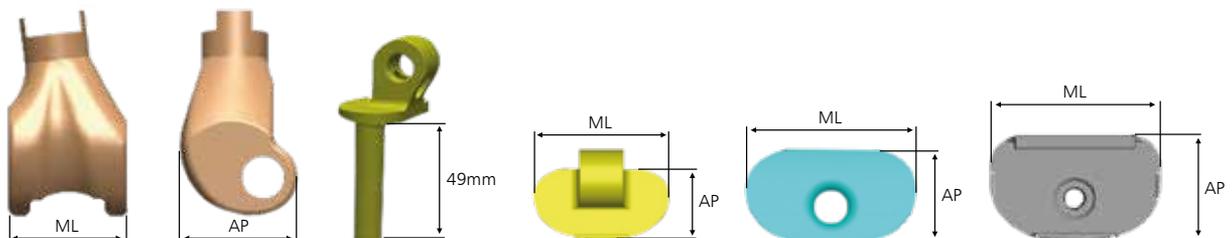
RESTOR[®] Bumper FR
Material: UHMWPE
Common to both sizes of Femur FR

**RESTOR[®] Tibia FR
Rotating Component**
Material: CoCr
AP-28mm ; ML-52mm
Common to both sizes of Tibia FR

**RESTOR[®] Tibial Insert FR -
Small/Standard,
8mm, 13mm, 16mm**
Material: XLPE
AP-30mm, Small ; 36mm, Standard
ML-60mm, Small ; 65mm, Standard

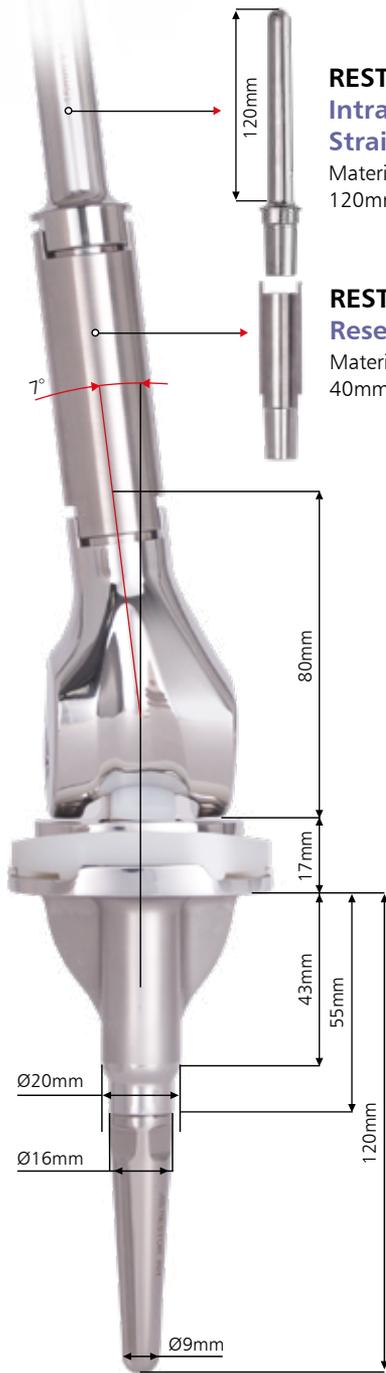
**RESTOR[®] Tibia FR
Keel Baseplate - Small/Standard**
Material: CoCr
AP-35mm, Small ; 41mm, Standard
ML-60mm, Small ; 65mm, Standard
Pre-assembled XLPE Tibial Sleeve
and Stem Extension

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



RESTOR^{RH}

Distal Femoral Replacement Resection Planning

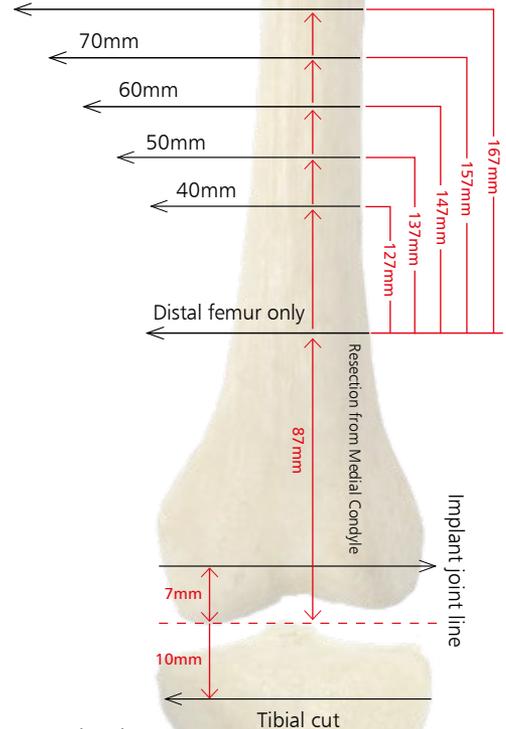


**RESTOR[®]
Intramedullary Stem,
Straight/Curved**
Material: Ti
120mm

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

Restor[®] Resection Level Guide

Resection Piece Cuts
80mm



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 femoral resection should be 7mm longer than the femoral component implanted.

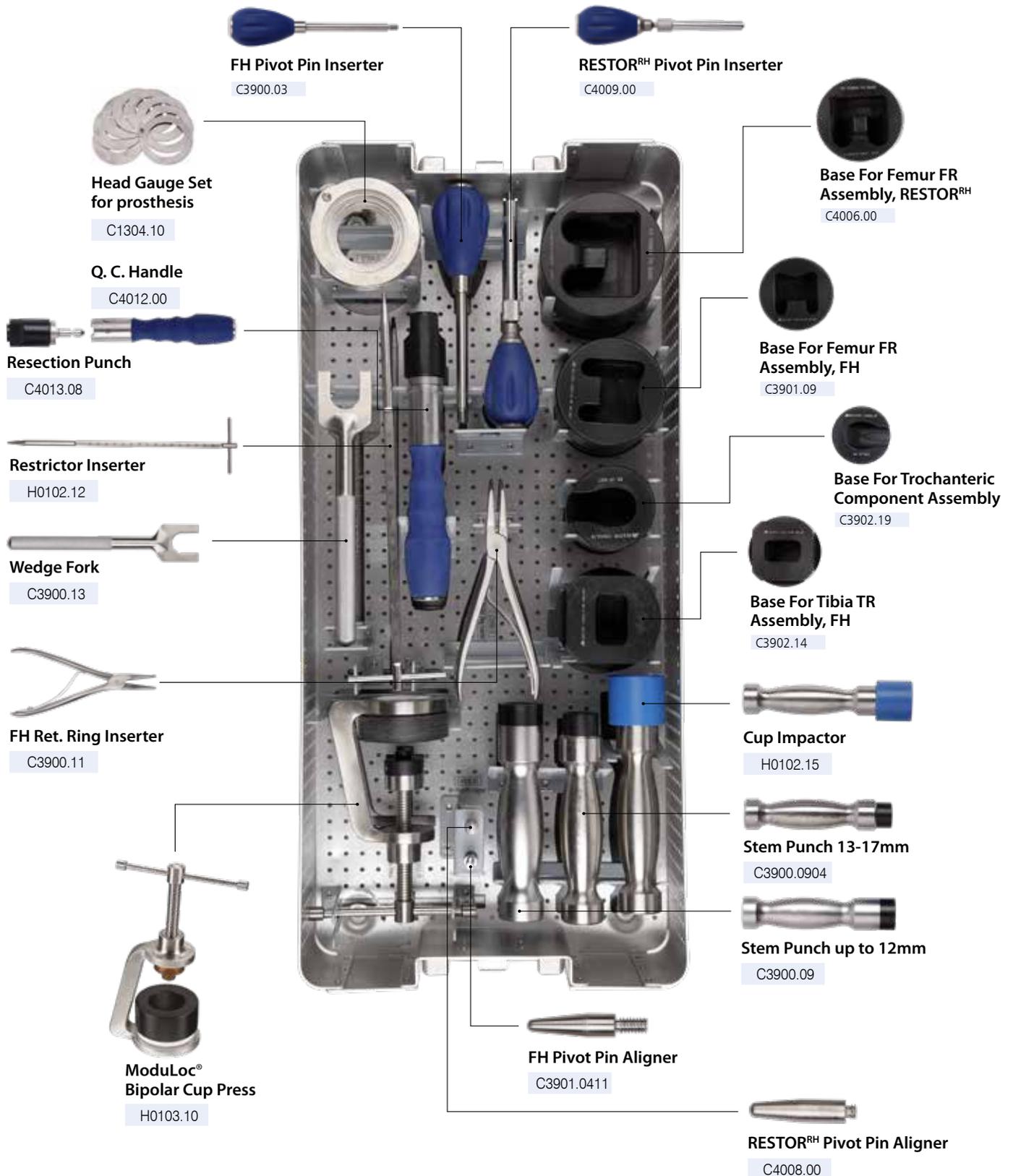
The length of the distal femoral component alone (without an additional resection piece) is 80mm (70mm for the distal femur + 10mm stem collar). This will require an 87mm distal femoral resection.

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}

Instrument Set

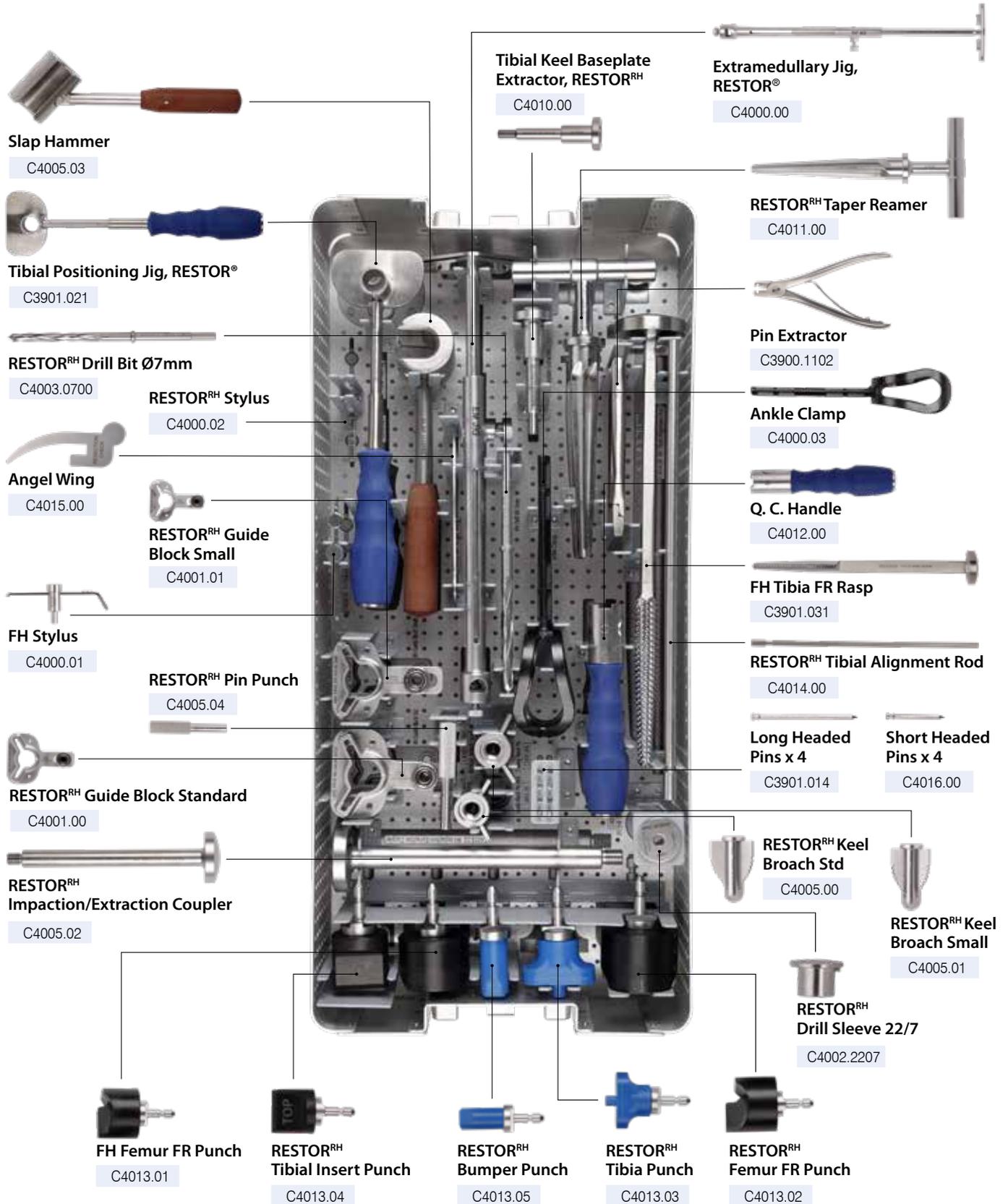
Assembly/Disassembly, Rotating Hinge



RESTOR^{RH}

Instrument Set

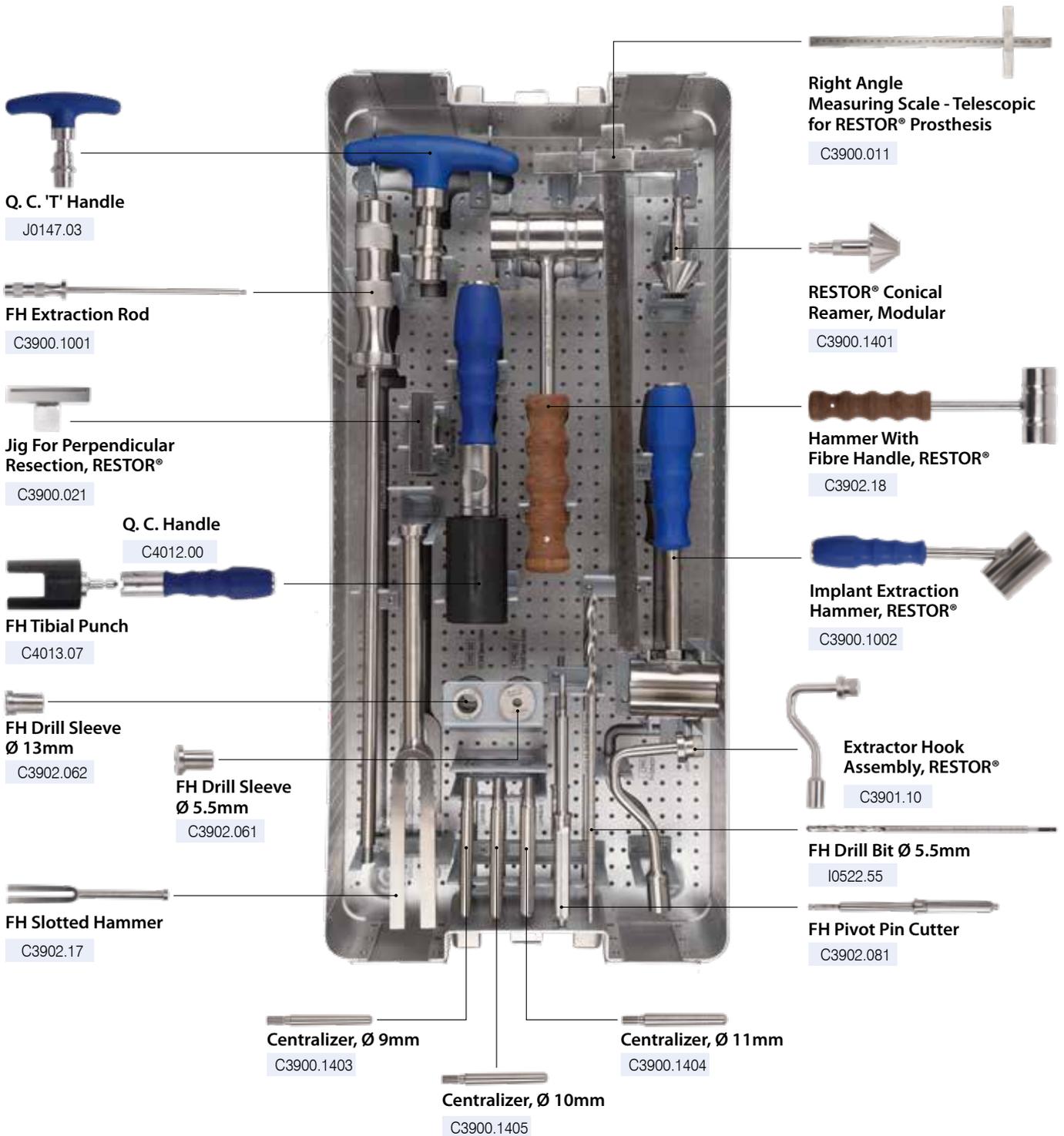
Instruments for Distal Femur



RESTOR^{RH}

Instrument Set

Common Instruments, Rotating Hinge



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

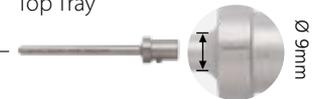


HA Collar Stem Spacer
C1601.0140

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



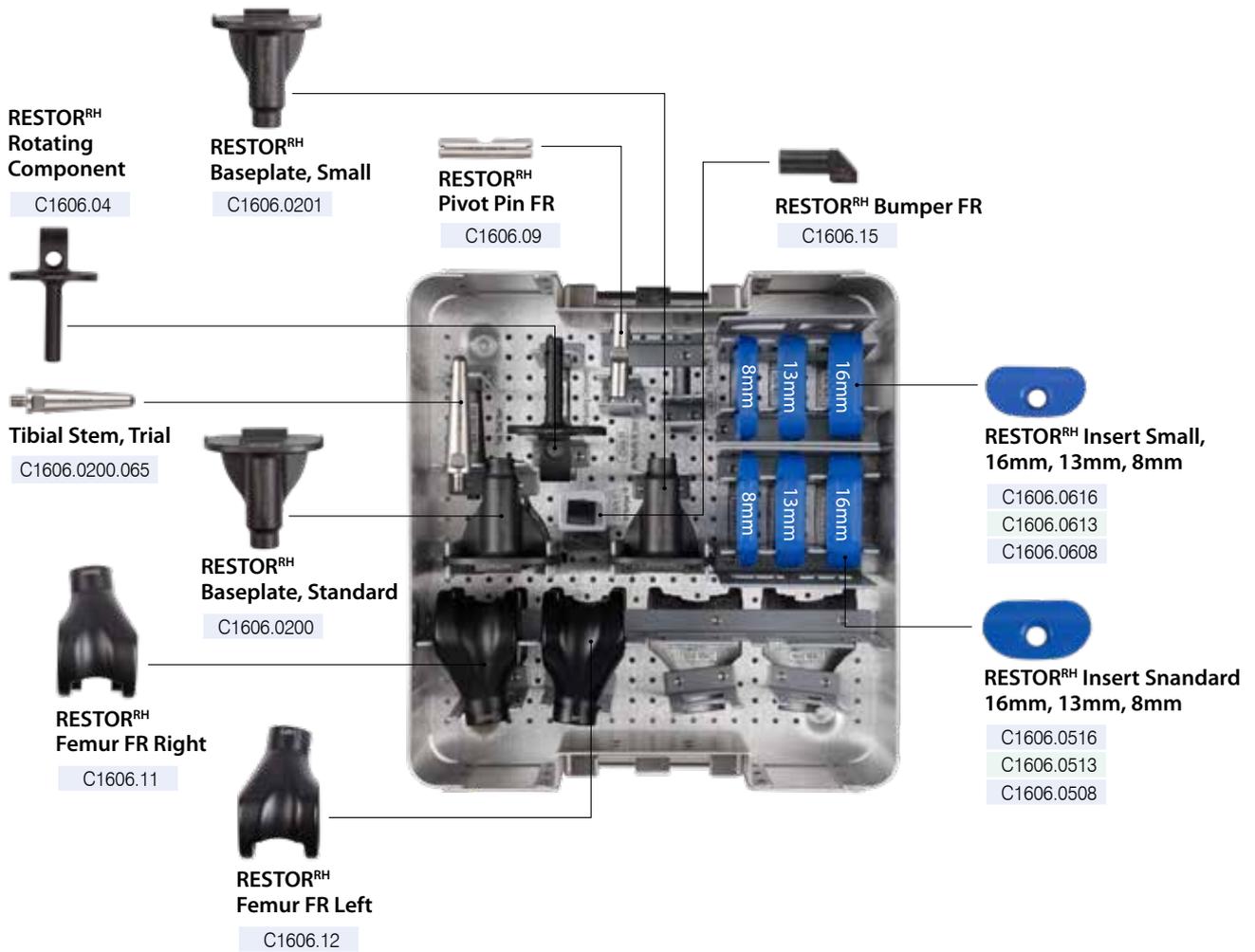
Code No.	Ø (mm)
Len. 120 mm	
C1601.0209	09
C1601.0210	10
C1601.0211	11
C1601.0212	12
C1601.0213	13
C1601.0215	15
C1601.0217	17



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

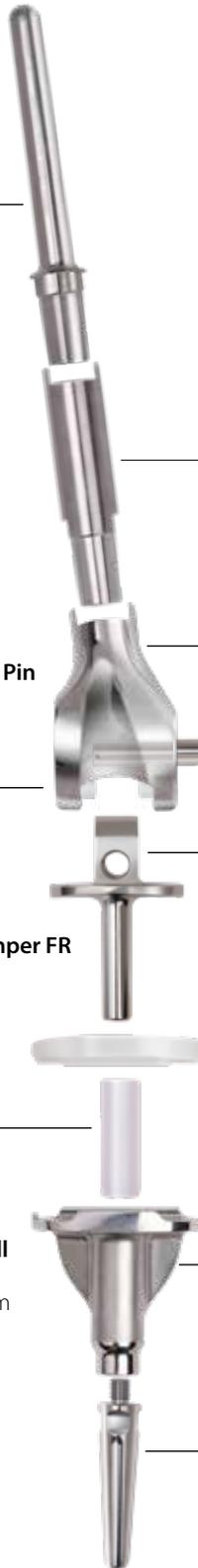
Length 120 mm	Ø (mm)
A1601.0209	09
A1601.0210	10
A1601.0211	11
A1601.0212	12
A1601.0213	13
A1601.0215	15
A1601.0217	17

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} Femoral Bush FR pair
A1606.08

RESTOR^{RH} UHMWPE Bumper FR
A1606.11

RESTOR^{RH} Pivot Pin Fr
A1606.09

RESTOR^{RH} Tibia FR 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

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-aluminum-vanadium alloy Ti₆Al₄V 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 multiple arthropathies, 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.



® Manufactured & marketed by

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