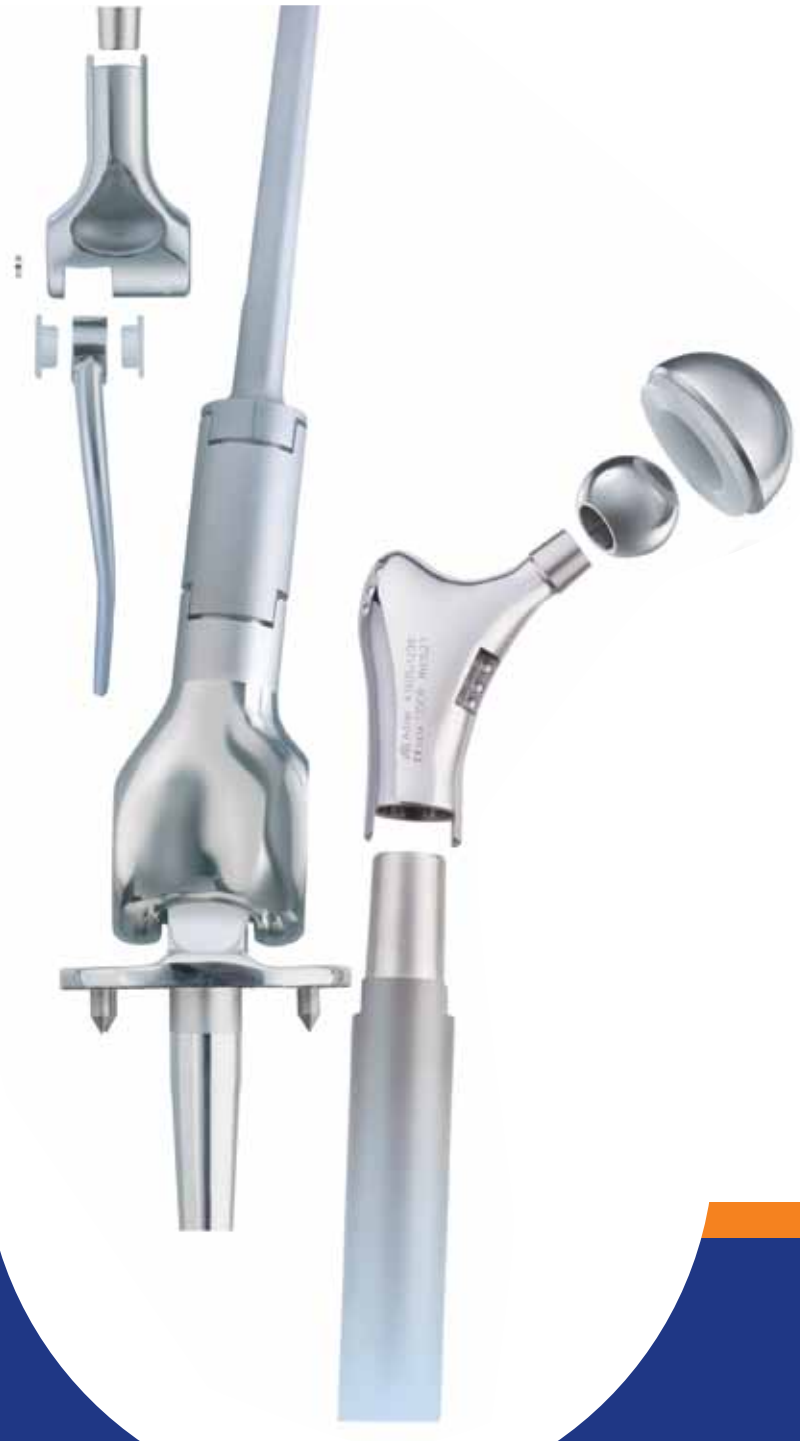
Specification Guide

Syncera®
Powered by smith&nephew



RESTOR®
Modular Resection Prosthesis

The Comprehensive Limb Salvage System

Table of Contents

Acknowledgement

The ADLER® product development team gratefully acknowledges the contribution and ongoing collaboration of the orthopaedic oncology team at the Tata Memorial Hospital, led by Prof. Ajay Puri, towards the development of the RESTOR modular resection system and its associated instrumentation.

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:

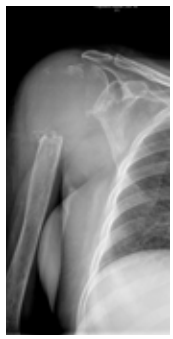
- The necessity of customizing a prosthesis to individual patient parameters, which is a time consuming and difficult process
- Lack of easy availability of off the-shelf modular designs which can be used without the long manufacturing lead time of a customized prosthesis
- Prohibitively high cost of 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 cost-effective solution to patients who could benefit from limb salvage surgery following tumors of :

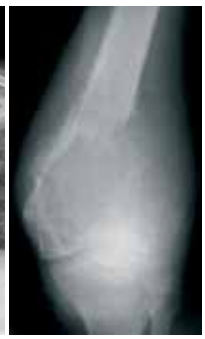
- Proximal, Distal & Total Femur
- Proximal Tibia
- Diaphyseal regions of the Femur/Humerus
- Proximal, Distal and Total Humerus

Indications

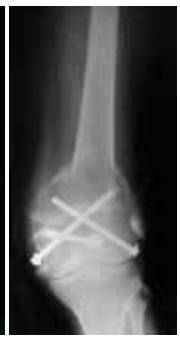
Indications for limb salvage surgery with reconstruction using the RESTOR system include :



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, 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 first generation megaprosthesis 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

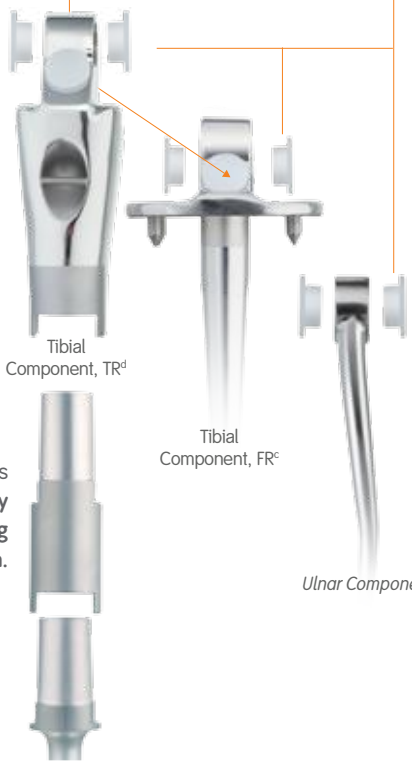
Hyperextension built in to the femoro-tibial articulating components
Allows passive locking during gait and prevents buckling on loading even in patients with extensive muscle resection

Intramedullary Stem with Hydroxyapatite (HA) coated collar
Enables extra-cortical bone bridging

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

Patellar groove built into the femoral component
Enables normal patellar tracking which is important as the patella is usually preserved.



Tibial Component, TR[d]

Tibial Component, FR[c]

Ulnar Component

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

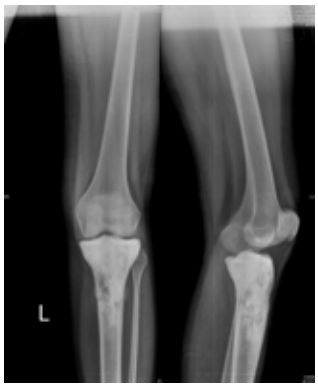
Standardized components
Off the shelf availability eliminates delay inherent in the manufacture of customized components.

Specialised Instrumentation
Facilitates and standardizes surgical technique.

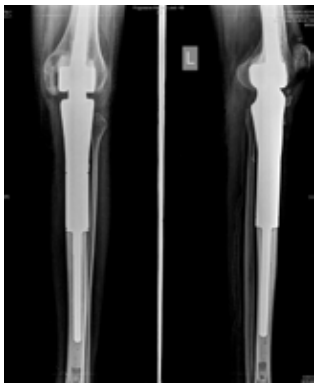
[b] Limb Salvage in Osteosarcoma-The Mumbai experience: Agarwal M. G., Puri A. et al, Clinical Orthopaedics and Related Research, 2007
[c] Femoral Resection [d] Tibial Resection [o] Revision of Broken Knee Megaprosthesis - New Solution to Old problems: Agarwal M. G., Puri A. et al, Clinical Orthopaedics 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

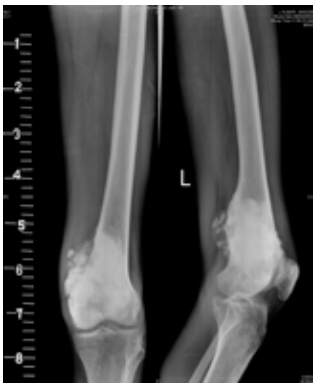
Component Selection Guide - Proximal Tibia Resection

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	
			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

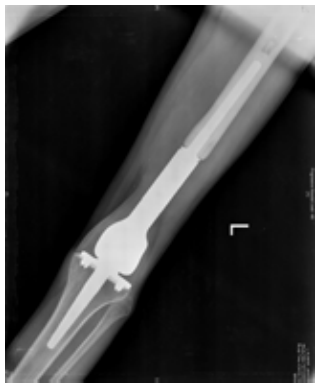
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c]Femoral Resection [d]Tibial Resection [f]Hydroxyapatite
[†] The use of a stem with a HA[f] coated collar adds 20mm to the overall length of the implant assembly

Distal Femur Resection

Distal Femur Resection, Pre-Op*



Distal Femur Resection, Post-Op*



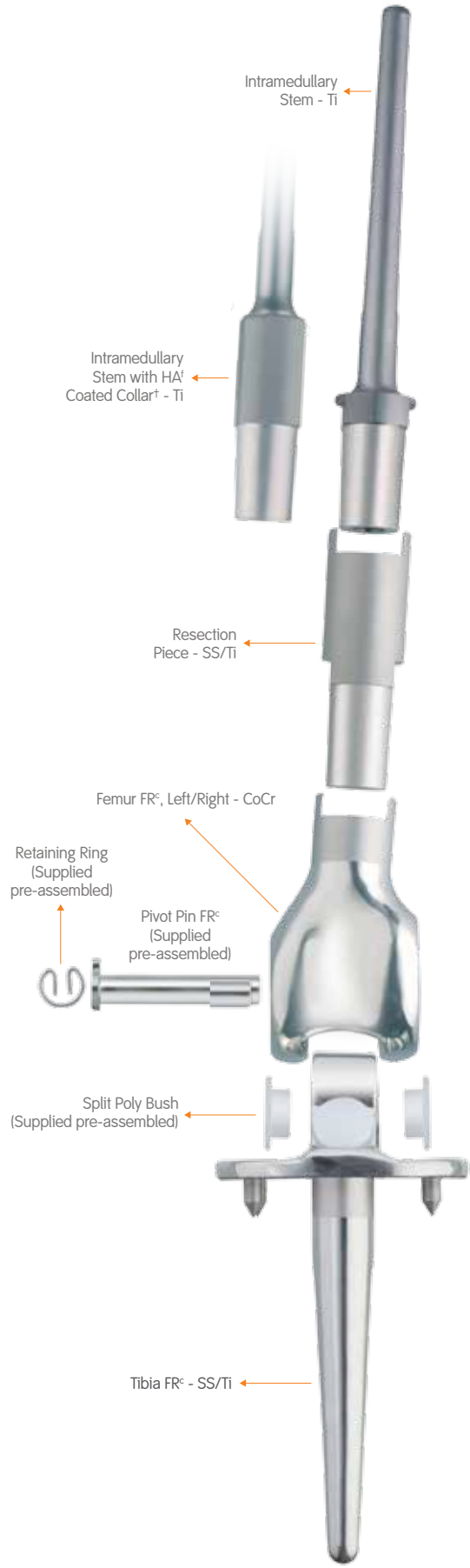
Condylar Component Dimensions

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

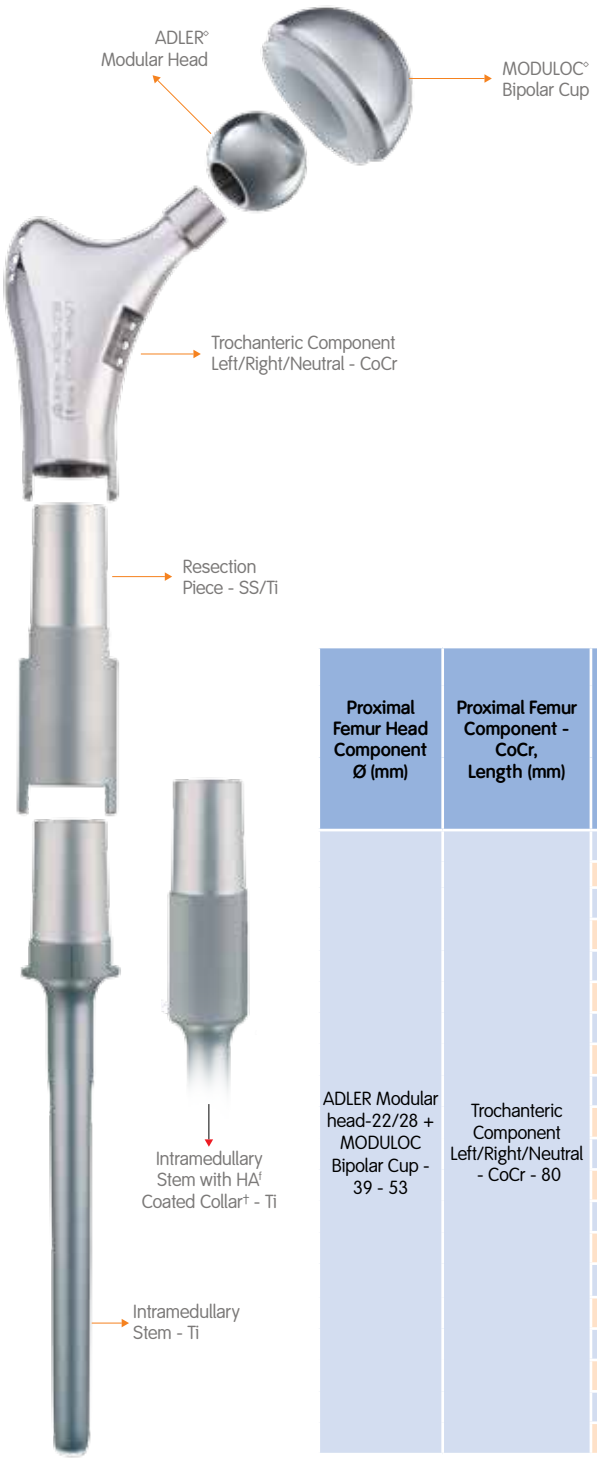
Component Selection Guide - Distal Femur Resection

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

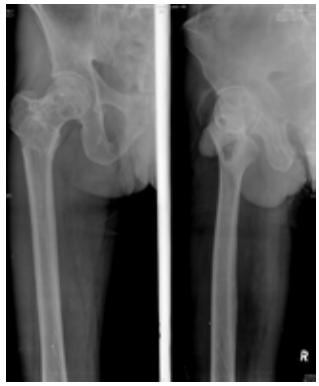
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai [c] Femoral Resection [d] Tibial Resection [f] Hydroxyapatite
[†] The use of a stem with a HA[f] coated collar adds 20mm to the overall length of the implant assembly



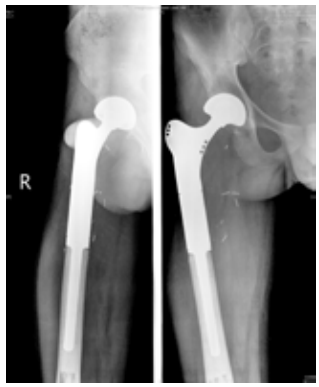
Proximal Femur Resection



Proximal Femur Resection, Pre-Op*



Proximal Femur Resection, Post-Op*

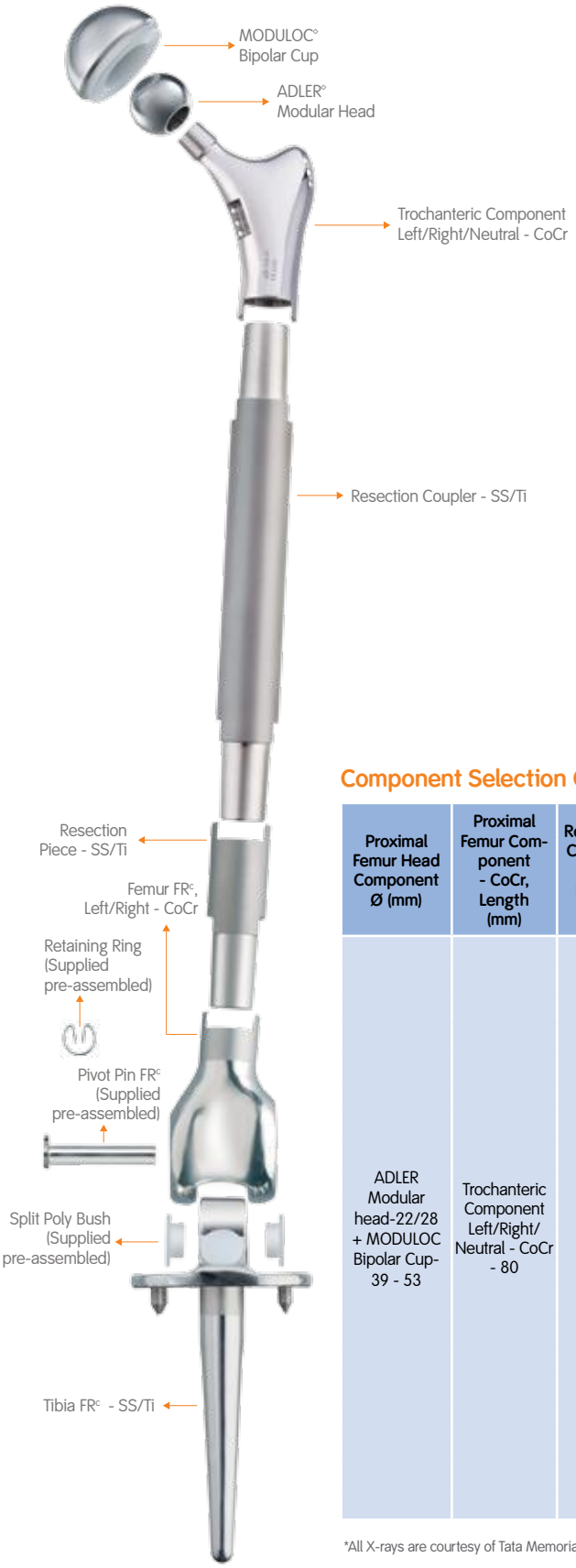


Component Selection Guide - Proximal Femur Resection

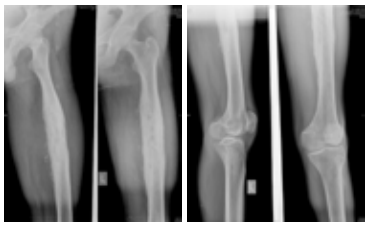
Proximal Femur Head Component Ø (mm)	Proximal Femur Component - CoCr, Length (mm)	Resection Piece - SS / Ti, Length (mm)	I.M. Stem - Ti, Ø (mm) Straight/ Curved	Total Resection Length (mm) With Head									
				NL[e] -3.5, Lat Offset 35.5		NL[e] -2.0, Lat Offset 36.5		NL[e] 0, Lat Offset 38.0		NL[e] +3.5, Lat Offset 40.5		NL[e] +7.5, Lat Offset 44.0	
			Standard	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	228	209	230	210	232	212	235	215
		140		238	218	238	219	240	220	242	222	245	225
		150		248	228	248	229	250	230	252	232	255	235
		160		258	238	258	239	260	240	262	242	265	245
		170		268	248	268	249	270	250	272	252	275	255
		180		278	258	278	259	280	260	282	262	285	265
		190		288	268	288	269	290	270	292	272	295	275
		200		298	278	298	279	300	280	302	282	305	285
		210		308	288	308	289	310	290	312	292	315	295
		220		318	298	318	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 HAf coated collar adds 20mm to the overall length of the implant assembly

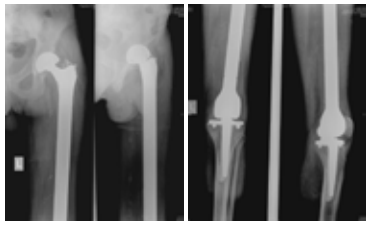
Total Femur Resection



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

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	22/+7.5	28/-3.5	28/0.0	28/+3.5	28/+7.5	28/+10	28/+12.5
H0407.2120	H0407.2200	H0407.2235	H0407.2275	H0407.2735	H0407.2800	H0407.2835	H0407.2875	H0407.2900	H0407.2925

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

A1601.1060

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	A1601.1026	A1601.1027
Ti	A1601.1036	A1601.1037

RESTOR
Tibia TR[d] - CoCr

A1601.1121

RESTOR, Straight
Intramedullary Stem with HA[f]
coated Collar

Len.120 mm	Ø (mm)
A1601.0149	09[a]
A1601.0150	10
A1601.0151	11
A1601.0152	12

RESTOR, Curved
Intramedullary Stem with HA[f]
coated Collar

Len.120 mm	Ø (mm)
A1601.0249	09[a]
A1601.0250	10
A1601.0251	11
A1601.0252	12

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

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

MODULOC® Trial Heads

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
H0105.2925	+12.5

MODULOC
Bipolar Trial, Quick Lock

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

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 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 Femur FR[c] Left, Trial

C1601.1011

RESTOR Femur FR[c] Right, Trial

C1601.1012

RESTOR Tibia TR[d], Trial

C1601.1121

RESTOR Tibia FR[c] Trial

Regular	Small
C1601.1040	C1601.1041

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 HA[f] Collar Stem Spacer, Trial

A1601.0140

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

[c] Femoral Resection [d] Tibial Resection

Illustrations not to scale. Specifications subject to change without notice

RESTOR◇ Instrument Set, Lower Limb

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

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

C1304.10

MODULOC Bipolar Cup Press

H0103.10

MODULOC Trial Head Disimpactor

H0103.12

Punch For Resection Coupler

C3902.24

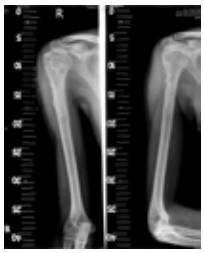
[c] Femoral Resection [d] Tibial Resection

[Δ] Not to be used if the Polyethylene Wedge is supplied pre-assembled with the component

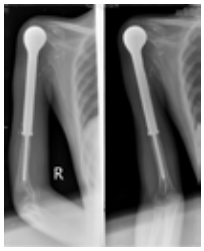
Illustrations not to scale. Specifications subject to change without notice

Proximal Humerus Resection

Proximal Humerus Resection, Pre-Op*

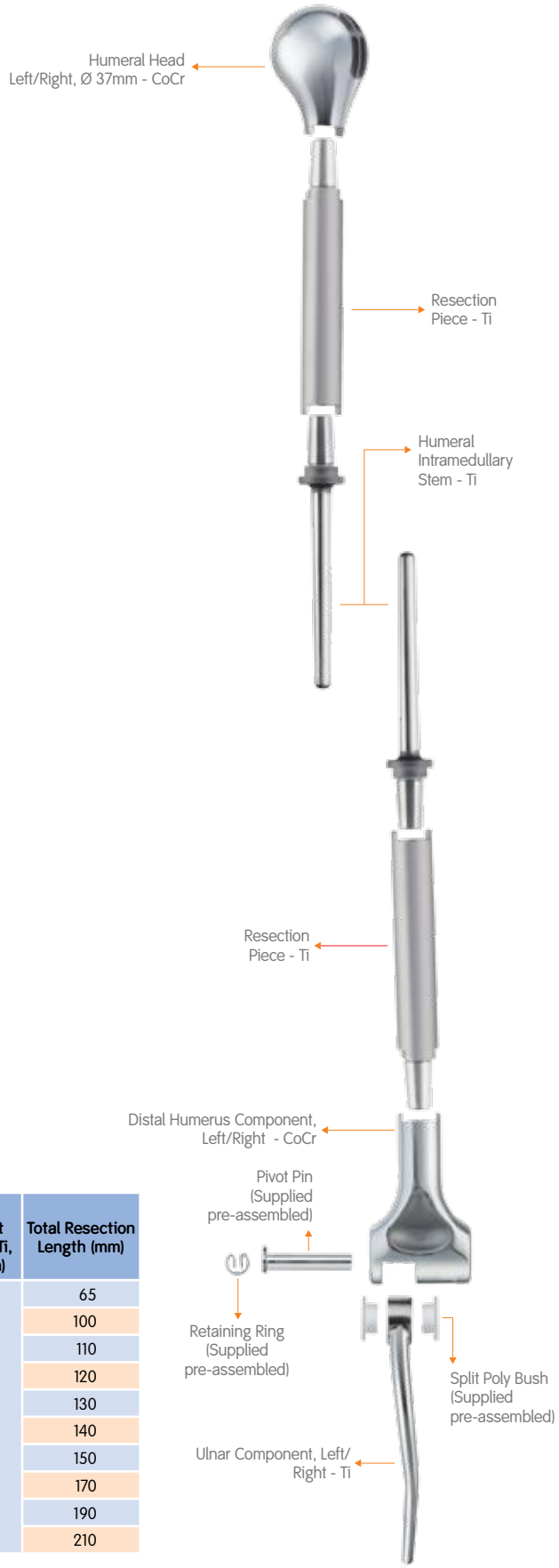


Proximal Humerus Resection, Post-Op*



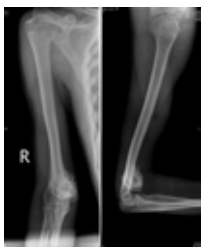
Component Selection Guide - Proximal Humerus Resection

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

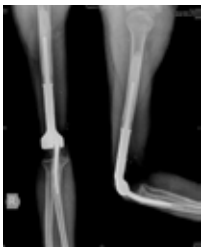


Distal Humerus Resection

Distal Humerus Resection, Pre-Op*



Distal Humerus Resection, Post-Op*



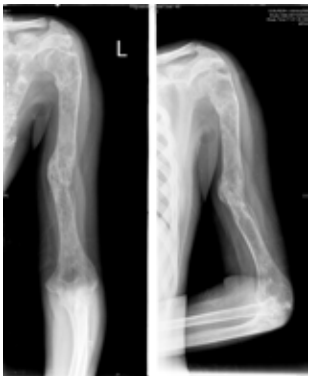
Component Selection Guide - Distal Humerus Resection

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

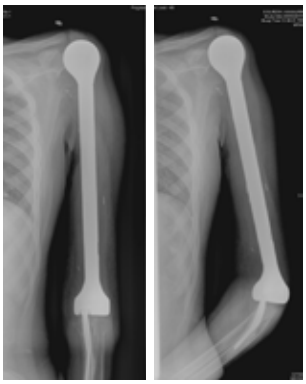
*All X-rays are courtesy of Tata Memorial Hospital, Mumbai

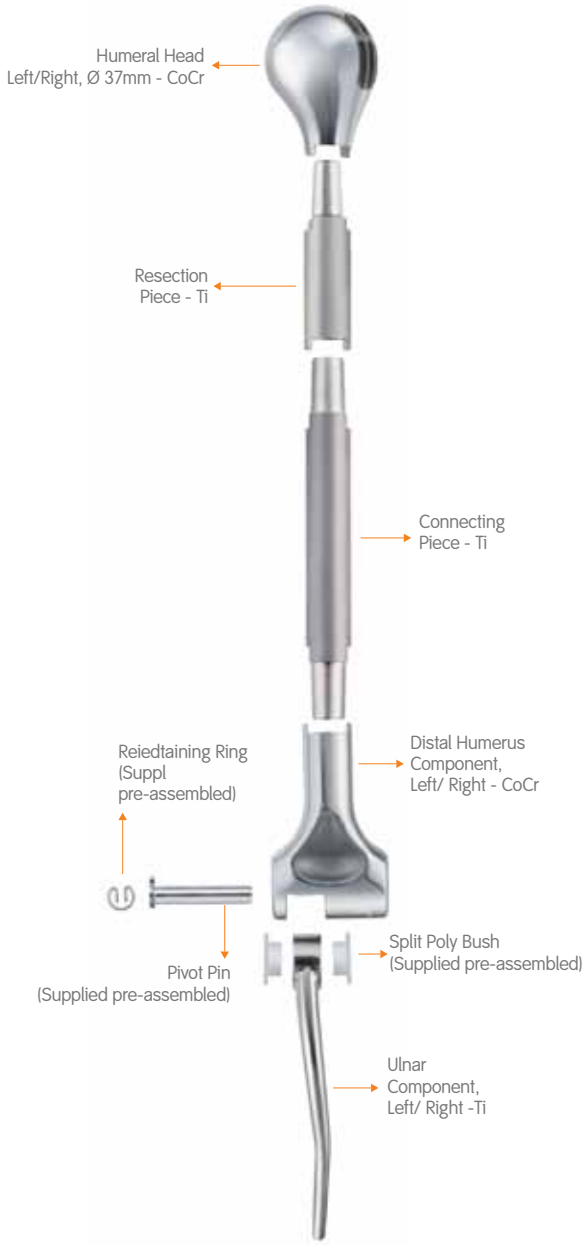
Total Humerus Resection

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

Implants Upper Limb

RESTOR[c]
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. [c]Femoral Resection [d]Tibial Resection

RESTOR® Instrument Set, Upper Limb

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

D0101.2103

Upper Tray, RESTOR Upper Limb Instrument Set

D0102.1801

Lower Tray, RESTOR Upper Limb Instrument Set

D0102.1802

RESTOR Humeral Head Trial

Left	Right
C1801.0137	C1801.0237

Resection Component Punch, Upper Limb, RESTOR

C3900.0801

Ulnar Component Punch, RESTOR

C3900.1500

Distal Humerus Component Punch, RESTOR

C3900.0903

Humeral I.M Stem Punch, RESTOR

C3900.0901

Connecting Component Punch, Upper Limb, RESTOR

C3900.0802

Humeral Head Punch, RESTOR

C3900.0902

Base for Humeral Head Assembly, RESTOR

C3900.0700

Base for Distal Humerus Component Assembly, RESTOR

C3900.0701

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

Pivot Pin Inserter, Upper Limb, RESTOR

C3900.0301

Ulnar Rasp, RESTOR

Left	Right
C3902.2045	C3902.2145

IM Stem Extractor, Upper Limb, RESTOR

C3902.2200

Ulnar Component Hook, RESTOR

C3900.1600

Wedge Fork, Upper Limb, RESTOR

C3900.18

Conical Reamer, Modular, Upper Limb, RESTOR

C3900.1901

Conical Reamer Centralizer, 6mm, Upper Limb, RESTOR

C3900.1902

RESTOR Distal Humerus Component, Trial

Left	Right
C1804.01	C1804.02

RESTOR Pivot Pin, Upper Limb, Trial

C1805.01

Slotted Hammer, Small, ADLER

C3900.1700

Retaining Ring Inserter, Upper Limb, RESTOR

C3900.1101

Articulation Aligner, Upper Limb, RESTOR

C3901.0412

RESTOR Ulnar Component, Trial

Left	Right	Length (mm)
C1806.5481	C1806.5482	4
C1806.6581	C1806.6582	5

RESTOR Humeral I.M Stem, Trial

Code No.	Length (mm)	Ø (mm)
C1803.0608	80	6
C1803.0610	100	6
C1803.0708	80	7
C1803.0710	100	7
C1803.0808	80	8
C1803.0810	100	8

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 Mediequip 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@adlermediequip.com.

DMN.X.2013.25.7a

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