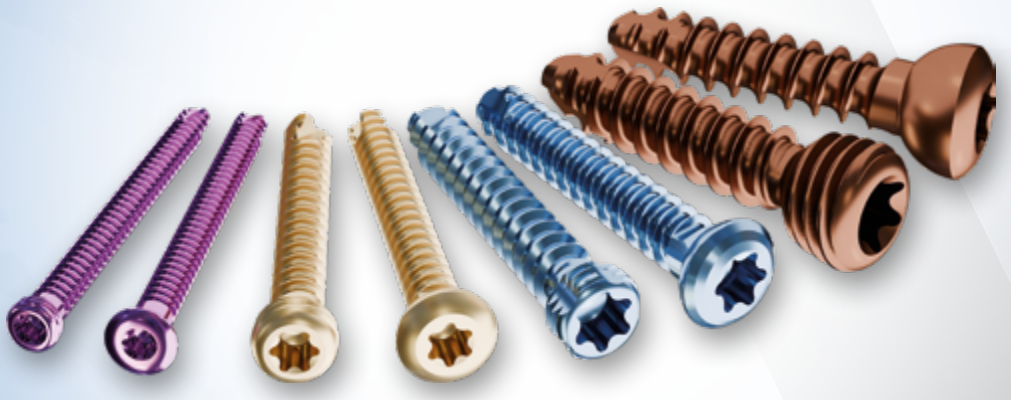
MEDGAL®
ORTHOPAEDIC IMPLANTS & INSTRUMENTS



INSTRUMENTS FOR USE BONE SCREWS

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1. SCOPE

The following instructions for use apply to bone screws.

2. DESCRIPTION AND MATERIAL

Screws and screw accessories are single-use implants designed to assist in the treatment of bone fractures by anastomosing bone fragments. These items are available in a variety of sizes, in sterile or non-sterile versions. They are designed for use both with other Medgal implants and as stand-alone products.
Implants and accessories are produced from:

- implantation steel, compliant with ISO 5832-1, with a chemical composition of:

Content of alloying elements - weight share [%]

Cr	Ni	Mo	Cu	C	Si	Mn	P	S	N	Fe
19,0	15,0	3,0	0,5	0,03	1,0	2,0	0,025	0,01	0,1	rest

- titanium alloy, compliant with ISO 5832-2, with a chemical composition of:

Content of alloying elements - weight share [%]

Fe	O	C	N	H	Ti
0,5	0,4	0,1	0,05	0,0125	rest

- titanium alloy, compliant with ISO 5832-3, with a chemical composition of:

Content of alloying elements - weight share [%]

Al	V	Fe	O	C	N	H	Ti
6,75	4,5	0,3	0,2	0,08	0,05	0,015	rest

3. NTENDED USE

Screws are used in osteosynthesis:
- for attaching plates to bone,
- for locking nails in the marrow cavity,
- for attaching external stabilizers to bones.

4. CONTRAINDICATIONS

- Insufficient vascularization that could prevent adequate blood supply to the fracture site or operated area.
- Open fractures with extensive injury of soft tissues.
- Insufficient or too weak bone substance for firm save anchoring of the implant.
- Patients without the ability or willingness to cooperate during treatment, which involves the risk of complications or damage.
- Advanced osteoporosis or weakening of bone tissue by previous implantation.
- Bone inflammation, infected pseudoarthrosis and soft tissues infection in the surgery field.
- Sensitization / allergic reaction of patient on implant alloy constituents.

5. TARGET USERS

Medgal products should only be used by healthcare professionals: e.g., orthopedic surgeons, trauma surgeons, radiologists, nurses, with specialized knowledge of the anatomy and surgical techniques associated with the products. Medgal recommends familiarization with surgical techniques before using the product.
The target patient group is long bone trauma patients with a developed skeletal system.

6. POSSIBLE COMPLICATIONS

- Loosening of the screws as a result of insufficient anchoring.
- Hypersensitivity on metal or allergic reactions.
- Osteonecrosis, osteoporosis, insufficient revascularization, bone resorption and poor osteogenesis, which can lead to secondary loss of reposition, delay or non-union of bone.
- Irritation of soft tissues and/or damage of the nerves as a result of surgical trauma.
- Damage of implant or bone as a result of improper implant selection or lack of complying the doctor's recommendations by patient.
- Complications resulting from improper removal of the implant (e.g., due to bone ingrowth).
- Cardiovascular, neurological or body malfunction complications.

CAUTION

The manufacturer is not responsible for any complications resulting from incorrect diagnosis, selection of the wrong implant or incorrect anastomosis of implant components.

7. WARNINGS AND PRECAUTIONS

- Products may only be used by qualified medical personnel.
- The implant is for single use. Once the implant is removed from the patient's body, it must be protected from reuse and then disposed of - following hospital procedures.
- The physician determines the implant's period of residence in the human body. The implant should be removed after the fracture has been treated, but after a period of no more than 2 years after implantation.
- In case of any ambiguity, please contact your regional MEDGAL representative or the manufacturer.

7.1. BEFORE SURGERY

Before implantation:

- the physician should conduct sensitization tests of the alloy components of the implant on the patient's body,
- based on X-ray imaging, the appropriate size of the implant and components must be determined,
- check the compatibility of the implants with the instruments, as well as the technical condition of the instruments (degree of wear and tear and possible damage),
- check the availability of all instrumentation components and implants scheduled for placement in the surgery room,
- verify sterility of implants and instruments.

7.2. DURING SURGERY

During the surgery:

- shape changes and modifications of the implant are not allowed,
- implants that consist of several parts should be used only in the recommended set,
- for implantation of implants and their removal from the patient's body after treatment, use MEDGAL instruments,
- if during implant insertion/use there is a change in parameters/damage to the implant, it should be replaced.

7.3. POSTSURGICAL RECOMMENDATIONS

After surgery:

- after surgery, an X-ray examination should be performed to ensure that the implant is in the correct position.
- the physician should inform the patient of the risks and complications that may arise as a result of improper management in the postoperative period.
- the surgeon should inform the patient of the need to report any unusual symptoms in the operated area. If alarming changes are detected, it is necessary to observe the patient.
- the implanted limb cannot carry the loads to which the healthy bone is subjected. The patient must be aware that excessive strain on the limb, or high activity in the post-operative period, can lead to implant damage, re-fracture of the bone and the need for reoperation.

8. PATIENT INFORMATION

- The patient is aware of the risks associated with general and orthopedic surgery, as well as general anesthesia.
- The patient received information on the benefits and possible risks of the implant, as well as on available alternative treatment options.
- The patient was informed about the necessity of follow-up examinations after the surgery, reporting unusual changes at the implant site and the possibility of subsequent removal of the implant.
- The patient should be given information on the material of the implant.
- If an MRI scan is scheduled, the patient must inform the medical staff of having an implant.
- The patient should be advised to carefully familiarize with the instructions contained in the "Patient Information Leaflet," available exclusively at www.medgal.com.pl
- The health care specialist should fill out the "Implant Card" and give it to the patient, as well as inform the patient to read the "Patient Information Leaflet" available on the website.

9. MAGNETIC RESONANCE

- Medgal implants have not been verified for MRI compatibility.
- Performing an MRI scan for steel implants may involve potential risks: occurrence of artifacts on MRI images, displacement or heating of the implant.
- Implants made of titanium and its alloys are considered non-ferromagnetic and should not be subjected to strong interactions in a magnetic field.
- Medgal implants are conditionally approved for MRI scanning.

WARNING

The user must familiarize oneself with the recommendations and warnings fo the manufacturer of the MRI device that will be used to perform the test to ensure the safety and proper conduct of the procedure.
Magnetic resonanse imaging may be affected if the examination area overlaps or is in close proximity to the implant.
Magnetic resonance imaging should not be performed if there are doubts about the integrity of the tissues, the proper attachment of the implant or the inability to determine its precise location.

10. CLINICAL BENEFITS

Bone screws provide internal stabilization of fractured long bones, which speeds up the healing process by keeping bone fragments in the correct position. Thanks to the nail locking, the risk of displacement of bony fragments is reduced, which is particularly important in multifracture and compound fractures.

11. RECOMMENDATIONS FOR IMPLANTS SUPPLIED AS STERILE

Sterilization is performed by radiation with gamma rays at a dose of at least 25 kGy or by steam (the sterilization method is indicated on the product label). The implants are supplied in sterile packaging with a sterility indicator in case of:
a) radiation sterilization - red color (dot-shaped indicator),
b) steam sterilization - dark brown / black color (indicator on the sleeve).
Before using a sterile implant, follow these rules:

- check the sterilization expiration date - do not use an implant with an expired sterilization expiration date,
- check whether the sterile packaging is not damaged - do not use implants with damaged packaging (the implant should be returned to the manufacturer),
- check whether the sterility indicator is placed on the sterile packaging
- remove products from packaging according to aseptic principles.

12. RECOMMENDATIONS FOR IMPLANTS SUPPLIED AS NON-STERILE

Before using a non-sterile product, follow these rules:

- the product should be subjected to a cleaning, disinfection and sterilization process,
- the hospital facility is responsible for the effectiveness of its cleaning, packaging and sterilization processes using its equipment, materials and trained personnel.

12.1. WASHING AND DISINFECTION

The cleaning and disinfecting agents selected from those available on the market should be approved for use with medical devices.

- **Pre-cleaning by hand with ultrasonic cleaning**

After removing the device from the packaging, remove any surface soiling (caused, for example, by damage to the unit packaging) using disposable cloths or brushes made of plastic (nylon brushes recommended).

Manufacturer's recommended process:

- Cleaning bath with Houghto-Clean 130
  Concentration **5% ± 0.5%**
  Temperature **60 °C ± 4 °C**
  Time **≥ 30 minutes**
- Rinsing with demineralized water
  Time **≥ 1 minute**
- Drying
  Temperature **130 °C ± 4 °C**
  Time **≥ 15 minutes**

During washing, each product should be completely disassembled or opened, ensuring full immersion and no contact between individual components.

- **Automatic cleaning and disinfection**

The recommended cleaning method is the process carried out in a washer-disinfector. The washer-disinfector
must meet the requirements of ISO 15883.
Hospital procedures and recommendations of chemical and equipment manufacturers must be followed, especially with regard to dosage, concentration, temperature, operating time and material compatibility.

Recommended washing procedure in a washer-disinfector:

- Pre-washing in cold water
  Time **≥ 8 minutes**
- Basic cleaning with Getinge Clean Universal Detergent
  Agent volume **60±1 ml**
  Temperature **60 °C ± 1 °C**
  Time **≥ 10 minutes**
- Neutralization with Getinge Clean Neutralizer
  Agent volume **20±1 ml**
  Temperature **60 °C ± 1 °C**
  Time **≥ 1 minute**
- Rinsing with demineralized water
  Time **≥ 4 minutes**
- Thermal disinfection with Getinge Clean Rinse Aid
  Agent volume **8±1 ml**
  Temperature **90 °C ± 1 °C**
  Time **≥ 5 minutes**
- Drying
  Temperature **90 °C ± 1 °C**
  Time **≥ 24 minutes**

After the implants are removed from the device, they must be packaged as immediately as possible in a package designed for the specified sterilization method, meeting the requirements of ISO 11607. The packaging must be done under controlled cleanliness conditions of ISO class 7 or lower.

13. STERILIZATION

The washed, disinfected and dried product can be sterilized in accordance with the the customer's current procedures. The recommended method of sterilization is - steam sterilization steam sterilization according to the following parameters:

Temperature **134 °C [-0, +3]**
Exposure time **≥ 5min 30s**
Pressure **3 bars [min.3,0301 max. 3,250]**
Drying time **≥ 30 [min]**

- The sterilization process must be validated according to ISO 17665.
- Sterile implants should meet the requirements of EN 556-1 for Assurance of sterility of the device at the S.A.L.=10-6 level, (where S.A.L. stands for Sterility Assurance Level).
- An implant supplied in a non-sterile version cannot be sterilized in the package in which it was delivered.

14. RESTERILIZATION

A steam-sterilized product can be resterilized. Responsibility for resterilization of the product is assumed by the user. In this case, the device must be washed and sterilized as described in sections 12 and 13.

CAUTION

Before starting the washing process of an implant, the packaging of which has been damaged, it is absolutely necessary to carry out a thorough visual inspection and check the implant - a damaged product (damage to the external surface, changes in shape) must not be sterilized again or iplanted in a patient.

- **Implants that have come into contact with the patient's blood or bodily fluidscannot be reused and sgould be disposed of.**
- **The product supplied as sterile - sterilized by radiation cannot be resterilized (regardless of the method used).**

15. PRODUCT STORAGE

After taking out from the outer packaging, the implants must be stored in dry rooms, ensuring free airflow. Otherwise, temperature fluctuations can cause formation of condensate inside the unit package, which may lead to corrosion. Method of storage should prevent from damage to the packaging / product. The storage facility should ensure maintenance of temperature T = 5÷25[°C] and relative humidity not higher than 65%. Avoid contact of the implant with chemicals that may cause corrosion. The implants shall be transported to the operating room on trays or in sterilization baskets.

16. NOTIFICATION

If a related incident occurs during the use of this equipment, inform the manufacturer and the relevant national authorities.
Contact address: customerservice@medgal.com.pl

17. UTILIZATION

Hospitals must comply with national regulations on medical waste disposal. Contaminated products should be disinfected before being sent for disposal.

18. SYMBOLS

	Ostrzeżenie Caution Avvertenza Upozornenie/pozri návod na použitie
	Zajrzyj do instrikcji używania Consult instructions for use Consultare le istruzioni per l'uso
	Nie używać powtórnie Do not reuse Non riutilizzare Nepoužívajte opakovane
	Użyć do Use by Data di scadenza Dátum exspirácie
	Numer katalogowy Catalogue number Codice Catalogo Kód produktu
	Data produkcji Date of manufacture Data di fabbricazione
	System pojedynczej bariery sterylnej z opakowaniem ochronnym na zewnątrz Single sterile barrier system with protective packaging outside Sistema di barriera sterile singolo con imballaggio protettivo esterno
	Niesterylny Non-sterile Non sterile
	Nie używać, jeśli opakowanie jest uszkodzone Do not use if package is damaged Non utilizzare se l'imballaggio è danneggiato
	Kod partii Batch code Codice del lotto Číslo šarže

	Nie sterylizować ponownie Do not resterilize Non resterylizzare
	Wytwórca Manufacturer Fabbricante
	Trzymać z dala od promieniowania słonecznego Keep away from sunlight Proteggere dalla luce solare
	Sterylizowany parą wodną Sterilized using steam Sterilizzato a vapore
	Sterylizowany przez napromieniowanie Sterilized using irradiation Sterilizzato mediante irradiazione
	Ograniczenie wilgotności Humidity limitation Limitazione dell'umidità
	Ograniczenie dopuszczalnej temperatury Limitation of temperature Limitazione della temperatura ammessa Teplotné limity skladovania
	Przepakować przed sterylizacją Repack before sterilization Riconfezionare prima della sterilizzazione
	Wyroby medyczne Medical devices Dispositivi medici
	Przechowywać w suchym miejscu Keep dry Tenere asciutto
	Deklaracja zgodności European Conformity Conformità Europea

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