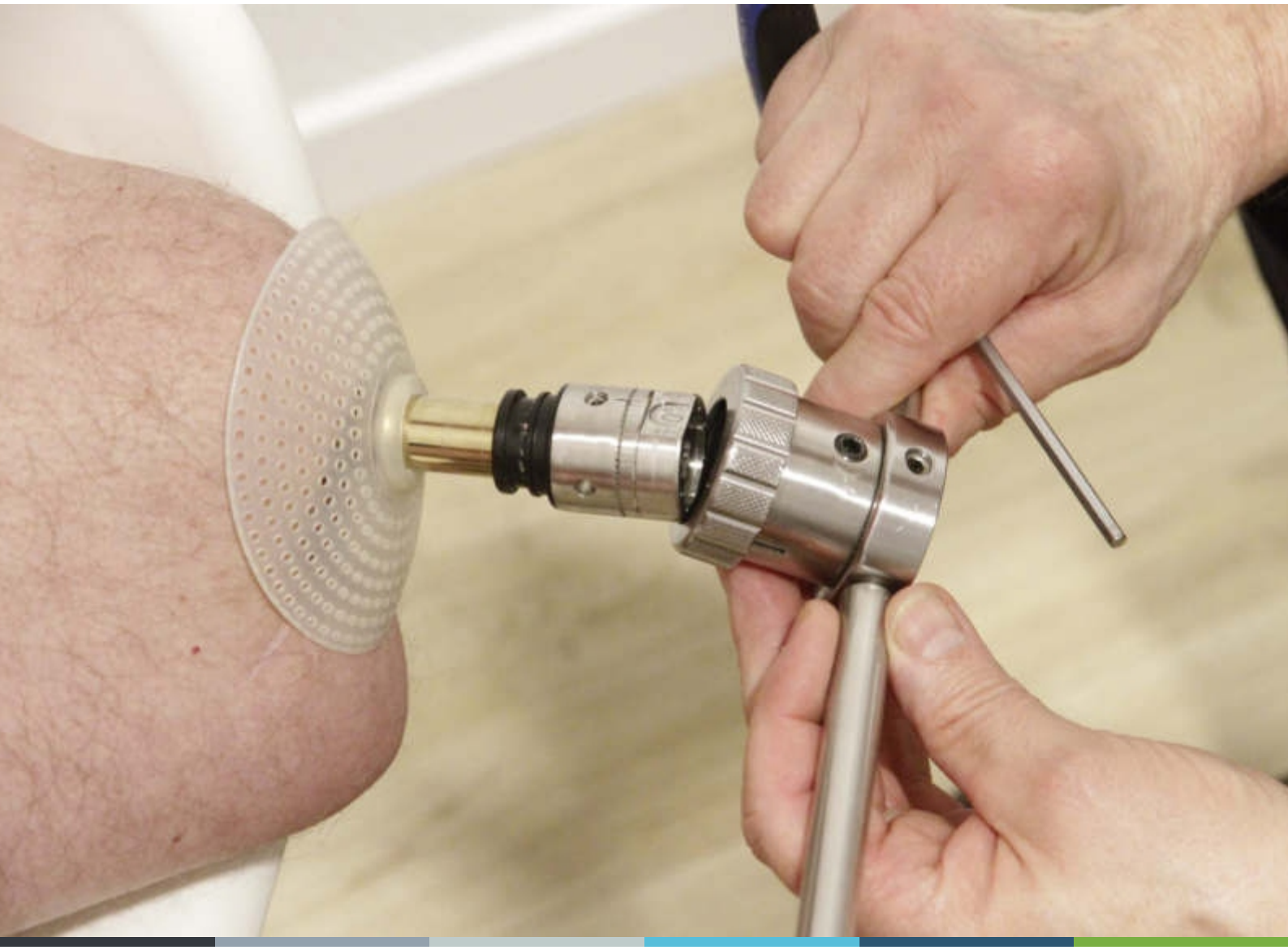
General information

# The ESKA® endostem adapted exoprosthesis care concept

"according to Dr. Grundei®"



ESKA Orthopaedic Handels GmbH

Prosthetist

# The ESKA endostem adapted exoprosthesis treatment concept Type I, Type II or Type III "according to Dr. Grundei®"

## A new form of treatment for limb amputees

The ESKA endostem adapted exoprosthesis treatment concept "according to Dr. Grundei®" is a prosthesis fitting concept that has been used for more than 20 years, for the people with limb amputation which eliminates the usage of the conventional prosthesis socket. This prosthesis treatment concept is modelled based on the anatomy of the human body and the stress during walking and standing are beared by the bones and joints.

### The benefits of the ESKA endostem adapted exoprosthesis treatment concept "according to Dr. Grundei®" are:

### No prosthetic shaft

- The forces are transmitted directly from the bone over the prothesis stem
- Precision in the positioning of the prothesis
- Safe and harmonious gait pattern
- The hip joint is stressed in a natural way

### Complete Mobility

- Full freedom of movement of the stump at all levels
- No disturbing marginal areas of a prosthetic socket
- Achievement of full freedom of movement after 8-12 months
- Larger radius of action, significantly more steps per day
- Free from pain and fatigue during walking

### Ease of use

- Attach and detach while sitting within a few seconds
- No skin irritation due to chafing, sweat or heat
- Volume variations in the residual limb have no influence on the fit of the exoprothesis
- The replacement of the ESKA endostem after 12-15 years is not expected, which is a usual case in endoprosthetics

## The ESKA endostem / three components

The implant is introduced directly into the femur and ensures a secure connection through the spongy metal surface which is developed 35 years ago by "Dr. Grundei" that provides a structural and functional connection between the bone and ESKA endostem.

## Long-term developments and innovative ideas created the ESKA endostem adapted exoprosthesis treatment concept "according to Dr. Grundei®"

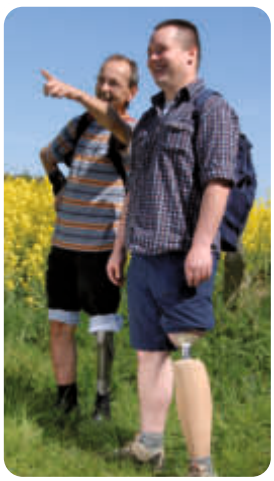
① ESKA Endostem (e.g. type I) with inner cone
Patent No. **DE 10 2009 027 255**
Patent No. **DE 10 2010 028 430**

② ESKA bridge module in double cone design (e.g. type I) with cone protection (n. Schelhas 1986)

③ Silicone cap used as stoma protection

④ ESKA bridge cylinder in the form of a metal cylinder including: inner cone, toothed disc slip clutch, torsion adjustment disc + locking body elements serve as a bridge connection
Patent No. **DE 10 2010 028 964**

⑤ ESKA connection adapter in cylindrical shape for the knee or foot
Patent No. **DE 10 2010 039 698**



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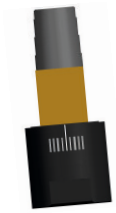
② 

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### Structure

The ESKA endostem adapted exoprosthesis treatment concept "according to Dr. Grundei®" is composed of various components: internal module (Endo- operation by surgeon) and external module (Exo- fixation by prosthetist) which assembled into a system. The ESKA Endo module (endostem) is implanted into the bone, for example in the Femur. The healing time is about 12 weeks.

The special feature of the ESKA endostem implant is the spongy metal surface. The three dimensional lattice structure promotes a quick and complete growth of the bone cells around the implant and a firm anchorage of the ESKA endo -stem with the bone is guaranteed from the experience over 35 years.

The ESKA bridge module establishes a connection between ESKA endostem and ESKA bridge cylinder. The bridge module is proximally connected to the distal end of the endostem and connected distally to the bridge cylinder and its subsequent components.

The silicone cap serves to protect the exit point (stoma).

The ESKA bridge cylinder which consists of the ESKA metal cylinder, the toothed disc slip clutch and the torsion adjustment disc are used for the assembly and the alignment of the connection adapter for the knee or suitable foot piece.

It is the responsibility of the qualified and ESKA certified prosthetist to assemble the components based on the respective statics and dynamics of the patient's gait and finally the selection of the prosthetic leg.

# Clinical intervention

## For more than 20 years the ESKA endostem adapted exoprosthesis treatment concept "according to Dr. Grundei®" has been applied

The implantation of the ESKA endostem and the ESKA bridge module is carried out in two operations, each performed under general anesthesia.

**STEP I**

In the first operation, the distal end of the femur of a transfemoral amputee is exposed and the ESKA endostem is implanted. If the endostem is implanted in the right position, then the stump is closed.

After the surgery, it takes around 12 weeks to heal the wound and the Osseointegration occurs along with it. The medical supervision is needed during this period.

STEP I **STEP II**

In the second operation, a circular skin passage (stoma) is prepared.
Through the stoma, the ESKA bridge module is connected with the ESKA endostem.

STEP I STEP II **STEP III**

The **qualified and ESKA certified prosthetist** with the help of two X-Ray images (in the direction: Anterior-Posterior (A-P) + Lateral-Medial (L-M)) and the measured specifications (sagittal plane trochanter-bending angle + mobility level) to determine the position of the knee axis and to plan the prosthetic leg.

The mobilisation takes place a few days after the second operation and under the supervision of the qualified and ESKA certified prosthetist, walking training may be started.

In addition, after successful implantation, each patient receives a patient passport from the attending physician, in which the regular control of the exo-fitting parts are documented.

This passport also contains the exact details of the exoprosthesis fitting and should also be carried at all times during air travel.

① Internal screw 15 Nm.


② Test- toothed metal cylinder

③ After previous test 0 °to 90 ° or 3 ° to 87 ° usable by toothed disc slip clutch right - left torsion adjustment disc + locking body elements (see mobility and body weight)

<u>Plastic locking body elements:</u>

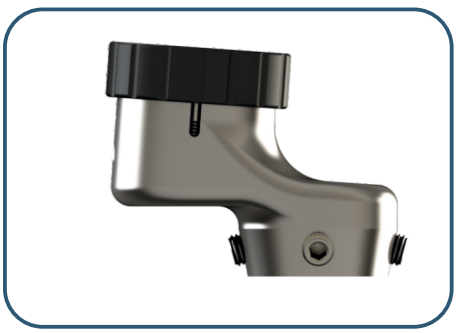
5Nm - white coloured, 10Nm - black coloured and 15Nm - brown coloured

<u>Metal locking body elements:</u>

20 Nm - gold coloured and 30 Nm - silver coloured

④ Test-the-Best Service case - 110 possibilities
- Connection adapter (long stump)
- Extension modules (short stump)
- Determining the bending angle 2 ° - 20 °
- Primary - Secondary
- Test up to 30 days

Then select the final components and assembly (see connection adapter)

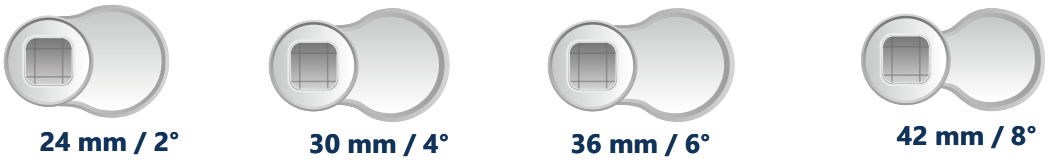


⑤ Test-the-Best Toolbox
Selected special tools incl. torque wrench and counterholder for bridge module and bridge cylinder

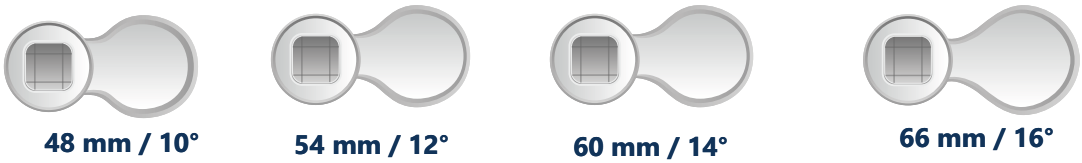
**Neutral** 50 parts for „**Test the Best“**

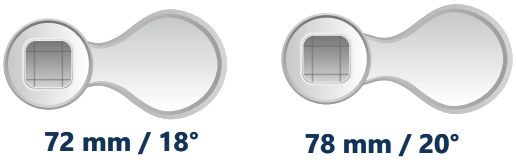
Long stump


**Tibia**



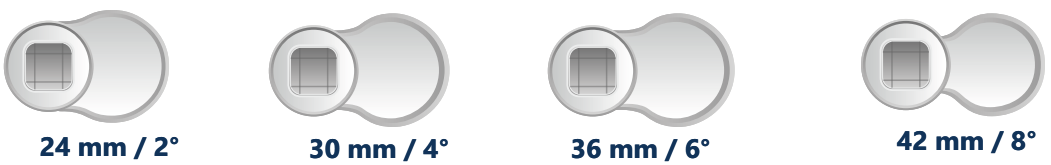

**Femur**

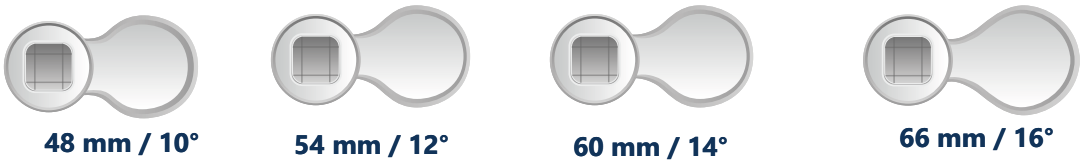


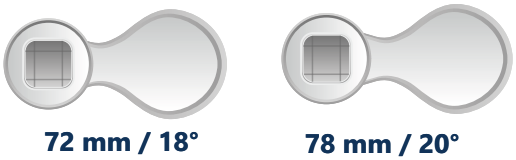




**Neutral**

short stump

## Neutral

Contracted stump

### Torsion plate with ESKA connection adapter in thread form

36 mm / 6°
42 mm / 8°
54 mm / 12°
60 mm / 14°
66 mm / 16°
72 mm / 18°
78 mm / 20°

15 mm / 4°
25 mm / 4°

15 mm / 0°
25 mm / 0°

15 mm / 0°
25 mm / 0°

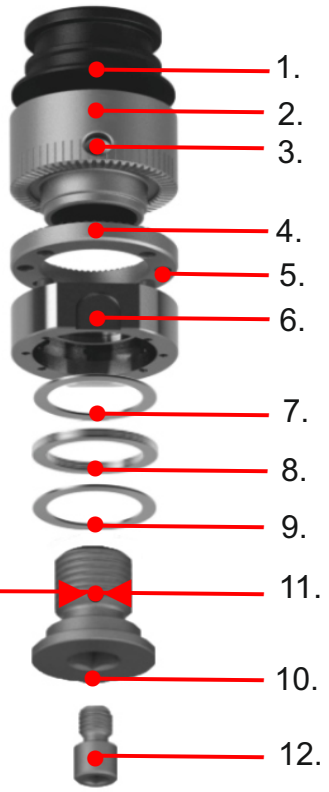
### ESKA extension modules

15 mm Länge
25 mm Länge
35 mm Länge
45 mm Länge
55 mm Länge
65 mm Länge
75 mm Länge

# ESKA Bridge cylinder - plus as a 12-piece metal cylinder with inner cone complete

ESKA bridge cylinder - plus consists of a guide cylinder (metal cylinder with an inner cone), an adjustment ring (toothed washer - slip clutch), a resistance washer (torsion adjustment washer, toothed) and locking body elements as a safety elements.

1. Topstopper
2. Guide cylinder (metal cylinder with inner cone)
3. Locking screw: Torque 5 Nm *glued with Loctite*
4. Adjustment ring (toothed washer - slip clutch) *glued with UHU Plus*
5. Locking body elements as safety elements
6. Resistance washer (torsion adjustment washer, toothed)
7. Pressure reducing washer (0.5mm)
8. Pressure reducing washer (2.5mm)
9. Pressure reducing washer (0.5 mm)
10. Definitive screw (with pin hole: Torque upto **25 Nm**)
11. PE - locking pin *glued with Loctite 245*
12. Locking screw
    only to be screwed,
    **do not glue it!!!**




For technical optimal patient care, the "service case" with the appropriate tools are **absolutely** necessary.

## Test adapter

6 mm to 78 mm for the thigh in neutral position, taking into account the bending angle 2 ° - 20 °

## Safety levels and assembly

(up to 160 Nm determined from body weight and mobility), always specify when ordering

### Overview
### Locking body elements-pressure

PLASTIC
- Plastic 5 Nm white colored
- Plastic 10 Nm black colored
- Plastic 15 Nm brown colored

METAL
- Metal 20 Nm gold colored
- Metal 30 Nm silver colored

### Recommendation

**Always specify the body weight when ordering a replacement**

**Active Patient Passive Patient**

**Mob. Classification**

1. up to 40 kg = 2 x Gold
2. up to 50 kg = 2 x Gold + 1 x White
3. up to 60 kg = 2 x Gold + 2 x Black
4. up to 70 kg = 2 x Gold + 2 x Brown

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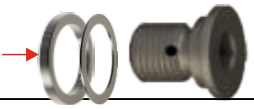
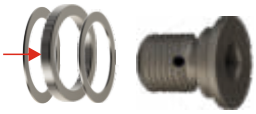
1. up to 80 kg = 4 x Gold
2. up to 90 kg = 2 x Gold + 2 x White
3. up to 100 kg= 4 x Gold + 2 x Black
4. up to 110 kg= 4 x Gold + 2 x Brown

**1.** Rubber  1 % Upon request

**2.** Rubber  2 % Upon request

**3.** tension Metal  87 % Standard

**4.** tension Metal  10 % Upon request

## - ST / PLUS -

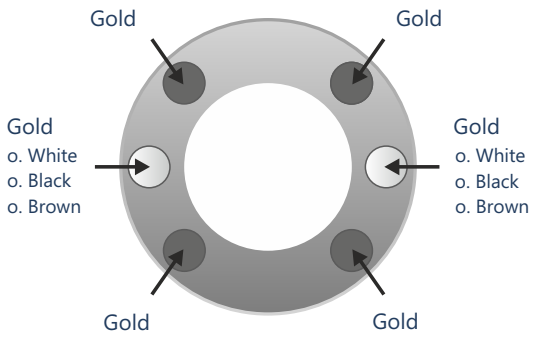
**Active Patient**
Metal (4 elements)
Plastic (2 elements)
"PLUS" on request: 6 metal elements

The mobility classification is used to assess the potential or therapeutic goal of an amputee's possible mobility.

(empirical values as of 09/2014)

**All locking body elements are glued firmly into the adjustment ring -resistance washer with Uhu® glue.**

### Mounting holes for locking body elements (see recommendation)




**Typ ESKA-V.M.**
**(Improved model)**

# What you should keep in mind?

From the experience of hundreds of satisfied ESKA endostem adapted exoprosthesis users, shows that there are significant advantages are gained over the conventional socket prosthesis. Through a conscious and careful use of the ESKA endostem adapted exoprosthesis treatment concept "according to Dr. Grundei®", complications can be excluded as far as possible.

## Care of the Stoma

Special attention must be paid to the stoma through which the bridge module leaves the body. With normal hygiene and regular cleaning: two times per day with water and perfume-free soap, the risk of infection can be reduced to an extremely low rate.

## Load

Excessive twisting of the prosthesis should always be avoided. If larger loads do occur, then the locking body elements and the toothed disc slip clutch direct the force outwards and hence protects against fracture of the bone. This protection mechanism prevents the damage to the bone.

The replacement of the ESKA endostem after 12-15 years is not expected, which is a usual case in the endoprosthetics.

## Material

The implants are made of a cobalt-chromium-molybdenum casting alloy (CoCrMo), which is coated with a titanium-niobium layer (TiNb). These materials in endoprosthetics are considered to be very compatible with the body and known to trigger allergic reactions only in extremely rare cases.

Generally, medications are not necessary in conjuction with the endostem adapted exoprosthesis treatment concept, "according to Dr. Grundei®".

## Direct billing

The operation and the ESKA endostem are invoiced by the clinics directly to the cost bearers. The exo fitting is invoiced by the ESKA certified prosthetist, who submits a cost estimate to the insured person's health insurance company.

## Exo prosthetist part

The exo fitting is carried out by the ESKA certified prosthetist with certified foot and knee fittings from selected manufacturers. According to our experience, calculating joints with computer -assistance gives the best results for the classification of the mobility classes for all standard fittings.

## Clinics

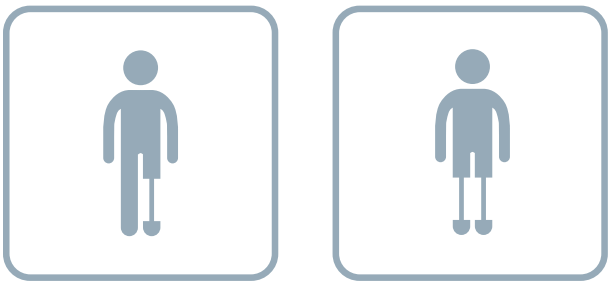
So far, we work together with the following clinics in Germany, where endo operations are performed.

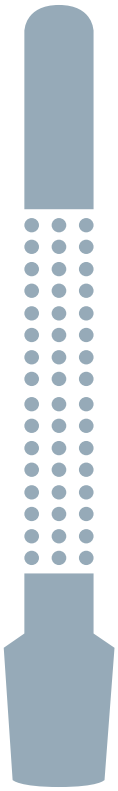
- Medizinische Hochschule Hannover (MHH)
  Unfallchirurgie Zentrum für Endo-Exoprothetik
  Frau Dr. Ernst
- Bundeswehrkrankenhaus Berlin
  Unfallchirurgie / Orthopädie
  Herr Prof. Dr. Willy
- Universitätsklinik Rostock
  Direktor Orthopädie und Polioklinik
  Herr Prof. Dr. med. habil Prof. Wolfram Mittelmeier
- Orthopädische Klinik Dortmund
  Direktor der Orthopädischen Klinik
  Herr Prof. Dr. med. Christian Lüring
- Berufsgenossenschaftliche Unfallklinik Murnau
  Septische und Rekonstruktive Chirurgie
  Herr Dr. von Stein
- Ameos Klinikum Eutin
  Klinik für Orthopädie, Unfall- und Rekonstruktive Chirurgie
  Frau Dr. med. Astrid Clausen
- Universitätsklinikum Münster (UKM)
  Klinik für Allgemeine Orthopädie und Tumororthopädie
  Herr Dr. Budny
- Berufsgenossentschaftliches Klinikum Halle
  Unfall- und Wiederherstellungschirurgie
  Herr Prof. Dr. Hofmann
- München Klinik Neuperlach
  Klinik für Orthopädie, Unfall- und Wiederherstellungschirurgie
  Hon.-Prof. med. univ. Pleven Dr. Heinz Röttinger
- Mare Klinik Kiel
  Orthopädie und Unfallchirurgie
  Herr Prof. Dr. med. Ludger Gerdesmeyer

## Trained ESKA certified partners

We will be happy to inform you by telephone about the ESKA trained and certified prosthetist nearby your area.

# Contact






## Manufacturer and distributor

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## Service partner

S&G moving
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Exoprothetik

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