





Endo-Model

Rotational and Hinge Knee Prosthesis



C€ 0482

Explanation of Pictograms				
***		Manufacturer	REF	Item number
MA	Т	Material (number)	C€	Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.



Endo-Model

Rotational and Hinge Knee Prosthesis

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02	Rotational	171100	LHUU-	IVIOUG

- 06 LINK PorEx Surface Modification (TiNbN = Titanium Niobium Nitride)
- 07 Hinged Knee Endo-Model

Implants

Total Rotational Knee Prostheses Endo-Model

- with anti-luxation device
- with LINK PorEx surface modification

Total Hinge Knee Prostheses Endo-Model

- Replacement Sets V02 hinged version
- 12 Patella Components,

Centralizer,

Spacers

Instruments

14 Basic instrument Set for Rotational Knee Prostheses Endo-Model

Complementary Instrument Sets for:

- Rotational Knee Prostheses Endo-Model size "x-small"
- Rotational Knee Prostheses Endo-Model trial prostheses
- Total Hinge Knee Prostheses Endo-Model
- 22 Additional Instrument Set V02

for Rotational Knee Prostheses Endo-Model (Monobloc) and Endo-Model - M (Modular)

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Important General Information



Rotational Knee Joint Prosthesis Endo-Model®

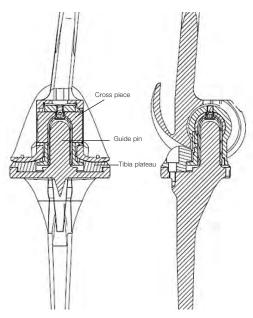
Building on the excellent results obtained with the **St. Georg Hinge Knee Prosthesis**, the rotational knee prosthesis was developed in 1979. It allows axial rotation and reduces the forces acting on the prosthesis anchorage.

The intracondylar **Endo-Model® Rotational Knee Prosthesis** is available in two versions (right and left) and four implant sizes

Material: CoCrMo Alloy, UHMW Polyethylene



Retaining the low friction principle, the physiological movement of the rotational knee prosthesis is optimal because the pivot point is within the physiological area. Flexion and rotation of the rotational knee prosthesis take place in a cross joint.



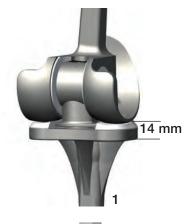




Over-extension amounts to 2°. The Endo-Model Rotational Knee Prosthesis allows flexion of up to 142°. In addition, the kinematics of this design provide physiological rotation, with elastic transmission of forces enabled by the special shape of the tibial running surface.

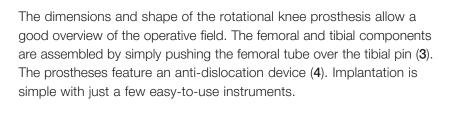
With every step, and even more in the case of a fall, torsional stresses arise and act on the implant anchorage, with a negative effect on the lifespan of the prosthesis. The elastic transmission of forces allowed by the construction of the prosthesis protects the bone cement/prosthesis and bone cement/bone interfaces.

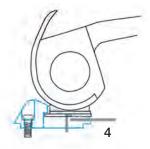
Because of the favourable dimensions of the rotational knee prosthesis, the resection required in the tibio femoral joint plane is very small - only 14 mm (1). The size of the intracondylar portion depends on the implant size but is only between 28 and 34 mm (2). This is an important positive point in terms of subsequent revision surgery.







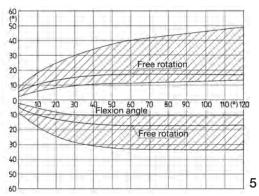






In knee replacement, advancement of the patella or of the patella bearing surface is often observed. By moving the femoral component dorsally relative to the tibial axis, physiological movement is achieved in the patello-femoral joint as well. This protects against progression of retropatellar arthrosis.

Rotation of the prosthesis ends in extension by form closure, which ensures a secure extension position. Rotation increases continuously with flexion. This rotation is limited primarily by the capsule-ligament apparatus (5).

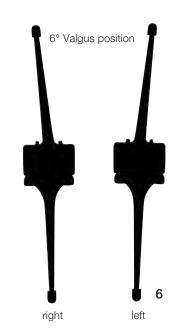


The extent of free rotation is a function of flexion, as is the region of smoothly slowed down rotation (for constructional reasons) (hatched area).

Engelbrecht E.: Die Rotationsendoprothese des Kniegelenks, Springer-Verlag 1984, ISBN: 978-3-642-69819-4 (Print) 978-3-642-69818-7 (Online)

The shape of the gliding surfaces, which are in contact with each other, provide that further rotation is damped elastically by the bodyweight's bearing-down on the joint.

The femoral component of the rotational knee prosthesis features a physiological valgus position of 6° (6).



Both prosthesis components are broadly supported on their corresponding gliding surfaces, such that the compressive strength of the cancellous bone is not exceeded. These bilateral surfaces of the femoral component are anatomically shaped (7).







The prosthesis stems increase the security of the alignment. The cross-section is rectangular with large transition radii and no sharp corners. Star-shaped polyethylene centralizers at the end of the stems ensure that each stem is centrally positioned in the medullary canal (8), thus avoiding any direct contact between the metal stem and the inner cortex.



The Endo-Model Rotational Knee Prosthesis offers optimum security of implant anchorage. Because the stems have no surface structuring at all, there is nothing to hinder extraction of the prosthesis in case of a revision procedure (9).

When the components are being knocked out of the cement bed, the centralizer usually breaks off and can then be drilled out in a second step.

If the cross joint is worn out, e.g. in the case of a malaligned prosthesis, it can be exchanged in a revision operation without the need to remove the femoral or tibial component.





Rotational Knee Joint Prosthesis Endo-Model with LINK PorEx Surface Modification



LINK PorEx (TiNbN = Titanium Niobium Nitride) Surface Modification

The hypoallergenic LINK PorEx modification leads to a ceramic-like surface, which significantly reduces the release of ions from the substrate and can improve tolerance in patients who are sensitive to metal.¹

This surface is extremely hard and possesses abrasion properties similar to those of ceramics. These qualities and the wetting angle of the surface give it a low friction coefficient when in contact with fluids.

Internal technical report: Study of the influence of TiNbN-coating on the ion release of CrCrMo-alloys in SBF buffer simulator testing

Comment:

Specified indikations/contraindications see catalog: 711_Endo-Model® Rotational and Hinge Knee Prostheses, Surgical Technique





Hinge Knee Joint Prosthesis Endo-Model

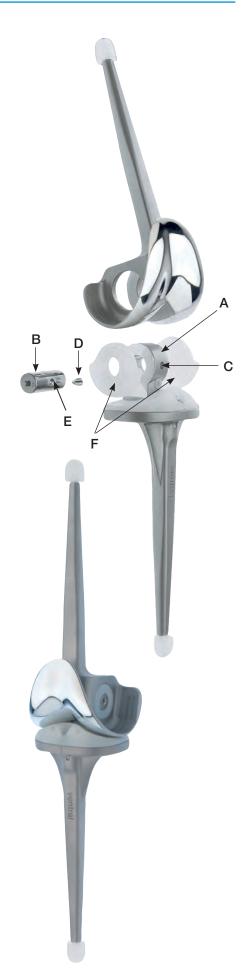
The external shape, dimensions and sizes of the Endo-Model Hinge Knee Prosthesis correspond to those of the Endo-Model Rotational Knee Prosthesis. As the implant beds required for the hinged and rotational versions are identical, the decision whether to use a rotational or a more stabilizing hinged knee prosthesis can be made intraoperatively.

Connecting piece A, which is fixed to the tibial component and links it to the femoral component of the hinge knee prosthesis. features a borehole for the joint axis B. The ventral borehole C is provided for the set screw D, whose tip fits into the borehole E on the axis. Once the upper and lower components have been joined, the axis is locked with the headless screw.

From inside the intracondylar box, polyethylene bearings for the prosthesis axis are pushed into the medial and lateral boreholes. The upper and lower prosthesis components are joined by introducing the tibial connecting piece into the intracondylar box of the femoral component, such that the prosthesis axis can be inserted (always from the medial aspect) using the threaded rod. Articulation takes place between the prosthesis axis and the two bearings.

The **Endo-Model Hinge Knee Prosthesis** is delivered readily assembled and in a sterile condition. To disassemble it, turn the set screw **D** anticlockwise. Screw the threaded rod onto the prosthesis axis B, which is then pulled out. Push the bearings F of the upper prosthesis component into the intracondylar box and remove them. (Note: The open bearing must be placed medially when the bearings are reinserted).

The package contains two sterile trial bearings (not autoclavable). These are inserted into the upper prosthesis component during surgery; after the trial run, they are exchanged for the definitive bearings. These, too, can be exchanged if necessary in a second intervention.





Rotational Knee Joint Prosthesis Endo-Model, with anti-luxation device

REF	with patella flange MAT EndoDur (CoCrMo)	(R) Radius*
15-8020/11	x-small/right	17 mm
15-8020/12	x-small/left	17 mm
15-8022/11	small/right	20 mm
15-8022/12	small/left	20 mm
15-8024/11	medium/right	23 mm
15-8024/12	medium/left	23 mm
15-8030/11	large/right	25 mm
15-8030/12	large/left	25 mm

* (R) Radius in the sagittal plane: Measured from the center of axis.



Replacement Set for Version V02,

with anti-luxation device

REF	Side	Size
15-0027/10	right/left	x-small
15-0027/11	right/left	small
15-0027/12	right/left	medium
15-0027/13	right/left	large

Each package contains:

- complete coupling mechanism,
- Bearing boxes,
- PE plateau and PE plateau anchoring screw.

Replacement Sets for Rotational Tibial Plateaus V02, with security screw,

MAT UHMWPE/CoCrMo

REF	Size
15-0027/17	x-small
15-0027/14	small
15-0027/15	medium
15-0027/16	large

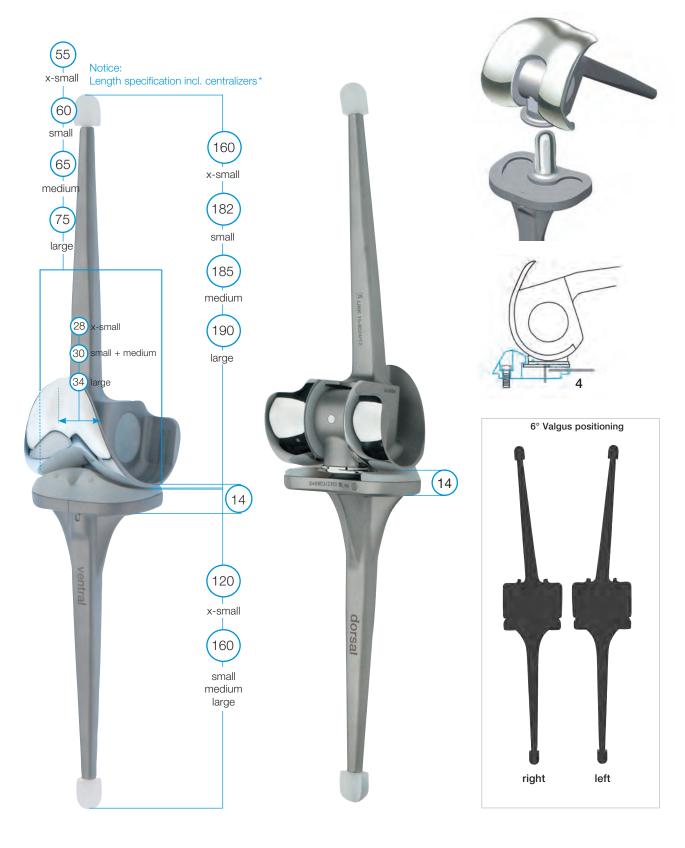
Each package contains:

PE plateau and PE plateau anchoring screw.

Further replacement sets available on request.

Required: Instrument Set for rotational bushing replacement, incl. additional Instrument Set V02, see page 22.





^{*} Centralizers are not included in prosthesis packing



Rotational Knee Joint Prosthesis Endo-Model, with anti-luxation device and LINK PorEx surface modification* to prevent metal-allergic reactions

REF	with patella flange MAT EndoDur (CoCrMo)/LINK PorEx*	(R) Radius**
15-9020/11	x-small/right	17 mm
15-9020/12	x-small/left	17 mm
15-9022/11	small/right	20 mm
15-9022/12	small/left	20 mm
15-9024/11	medium/right	23 mm
15-9024/12	medium/left	23 mm
15-9030/11	large/right	25 mm
15-9030/12	large/left	25 mm
** (R) Radius in the sagittal plane: Measured from the center of axis.		

Same dimensions as models with anti-luxation device, see page 09.

Required: Additional Instrument Set V02, see page 22.



Replacement Sets, for Rotational Tibia Plateaus V02, with security screw,

REF	MAT CoCrMo/LINK PorEx*, UHMWPE
15-0037/17	x-small
15-0037/14	small
15-0037/15	medium
15-0037/16	large

Each package contains:

• PE plateau and PE plateau anchoring screw

Replacement Sets,

with anti-luxation device

REF	MAT EndoDur – S (CoCrMo)/ LINK PorEx*, UHMWPE
15-3027/10	x-small
15-3027/11	small
15-3027/12	medium
15-3027/13	large

Each package contains:

- Complete coupling mechanism,
- · Bearing boxes,
- PE plateau and PE plateau anchoring screw.

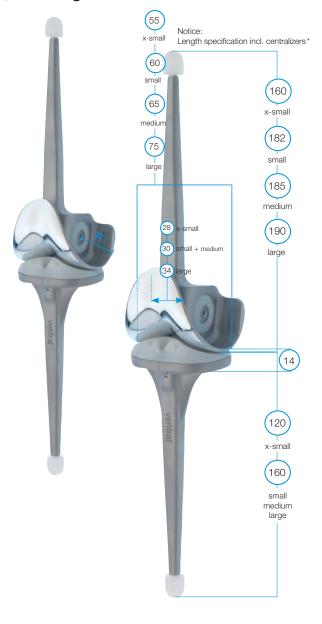
Required: Additional Instrument Set V02, see page 22.

^{*} LINK PorEx: TiNbN = Titanium-Niobium-Nitride; hypoallergenic coating (gold colour).



Total Hinge Knee Joint Prosthesis Endo-Model, with hinge axis

REF	with patella flange MAT EndoDur (CoCrMo)	(R) Radius*		
15-2459/11	x-small / right	17 mm		
15-2459/12	x-small / left	17 mm		
15-2460/11	small / right	20 mm		
15-2460/12	small / left	20 mm		
15-2461/11	medium / right	23 mm		
15-2461/12	medium / left	23 mm		
15-2462/11	large / right	25 mm		
15-2462/12	large / left	25 mm		
* (R) Radius in the sagittal plane: Measured from the center of axis.				



Replacement Sets for Hinge Knee Prostheses V02, with security screw, MAT UHMWPE/CoCrMo

REF	Side	Size
15-0027/20	right	x-small
15-0027/21	right	small
15-0027/22	right	medium
15-0027/23	right	large
15-0027/30	left	x-small
15-0027/31	left	small
15-0027/32	left	medium
15-0027/33	left	large

Each package contains:

- complete coupling mechanism,
- bearing boxes,
- PE plateau and PE plateau anchoring screw.

Required: Additional Instrument Set V02, see page 22.

Replacement Sets for Hinge Knee Tibial Plateaus V02, with security screw MAT UHMWPE/CoCrMo

REF	Size
15-0027/27	x-small
15-0027/41	small
15-0027/42	medium
15-0027/43	large

Each package contains:

PE plateau and PE plateau anchoring screw.



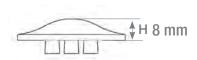


Patella Components

REF	MAT UHMWPE	
centric	Size	Ø
15-2521/30	small	30 mm
15-2521/35	medium	35 mm
15-2521/40	large	40 mm
3-pegs	Size	Ø
15-2522/30	small	30 mm
15-2522/35	medium	35 mm
15-2522/40	large	40 mm



Information on instruments and surgical technique available on request.



Centralizers*

REF	MAT UHMWPE
15-2975/01	Set consisting of:
15-2975/12 15-2975/14 15-2975/16	small medium large







^{*} not included in prosthesis packing.

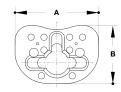


Proximal Tibial Spacers*











REF	MAT UHMWPE	Н	А	В
15-2516/70	Set consisting of:			
15-2516/55	x-small	5 mm	55 mm	42 mm
15-2516/60	x-small	10 mm	55 mm	42 mm
15-2516/65	x-small	15 mm	55 mm	42 mm
15-2516/29	Set consisting of:			
15-2516/05	small	5 mm	60 mm	45 mm
15-2516/10	small	10 mm	60 mm	45 mm
15-2516/15	small	15 mm	60 mm	45 mm
15-2517/29	Set consisting of:			
15-2517/05	medium	5 mm	65 mm	45 mm
15-2517/10	medium	10 mm	65 mm	45 mm
15-2517/15	medium	15 mm	65 mm	45 mm
15-2519/29	Set consisting of:			
15-2519/05	large	5 mm	75 mm	48 mm
15-2519/10	large	10 mm	75 mm	48 mm
15-2519/15	large	15 mm	75 mm	48 mm

Distal Femoral Spacers

recommended for long stem knee prosthesis version - on request.



* Important Information: Proximal tibial spacers

straight – must not be combined with each other!

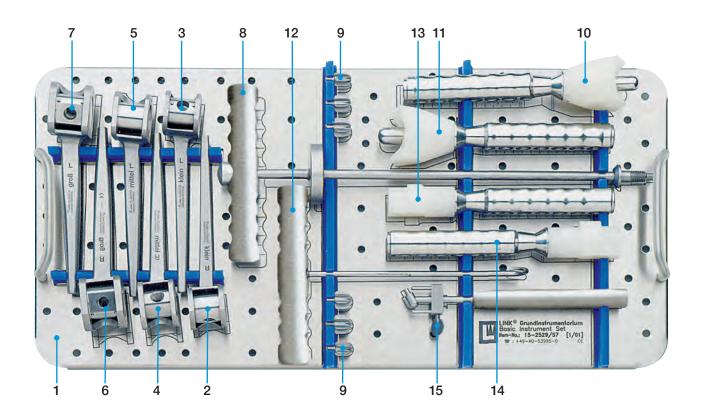


Basic Instrument Set for Rotational Knee Prostheses Endo-Model



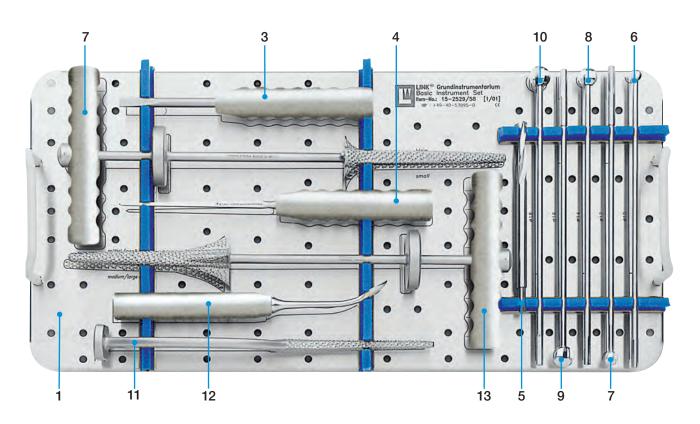
REF	Basic Instrument Set, complete
15-2529/50	Set in 2 standard containers, on 3 trays with product illustrations and storage racks.
05-2003/03	N31 Standard Container, empty, 575 x 275 x 170 mm
05-2001/03	N11 Standard Container, empty, 575 x 275 x 100 mm





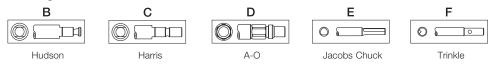
1	15-2529/57	Lower Instrument Tray with product illustrations, empty, 550 x 265 x 50 mm	
		Femoral Saw Guides with swivel axes	
2	15-2532/31	right small	
3	15-2532/32	left small	
4	15-2532/41	right medium	
5	15-2532/42	left medium	
6	15-2532/51	right large	
7	15-2532/52	left large	
8	15-2534/15	Threaded Rod with handle, for saw guides and trial prostheses	
9	15-2535/01	Metal Trial Centralizer, set of 3 pieces (2 sets included)	
		Impactor for femoral components:	
10	15-2537	small / medium	
11	15-2537/02	large	
12	130-120	Bone Hook, 210 mm	
		Impactor for tibial components:	
13	15-2538	small / medium	
14	15-2538/02	large	
15	15-8035	Introducer for tibial plateaus with anti-luxation device	



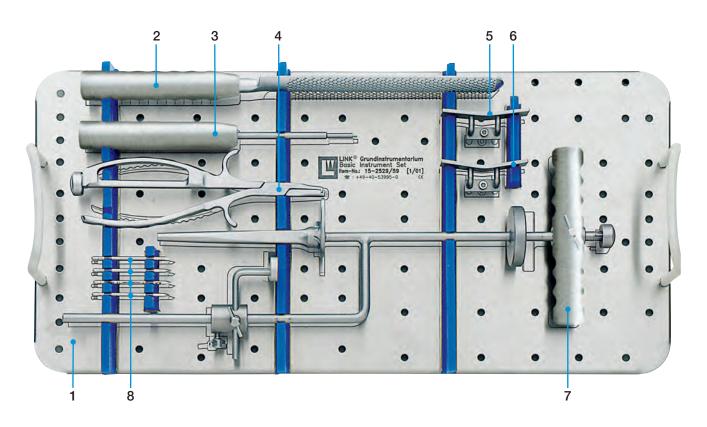


1	15-2529/58	Upper Instrument Tray with product illustrations, empty, 550 x 265 x 50 mm
2	15-2533/04	Tibia Reamer, small
3	322-145	Screwdriver, 210 mm
4	15-2600	Bone Awl, 260 mm
5	335-182E	Twist Drill, 160 mm, Ø 8 mm, * fittings optional
		Ball reamers 250 mm, * fittings optional
6	15-1133/02E	Ø 10 mm
7	15-1133/03E	Ø 12 mm
8	15-1133/04E	Ø 14 mm
9	15-1133/05E	Ø 16 mm
10	15-1133/06E	Ø 18 mm
11	15-2542	Femur Rasp
12	15-1037	Raspatory
13	15-2533/05	Tibia Reamer medium and large

* Fittings:



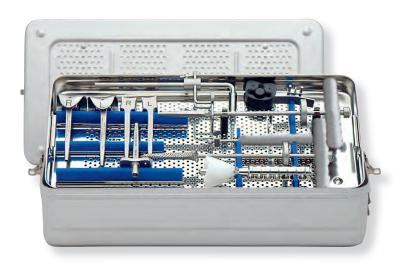




1	15-2529/59	Instrument Tray with product illustrations, empty, 550 x 265 x 50 mm
2	15-2622	Rasp, 350 mm
3	175-600	Hex Screwdriver, 230 mm, hex 3 mm
4	317-586	Driver and Extraction Forceps, for fixation pins, 210 mm
		Patella Glide Resection Guides, for femoral components:
5	15-2530/01	small / medium
6	15-2530/05	large
7	15-2536/10	Tibial Saw Guide, with alignment rod
8	317-585/65	Fixation Pins, Ø 3 mm, 65 mm (4 each included)



Complementary Instrument Set for Rotational Knee Prostheses Endo-Model – Size "x-small"



REF	for implants size: x-small
15-2529/65	Set, complete, in 1 standard container, on 1 tray with storage racks
05-2001/03	N11 Standard Container, only, 575 x 275 x 100 mm
15-2529/66	Tray, empty, stainless steel, 550 x 265 x 50 mm
15-8035/01	Introducer for tibial plateau x-small, with anti-luxation device
15-2536/09	Tibial Saw Guide with alignment rod, x-small
15-2534/94	Tibial Trial Prosthesis, x-small
15-2515/00	Tibial Trial Spacers, x-small, set of 3 ea.
	Femoral Saw Guides with swivel axes,
15-2532/29	right, x-small
15-2532/30	left, x-small
15-2530/00	Patella Glide Resection Guide for femoral components x-small
15-2537/03	Impactor for femoral components x-small
15-2533/03	Tibia Reamer with handle, x-small
	Femoral Trials with patella flange:
15-2534/03	right, x-small
15-2534/04	left, x-small



Complementary Instrument Set for Rotational Knee Prosthesis Endo-Model – Trial Prostheses

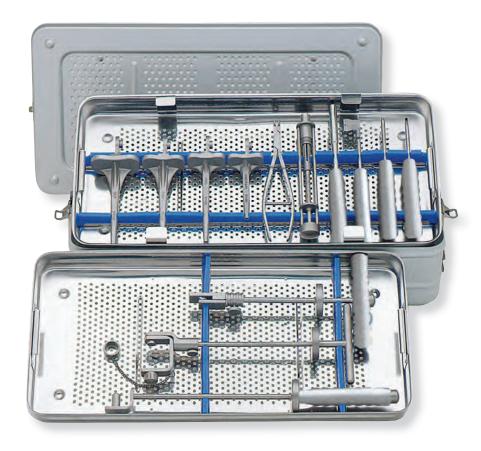


REF	with Trial Prostheses
15-2529/85	Set with patella flange, complete, in 1 standard container on 1 tray with storage racks
05-2002/03	N21 Standard Container, only, 575 x 275 x 130 mm
15-2529/81	Tray, empty, stainless steel, 550 x 265 x 50 mm
	Femoral Trials* with patella flange
15-2534/07	right, small
15-2534/08	left, small
15-2534/19	right, medium
15-2534/20	left, medium
15-2534/25	right, large
15-2534/26	left, large
	Tibial Trials*
15-2534/95	small
15-2534/96	medium
15-2534/97	large
	Tibial Trial Spacers, set of 3 ea.
15-2515/01	small
15-2515/02	medium
15-2515/03	large

^{*} Instruments for implant size "x-small" see page 20.



Complementary Instrument Set for Total Hinge Knee Prostheses Endo-Model



For the implantation of an Endo-Model Total Hinge Knee the basic instrument set for the Endo-Model Rotational Knee System (Item. no. 15-2529/50) is required.

REF	Basic Instrument Set, complete
15-2589/11	Set, complete, in 1 standard container, on 2 trays with storage racks
05-2002/03	N21 Standard Container, only, 575 x 275 x 130 mm





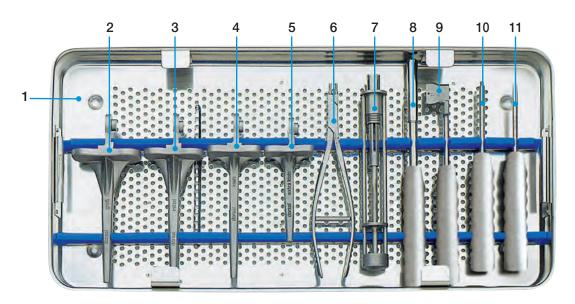




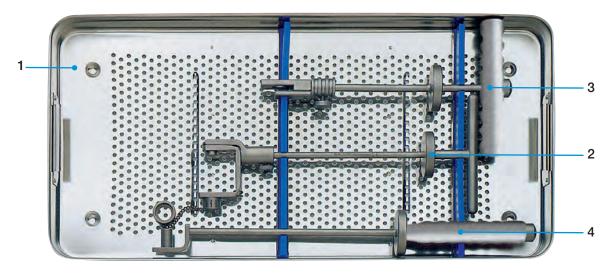








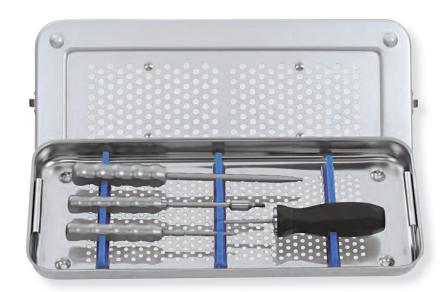
1	15-2589/04	Lower Tray, empty, 550 x 265 x 50 mm
		Tibial Trials
2	15-2587/31	large
3	15-2587/32	medium
4	15-2587/33	small
5	15-2587/34	x-small
6	15-2042	Inserting Forceps, 215 mm
7	15-2582/05E	Trephine for axle hole, * fittings optional
8	15-2596	Trial Axle, 250 mm
9	15-2587/40	Coupling Jig for femoral component and tibial trials, all sizes, 250 mm
10	15-2540	Threaded Rod, 210 mm
11	15-2550	Screwdriver, 210 mm



1	15-2589/06	Upper Tray, empty, 550 x 265 x 50 mm
2	15-2581	Introducer and Drill Guide for femoral components
3	15-2588/01	Inserter for tibial trials, all sizes
3	15-2586	Inserter, 420 mm



Additional Instrument Set V02 for Rotational Knee Prostheses Endo-Model (Monobloc) and Endo-Model – M (Modular)



REF	for Rotational Knee Prostheses Endo-Model and Endo-Model – M (with V02 coupling mechanism)	
15-2529/90	Set, complete, in 1 small container K1, on 1 tray with storage racks	
05-1000/01	Small Container K1, only, 460 x 190 x 92 mm	
15-2529/91	Tray, empty, 405 x 165 x 50 mm	
64-8008/02	Hex Screwdriver with metal handle, wrench size 3.5 mm, 250 mm	
15-2544	Separate Rod for removal of the rotating bushing version V02, Ø M5, 210 mm	
10-5373/01	Hex Screwdriver with metal handle, wrench size 2.5 mm, 180 mm	
15-2545	Torque Wrench, wrench size 2.5 mm, 205 mm	



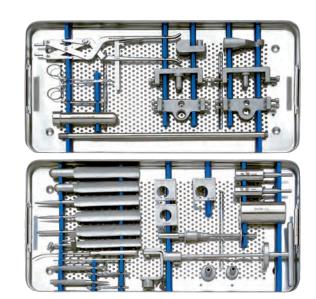
Special Instrument Set for Rotational Bushing Replacement

T-axis (cross) without removal of implants

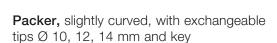
In case of a damaged joint mechanism of an implanted prosthesis or in case of joint instability provided that the implant components are well fixed, the Total Knee System offers the following solutions:

- exchange of the bushing of a Rotational Knee Prosthesis
- complete exchange of the T-axis (cross joint), if a
 Rotational Knee with an anti-luxation device or a
 Hinge Knee is indicated. In the latter case, the tibial
 components must be replaced, however.
- exchange of the axis or the polyethylene bearings in a Hinge Knee Prosthesis.

More information about exchange of bushing and the special instrument set available on request.







REF	
15-2543/01	Set consisiting of:
15-2543/02	Handle, 370 mm
15-2543/03	Tip Ø 10 mm
15-2543/04	Tip Ø 12 mm
15-2543/05	Tip Ø 14 mm
15-2543/06	Key 8/9 mm



Intramedullary Plugs, UHMWPE

REF	Ø
109-130/08	8 mm
109-130/09	9 mm
109-130/10	10 mm
109-130/11	11 mm
109-130/12	12 mm
109-130/13	13 mm
109-130/14	14 mm
109-130/15	15 mm
109-130/16	16 mm
109-130/17	17 mm
109-130/18	18 mm
109-130/19	19 mm
109-130/20	20 mm



131-250/26

Inserter for intramedullary plugs, graduaded, 355 mm (2 pieces)

131-250/23

T-handle for inserter, 70 mm

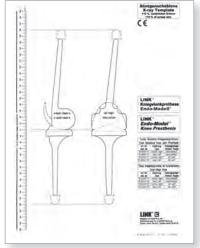


15-2599/01

X-ray Templates for Endo-Model® Total Knee Prosthesis (rotational and hinge version)

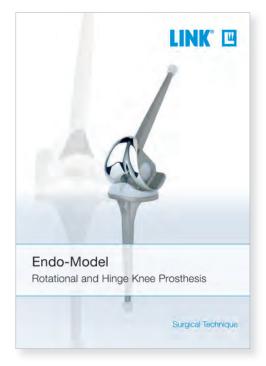
110% actual size,

1 set of: x-small, small, medium, large









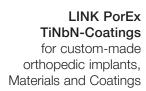
Endo-Model Rotational and Hinge Knee Prosthesis, Surgical Technique



Product Rationale & Teaserflyer



Endo-Model Knee System Literature Research









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Important Information



Please note the following regarding the use of our implants:

1. Choosing the right implant is very important.

The size and shape of the human bone determines the size and shape of the implant and also limits the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. Correct handling of the implant is very important.

Under no circumstances should the shape of a finished implant be altered, as this shortens its life span. Our implants must not be combined with implants from other manufacturers. The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. Implants must not be reused.

Implants are supplied sterile and are intended for single use only. Used implants must not be used again.

4. After-treatment is also very important.

The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. Unless otherwise indicated, implants are supplied in sterile packaging.

Note the following conditions for storage of packaged implants:

- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the "Use by" date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The "Use by" date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. Traceability is important.

Please use the documentation stickers provided to ensure traceability.

7. Further information on the material composition is available on request from the manufacturer.

Follow the instructions for use!

Waldemar Link GmbH & Co. KG, Hamburg

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