




Endo-Model Knee Fusion Nail SK

Modular & Monoblock System

Explanation of Pictograms			
	Manufacturer		Article number
	Material (number)	RX only	Caution: Federal law restricts this device to sale by or on the order of a physician

Endo-Model Knee Fusion Nail SK

Modular & Monoblock System

System Description

- 02 System Overview
- 04 System Description

Implants, modular

- 04 Endo-Model Knee Fusion Nail, modular

Cemented Stems

- 05 Endo-Model-M Stems, modular, cemented

Cementless Stems

- 06 Endo-Model-M Stems, modular, cementless, conical
- 07 Endo-Model-M Stems, modular, cementless, cylindrical

Implants, monoblock

- 08 Endo-Model Knee Fusion Nail, monoblock, cemented

Instruments

- 09 Instrument Set for Endo-Model Knee Fusion Nail

Surgical Technique

- 10 Preoperative Planning, Surgical Technique
- 14 Special Cases

15 **Case History**

Accessories

- 16 X-ray Templates
Instructions for Cleaning and Maintenance
Literature

17 **Indications/Contraindications**

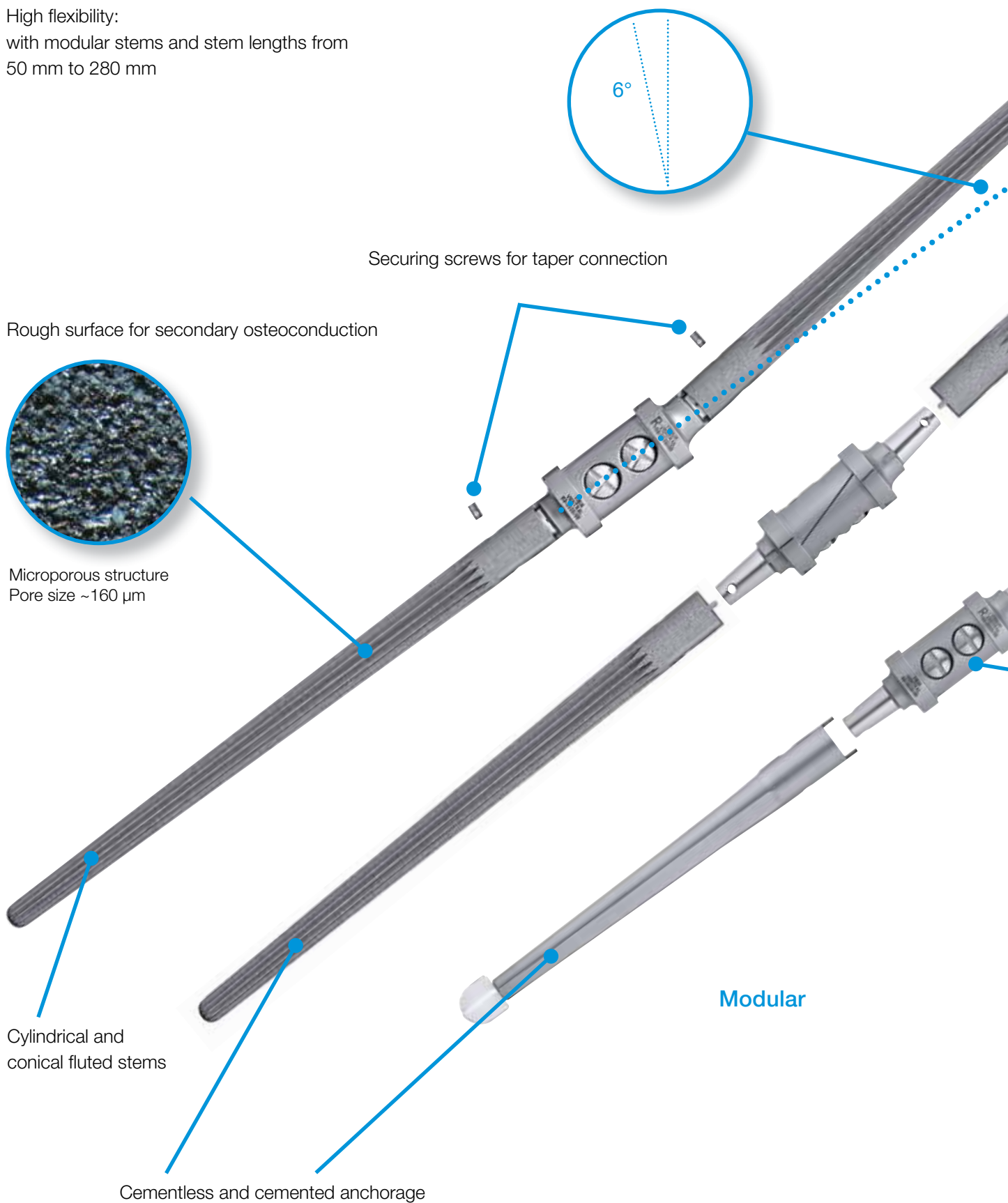
18 **Notes**

Important Information

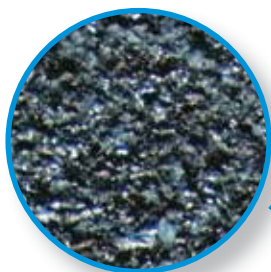
System Overview

Femoral anatomically adapted with 6° valgus

High flexibility:
with modular stems and stem lengths from
50 mm to 280 mm



Rough surface for secondary osteoconduction



Microporous structure
Pore size ~160 μm

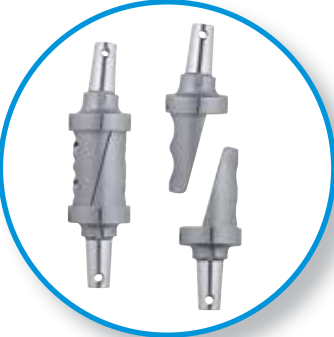
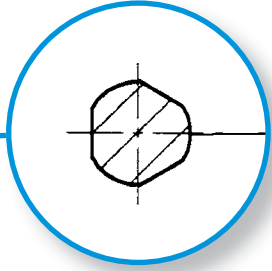
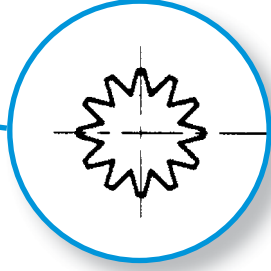
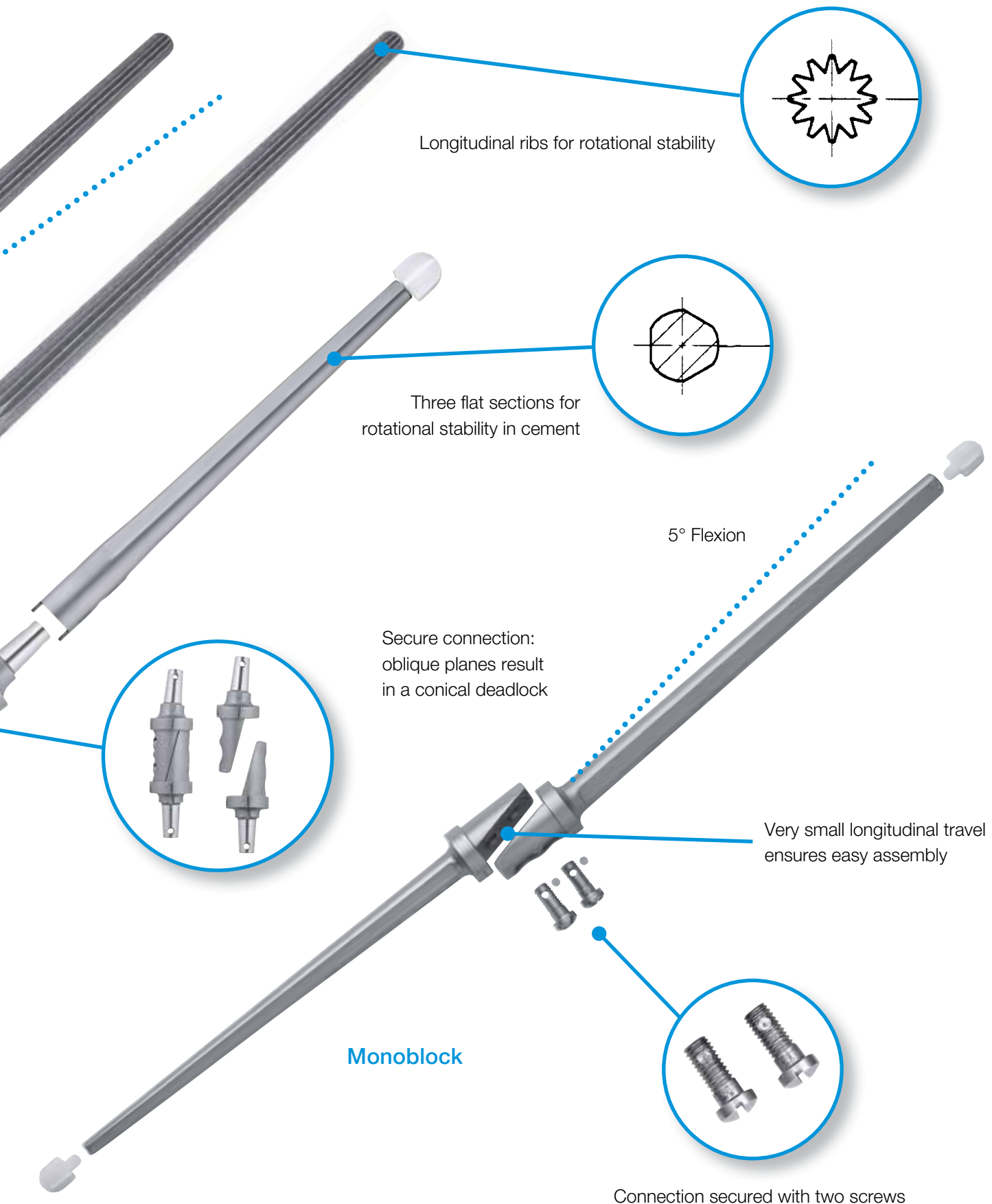
Securing screws for taper connection

6°

Cylindrical and
conical fluted stems

Cementless and cemented anchorage

Modular

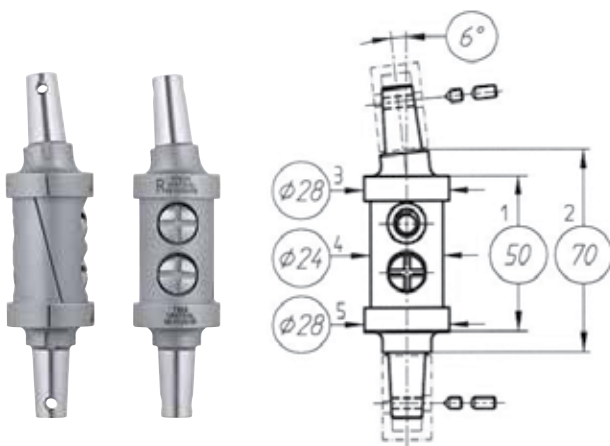


System Description

The Link Endo-Model Fusion Nail unites high flexibility with a maximum of security and ensures a simple and intuitive usage, since its introduction 1978.

Endo-Model Knee Fusion Nail, modular

MAT CoCrMo and UHMWPE



Set

femoral and tibial component, 2 screws, 4 lock bolts

REF (set)	Version
15-0028/08	right
15-0028/07	left

The cemented Fusion Nail is made of EndoDur CoCrMo alloy. The modular interconnection can be combined with every modular stem with female taper from the Endo-Model family allowing both press-fit Tilastan and cemented CoCrMo stems to be used.

The oblique plane and engagement of the components with only a small difference in longitudinal travel (approx. 3 mm) in the ring-shaped pockets create a stable and force-locking connection that is secured with two screws.

The cemented Fusion Nail does not require bony apposition therefore leg length can be flexibly adjusted or restored. The conical stems are triangular in diameter to provide rotational stability in the cement bed. The femoral part of the Knee Fusion Nail is anatomically oriented.

Cementless application must be viewed under the aspect of secure intramedullary anchorage – with or without bone graft.

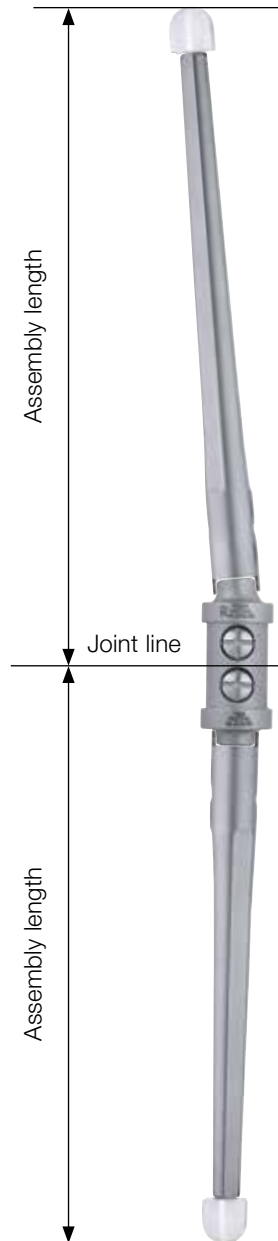
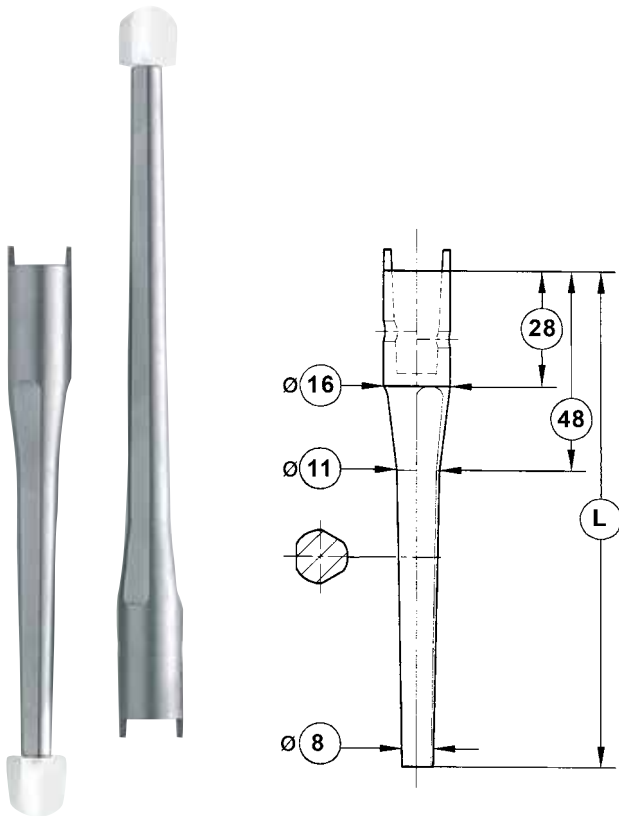
Cemented Stems

Endo-Model-M Stems, modular, cemented

MAT CoCrMo

REF	L mm	Assembly length mm*
15-2950/01	50	100
15-2950/02	80	130
15-2950/03	95	145
15-2950/04	120	170
15-2950/05	135	185
15-2950/06	160	210
15-2950/07	200	250
15-2950/08	240	290
15-2950/09	280	330

* Assembly length until joint line:
L + 35 mm (Fusion Nail) + 15 mm (centering star)



Centralizers

MAT UHMWPE



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

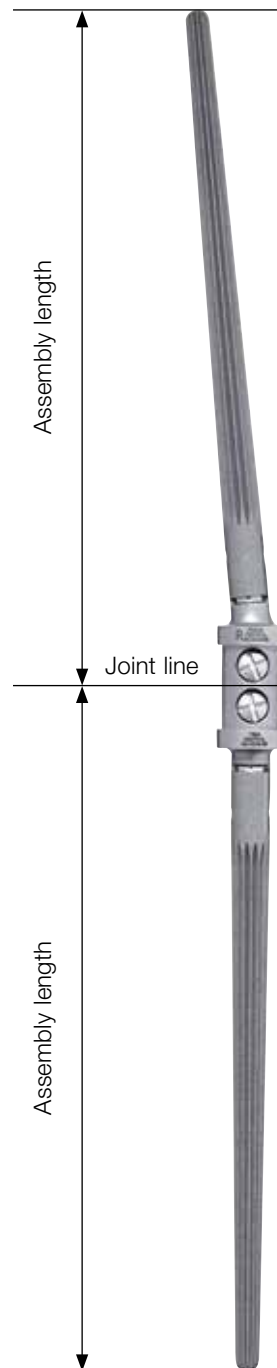
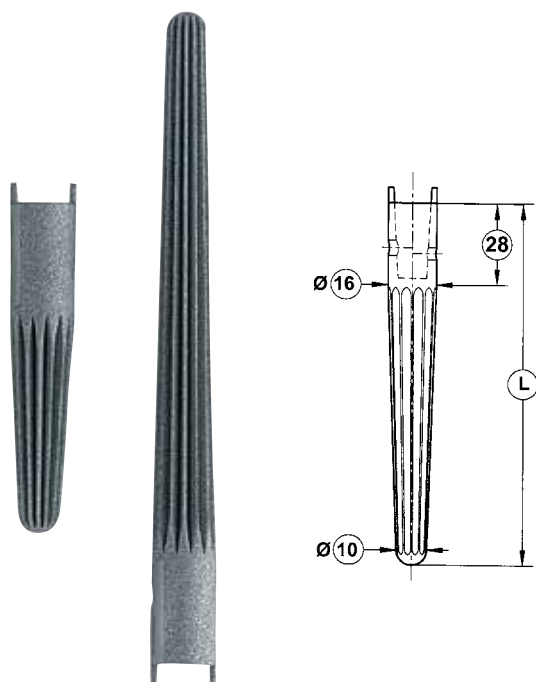
Cementless Stems

Endo-Model-M Stems, modular, cementless, conical

MAT Tilastan

REF	L mm	Assembly length mm*
15-2952/01	50	85
15-2952/02	80	115
15-2952/03	95	130
15-2952/04	120	155
15-2952/05	135	170
15-2952/06	160	195
15-2952/07	200	235
15-2952/08	240	275
15-2952/09	280	315

* Assembly length until joint line:
L + 35 mm (Fusion Nail)

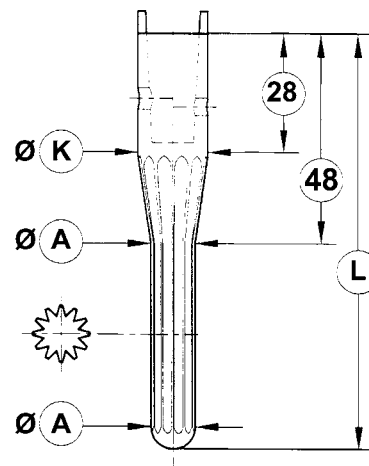


Cementless Stems

Endo-Model-M Stems, modular, cementless, cylindrical

MAT Tilastan

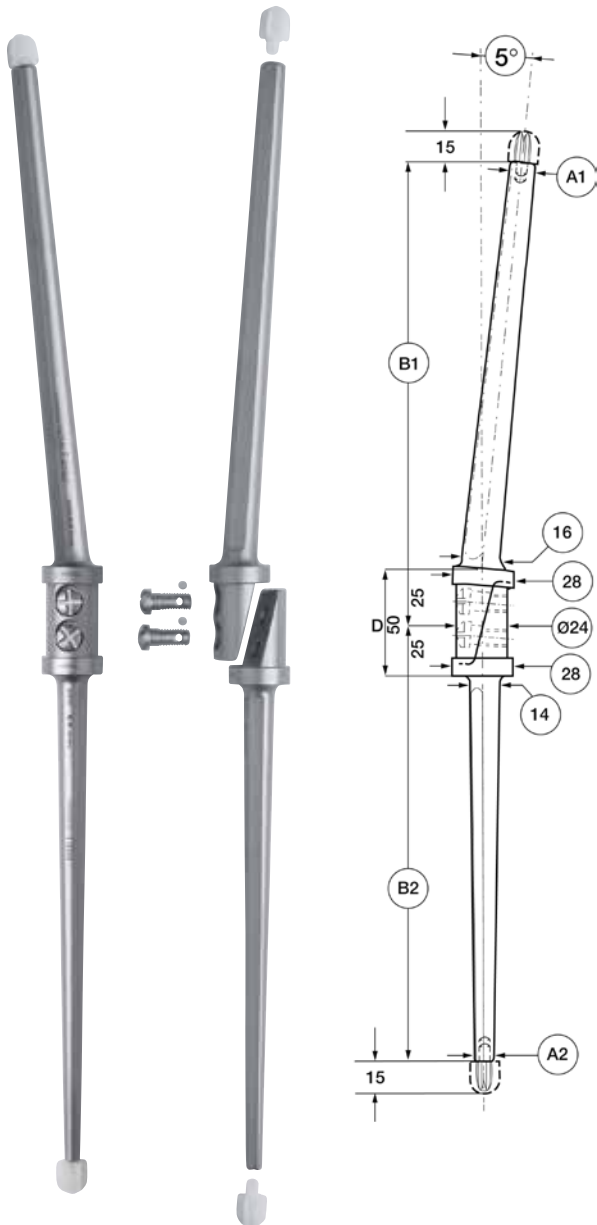
REF	L mm	Ø A mm	Ø K mm	Assembly length mm*
15-2951/01	60	10	16	95
15-2951/02	60	12	16	95
15-2951/03	60	14	16	95
15-2951/04	60	16	16	95
15-2951/05	60	18	18	95
15-2951/06	120	12	16	155
15-2951/07	120	14	16	155
15-2951/08	120	16	16	155
15-2951/09	120	18	18	155
15-2951/10	160	12	16	195
15-2951/11	160	14	16	195
15-2951/12	160	16	16	195
15-2951/13	160	18	18	195
15-2951/14	200	12	16	235
15-2951/15	200	14	16	235
15-2951/16	200	16	16	235
15-2951/17	200	18	18	235
15-2951/18	240	12	16	275
15-2951/19	240	14	16	275
15-2951/20	240	16	16	275
15-2951/21	240	18	18	275
15-2951/22	280	12	16	315
15-2951/23	280	14	16	315
15-2951/24	280	16	16	315
15-2951/25	280	18	16	315



* Assembly length until joint line:
L + 35 mm (Fusion Nail)

Cemented Stems

Endo-Model Knee Fusion Nail, Monoblock, cemented



Femoral components, incl. 1 set of centralizers, Ø 14 mm assembled, **MAT** CoCrMo

REF	Version	Size	Ø A1 mm	Length B1
15-8430/21	right	1	12	180 mm
15-8430/22	right	2	12	220 mm
15-8430/23	right	3	12	260 mm
15-8431/21	left	1	12	180 mm
15-8431/22	left	2	12	220 mm
15-8431/23	left	3	12	260 mm

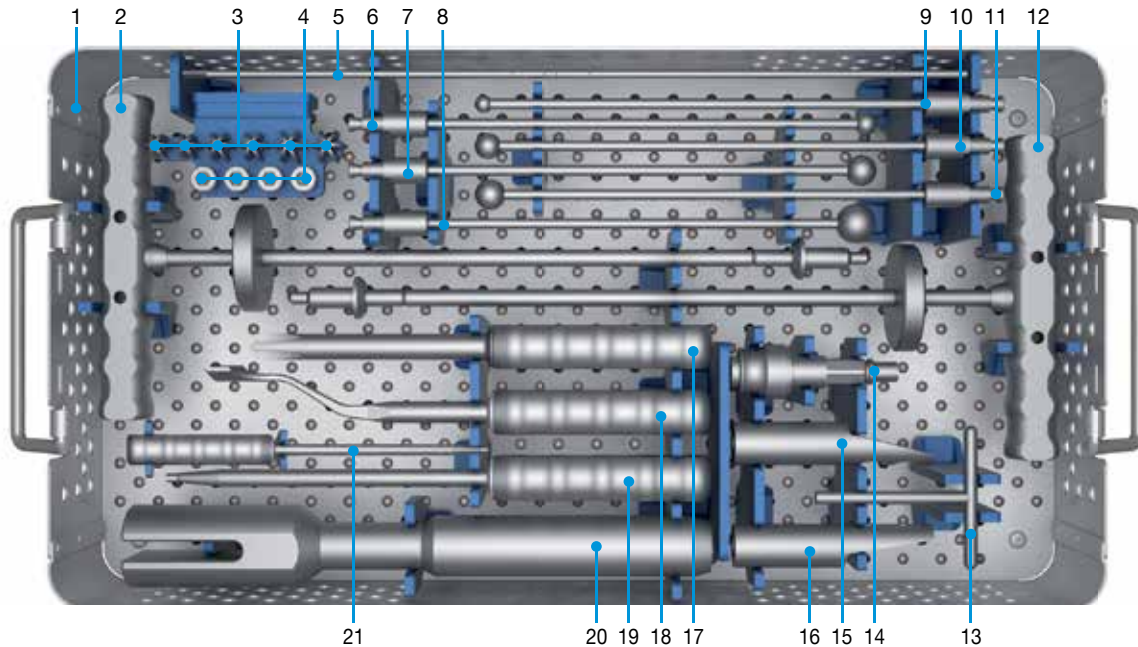
Tibial components,

incl. 1 set of centralizers, set of 2 assembly screws, 4 lock bolts, Ø 14 mm assembled, **MAT** CoCrMo

REF	Version	Size	Ø A2 mm	B2 mm
	right / left			
15-8429/21	X	1	9	170
15-8429/22	X	2	9	210
15-8429/23	X	3	7	250

Instrument Set for Endo-Model Knee Fusion Nail

15-8450/00 Instrument Set, complete



1	15-8450/10	Instrument tray, empty, 550 x 265 x 50 mm
2	15-2534/15	Threaded rod with handle
3	15-2535/01	Trial centralizer, Ø 12, 14, 16 mm, 2 Sets (per Ø 2 pcs.)
4	15-8450/07	Screws, 4 pcs.
5	131-250/26	Inserter
6	15-1133/01B	Ball reamer
7	15-1133/02B	Ball reamer
8	15-1133/03B	Ball reamer
9	15-1133/04B	Ball reamer
10	15-1133/05B	Ball reamer
11	15-1133/06B	Ball reamer
12	15-2534/15	Threaded rod with handle
13	131-250/23	T-Handle
14		Adapter, optional
	16-3283/01	Adapter, Hudson female/Triangular male
	16-3284/00	Adapter, Hudson female/AO male
	16-3286/00	Adapter, Hudson male/Harris female
15	15-8450/14	Insertor-Extractor for tibial components
16	15-8450/03	Insertor-Extractor for femoral components
17	16-3290/00	Cross slot screwdriver
18	15-1040	Chisel n. Lexar
19	64-8008/02	Hex screwdriver, 3.5 mm
20	130-686	Slotted driver
21	64-1181/16	Hex screwdriver, 2 mm

Preoperative Planning

Measurement tables and X-ray templates are available for the preoperative planning of surgery with Endo-Model Fusion Nail which enable the surgeon to plan precisely for the implants that will be used.

True-to-scale radiographs or precise knowledge of the actual magnification factor are the foundation for exact preoperative planning. LINK X-ray templates show the implant illustrations in 110% magnification as standard. If different scales are desired, we will meet these wishes as far as technically possible. We provide data for digital planning on request to providers of digital planning software in the current formats.

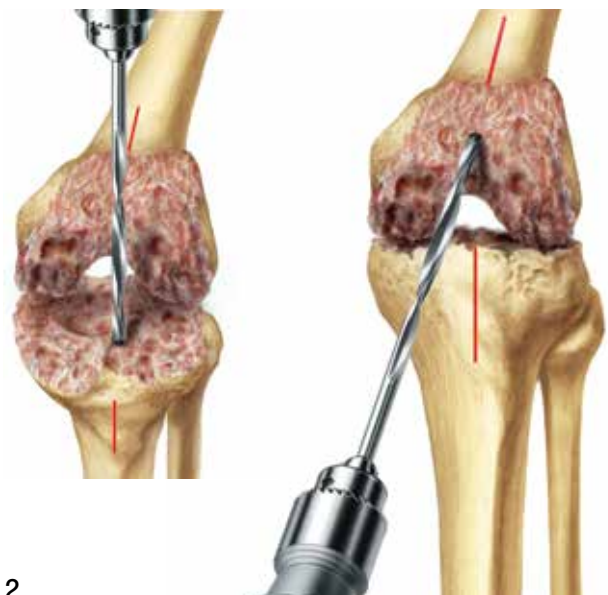
Despite good preoperative planning, unforeseeable extensive bone loss in revision cases often presents a challenge for the surgeon. In those cases, the Endo-Model Fusion Nail demonstrates its ease of use due to its modularity and simplicity.

In contrast to the use of primary knee joint prostheses, management of extensive bone loss depends on the conditions in each individual situation. Structural changes in the muscles and ligaments, fixation conditions etc. increase the operative demands of prostheses. Accordingly, management of extensive bone loss presents particular problems and is therefore subject to greater risk compared with the use of normal joint prostheses.

Surgical Technique



After opening the knee joint, with the leg in extension, opposite areas of the femur and tibia in correct rotational position are marked. This is best achieved using a colored marker pen or by making a notch on the bone using an osteotome or a rongeur (Fig. 1).



After marking the entrance point with a bone awl the femoral and tibial medullary canals are opened with a drill (Fig. 2).



3

Using long ball reamers, tibia and femur are prepared in 1 mm increments (Fig. 4) to receive the nail components. When a cemented stem is used, the diameter of the last used reamer has to be at least 1 mm bigger than the maximum diameter of the stem (table on page 4).

If the medullary canal is wide UHMWPE centralizers of dia. 12, 14 or 16 mm are available to position the nail component in the middle of the canal. When performing the trial implantation, trial metal centralizers should be applied.

The reaming depth of the bone has to be adjusted according to the used stem (see assembly length tables pages 05-07).

If cementless stems are used, the preparation has to be done with the corresponding press-fit reamers from the Endo system.

Both femoral and tibial joint (shaft) surfaces are resected plane-parallel in such a way as to achieve sufficient surface contact of vital bone tissue between femur and tibia (Fig. 3).



4



5

For assembly information and instructions: Please see the catalogue 719 LINK Endo-Model-M; Surgical Technique

The entrance point to accept the central section of the Fusion Nail is enlarged further around the reamed canals in the tibia and femur, using a gouge and/or a reamer. The diameter of these openings corresponds to the size of the flange on the central section of the Fusion Nail (approx. Ø 28 mm). The required depth of these openings in the femur and tibia is 25 mm each. The central section of the nail is thus to be inserted with one half in the femur and the other in the tibia.

The tibial and femoral Inserter-Extractor is connected to the implants with the temporary screws. Insert the implants into the prepared bone. Femur and tibia are then placed in the desired position relative to each other while, at the same time, fitting both components together on a trial basis. After the trial repositioning and before removing the Fusion Nail components, marks are placed on the implants as well as on the bone to determine the position of the implants for the final insertion. The insertion depth is also marked on the implants.

Tip:

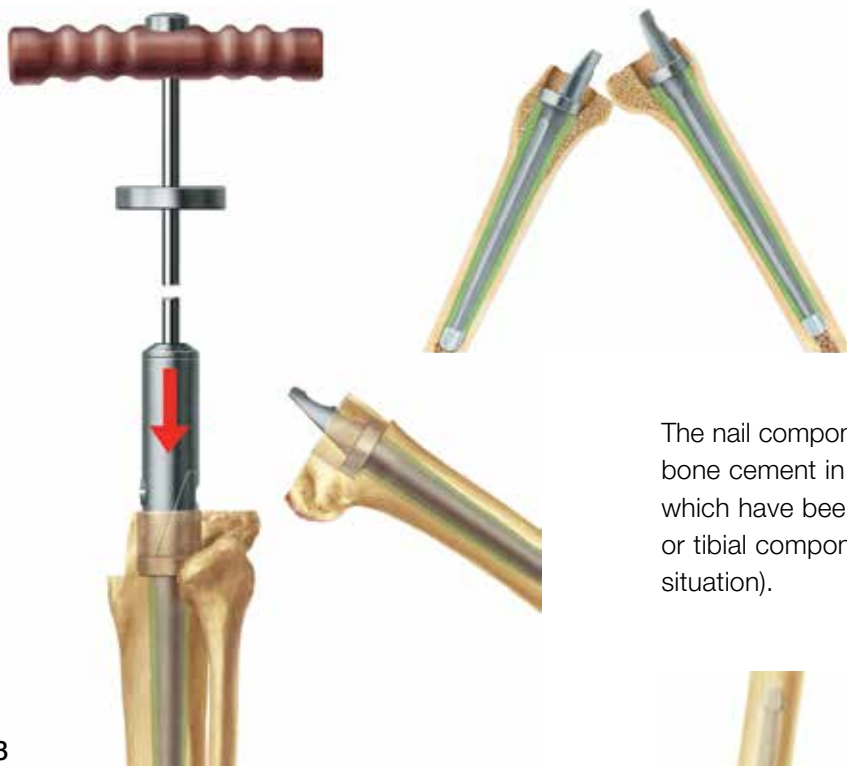
If it should prove difficult to insert either of the components, it may be necessary to enlarge the medullary canal using an intramedullary reamer, a ball reamer or a curette.



Anteriorly, a 30 x 30 mm fenestration in the axial direction has to be prepared with an oscillating saw. This anterior opening is necessary in order to be able to place the assembly screws anteriorly after the nail components have been driven home completely. The resected cortical bone is then used to later close the anterior fenestration.

If femur and tibia cannot be joined together, the remaining gap is bridged only by the Fusion Nail itself or filled in addition with bone graft. The anterior fenestration is not required if the gap measures 50 mm or more or its height has to be reduced according to the smaller distance (see special cases on page 14).





The nail components are inserted into the prepared bone cement in accordance with the markings which have been made on them (whether femoral or tibial component first, depends on the individual situation).

8

After cement hardening, both components of the Fusion Nail are joined together and secured with two assembly screws, with the UHMWPE lock bolts placed in the threaded shaft. If bone contact between femur and tibia can be achieved, the bone surfaces must be free of cement. To facilitate bony union the contact surfaces should be freshened. If appropriate, additional bone material can be introduced between the contact surfaces.



9

The gap to be bridged has to be filled preferably with cement if bony contact between femur and tibia cannot be achieved.

Before joining the components anchoring holes for the cement used to fill the gap (abt. 5-6 mm wide and abt. 10 mm deep) should be prepared in the contact surface areas to improve the bond between femur and tibia.



10

Special cases of bridging joint-space defects

Joint space gaps must be filled by bone graft Fig. 11 or bone cement Fig.12



The central part of the Fusion Nail is 50 mm. It is sometimes preferable to shift more of this 50 mm into the femur, to avoid the tibial tubercle (Fig. 12 & 13).

Case History

54 years old female patient, suffering 28 years of chronic polyarthritis; multiple operations, including arthroplasties in various joints.



3/93 patient arrived with a centrally located crater of approximately Ø 2,54 cm within the knee joint. Total painful loss of function in the extremity.

Infection with Staphylococcus Aureus and Pseudomonas Aeruginosa.

Soft tissue defects and substantial loss of bone stock following removal of prosthesis.



3/93 revision with implantation of LINK Endo-Model Fusion Nail.

- primary stability
- primary wound healing
- mobilization under full load
- discharge 44 days postoperatively, painless, fully mobilized
- follow-up 1999. Patient without complaints

X-ray Templates

15-8450/50

X-ray templates for Fusion Nail
110% actual size, Set of 6 sheets

Instructions for Cleaning and Maintenance

Specific instructions for instruments are available on request from info@linkbio.com

Literature

Interpositionsnagel bei diaphysären Kochendefekten und Arthrodesenagel bei gescheitertem Kniegelenkersatz;
Chirurg 56: 712-717 (1985). Endo-Klinik Hamburg, Germany

Knee Arthrodesis using an intramedullary implant
J. Bone Joint Surg. (BR) 1997; 97-B:SUPP II, 177. Endo-Klinik Hamburg, Germany

Wodtke JFK
Der Arthrodesenagel Endo-Modell
Waldemar Link GmbH & Co. KG, (1999) Endo-Klinik Hamburg, Germany

Cemented modular intramedullary nail in failed knee arthroplasty-a report of 2 cases
Acta Orthop Scand 1999; 70 (3): 305-307

Wodtke JFK
Endo-Model Knee Fusion Nail
Waldemar Link GmbH & Co. KG, (2000) Endo-Klinik Hamburg, Germany

Additional Catalogues



For more information please register for our LINK Media Library (linkorthopaedics.com)

The Knee Fusion Nail was cleared within the Megasystem-C (#K151008). The indications and contraindications for the Megasystem-C encompass a number of procedures in the lower limb, including limb salvage/oncology as well as knee and hip replacement.

The LINK MEGASYSTEM-C is intended to be used with the components of the Endo-Model SL Rotating and Non-Rotating Hinge Knee or Endo-Model Knee System (#K143179) which can be integrated for knee joint replacement and with the MP Reconstruction Prosthesis (#K142187) for hip replacement.

The LINK MEGASYSTEM-C is indicated for treatment of any of the following Limb Salvage/Oncology procedures:

- 1) Revision for loosened femoral prosthesis components involving extensive bone loss.
- 2) Surgical intervention for severe trauma.
- 3) Oncology cases where extensive resection and replacement of bone is required from tibia to hip area.

The device is to be used with bone cement unless a proximal femur or a modular stem is indicated for use.

For the use of the LINK Endo-Model SL Rotating and Non-Rotating Hinge Knee System additional indications should be noted:

- 1) Bone necroses.
- 2) Bicondylar arthrosis by partly damaged collateral ligaments.
- 3) Revision after primary total knee replacement.
- 4) Revision surgery after hinge knee or rotational knee joint.
- 5) Revision surgery by insufficient / inadequate bone mass.
- 6) Arthrosis of patella flange.
- 7) Valgus/varus deformities $<10^\circ$.
- 8) Valgus/varus deformities $10-15^\circ$.
- 9) Valgus/varus deformities $15-20^\circ$.

For the use of the LINK Endo-Model SL Non-Rotating Hinge Knee System additional indications should be noted:

- 10) Bicondylar arthrosis by completely damaged collateral ligaments and muscular instability.
- 11) Valgus/varus deformities $20-30^\circ$.

Contraindications:

A. As related to bone tumors:

Not all bone tumors may be treated successfully by segmental resection. Any condition that may have already resulted in local or distant spread of the tumor may be a contraindication. Some examples of such conditions include:

- 1) Pathological fracture.
- 2) Overt infection.
- 3) Inopportune placement of biopsy incision.
- 4) Rapid disease progression beyond a respectable margin.

B. As related to failed previous prosthesis and trauma:

- 1) Acute or chronic infections, local and systemic.
- 2) Allergies to (implant) materials.
- 3) Revision in septic environment.
- 4) For preparation of the prosthesis bearing insufficient length of intact diaphysis (less than 80 mm).
- 5) Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk.
- 6) Insufficient bone integrity which prevents a stable anchorage of the prosthesis.
- 7) Adiposity.
- 8) Lacking or foreseeable not assured compliance.
- 9) Foreseeable overload/overstressing of joint prosthesis.

For the use of the LINK Endo-Model SL Rotating Hinge Knee System additional contraindications should be noted:

- 1) Insufficient musculature

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

All content in this catalog, including text, pictures and data, is protected by law. Every instance of use, whether in part or in whole and which is not permitted by law, is subject to our prior consent. In particular, this applies to the reproduction, editing, translation, publishing, saving, processing, or passing on of content stored in databases or other electronic media and systems, in any manner or form. The information in the catalogs is solely intended to describe the products and does not constitute a guarantee.

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.

Products shown in this document may not be available in your country. The product availability is subject to the approval and/or registration regulations of the respective country. Please contact Waldemar Link GmbH & Co. KG if you have questions about the availability of LINK products in your country.

Waldemar Link GmbH & Co. KG and/or other corporate affiliated entities own, use or have applied for the following trademarks in many jurisdictions: LINK, BiMobile, SP II, Modell Lubinus, E-Dur, EndoDur, T.O.P. II, BetaCup, CombiCup PF, CombiCup SC, CombiCup R, MobileLink, C.F.P., LCU, SP-CL, LCP, MIT-H, Endo-Model, Endo-Model SL, MP, MEGASYSTEM-C, GEMINI SL, SPAR-K, LCK, Link OptiStem, HX, TiCaP, X-LINKed, PorAg, LINK PorEx, BiPorEx, PorEx-Z, TrabecuLink, Tilastan, customLINK, RescueSleeve, Stactip, VACUCAST.

Other trademarks and trade names may be used in this document to refer to either the entities claiming the marks and/or names or their products and are the property of their respective owners.

This publication is intended for distribution in the U.S. only.