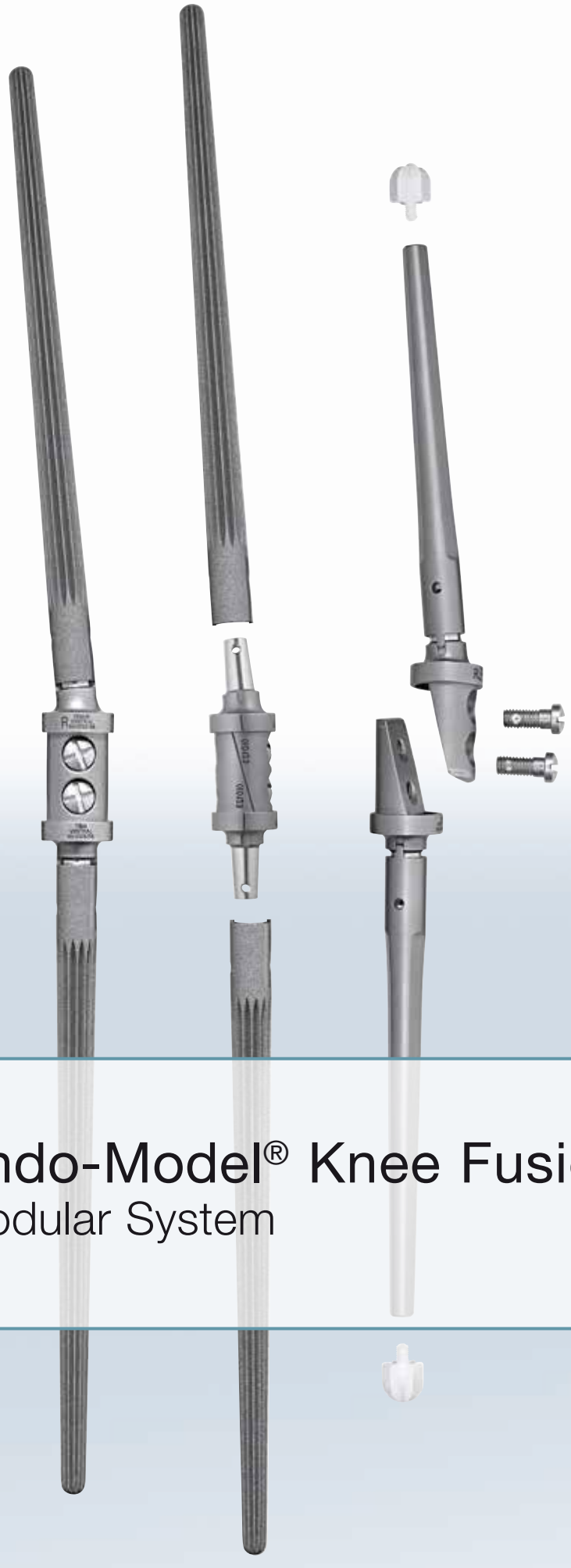
LINK®



Endo-Model® Knee Fusion Nail SK

Modular System

Presented by:

Exclusive for use in US market.

CE 0123

Waldemar Link GmbH & Co. KG

Barkhausenweg 10 · 22339 Hamburg, Germany
P.O. Box 63 05 52 · 22315 Hamburg, Germany
Tel.: +49 40 53995-0 · Fax: +49 40 5386929
info@linkhh.de · www.linkorthopaedics.com

Endo-Model® Knee Fusion Nail SK
Modular System

System Overview

Femoral anatomicaly adapted with 6° valgus

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

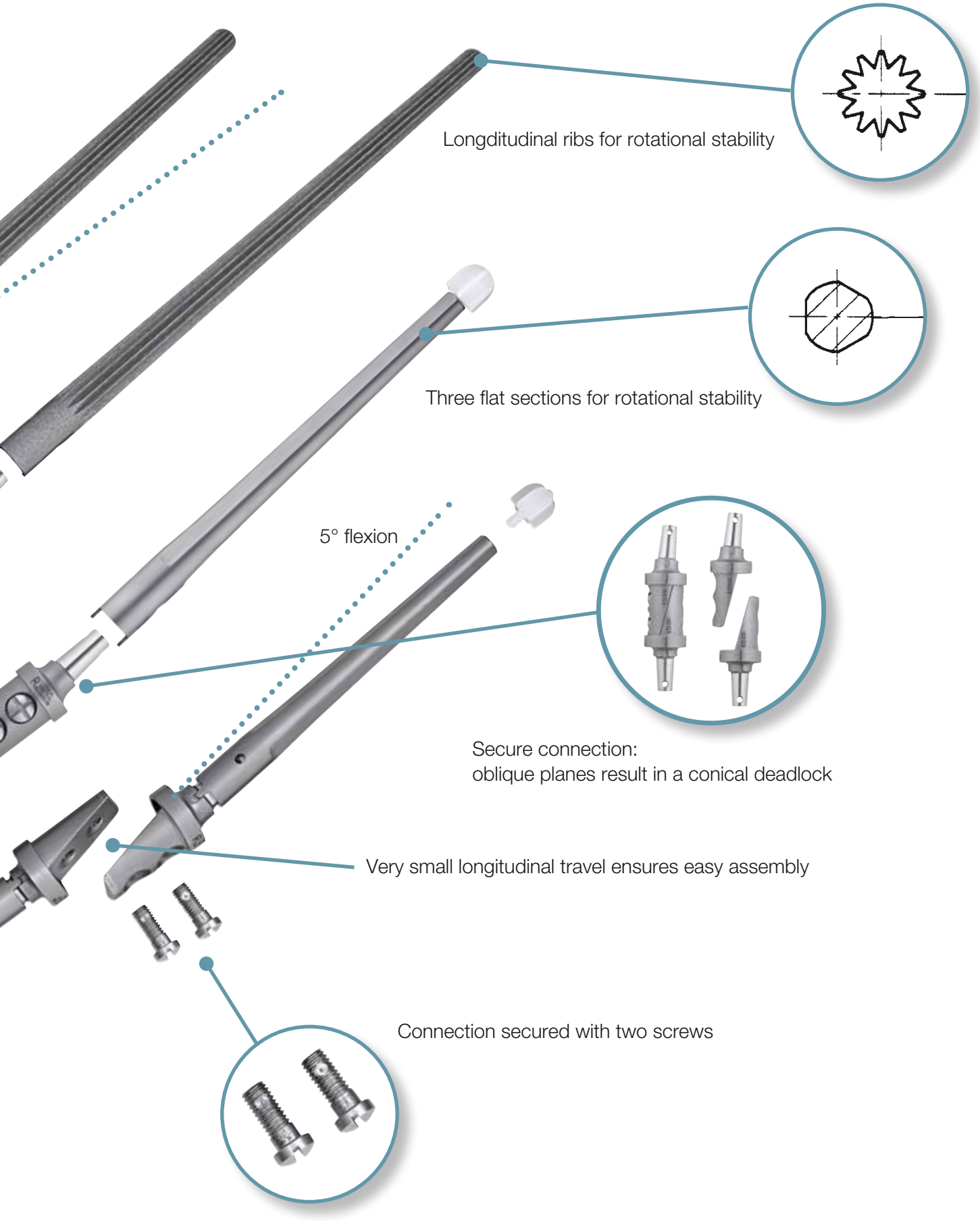
Securing screws for taper connection

Rough surface for high primary stability

Microporous structure
Pore size ~160 µm

Cylindrical and conical
stems

Cemented and cementless anchorage


Longditudinal ribs for rotational stability
Three flat sections for rotational stability
5° flexion
Secure connection:
oblique planes result in a conical deadlock
Very small longitudinal travel ensures easy assembly
Connection secured with two screws

System Description

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

The cemented Fusion Nail, as well as the modular version, are made of very strong 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.

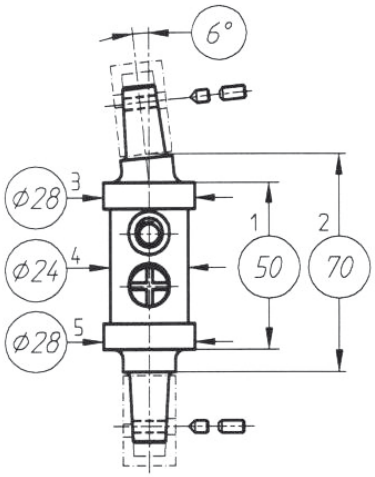
The oblique plane and engagement of the components in the ring-shaped pockets create a stable and force-locking connection that is secured with two screws.

The Fusion nail does not require bony apposition therefore leg length can be flexibly adjusted or restored.

Endo-Model® Knee Fusion Nail, modular
Material: CoCrMo and UHMWPE

Set
femoral and tibial component, 2 screws, 4 lock bolts

Item no. (set)	Version
15-0028/08	right
15-0028/07	left



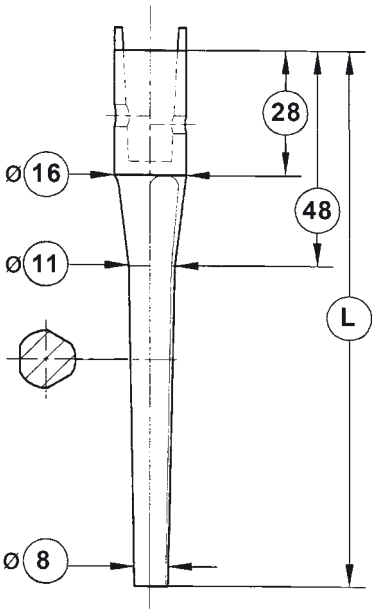
Centralizers
Material: UHMWPE

Ø 12 mm Ø 14 mm Ø 16 mm

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

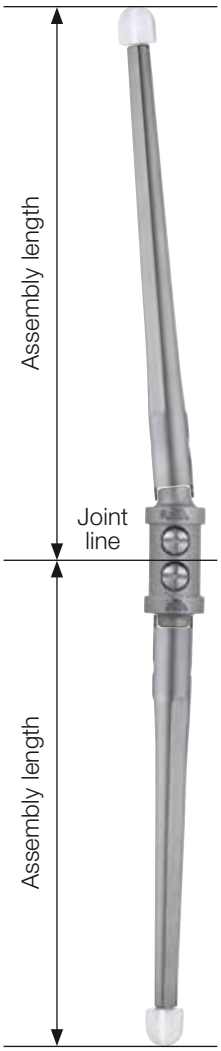
Cemented stems

Endo-Model®-M Stems, modular, cemented
Material: CoCrMo



Item no.	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 + 35mm (Fusion Nail) + 15mm (centering star)

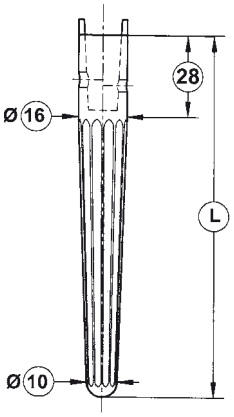


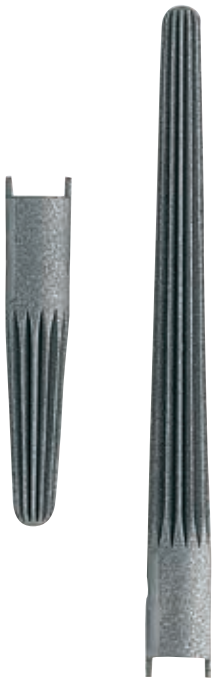
Cementless stems

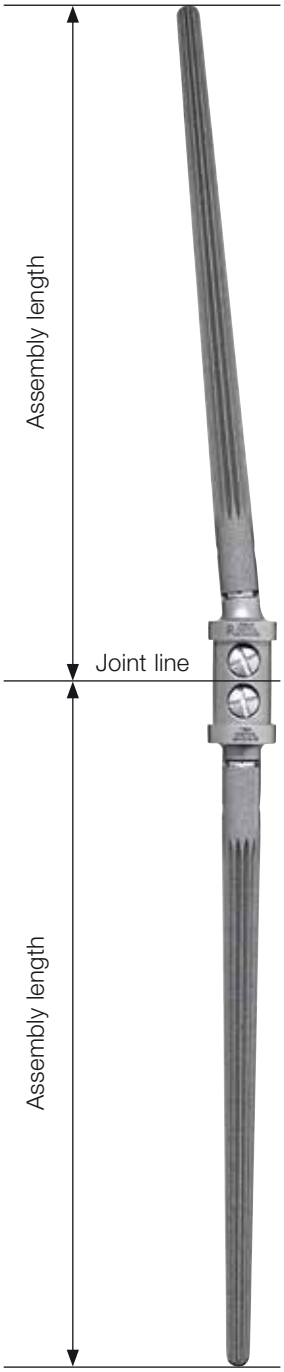
Endo-Model®-M Stems, modular, cementless, conical
Material: Tilastan®

Item no.	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	160
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 + 35mm (Fusion Nail)



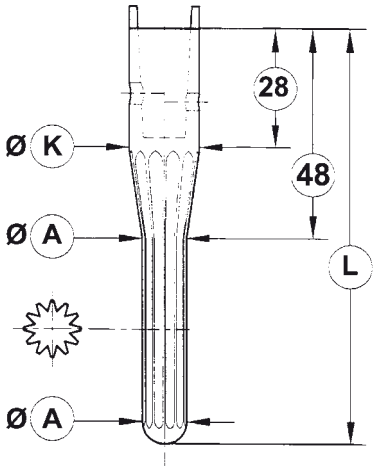




Additional cementless stems

Endo-Model®-M Stems, modular, cementless, cylindrical
Material: Tilastan®

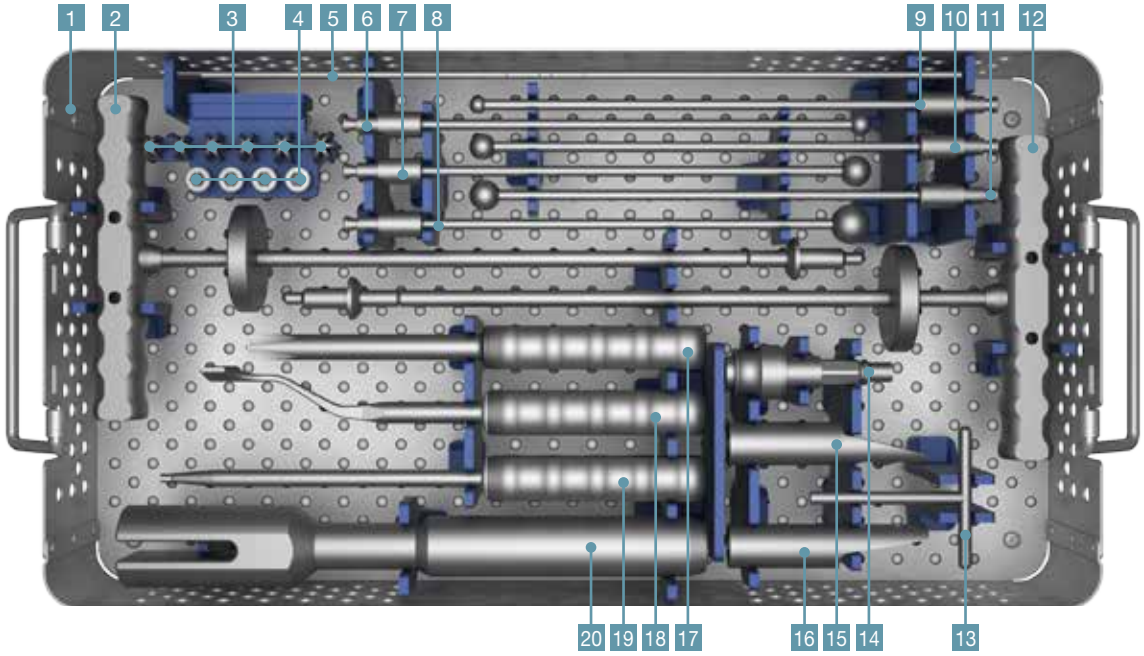
Item no.	L mm	Ø A mm	Ø K mm	Assembly length mm*
15-2951/01	60	10	16	95
15-2951/02	60	12	16	95
15-2951/03	60	14	16	95
15-2951/04	60	16	16	95
15-2951/05	60	18	18	95
15-2951/06	120	12	16	155
15-2951/07	120	14	16	155
15-2951/08	120	16	16	155
15-2951/09	120	18	18	155
15-2951/10	160	12	16	195
15-2951/11	160	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 + 35mm (Fusion Nail)

Instrumentset for Endo-Model® Knee Fusion Nail

15-8450/00 Instrument Set, complete



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

Preoperative Planning

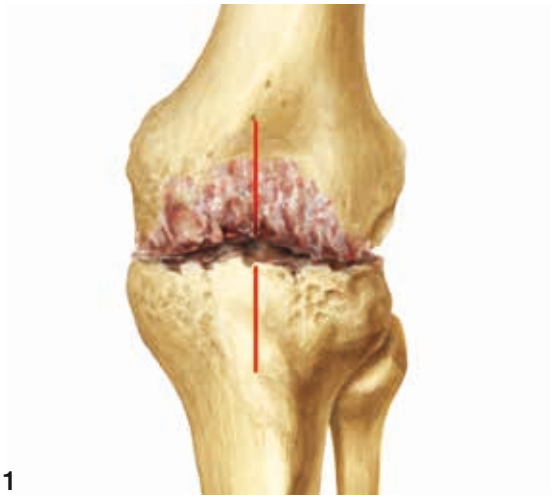
Measurement tables and X-ray templates are available for the preoperative planning of surgery with Endo-Modell® Fusion Nail which enable the surgeon to plan precisely for the implants that will be used.

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-Modell® Fusion Nail demonstrates its ease of use due to its modularity and simplicity.

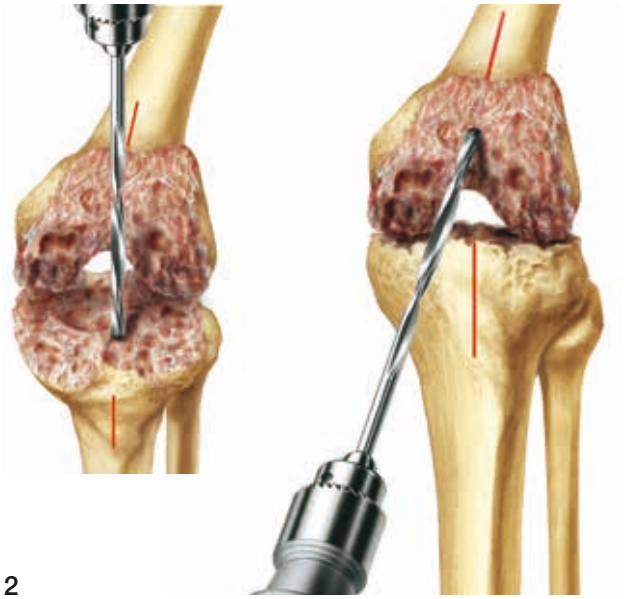
In contrast to the use of primary knee joint prostheses, management of extensive bone loss depends on the conditions in each individual situation. Structural changes in the muscles and ligaments, fixation conditions etc. increase the operative demands of prostheses. Accordingly, management of extensive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

Surgical Technique



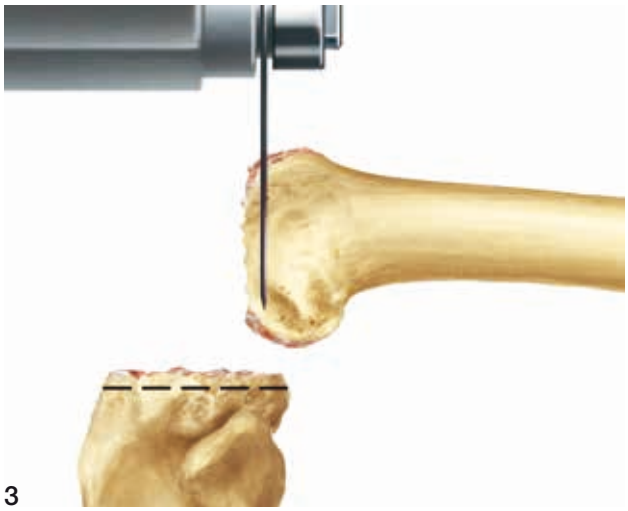
1

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).



2

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



3

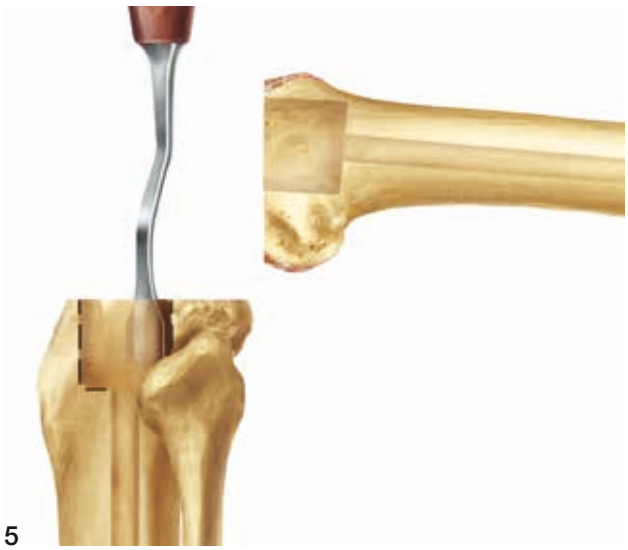
Both femoral and tibial joint (shaft) surfaces are resected plane-parallel in such a way as to achieve sufficient surface contact of vital bone tissue between femur and tibia (Fig. 3).

Using long ball reamers, tibia and femur are prepared in 1mm 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 1mm 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 16mm 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 bore has to be adjusted according 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.

4

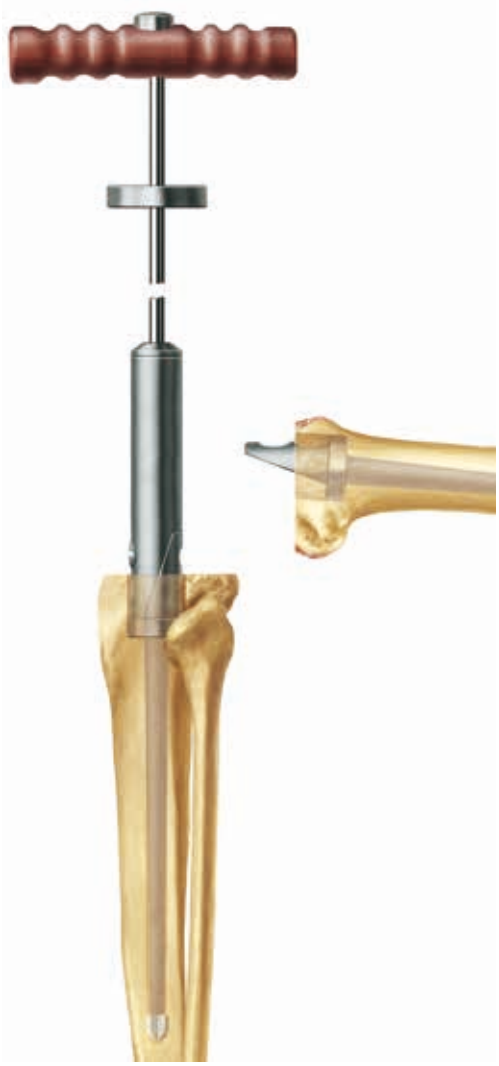


5

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 28mm). The required depth of these openings in the femur and tibia is 25mm 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.

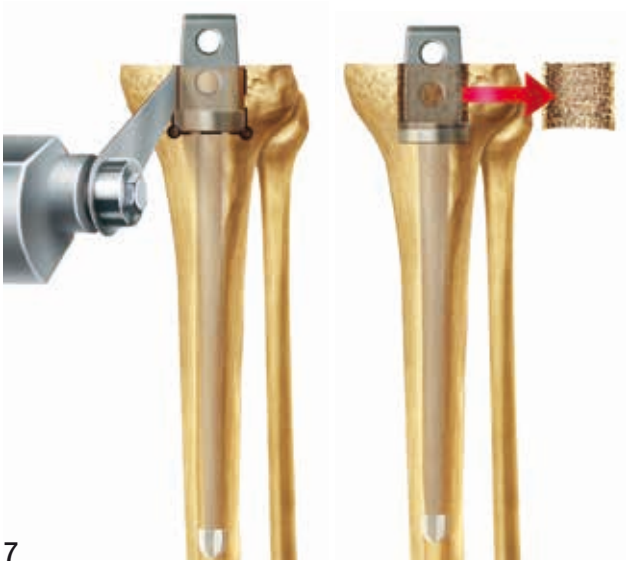
Tip:
If it should prove difficult to insert either of the components, it may be necessary to enlarge the medullary canal using an intramedullary reamer, a ball reamer or a curette.



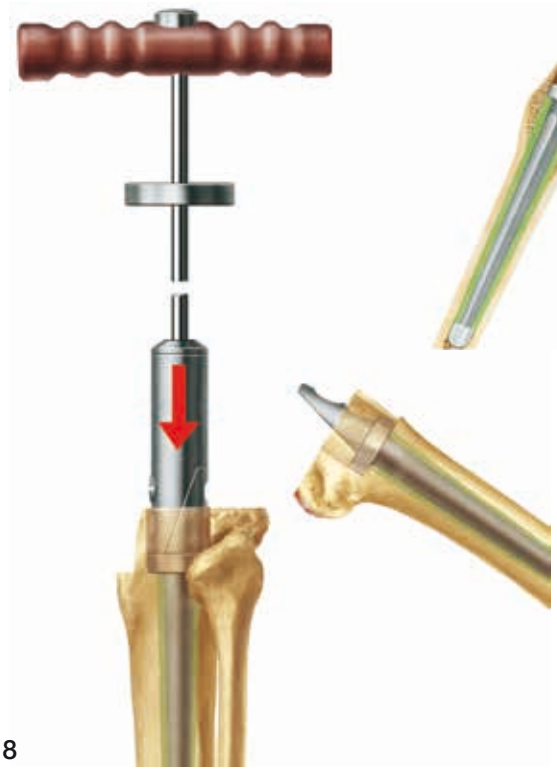
6

Anteriorly, a 30x30mm 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 17).



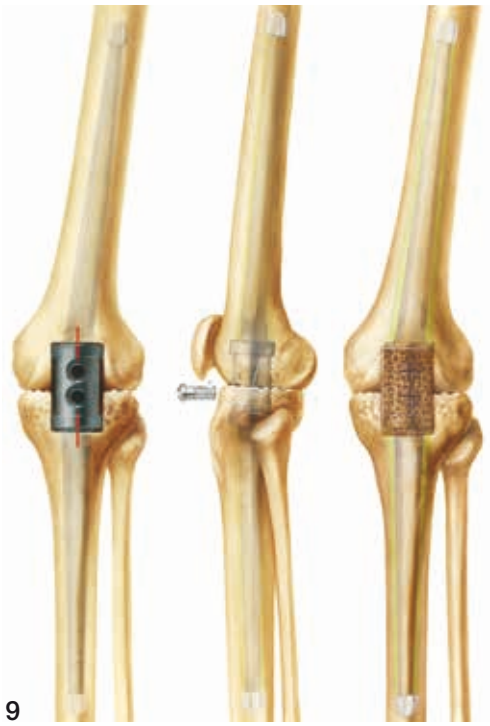
7



8

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).

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 appropiate, additional bone material can be introduced between the contact surfaces.

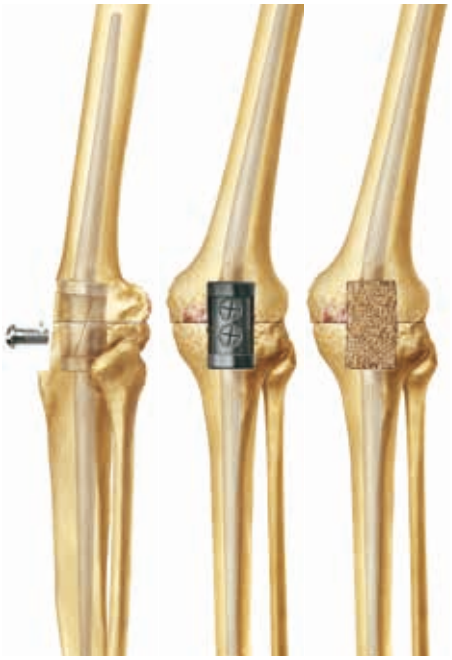


9

10

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.

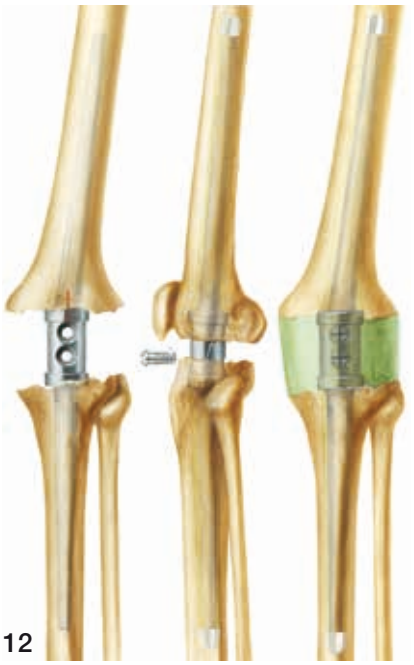
Special cases of bridging joint-space defects



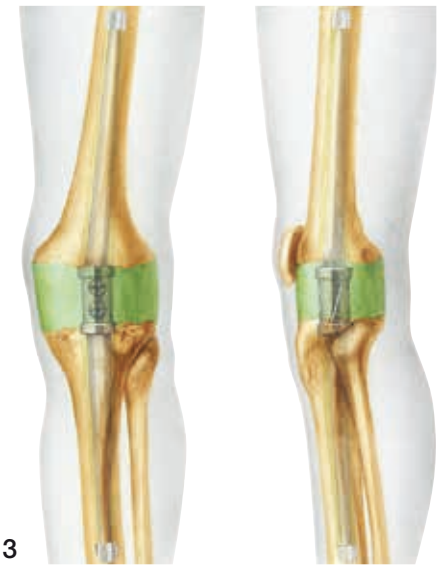
11

Any remaining space between femur and tibia, bridged by the fusion Nail as possibly filled with bone graft reduces the necessary depth of the implant bed in femur and tibia, in case of a 50mm distance, altogether.

Example:
The central part of the Fusion Nail is 50mm. If a gap of 20 mm between femur and tibia is to be bridged the depth of the implant bed in femur and tibia comes up to 15mm each. In this situation it may be advisable, however, to plan the total depht of 30mm for only the femur or tibia.



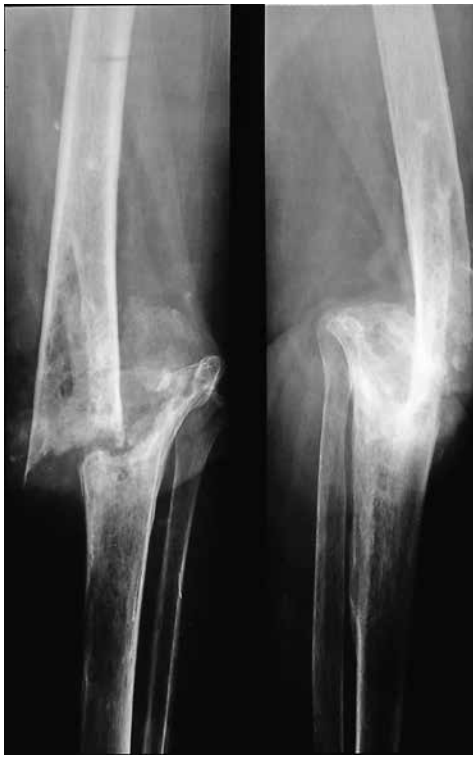
12



13

Case History

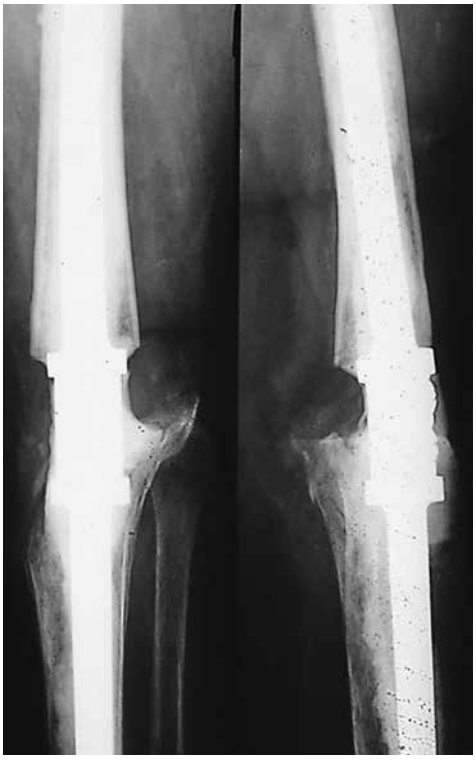
54 years old female patient, suffering 28 years of chronic polyarthritis; multiple operations, including arthroplasties in various joints.



3/93 patient arrived with a centrally located crater of approximately one inch diameter within the knee joint. Total painful loss of function in the extremity.

Infection with staphylococcus aureus and pseudo-monas 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 customer@linkhh.de

Literature

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

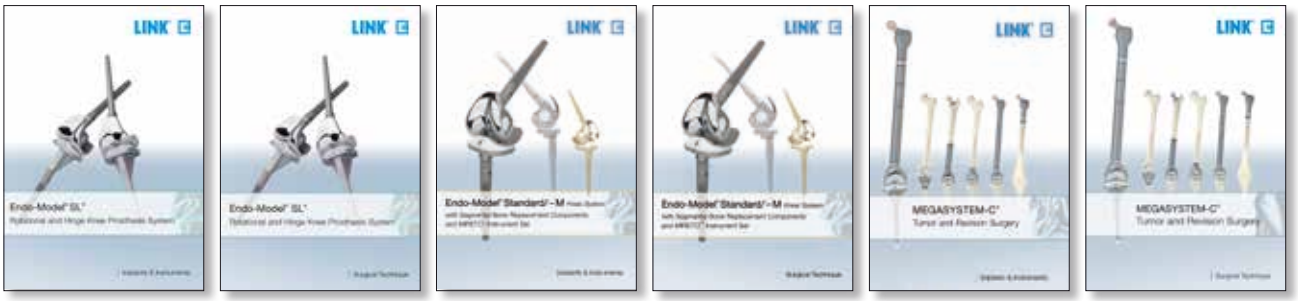
Knee Arthrodesis using an intramedullary implant
J. Bone Joint Surg. (BR) 1997; 97-B:SUPP II, 177. Endo-Klinik Hamburg, Germany

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



Katalog / Catalogue:
733 Endo-Model® SL®; Implants & Instruments or Surgical Technique
719 Endo-Model®-M; Implants & Instruments or Surgical Technique
909 MEGASYSTEM C® Implants & Instruments or Surgical Technique

Indications	
Instability of the knee joint which can not be supplied by modern endoprosthetic	X
Flacid paralysis, neuropathic joint disease or insufficient extensor mechanism of the knee joint.	X
Severe joint destruction as a result of existing or previous inflammation or trauma which prevents the supply with an endoprosthesis.	X
Persistent prosthesis or joint infection, soft tissue defects or wound healing disorder with hardly or severely controllable spectrum of pathogens	X
Tumors which require extensive resection, by which the articulating surface cannot be maintained and the supply with endoprosthesis is inadequate.	X
Contraindications	
Poor general state of health	X
Allergies to (implant) materials	X
Insufficient bone integrity which prevents a stable anchorage of the knee fusion nail	X
Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk	X
Condition after arthodesis in contralateral hip- or knee-joint	X
Relative Contraindications	
Severe degenerative alteration of the spinal column	X
Amputation of contralateral knee-joint	X
Degenerative alteration in ipsilateral hip- or foot-joint	X

Numerical Index

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 stresses.
   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 lifespan. 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's strength, which cannot be compared with that of healthy bone!

5. **Unless otherwise indicated, the 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 up until the expiration date indicated on the packaging.
- Store implants in a permanent building.
- Protect against frost, dampness, direct sunlight and mechanical damage.
- Implants may be stored in their original packaging for up to 5 years from the date of manufacture. The expiration 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, Germany

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

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

Waldemar Link GmbH & Co. KG

Barkhausenweg 10 · 22339 Hamburg, Germany
P.O. Box 63 05 52 · 22315 Hamburg, Germany
Tel.: +49 40 53995-0 · Fax: +49 40 5386929
info@linkhh.de · www.linkorthopaedics.com

LINK®