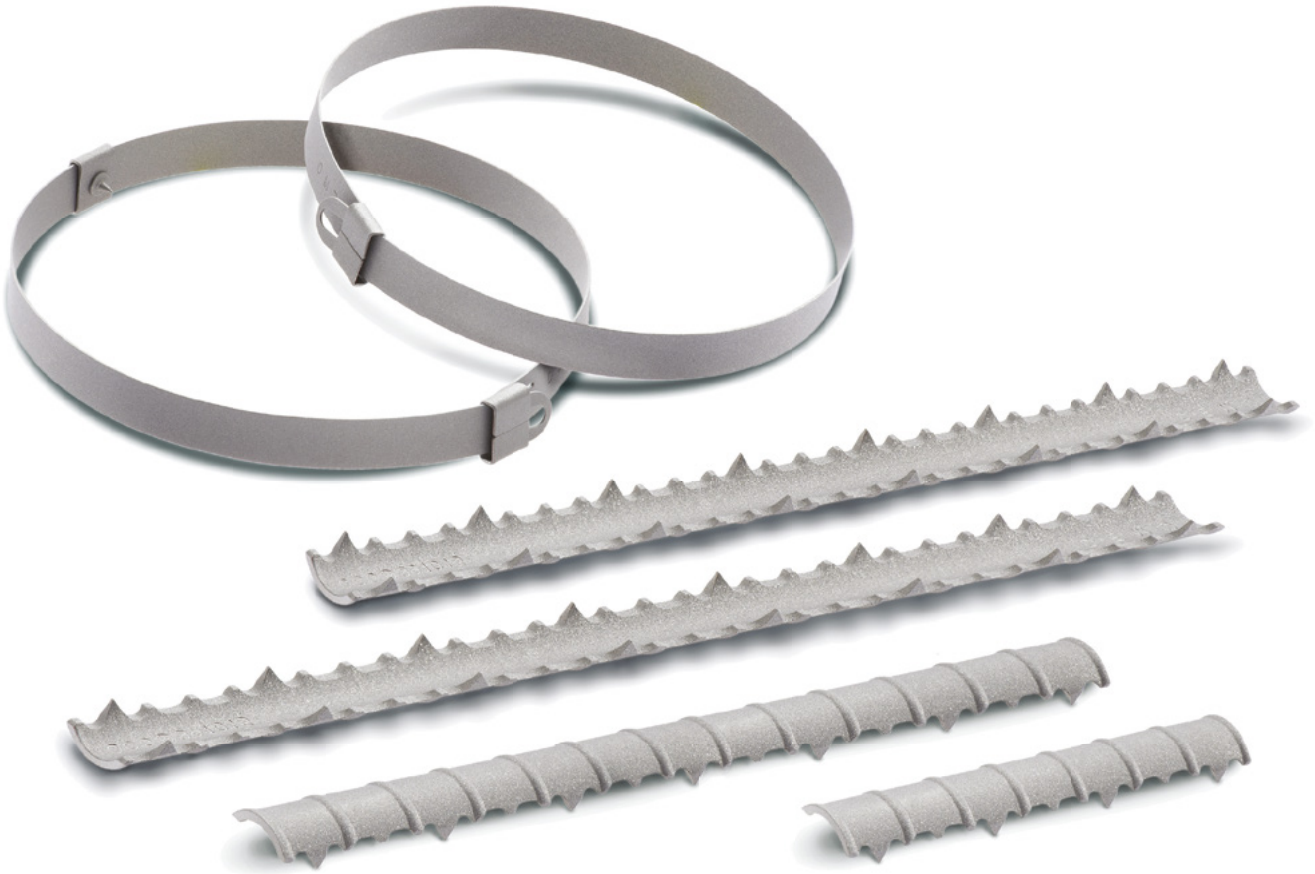
ImplanTec
SURGICAL TECHNIQUE

hbmedical



CCG® - THE COMPRESSION CERCLAGE AND STABILISATION SYSTEM

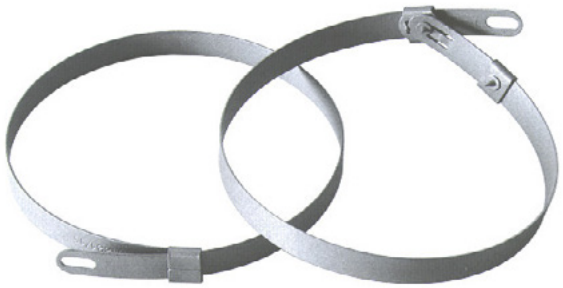
TABLE OF CONTENTS

THE CCG® - CERCLAGE SYSTEM

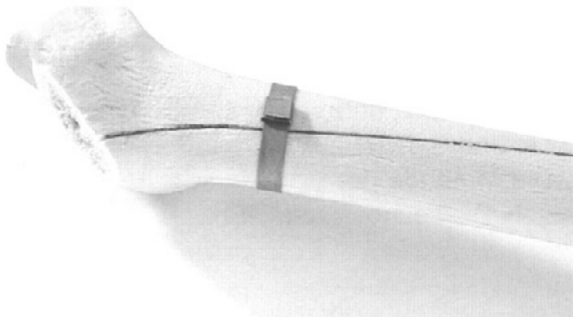
The CCG® system was developed by Dr. Ferdinand Gundolf in the year 1993 in Kufstein (Tyrol). It consists of biocompatible titanium bands with a broad contact face so that the bone is not constricted and the blood flow is not disrupted either, as well as titanium stabilisers that are capable not only of primarily stabilising the bone, but also of strengthening it sustainably through osseo-integration of the rough titanium surfaces.

Since its introduction, the CCG® system has internationally established itself impressively in a broad range of indications. In addition to traumatology indications, the CCG® system has proved itself especially in the area of hip revision surgery as a protection from fissures when reaming the new implant bed, and as a corticalis reinforcement.

The clinical successes in the last 20 years confirm the concept and have made the Gundolf Compression Cerclage system one of the leading cerclage systems.



The CCG® system consists of the CCG® band and the CCG®-GF band. The CCG®-GF band was primarily developed for conical bones, notably the proximal and distal ends of the femur.



LARGE BONE CONTACT SURFACE

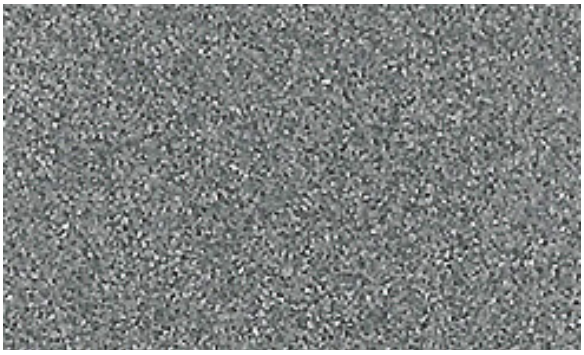
Thanks to the large surface area, the disadvantages of a cerclage wire can be eliminated. The CCG® cerclage does not cut into the bone and allows for controlled compression.

ONE SIZE

With a length of 27 cm, the CCG® cerclage is long enough to go around the greater trochanter as well as thinner bones. The continuous adjustability allows application for all diameters of long bones which contributes to a substantial simplification of inventory.

MATERIAL AND SURFACE ROUGHNESS

The CCG® und CCG®-GF band are manufactured from pure wrought titanium according to EN ISO 5832-2. The rough blasted surface has a mean roughness of 2–4 µm which supports osteointegration of the band.

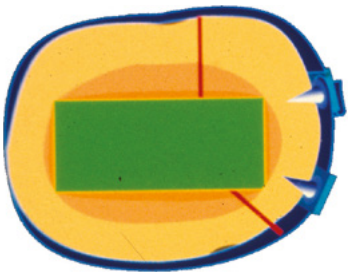


CCG® BAND WITH LINKAGE AND FIXATION SPIKES

As the band fastener is rotatable the band can be shaped to fit conical bones shape with minimal surface compression.

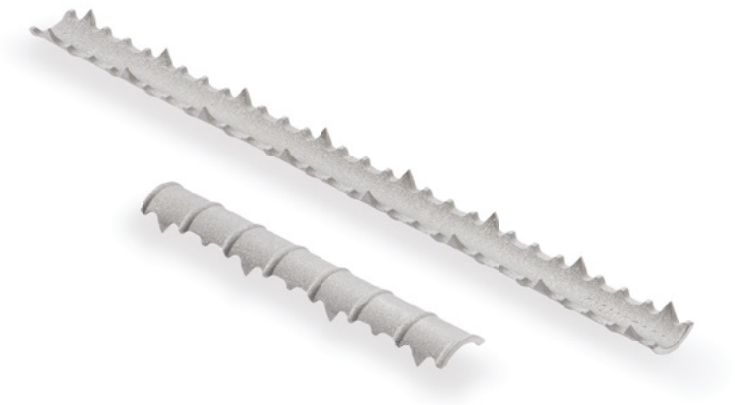
The fixation spikes prevent the band from slipping down the bone and secure loose pieces of bone such as fracture segments or bone chips in position. In particular, the fixation spikes reduce the risk of axial slippage of the greater trochanter after osteotomy utilising Dr. Gundolf's technique.

In principle, the CCG® system can be used in all circumstances where a cerclage wire would previously have been employed. Wire cerclage has well known shortcomings: wire breakage is relatively frequent; furthermore, the wire can cut into the bone and then ceases to exert adequate compression.



DESIGN FEATURES

The CCG® Stabiliser consists of a curved element manufactured from commercially pure titanium according to ASTM F67. The stabiliser is firmly attached to the bone by CCG® Compression Cerclage bands. The CCG® Stabiliser is locked to the bone by little spikes along the edges which penetrate into the bone to a controlled depth.



The excellent primary stability of the CCG® System on the bone is due to the frictional resistance between the CCG® bands and the stabilisers, the stabiliser spikes anchored in the bone, and the CCG®-GF bands, fixation pins.

The secondary stability of the CCG® System is a result of the osseointegration of the CCG® bands and CCG® Stabilisers, achieved through the boneinducing effect of the rough titanium surface. The bone can penetrate though the apertures between the spikes, where it finds ideal conditions for ongrowth on the roughened inside of the curved surface. Osseointegration takes place within a short time, leading to the ingrowth of the CCG® band and CCG® Stabiliser.

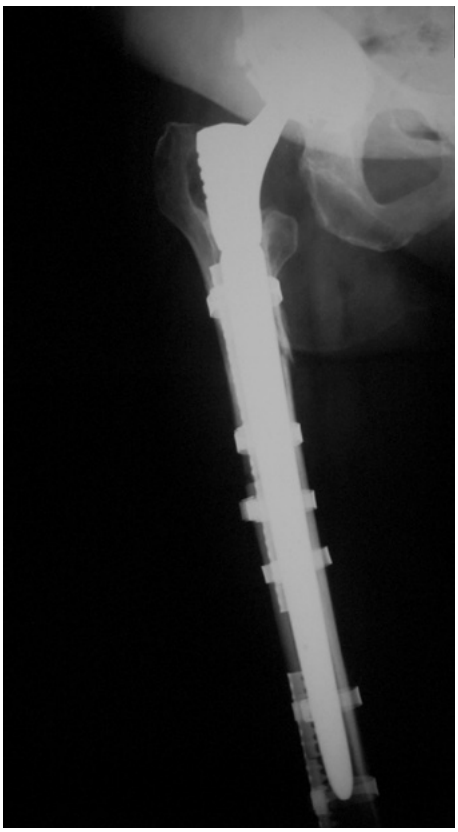
This process prevents any micromovements between the CCG® Stabiliser and the CCG® bands, thereby excluding titanium abrasion on the contact surfaces.

NEW ALTERNATIVES FOR HIP REVISION SURGERY

In addition to the intramedullary support by the hip stem, the combined CCG® System provides an effective external reinforcement of the cortical bone and thus effectively becomes a functional part of the weakened cortical bone. Contrary to an endoprosthesis with a screwed plate there is no conflict between screws and the stem of the prosthesis.

NEW ALTERNATIVES FOR TRAUMATOLOGY

In isolated fractures of the femur it is possible to achieve stable load-bearing osteosynthesis with CCG® Stabilisers. Due to the adaptive mode of fixation the system is well suited for geriatric bone surgery and may also serve as a last resort for very elderly patients.



While the CCG® Stabiliser achieves the load-bearing stability of a conventional bone plate after 4 - 6 weeks, it differs substantially from the latter through the preservation of elasticity and consequently the vitality of the supported bone.

The CCG® system is suitable for particular forms of osteosynthesis, particularly for cerclage of the greater trochanter and femur associated with revision to hip arthroplasties. In contrast to cerclage wires, the CCG® compression band allows a functional compression to be achieved. It is assumed that an implant revision is already indicated in this connection.

INDICATIONS

- Reattachment of the greater trochanter
- Bone support in case of a damaged proximal femur (e.g. by bone cement, loosened stem, or polyethylene wear particles), with a possible cancellous bone graft in the proximal femur area.
- Cerclage of bone fissures.
- Fracture protection during rasping of a new prosthetic canal and prior to implantation of a new stem.
- Closing of cortical fenestration.
- Fractures in the area of the femoral prosthesis stem.
- To improve bone-implant contact.

In general, CCG® and CCG®-GF have the same function. In the case of conical shape of the bone, primarily above the lesser trochanter, the CCG®-GF is indicated rather than the CCG®. CCG® stabilisers are specially indicated in fractures and shaft fissures in which the use of CCG® bands alone would not grant sufficient stability.

Generally, use of the CCG® band as preventive shattering protection is recommended for:

- dysplastic cases
- obvious osteoporosis
- older patients

Fissures and bone shattering caused by stem implants can be stabilised with the CCG® band under strict observation of the osteosynthesis rules.

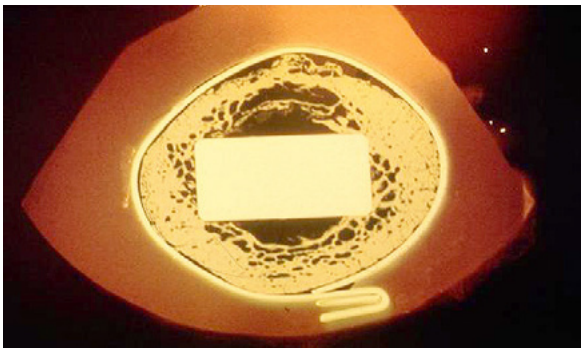
CONTRAINDICATIONS

- An implant of suitable design and length is a prerequisite for a successful use of the CCG system in hip revisions. Complications such as unstable implantations, implant subsidence, stem and prosthesis breakage cannot be prevented entirely by the CCG system. Therefore CCG is not indicated in such cases.

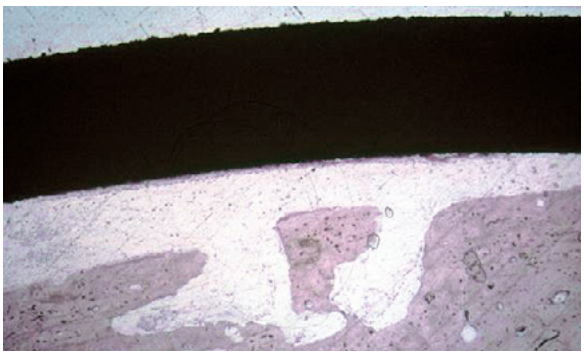
- The CCG system is not indicated in cases with large defects of the cortical bone and hence unavoidable contact with the implant which would lead to metal wear.

HISTOLOGY

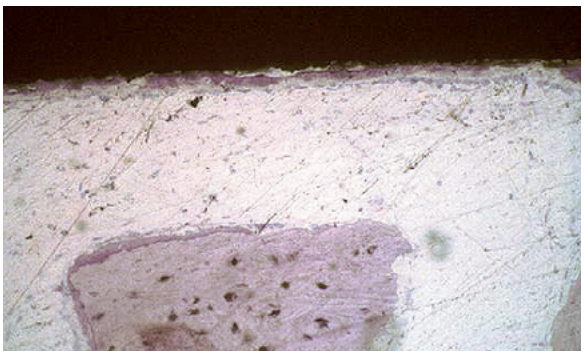
Institute for Pathology and Bacteriology, Vienna, Baumgartner Höhe 1, A-1145 Wien, MedicalDirector: Prim. Univ. Prof. Dr. F. Lintner.



MICRORADIOGRAPHY
THREE WEEKS POSTOPERATIVELY
The titanium band is firmly and uniformly positioned on the bone of the femur. No evidence of necrosis.



DETAIL FROM HISTOLOGICAL SECTION
THREE WEEKS POSTOPERATIVELY
On the inner surface of the titanium band, separate from the bone of the femur, there is an elongated ridge of bone occupied by osteoblasts. Ground section, not decalcified, toluidine blue staining



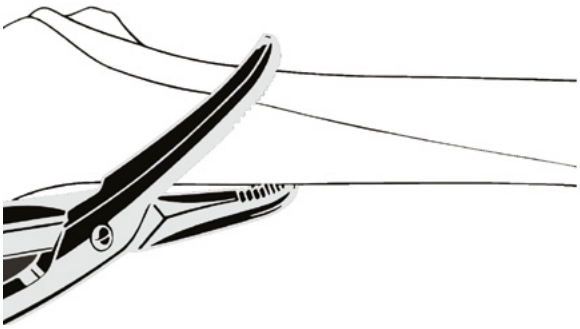
DETAIL FROM THE HISTOLOGICAL SECTION
ENLARGED
PICTURE ABOVE
The osteoblastic line on the inner side of the titanium band and the bone of the femur provides evidence of the tendency towards union or bone healing.

CCG®-BAND

The number of the required bands depends on the indications: as a fracture protection, one band in the area of the implant tip is sufficient. In cases with weakened bone or during removal of the greater trochanter, several bands may be necessary – one in the trochanter area, one in the lower third of the prosthesis, and, should the distance be too long, one in between.

Please consult the special surgical technique for surgeries including the removal of the greater trochanter. Documentation Dr. Gundolf No. 87

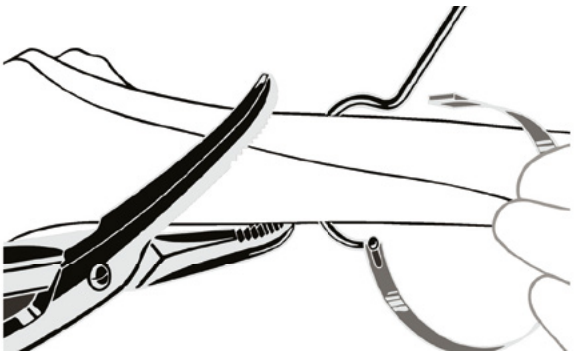
The bone fragments which are to be fixed need to be brought together with repositioning forcepts. Repositioning cannot be accomplished by the CCG® band.



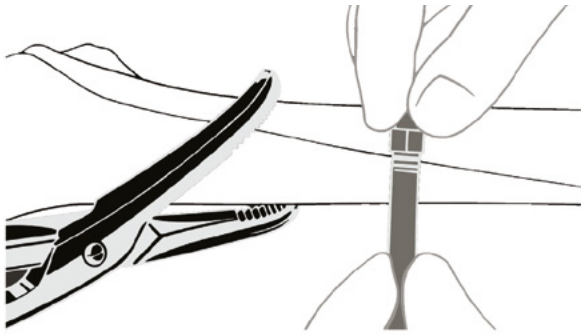
The bone needs to be subperiostally uncovered at the cerclage site with a small rasp or a curette.

The bone must not be exposed by the loop awl.

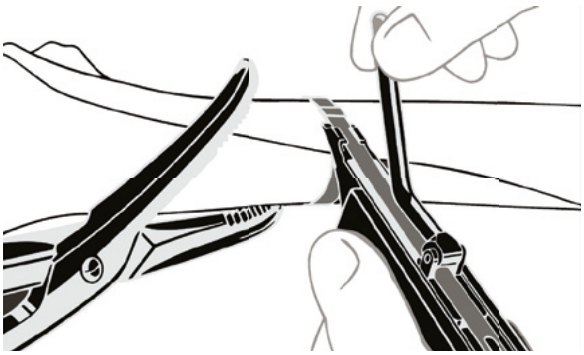
Introduce the CCG® loop awl, maintaining contact with the bone by palpation. When using the CCG®-GF band, slide the moveable spike into a suitable position.



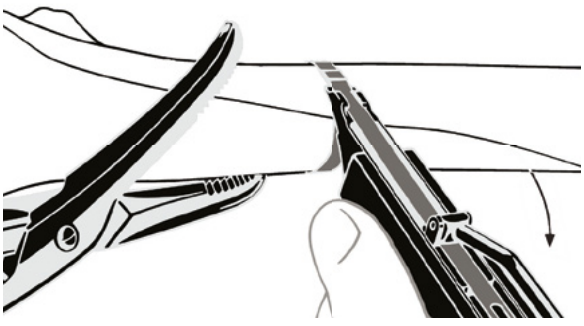
Hook the ends of the band together, taking care that the band fastener faces outwards. Then carefully tighten the band.



Insert the CCG® band through the clasp and tighten it by hand. A slight pressure on the clasp will prevent the band from sticking.

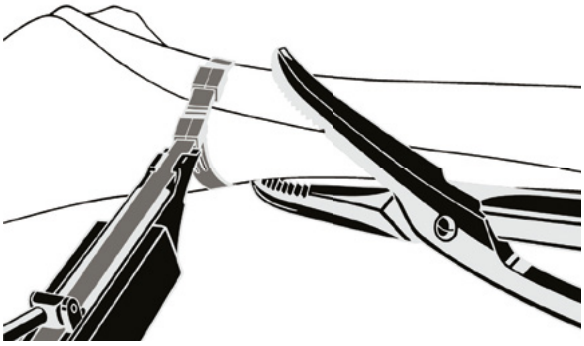


Bring the carriage of the cerclage tightener all the way to the front by turning the knob on the handle counterclockwise. Insert the CCG® band into the cerclage tightener, pull it tight and secure it with the lever.



The compression is carefully carried out by turning knob on the handle clockwise with thumb and index finger only. The intended compression has been achieved when the band cannot be tightened further.

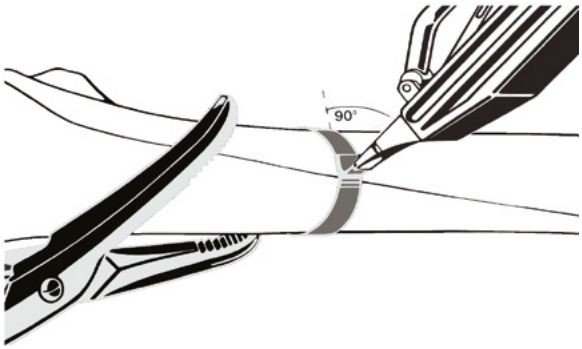
When the CCG®-GF band is being fitted to a bone of conical profile, of the surgeon positions one or more spikes then tightens the band exactly as described above.



To adapt it to the conical profile, the band which has been inserted into the CCG® cerclage device is turned within the rotatable band fastener in the direction of the bone end, until it visibly conforms to the conical profile.

ATTENTION Excessive tightening force may cause undesirable overcompression and breakage of the band. If the cleft in the band begins to open, the permitted degree of compression has already been slightly exceeded. The compression must not be increased any further.

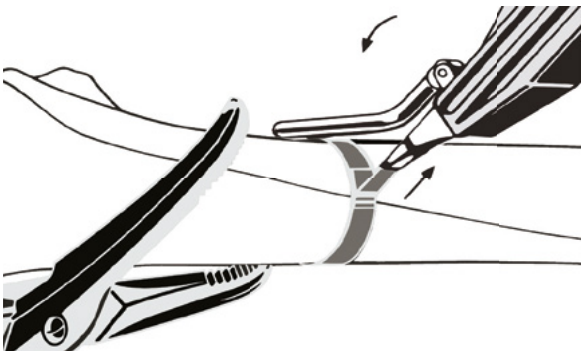
The CCG® band is constructed in such a way that the cleft will rupture before it damages or destroys the bone by overtightening.



Bend the CCG® cerclage tightener and the band slowly and to not more than a maximum of 90°!

ATTENTION The bending operation must be carried only just far enough to prevent the band from slipping back. Any excessive or rapid bending movement beyond 90° could cause overloading due to increased tension while bending moments may break the CCG® band. After removing the CCG® cerclage tightener, further bending should be performed with the CCG® fixator. At this stage there is no risk of breakage.

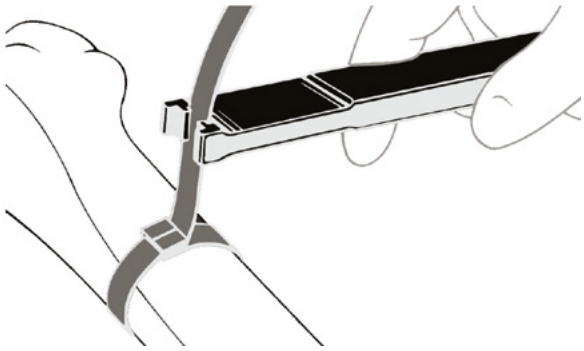
Special emphasis is placed upon the need to avoid this serious technical error.



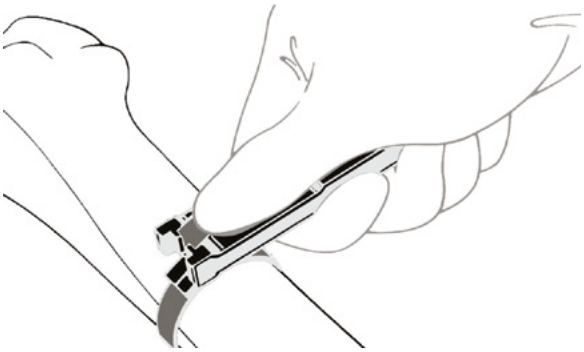
Loosen the lever and remove the CCG® cerclage tightener.

Fit the CCG® fixator on to the CCG® band and bend the CCG® band backwards.

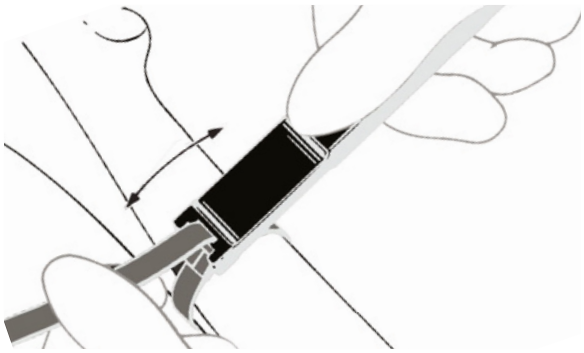
Use of the CCG® fixator is the best way of avoiding breakage of the CCG® band while bending it backwards, and prevents any incorrect shortening of the band.

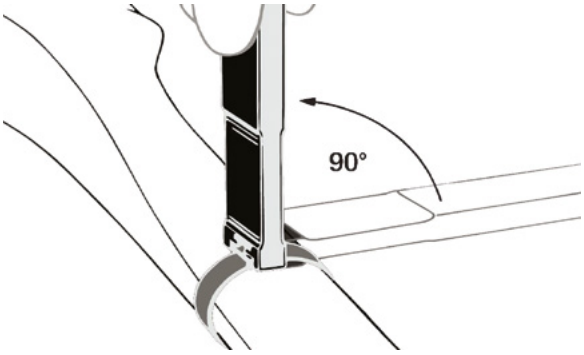


Bend the CCG® band over and press it firmly into the cutting edge of the fixator with a thumb.

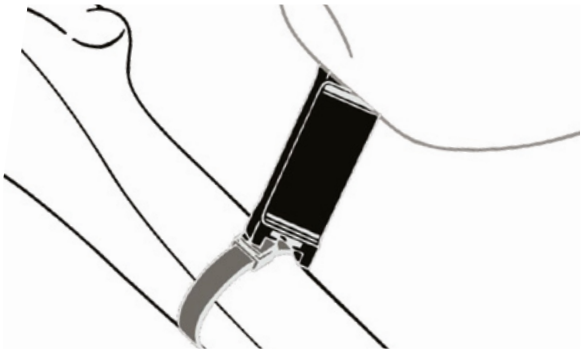


Move the band back and forth a few times until it breaks off while the other hand holds the CCG® fixator.





Bend the end of the band over by slowly straightening the CCG® fixator by 90°. Then pull the CCG® fixator off.

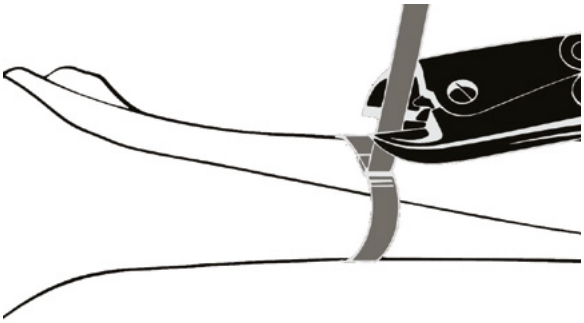


Apply the CCG® fixator with a stirrup to the middle of the band end and drive the end into place.

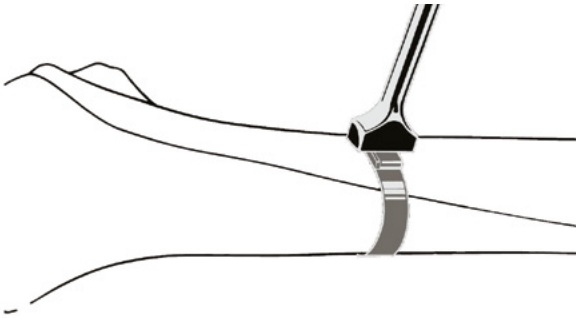
ATTENTION A band which has been applied and has to be removed again must never be reused. The cerclage must be repeated with a new band.

HANDLING WITH THE WIRE CUTTER AND IMPACTOR

Instead of using the CCG® fixator, cut off the CCG® cerclage with wire cutters about 1 cm above the clasp.

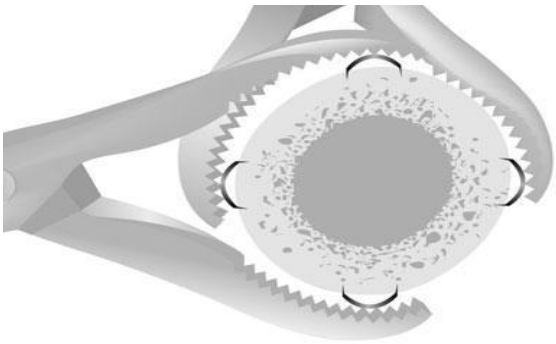


Then bend the end of the band over the clasp and use an impactor to fix it in place.

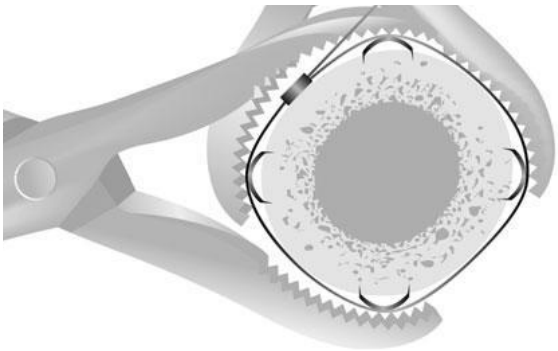


CCG®-STABILISER

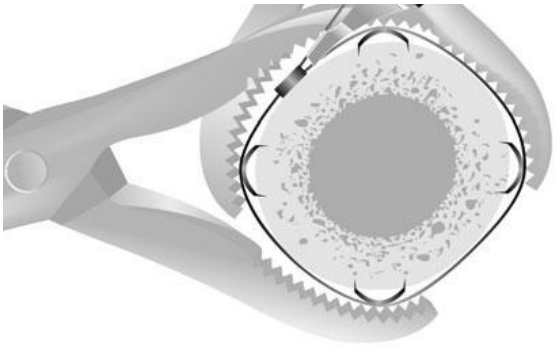
The CCG® Stabiliser is to be used only in conjunction with the CCG® bands.



The correct choice of length and number of stabilisers depends on the cortical bone to be supported. A single CCG® Stabiliser is sufficient only in the case of intramedullary implants, such as prosthetic stems. 3 to 4 stabilisers are required for osteosynthesis, with two on opposite sides in each case. It is advisable to use two stabilisers on opposite sides to secure stress areas, e.g. at the prosthetics tip.
The length of the stabilisers is chosen depending on the structure of the bone. In case of doubt the next length up should be selected.



The stabilisers are positioned in the longitudinal direction axially to the bone and secured with reduction forceps pressing the anchorage spikes into the bone. The first CCG® band should be applied with the reduction forceps still in place.
Once one end has been encircled the reduction forceps should be applied to the other end of the stabilisers, where the procedure is repeated. Reduction forceps should also be used for pre-fixing when placing the inner cerclage bands where, again the stabiliser spikes should be pressed into the bone. In this way the stabiliser adapts to the curvature of the bone.

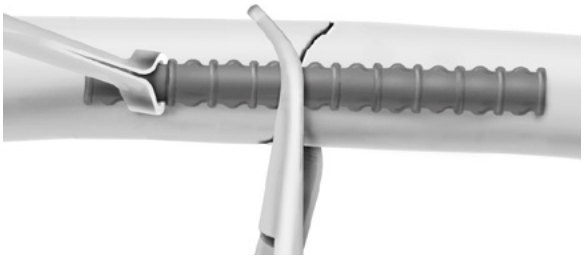


When using CCG®-GF bands it is important to ensure that the pin of the fixed loop at the end of the band is placed on one side of the stabiliser and the pin of the sliding loop on the other.
In this way the stabiliser adapts to the bone curvatures.

When using several stabilisers it is important to ensure that they are positioned in parallel, and opposite to one another whenever possible. Contact between stabilisers must be avoided in all cases.

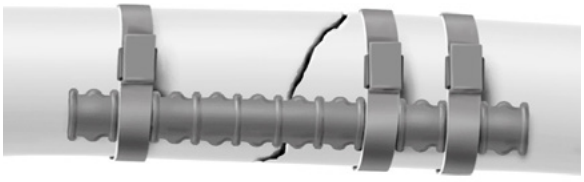
The CCG® Stabiliser should be positioned so that direct contact with other metal implants is avoided.

The spikes along the edges of the CCG® Stabiliser are pressed into the bone with the reduction forceps and, if necessary, tapped in with light hammer blows.



It is also recommended to tap the pins of the CCG®-GF band carefully with a hammer in order to fix them to the bone.

The CCG® bands have to be placed between two ribs at 90° to the CCG® Stabiliser. The bands should be applied to the bone with the periosteum completely stripped. In fractures one or two bands should be placed over the fracture line.



POSTOPERATIVE TREATMENT

The postoperative treatment depends on the surgical result. In principle, mobilisation can be started early after implantation. The mobilisation options, such as partial weight, full weight, crutches, three-point gait, four-point gait, etc., are based on the recommendations by the surgeon. Thereby the patient's condition and bone quality are always taken into account. Physiotherapy during the stay in hospital is certainly recommended.

STERILISATION

IMPLANTS

All the implants described in this surgical technique are delivered in sterile condition by the manufacturer. Re-sterilisation is not permissible.

INSTRUMENTS

The system elements and instruments are delivered in unsterile condition. These must be cleaned, disinfected and sterilised using a validated method before use. The cleaning manual (Lit. Nr. 860501) includes a validated procedure for the preparation of a medical device for its reuse.

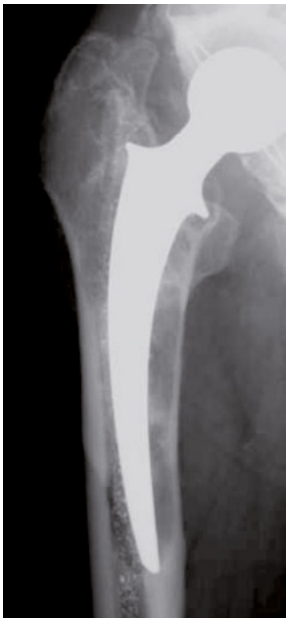
The operator is responsible for achieving the desired results with the procedure actually performed and the equipment, materials and staff used in the treatment facility. This usually requires a validation and routine monitoring of the method.

The instrument manufacturer and dealers do not accept liability for sterilisation of the products by the buyers.

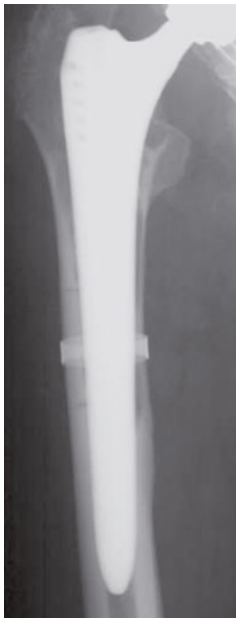
1 REVISION - STEM REPLACEMENT

Switch from a cemented prosthesis to a cementless rev straight-stem prosthesis. Fenestration closure with a CCG band.

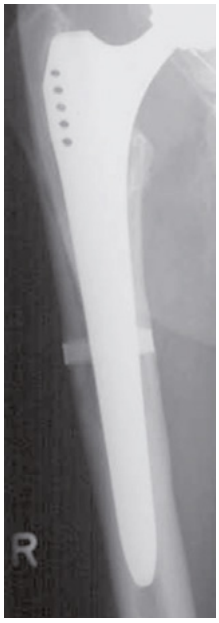
Preoperative x-ray



Postoperative x-ray



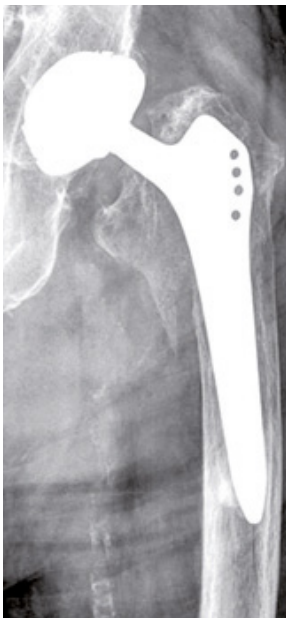
Follow up 2 years



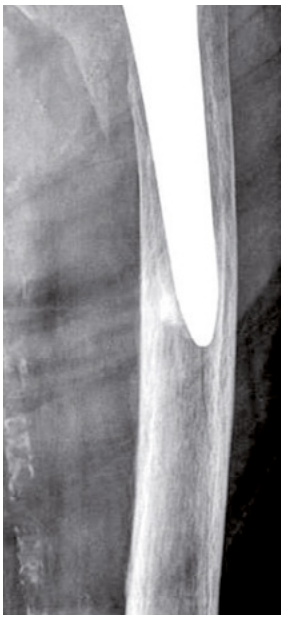
2 PERI-PROSTHETIC FRACTURE

Peri-prosthetic fracture of an HTEP in situ for 30 years. Implantation of a long-stem prosthesis. The weakened corticalis is stabilised with 2 CCG® stabilisers and 9 CCG® bands. The CCG® system is also used for protective cerclage in the distal cortical anchoring area.

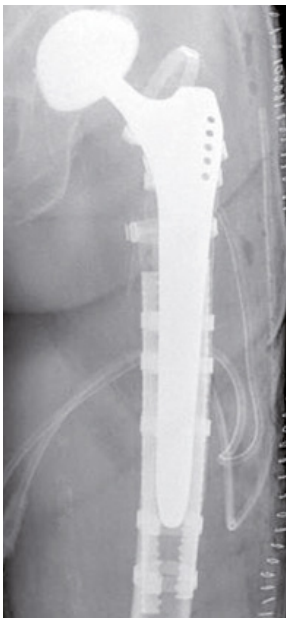
Preoperative x-ray



Preoperative x-ray



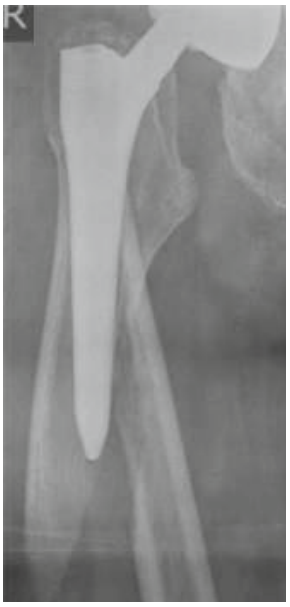
Postoperative x-ray



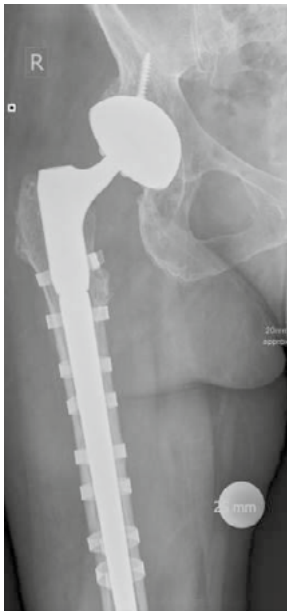
3 PERI-PROSTHETIC FRACTURE

Treatment of a peri-prosthetic fracture with a revision long-stem prosthesis. For additional splinting of the fracture zone from the outside, 1 CCG® stabiliser and 8 CCG® bands are applied.

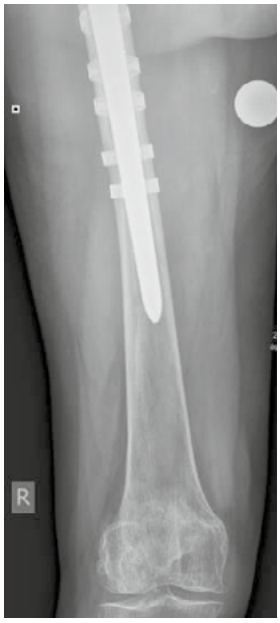
Preoperative x-ray



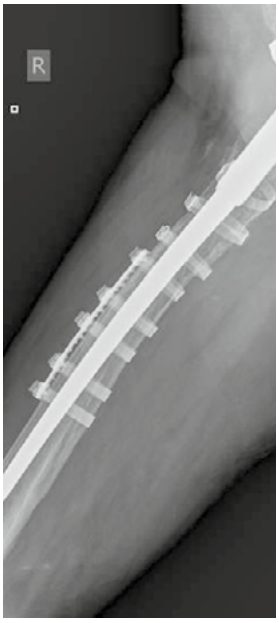
Postoperative x-ray a/p



Postoperative x-ray a/p



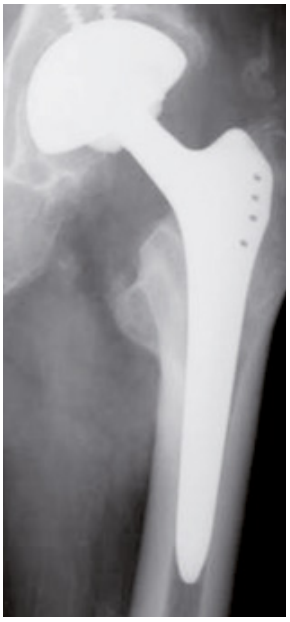
Postoperative x-ray axial



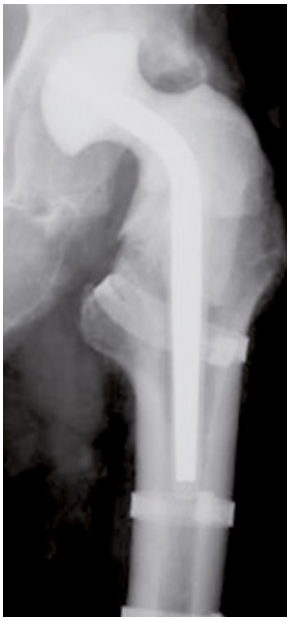
4 TWO-PART REPLACEMENT OF PROSTHESIS AFTER STAPHYLOCOCCUS AUREUS

Two-stage replacement of prosthesis due to an infection with Staphylococcus aureus. Implantation of a spacer and fixation with three CCG® bands. After 2 months treatment with a long-stem prosthesis.

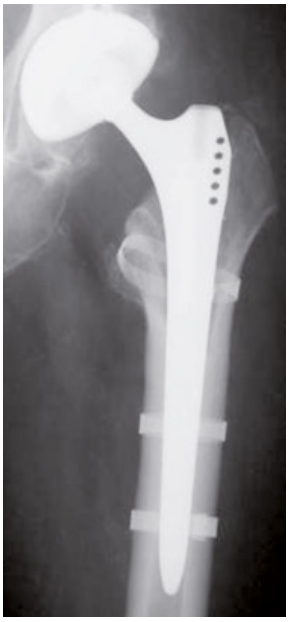
Preoperative x-ray



Postoperative x-ray



2 months
Postoperative x-ray



IMPLANTS

Art. No.	Description	Lenght
91001	CCG® Band	27cm
91002	CCG®- GF Band with Joint and Fication-Spike	27cm

Implantatmaterial: Pure titanium according to EN ISO 5832-2

91007	CCG® Stabiliser	7cm
91011	CCG® Stabiliser	11cm
91015	CCG® Stabiliser	15cm
91017	CCG® Stabiliser	17cm

Implant material: Pure titanium according to ASTM F67, grade 4

Recommendation

Stabiliser 7cm: minimum 2 CCG® bands
Stabiliser 11cm und 15cm: minimum 3 CCG® bands
Stabiliser 17cm: minimum 4 CCG® bands

INSTRUMENTS

No.	Art. No.	Description
1	910001	Cerclage tightener
2	910002	Loop awl large
3	910003	Loop awl small
4	910004	CCG® Fixator

REFERENCES

GUNDOLF F
Trochanter major-Abnahme in der Hüft-Endoprothetik
1996; Dr. med. Ferdinand Gundolf, A-6330 Kufstein, Kemterstraße 1, ISBN 3-9500499-0-8

CLAUSEN J D, SCHMOTZER H
Biomechanical Comparsion of CCG Titanium Cerclage Bands and Stainless Steel Wires used to Maintain Union of Femoral Fractures
Precision Implants AG; 1999, CH-5000, Aarau, Schachenallee 29/G1

LINTNER F, HUBER M, BÖHM G, KISS H, GUNDOLF F
Is it possible to stabilize a fracture of the femur, a fracture of the femur after THR and THR-loosening and to enhance bone healing when using a titanium band cerclage?
Kann eine Bandcerclage aus Titanium zu einer günstigeren knöchernen Stabilisierung nach TEP, TEPLockerung und Femurschaftfraktur führen?
Pathologisch-Bakteriologisches Institut SMZ-Otto Wagner Spital, Baumgartner Höhe, Wien; Orthopädische Abteilung des Landeskrankenhauses Salzburg; Orthopädie Kufstein

KOROVESSIS P, BAIKOUSIS A, STAMATAKIS M
First experience with the use of compression cerclage Gundolf in orthopaedic and traumasurgery. A preliminary report.
Arch Orthop Trauma Surg 1998; 117(8): 448–52

WEISSINGER W, HELMREICH C, PÖLL G
Periprosthetic Fractures of the Hip
ACTA Chirurgiae Orthopaedicae et Traumatologiae Cechosl., 76, 2009. p 179 - 185

HUBER M, KISS H, GUNDOLF F, LINDTNER F
Der Einsatz von Titanbandcerclagen im Rahmen der Revisionsoperation totaler Hüftendoprothesen aus dem Blickwinkel der Histomorphologie.
Poster, Österreichischer Orthopädiekongress, Salzburg 2001

VOLKER-IRMER C
Vergleich der Primärstabilität von Titanbandverclagen und Edelstahldrahtcerclagen: eine biomechanische Untersuchung am Modell eine Fraktur im Bereich eines einliegenden Gamma-Nagels
Inaugurale Dissertation, Medizinische Faktultät der Ernst-Moritz-Arndt-Universität Greifswald 2011

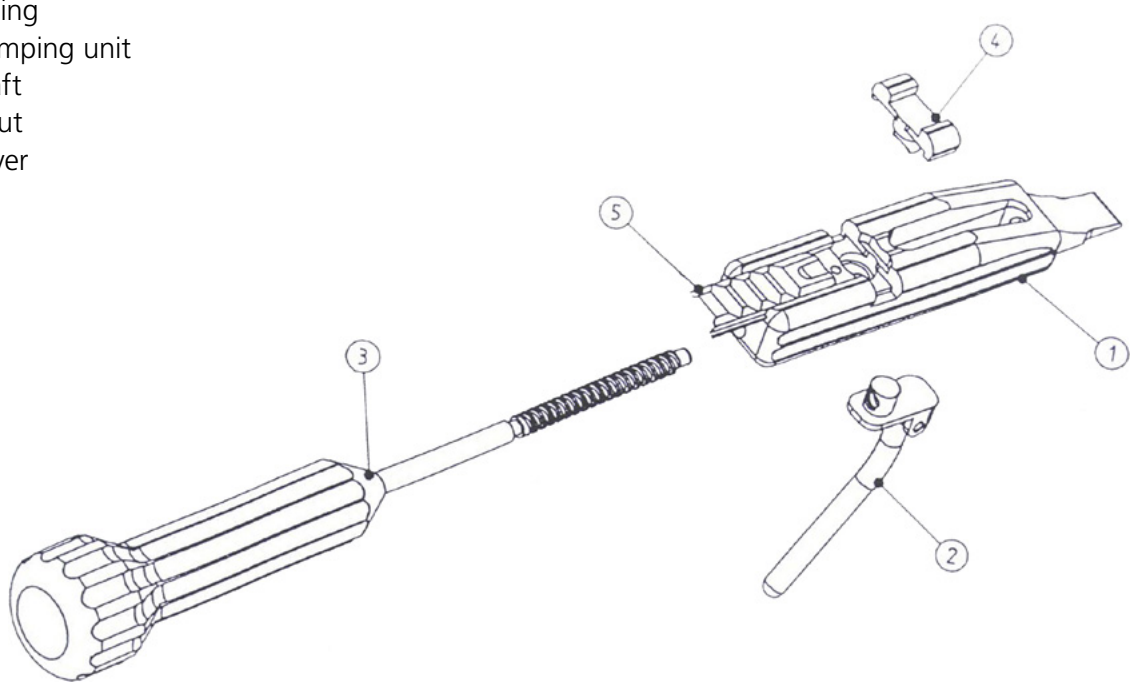
NEUMANN D, THALER CH, DORN U
Management of Vancouver B2 and B3 femoral periprosthetic fractures using a modular cementless stem without allografting
International Orthopaedics (SICOT) (2012) 36:1045-1050

INSTRUCTIONS FOR CLEANING

CERCLATEUR (ART. NO. 910001) CCG® - COMPRESSION CERCLAGE SYSTEM

See Cleaning Instructions Lit. No. 860502!

1. Casing
2. Clamping unit
3. Shaft
4. T-nut
5. Cover



DISASSEMBLY FOR CLEANING

1. Push cover back towards the twist grip
2. Lift out t-nut
3. Hold on to clamping unit underneath, turn shaft anti-clockwise until it can be pulled out of the casing
4. Remove clamping unit from casing groove
5. Remove cover (for general cleaning)

ASSEMBLY AFTER CLEANING

1. Push cover arrow-first into the casing as far as the hole for the t-nut
2. Place clamping unit in casing and push backwards so that the tip of the arrow points towards the twist grip. Tilt clamping unit lever forwards and press clamping unit to the casing in the direction of the arrow
3. Push shaft into the casing and turn clockwise until the end stop is reached. Hold cerclateur in this position and turn it over
4. Insert t-nut in the hole and close the cover

INFORMATION FOR THE PATIENT

Undesired effects that harm the patient can occur when performing MRI / CT scans. Possible effects include artefacts, warming of the implant, induction of electrical currents, loosening of the implant. The manufacturer's instructions for use must be studied before the device is used. In case of doubt, reference implants must be tested for suitability in the respective MRI / CT instrument within the scope of an individual risk assessment. The patient must be informed about the risks.

STORAGE CONDITIONS

STORAGE OF THE STERILE IMPLANTS

Implants should always be stored in their unopened packaging. The packaging of the implants is designed so that they can be stored at normal room temperature / relative humidity (corresponds with the customary "storage and work climate" in our latitudes, i.e. between approx. +15°C and +35°C, depending on the season, with the respective normal relative humidity) without risking a deterioration of the packaging, sterility of the product, etc. Sterile implants must not be exposed to sunlight without protection (i.e. light protection provided by the outer carton).

ImplanTec

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hbmedical

HB-Medical B.V.
Tivolilaan 205, 6824 BV Arnhem
The Netherlands
T: +31 (0)26 3618804
E: info@hb-medical.nl
I: www.hb-medical.nl