LINK®

TrabecuLink Tibial Cones

Stable – Elastic – Versatile

Product Rationale

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.

The dynamic **LINK Tibial Cones** are an attractive solution for cementless restoration of bone defects [10] and to provide additional support for the prosthesis if there is bone loss in the proximal tibia. The combination of the **dynamic design** [5,6] of the cones and the biocompatible material **Tilastan – E** [11,12] is ideal for ensuring stable, long-lasting fixation and successful bone regeneration.

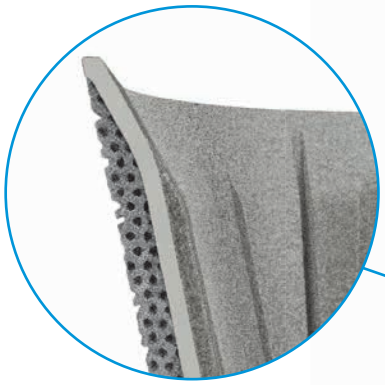
The **3-dimensional TrabecuLink structure**, with its pore size, porosity and structure depth, also provides an excellent basis for promoting osteoconduction and microvascularization, taking into account the requirements for the structure-covering protein layer (fibronectin - vitronectin - fibrinogen). [1,2]

Tibial Cones can be used in combination with the long-established **LINK Endo-Model knee family** in a wide range of sizes and versions. The choice of sizes corresponds to the dimensions of the hinged knee prostheses.

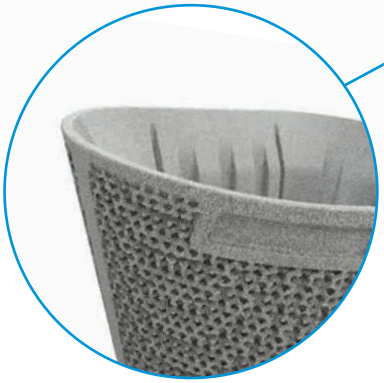
- **Stable** – with cementless fixation
- **Elastic** – due to integral bending axes in the inner metal wall
- **Versatile** – for a broad range of solutions [7]

4 Sizes and 4 Versions

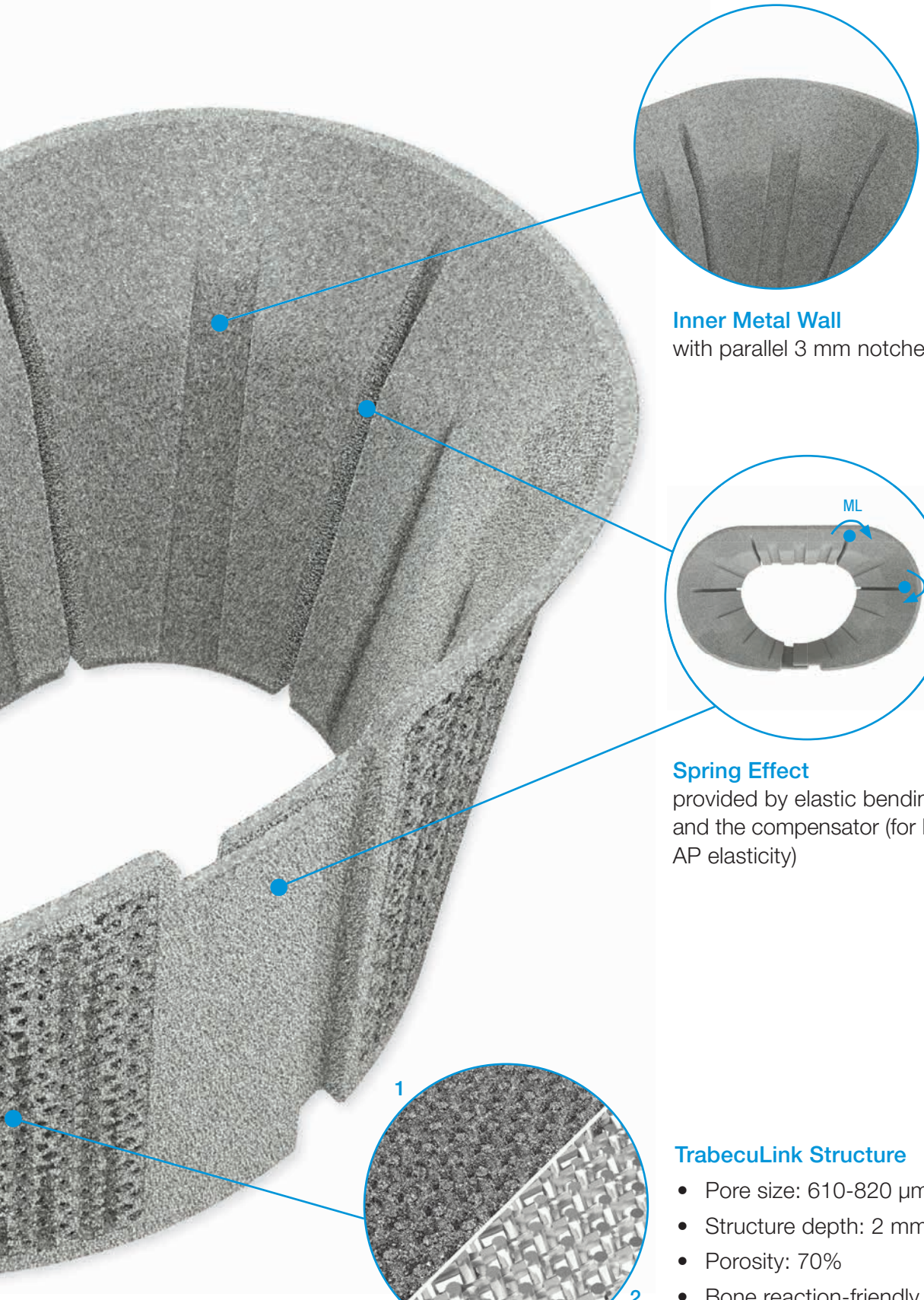
- XS, S, M, L
- Full, right-half, left-half, half



Cementless Implantation in the Bone
for bone regeneration



Extraction Pockets
for gripping with instruments



Inner Metal Wall
with parallel 3 mm notches

Spring Effect
provided by elastic bending axes and the compensator (for ML and AP elasticity)

TrabecuLink Structure

- Pore size: 610-820 µm
- Structure depth: 2 mm
- Porosity: 70%
- Bone reaction-friendly

1 Real TrabecuLink® structure
2 Geometric TrabecuLink® structure

Highlights

Stable – in metaphyseal fixation [9,13]

- Reinforcement of the bone structure in cases of tibial, metaphyseal bone defects
- High primary stability in the metaphyseal region, both for the cone itself and for the tibial component cemented in the cone
- Cementless interface with the bone for bone regeneration

Elastic – due to integral bending axes in the inner metal wall

- Mechanical compression promotes bone regeneration [5,6]
- Bending axes for adaptation to bone surfaces: oriented vertically in the cone
- Good fit ensured by structural elasticity, which also facilitates insertion of the tibial cones
- Spring effect for easier intraoperative positioning

Versatile – for a broad range of solutions [7]

- Can be combined with all the tibial components of the LINK Endo-Model knee family
- Sizes correspond to the sizes of the hinged knee prostheses
- Customized models can be manufactured

Protective – due to inner metal wall

- Prevents penetration of bone cement into the TrabecuLink structure
- Reliable cement fixation by means of specially positioned “notches” (revision-friendly)

Environmentally friendly [3,8]

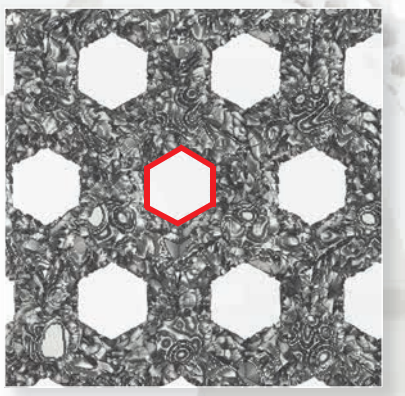
- Resource-saving manufacturing of proven Titanium alloy

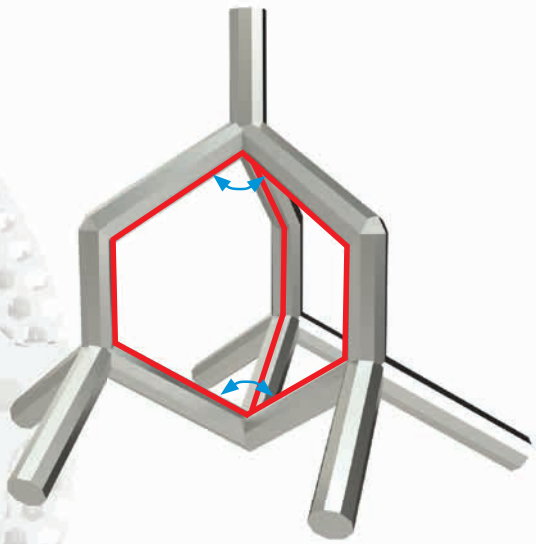
Example of a patient-specific custom-made implant

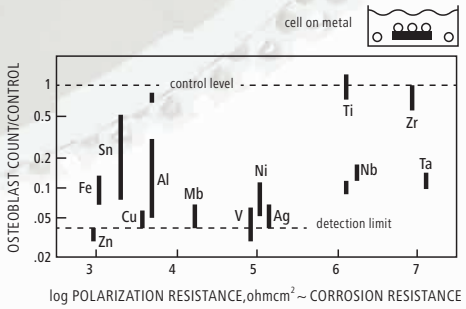
TrabecuLink

3-dimensional structure – for optimal bone ongrowth

- Pore geometry (porosity: 70%, pore size: 610-820 µm, structure depth: 2 mm) ensures excellent cell ongrowth [1,2,4]







Results of experiments with osteoblasts cultured on metal discs.

The abscissa is the logarithm of the polarization resistance of the metal, and depicts its corrosion resistance. The ordinate is the normalized cell count, also on a logarithmic scale. Growth inhibition is absent for Ti and Zr, but is strong for corrosion-resistant Nb and Ta. Growth inhibition is observed for all the less corrosion-resistant metals.[4]

Biomaterials

for joint prostheses

Biomaterials for joint prostheses should not be cytotoxic and, if intended for cementless anchorage, they should promote the deposition of bone precursor cells. On this basis, Steinemann [4] conducted tests with samples of widely differing materials in cultures with fibroblasts and osteoblasts. The result shows that titanium and zirconium were the only implant materials that supported osteoblast proliferation. Niobium and tantalum, in contrast, greatly hindered growth.[4]

Further information on this can be found in the special issue **DirectLINK 1-2017 “Periprosthetic Infections”** at https://www.linkorthopaedics.com.

1 Sizing the implant

2 Insertion of the trial cone

3 Trial reduction:

- Trial tibial component
- Trial stems
- Trial washers as required
- Trial cone
- Trial femoral component

4 Insertion of the final TrabecuLink Tibial Cone

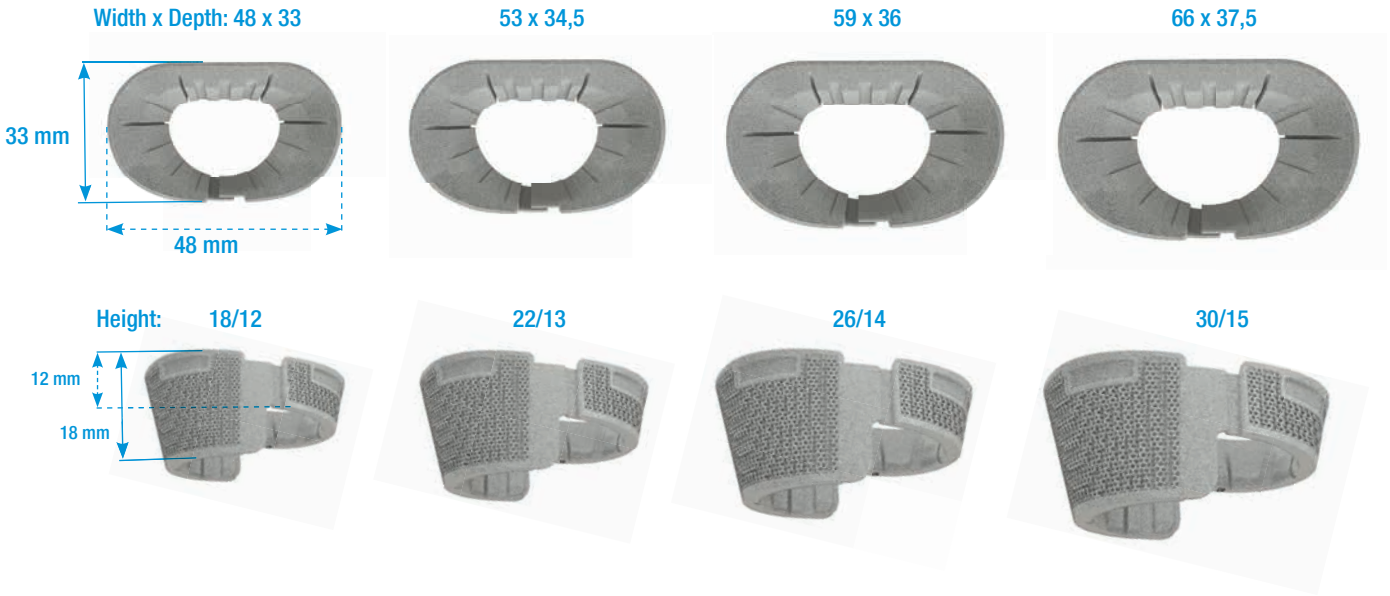
5 TrabecuLink Tibial Cone in situ

6 Cement application and insertion of the tibial component

Note: The surgical procedures for Endo-Model implants are described in the implant-specific surgical techniques.

TrabecuLink Tibial Cones

For use with Endo-Model tibial components standard and modular version,
Material: Tilastan – E (TiAl6V4)



Combination Chart:

Sizes of Knee Prostheses

Sizes of Tibial Cones	XS	S	M	L
XS	■	■	▨	▨
S		■	■	▨
M			■	■
L				■

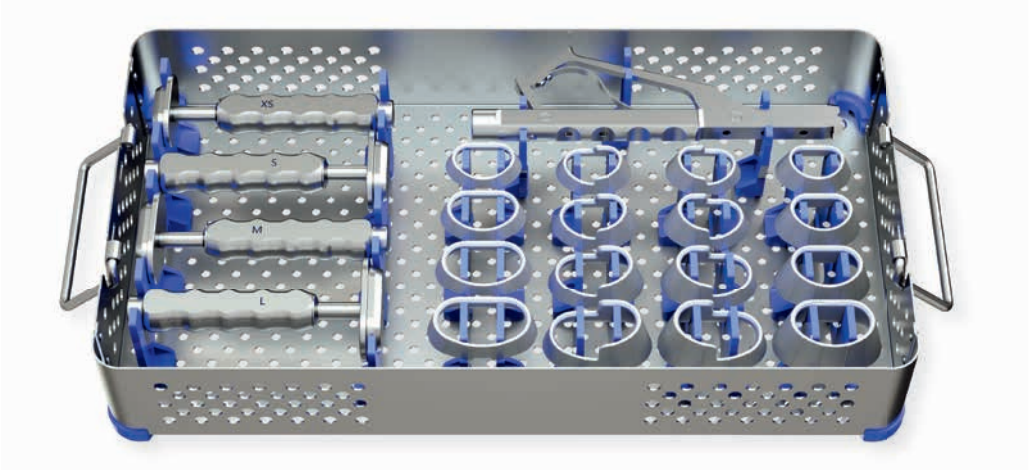
■ Combination for the entire Endo-Model knee family (Endo-Model, Endo-Model – M, Endo-Model SL*)

■ Combination only with Endo-Model and Endo-Model – M

▨ Only after prior use of all trial components and 5 mm deeper positioning (Endo-Model, Endo-Model – M)

□ This combination is not permited

* The geometry of the Endo-Model SL tibial components only allows a combination with tibial cones in the same size.



References (general)

1 Cecile M. Bidan, Krishna P. Kommareddy, Monika Rumpler, Philip Kollmannsberger, Yves J.M. Brechet, Peter Fratzl, John W.C. Dunlop. et al.; How Linear Tension Converts to Curvature: Geometric Control of Bone Tissue Growth; *PLoS ONE 7(5): e36336. https://doi org/10.1371/journal.pone.0036336* (2012)

2 Pascal Joly, Georg N. Duda, Martin Schöne, Petra B. Welzel, Uwe Freudenberg, Carsten Werner, Ansgar Petersen, et al.; Geometry-Driven Cell Organization Determines Tissue Growth in Scaffold Pores: Consequences for Fibronectin Organization; *PLoS ONE 8(9): e73545. https://doi.org/10.1371/journal.pone.0073545* (2013)

3 Dr. Malte Drobe, Franziska Killiches; Vorkommen und Produktion mineralischer Rohstoffe – ein Ländervergleich; *Bundesanstalt für Geowissenschaften und Rohstoffe Hannover; http://www.bgr.bund.de/DE/Themen/Min_rohstoffe/Downloads/studie_rohstoffwirtschaftliche_einordnung_2014.pdf?__blob=publicationFile&v=4 (2014)*

4 Steinemann SG; Compatibility of Titanium in Soft and Hard Tissue – The Ultimate is Osseointegration; *Materials for Medical Engineering, WILEY-VCH, Volume 2, Page 199-203*

5 Gerald Küntscher; Praxis der Marknagelung; *Friedrich-Karl Schattauer-Verlag (1962)*

6 R. Texhammer, C. Colton et al.; AO-Instrumente und Implantate (Technisches Handbuch); *Springer Verlag, 2. Auflage, S.25 (2011)*

7 Gabriele Panegrossi, corresponding author Marco Ceretti, Matteo Papalia, Filippo Casella, Fabio Favetti, and Francesco Falez; Bone Loss Management in Total Knee Revision Surgery; *Int Orthop. 2014 Feb; 38(2): 419–427; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3923937/ (2014)*

8 Conflict Minerals: MEPs Secure Mandatory Due Diligence for Importers; *Press release - External/international trade – 22-11-2016 - 19:07*; *http://www.europarl.europa.eu/news/en/news-room/20161122IPR52536/conflict-minerals-meps-secure-mandatory-due-diligence-for-importers (2016)*

9 Henricson A, Linder L, Nilsson KG.; A Trabecular Metal Tibial Component in Total Knee Replacement in Patients Younger than 60 Years: a Two-year Radiostereophotogrammetric Analysis; *J Bone Joint Surg Br. 2008;90:1585–1593. doi: 10.1302/0301-620X.90B12.20797 (2008)*

10 P. K . Sculco, M. P. Abdel, A. D. Hanssen, D. G. Lewallen; The Management of Bone Loss in Revision Total Knee Arthroplasty; *Bone Joint J 2016;98-B(1 Suppl A):120–4 (2016)*

11 Peter Heinl, Lenka Müller, Carolin Körnera, Robert F. Singera, Frank A. Müllerb; Cellular Ti–6Al–4V Structures with interconnected Macro Porosity for Bone Implants Fabricated by Selective Electron Beam Melting; *Acta Biomaterialia Volume 4, Issue 5, September 2008, Pages 1536–1544 (2008)*

12 Hong Wang, Bingjing Zhao, Changkui Liu, Chao Wang, Xinying Tan, Min Hu; A Comparison of Biocompatibility of a Titanium Alloy Fabricated by Electron Beam; *PLOS ONE | DOI:10.1371/journal.pone.0158513 July 8 2016, (2016)*

13 Ivan De Martino, Vincenzo De Santis, Peter K Sculco, Rocco D'Apolito, Joseph B Assini, Giorgio Gasparini; Tantalum Cones Provide Durable Mid-Term Fixation in Revision TKA; Clin Orthop Relat Res 473 (10), 3176-3182 (2015)

Important Information

Please note the following regarding the use of our implants:

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

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

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

4. **After-treatment is also very important.**
   The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. **Unless otherwise indicated, implants are supplied in sterile packaging.**
   Note the following conditions for storage of packaged implants:
- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the “Use by” date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The “Use by” date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. **Traceability is important.**
   Please use the documentation stickers provided to ensure traceability.

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

Follow the instructions for use!

Waldemar Link GmbH & Co. KG, Hamburg

Waldemar Link GmbH & Co. KG
Barkhausenweg 10 · 22339 Hamburg · Germany
Phone +49 40 53995-0 · info@linkhh.de
www.linkorthopaedics.com