ADLER® Advanced Recon Series

restor®

Modular Resection Prosthesis, Fixed Hinge



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.

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

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

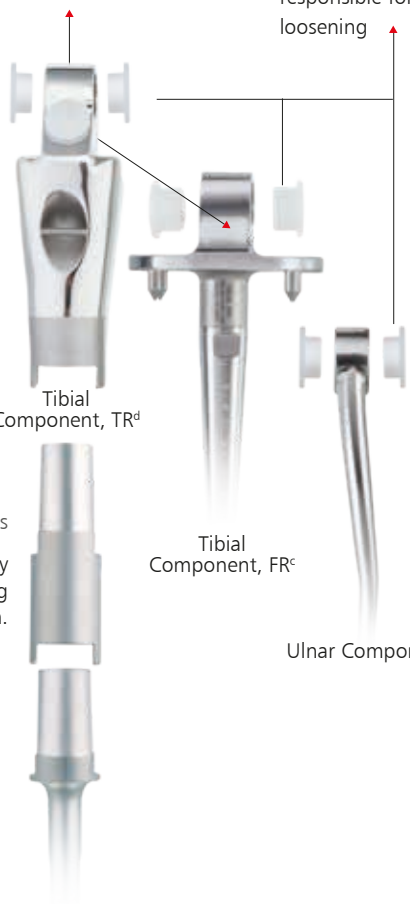
Enables normal patellar tracking which is important as the patella is usually preserved.

Polyethylene wedge/bumper 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]

Ulnar Component

Modular components

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

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

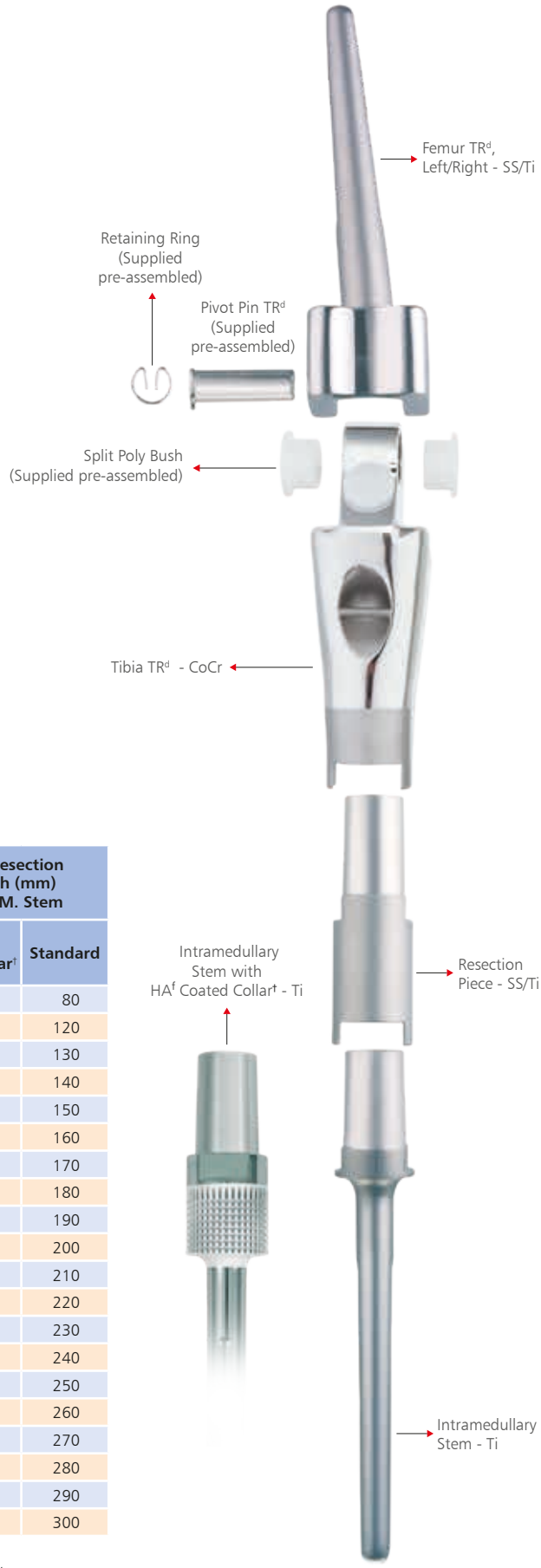
Proximal Tibia Resection

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	
			With HA[f] Coated Collar[†]	Standard	with HA[f] Coated Collar[†]	Standard
Femur TR[d] -Left/Right	Tibia TR[d] - 80	Nil	10, 11, 12, Straight/Curved		100	80
		40			140	120
		50			150	130
		60			160	140
		70			170	150
		80			180	160
		90			190	170
		100			200	180
		110			210	190
		120			220	200
		130			230	210
		140			240	220
		150			250	230
		160			260	240
		170			270	250
		180			280	260
		190			290	270
		200			300	280
		210			310	290
		220			320	300

*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c]Femoral Resection [d]Tibial Resection [f]Hydroxyapatite
[†] The use of a stem with a HA[f] coated collar adds 20mm to the overall length of the implant assembly

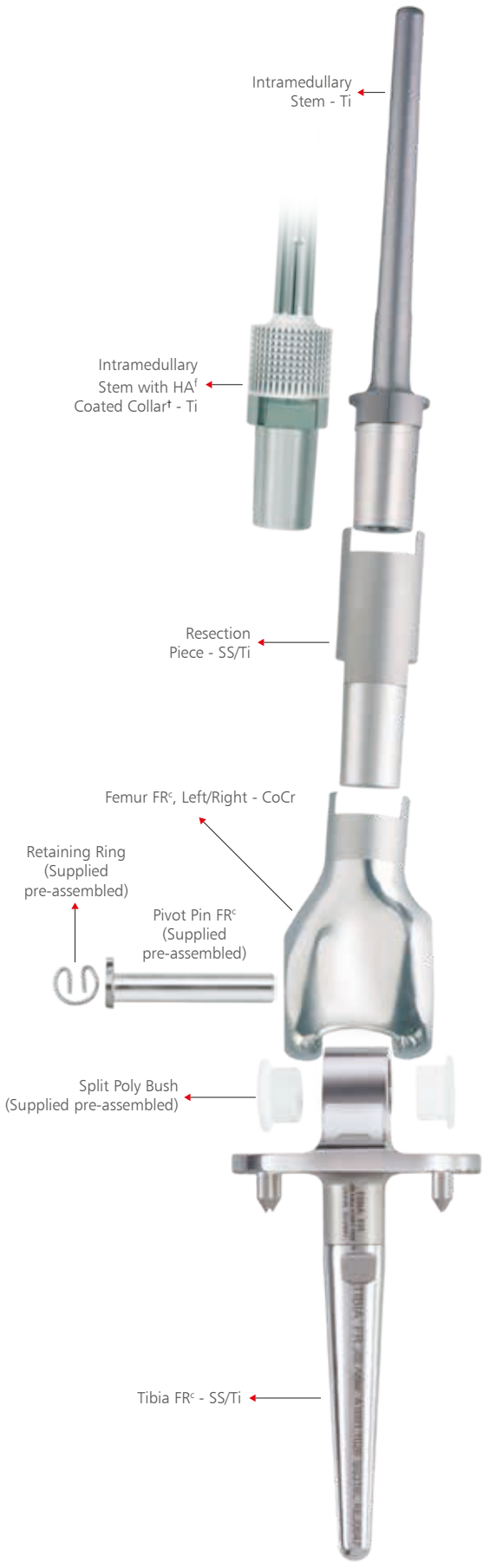
Distal Femur Resection

Distal Femur Resection, Pre-Op*



Distal Femur Resection, Post-Op*





Condylar Component Dimensions

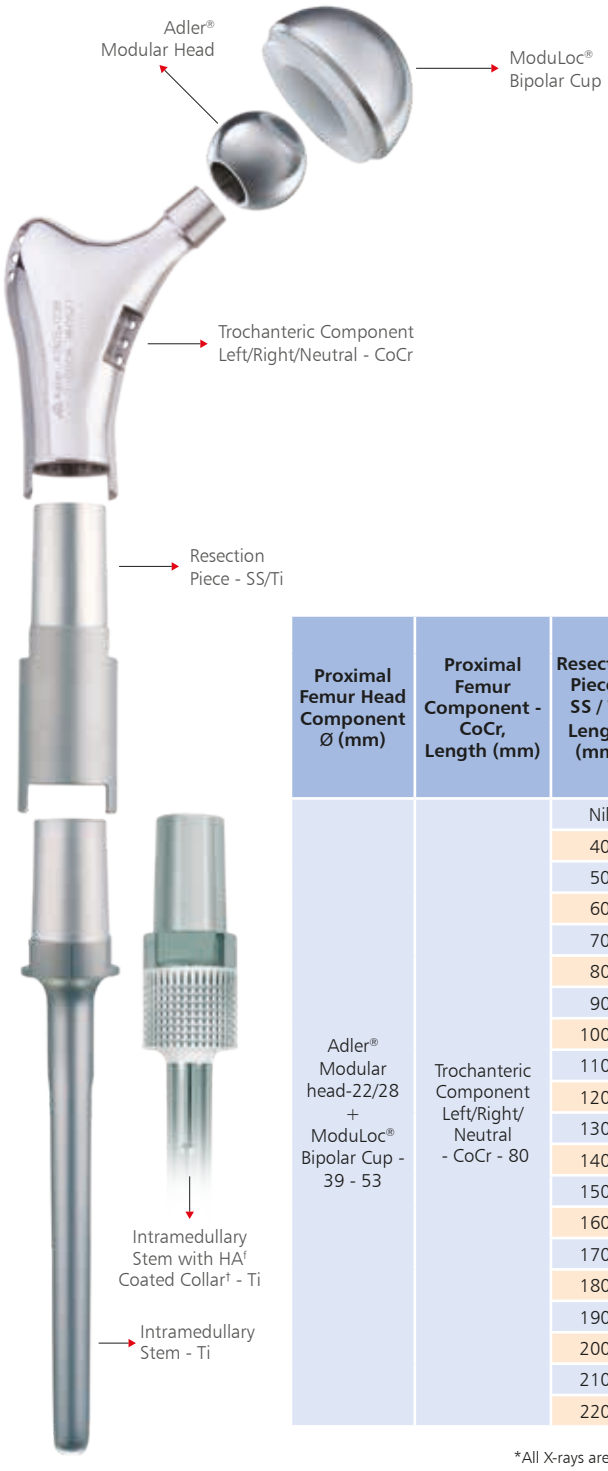
Length (mm)	Tibia FR[c] - Regular	Tibia FR[c] -Small	Femur FR[c] -Left/Right
M-L	65	60	45
A-P	40	35	40

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	
			with HA[f] Coated Collar[†]	Standard	with HA[f] Coated Collar[†]	Standard
Tibia Fr[c]- Regular/Small	Femur Fr[c] - Left/Right-80	Nil	10, 11, 12, Straight/Curved		100	80
		40			140	120
		50			150	130
		60			160	140
		70			170	150
		80			180	160
		90			190	170
		100			200	180
		110			210	190
		120			220	200
		130			230	210
		140			240	220
		150			250	230
		160			260	240
		170			270	250
		180			280	260
		190			290	270
		200			300	280
		210			310	290
		220			320	300

*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c] Femoral Resection [d] Tibial Resection [f] Hydroxyapatite
[†] The use of a stem with a HA[f] coated collar adds 20mm to the overall length of the implant assembly

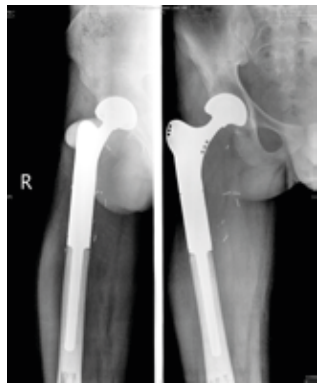
Proximal Femur Resection



Proximal Femur Resection, Pre-Op*



Proximal Femur Resection, Post-Op*

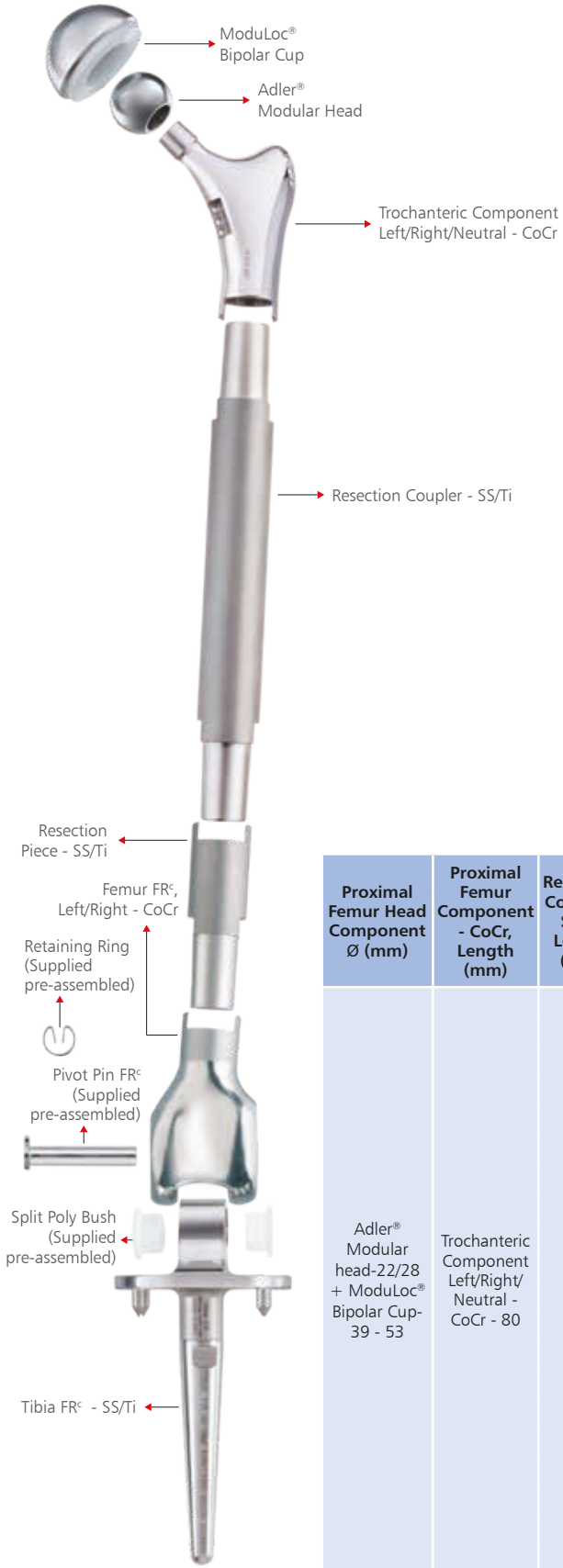


Component Selection Guide - Proximal Femur Resection

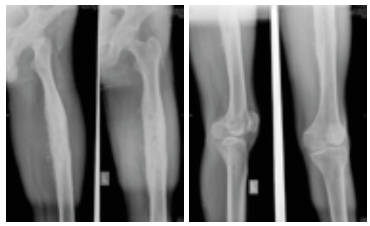
Proximal Femur Head Component Ø (mm)	Proximal Femur Component - CoCr, Length (mm)	Resection Piece - SS / Ti, Length (mm)	I.M. Stem - Ti, Ø (mm) Straight/Curved		Total Resection Length (mm) With Head									
					NL[e] -3.5, Lat Offset 35.5		NL[e] -2.0, Lat Offset 36.5		NL[e] 0, Lat Offset 38.0		NL[e] +3.5, Lat Offset 40.5		NL[e] +7.5, Lat Offset 44.0	
			With HA[f] Coated Collar[†]	Std.	HA[f] Collar Stem[†]	Std. Stem	HA[f] Collar Stem[†]	Std. Stem	HA[f] Collar Stem[†]	Std. Stem	HA[f] Collar Stem[†]	Std. Stem	HA[f] Collar Stem[†]	Std. Stem
Adler® Modular head-22/28 + ModuLoc® Bipolar Cup - 39 - 53	Trochanteric Component Left/Right/ Neutral - CoCr - 80	Nil	10, 11, 12 Straight/Curved		98	78	99	79	100	80	102	82	105	85
		40			138	118	139	119	140	120	142	122	145	125
		50			148	128	149	129	150	130	152	132	155	135
		60			158	138	159	139	160	140	162	142	165	145
		70			168	148	169	149	170	150	172	152	175	155
		80			178	158	179	159	180	160	182	162	185	165
		90			188	168	189	169	190	170	192	172	195	175
		100			198	178	199	179	200	180	202	182	205	185
		110			208	188	209	189	210	190	212	192	215	195
		120			218	198	219	199	220	200	222	202	225	205
		130			228	208	229	209	230	210	232	212	235	215
		140			238	218	239	219	240	220	242	222	245	225
		150			248	228	249	229	250	230	252	232	255	235
		160			258	238	259	239	260	240	262	242	265	245
		170			268	248	269	249	270	250	272	252	275	255
		180			278	258	279	259	280	260	282	262	285	265
		190			288	268	289	269	290	270	292	272	295	275
		200			298	278	299	279	300	280	302	282	305	285
		210			308	288	309	289	310	290	312	292	315	295
		220			318	298	319	299	320	300	322	302	325	305

*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c]Femoral Resection [d]Tibial Resection [e]Neck Length [f]Hydroxyapatite
[†]The use of a stem with a HA[f] coated collar adds 20mm to the overall length of the implant assembly

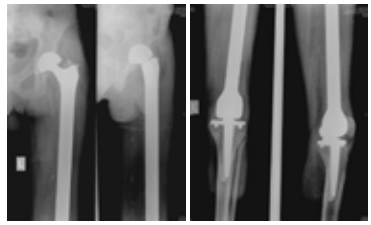
Total Femur Resection



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



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® 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® Resection Coupler - SS/Ti

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



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

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



RESTOR®, Curved Intramedullary Stem

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



RESTOR® Straight, HA Collar Intramedullary Stem, Ti

Length 120 mm	Ø (mm)
A1601.0153	09[a]
A1601.0154	10
A1601.0155	11
A1601.0156	12



RESTOR® Curved, HA Collar Intramedullary Stem, Ti

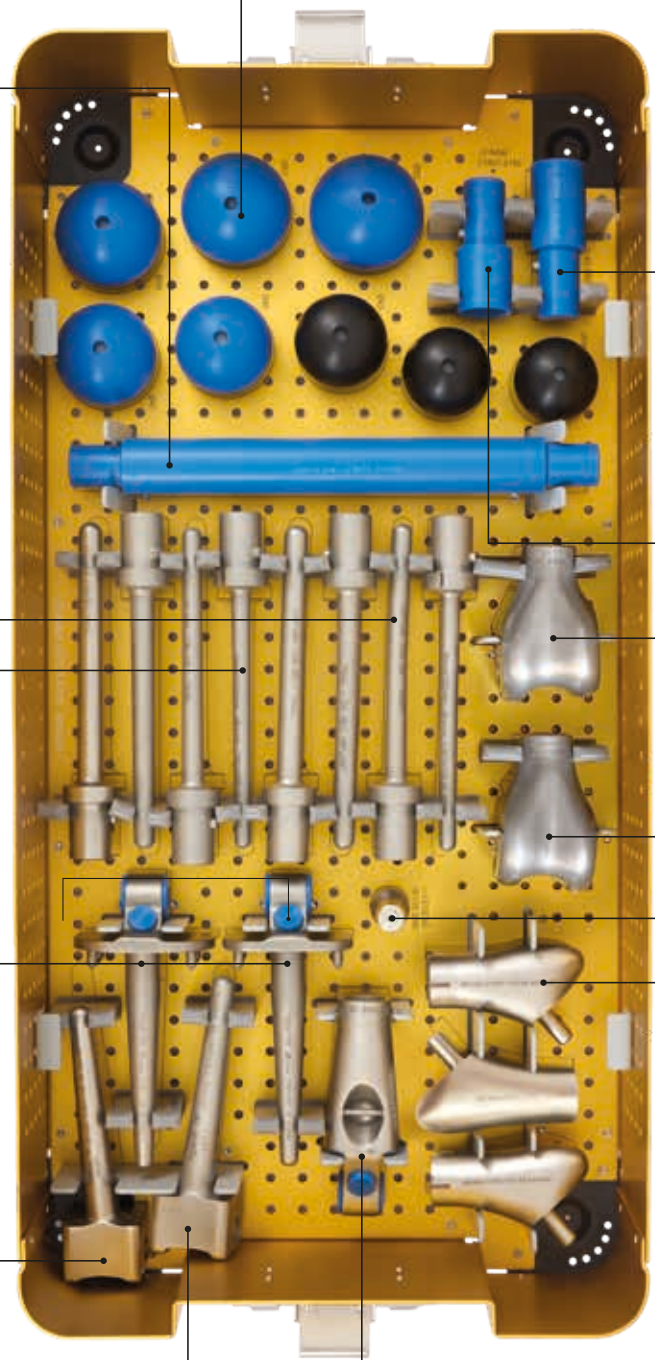
Length 120 mm	Ø (mm)
A1601.0253	09[a]
A1601.0254	10
A1601.0255	11
A1601.0256	12

[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 - Fixed Hinge

Lower Limb, Trial Implants - Base Tray



RESTOR®
Resection Coupler, Trial



Length 180mm
C1604.0180

ModuLoc®
Bipolar Cup, Trial

Ø (mm)	Code No.
39	H0103.1539
41	H0103.1541
43	H0103.1543
45	H0103.1545
47	H0103.1547
49	H0103.1549
51	H0103.1551
53	H0103.1553
55	H0103.1555

RESTOR®
Curved, Intramedullary Stem, Trial



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

RESTOR®
Straight, Intramedullary Stem, Trial



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

RESTOR®
Tibia FR[c] Trial



Regular	Small
C1601.1040	C1601.1041

RESTOR®
Resectio Piece, 40 mm, Trial



C1601.0304

RESTOR®
HA Collar Stem Spacer, Trial



C1601.0140

RESTOR®
Femur FR[c] Left, Trial



C1601.1011

RESTOR®
Femur FR[c] Right, Trial



C1601.1012

Trial Rasp Adaptor, Legend™/Endofit®



Code
H0105.3500

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



C1601.1162

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



C1601.1161

RESTOR®
Tibia TR[d], Trial



C1601.1121

RESTOR®
Trochanteric Component, Offset, 38mm, Trial



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

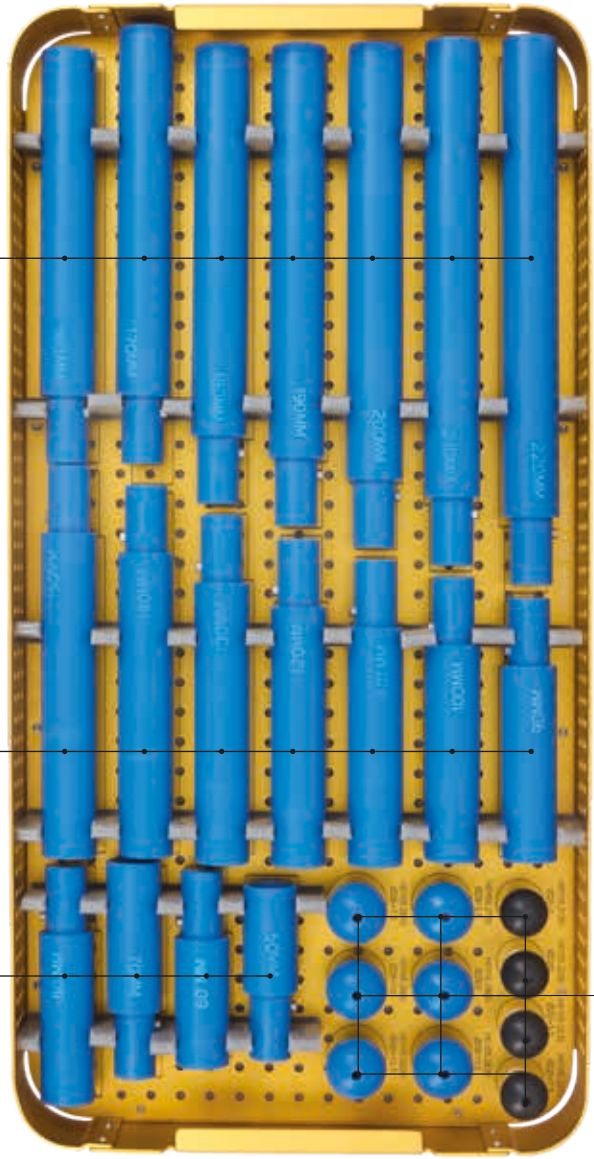
[c] Femoral Resection [d] Tibial Resection

RESTOR® Instrument Set - Fixed Hinge
Lower Limb, Trial Implants - Upper Tray



RESTOR® Fixed Hinge, Lower Limb, Trial Implants
Aluminium Case including Lid, Upper Tray & Base

D0101.4100



RESTOR®
Resection Piece, Trial



Code No.	Length (mm)
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
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C1601.0321	210
C1601.0322	220

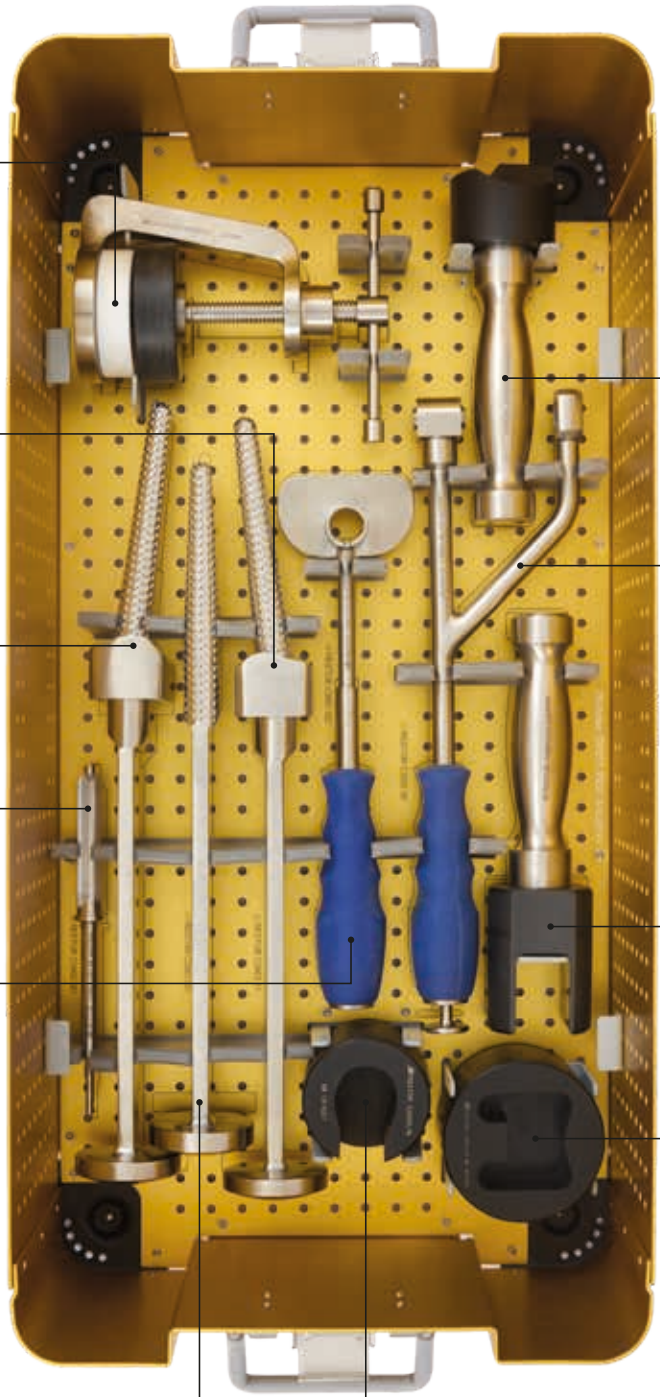
ModuLoc®
Trial Head Ø 28 mm



Code	NL(mm)
H0105.2120	-2.0
H0105.2200	0.0
H0105.2235	+3.5
H0105.2275	+7.5
H0105.2735	-3.5
H0105.2800	0.0
H0105.2835	+3.5
H0105.2875	+7.5
H0105.2900	+10.0
H0105.2925	+12.5

RESTOR® Instrument Set - Fixed Hinge

Lower Limb, Instruments - Base Tray



ModuLoc®
Bipolar Cup Press



H0103.10

RESTOR®
Notch Cutter/Rasp
Cemented, Right



C3902.11

RESTOR®
Notch Cutter/Rasp
Cemented, Left



C3902.12

RESTOR® Cutter
For Pivot Pin



C3902.081

RESTOR®
Tibial Positioning Jig



C3901.021

RESTOR® Punch For
Femur FR[c]



C3902.13

RESTOR® Pivot Pin
Drill Guide



C3902.06

RESTOR®
Tibial Punch



C3901.0211

RESTOR®
Base For Femur FR[c]
Assembly



C3901.09

RESTOR®
Rasp For Tibia Fr[c],
Cemented



C3901.031

RESTOR®
Base For Trochanteric
Component Assembly

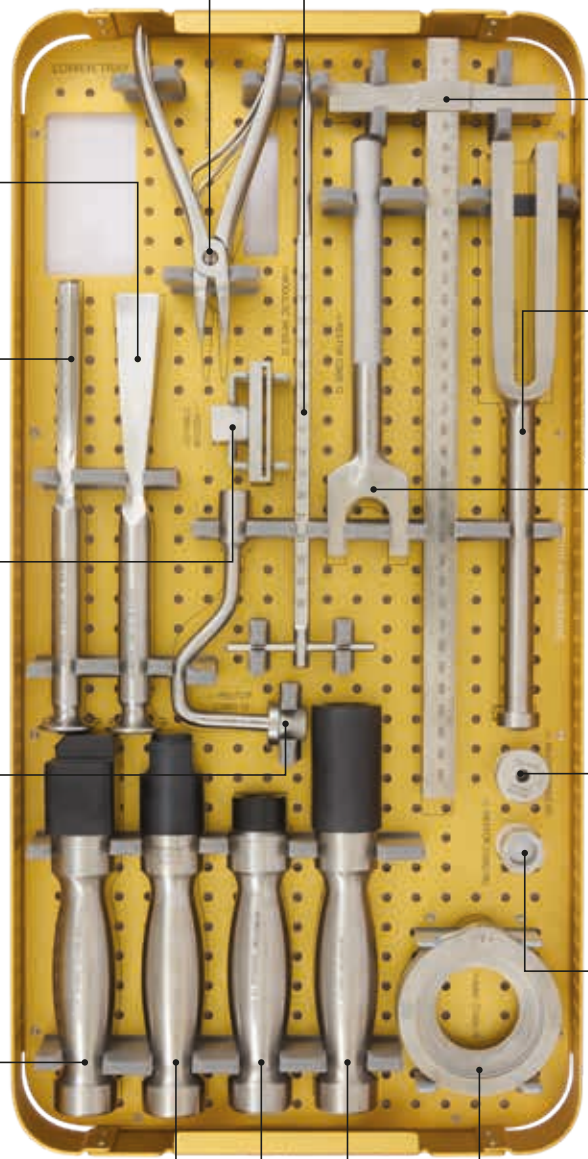


C3902.19

[c] Femoral Resection [d] Tibial Resection

RESTOR® Instrument Set - Fixed Hinge

Lower Limb, Instruments - Lower Tray



RESTOR®
Cutting Block
Holding Pin Extractor



C3900.1102

RESTOR®
Retaining Ring Inserter



C3900.11

RESTOR®
Inserter For Cement Restrictor

H0102.12

RESTOR®
Right Angle Measuring Scale - Telescopic for RESTOR® Prosthesis



C3900.011

RESTOR®
Straight Chisel, 25mm



C3902.051

RESTOR®
Slotted Hammer



C3902.17

RESTOR®
Curved Chisel, 10mm



C3902.05

RESTOR®
Wedge Fork



C3900.13

RESTOR®
Jig For Perpendicular Resection



C3900.021

RESTOR®
Extractor Hook Assembly



C3901.10

RESTOR®
Drill Sleeve Ø 5.5mm



C3902.061

RESTOR®
Drill Sleeve Ø 13mm



C3902.062

RESTOR®
Punch For Femur TR[d], (MP)



C3902.23

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



C1304.10

RESTOR®
Resection Component Punch



C3900.08

RESTOR®
Intramedullary Stem Punch



C3900.09

RESTOR®
Punch for Resection Coupler



C3902.24

[c] Femoral Resection [d] Tibial Resection

RESTOR® Instrument Set - Fixed Hinge

Lower Limb, Instruments - Upper Tray



RESTOR® Fixed Hinge, Lower Limb, Instruments - Aluminium Case including Lid, Upper Tray, Lower Tray & Base

D0101.4000

RESTOR® Extramedullary Jig

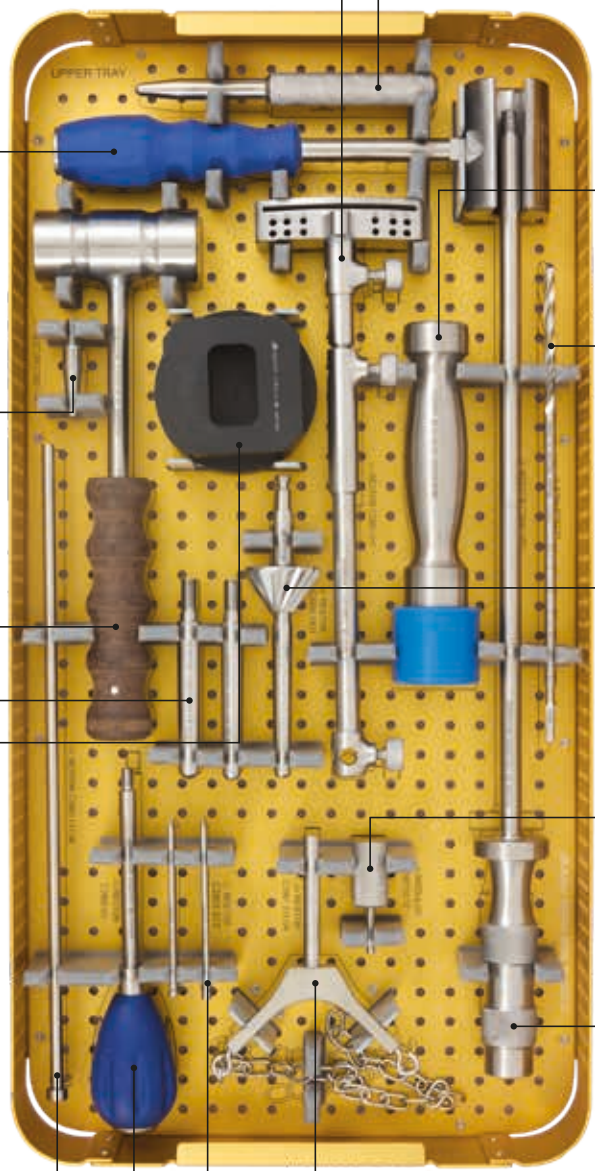


C3901.011

RESTOR® Articulation Aligner



C3902.15



RESTOR® Implant Extraction Hammer



C3900.1002

ModuLoc® Bipolar Cup Impactor



H0102.15

Drill Bit 5.5mm

I0522.55

RESTOR® Pivot Pin Aligner



C3901.0411

RESTOR® Conical Reamer, Modular



C3900.1401

RESTOR® Hammer With Fibre Handle



C3902.18

RESTOR® Conical Reamer Centralizer



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

ModuLoc® Trial Head Disimpactor



H0103.12

RESTOR® Implant Extraction Rod



C3900.1001

RESTOR® Base For Tibia TR[d] Assembly



C3902.14

RESTOR® Extramedullary Jig, Ankle Support Sub Assembly



C3901.011.04

RESTOR® Extramedullary Jig, Ankle Support Allignment Rod

C3901.011.06

RESTOR® Pivot Pin Inserter



C3900.03

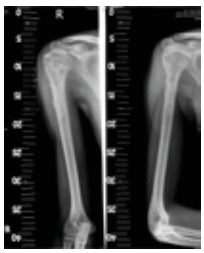
RESTOR® Extramedullary Jig, Cutting Block Holding Pin

C3901.013

[c] Femoral Resection [d] Tibial Resection

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
	45			100
	55			110
	65			120
	75			130
	85			140
	105			160
	125			180
	145			200

Distal Humerus Resection

Distal Humerus Resection, Pre-Op*



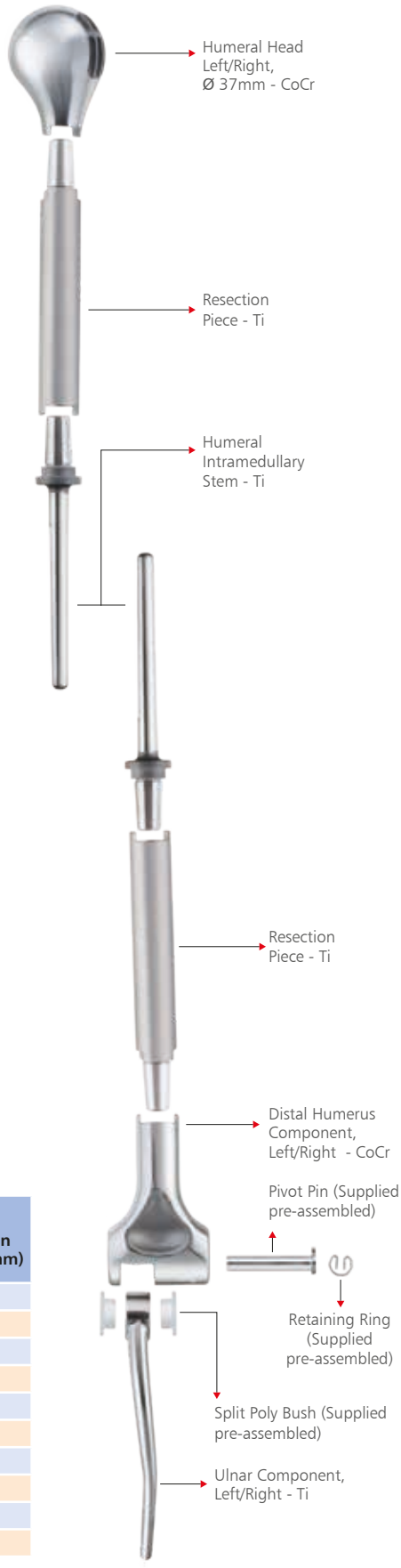
Distal Humerus Resection, Post-Op*



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
	45					110
	55					120
	65					130
	75					140
	85					150
	105					170
	125					190
	145					210

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

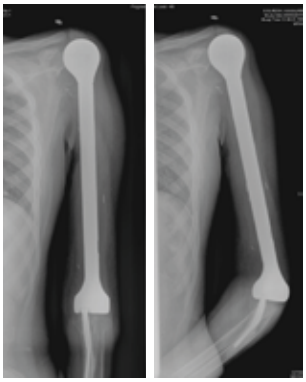


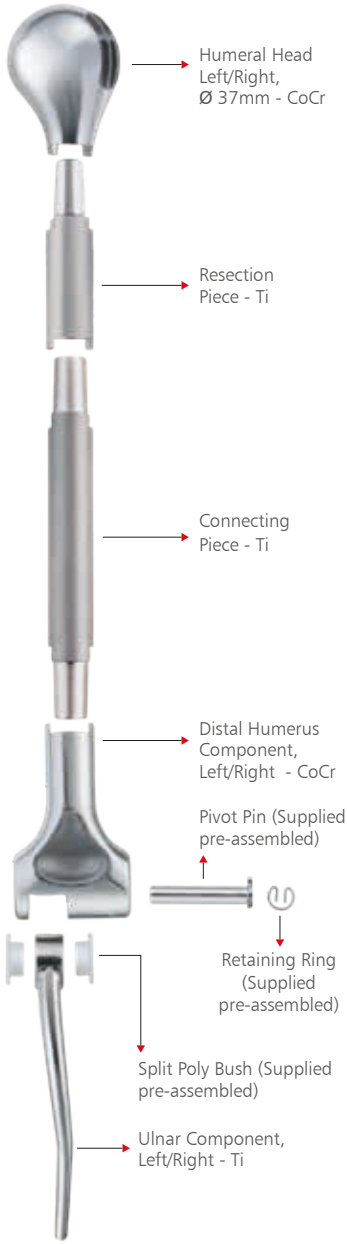
Total Humerus Resection

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
	45					225
	55					235
	65					245
	75					255
	85					265
	105					285
	125					305
	145					325

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



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
A1802.0145	45
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)
A1803.0508	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

Illustrations not to scale. Specifications subject to change without notice

[a]Not in standard manufacturing program. Available on request.

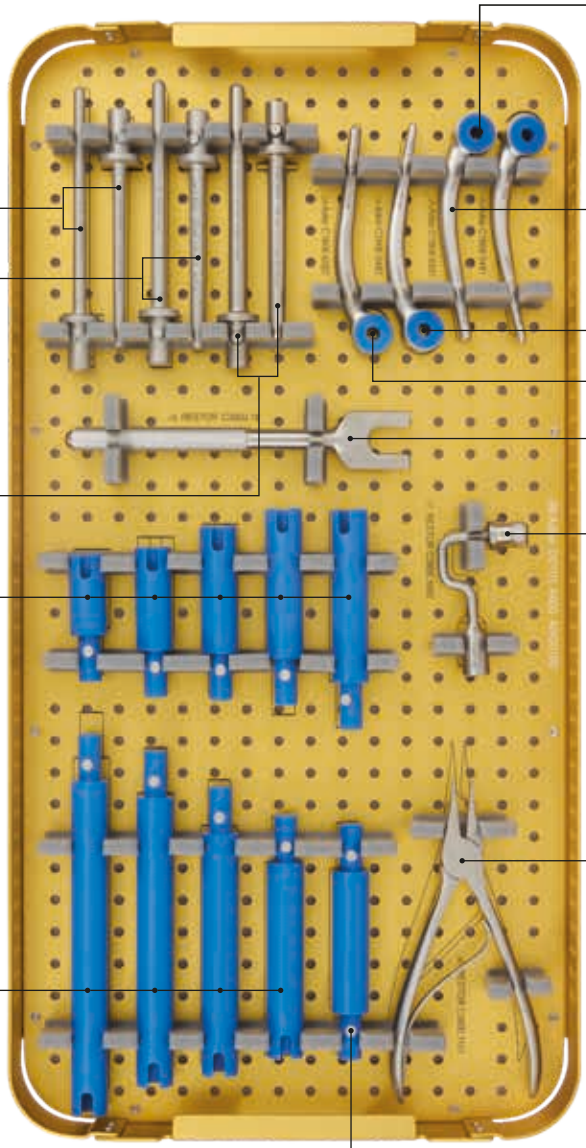
RESTOR® Instrument Set - Fixed Hinge

Upper Limb, Trial Implants & Instruments - Upper Tray



RESTOR® Fixed Hinge, Upper Limb, Instruments - Aluminium Case including Lid, Upper Tray & Base

D0101.4400



RESTOR® Humeral IM Stem, Ø 6 mm, Trial



Code No.	Length (mm)
C1803.0608	80
C1803.0610	100

RESTOR® Humeral IM Stem, Ø 7 mm, Trial



Code No.	Length (mm)
C1803.0708	80
C1803.0710	100

RESTOR® Humeral IM Stem, Ø 8 mm, Trial



Code No.	Length (mm)
C1803.0808	80
C1803.0810	100

RESTOR® Resection Piece, Upper Limb, Trial



Code No.	Length (mm)
C1802.0135	35
C1802.0145	45
C1802.0155	55
C1802.0165	65
C1802.0175	75
C1802.0185	85
C1802.0405	105
C1802.0425	125
C1802.0445	145

RESTOR® Connecting Piece, Upper Limb, Trial



C1807.1060

RESTOR® Ulnar Component, Left, Ø 5 mm, Trial



C1806.6581

RESTOR® Ulnar Component, Left, Ø 4mm, Trial



C1806.5481

RESTOR® Ulnar Component, Right, Ø 4mm, Trial



C1806.5482

RESTOR® Ulnar Component, Right, Ø 5mm, Trial



C1806.6582

RESTOR® Wedge Fork, Upper Limb



C3900.18

RESTOR® Ulnar Component Hook



C3900.1600

RESTOR® Retaining Ring Inserter, Upper Limb



C3900.1101

RESTOR® Instrument Set - Fixed Hinge

Upper Limb, Trial Implants & Instruments - Base Tray



RESTOR®
Humeral Head Right, Trial
C1801.0237

RESTOR®
Humeral Head Left, Trial
C1801.0137

RESTOR®
Base for Humeral Head Assembly
C3900.0700

RESTOR®
Base for Distal Humerus
Component Assembly
C3900.0701

RESTOR®
Distal Humerus
Components Punch
C3900.0903

RESTOR®
Connecting Component
Punch, Upper Limb
C3900.0802

RESTOR®
Humeral Head Punch
C3900.0902

RESTOR®
Conical Reamer,
Modular, Upper Limb
C3900.1901

RESTOR®
Conical Reamer
Centralizer, 6mm,
Upper Limb
C3900.1902

QC 'T' Handle, Soft Grip,
Hudson Type, Small
J0147.03

RESTOR®
Pivot Pin, Upper Limb, Trial
C1805.01

RESTOR®
Articulation Aligner, Upper Limb
C3901.0412

RESTOR®
Distal Humerus
Component, Right, Trial
C1804.02

RESTOR®
Distal Humerus
Component, Left, Trial
C1804.01

RESTOR®
Pivot Pin Inserter,
Upper Limb
C3900.0301

RESTOR®
Ulnar Rasp, Left
C3902.2045

RESTOR®
Ulnar Rasp, Right
C3902.2145

ADLER ®
Slotted Hammer,
Small, New
C3900.1701

RESTOR®
IM Stem Extractor2,
Upper Limb
C3902.2200

RESTOR®
Humeral IM Stem Punch
C3900.0901

RESTOR®
Ulnar Component Punch
C3900.1500

RESTOR®
Resection Component
Punch, Upper Limb
C3900.0801

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 ASTM F-75, wrought titanium-aluminium-vanadium alloy Ti_6Al_4V ELI (ISO 5832-3/ASTM F-136), 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/ASTM F-648). 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***.



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DesignVault

AHPL.PBMN.11.REV01