LINK®

Endo-Model Knee Fusion Nail SK

Monoblock and Modular System

Surgical Technique

CE 0482

Explanation of Pictograms			
	Manufacturer	REF	Article number
MAT	Material (number)	CE	Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

Endo-Model Knee Fusion Nail SK
Monoblock and Modular System

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Important Information

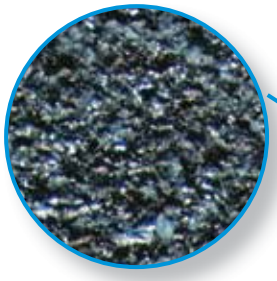
System Overview

Femoral anatomically adapted with 6° valgus

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

Securing screws for taper connection

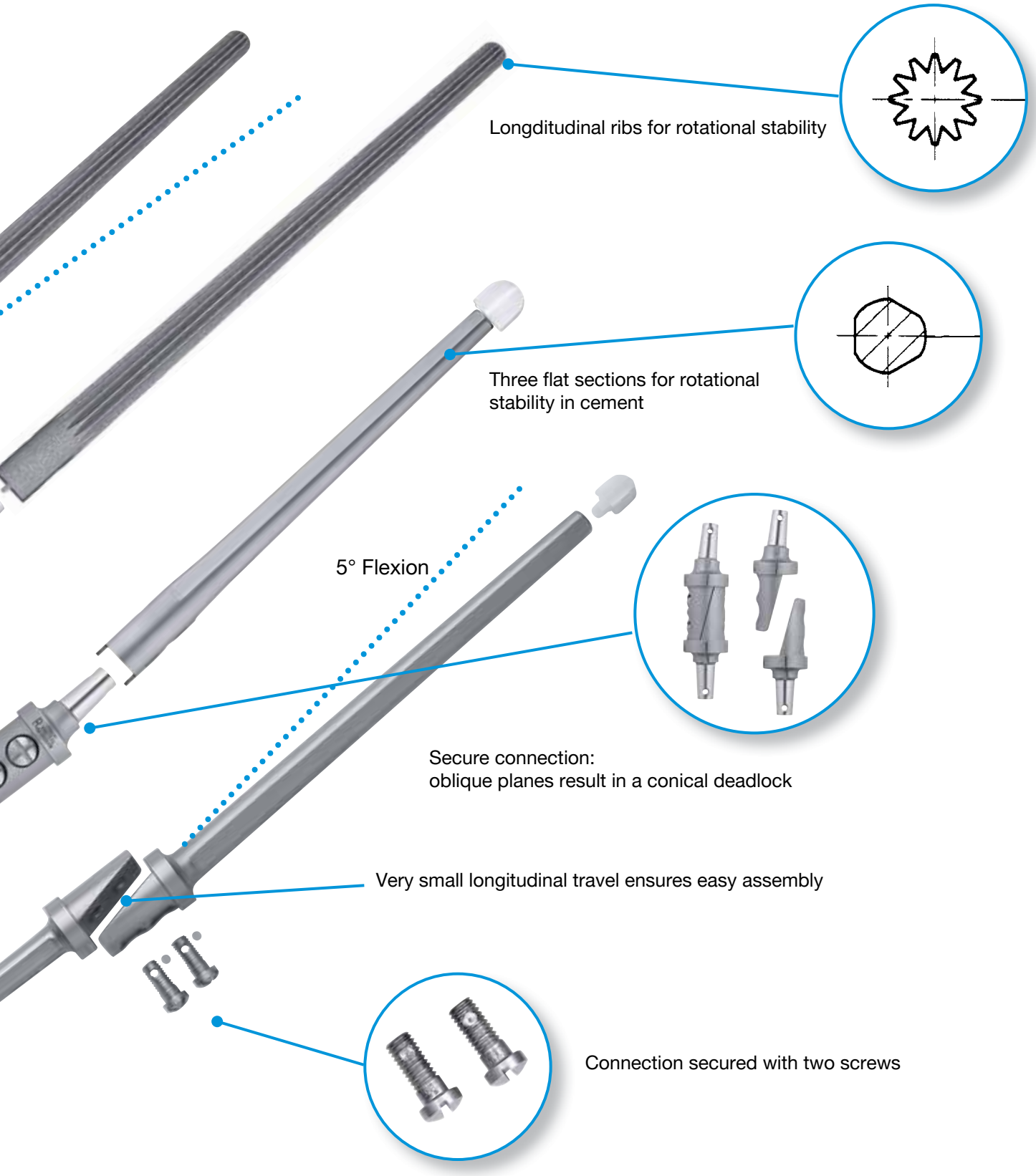
Rough surface for secondary osteoconduction



Microporous structure
Pore size ~160 µm

Cylindrical and tapered
fluted stems

Cementless and cemented anchorage


Longditudinal ribs for rotational stability
Three flat sections for rotational stability in cement
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 it‘s introduction 1978.

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.

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

Fig. 1

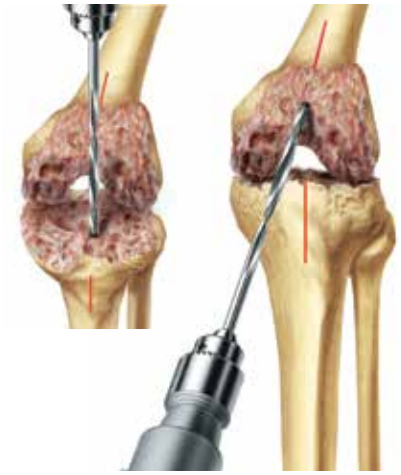


Fig. 2

Fig. 3

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).

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).

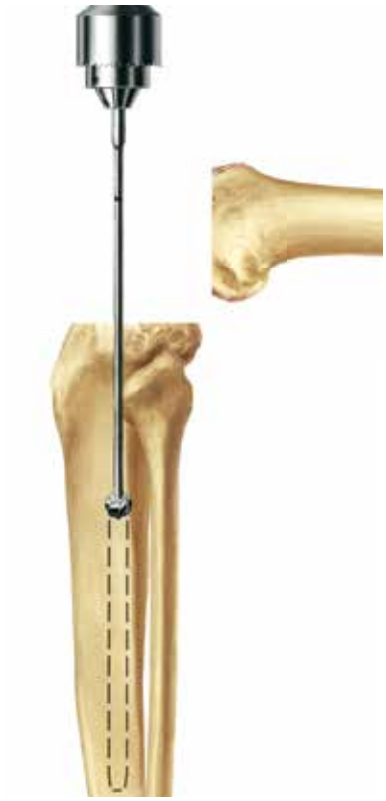


Fig. 4

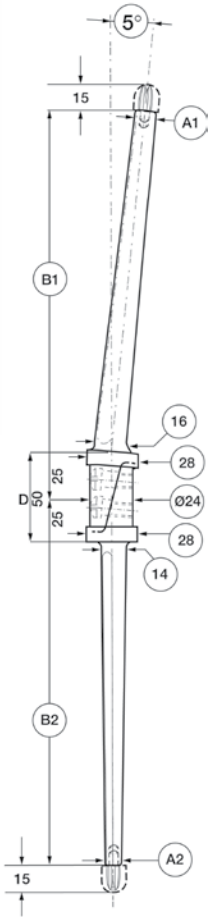


Fig. 5

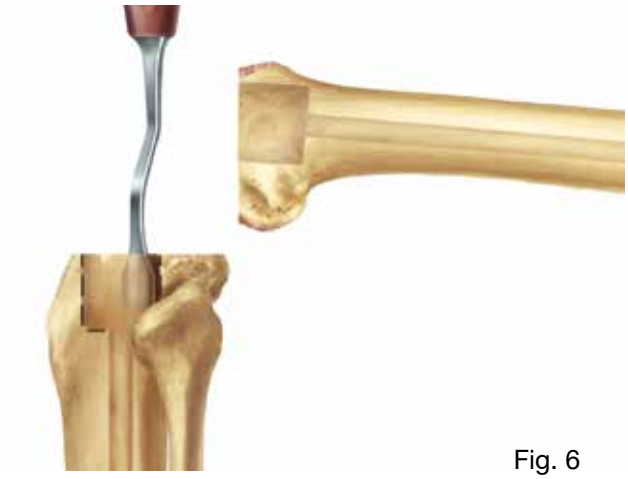


Fig. 6

Preparation of the stem

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 (Fig. 5).

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 the used stem (see assembly length tables pages 13-17).
If cementless stems are used, the preparation has to be done with the corresponding press-fit reamers from the Endo system.

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 (Fig. 6).

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

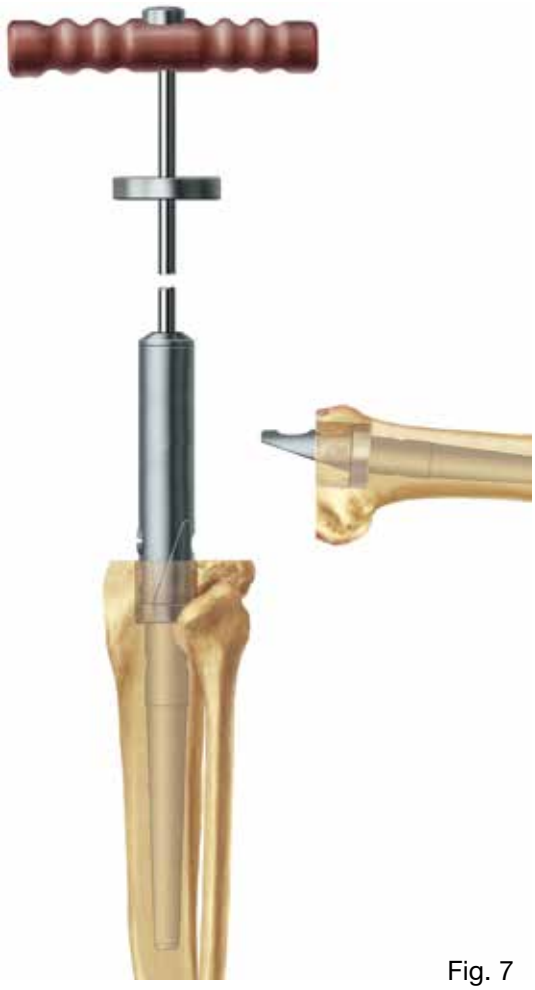


Fig. 7

Ventrally a 30 x 30 mm fenestration in axial direction has to be prepared with an oscillating saw (Fig. 8).

Trial Implants*

Using the inserter attached to the threaded rod and handle the tibial and femoral trial components of the Fusion Nail are introduced into the prepared cavities. Femur and tibia are then positioned on each other while, at the same time, fitting both components together on a trial basis.

After the trial repositioning and before removing the Trial Fusion Nail components marks are placed on the Trials 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 trials.

Note:

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

Fig. 8

*Prior to insertion, the modular Fusion Nail trial components must be screwed to the predefined size of the Endo-Model-M (MIRETO) trial stem system (Fig. 8).

Fig. 9

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 (Fig. 9).
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.

Note:
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.

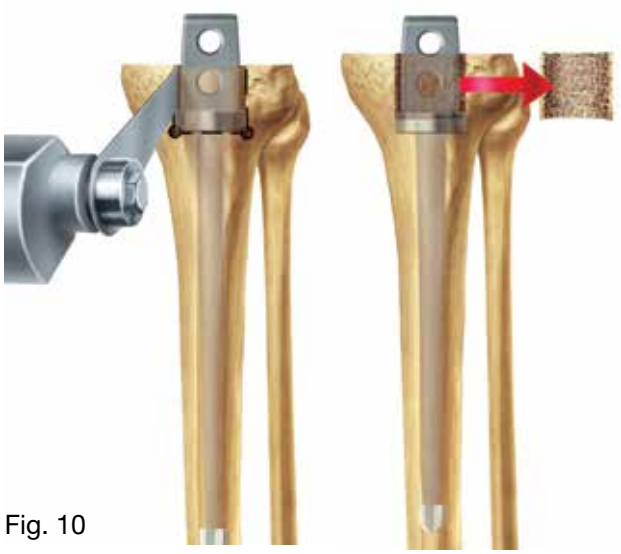


Fig. 10

If necessary, anteriorly a 30 x 30 mm fenestration in the axial direction has to be re-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 (Fig. 10).

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 10 + 11).

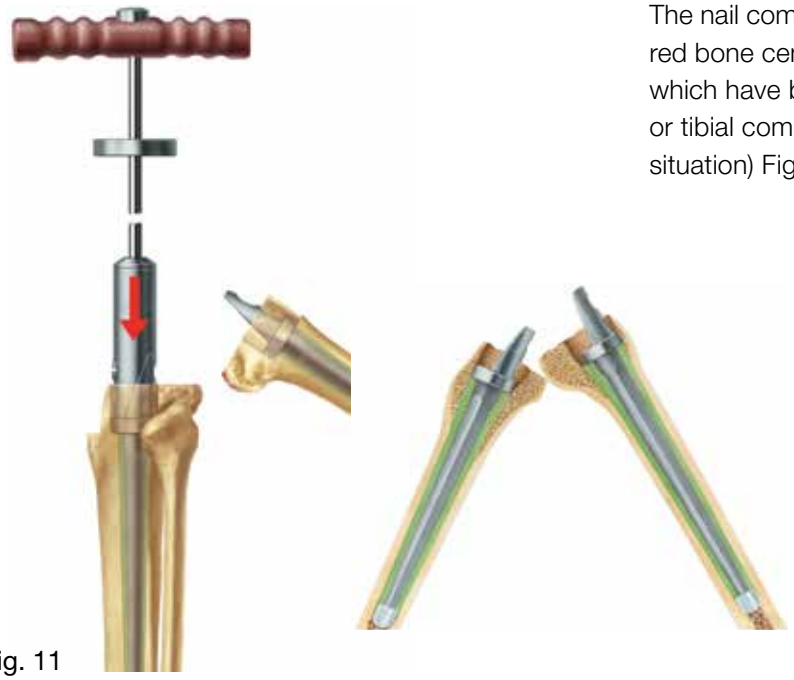


Fig. 11

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) Fig. 11.

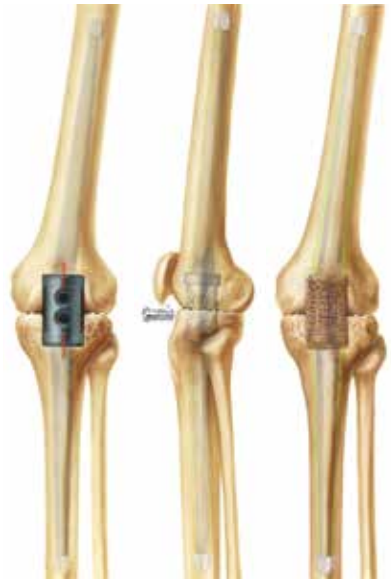


Fig. 12

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 (Fig. 12).

Fig. 13

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 (Fig. 13).

Special cases of bridging joint-space defects

Fig. 14

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 50 mm distance, altogether.

Example:
The central part of the Fusion Nail is 50 mm. 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 15 mm each. In this situation it may be advisable, however, to plan the total depht of 30 mm for only the femur or tibia.

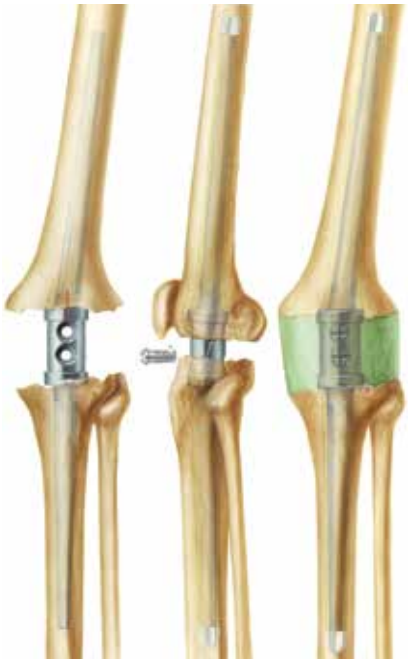


Fig. 15

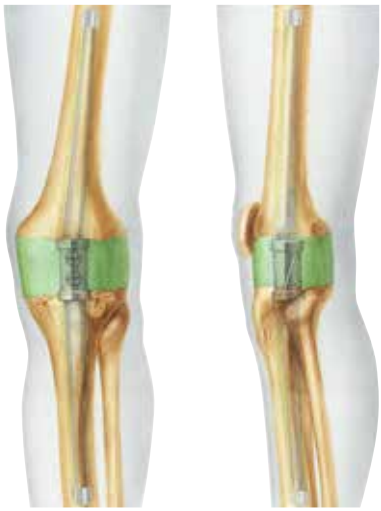


Fig. 16

Special cases of bridging joint-space defects

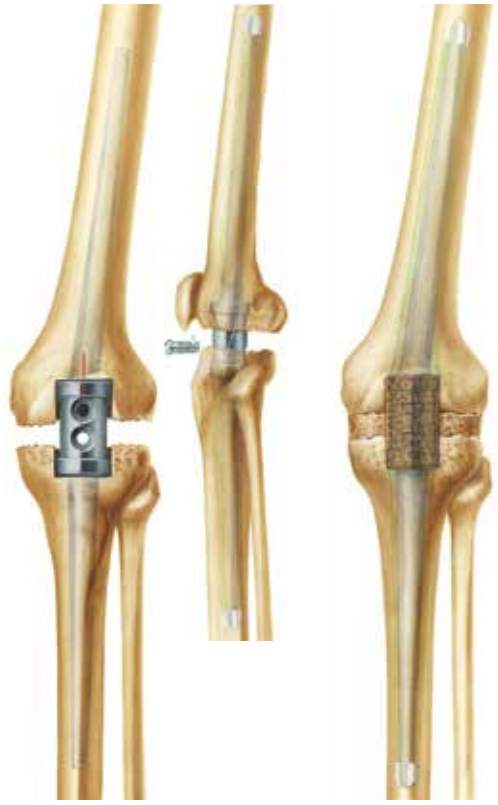
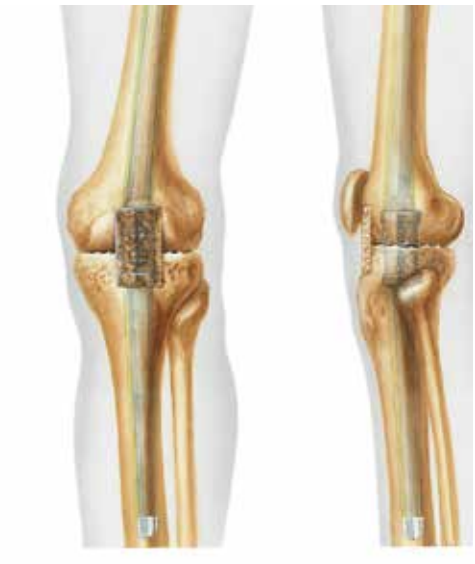
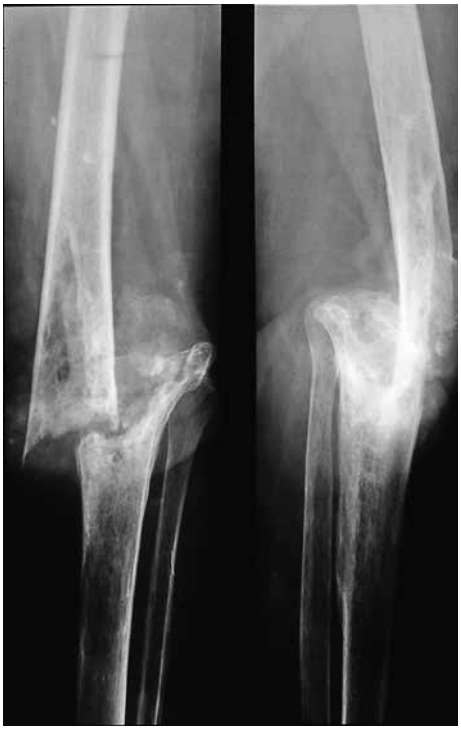


Fig. 17



Case History

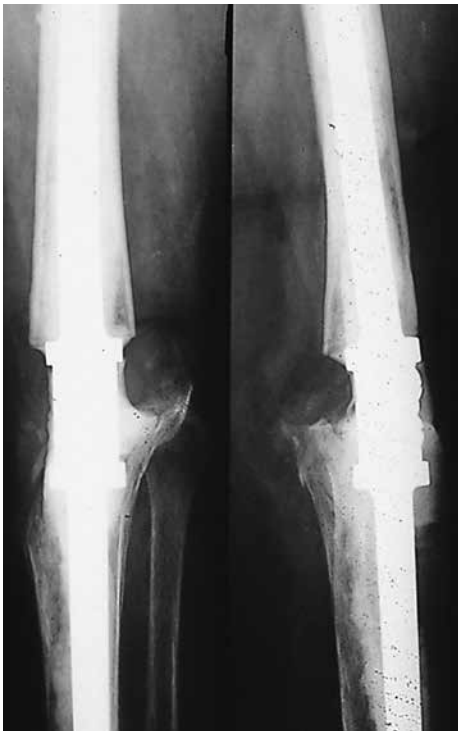
54 years old female patient,
suffering 28 years of chronic polyarthritis;
multiple pre-operations,
including arthroplasties in various joints.



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 pseudomonas aeruginosa.

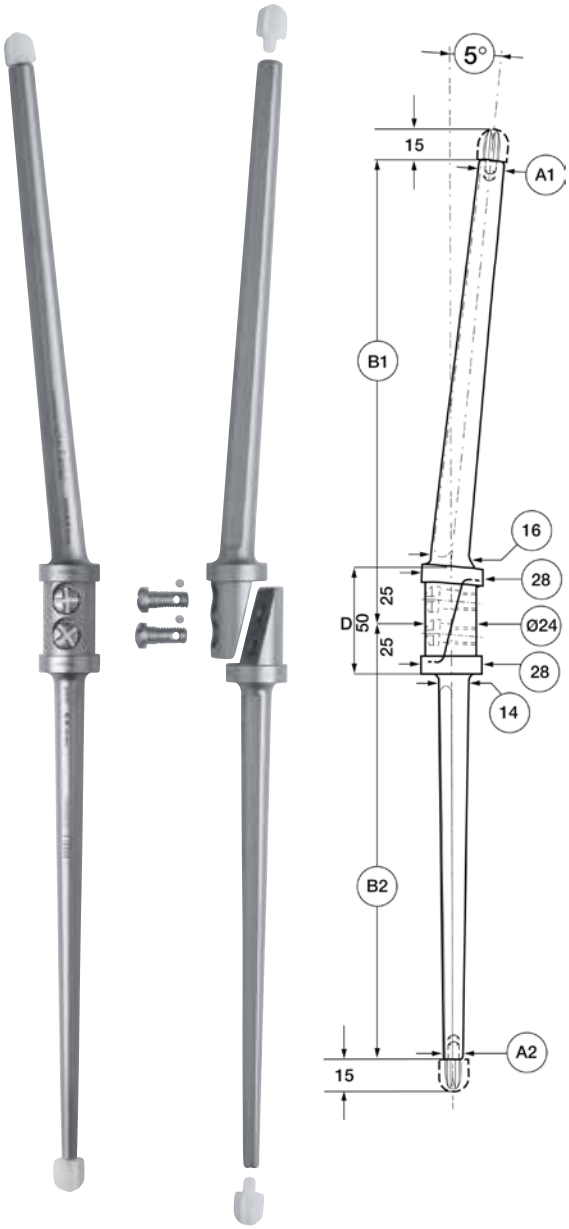
Soft tissue defects and substantial loss of bone stock following removal of prosthesis.



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

Endo-Model Knee Fusion Nail (Monobloc), 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

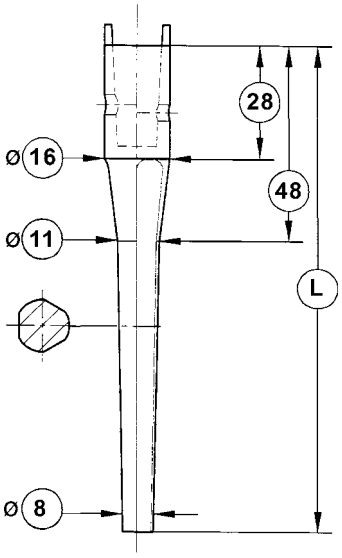
Tibial components,
incl. 1 set of centralizers, set of 2 assembly screws,
4 lock bolts, Ø 14 mm assembled, MAT CoCrMo

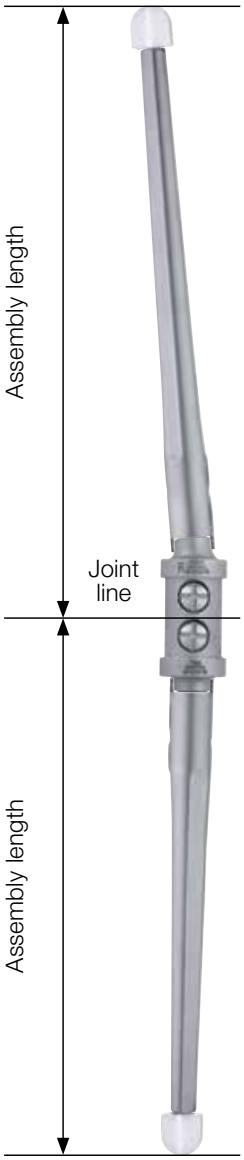
REF	Version	Size	Ø A2 mm	B2 mm
	right left			
15-8429/21	X	1	9	170
15-8429/22	X	2	9	210
15-8429/23	X	3	7	250

Cemented Stems

Endo-Model-M Stems, modular, cemented

MAT CoCrMo

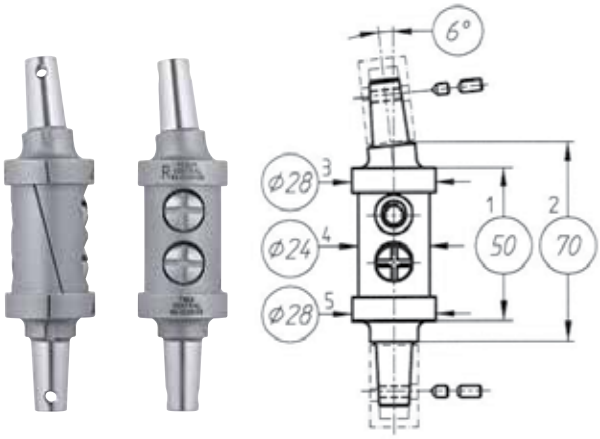




REF	L mm	Assembly length in mm*
15-2950/01	50	100
15-2950/02	80	130
15-2950/03	95	145
15-2950/04	120	170
15-2950/05	135	185
15-2950/06	160	210
15-2950/07	200	250
15-2950/08	240	290
15-2950/09	280	330

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

Endo-Model Fusion Nail, modular



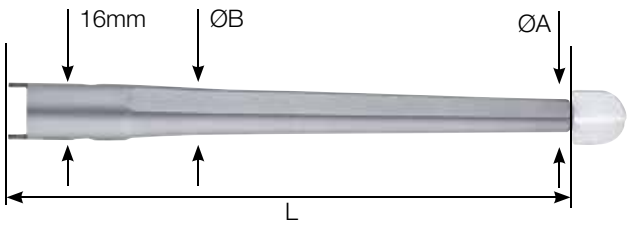
Set
Femoral and tibial Components
2 screws, 4 lock bolts
MAT CoCrMo and UHMWPE

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

Cemented Stems

Cemented Stems
MAT CoCrMo

REF	Size	L mm	ØA mm	ØB mm
15-0604/01	1	120	7	10
15-0604/02	2	120	12	16
15-0604/03	3	150	10	14
15-0604/04	4	150	12	16
15-0604/05	5	175	8	12
15-0604/06	6	175	10	14



Centralizer

MAT UHMWPE

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

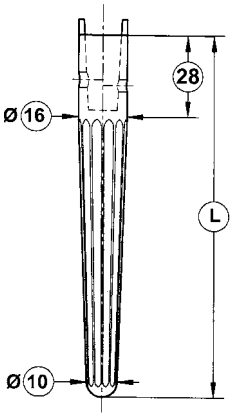
Cementless Stems

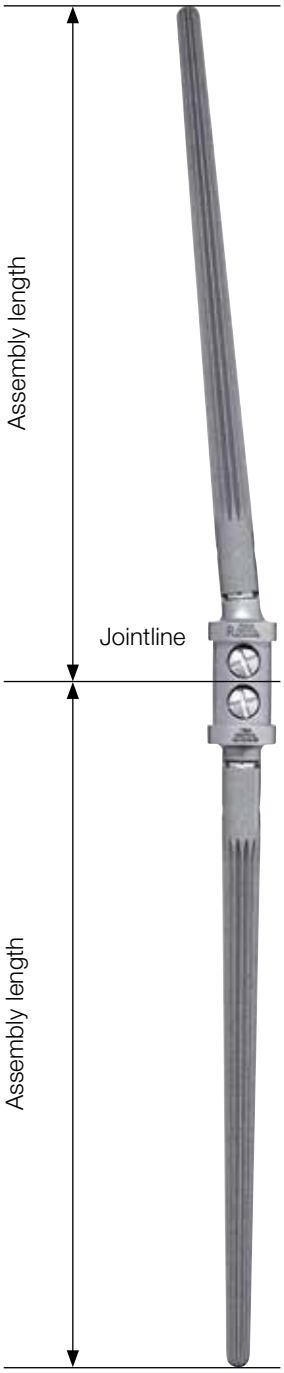
Endo-Model -M Stems, modular, cementless, tapered

MAT Tilastan

REF	L mm	Assembly length in 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)



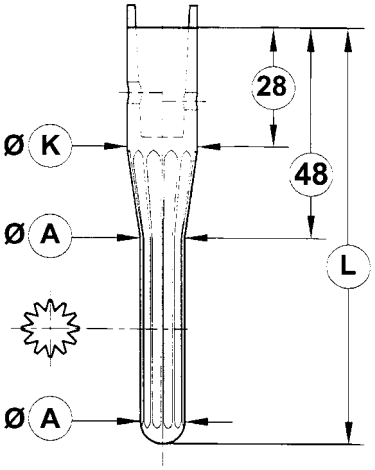


Cementless Stems

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

MAT Tilastan

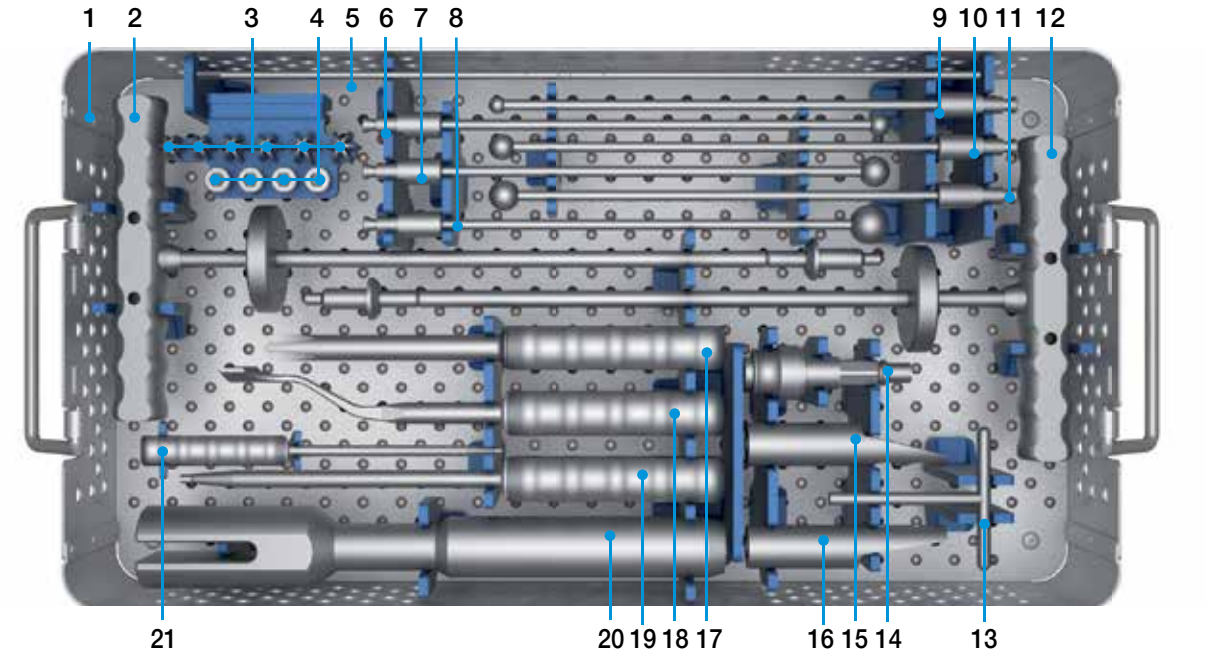
REF	L mm	Ø A mm	Ø K mm	Assembly length in mm*
15-2951/01	60	10	16	95
15-2951/02	60	12	16	95
15-2951/03	60	14	16	95
15-2951/04	60	16	16	95
15-2951/05	60	18	18	95
15-2951/06	120	12	16	155
15-2951/07	120	14	16	155
15-2951/08	120	16	16	155
15-2951/09	120	18	18	155
15-2951/10	160	12	16	195
15-2951/11	160	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	18	315



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

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	**Inserter-Extractor** for tibial Components
16	15-8450/03	**Inserter-Extractor** for femorale Components
17	16-3290/00	**Cross slot screwdriver**
18	15-1040	**Chisel n. Lexer**
19	64-8008/02	**Hex screwdriver**, 3.5 mm
20	130-686	**Slotted driver**
21	64-1181/16	**Hex screwdriver**, 2.0 mm, 220 mm

Instrument Set for Trial Implants

15-8451/00 **Instrument set, complete** (not illustrated)

Trial Implants for Knee Fusion Nail, modular
MAT Stainless steel

REF	Description	Version
15-8451/10	Instrument tray, empty	
15-8450/11	Tibia	-
15-8450/12	Femur	right
15-8450/13	Femur	left

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: E-mail customer@linkhh.de

Literature

Special Prints

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

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J. Bone Joint Surg. (BR) 1997; 97-B:SUPP II, 177. Endo-Klinik Hamburg, Germany

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

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Additional Literature

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

Indications/Contraindications

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

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!

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