LINK®

Endo-Model®

Rotational and Hinge Knee Prosthesis

Implants & Instruments

LINK®

Presented by:

CE 0123

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Endo-Model®

Rotational and Hinge Knee Prosthesis

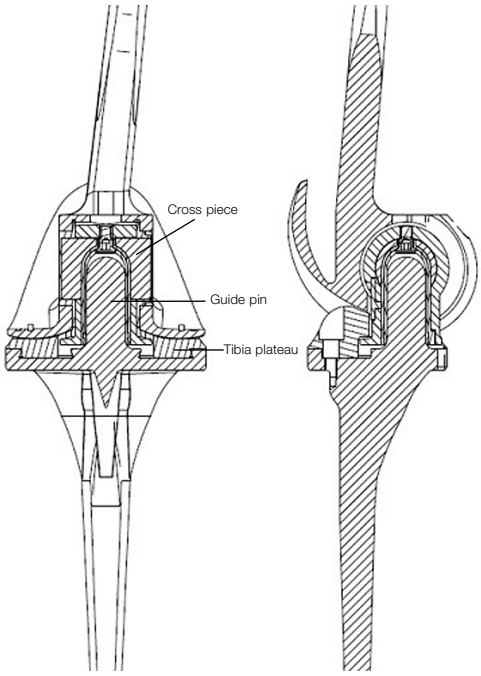
Rotational Knee Joint Prosthesis Endo-Model®

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

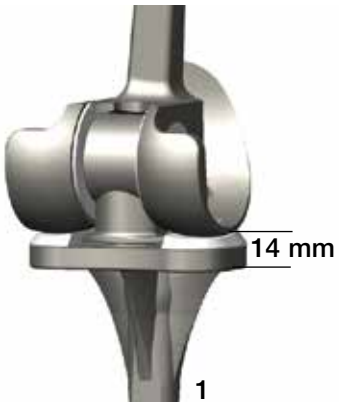
Retaining the low friction principle, the physiological movement of the rotational knee prosthesis is optimal because the pivot point is within the physiological area. Flexion and rotation of the rotational knee prosthesis take place in a cross joint.



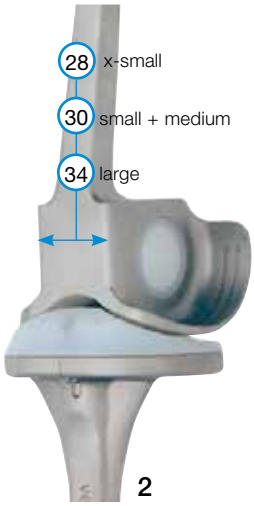
Over-extension amounts to 3°. The Endo-Model® Rotational Knee Prosthesis allows flexion of up to 165°. In addition, the kinematics of this design provide physiological rotation, with elastic transmission of forces enabled by the special shape of the tibial running surface.

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 life-span 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.



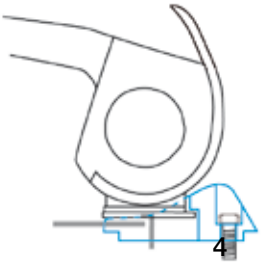
1



2


3

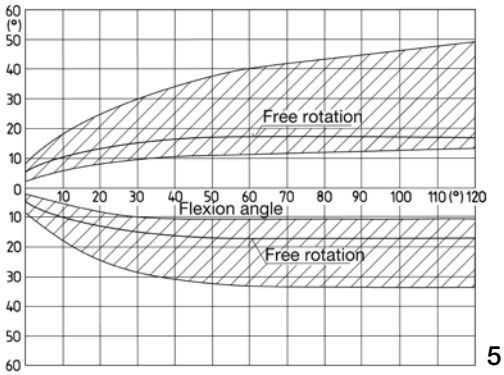
The dimensions and shape of the rotational knee prosthesis allow a good overview of the operative field. The femoral and tibial components are assembled by simply pushing the femoral tube over the tibial pin (**3**). The prostheses feature an anti-dislocation device (**4**). Implantation is simple with just a few easy-to-use instruments.


4

Rotational Knee Joint Prosthesis Endo-Model®

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**).



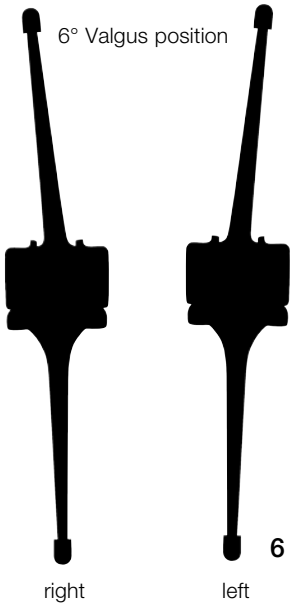
5

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**).



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**).

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.

8

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.

9

Rotational Knee Joint Prosthesis Endo-Model® with PorEx® Modification

PorEx® (TiNbN = Titanium Niobium Nitride)
Surface Modification
The hypoallergenic 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. [1]

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

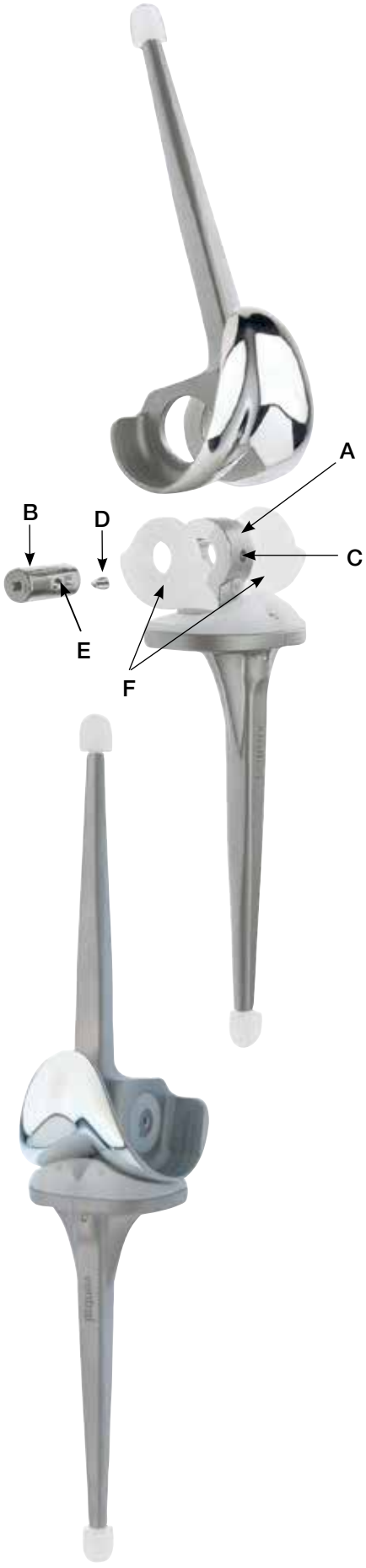
Comment:
Specified indikations/contraindications see catalogue:
711_Endo-Model® Rotational and Hinge Knee Prostheses, Surgical Technique

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

Item no.	CoCrMo alloy	(R) Radius*
15-8020/11	x-small / right	17 mm
15-8020/12	x-small / left	
15-8022/11	small / right	20 mm
15-8022/12	small / left	
15-8024/11	medium / right	23 mm
15-8024/12	medium / left	
15-8030/11	large / right	25 mm
15-8030/12	large / left	

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

Version V02
- New coupling mechanism
- Centralizers are not included in prosthesis packing
- Tibial plateau anchoring screw and trial screw with hexagon socket size 3.5 mm

Required: Additional Instrument Set V02, see page 24.

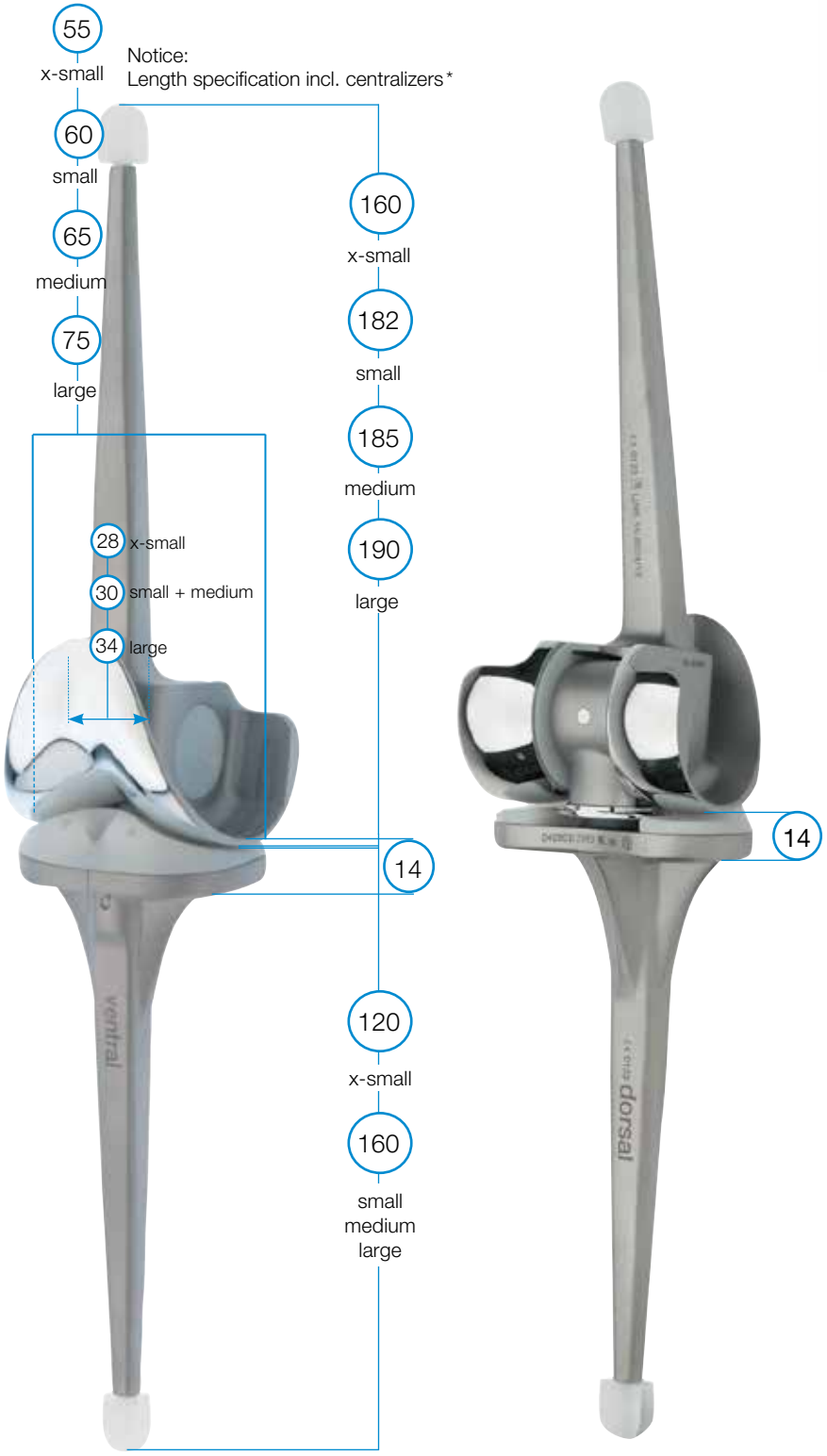
Replacement Set for version V02, with anti-luxation device

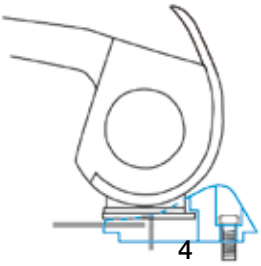
Item no.	Side	Size
15-0027/10	right/left	x-small
15-0027/11	right/left	small
15-0027/12	right/left	medium
15-0027/13	right/left	large

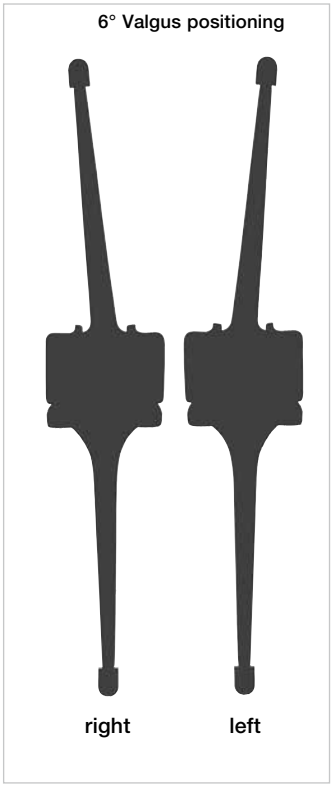
Version V02
Each package contains:
- complete coupling mechanism,
- Bearing boxes,
- PE plateau and PE plateau anchoring screw.

Further replacement sets available on request.

Required: Instrument Set for rotational bushing replacement, incl. additional Instrument Set V02, see pages 24 and 25.





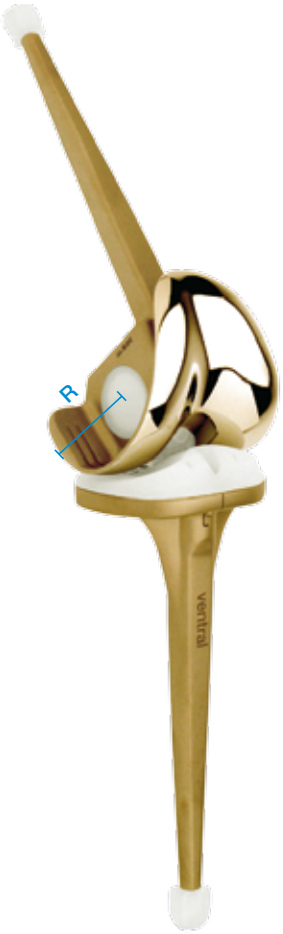


* Centralizers are not included in prosthesis packing

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

Item no.	CoCrMo/PorEx®*	(R) Radius**
15-9020/11	x-small / right	17 mm
15-9020/12	x-small / left	
15-9022/11	small / right	20 mm
15-9022/12	small / left	
15-9024/11	medium / right	23 mm
15-9024/12	medium / left	
15-9030/11	large / right	25 mm
15-9030/12	large / left	

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



Same dimensions as models with anti-luxation device, see page 08 and 09.

Replacement Set, with anti-luxation device

Item no.	CoCrMo/PorEx®*
15-3027/10	x-small
15-3027/11	small
15-3027/12	medium
15-3027/13	large

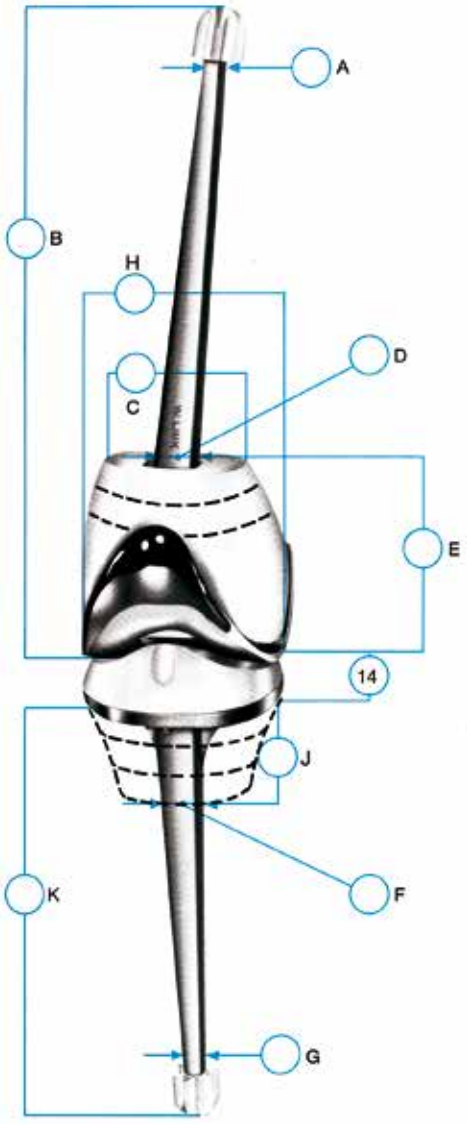
* PorEx®: TiNbN = Titanium Niobium Nitride; hypoallergenic coating (gold colour).

Rotational Knee Joint Prosthesis Endo-Model®,
with replacement of distal femoral and/or proximal tibia bone stock

Custom-made to individual specification:

Dimensional specifications according to illustrations A - K or X-ray images with indication of film/focal distance (information on request).

CoCrMo alloy
Distal femur replacement right left
Proximal tibia replacement right left
Distal femur and proximal tibia replacement right left



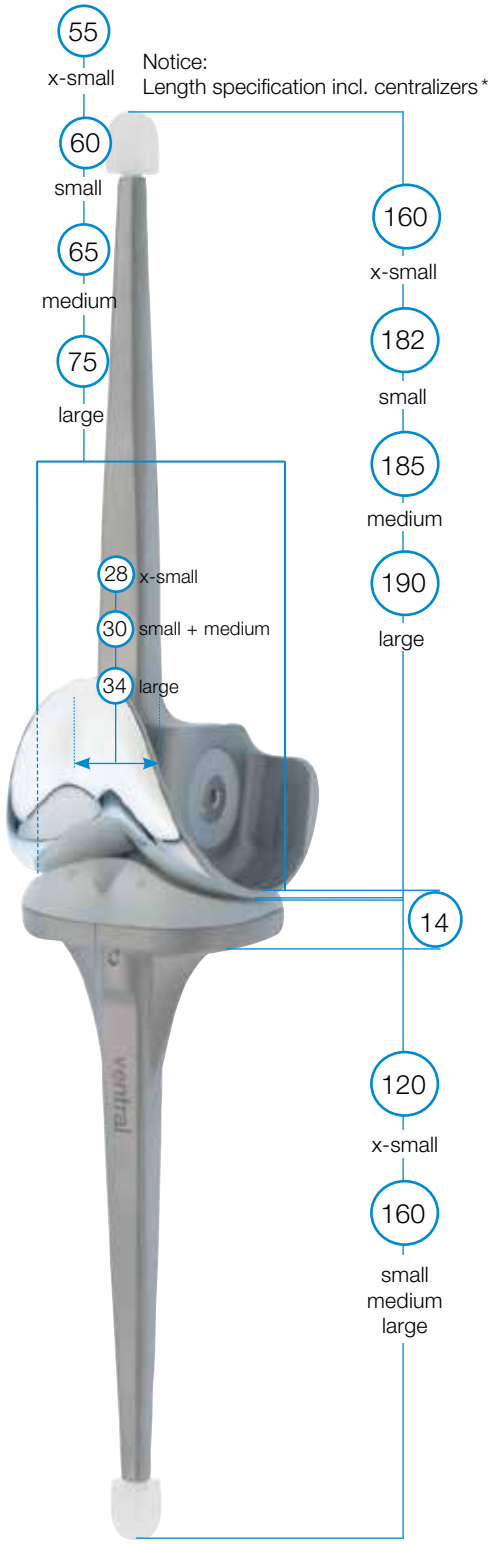
Hinge Knee Joint Prosthesis Endo-Model®, with hinge axis

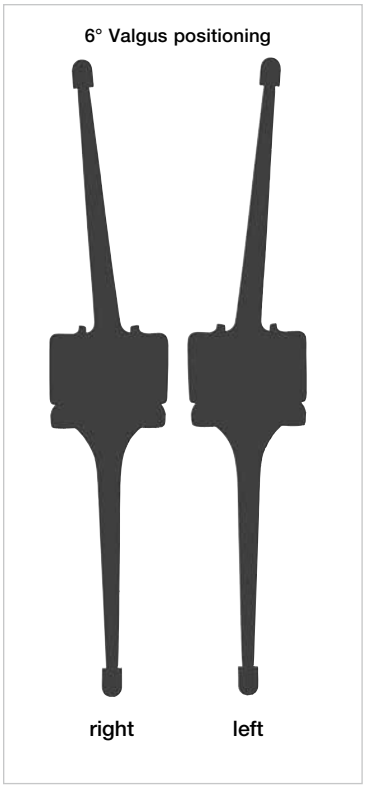
Item no.	CoCrMo alloy	(R) Radius*
15-2459/11	x-small / right	17 mm
15-2459/12	x-small / left	
15-2460/11	small / right	20 mm
15-2460/12	small / left	
15-2461/11	medium / right	23 mm
15-2461/12	medium / left	
15-2462/11	large / right	25 mm
15-2462/12	large / left	

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

Version V02:
- Centralizers are not included in prosthesis packing
- Tibial plateau anchoring screw and trial screw with hexagon socket size 3.5 mm

Required: Additional Instrument Set V02, see page 24.





* Centralizers are not included in prosthesis packing

Patella Components, centric*

Item no.	UHMW Polyethylene	Ø
15-2521/30	small	30 mm
15-2521/35	medium	35 mm
15-2521/40	large	40 mm

* Information on instruments and surgical technique available on request.

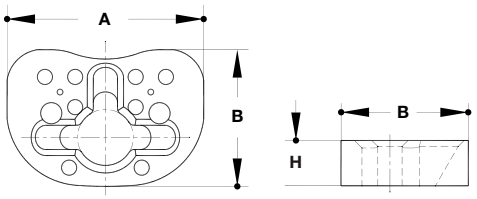
Centralizers*

Item no.	UHMW Polyethylene
15-2975/01	Set consisting of:
15-2975/12 15-2975/14 15-2975/16	small medium large

Ø 12 mm Ø 14 mm Ø 16 mm

* not included in prosthesis packing.

Proximal Tibial Spacers*



Item no.	UHMW Polyethylene	H	A	B
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!

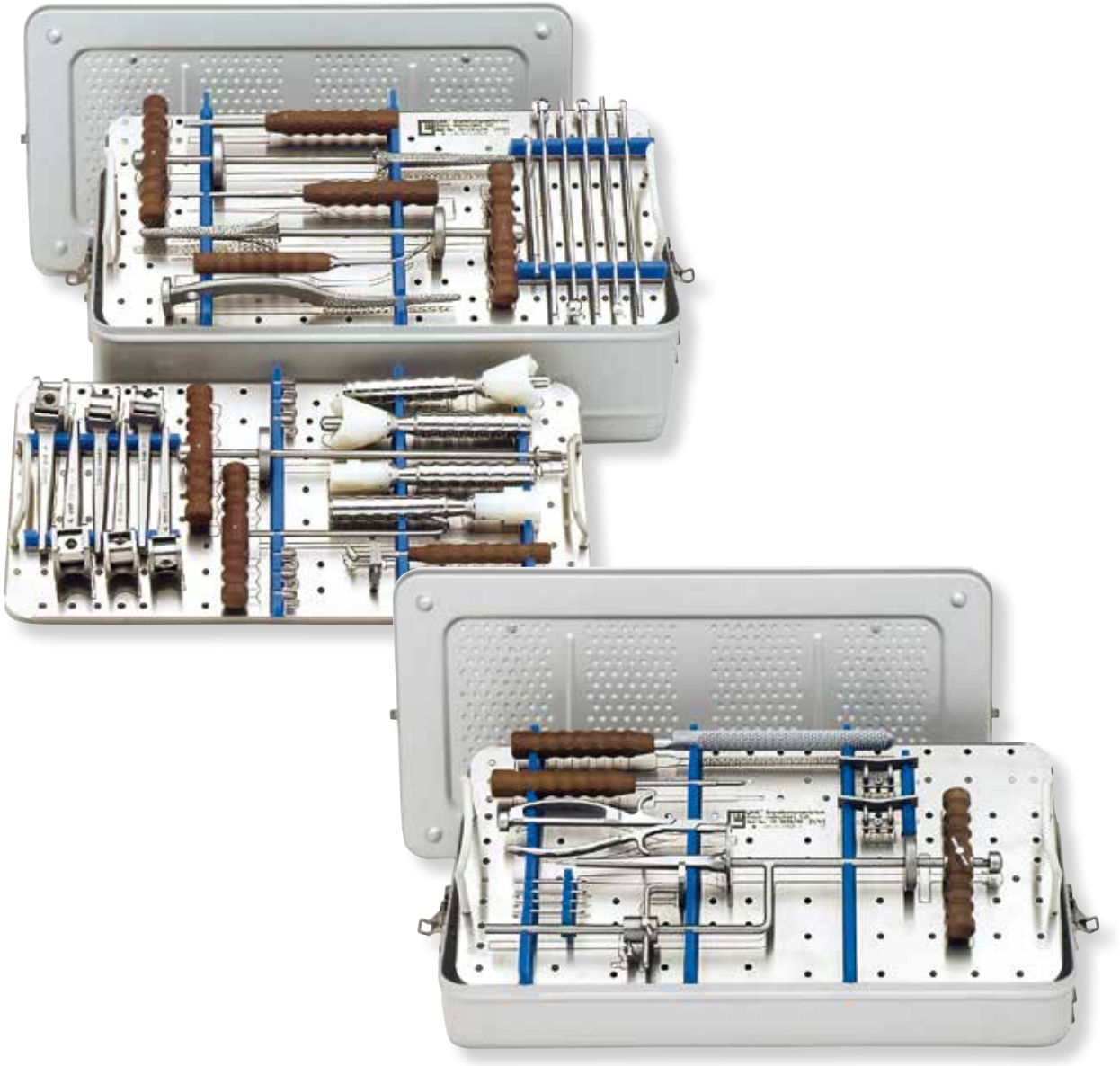
Total Femur Replacement Endo-Model®

The modular Total Femur Replacement is manufactured on basis of the remaining bone stock and patient-related measurements. For this purpose special forms are available for the surgeon to enter the measurements and the patient's name.

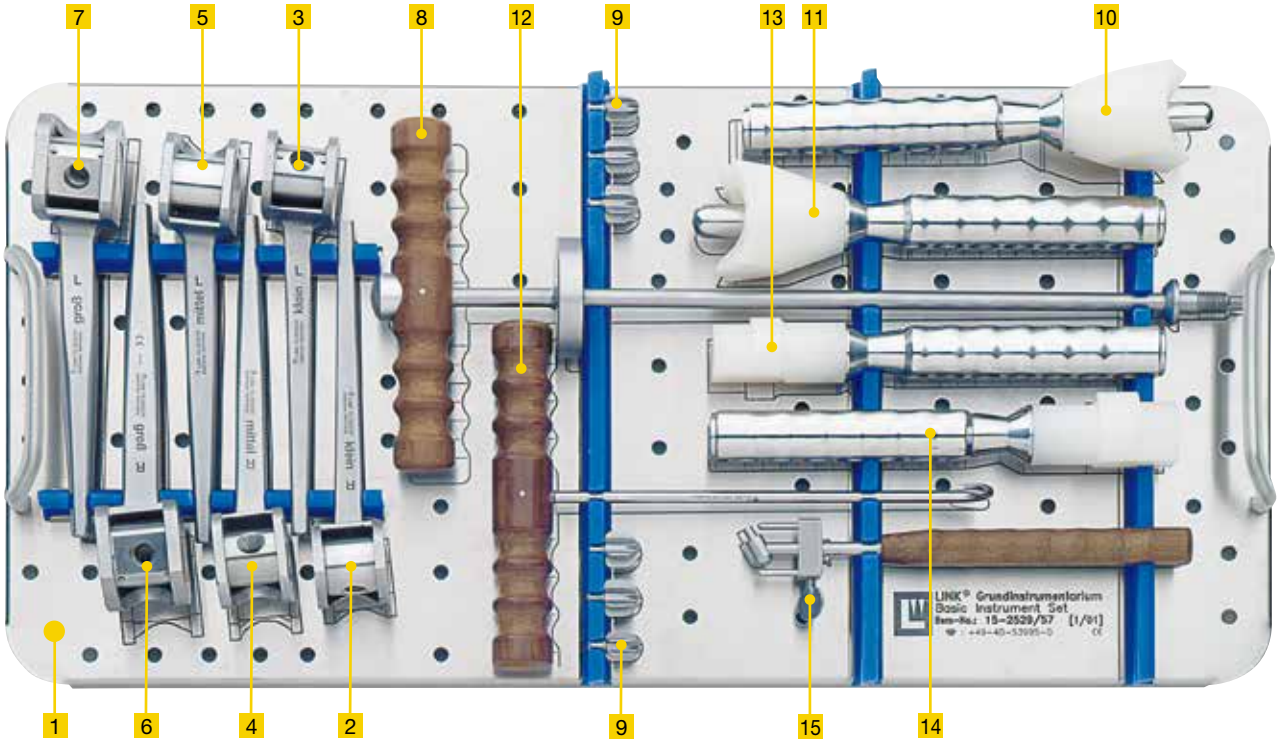
The knee section features a Rotational or Hinge Knee Prosthesis with or without patellar flange. The solid connection to the hip joint is provided by a push-through stem. The neck component with taper is mounted on the push-through stem and allows the use of femoral heads or – in case of loss of the acetabulum – of a saddle.

Further information available on request.

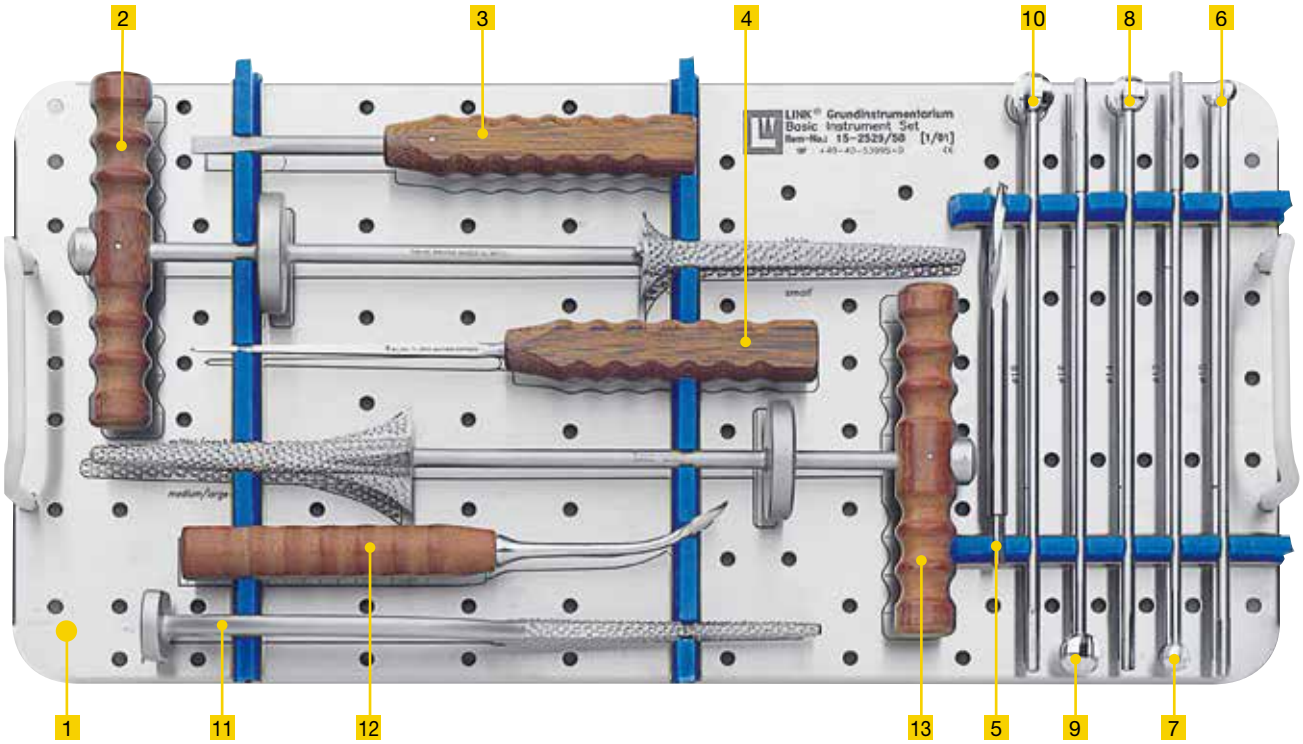
Basic Instrument Set
for Rotational Knee Prosthesis Endo-Model®



Item no.	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

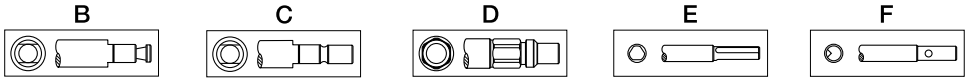


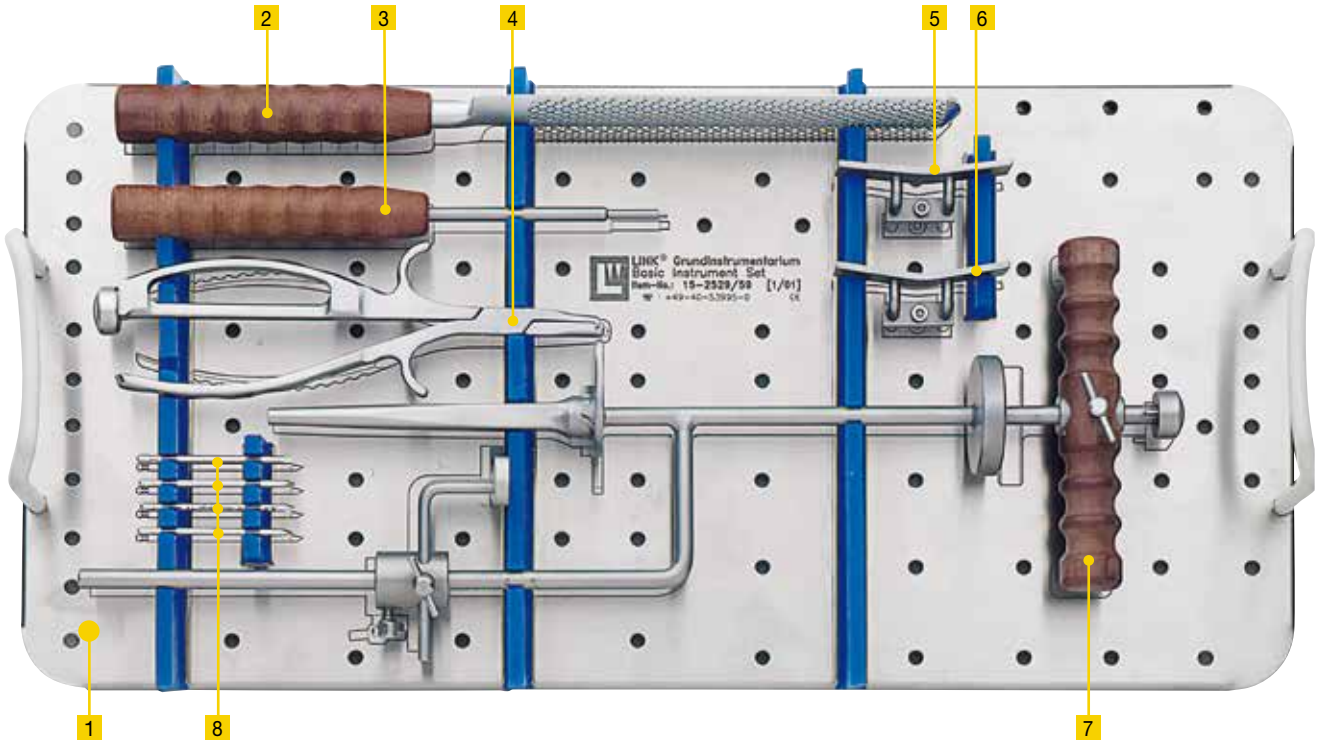
1	15-2529/57	**Lower Instrument Tray** with product illustrations, empty, 550 x 265 x 50 mm	
		Femoral Saw Guides with swivel axes	
2	15-2532/31	right	small
3	15-2532/32	left	small
4	15-2532/41	right	medium
5	15-2532/42	left	medium
6	15-2532/51	right	large
7	15-2532/52	left	large
8	15-2534/15	**Threaded 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 Prosthesis Endo-Model® – Size „x-small“

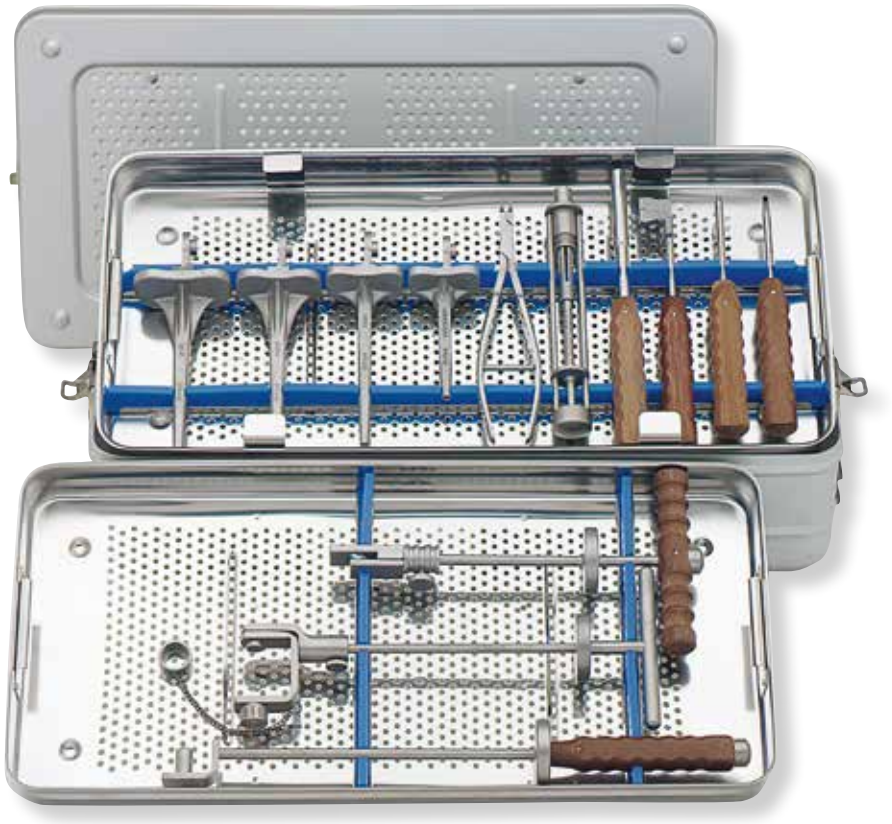
Item no.	for implants size: x-small
15-2529/65	**Set,** complete, in 1 standard container, on 1 tray with storage racks
05-2001/03	**N11 Standard Container,** only, 575 x 275 x 100 mm
15-2529/66	**Tray,** empty, stainless steel, 550 x 265 x 50 mm
15-8035/01	**Introducer** for tibial plateau x-small, 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.
15-2532/29 15-2532/30	**Femoral Saw Guides** with swivel axes, right, x-small 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
15-2534/01 15-2534/02	**Femoral Trials** without patella flange: right, x-small left, x-small
15-2534/03 15-2534/04	**Femoral Trials** with patella flange: right, x-small left, x-small

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

Item no.		with Trial Prostheses
15-2529/80	A	**Set without patella flange,** complete, in 1 standard container on 1 tray with storage racks
15-2529/85	B	**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
	A	**Femoral Trials*** without patella flange
15-2534/05		right, small
15-2534/06		left, small
15-2534/17		right, medium
15-2534/18		left, medium
15-2534/23		right, large
15-2534/24		left, large
	B	**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.

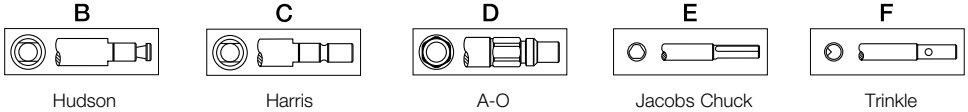
Complementary Instrument Set for Total Hinge Knee Endo-Model®

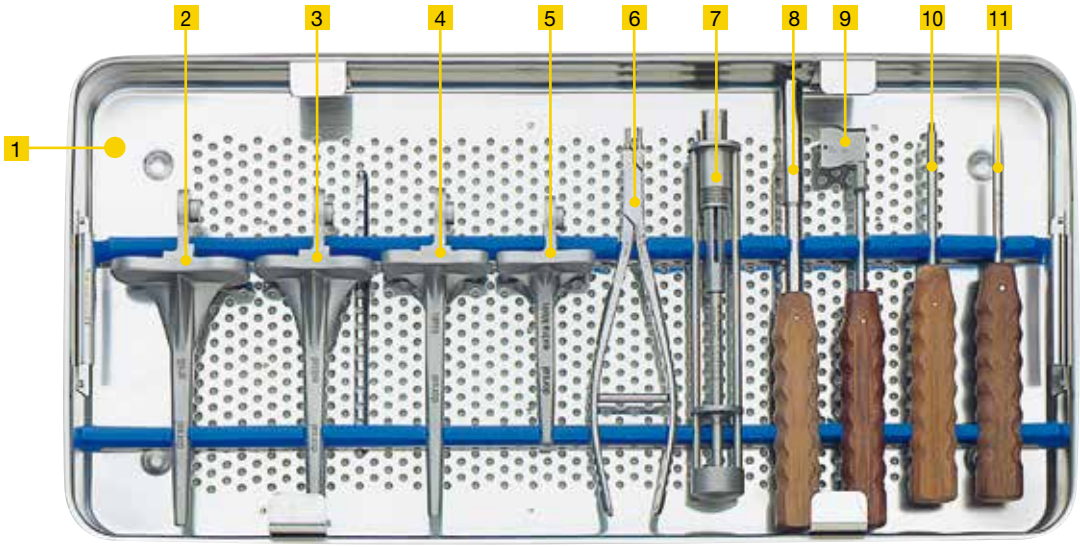


For the implantation of an Endo-Model® Total Hinge Knee the basic instrument set for the Endo-Model® Rotational Knee System (Item. no. 15-2529/50) is required.

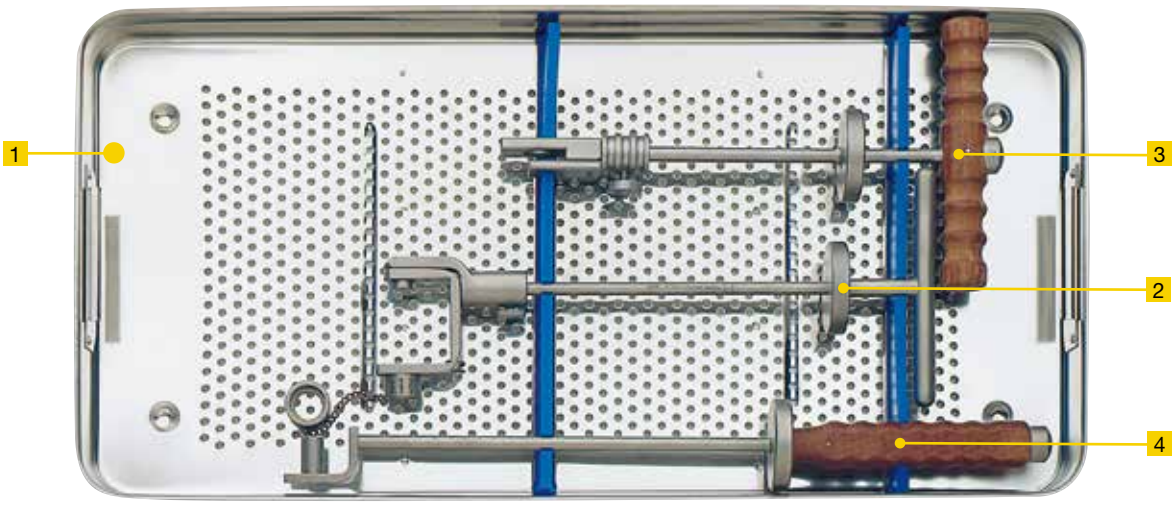
Item no.	Basic Instrument Set, complete
15-2589/11	**Set,** complete, in 1 standard container, on 2 trays with storage racks
05-2002/03	**N21 Standard Container,** only, 575 x 275 x 130 mm

*** Fittings:**





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
4	15-2586	**Inserter,** 420 mm

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

Item no.	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

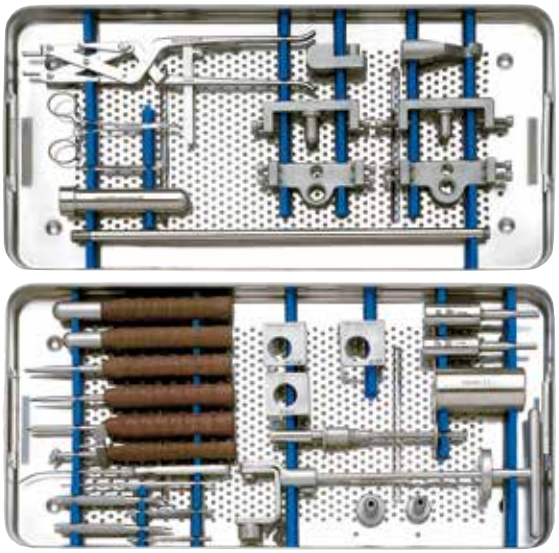
Special Instrument Set for Rotational Bushing Replacement

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:

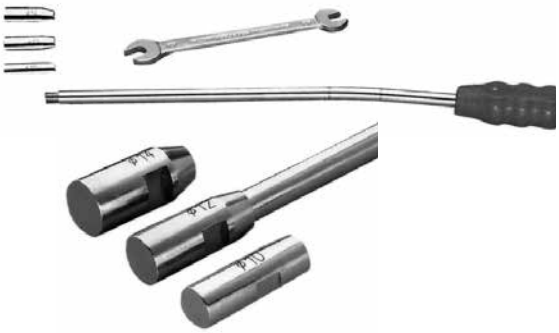
- exchange of the bushing of a Rotational Knee Prosthesis
- complete exchange of the T-axis (cross joint), if a Rotational Knee with an anti-luxation device or a Hinge Knee is indicated. In the latter case, the tibial components must be replaced, however.
- exchange of the axis or the polyethylene bearings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

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



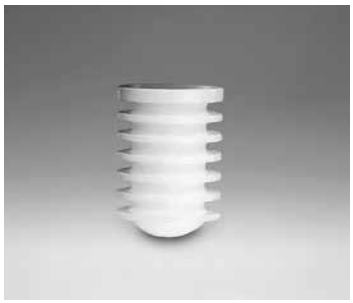
Packer, slightly curved, with exchangeable tips Ø 10, 12, 14 mm and key

Item no.	
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

Item no.	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)

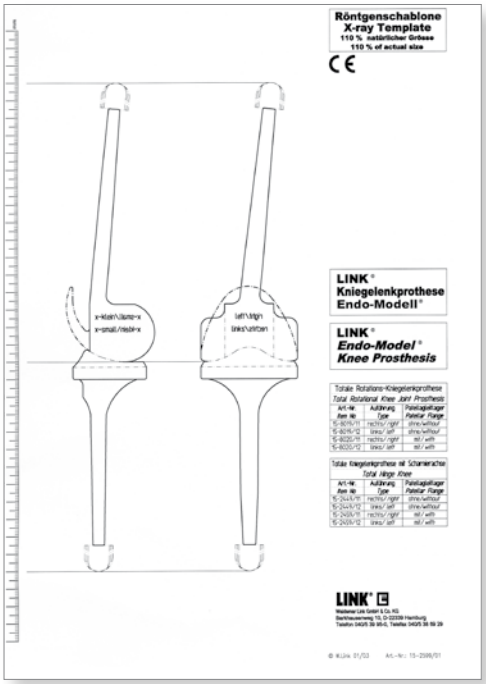
131-250/23
T-handle for inserter, 70 mm

15-2599/01

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

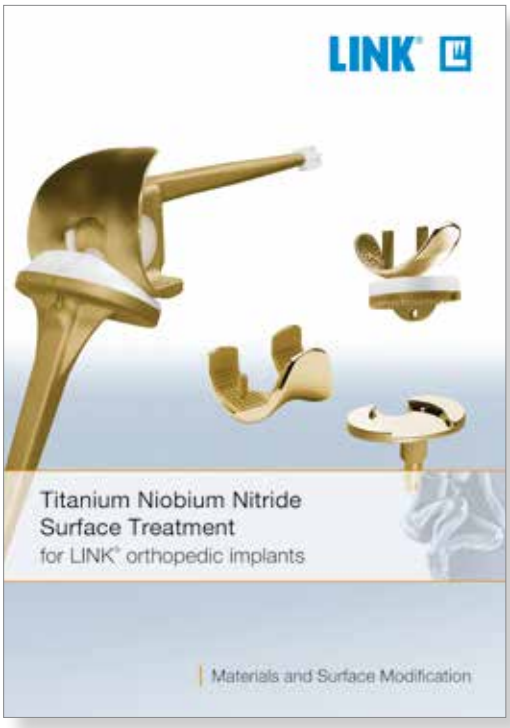
110% actual size,

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



Further Information on
the Surgical Technique of the Endo-Model®
Rotational and Hinge Knee Prosthesis
available on request.

Further information on
TiNbN Surface Modification for metal sensitive patients
available on request.



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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 determine the size and shape of the implant and also limit 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 reused.

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

The Surgical Technique described has been written to the best of our knowledge and belief, but it does not relieve the surgeon of his/her responsibility to duly consider the particularities of each individual case.

Unless otherwise indicated, all instruments are made of surgical stainless steel.

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