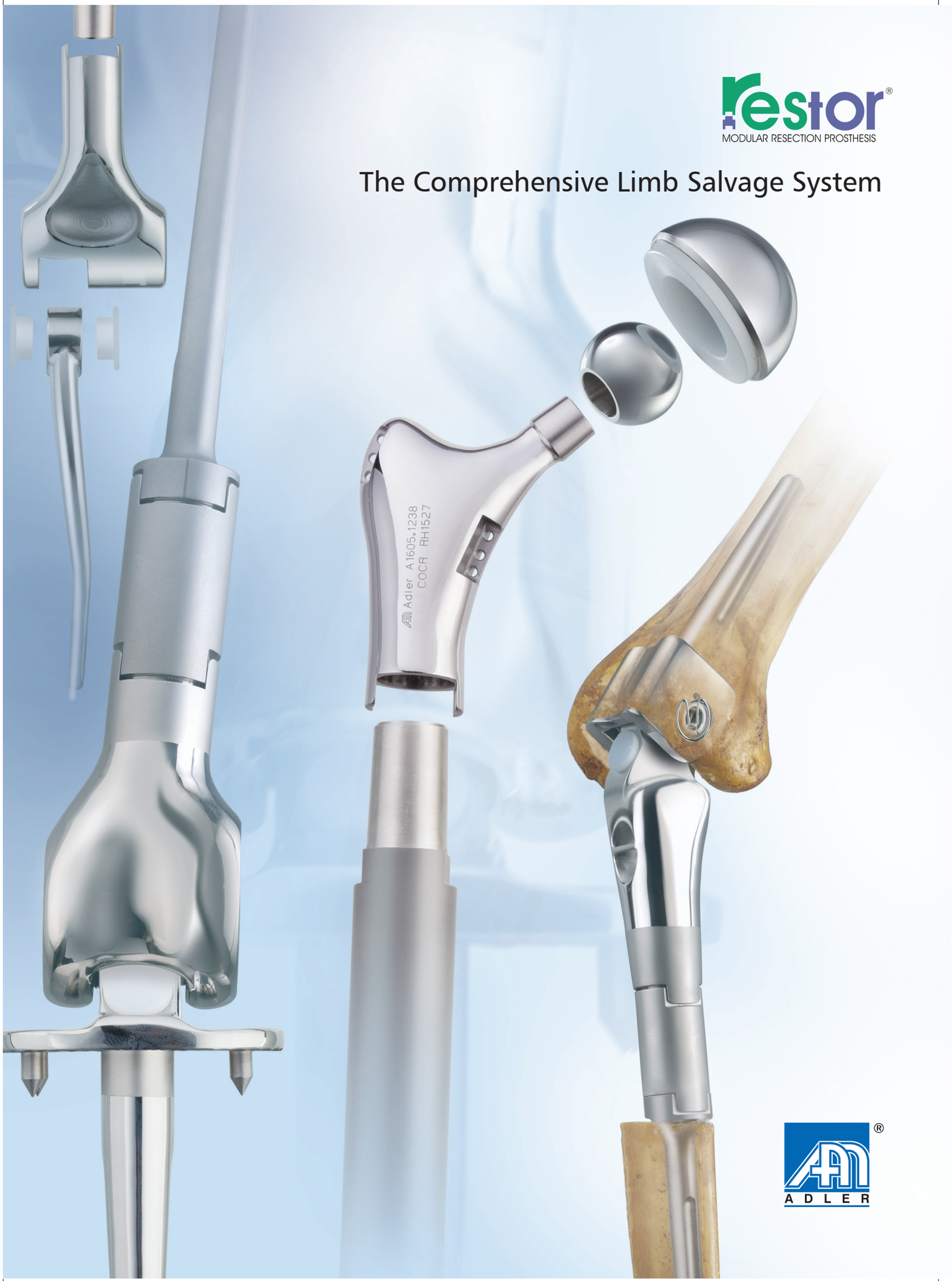

restor®
MODULAR RESECTION PROSTHESIS
The Comprehensive Limb Salvage System
Adler A1605.1238
COCR RH1527
ADLER®

RESTOR™
MODULAR RESECTION PROSTHESIS

The management of malignant bone tumors has made vast strides in the last few decades. From an era where amputation was the only option, to the current day function preserving resections and complex reconstructions has been a major advance.

Contemporary limb salvage surgery aims to compensate the loss of diseased bone and soft tissue with reconstructions that retain near-normal limb function .

The recent past has seen an increasing acceptance of limb salvage surgery whereby the operating surgeon successfully removes the diseased area of the bone and compensates the resulting loss of bone and muscle with the objective of not only avoiding an amputation but retaining near-normal limb function.

The use of ''megaprostheses'', so named due to the large segments of bone usually replaced, has gained acceptance in limb salvage surgery over the last few years. Megaprostheses offer a patient the twin benefits of restoring structural skeletal stability while retaining functional joint mobility.

The widespread use of limb salvage surgery with megaprostheses has been constrained due to various factors, some of which include;

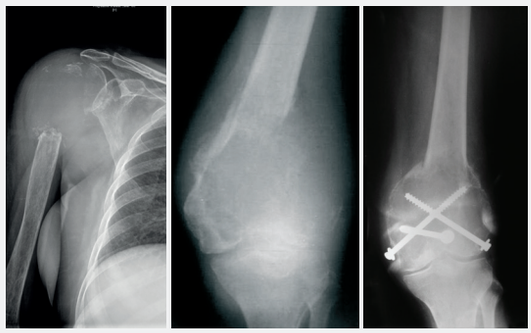
- The necessity of customizing a prosthesis to individual patient parameters, which is a time consuming and difficult process
- Lack of easy availability of off the-shelf modular designs which can be used without the long manufacturing lead time of a customized prosthesis
- Prohibitively high cost of contemporary modular prosthesis designs

RESTOR® (Resection of Tumor and Optimal Reconstruction), a cemented, modular resection prosthesis system that enables reconstruction following limb salvage surgery, was conceived to address these issues and provide a clinically proven and cost-effective solution to patients who could benefit from limb salvage surgery following tumors of :

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

Indications

Indications for limb salvage surgery with reconstruction using the RESTOR® system would include -



Osteosarcoma of the upper end of the Humerus

Metastasis from renal carcinoma

Recurrent Giant Cell Tumor of the lower end of the femur

- Primary malignant bone tumors
- Metastatic bone tumors
- Benign bone tumors (where intra-lesional methods may be unsuitable)

The RESTOR® system may also be a suitable option for revision of a conventional joint replacement prosthesis with extensive bone loss.

Achieving adequate oncological clearance while retaining function is the guiding principle of limb salvage surgery. At no stage must the primary goal of achieving oncological clearance be compromised in an attempt to retain function.

Limb salvage surgery must not be contemplated if adequate oncological clearance would be compromised.

The System

ResTOR® is supported by nearly seven years of prior experience with the first generation customized megaprosthesis (TMH-NICE), a collaborative effort between orthopaedic oncologists Dr. Ajay Puri, Dr. Manish Agarwal and the team at the Tata Memorial Hospital, Mumbai with the Adler® product development team. The clinical performance of the TMH-NICE prosthesis was validated in an institutional review board approved prospective trial. Early results were published[b]. The extensive clinical experience gained with the first generation implant and detailed analysis of failures that occurred formed the basis on which the RESTOR® system evolved. As compared to the first generation implant, RESTOR® witnessed major transformations in engineering design, materials and manufacturing technologies, all of which are targeted towards achieving contemporary survivorship benchmarks for limb salvage prostheses. Early clinical results[o] appear to indicate that implant survivorship with the system would achieve benchmarks currently considered state-of-the-art.

Separate left & right sided femoral components with normal valgus angulation

Helps in recreating normal anatomy

Hyperextension built in to the femoro-tibial articulating components

Allows passive locking during gait and prevents buckling on loading even in patients with extensive muscle resection

Patellar groove built into the femoral component

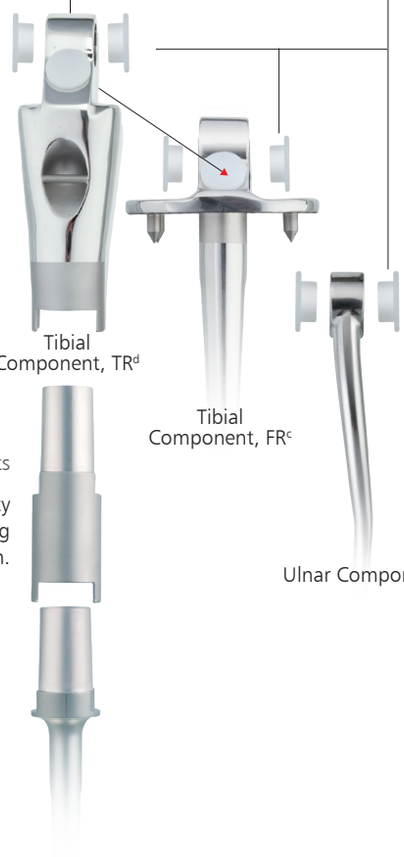
Enables normal patellar tracking which is important as the patella is usually preserved.

Polyethylene wedge incorporated in the tibial component

Cushions impact in terminal extension thereby reducing the loading at the bone cement interface

Polyethylene bushings prevent metal on metal articulation

Reduces metallic debris, thereby decreasing one of the major factors responsible for aseptic loosening



Tibial Component, TR[d]

Tibial Component, FR[c]

Modular components

Enables intra-operative flexibility in size selection depending on the actual resection.

Ulnar Component

Standardized components

Off the shelf availability eliminates delay inherent in the manufacture of customized components.

Specialised Instrumentation

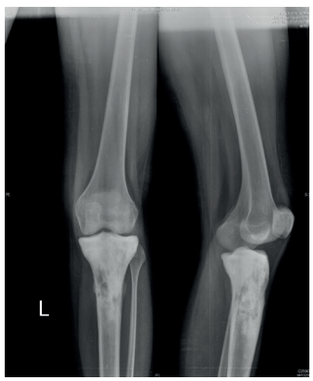
Facilitates and standardizes surgical technique.

[b] Limb Salvage in Osteosarcoma-The Mumbai experience: Agarwal M. G., Puri A. et al, Clinical Orthopaedics and Related Research, 2007

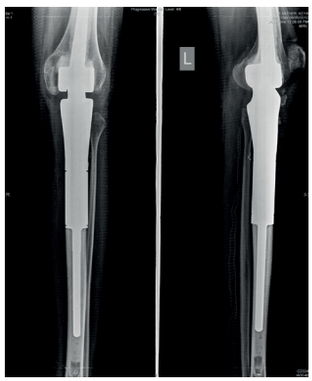
[c] Femoral Resection [d] Tibial Resection [o] Revision of Broken Knee Megaprosthesis - New Solution to Old problems: Agarwal M. G., Puri A. et al, Clinical Orthopaedics and Related research, 2010

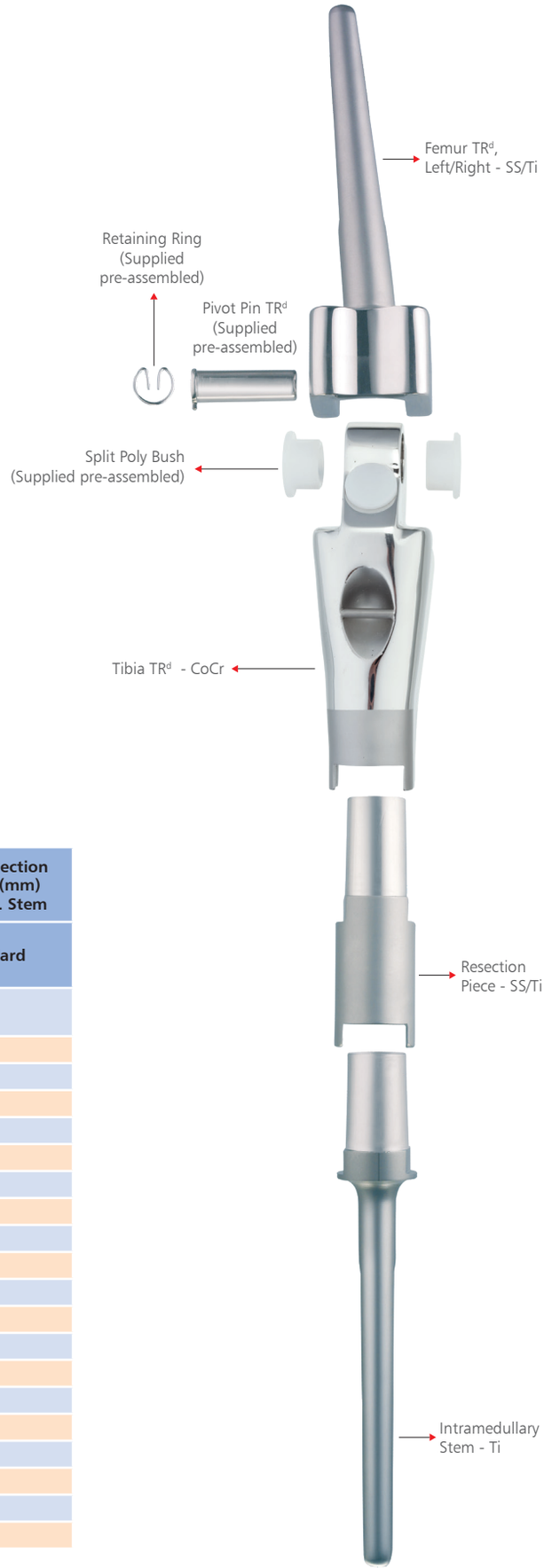
Proximal Tibia Resection

Proximal Tibia Resection, Pre-Op*



Proximal Tibia Resection, Post-Op*





Condylar Component Dimensions

Length (mm)	Femur TR[d] -Left/Right	Tibia TR[d]
M-L	36	35
A-P	34	35

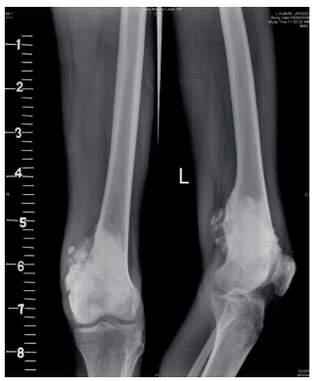
Component Selection Guide - Proximal Tibia Resection

Distal Femur Component - SS / Ti	Proximal Tibia Component - CoCr, Length (mm)	Resection Piece - SS / Ti, Length (mm)	I.M. Stem - Ti, Ø (mm) Straight/Curved	Total Resection Length (mm) with I.M. Stem
			Standard	Standard
Femur TR[d] -Left/Right	Tibia TR[d] - 80	Nil	10, 11, 12, Straight/Curved	80
		40		120
		50		130
		60		140
		70		150
		80		160
		90		170
		100		180
		110		190
		120		200
		130		210
		140		220
		150		230
		160		240
		170		250
		180		260
		190		270
		200		280
		210		290
		220		300

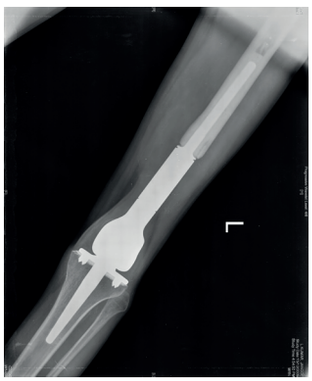
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c]Femoral Resection [d]Tibial Resection [f]Hydroxyapatite

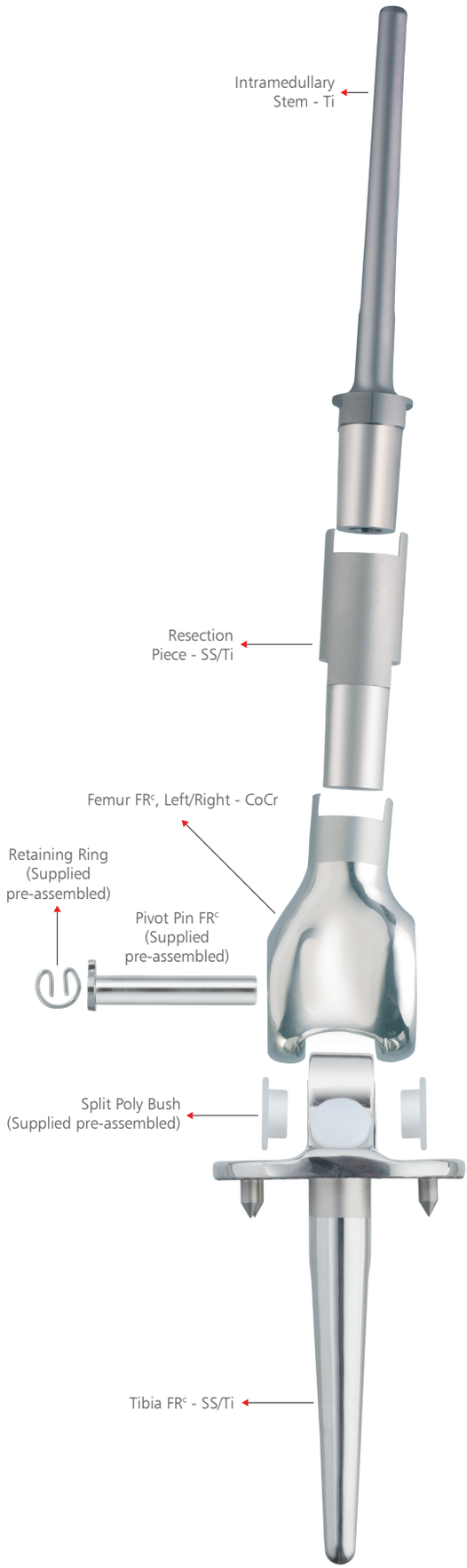
Distal Femur Resection

Distal Femur Resection, Pre-Op*



Distal Femur Resection, Post-Op*





Condylar Component Dimensions

Length (mm)	Tibia FR[c] - Regular	Tibia FR[c] -Small	Femur FR[c] -Left/Right
M-L	65	60	45
A-P	40	35	40

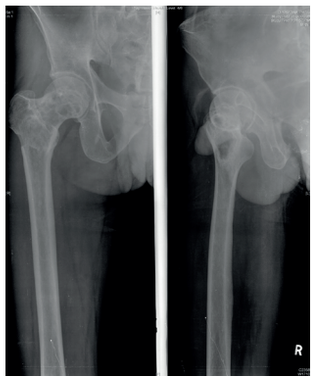
Component Selection Guide - Distal Femur Resection

Proximal Tibia Component - SS / Ti	Distal Femur Component - CoCr Femur FR, Length (mm)	Resection Piece - SS / Ti, Length (mm)	I.M. Stem - Ti, Ø (mm) Straight/Curved	Total Resection Length (mm) with I.M. Stem
			Standard	Standard
Tibia Fr[c]- Regular/Small	Femur Fr[c] - Left/Right-80	Nil	10, 11, 12, Straight/Curved	80
		40		120
		50		130
		60		140
		70		150
		80		160
		90		170
		100		180
		110		190
		120		200
		130		210
		140		220
		150		230
		160		240
		170		250
		180		260
		190		270
		200		280
		210		290
		220		300

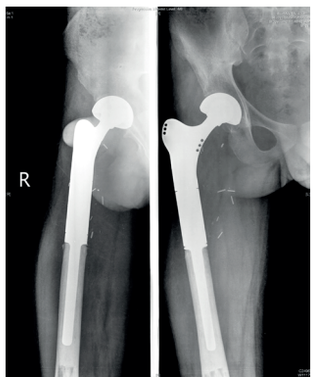
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c] Femoral Resection [d] Tibial Resection [f] Hydroxyapatite

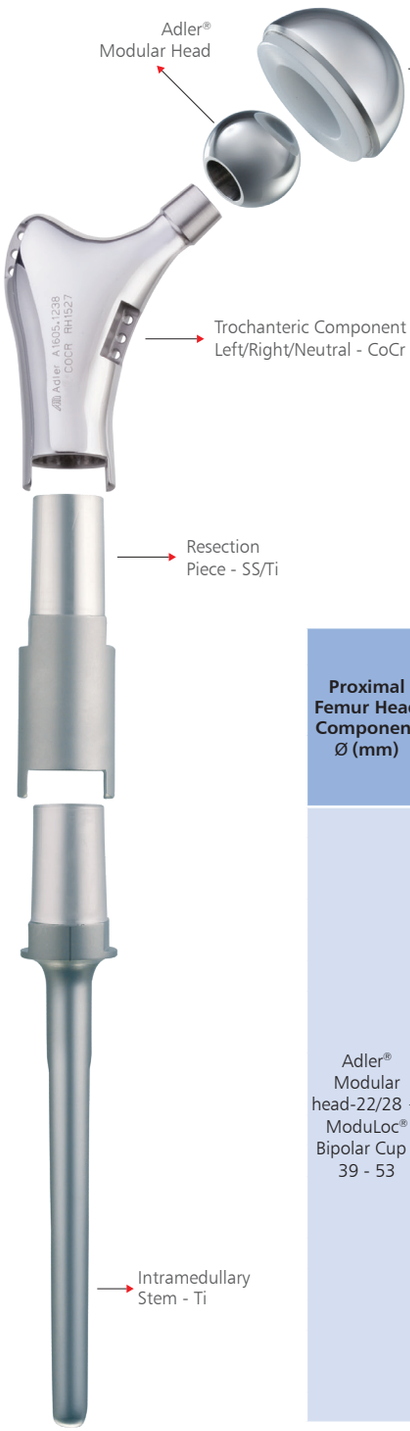
Proximal Femur Resection

Proximal Femur Resection, Pre-Op*



Proximal Femur Resection, Post-Op*



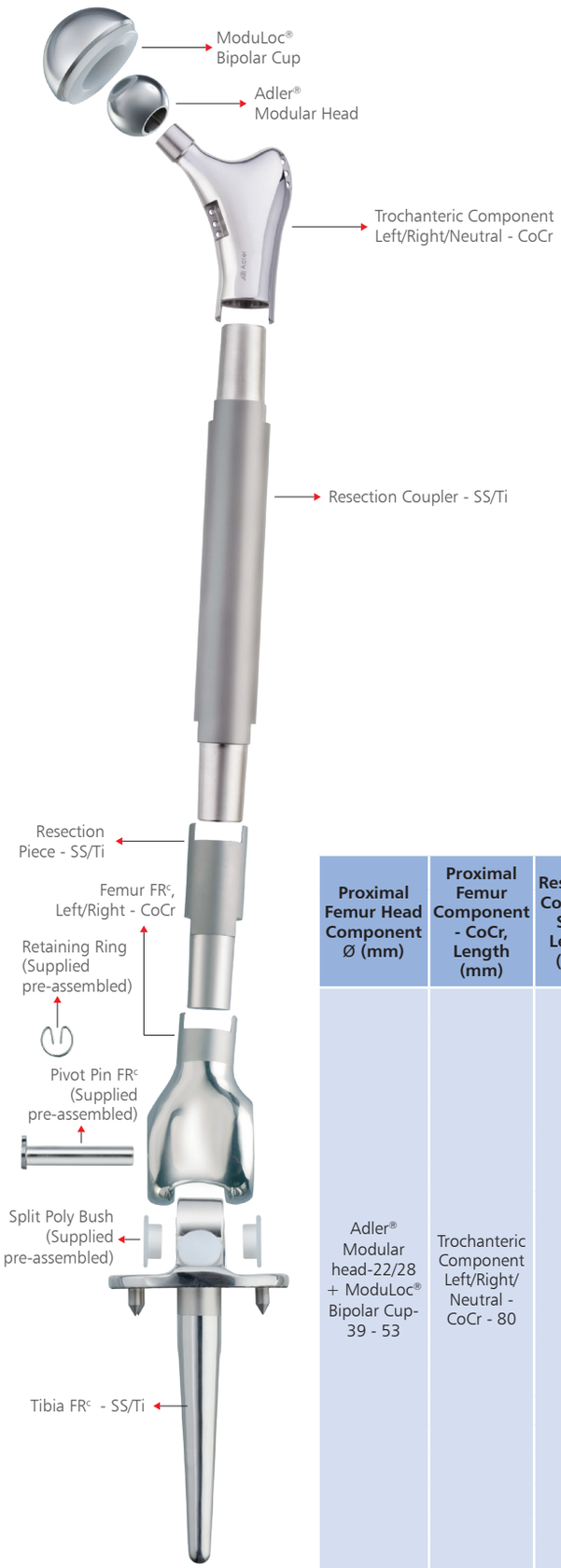


Component Selection Guide - Proximal Femur Resection

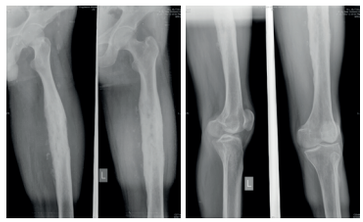
Proximal Femur Head Component Ø (mm)	Proximal Femur Component - CoCr, Length (mm)	Resection Piece - SS / Ti, Length (mm)	I.M. Stem - Ti, Ø (mm) Straight/ Curved	Total Resection Length (mm) With Head				
				NL[e] -3.5, Lat Offset 35.5	NL[e] -2.0, Lat Offset 36.5	NL[e] 0, Lat Offset 38.0	NL[e] +3.5, Lat Offset 40.5	NL[e] +7.5, Lat Offset 44.0
			Standard	Standard Stem	Standard Stem	Standard Stem	Standard Stem	Standard Stem
Adler® Modular head-22/28 + ModuLoc® Bipolar Cup - 39 - 53	Trochanteric Component Left/Right/Neutral - CoCr - 80	Nil	10, 11, 12, Straight/Curved	78	79	80	82	85
		40		118	119	120	122	125
		50		128	129	130	132	135
		60		138	139	140	142	145
		70		148	149	150	152	155
		80		158	159	160	162	165
		90		168	169	170	172	175
		100		178	179	180	182	185
		110		188	189	190	192	195
		120		198	199	200	202	205
		130		208	209	210	212	215
		140		218	219	220	222	225
		150		228	229	230	232	235
		160		238	239	240	242	245
		170		248	249	250	252	255
		180		258	259	260	262	265
		190		268	269	270	272	275
		200		278	279	280	282	285
		210		288	289	290	292	295
		220		298	299	300	302	305

*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c]Femoral Resection [d]Tibial Resection [e]Neck Length [f]Hydroxyapatite

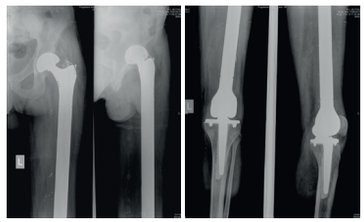
Total Femur Resection



Total Femur Resection, Pre-Op*



Total Femur Resection, Post-Op*



Condylar Component Dimensions

Length (mm)	Tibia FR[c] - Regular	Tibia FR[c] -Small	Femur FR[c] -Left/Right
M-L	65	60	45
A-P	40	35	40

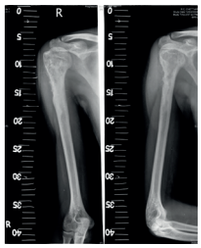
Component Selection Guide - Total Femur Resection

Proximal Femur Head Component Ø (mm)	Proximal Femur Component - CoCr, Length (mm)	Resection Coupler - SS/Ti, Length (mm)	Resection Piece - SS/Ti, Length (mm)	Distal Femur Component - CoCr, Length (mm)	Proximal Tibia Component - SS/Ti	Total Resection Length (mm) With Head				
						NL[e]-3.5, Lat Offset 35.5	NL[e]-2.0, Lat Offset 36.5	NL[e] 0, Lat Offset 38	NL[e]+3.5, Lat Offset 40.5	NL[e]+7.5, Lat Offset 44
Adler® Modular head-22/28 + ModuLoc® Bipolar Cup-39 - 53	Trochanteric Component Left/Right/ Neutral - CoCr - 80	180	Nil	Femur FR[c] - Left/Right - 80	Tibia FR[c] - Regular/Small	338	339	340	342	345
			40			378	379	380	382	385
			50			388	389	390	392	395
			60			398	399	400	402	405
			70			408	409	410	412	415
			80			418	419	420	422	425
			90			428	429	430	432	435
			100			438	439	440	442	445
			110			448	449	450	452	455
			120			458	459	460	462	465
			130			468	469	470	472	475
			140			478	479	480	482	485
			150			488	489	490	492	495
			160			498	499	500	502	505
			170			508	509	510	512	515
			180			518	519	520	522	525
			190			528	529	530	532	535
			200			538	539	540	542	545
			210			548	549	550	552	555
			220			558	559	560	562	565

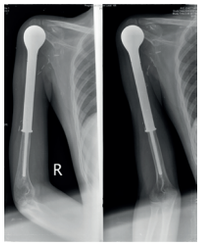
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c]Femoral Resection [d]Tibial Resection [e]Neck Length

Proximal Humerus Resection

Proximal Humerus Resection, Pre-Op*

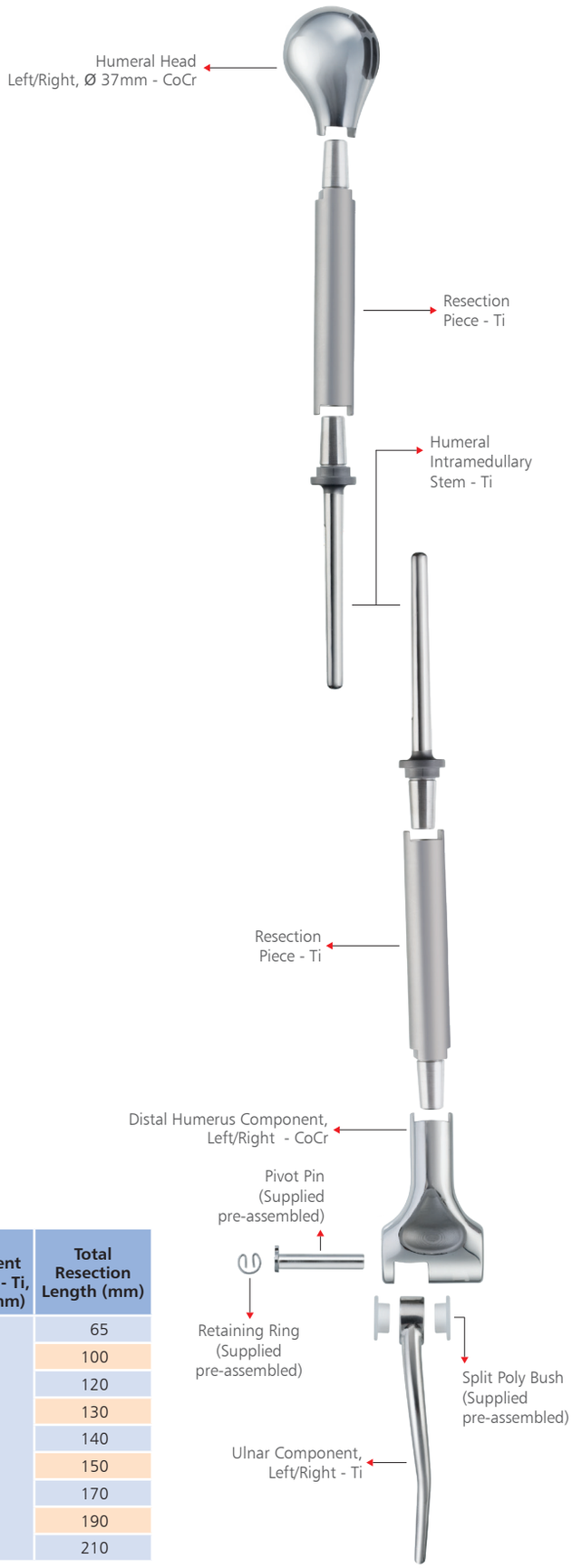


Proximal Humerus Resection, Post-Op*



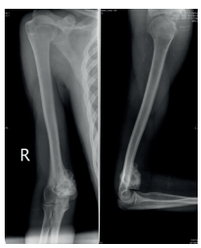
Component Selection Guide - Proximal Humerus Resection

Proximal Humerus Component-CoCr, Length (mm)	Resection Piece - Ti, Length (mm)	Humeral I.M. Stem -Ti, Ø (mm)	Humeral I.M. Stem -Ti, Length (mm)	Total Resection Length (mm)
Humeral Head-Left/Right - 55	Nil	6, 7, 8	80,100	55
	35			90
	55			110
	65			120
	75			130
	85			140
	105			160
	125			180
	145			200

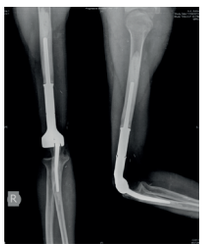


Distal Humerus Resection

Distal Humerus Resection, Pre-Op*



Distal Humerus Resection, Post-Op*



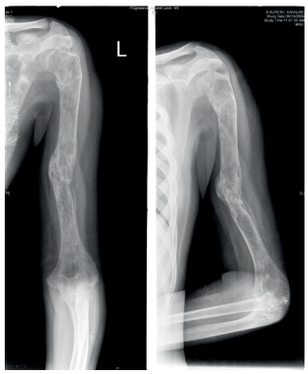
Component Selection Guide - Distal Humerus Resection

Distal Humerus Component - CoCr, Length (mm)	Resection Piece - Ti, Length (mm)	Humeral I.M. Stem - Ti, Ø (mm)	Humeral I.M. Stem Length (mm)	Ulnar Component Left/Right - Ti, Ø (mm)	Ulnar Component Left/Right - Ti, Length (mm)	Total Resection Length (mm)
Distal Humerus Component-Left/Right - 65	Nil	6, 7, 8	80,100	4, 5	80	65
	35					100
	55					120
	65					130
	75					140
	85					150
	105					170
	125					190
	145					210

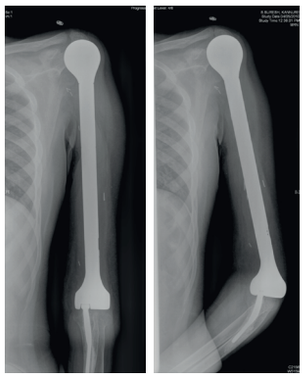
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai

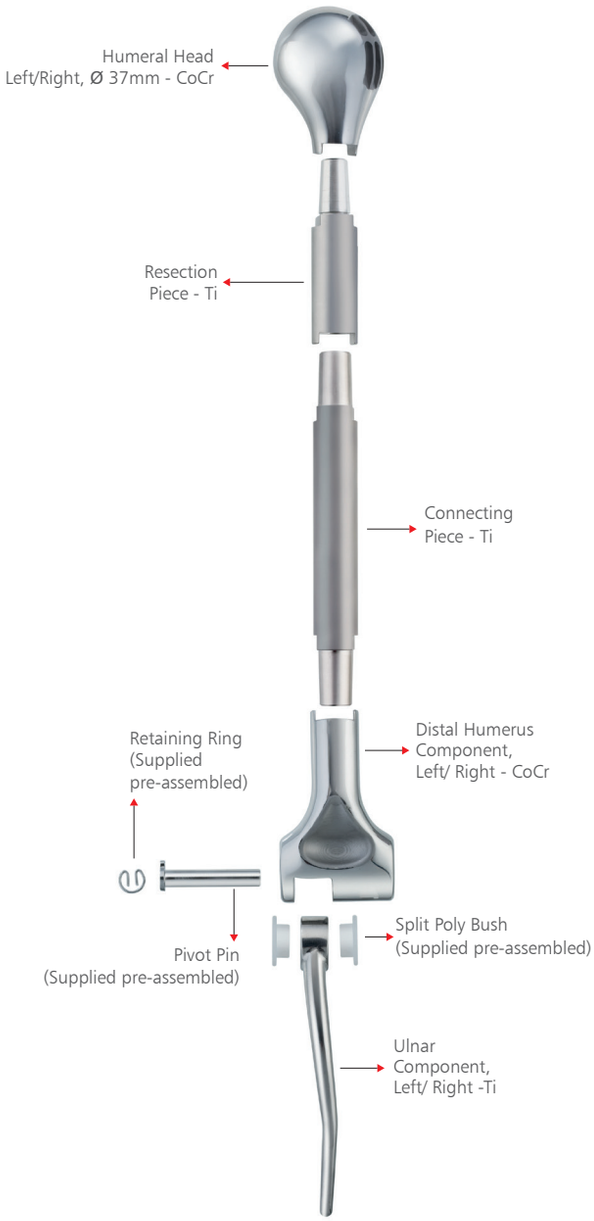
Total Humerus Resection

Total Humerus Resection, Pre-Op*



Total Humerus Resection, Post-Op*





Component Selection Guide Total Humerus Resection

Proximal Humerus Component - CoCr, Length (mm)	Resection Piece - Ti, Length (mm)	Connecting Piece - Ti, Length (mm)	Distal Humerus Component - CoCr, Length (mm)	Ulnar Component Left/Right - Ti, Ø (mm)	Ulnar Component Left/Right - Ti, Length (mm)	Total Resection Length (mm)
Humeral Head- Left/Right - 55	Nil	60	Distal Humerus- Left/Right Component - 65	4, 5	80	180
	35					215
	55					235
	65					245
	75					255
	85					265
	105					285
	125					305
	145					325

*All X-rays are courtesy of Tata Memorial Hospital, Mumbai

Implants Upper Limb

RESTOR®
Humeral Head, Left, CoCr

A1801.0337

RESTOR®
Humeral Head, Right, CoCr

A1801.0437

RESTOR®
Resection Piece - Ti,
Upper Limb

Titanium	Length (mm)
A1802.0135	35
A1802.0155	55
A1802.0165	65
A1802.0175	75
A1802.0185	85
A1802.0405	105
A1802.0425	125
A1802.0445	145

RESTOR® Humeral
Intramedullary Stem - Ti

	Ø (mm)	Length (mm)
A1803.0506	5	80
A1803.0608	6	80
A1803.0610	6	100
A1803.0708	7	80
A1803.0710	7	100
A1803.0808	8	80
A1803.0810	8	100

RESTOR® Connecting
Piece - Ti, Upper Limb

Titanium	Length (mm)
A1807.1060	60

RESTOR®
Distal Humerus
component, Left, CoCr

A1804.03

RESTOR®
Distal Humerus
component, Right, CoCr

A1804.04

RESTOR®
Pivot Pin,
Upper Limb

A1805.01

RESTOR®
Retaining ring,
Upper Limb

A1805.02

Split Poly Bush
for RESTOR®
Upper Limb, pair

A1806.5481.02

RESTOR® Ulnar
Component, Left

Ø 4mm	Ø 5mm
A1806.5481	A1806.6581

RESTOR® Ulnar
Component, Right

Ø 4mm	Ø 5mm
A1806.5482	A1806.6582

[a]Not in standard manufacturing program. Available on request. [c]Femoral Resection [d]Tibial Resection

Implants Lower Limb

ModuLoc® Bipolar Cup

39/22	41/22	43/22	45/28	47/28	49/28	51/28	53/28
H0306.0639	H0306.0641	H0306.0643	H0306.0645	H0306.0647	H0306.0649	H0306.0651	H0306.0653

Adler® Modular Head, Hi-N Steel

22/-2.0	22/0.0	22/+3.5	28/-3.5	28/0.0	28/+3.5	28/+7.5
H0407.2120	H0407.2200	H0407.2235	H0407.2735	H0407.2800	H0407.2835	H0407.2875

RESTOR® Trochanteric Component - CoCr
Offset, 38mm

Neutral	15° Anteversion	
	Left	Right
A1605.1038	A1605.1138[a]	A1605.1238[a]

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® Resection Coupler - SS/Ti

S.Steel	Titanium	Length (mm)
A1604.0180	A1604.1180	180

RESTOR®
Pivot Pin, FR[c]
A1601.0810

RESTOR®
Pivot Pin, TR[d]
A1601.0811

Split Poly Bush for RESTOR®
Tibia FR[c]/ TR[d], pair
A1805.03

RESTOR®
Retaining Ring
A1601.0912

Note: All RESTOR® components are supplied pre-sterile with double packaging packed into outer boxes. Sterilisation is carried out using gamma irradiation / ethylene oxide gas using validated sterilisation parameters and processes. For convenience, small components used in intra-operative assembly (Pivot Pin and Retaining Ring) are included in the relevant femur or tibia component boxes.

RESTOR®
Femur FR[c]- CoCr,
Left with Pivot Pin
& Retaining Ring
A1601.1011

RESTOR®
Femur FR[c]- CoCr,
Right with Pivot Pin
& Retaining Ring
A1601.1012

RESTOR®
Femur TR[d]- Left
with Pivot Pin &
Retaining Ring, (MP)

SS	A1601.1161
Ti	A1601.1171

RESTOR®
Femur TR[d]- Right
with Pivot Pin &
Retaining Ring, (MP)

SS	A1601.1162
Ti	A1601.1172

RESTOR® Tibia FR[c] - SS/Ti

	Regular	Small
SS	A1601.1040	A1601.1041
Ti	A1601.1050	A1601.1051

RESTOR®
Tibia TR[d] - CoCr
A1601.1121

RESTOR®, Straight
Intramedullary Stem

Len. 120 mm	Ø (mm)
A1601.0109	09[a]
A1601.0110	10
A1601.0111	11
A1601.0112	12

RESTOR®, Curved
Intramedullary Stem

Len.120 mm	Ø (mm)
A1601.0209	09[a]
A1601.0210	10
A1601.0211	11
A1601.0212	12

[a]Not in standard manufacturing program. Available on request. [c]Femoral Resection [d]Tibial Resection [f]Hydroxyapatite

Illustrations not to scale. Specifications subject to change without notice

RESTOR® Instrument Set, Lower Limb

ModuLoc® Trial Head

Code	NL(mm)
H0103.3434	-3.5
H0103.3419	-2.0
H0103.3400	+0.0
H0103.3435	+3.5
H0103.3475	+7.5

ModuLoc® Bipolar Cup, Trial

Ø (mm)	Code No.
39	H0103.0639
41	H0103.0641
43	H0103.0643
45	H0103.0645
47	H0103.0647
49	H0103.0649
51	H0103.0651
53	H0103.0653
55	H0103.0655

Trial Rasp Adaptor, Legend™/Endofit®

Code
H0105.3500

RESTOR® Trochanteric Component, Offset, 38mm, Trial

Neutral	15° Anteversion	
	Left	Right
C1605.1038	C1605.1138	C1605.1238

RESTOR® Resection Coupler, Trial

Length 180mm
C1604.0180

RESTOR® Femur FR[c] Left, Trial

C1601.1011

RESTOR® Femur FR[c] Right, Trial

C1601.1012

RESTOR® Tibia FR[c] Trial

Regular	Small
C1601.1040	C1601.1041

Aluminium Case, 2-Part, 600 X 275 X 95, Adler®

D0101.2103

Upper Tray, RESTOR® Trial Instrument Set

D0102.1305

Lower Tray, RESTOR® Trial Instrument Set

D0102.1304

RESTOR® Pivot Pin, FR[c], Trial

C1601.0810

RESTOR® Retaining Ring, Trial

C1601.0912

RESTOR® Pivot Pin, TR[d], Trial

C1601.0811

RESTOR® Femur TR[d]- Left, Trial, (MP)

C1601.1161

RESTOR® Femur TR[d]- Right, Trial, (MP)

C1601.1162

RESTOR® Tibia TR[d], Trial

C1601.1121

RESTOR® Resection Piece,Trial

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

RESTOR® Straight, Intramedullary Stem, Trial

Len. 120 mm	Ø (mm)
C1601.0109	09
C1601.0110	10
C1601.0111	11
C1601.0112	12

RESTOR® Curved, Intramedullary Stem, Trial

Len.120 mm	Ø (mm)
C1601.0209	09
C1601.0210	10
C1601.0211	11
C1601.0212	12

[c] Femoral Resection [d] Tibial Resection

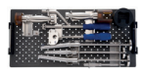
Illustrations not to scale. Specifications subject to change without notice

RESTOR® Instrument Set, Lower Limb (Cont'd)

Aluminium Case, 2-Part, 600 X 275 X 160, Adler®
D0101.2102

Upper Tray, RESTOR® Instrument Set
D0102.1303

Middle Tray, RESTOR® Instrument Set
D0102.1302



Lower Tray, RESTOR® Instrument Set
D0102.1301

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

Jig For Perpendicular Resection, RESTOR®
C3900.021

RESTOR® Conical Reamer, Modular

Code No.
C3900.1401

RESTOR® Conical Reamer Centralizer

Code No.	Ø (mm)
C3900.1403	09
C3900.1404	11
C3900.1405	10

Extramedullary Jig, RESTOR®
C3901.011

Extramedullary Jig, RESTOR®, Cutting Block Holding Pin
C3901.013

RESTOR® Cutting Block Holding Pin Extractor
C3900.1102

Resection Component Punch, RESTOR®
C3900.08

Intramedullary Stem Punch, RESTOR®
C3900.09

Implant Extraction Rod, RESTOR®
C3900.1001

Implant Extraction Hammer, RESTOR®
C3900.1002

Retaining Ring Inserter, RESTOR®
C3900.11

Wedge Fork, RESTOR®
C3900.13

Tibial Positioning Jig, RESTOR®
C3901.021

Tibial Punch, RESTOR®
C3901.0211

Rasp For Tibia Fr[c], Cemented, RESTOR®
C3901.031

Pivot Pin Aligner, RESTOR®
C3901.0411

Base For Femur FR[c] Assembly, RESTOR®
C3901.09

Base For Tibia TR[d] Assembly, RESTOR®
C3902.14

Extractor Hook Assembly, RESTOR®
C3901.10

Curved Chisel, 10mm, RESTOR®
C3902.05

Straight Chisel, 25mm, RESTOR®
C3902.051

Pivot Pin Drill Guide, RESTOR®
C3902.06

Drill Sleeve Ø 5.5mm, RESTOR®
C3902.061

Drill Sleeve Ø 13mm, RESTOR®
C3902.062

Cutter For Pivot Pin, RESTOR®
C3902.081

Notch Cutter/Rasp Cemented, Right,
C3902.11

Notch Cutter/Rasp Cemented, Left, RESTOR®
C3902.12

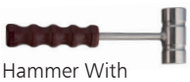
Punch For Femur FR[c], RESTOR®
C3902.13

Punch For Femur TR[d], RESTOR®, (MP)
C3902.23

Pivot Pin Inserter, RESTOR®
C3900.03

Articulation Aligner, RESTOR®
C3902.15

Slotted Hammer, RESTOR®
C3902.17



Hammer With Fibre Handle, RESTOR®
C3902.18

Base For Trochanteric Component Assembly
C3902.19

Inserter For Cement Restrictor, RESTOR®
H0102.12

ModuLoc® Bipolar Cup Impactor
H0102.15

Drill Bit 5.5mm
I0522.55

C1304.10

Head Gauge Set for prosthesis consists of C1304.10.01 to C1304.10.08 - 1pc. each, Adler®

ModuLoc® Bipolar Cup Press
H0103.10

ModuLoc® Trial Head Disimpactor
H0103.12

[c] Femoral Resection [d] Tibial Resection
[Δ] Not to be used if the Polyethylene Wedge is supplied pre-assembled with the component

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 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
ADLER HEALTHCARE PVT. LTD.
Plot # A-1, MIDC, Sadavali (Devrukh) Tal. Sangameshwar, Dist. Ratnagiri. Pin - 415804. India.
Tel: 8055136000 / 8055146000 • e-mail: info@adler-healthcare.com • www.adlerhealthcare.com

AHPL.II.2024.10.a

DesignVault