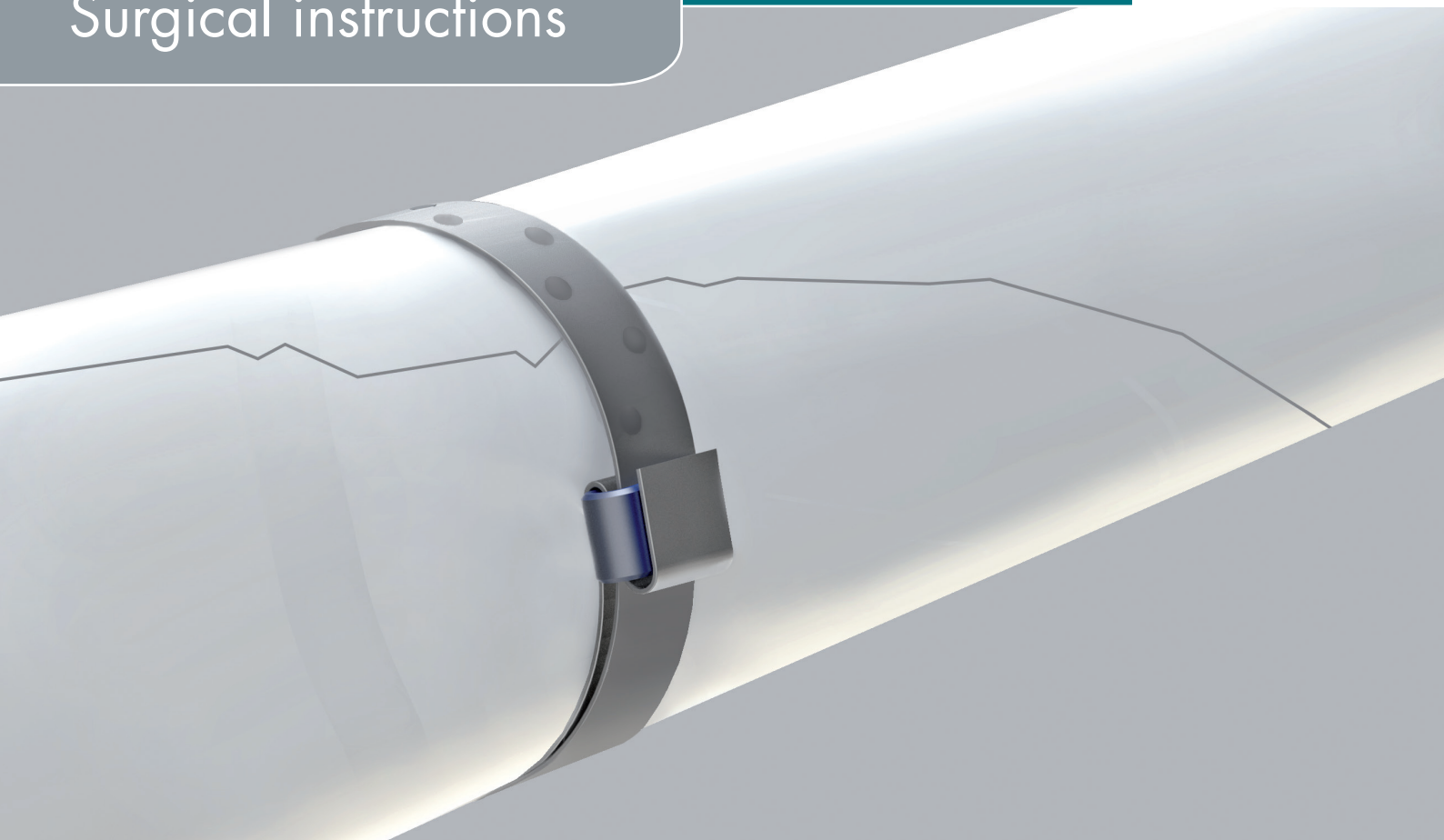


LC TITANIUM STRIP

Surgical instructions



Low-Contact titanium strip with clamp



Königsee
Implantate

Preface

Introduction

Many thanks for the trust you place in the LC titanium strip from Königsee Implantate.

This surgical instruction outlines the implantation and explantation procedure for the Low-Contact titanium strip. In addition, the surgical instruction contains general information about how to handle instruments and implants. Both documents are available in a variety of languages at www.koenigsee-implantate.com.

You must carefully read through both the surgical instruction and instruction for use before using the LC titanium strip for the first time and keep them in a safe place. We also advise that you receive instruction from an experienced surgeon to guarantee safe use of the instrument.

Qualification

To guarantee proper use, all of the instructions contained in this surgical instruction must be followed while taking into account any patient-specific requirements. In the Low-Contact titanium stripe system, all of the implants and instruments are coordinated with one another and can only be used in the area indicated.

We strongly discourage you from combining these products with other products that do not form part of the Königsee Implantate portfolio.

Safe use depends on faithful adherence to this surgical instruction the surgeon's personal specialist knowledge, as well as proper handling of the implants and instruments. Königsee Implantate accepts no responsibility for injuries and/or damages caused by errors of judgement, improper use or failure to comply with the manuals. All of the warning notices and precautionary measures listed must be observed.

If you have any questions or suggestions with regard to our products, please contact your responsible contact in the Field Service team or our Product Training department.

Use

Our implants and instruments are delivered in a non-sterile state. Please refer to the instruction for use for recommendations on cleaning and sterilisation. Please check all of the products for damage before use. Implants are only suitable for single use. Information on MRI suitability can also be found in the instruction for use.



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Goal of surgical instructions

Since titanium strip cerclages were introduced in revision endoprosthetics in 1993, their indications in traumatology (particularly traumatology of the elderly) have been expanded and very successfully too (1, 3, 4, 5).

As a further development, the low-contact titanium strip with clamp has a much greater breaking strength and lower osteointegration (which sometimes makes it much harder to remove any metal as required). Also, it does not rest entirely flat due to the knobbed surface facing the bone.

The titanium strip can be used for primary and direct fracture reduction or fracture reduction against an osteosynthesis plate.

In endoprosthetics (particularly revision endoprosthetics), the cortex - which is often weakened by primary care can be effectively and externally stabilised, there by counteracting fissures during the preparation process (7/8).

Windows created to remove the primary prosthesis can be closed with the LC titanium strip, without interfering with the intramedullary instruments or the intramedullary implant.

In the case of periprosthetic fractures with a fixed implant, plates can be stably fixed to bones, particularly in areas where even monocortical, fixed-angle screw systems can interfere with the intramedullary implant or where there is no longer a loadable cortex, e.g. in the event of Vancouver type B3 fractures (1).

At the same time, the risk of the osteosynthesis plates suffering fatigue fractures can be successfully minimised due to the frictional connections between the compression-loaded medial cortex, the tensile-loaded lateral cortex and the osteosynthesis plates fitted here.

Particularly in elderly traumatology, an equally strong hold can be achieved e.g. compared with wire or cable cerclages with a force which is selectively much lower due to the flat contact surface of the titanium strip from Königsee. The risk of the cortex being broken or of wire or cable cerclages being cut through during the reduction process, e.g. by means of reduction forceps, is therefore reduced.

All three applications can be combined, too. The following work steps are identical.

Description and selection of the implant

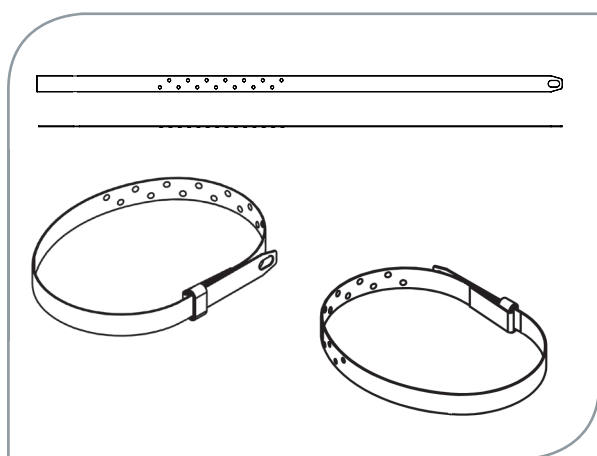


Fig. 1 item no. 7.440.01

- Material: Pure titanium
- Length 260 mm
- Width 8.0 mm
- Thickness 0.4 mm
- The side facing the bone has a knobbed structure measuring 70 mm long. The remaining surface is completely smooth.
- At one end, there is a recess for hooking the band into the bypass instrument.
- The clamp for fixing the band is situated at the opposite end.

The benefits of treatment with the LC titanium strip

- low osteointegration due to evenly distributed area forces on the bone (compared with cables and wires)
- knobs on the side “facing the bone” prevent the band from slipping and also reduce osteointegration
- periosteal circulation is only slightly impaired
- high breaking strength
- metal removal much easier compared with cables or wires
- band can be re-tensioned
- universal use on the femur and humerus

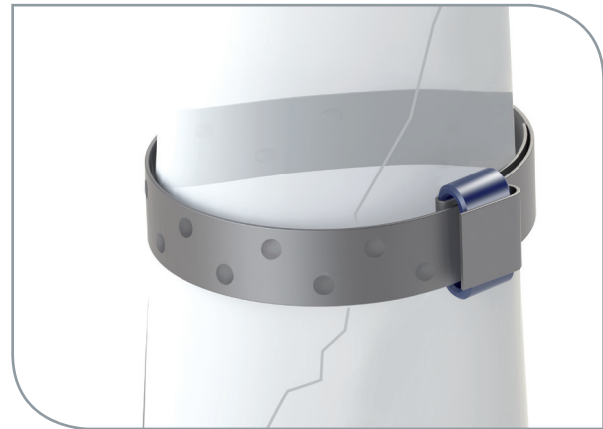


Fig. 2

Indications and contraindications

Indications

- revision arthroplasty of the femur and of the humerus respectively
- periprosthetic fractures of the femur and of the humerus respectively
- repeated stress fracture of the femur and of the humerus respectively
- age-based traumatology - osteoporotic fractures of the femur and of the humerus respectively

Contraindications

- Vancouver B2 loosened prostheses represent a contraindication for the exclusive application of the low-contact titanium strip; in any case, the prosthesis shaft must additionally be changed here.
- extensive soft tissue damage in the operating area
- inflammation in the operating area
- poor patient compliance

Warnings

- If the bone is bypassed, it must be ensured that the band is strictly guided along the periosteum to avoid any lesions on vessels, nerves or soft tissue.
- Necessary implant deformations should be observed precisely in the context of these instructions.
- Manipulation of the shape and surface may weaken the implant, thus causing product failure.
- The implant's performance features will fully develop if the patient limits their physical activities.
- You must guarantee compatibility only with application-specific Königsee products.

Introduction

Target group

- The treatment with a LC titanium strip is for adult patients.

Side effects

At the present time, this implant is not known to have any side effects. By way of precaution, we would like to point out that, as is the case with all osteosynthesis, material sensitivity or allergic reactions may occur.

Patient influence factors

- With respect to patients who regularly present with polymorbidity and who have reduced bone substance, the LC titanium strip from Königsee is a quick-to-apply, tissue-conserving and stable product which meets the particular requirements of these patients.
- Activities involving too much physical strain can lead to implant failure.
- Degenerative diseases and nicotine consumption may reduce the implant's service life and slow down the healing process.
- Tests must be performed beforehand if it is expected that the patient is sensitive to foreign bodies or has possible allergies.
- Dependencies of any kind, senility and mental illness may reduce the patient's diligence in following doctors' instructions and thus increase the possibility of complications.

Explanation of the symbols and abbreviations



CE label and number of the notified body



Read the instructions for use



Manufacturer's name and address

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Products with the add-on "™" are trademarks of Königsee Implantate.

Documents with the add-on "©" are protected by copyright.

Surgical instructions

The operation technology is generically described using the most frequent LC titanium strip application on the femur.

Positioning

The positioning depends on the relevant fracture shape. LISS positioning is advised in the event of periprosthetic femur fractures.

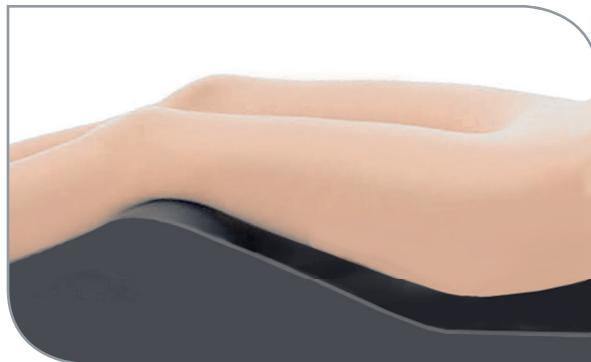


Fig. 3

Access

Access depends on the fracture type and the requirements of other implants to be inserted. We advise lateral access to the femur in the event of a periprosthetic femur fracture.

Reduction

- length reduction of the femur
- The handle (item no. 10.307.03) is assembled by pulling the quick coupling on the strip loop instrument (item no. 10.271.11/12).
- First of all, bypass the femur near the bone with the strip loop instrument.

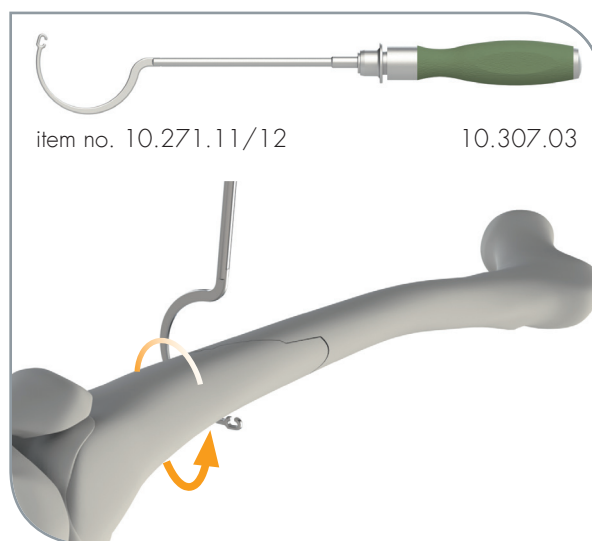


Fig. 4

Surgical instructions

Tensioning the LC titanium strip

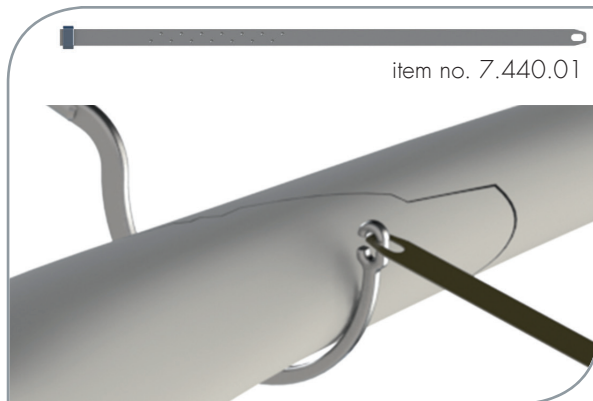


Fig. 5

- Hang the LC titanium strip (item no. 7.440.01) in the bypass hooks.

Important Ensure that the knobbed side of the band is facing the bone.

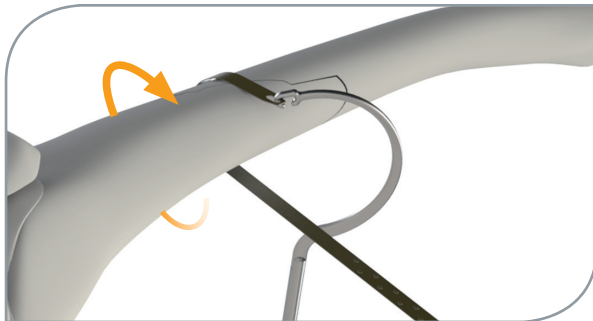


Fig. 6

- Carefully pull through the strip loop instrument.

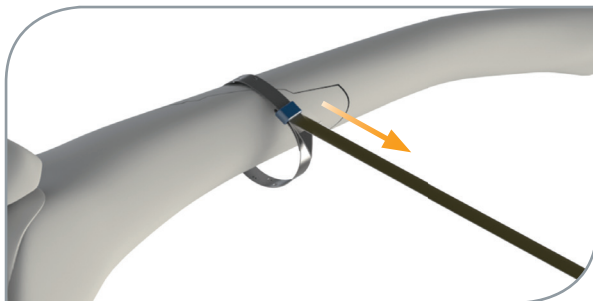


Fig. 7

- Slide the end through the clamp of the LC titanium strip.

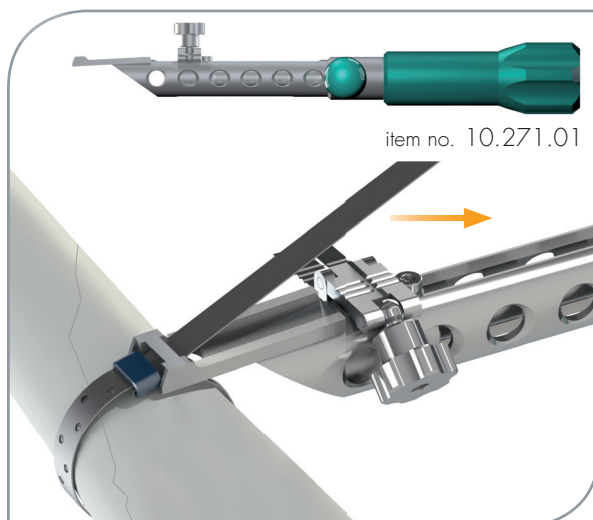


Fig. 8

- Pull the titanium band into the universal clamping device (item no. 10.271.01) and push the clamping device along as far as the clamp.

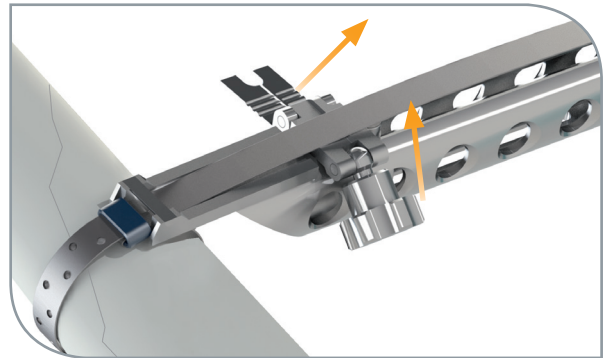


Fig. 9

- Turn the clamping piece on the universal clamping device.

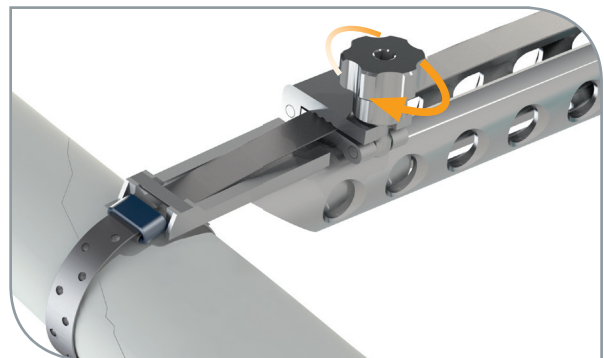


Fig. 10

- Slowly tension the strip and reduce the fracture. Unlike when using reduction forceps, selective pressure points on the bone are thus avoided.
- The strip is sufficiently tensioned if the universal clamping device can no longer be turned with moderate force.
- Care should be taken to ensure that the clamp remains in the wound's inspection window.

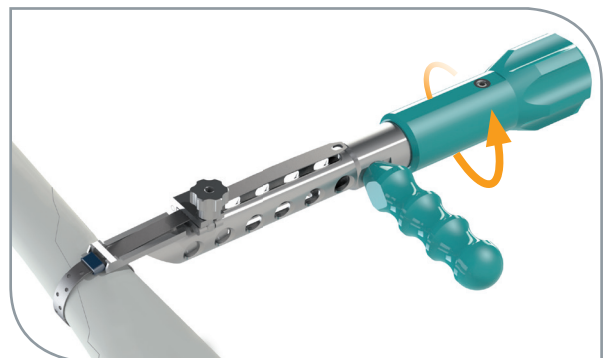


Fig. 11

Note

- Alternatively, an osteosynthesis plate can be fixed to the bone in the same way, firstly in areas where fixed-angle, monocortical anchoring is also not possible due to intramedullary implants and poor bone substance, and secondly to prevent plate breakage caused as a result of the osteosynthesis plate being positioned close to the fracture and there being frictional connections between the compression-loaded and bending-loaded sides of the bone.

Surgical instructions

Fastening the LC titanium strip

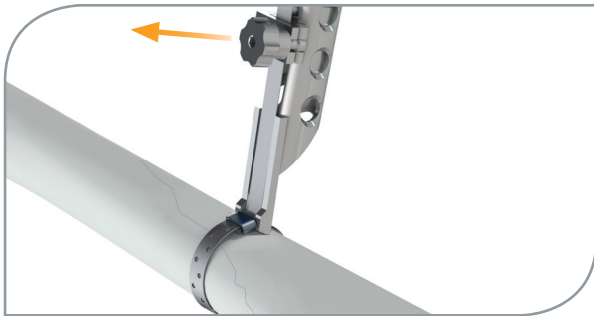


Fig. 12

- Move the universal clamping device 90° to the clamp.

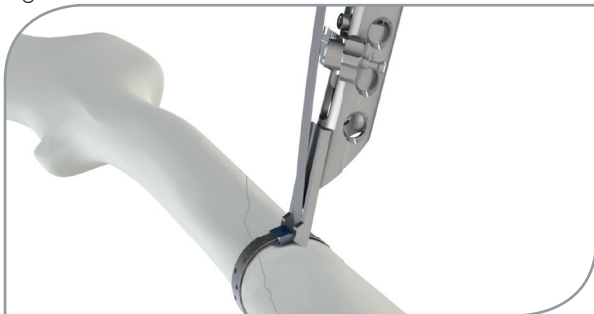


Fig. 13

- Loosen the universal clamping device and remove it.

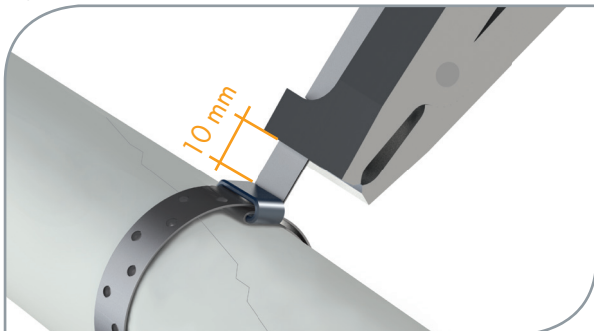


Fig. 14

- The titanium strip must be set down approx. 10 mm from the clamp with the power cutter (item no. 10.271.05).

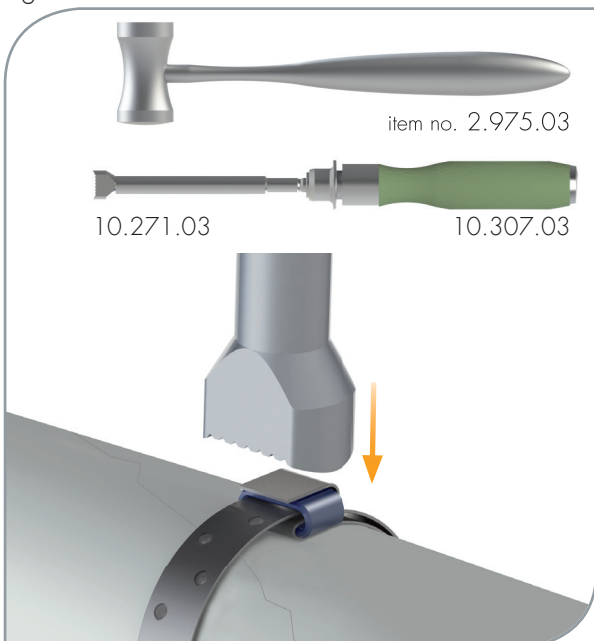


Fig. 15

- Use a pestle (item no. 10.271.03) with handle (item no. 10.307.03) and a metal hammer (item no. 2.975.03) to press the remaining projection towards the clamp by a further 90°.

The wound is closed in layers.

Sample cases

Pre-operative, sample case 1



Fig. 16

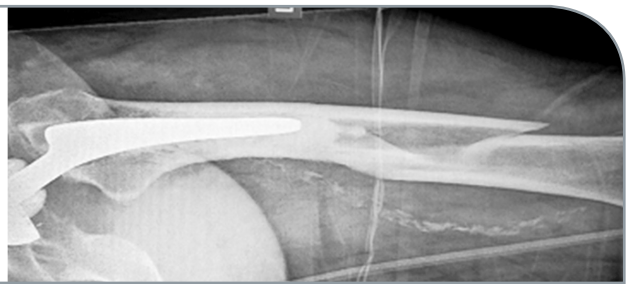


Fig. 17

65-year-old man

The leg twisted when standing up from a stool. Personal medical history: PAOD, ankylosing spondylitis, Crohn's disease, diabetes mellitus, art. hypertension, COPD

- Check after 10 weeks of mobilisation with partial weight bearing

Postoperative, sample case 1



Fig. 18

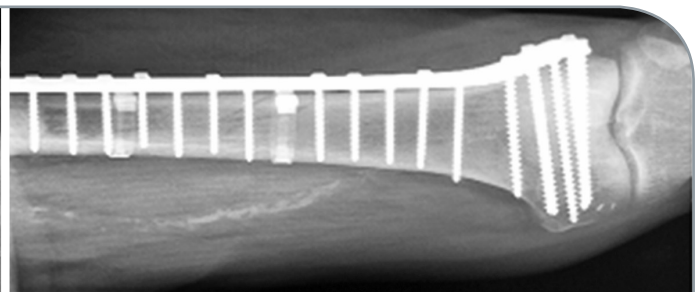


Fig. 19

- Check after five months, pain-free with full weight bearing, former activity level and mobility achieved

Pre-operative, sample case 2

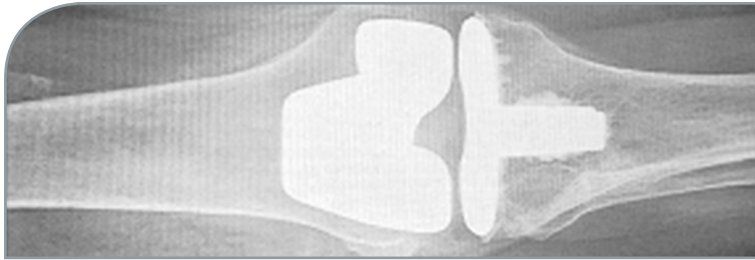


Fig. 20

59-year-old woman

Pain when moving from her wheelchair

Personal medical history: Rheumatoid arthritis

Renal failure requiring dialysis



Fig. 21

Diabetes mellitus

Condition after hip TEP on both sides and knee TEP on both sides. With multiple revision operations due to the hip TEP dislocating.

Postoperative, sample case 2

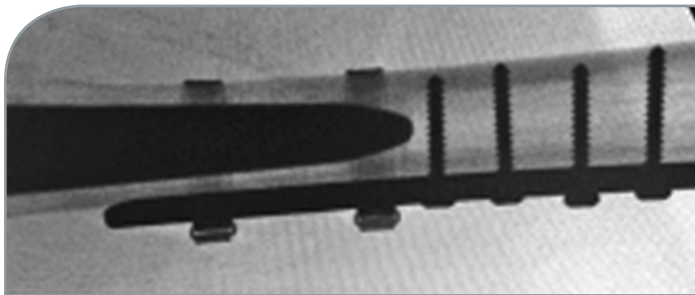


Fig. 22

Three weeks postoperative, pain-free and mobile with 20 kg partial weight bearing

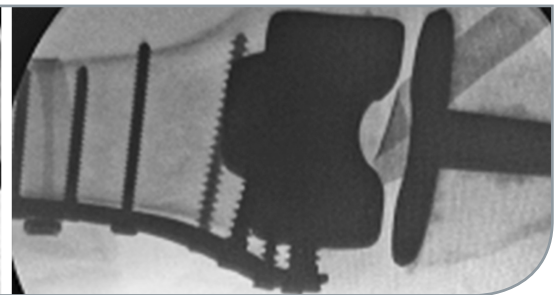


Fig. 23

Pre-operative, sample case 3



Fig. 24

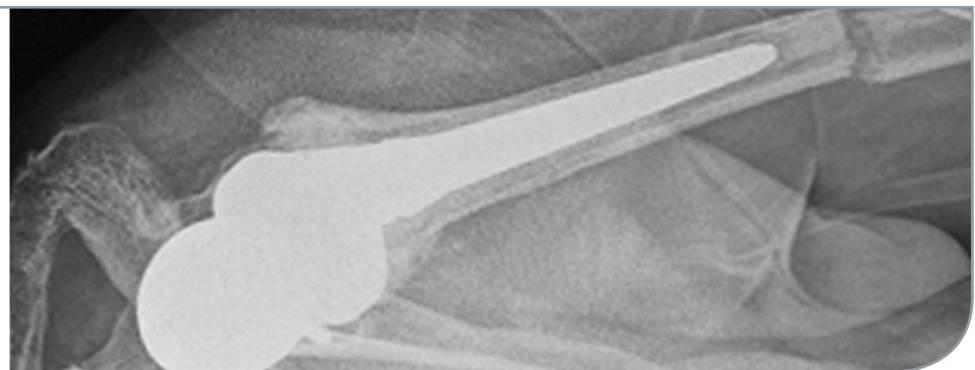


Fig. 25

81-year-old woman after falling down stairs and implantation of an inverse shoulder prosthesis one year

beforehand, auricular fibrillation with Marcumar treatment, dementia, art. hypertension, renal failure

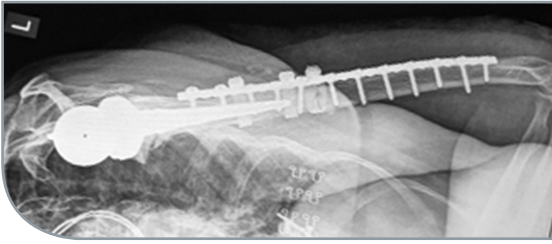


Fig. 26

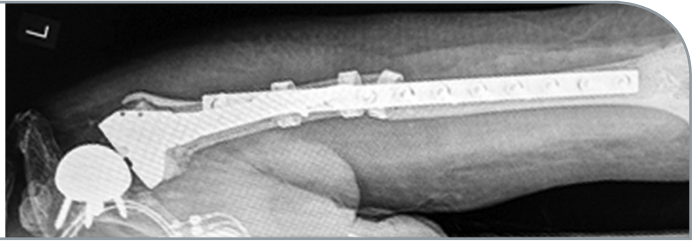


Fig. 27

Postoperative checks. Pain in the arm again six months after treatment, elbow freely mobile, shoulder mobility as after implantation of the inverse prosthesis

After-treatment

Depending on how stable the osteosynthesis is, functional after-treatment with ground contact at the very least should be aimed for.

Implant removal

The metal is easily removed using a side cutter and flat-nosed pliers, by either bending the LC titanium band backwards and pulling it through the clamp or by cutting through it.




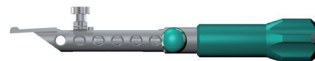
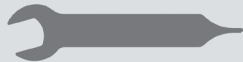

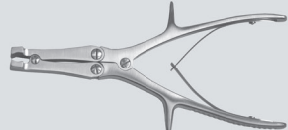


Ordering information

LC titanium strip with clamp; item no. 7.440.01



7.440.01

LC titanium strip with clamp

Item description	Item no.	Quantity	Figure
Implants			
LC titanium strip with clamp; 8.0 mm x 0.4 mm; length 260 mm	7.440.01	5	
Instruments			
Strip loop instrument; 1/4"-coupling; straight; Ø 45 mm; length 205 mm	10.271.11/45	1	
Strip loop instrument; 1/4"-coupling; straight; Ø 65 mm; length 255 mm	10.271.11/65	1	
Strip loop instrument; 1/4"-coupling; beveled; Ø 45 mm; length 175 mm	10.271.12/45	1	
strip loop instrument; 1/4"-coupling; beveled; Ø 65 mm; length 185 mm	10.271.12/65	1	
Universal clamping device	10.271.01	1	
Assembly and disassembly tool for universal clamping device; length 145 mm	10.271.02	1	
Pestle for LC titanium strip 8.0 mm x 0.4 mm; 1/4"-coupling; length 125 mm	10.271.03	1	
Power cutter	10.271.05	1	
Handle with 1/4"-coupling; length 162 mm	10.307.03	1	
Metal hammer; weight 300 g	2.975.03	1	

References and picture credits

Product photos and 3D representations

www.koenigsee-implantate.com

Dr. med. Stefan Hegemann

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CE 1275

certified according to
EC directive 93/42/EEC
DIN EN ISO 13485

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