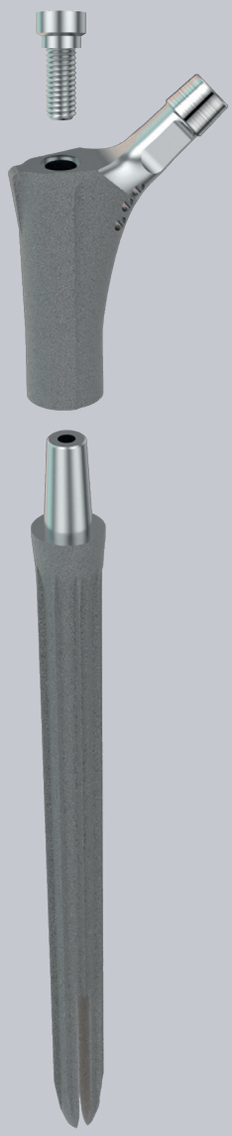
Recon-i

Surgical Technique

Hip Replacement



Stem-RR

Modular Revision Stem
Cementless

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Important Note

Lincotek Bologna S.r.l., does not practice medicine. This surgical technique / brochure has been developed in consultation with an experienced team of surgeons to provide their peers with general guidance when implanting the Predicate Acetabular System. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each patient individually.

Indications

Indications according to IFU:

- Extensive primary and secondary destruction of the joint to the extent that the functional efficiency of the locomotive apparatus is reduced;
- Severe pathological condition affecting the articulation caused by degenerative and rheumatoid arthritis;
- Joint fracture or bone necrosis;
- Post-surgical conditions after previous operations with or without consequent use of a prosthesis.

Contraindications

- On-going inflammatory process in the periarticular region;
- Severe loss of bone tissue such as to inhibit a primary stabilisation of the prosthesis;
- Degenerative changes in the patient's neurological condition;
- Severe instability in the ligament area that cannot be remedied;
- Foreseeable causes of fatigue of the implanted joint due to obesity or excessive physical activity;
- Severe osteoporosis;
- Bone cancer in the implant anchoring area;
- Alcohol and drug abuse;
- Allergy to the materials employed;
- Lack of collaboration by the patient.

Relative contraindications:

- Adiposity
- Lacking or foreseeable not assured compliance
- Foreseeable overload/overstressing of the joint prosthesis
- Osteoporosis

Risk Factors

Complications:

- Hematomas in the region of the operation;
- Late onset of acute infections in the region of the operation;
- Momentary or persistent functional alterations in the nerves of the anatomical area concerned;
- Venous thrombosis, pulmonary embolism, heart failure;
- Change in position and/or loosening of the prosthesis;
- Joint dislocation;
- Shortening or lengthening of the limb concerned;
- Pathological bone fracture caused by changes in load;
- Allergic reactions or metallosis in the peripheral region of the implant;
- Periarticular ossification.

Preoperative Planning

The device should be implanted only by surgeons familiar with the joint replacement procedures described in the specific surgical techniques.

Preoperative planning provides useful information for the correct placement of the implant but does not necessarily indicate the appropriate sizing. The correct stem and cup size must be determined during surgery.

To achieve the best results preoperative planning using special templates (with specific magnification always advisable). It's suggested to do AP radiograph with adequate contrast.

The templates show both the profile of the cup and the center of rotation of the femoral head and the A-P main dimensions of the stem and the relative center of rotation according to the different head sizing.

In order to achieve successful hip replacement surgery, it is crucial to plan the procedure preoperatively, taking into consideration the patient's individual anatomy and level of physical activity.

The surgeon should conduct a thorough evaluation of the patient's clinical condition to determine the correct implant type and size, as well as its final intraosseous position.

To ensure optimal results, surgery should be planned in advance using appropriate templates, which must be compatible with the magnification factor of the X-rays.

Special X-ray templates are available in a standard 1.1:1 and 1.15:1 scale.
The implant size should be selected from adequate AP and ML X-rays, ensuring legibility and large enough to accommodate the whole template. A second X-ray of the unaffected joint can be helpful.

Improper preoperative planning can result in the selection of incorrect implant types or incorrect positioning of implants.

It is desirable to have a load-bearing, stable acetabular fossa with solid lateral osseous coverage for acetabular surgeries and to evaluate properly the femoral bone conditions to select the adequate stem type.

The inclination of the cup should not be significantly above or below 45°, and anteversion should not be significantly above or below 15°.

Deviating from these boundaries may lead to a reduced range of motion, potentially resulting in subluxation or dislocation of the joint. The combined stem/cup anteversion should be around 30° to improve the range of motion and reduce the dislocation risk and any potential impingement risks.

During hip replacement surgery, various surgical approaches can be utilized to implant the components.

The following steps are applicable for both postero-lateral and other surgical access routes.

The patient is placed in a lateral position for the procedure. The incision is made postero-laterally, followed by opening of the fascia-lata.

The external rotator muscles are then resected, and the joint capsule is incised.
The femoral head is dislocated dorsally to allow for easy access and removal of the head from the socket. This is achieved by flexing the hip and abducting the leg, which allows the femoral head to dislocate freely.

These steps are critical for a successful hip replacement surgery, regardless of the surgical approach utilized.

Before acetabular reaming, it is essential to have a clear and direct view of the acetalar site, regardless of the surgical approach selected, and before femurs broaching a good visibility must be achieved and the relative position of the great trochanter and the calcar should be properly evaluated.

This requires the removal of any soft tissues and osteophytes that could obstruct visibility, allowing for a complete view of the entire acetabular socket and neck-femur region.

This is crucial to identify the presence of any cavitary or segmental defects and ensure accurate diagnosis and treatment.

Specific acetabular and femoral retractors are needed to facilitate acetabular exposure.

Choice of Stem Size and Stem Type

The proximal body size is selected in a way that, in frontal plane, the outline fills as much of the proximal femoral metaphysis as possible. In the sagittal plane, it must be ensured that the stem is suited to the anterior bow of the femur.

The proximal part in cases where the femoral metaphysis is highly damaged does not need to fit this specification and is needed only for a restoring the centre of rotation, while the implant stability is based on the distal stem fixation into the femoral diaphysis.

The distal stem is fixed distally and therefore not need to fit closely in the distal area.

The size of prosthesis should be chosen so that the centre of rotation is correctly situated in the middle of the head respectively at a level with greater trochanter. Anteversion must be checked in the sagittal plane.

The size of the distal stem is selected withing the diameter range that really fits the distal canal. The length of the distal stems depends on the length of the specific femur.

Preoperative planning gives an initial estimate but cannot conclusively determine the size of stem to be used. This is decided intraoperatively.

Positioning of Patient and Surgical Approach

All surgical approaches can be used while implanting Stems.

All the following steps apply for postero-lateral surgical approach and all other surgical access routes.

The patient lies on his/her side. The incision is done postero-laterally. After opening of the "fascialata", external rotator muscles are resected and the joint capsule is incited.

Then, the femoral head is dislocated in dorsal direction so that it lies free.

Surgical Technique

Determination of the Resection Level

The resection level has been defined in the pre-op planning. Resection should be sparing so that more bone can be resected later on if necessary.
The angle of resection is perpendicular to the femoral neck axis [▶Fig.1]. Alternatively, a bone broach can be used to determine the resection level.

Then the resection is carried out at the planned level. In many revision cases where a previous implant was already positioned resection step does not need to be performed.

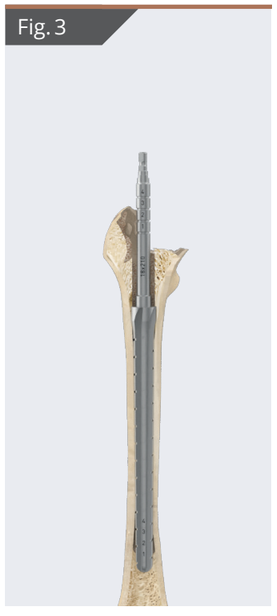
Fig. 1

Canal Reaming

Manual reaming of the femoral medullary cavity is carried out, using the reamers [▶Fig.2] of the predetermined length during the preoperative plan with a progression of 2 mm at a time, until the appropriate diameter is reached.
The reamers are provided with reference marks [▶Fig.3] to identify the center of rotation of the prosthetic head.

Fig. 2

Fig. 3



The preparation of the metaphysis is carried out, if necessary, using the dedicated broaches which are guided, in their action, by the axis of the reamer which, remaining in place, guarantees perfect alignment.
The sinking of the broach is indicated by the reference line [▶Fig.4] [▶Fig.5], marked on the handle of the same, which corresponds to the foreseeable center of rotation of the final prosthesis.
During this phase, the angle of rotation of the broaches should be considered as a function of the anteversion angle of the neck.

Fig. 4

Fig. 5

After preparing the diaphyseal canal and the metaphyseal housing of the prosthesis, remove the distal reamer using the same t-handle that was used for reaming (Fig.6)

Fig. 6

Final Stem Impaction

After removing the reamer, the stem of the prosthesis is implanted.
Choose the distal body (stem) corresponding to the size of the last reamer used and place the Proximal Impactor on top of the stem [▶Fig.7].
Fully insert the Straight Hex Screwdriver [▶Fig.8].
The Proximal Impactor already contains a screw which has to be tightened with the Straight Hex Screwdriver so that the Proximal Impactor is firmly connected with the stem. Then proceed to insert everything into the canal.
The stem is then carefully impacted using a 500g mallet.
Proceed with caution to avoid fractures of the femur, which could arise due to hoop stresses.

Fig. 7

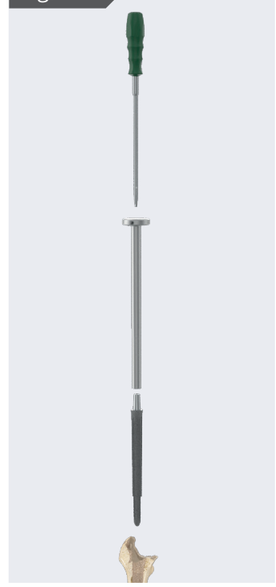
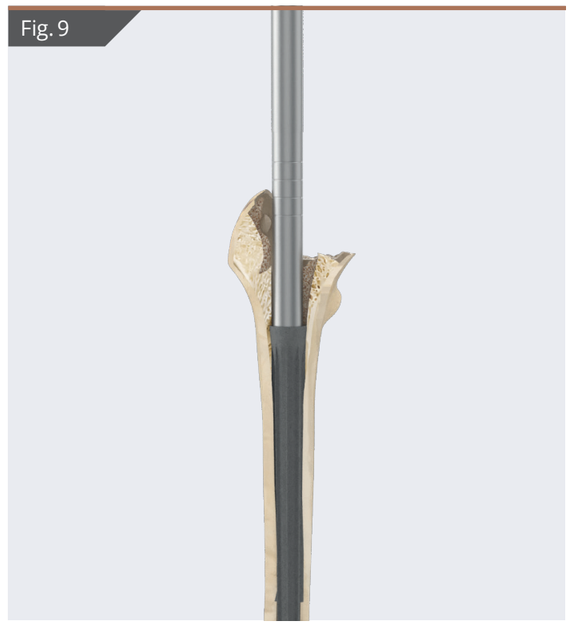


Fig. 8

Once the impaction is complete, the circular reference lines [▶Fig.9] indicate the height of the proximal part of the prosthesis. The stem should not be impacted deeper than the preplanned level. If stable anchorage is not achieved at the preplanned level owing to compromised bone quality, the stem can be driven in further and the resulting shortening of the leg can be corrected by up to 30 mm using the Proximal Bodies (+10mm, +20mm, +30mm). Leg length can also be increased using the Proximal Bodies.

Fig. 9



Trial Reduction

The acetabular cup is usually implanted before the stem. Trial reduction can then be carried out.

The corresponding proximal trial part [▶Fig.10] is fixed to the implanted distal part [▶Fig.10] giving it adequate ante / retroversion.

The trial head is placed on the cone of the trial [▶Fig.11] and the joint is reduced.

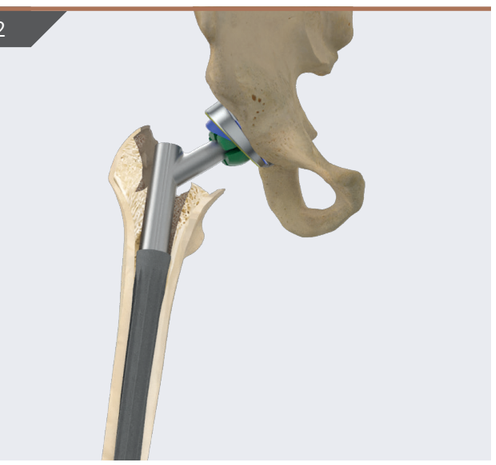
Fig. 10

Fig. 11

Once the correctness of the implant has been verified [▶Fig.12], the bone is marked with the electro-coagulator in correspondence with the reference line present on the trial which will indicate the correct ante / retroversion of the final proximal part.

The stability and range of motion of the joint are examined with the help of the trial components.

Fig. 12



Finally, the trial head [▶Fig.13] and proximal segment [▶Fig.14] are removed by hand.

Fig. 13

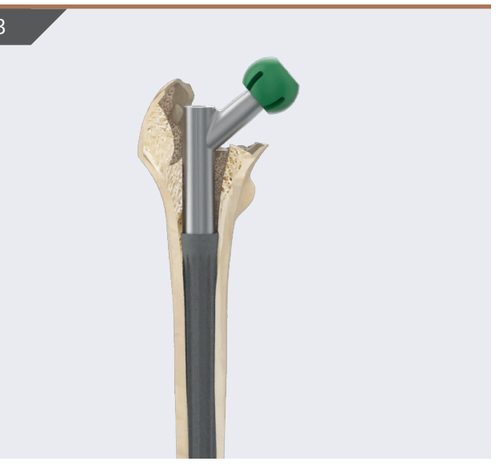
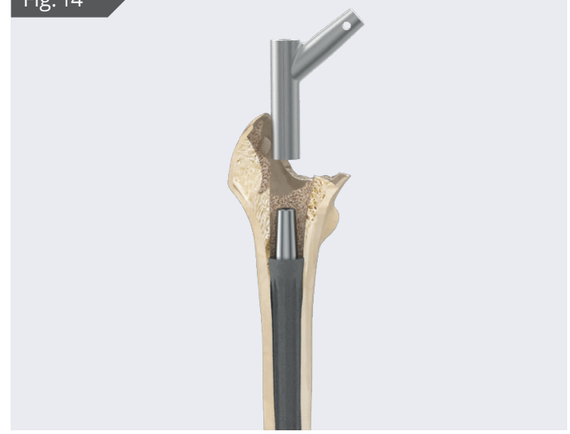


Fig. 14



Inserting the Final Stem

After the trial instruments are removed, the cone of the distal part of the prosthesis is carefully cleaned and dried to prevent any residues of the preparation of the femoral canal from hindering the correct conical coupling of the prosthetic components.

Proceed with the implantation of the proximal part of the prosthesis [▶Fig.15] using the appropriate impactor [▶Fig.15], taking care to make the shoulder present on the implant coincide with the reference line previously marked on the bone.

The universal fixation screw is inserted and in the screwing phase the correct ante / retroversion is maintained through the counter torque handle. [▶Fig.16]

Fig. 15

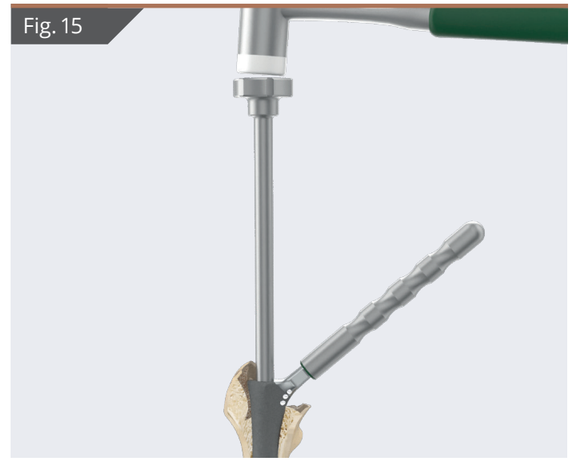


Fig. 16

Finally, the access hole to the fixing screw is sealed using the special universal closure cap. [▶Fig.17]

It is possible to check the neck length of the joint prosthetic head again before applying the final component.

Fig. 17

Final Trial Reduction

At this point the correct head-neck-length can be checked again with the trial heads and trial liners.

Final Head Implantation

Remove the appropriate prosthesis head (diameter, length, material) from the sterile packaging. Clean and dry the taper of the stem thoroughly. This is particularly important with ceramic heads.
Mount the head by hand using axial pressure and a turning motion.

Impact the head lightly if necessary, using the impactor for prosthesis heads. [▶Fig. 18]

Fig. 18

Reduction and suture:
Clean the joint surfaces thoroughly and then finally reduce the joint and test the final configuration and stability.
[▶Fig.19] [▶Fig.20]

Fig. 19

Fig. 20

Proximal Body Removal

In the event that the operator realizes that the ante / retroversion angle is not correct, it is possible to separate the components using a special tool. Once the closing cap and fixation screw (if already inserted) have been removed, screw the bushing to the prosthesis and insert the threaded rod, which, once it reaches the bottom of the hole on the cone, creates a distracting force that separates the two components. In this way the operator can repeat the insertion manoeuvre of the proximal part with the correct angulation.

It is also possible to extract only the distal part using the adapter assembled on the extractor, then screwing the instrument so configured on the coupling cone.

Ordering Information
Implants and Instruments

Stem-RR: Distal Bodies

Item Code	Description	Coating	Type	Main Material
XM05.1000.000.00	Stem RR Distal Body L.130 D.14		130	Ti6Al4V - ISO 5832/3
XM05.1001.000.00	Stem RR Distal Body L.130 D.16		130	Ti6Al4V - ISO 5832/3
XM05.1002.000.00	Stem RR Distal Body L.130 D.18		130	Ti6Al4V - ISO 5832/3
XM05.1003.000.00	Stem RR Distal Body L.130 D.20		130	Ti6Al4V - ISO 5832/3
XM05.1004.000.00	Stem RR Distal Body L.160 D.14		160	Ti6Al4V - ISO 5832/3
XM05.1005.000.00	Stem RR Distal Body L.160 D.16		160	Ti6Al4V - ISO 5832/3
XM05.1006.000.00	Stem RR Distal Body L.160 D.18		160	Ti6Al4V - ISO 5832/3
XM05.1007.000.00	Stem RR Distal Body L.160 D.20		160	Ti6Al4V - ISO 5832/3
XM05.1008.000.00	Stem RR Distal Body L.160 D.22		160	Ti6Al4V - ISO 5832/3
XM05.1009.000.00	Stem RR Distal Body L.210 D.16		210	Ti6Al4V - ISO 5832/3
XM05.1010.000.00	Stem RR Distal Body L.210 D.18		210	Ti6Al4V - ISO 5832/3
XM05.1011.000.00	Stem RR Distal Body L.210 D.20		210	Ti6Al4V - ISO 5832/3
XM05.1012.000.00	Stem RR Distal Body L.210 D.22		210	Ti6Al4V - ISO 5832/3
XM05.1013.000.00	Stem RR Distal Body L.130 D.14 CaP	CaP	130	Ti6Al4V - ISO 5832/3
XM05.1014.000.00	Stem RR Distal Body L.130 D.16 CaP	CaP	130	Ti6Al4V - ISO 5832/3
XM05.1015.000.00	Stem RR Distal Body L.130 D.18 CaP	CaP	130	Ti6Al4V - ISO 5832/3
XM05.1016.000.00	Stem RR Distal Body L.130 D.20 CaP	CaP	130	Ti6Al4V - ISO 5832/3
XM05.1017.000.00	Stem RR Distal Body L.160 D.14 CaP	CaP	160	Ti6Al4V - ISO 5832/3
XM05.1018.000.00	Stem RR Distal Body L.160 D.16 CaP	CaP	160	Ti6Al4V - ISO 5832/3
XM05.1019.000.00	Stem RR Distal Body L.160 D.18 CaP	CaP	160	Ti6Al4V - ISO 5832/3
XM05.1020.000.00	Stem RR Distal Body L.160 D.20 CaP	CaP	160	Ti6Al4V - ISO 5832/3
XM05.1021.000.00	Stem RR Distal Body L.160 D.22 CaP	CaP	160	Ti6Al4V - ISO 5832/3
XM05.1022.000.00	Stem RR Distal Body L.210 D.16 CaP	CaP	210	Ti6Al4V - ISO 5832/3
XM05.1023.000.00	Stem RR Distal Body L.210 D.18 CaP	CaP	210	Ti6Al4V - ISO 5832/3
XM05.1024.000.00	Stem RR Distal Body L.210 D.20 CaP	CaP	210	Ti6Al4V - ISO 5832/3
XM05.1025.000.00	Stem RR Distal Body L.210 D.22 CaP	CaP	210	Ti6Al4V - ISO 5832/3
XM05.1026.000.00 *	Stem RR Distal Body L.130 D.14 BACT	BACT	130	Ti6Al4V - ISO 5832/3
XM05.1027.000.00 *	Stem RR Distal Body L.130 D.16 BACT	BACT	130	Ti6Al4V - ISO 5832/3
XM05.1028.000.00 *	Stem RR Distal Body L.130 D.18 BACT	BACT	130	Ti6Al4V - ISO 5832/3
XM05.1029.000.00 *	Stem RR Distal Body L.130 D.20 BACT	BACT	130	Ti6Al4V - ISO 5832/3
XM05.1030.000.00 *	Stem RR Distal Body L.160 D.14 BACT	BACT	160	Ti6Al4V - ISO 5832/3
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XM05.1039.000.00 *	Stem RR Distal Body L.130 D.14 BACT + CaP	BACT + CaP	130	Ti6Al4V - ISO 5832/3
XM05.1040.000.00 *	Stem RR Distal Body L.130 D.16 BACT + CaP	BACT + CaP	130	Ti6Al4V - ISO 5832/3
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XM05.1051.000.00 *	Stem RR Distal Body L.210 D.22 BACT + CaP	BACT + CaP	210	Ti6Al4V - ISO 5832/3

* Special request items

Stem-RR: Proximal Bodies

Item Code	Description	Coating	Type	Main Material
XM05.1052.000.00	Stem RR Proximal Body A1		A1	Ti6Al4V - ISO 5832/3
XM05.1053.000.00	Stem RR Proximal Body A2		A2	Ti6Al4V - ISO 5832/3
XM05.1054.000.00	Stem RR Proximal Body A3		A3	Ti6Al4V - ISO 5832/3
XM05.1055.000.00	Stem RR Proximal Body A4		A4	Ti6Al4V - ISO 5832/3
XM05.1056.000.00	Stem RR Proximal Body B1		B1	Ti6Al4V - ISO 5832/3
XM05.1057.000.00	Stem RR Proximal Body B2		B2	Ti6Al4V - ISO 5832/3
XM05.1058.000.00	Stem RR Proximal Body B3		B3	Ti6Al4V - ISO 5832/3
XM05.1059.000.00	Stem RR Proximal Body B4		B4	Ti6Al4V - ISO 5832/3
XM05.1060.000.00	Stem RR Proximal Body A1 CaP	CaP	A1	Ti6Al4V - ISO 5832/3
XM05.1061.000.00	Stem RR Proximal Body A2 CaP	CaP	A2	Ti6Al4V - ISO 5832/3
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XM05.1063.000.00	Stem RR Proximal Body A4 CaP	CaP	A4	Ti6Al4V - ISO 5832/3
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XM05.1065.000.00	Stem RR Proximal Body B2 CaP	CaP	B2	Ti6Al4V - ISO 5832/3
XM05.1066.000.00	Stem RR Proximal Body B3 CaP	CaP	B3	Ti6Al4V - ISO 5832/3
XM05.1067.000.00	Stem RR Proximal Body B4 CaP	CaP	B4	Ti6Al4V - ISO 5832/3
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XM05.1069.000.00 *	Stem RR Proximal Body A2 BACT	BACT	A2	Ti6Al4V - ISO 5832/3
XM05.1070.000.00 *	Stem RR Proximal Body A3 BACT	BACT	A3	Ti6Al4V - ISO 5832/3
XM05.1071.000.00 *	Stem RR Proximal Body A4 BACT	BACT	A4	Ti6Al4V - ISO 5832/3
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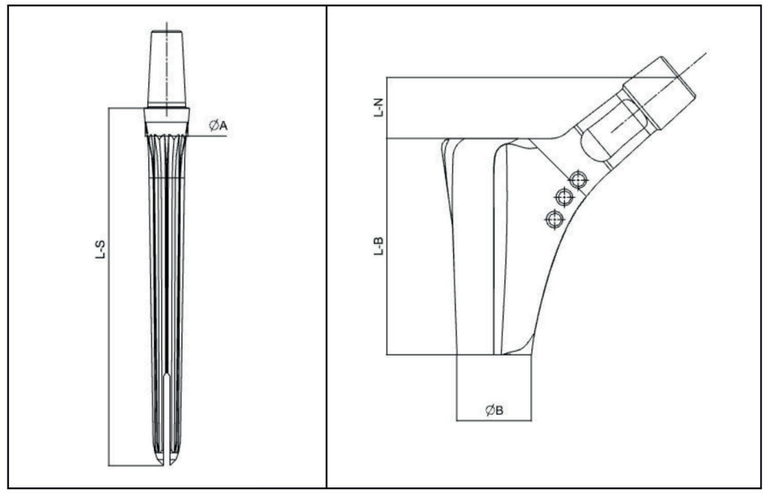
XM05.1082.000.00 *	Stem RR Proximal Body B3 BACT + CaP	BACT + CaP	B3	Ti6Al4V - ISO 5832/3
XM05.1083.000.00 *	Stem RR Proximal Body B4 BACT + CaP	BACT + CaP	B4	Ti6Al4V - ISO 5832/3

* Special request items

Stem Dimensions



Proximal Body Dimensions

Size	L-B	L-N	ØB
A1	55	15	17
A2	65	15	17
A3	75	15	17
A4	85	15	17
B1	55	15	21.5
B2	65	15	21.5
B3	75	15	21.5
B4	85	15	21.5

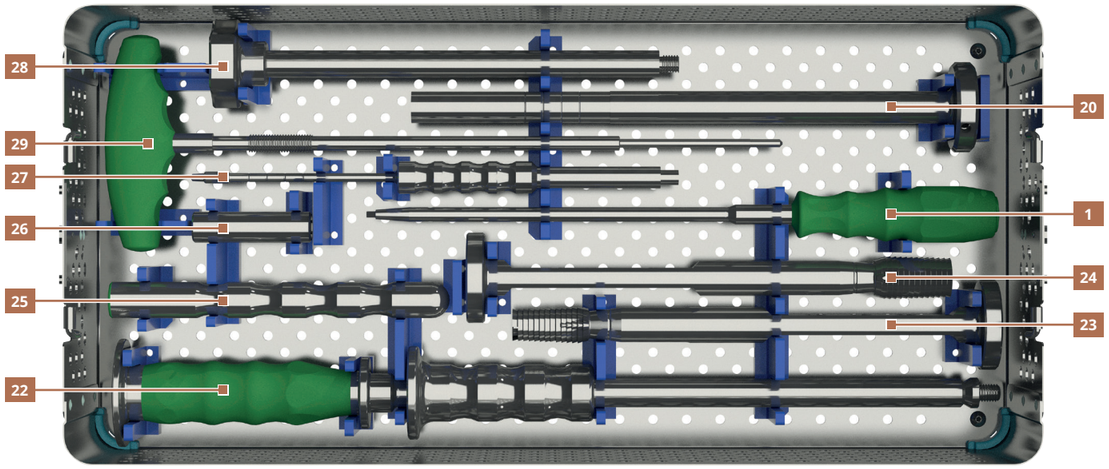
Distal Body Dimensions

Size (mm)	L-S	ØA
130 X 14	130	14
130 X 16	130	16
130 X 18	130	18
130 X 20	130	20
160 X 14	160	14
160 X 16	160	16
160 X 18	160	18
160 X 20	160	20
160 X 22	160	22
210 X 16	210	16
210 X 18	210	18
210 X 20	210	20
210 X 22	210	22

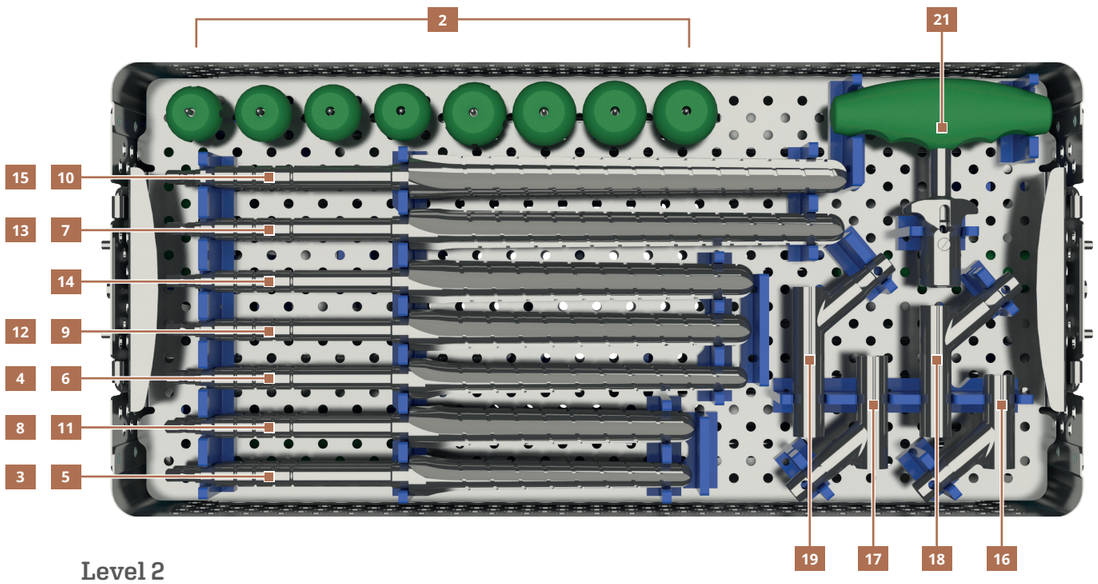
Safest Proximal x Distal Body Combinations

Size	14	16	18	20	22
A1	v	v			
A2	v	v			
A3	v	v			
A4	v	v			
B1		v	v	v	v
B2		v	v	v	v
B3		v	v	v	v
B4		v	v	v	v

Stem-RR Instrument Set | BO76.4002.000.00



Level 1



Level 2

Set Content

N°	Item Code	Description	Qty per SET
	BO76.4002.001.00	TRAY STEM RR	1
1	**BO76.5079.000.00**	Straight Hex Screwdriver	1
2	**XM01.5104.000.00**	Trial Ball Head 32S	1
	XM01.5105.000.00	Trial Ball Head 32M	1
	XM01.5106.000.00	Trial Ball Head 32L	1
	XM01.5107.000.00	Trial Ball Head 32XL	1
	XM01.5108.000.00	Trial Ball Head 36S	1
	XM01.5109.000.00	Trial Ball Head 36M	1
	XM01.5110.000.00	Trial Ball Head 36L	1
	XM01.5111.000.00	Trial Ball Head 36	1
3	**XM05.5000.000.00**	Reamer RR Distal Body L.130 D.14	1
4	**XM05.5001.000.00**	Reamer RR Distal Body L.130 D.16	1
5	**XM05.5002.000.00**	Reamer RR Distal Body L.130 D.18	1
6	**XM05.5003.000.00**	Reamer RR Distal Body L.130 D.20	1
7	**XM05.5004.000.00**	Reamer RR Distal Body L.160 D.14	1
8	**XM05.5005.000.00**	Reamer RR Distal Body L.160 D.16	1
9	**XM05.5006.000.00**	Reamer RR Distal Body L.160 D.18	1
10	**XM05.5007.000.00**	Reamer RR Distal Body L.160 D.20	1
11	**XM05.5008.000.00**	Reamer RR Distal Body L.160 D.22	1
12	**XM05.5009.000.00**	Reamer RR Distal Body L.210 D.16	1
13	**XM05.5010.000.00**	Reamer RR Distal Body L.210 D.18	1
14	**XM05.5011.000.00**	Reamer RR Distal Body L.210 D.20	1
15	**XM05.5012.000.00**	Reamer RR Distal Body L.210 D.22	1
16	**XM05.5052.000.00**	Reamer RR Proximal Body 1	1
17	**XM05.5053.000.00**	Reamer RR Proximal Body 2	1
18	**XM05.5054.000.00**	Reamer RR Proximal Body 3	1
19	**XM05.5055.000.00**	Reamer RR Proximal Body 4	1
20	**XM05.5137.000.00**	Stem RR Distal Body Impactor	1
21	**XM05.5138.000.00**	T-Handle Zimmer	1
22	**XM05.5139.000.00**	Stem RR Extractor	1
23	**XM05.5140.000.00**	Proximal Body Broach A	1
24	**XM05.5141.000.00**	Proximal Body Broach B	1
25	**XM05.5142.000.00**	Counter-torque Handle	1
26	**XM05.5143.000.00**	Distal Extractor Component	1
27	**XM05.5144.000.00**	Stem RR - Locking Screw Extractor	1
28	**XM05.5145.000.00**	Stem RR Proximal Impactor	1
29	**XM05.5146.000.00**	Stem RR Separator	1
	XM01.5098.000.00 *	Trial Ball Head 22S	1
	XM01.5099.000.00 *	Trial Ball Head 22M	1
	XM01.5100.000.00 *	Trial Ball Head 28S	1
	XM01.5101.000.00 *	Trial Ball Head 28M	1
	XM01.5102.000.00 *	Trial Ball Head 28L	1
	XM01.5103.000.00 *	Trial Ball Head 28XL	1
	XM01.5112.000.00 *	Trial Ball Head 40S	1
	XM01.5113.000.00 *	Trial Ball Head 40M	1
	XM01.5114.000.00 *	Trial Ball Head 40L	1
	XM01.5115.000.00 *	Trial Ball Head 40XL	1
	XM01.5211.000.00 *	Trial Ball Head 28XXL	1

* Special request items

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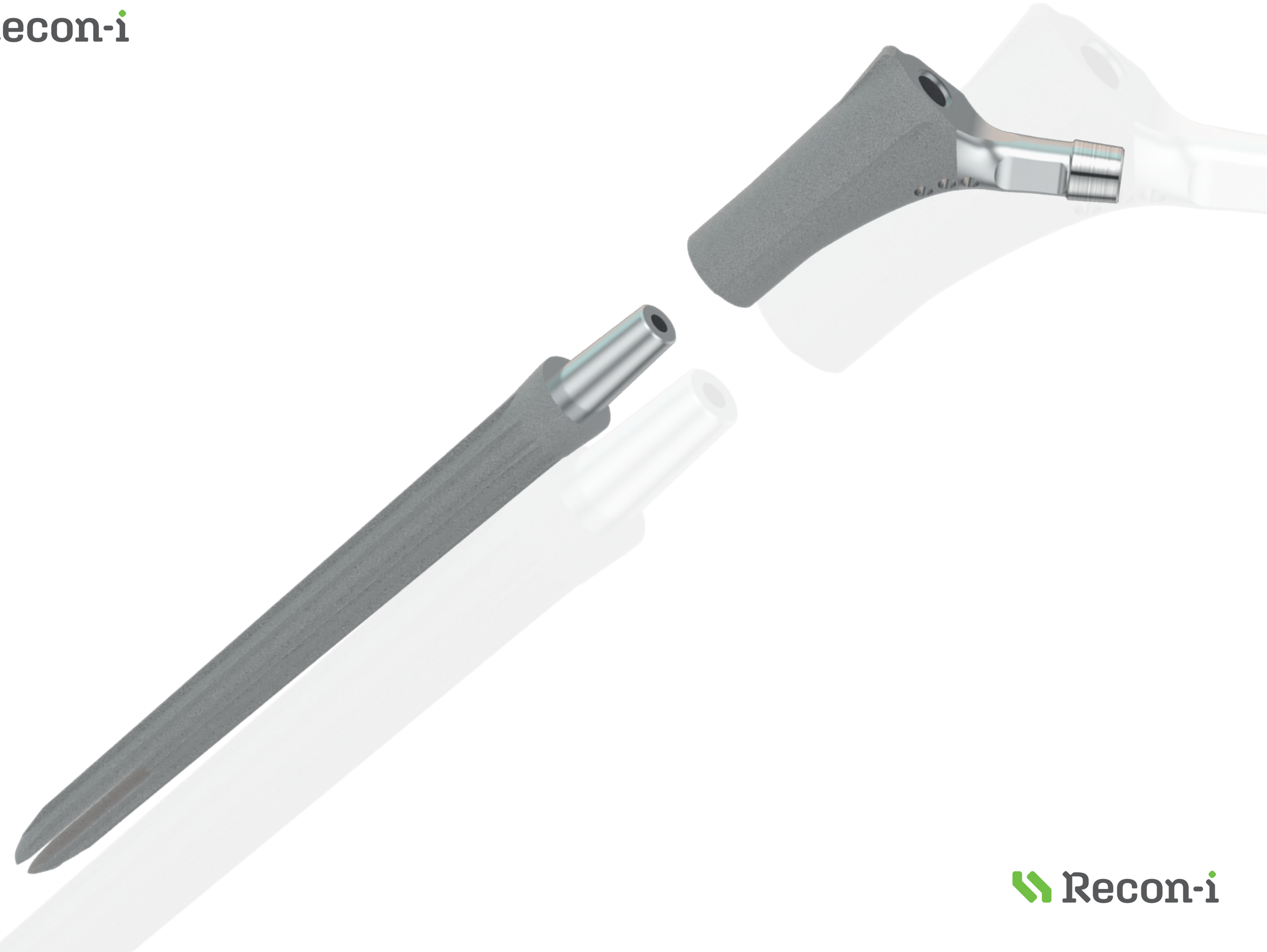

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Intelligent Joint Reconstruction