The specialist for small bones

NORMED®

Germany

GB/USA

CE 0123

Instructions for use for Normed Products

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1. Indications / Contraindications of Normed products

The Normed Systems range consists of various system components for all indications for skeletal osteosynthesis of small bone fragments, which were damaged due to trauma or require reconstruction or arthrodesis. The implants are intended to **support normal bone healing for osteotomies, fractures and reconstruction,** however not for the substitution of normal body structures or for carrying of the body weight in the case of insufficient bone healing. Therefore it should be noted that due to the limited strength of the implants, weight bearing by body weight should be avoided, unless explicitly stated otherwise in our OP instructions. A delayed healing phase, insufficient bone connection or subsequent bone resorption or trauma can over strain the implant and possibly result in loosening, bending, and cracking or even rupture of the implant. As a rule, all implants are designed to fulfil their function up to the bone healing (approx. 6-10 weeks)
The individual product systems are differentiated by the diameter of the respective titanium screw, a description and an individually assigned colour code.

The following contraindications must be excluded for the application of Normed products:

- Florid infections and / or tumours in the treatment area
- Known or possible intolerance to foreign bodies for the products to be applied
- Circulatory disorders, metabolic diseases and systemic diseases
- Patients, who on the basis of their physical and mental condition are not able to keep up with post operative treatment
- Serious damage to the bone structure, as well as degenerative disease processes that may interfere with the healing process
- Drugs, alcohol and medication dependency

2. Material information

Normed **implants** are made of commercially pure titanium ASTM F67 - 95 or Ti6Al4V alloy, produced in compliance with ASTM F136. The surface of the implants is chemically passive, the material is anti-magnetic.

The appropriate Normed **armamentarium** is manufactured from various types of steel (stainless).

Normed products are delivered in **sterile containers** made of stainless steel, aluminium and / or various plastics.

3. Possible side effects

- Infections
- Pain
- Allergic reactions against the implant material
- Nerve damage and vascular injury, wound healing disorders
- Movement restrictions
- Insufficient and / or delayed bone healing
- Displacement of the implant with bone growth
- In case of excessive force and / or weight influence, risk of rupture, bending, loosening or migration of the implant

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4. Packaging, transport & storage

Normed - implants and instruments are supplied in **non-sterile** and / or **sterile** condition. Products, which are not explicitly marked as "sterile" or with the sterile symbol, are supplied non-sterile.

Sterile products by Normed are packed and gamma sterilised in compliance with DIN EN ISO 11607 Part 1/2 and EN 868 Parts 2 - 10 and in compliance with applicable national standards. Therefore, they can be stored until use in the closed sterile container according to the storage conditions specified on the product label. As a general rule, the shipping packaging is non-sterile. With the use of packaged sterile implants, make sure to maintain the sterility of the product up to immediate use. Furthermore, should additional transport be required, the transport instructions on the label must be adhered to. If the expiry date of the sterile packaging for a sterile product has elapsed, these sterile products may no longer be used. In the case of (inadvertently) opened or damaged packaging, the implants must be regarded as non-sterile and need to be re-sterilised. Any ***re-sterilisation*** of sterile packaged products for which the expiry date of the sterile packaging has elapsed, must be checked individually by the manufacturer. Should re-sterilisation not be possible, the content including the packaging must be disposed of.

Non-sterile products must be stored in the packaging in a dry environment (humidity 80%) at a temperature range of -20 °C / -4°F to 60 °C / 140 °F at normal atmospheric pressure, until processing and sterilisation. There are no special transport conditions to consider. In order to avoid corrosion, please take special care that no chemicals are in close proximity. Before application in the operating theatre, all non-sterile products must be cleaned and sterilised.

The label on the packaging indicates the corresponding LOT - No. (batch number) of the product. During the operation, it is recommended that this LOT No. be recorded in the patient file or the Normed patient record, as tracking of the product is ensured by this number.

5. Information on cleaning, sterilisation and maintenance

Before non-sterile products can be used on the patient, the supplied products must undergo a complete treatment process as part of a validated method. The user is responsible for ensuring correct cleaning and sterilisation methods and their validation. Proper preparation, sterilisation, and functional testing must be performed by qualified personnel.

All Normed products are classified according to the RKI guidelines of the Robert-Koch-Institute / Berlin. Product-specific preparation instructions can be viewed on our website www.normed-online.com .

Our **implants** are provided with a coloured oxide coating. Slight differences in colour may occur when cleaning and sterilising, these have no impact on the implant quality. Our **instruments and containers** require professional and continuous maintenance and correct preparation. For the maintenance and care of joints, respective suitable care products (e.g. instrument care oil) may be applied. Container seals must be renewed after 500 sterilisation cycles.

IMPORTANT: **The following instructions for cleaning and sterilisation must be integrated into validated processes of the facilities. National standards, regulations and / or restrictions must be included in this process!**

Further information on the preparation can be viewed on the website of the Working Group for instrument preparation www.a-k-i.org .

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6. Cleaning (non-sterile products)

Normed products are suitable for cleaning with **alkaline or enzymatic cleaning agents.** Only chemical and cleaning agents which have been approved by the manufacturer for surgical products made from titanium, aluminium, plastics and / or various types of steel should be applied. Highly alkaline cleaning solutions can lead to staining and anodised surfaces and loss of elasticity in the case of silicone parts. The use of demineralised water prevents staining and corrosion. It is recommended using disinfectants with corrosion protection. Cleaning agents containing **natron** or acid neutralisation agents may not be used for sterile containers.

For cleaning, the implants are removed from the sales packaging and sorted into suitable equipment / sieves.

Pre-treatment:

Prior to cleaning and sterilisation, all product components must be taken apart. Joint instruments must be opened. Products must be positioned in such a way that water can flow from hollow parts and no unwashed areas remain.

In the case of reprocessing, used products must be cleaned as quickly as possible after use. To remove remaining bone material in cannulated products, these should be cleaned already intraoperatively. Inaccessible areas must be paid special attention to. Residues can be removed with a pH-neutral solution in cold water (< 40° C / 104°F) using a soft brush (not metal). No fixing agents, abrasives or hot water (> 40° C / 104° F) must be used.

Cleaning method:

We recommend the following method for the cleaning of our products:

- **Mechanical cleaning** (≥ 90° C / 194° F, ≥ 5 min)
- **Thermal disinfection** (≤ 95° C / 203° F, ≥ 5 min)

The instructions by the machine or cleaning agent manufacturers on operating and loading, water temperature, disinfectants or solution concentration, application time, rinsing time and drying stage must be followed to obtain an optimum cleaning result and to avoid material damage.

IMPORTANT: **Manual cleaning and chemical disinfection and cleaning with ultrasound are allowed, but not recommended. Validated methods must be applied!**

Function testing / visual inspection:

When removing the instruments from the cleaning units, they must be checked **for visual contamination**. If contamination is present, the cleaning cycle must be repeated.

The functional testing / visual control must be performed after cleaning, following the assembly of the product components.

The products must be examined for obvious **mechanical damage** (fracture, deformation, corrosion, etc.) and for **fault-free functioning**. Damaged or not fully functional products may never be used in patients, but must be sent for qualified repair or if necessary, discarded or replaced.

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7. Sterilisation (non-sterile products)

Sterilisation must be performed prior to use of the product. Only completely cleaned and dried products may be sterilized. For sterilisation, the products are arranged in appropriate storage systems. Screen baskets and implant cassettes should be sterilised in the recommended sterilisation containers and / or containers.

Sterilisation packaging:

The sterilisation packaging depends on the chosen method of sterilisation. The products must be packaged in accordance with applicable standards and in accordance with the requirements for the sterilisation method to be performed.

Sterilisation packaging...

a) May not hinder the sterilisation
b) Must ensure sterility until use
c) Must not impede the removal and handling of sterile supplies.

Sterile containers:

Sterile containers and load must be clean and dry when loading.
For sterilisation in implant-storage containers, we recommend only stacking a maximum of two titanium plates above each other in order to guarantee the sterility of the implants.

The sterilisation of the different container loading and packing configurations, as well as the storage time which depends on the storage conditions, must be determined by the responsible hygiene specialist.

Sterile containers must be fitted with a new **paper filter** prior to each application. It is important to ensure that the indicator faces towards the interior of the container and is secured with the retaining plate. The indicator colour is printed on the filter and changes colour in the sterilisation cycle.

The lid and tub of the container must be connected via the closure mechanism prior to insertion into the steriliser. After sterilisation, the sterile containers can be secured with a **seal.**

Condensation must be avoided to reduce subsequent corrosion and / or pollution. Packaging of sterile goods which are damaged or moist when being removed from the sterilisation chamber must be considered as non-sterile and may not be used - there is an imminent danger of recontamination!

Sterile containers must show no signs of damages which impact on function and must be subjected to regular visual inspections. Defective sterile containers must be taken out of service and may not be used for sterilisation and / or storage of sterilised products.

Sterilisation methods:

We recommend the following method for the sterilisation of our products:

- **Fractionated steam sterilisation procedure** (≥ 132° C / 270° F, ≥ 5 min.)
  Drying: at least 10 min.

The manufacturer's specifications for the sterilisation must be adhered to precisely.

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8. Information on storage of processed products

Prepared instruments or implant systems must be stored in the recommended sterilisation containers and / or containers in a clean environment, in a dry and dust-free condition and at an ambient temperature of 5°C / 41°F to a maximum of 40° C / 104° F.

A **storage period** of 6 weeks in open shelves and 3 months under protected conditions (e.g. closed cupboard) is recommended for sterile containers.

9. Product application

IMPORTANT: **The treating physician is responsible for the selection of patients, appropriate training and information, sufficient experience in the choice and placement of implants and for the decision to leave or remove implants postoperatively. This also applies to the prevention or reduction of general risks and the requirement of aseptic operation conditions for the patient during surgery.**

Only cleaned and sterilised Normed products or sterile packaged Normed products with valid expiration date may be implanted or used for the product application! Product systems and implants without proof of sterilisation may not be used on the patient!

Recommendations for physician & patient:

Prior to surgery, the patient should be sufficiently informed about the **risks and side effects** of the products used and the expected **outcome of surgery**, e.g. temporary restriction in movement. In addition, the physician should inform the patient that **medical follow-ups** are essential for the operation success.

The physician should instruct his patients to immediately report any changes in the operated area to him, so that he can take appropriate **measures for continued treatment.**

The following criteria are crucial for the success of an operation:

- **The correct product selection**

  The product selection and the surgical technique applied must be in accordance with the type of bone defect, anatomical location, operation indication, accepted medical standards, weight of patient, physical condition and activity level of the patient and the patient's cooperativeness.

- **Compliance with the following information on the individual product groups**

a. Plate-screw systems

If required, plates can be adjusted to the bone. With appropriate caution, **careful bending of the plate is possible to a limited degree** with a suitable plate bending instrument; multiple deformations must be avoided. Multiple bending of the plate not in accordance with the indication, as well as sharp angles and small bending radii can weaken the plate and result in fracture or failure of the implant as well as a shortening of the service life. In the case of angle-stable implants, the drill guide must be inserted into the screw hole closest to the bending area prior to bending. This prevents impairment of the screw thread.

In the case of **shortening of the bone plate**, cutting surfaces must be trimmed with appropriate instruments. The surgeon must ensure that the stability, load-bearing capacity and fixation of the plate are maintained.

Before insertion of the screw, a suitable and sufficiently large drill **must be used for pre-drilling.** In order to **define the screw length,** the drill depth is determined by means of a gauge. In the case of fixed angle, uni-directional screws, drilling must be effected with a drill sleeve screwed to the plate.

If not expressly specified in our OP instruction, in a normal case, the use of a **tap** is not necessary, except in cases involving particularly hard bone matter.

Taking up **and insertion of the bone screw** with a turnscrew must occur with sufficient pressure and exactly perpendicular to prevent any risk of damage. At the end of tightening resistance is to be expected. Thereafter, the screw must be carefully turned to the end, to prevent bone damage or damage to the products.

b. Cannulated screw systems with Kirschner wire

It is recommended inserting cannulated screws into the bone **by means of Kirschner wire and to check the correct positioning of the Kirschner wire with an x-ray machine.**

Before insertion of the screw, a suitable and sufficiently large cannulated drill **must be used for pre-drilling via the Kirschner wire.**

In order **to define the screw length,** the drill depth is determined by means of a gauge.

It is recommended processing the bone with an appropriate **tap** prior to insertion of the cannulated screw, in order to prevent any damage to the bone. Thereafter, the cannulated screw is inserted over the Kirschner wire.

In the case of hard bone, it may be advisable to use an appropriate **cannulated tap** prior to insertion of the screw.

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c. Rotating instruments and spiral drill

Rotating instruments and medical spiral drills should be used for bone as well as hard and soft tissues. The selection of the respective required instrument is at the discretion of the surgeon.

The instructions for use **by the drive manufacturer** must be adhered to precisely for the combined use with our products. Only technically faultlessly maintained and sterilised drives may be used. Appropriate protective clothing must be worn **at application**.

During application, **appropriate cooling** must be provided, in order to avoid excessive heat development and to prevent potential resulting irreversible bone and tissue damage. Here, the revolutions per minute for handling must be chosen appropriately, so that the force does not result in excessive strain, as this can cause damage and / or breakage of the product and lead to injuries of third parties. Likewise, excessive contact forces must be avoided.

Appropriate drill sleeves and drilling cannulas must be used for the **protection of tissue**.

IMPORTANT: **Rotating instruments and spiral drills with signs of damage may not be used. The instruments are not suitable for the machining of metal, as this may lead to injury and infection.**

d. Bending templates

Bending templates serve the purpose of **templates for implantation** of sterile and / or sterile packaged implants, in order to priorly assess the specific bone conditions for the accurate selection of implants. The opening of unsuitable packaging of sterile products can thus be minimised. In addition, they serve as a template for possible implant adjustments.

Bending templates may **not be implanted,** as the material properties are not designed for implantation.

10. Warnings & precautions for product use

Incorrect product selection, not in compliance with above stated criteria, may lead to a loosening, bending or breakage of the product or fracture of the bone.

IMPORTANT:

Use, reuse or reprocessing of explanted, contaminated, used or damaged implants, e.g. by scratches, is not permitted. This also applies to contact with body fluids. The reuse of a used implant may lead to possible mechanical failure and an increased risk of infection. An implant that appears undamaged can show signs of fatigue due to previous unknown stress, which can lead to a premature failure or shortening of the service life of the implant.

Under no circumstances may damaged or not fully functional products be used in patients.

Only appropriate instruments may be used for insertion of our products. A combination of Normed products with products from other manufacturers may not take place, as this could lead to incalculable risks for patients, users and third parties. Failure to do so can result in breakage, failure and shortening of the service life of the products.

Exception: Use of our products in combination with motor / drive systems -
However, in this case the instructions by the drive manufacturer for a combined use with other products must be adhered to precisely!

11. Warnings regarding Creutzfeldt-Jakob disease (CJD)

Critical and semi critical medical devices, which have been used in patients with clinically probable or possible Creutzfeldt-Jakob disease (CJD), must be disposed of by incineration. Pending clarification of diagnostic, these medical devices must be stored under safe conditions!

IMPORTANT: **These warnings can be found on the website of the Robert Koch Institute www.rki.de and are published in the Federal Health Gazette 7 / 1998 - and are subject to potential changes at all times.**

12. Warranty & Disclaimer

Our products are made from high quality materials and are subjected to quality control prior to delivery. The user is obliged to check the product himself, prior to application, for suitability and use for the intended purposes.

Normed, as the manufacturer of the products, shall not be liable for any direct or consequential damages resulting from improper use, handling or improper preparation, sterilisation, maintenance and care. If products are repaired by companies or persons who have not been authorised by Normed for repair, warranty shall be forfeited.

Failure to follow the above instructions, improper handling or improper use of products supplied by us shall result in the exclusion of all warranty claims. Normed cannot be held liable for any resulting damages.

For any arising problems, please contact our **customer service** at the telephone number **+49 (0) 7461/93 43-0** or e-mail address info@normed-online.com.

13. Service life and disposal of products

Frequent reprocessing has little effect on surgical products.
The product life is usually determined by wear and damage resulting from product use.

Please submit the surgical products to professional disposal (medical waste) or a recycling system, after end of its service life.

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14. Symbol explanations in accordance with EN 980

	Do not re-use		Expiry date (year-month)
	Manufacturer		Storage temperature range
	Non-sterile		See instructions
	Sterile: Gamma sterilisation		Health Industry Bar Code
	Item number		CE ID
	Lot number	R_x ONLY	USA: Prescription

More information on Normed products can be requested from Normed Technik GmbH at any time.

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