



» KIRSCHNER DRILL WIRES,
STEINMANN NAILS,
BUNDLE NAILS,
BONE WIRESE,
CERCLAGE WIRES «





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Instructions for use – please read before use 4/ 14



To minimize risks to patients, users, or potentially third parties, these instructions for use must be carefully followed!



The application, preparation and testing of medical devices, hereinafter referred to as " **bone implants** ", may only be carried out by trained specialists.



Tekno-Medical bone implants are Class IIb medical devices for single use , are supplied **non-sterile** and must undergo the complete cleaning and sterilization cycle before use.

1 SCOPE

The scope of these instructions for use refers to the following products of Tekno-Medical Optik-Chirurgie GmbH (hereinafter referred to as "Tekno-Medical"):



- Kirschner drill wires, bundle nails & Steinmann nails,
- bone wires,
- Cerclage wires.

(See product list in the last section.)

2 EXAMS

Bone implants are extremely sensitive to damage. Even minor scratches or dents can cause internal stresses that significantly reduce their strength. Therefore, extremely careful handling is essential.

- Before unpacking: Check the outer packaging for damage/transport damage and condensation.
- Check that the label matches the contents. The label is considered part of the product and must be retained for traceability purposes (lot number).
- Visual inspection of the bone implant for damage (discoloration, cracks, chips, burrs or other damage).
- Returns of unused bone implants must only be made in protective packaging.

3 DESCRIPTION

Bone implants from Tekno-Medical Optik Chirurgie GmbH are used in osteosynthesis and to correct degenerative changes in the skeleton. These bone implants serve only to promote healing and do not represent a replacement for healthy tissue and bone.

4 INTENDED PURPOSE

Bone implants from Tekno-Medical are used to support osteosynthesis .



Use outside of its intended purpose may lead to complications or harm to the patient, and may require re-operation.

4.1 Intended use: Kirschner drill wire

For closed reduction and fixation of a fracture. Procedures for surgical fracture treatment include:

- percutaneous intramedullary splinting, e.g., on the metacarpal bones
- Percutaneous "pinching" as fixation of a fracture by inserting a Kirschner wire, if possible with fixation of the wire in the opposite cortex.

They are frequently used together with cerclage wires as a tension band. In this process, dynamic tensile forces, for example from muscles attaching to the fragment, are converted into compressive forces. The drill wires are screwed into the bone using a drill without pre-drilling. Threaded drill wires are used with external fixators.

Kirschner wires can also be used in combination with other medical devices, e.g.:

- as a guide wire for the implantation of slotted screws or for other instruments,
- For the temporary fixation of bone plates.

When combining with other instruments or implants, compatibility must be checked before use to avoid delays in the surgical procedure.

4.2 Intended use: Bone wire

Bone wires are used as a standalone procedure to treat a fracture by wire entanglement. The soft wire is usually wrapped around the bone several times and tightened by twisting.



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4.3 Intended use: cerclage wire

Cerclage wires are used as a standalone procedure to treat fractures by wire encircling the bone . The soft wire is usually wrapped around the bone several times and tightened by twisting.

The pre-cut wires with eyelets are used in the folding cerclage process.

Cerclage wires are also used for the fixation of fragments under a plate, for rotationally stable fragment fixation during intramedullary nailing. used .

5 INDICATIONS

Bone implants are indicated for a wide range of applications in orthopedic trauma surgery, such as:

- Treatment of bone fractures
- Repositioning and fixation of metaphyseal fractures,
- Diaphyseal fractures and dislocations of the hand and foot bones,
- Temporary arthrodesis of small joints,
- Temporary intraoperative fixation of fracture fragments,
- Fractures of the musculoskeletal system,
- Closed / open fracture.

The treating physician is responsible for selecting the right bone implant for specific applications or surgical use, providing appropriate training and information, and having sufficient experience in handling the bone implants.

6 CONTRAINDICATIONS

6.1 Absolute contraindications

Health conditions that preclude sufficient implant support or inhibit the healing process, e.g.:

- Fractures of the spine,
- Impairment of blood supply,
- insufficient bone quality or quantity (osteoporosis),
- extreme obesity,
- acute and chronic, local or systemic infections,
- deep and superficial infections,
- Twisting or severe inclination of the fracture,
- Muscle, nerve or vascular diseases that endanger the affected limb,
- Local bone tumors,
- Systemic diseases and metabolic dysfunctions,
- serious malformations,
- serious falls,
- Mental conditions that make participation in the rehabilitation program impossible (Parkinson's disease, alcoholism, drug use, etc.),
- strenuous physical activities involving strong vibrations, where the implants are exposed to impacts and/or excessive stress (e.g. heavy physical labor, etc.),
- Allergy or other reactions to the material used.

6.2 Relative contraindications

Fusion of the proximal interphalangeal joint.

7 PATIENT POPULATION

Due to the variety of bone implants in terms of diameter (0.6-6.0 mm) and length (50-600 mm), there is no restriction on the patient target group.

8 COMBINATIONS

For metallurgical, mechanical and structural reasons, implants made of different materials must not be combined.



9 STORAGE BEFORE PROCESSING

The bone implants must be stored in their packaging or in a protective container. Protect any areas that could cause injury (e.g., points and edges).



The implants must be stored in a dry, clean, and dust-free environment, protected from direct sunlight and at a constant humidity level. The distance between the floor and the shelf should be at least 30 cm.

Pay particular attention to ensuring that no aggressive chemicals are located in the immediate vicinity of the storage location.

10 IMPORTANT INFORMATION / WARNINGS

10.1 Important information for doctors and operating room staff



These products are not intended for use on the heart, central nervous system, or circulatory system!

- The correct selection of the bone implant is of utmost importance. The appropriate implant type and size must be tailored to the individual patient. The patient's weight and activity level, as well as the fracture being treated, must be taken into account. Using the largest possible bone implant and positioning it correctly prevents bending, breaking, cracking, and loosening of the implant. This also minimizes the force transmitted to the bone.
- Choosing the wrong bone implant can lead to implant failure!
- It is absolutely essential that the user is familiar with the appropriate surgical technique for the instruments and implants used. The surgeon alone is responsible for the selection and use of the bone implant.
- Bone implants may only be used in procedures specifically designed for this purpose, where the intended use of the implant is expressly required and defined.
- Before every operation, it must be checked whether the patient is exceptionally sensitive or possibly allergic to the implant material.
- Drill wires with partial or full threads, as well as those with drill tips, can break if used improperly. The manufacturer accepts no liability for this.
- For the application of the wires, appropriate drilling equipment (with three-jaw chuck) must be used.
- Trained professionals are obligated to inspect the bone implant for integrity before each use/procedure. If it shows damage or deformation, primarily at the tips and edges, it must not be used.
- For bone implants with a deliberately roughened surface (e.g. threads or knurling), the increased diameter may need to be taken into account (e.g., in combination with other instruments or implants).
- Before use, the diameter of the bone implant must be checked with a suitable measuring instrument or template. **Implants that are too thin are at risk of breakage.**
- In general, the doctor must inform the patient about indications, contraindications, undesirable side effects and postoperative treatment, and document this information.
- Regular medical check-ups should be performed after implantation.

10.2 Risks / Intolerances

- Following the insertion of metal implants, an inflammatory reaction of varying severity can occur. Other symptoms may include: local or generalized eczema, impaired wound healing, and pain.
- If you have a proven allergy to nickel, cobalt and chromium, do not use implants made of material containing these substances (e.g. implant steel 1.4441).
- Titanium implants can also trigger inflammatory reactions, which can lead to a lack of osseointegration. (Titanium particles in tissue can also trigger an inflammatory response.)
- Inadequate cleaning and sterilization can lead to infections in the patient .
- Faulty reprocessing procedures can lead to surface discoloration or corrosion of the implant.
- Improper use during implantation or overloading the implant before, during, and after implantation can lead to fractures or deformations of the implant. This may harm the patient.
- The doctor must carefully consider any potential risks from external electrical and electromagnetic influences (radiation, magnetic fields) in connection with diagnostic and therapeutic procedures (e.g., X-ray, MRI) before the examination.



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10.3 Complications

The following complications have been observed on several occasions and therefore require the special attention of the treating physician:

- Bending, breaking, loosening or detachment of the implant,
- Loss of anatomical position in the event of insufficient healing of the fracture,
- superficial and deep infections,
- Vascular diseases such as thrombophlebitis, pulmonary embolism, hematomas,
- Allergies, tissue and foreign body reactions near bone implants,
- Impaired or absent fracture healing,
- Bone deformation and refracture,
- Displacement of the bone implant,
- Cardiovascular dysfunction.

10.4 Modifications

- Modifications to bone implants may only be carried out by trained users with appropriate instruments.
- Material fatigue must be avoided!

10.5 Further information

- A surgical description or instruction manual can never be complete and include all risks and complications that must be considered.
- Before the procedure, the surgeon must familiarize himself with the implants, instruments and corresponding techniques.
- Before starting treatment, please ensure that the necessary instruments are available and suitable for use with our bone implants.
- The bone implants must not come into contact with objects that could damage their surface. They must not be mechanically processed or otherwise altered unless the design and surgical technique expressly permit it. In the latter case, the modification must be carried out with the appropriate instruments in accordance with the literature.
- Bending bone implants must be done carefully. Extreme deformation of the bone implant must be avoided at all costs. Repeated bending back and forth leads to fatigue or fracture of the bone implant. Chips and pressure points also significantly reduce its mechanical strength.
- To ensure complete traceability, the article number and batch number (lot number) of the bone implant used must be documented in the surgical report.
- All serious incidents relating to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- The physician must determine the extent of the injuries/changes requiring surgical treatment and select the appropriate bone implants. Furthermore, the physician must determine the correct timing and surgical procedure for the patient, particularly in cases of comorbidities and complex multiple injuries.
- Complications that may arise due to incorrect indication, handling of the bone implant, surgical technique or asepsis are the responsibility of the surgeon and cannot be attributed to the manufacturer of the bone implants.

10.6 Postoperative risks

- Bone implants can never bear the full load of the treated bone segment. Therefore, the doctor must inform the patient about the load limits and prescribe appropriate postoperative behavior.
- Early weight-bearing increases stress on the implant and can lead to fracture, bending, or loosening. This is particularly important to consider in patients subjected to heavy loads or those experiencing delayed healing or bone fusion. Weight-bearing can be considered when a stable fracture with good bone-to-bone contact is present. Full weight-bearing before complete fracture healing is contraindicated.
- Postoperative instructions for the patient, proper nursing care, and regular medical check-ups are of great importance.

10.7 Removal of bone implants

- The wires can be removed once the goal of the operation has been achieved, i.e., once the fracture has healed. If the wires become loose, they must be removed promptly, as otherwise they could pierce the skin from the inside, break, or migrate, potentially damaging tendons, nerves, and/or blood vessels.
- If the wires remain in the body for too long, they can become difficult or even impossible to remove.
- The final decision regarding the removal of the bone implant is made by the surgeon or treating physician.



Implanted, contaminated implants must not be placed in the sterilization tray to avoid contamination of the contents of the sterilization tray.



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10.8 Materials used

The bone implants are manufactured from materials that meet the requirements of the following harmonized standards (the specifications are given in **weight percent** [wt.%, % (m/m)]):

- DIN EN ISO 5832-1 Stainless steel (1.4441)
(Article number begins with **M33**)

C% (max.)	Si% (max.)	Mn% (max.)	P% (max.)	S% (max.)	Cr%	Ni%	N% (max.)	Mo%	Cu% (max.)
1.4441 [X2CrNiMo18-15-3]									
0.03	1.00	2.00	0.025	0.01	17.00-19.00	13.00-15.00	0.10	2.25-3.00	0.5

- DIN EN ISO 5832-3 Titanium-6-aluminium-4-vanadium wrought alloy (Ti6Al4V)
(Article number begins with **M34**)

Al%	V%	Fe% (max.)	O% (max.)	C% (max.)	N% (max.)	H% (max.)	Ti%
3.7164 [Ti-6Al-4V ELI]							
5.50-6.75	3.50-4.50	0.3	0.2	0.08	0.05	0.015	Main component

The bone implants do not contain:

- Tissue of human or animal origin,
- Ingredients of medicines,
- Software.

11 REPROCESSING (CLEANING, DISINFECTION AND STERILIZATION)

In general, medical devices may only be reprocessed by individuals who possess the necessary expertise for the intended tasks. Detailed information on the reprocessing of medical devices can be found in the AKI's "Red Brochure." Links to laws, standards, and reprocessing expert committees can also be found at www.aki.org.



Staff should be aware of this instruction and recommendation to ensure safe and effective reprocessing and to prevent damage or misuse of the bone implants.

11.1 General principles

All Tekno-Medical bone implants must be cleaned, disinfected, and sterilized before use, as they are delivered non-sterile. Effective cleaning and disinfection are essential prerequisites for effective sterilization.

As part of your responsibility for the sterility of the bone implants, please note:

- that, in principle, only sufficiently device- and product-specific validated procedures are used for cleaning/disinfection and sterilization,
- that the equipment used (washer-disinfector, sterilizer, etc.) is regularly serviced, checked and calibrated and
- that the validated parameters are adhered to in every cycle.

Make sure to collect soiled or explanted implants separately and do not place them back in the sterilization tray to avoid contamination of the loaded sterilization tray.

Please observe the legal regulations applicable in your country as well as the hygiene regulations of the doctor's office or hospital. This applies in particular to the different requirements (e.g., in Germany according to Annex 7 of the KRINKO RKI BfArM recommendation on reprocessing) regarding effective prion inactivation (not applicable to the USA).

Reprocessing may only be carried out by trained specialists in the central sterilization unit of the hospital or in the reprocessing room of the doctor's office. The hospital or doctor's office is also responsible for selecting and using the necessary protective equipment and hygiene measures.



Contaminated and explanted implants must never be reprocessed and reinserted!

The use of non-sterile/contaminated implants can lead to infections in the patient. This may lead to complications, delays, or a failure of the healing process.



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11.2 Basics

For cleaning and disinfection, a washer-disinfector (WD) should be used whenever possible, or in accordance with country-specific requirements (e.g., in Germany, a machine-based process is mandatory for critical B-products). Manual methods – even using an ultrasonic bath – should only be used if a machine-based process is unavailable, due to their significantly lower effectiveness and reproducibility.

When selecting the cleaning agent used, care should be taken to ensure that...

- This is generally suitable for cleaning metal implants.
- The cleaning agent is suitable for ultrasonic cleaning (no foaming).

The concentrations, temperatures, contact times, and rinsing instructions provided by the manufacturer of the cleaning agent or cleaning and disinfection agent must be strictly followed. Use only freshly prepared solutions and only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g., purified water/highly purified water).

Should you deem a lower water quality to be sufficient, this is your sole responsibility.

For drying, use only a soft, clean and lint-free cloth and/or filtered air (oil-free, low in germs and particles).



Exercise caution with products that have rough surfaces, threads, sharp edges, or similar features where particles from the cloth can stick.

11.3 Manual pre-cleaning

Soak implants in cold deionized water for at least 5 minutes. If possible, clean them under cold running water with a soft brush until no residue is visible.

Place implants in an ultrasonic bath at 40°C with alkaline or enzymatic cleaner and sonicate for 15 minutes.

Remove the implants and rinse them with cold water.

The cleaning solution should be changed at least once a day, and more often if necessary. Excessive soiling impairs the cleaning effect and increases the risk of corrosion. National laws and regulations must be observed.

11.4 Machine cleaning

Step	parameter	
Pre-rinse	Washing temperature + water quality	Cold city water
	Exposure time	60s
Pre-rinse	Washing temperature + water quality	Cold city water
	Exposure time	180s
Clean	Cleaning temperature	45°C
	Water quality	City water
	Exposure time	300 s (worst case condition), RKI recommendation 600 s
	Cleaning agent concentration	Neodisher Medizyme 0.50%
Neutralization	Washing temperature	40°C
	Water quality	City water
	Exposure time	180s
	Neutralizing agent concentration	Neodisher Z 0.10%
Rinse	Washing temperature	40°C
	Water quality	demineralized water
	Exposure time	120 s

11.5 Mechanical (thermal) disinfection

Step	parameter	
Thermal disinfection	Disinfection temperature	90°C (A ₀ 3000)
	Water quality	demineralized water
	Exposure time	300 s
Dry	The implants are dried by the drying cycle of the cleaning/disinfection device. If necessary, additional manual drying can be achieved using a lint-free cloth.	



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11.6 Controls

After cleaning or cleaning and disinfection, inspect all products for corrosion, damaged surfaces, chipping, soiling, and discoloration, and discard any affected products. (Further information can be found in DIN 96298-4.)



Caution : Always thoroughly check wires on reels for residual contamination!

Cervical and bone wires that are stored, cleaned, disinfected, and sterilized in a coiled state may, after repeated reprocessing, exhibit contamination between the individual layers that cannot be removed by the standard procedure. In this case, the wires must be subjected to further cleaning and disinfection, possibly separately.



If residual contamination cannot be removed, the products must be disposed of!

11.7 Packaging

If possible, place the cleaned and disinfected products into the corresponding sterilization tray.

Pack the products or sterilization trays in sterilization containers, or very large products in single-use sterilization packaging (single or double packaging) that meets the following requirements (material/process):

- DIN EN ISO 11607-1, DIN EN 868-2 and DIN EN 868-8,
- Suitable for steam sterilization (temperature resistance up to at least 138 °C, sufficient steam permeability)
- adequate protection of the products or sterilization packaging from mechanical damage
- Regular maintenance according to the manufacturer's specifications (sterilization container)
- A maximum weight of 10 kg per sterilization container must not be exceeded.

11.8 Sterilization



Bone and cerclage wires: Cable ties holding the reels or wires together must be removed before sterilization!

Sterilization of the products using a fractionated pre-vacuum process (according to DIN EN ISO 17665-1) taking into account the respective national requirements.

Step	parameter
Pre-vacuum:	3 times
Sterilization temperature:	134 °C
Sterilization time:	5 min
Drying time:	20 min.

The use of any other sterilization method is outside our responsibility.

Rapid sterilization is strictly prohibited. Furthermore, do not use hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

11.9 Material resistance

When selecting cleaning and disinfecting products, ensure that they do not contain the following ingredients:

- organic, mineral and oxidizing acids (minimum permissible pH value 5.5),
- Alkalis / strong alkalis (max. permissible pH value 11),
- organic solvents (e.g. alcohols, ethers, ketones, gasolines),
- Oxidizing agents (e.g. hydrogen peroxide),
- Halogens (chlorine, iodine, bromine),
- aromatic/halogenated hydrocarbons.

Never clean any products, sterilization trays and sterilization containers with metal brushes or steel wool.

11.10 Information on the validation of the processing

The following chemicals and machines were used in the validation of the automated processing:

Cleaning agents:	Neodisher Medizym 0.5% (v/v)
Neutralizer:	Neodisher Z 0.1% (v/v)
Cleaning and disinfection device (RDG):	Miele PG 8535
Steam autoclave:	Lautenschläger ZentraCert
Laboratory:	CleanControlling Medical GmbH & Co. KG

If the chemicals and machines described here are not available, it is the user's responsibility to validate their process accordingly.



It is the user's responsibility to ensure that the reprocessing process, including resources, materials and personnel, is suitable to achieve the required results.

The state of the art and national laws require adherence to validated processes.



Instructions for use – please read before use 11/ 14

11.11 Storage

The bone implants must be stored in a clean, dry environment in their packaging or a protective container. Protect any areas that could cause injury (e.g., points and edges).



Sterilized implants must be stored in suitable packaging in a dry, clean, and dust-free environment, protected from direct sunlight and at a constant humidity level. The distance between the floor and the shelf should be at least 30 cm.



The storage period must be determined by the user.

Pay particular attention to ensuring that no aggressive chemicals are located in the immediate vicinity of the storage location.

11.12 Transport

Bone implants should always be transported in a closed container or protective packaging to prevent damage from unintentional movement. Particular attention should be paid to protecting any sharp points.

11.13 Reusability

Tekno-Medical's bone implants are marketed as " **single use** " ("**single-use product**").

Bone implants are intended for single use only. Single-use products must not be reused, as they are designed to no longer function as intended after their first use. Repeated use of the bone implant can lead to overloading and breakage of the implant due to wear and tear or bending.

Implants must not be reused after explantation! **Re-implantation is not permitted!**

If the bone implant is not used after reprocessing, it can be stored again and reprocessed upon re-request, provided it has not had any patient contact or contact with other potentially contaminated fluids or objects.

12 DISPOSAL AND RETURN

Expired or explanted bone implants must be disposed of by the hospital. To prevent infections and microbiological hazards, the products to be disposed of must undergo the entire reprocessing procedure.

Returned, used bone implants must also undergo the entire reprocessing process and be labeled as "hygienically safe" before being sent back. Return shipment must be in suitable and secure packaging.

urns, please use our RMA application form with decontamination certificate.

Forms available at: <https://www.tekno-medical.com/de/service/reparaturservice/>

13 REPORTING PRODUCT PROBLEMS

In accordance with the requirements of Regulation (EU) 2017/745 on medical devices and our quality management system, all product problems must be reported to the manufacturer.

During business hours you can reach us by phone at +49 (0) 07461 / 1701-0.

Outside of regular business hours, please send an email to safety@tekno-medical.com.

Serious incidents must also be reported to the local authority responsible for their location.

14 WARRANTY

The products are manufactured from high-quality materials and undergo quality control before delivery. Should any defects occur, please contact our service department. Tekno-Medical cannot guarantee that the products are suitable for any specific procedure. Tekno-Medical accepts no liability for accidental or consequential damages. Tekno-Medical accepts no liability if these instructions for use have been demonstrably violated.



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15 BRIEF SAFETY AND CLINICAL PERFORMANCE REPORT (SSCP)

The Summary of Safety and Clinical Performance (**SSCP**) report is available in the European database for medical devices (**Eudamed**).

The URL of the public Eudamed website is: <https://ec.europa.eu/tools/eudamed>.

Document name: TD-II-005_SSCP_D



Manufacturer:
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstrasse 11
78532 Tuttlingen, Germany
SRN: DE-MF-000005822

Alternatively, the SSCP can be requested directly from Tekno-Medical!

Please send an email to: safety@tekno-medical.com.

16 SYMBOLS

The symbols used in this instruction and on the label have the following meaning according to DIN EN ISO 15223-1:

	Danger!		Manufacturer
	Medical device		Date of manufacture
	Non-sterile		Follow the instructions for use.
	Catalog number		Protect from sunlight
	Batch designation		Store in a dry place
	Do not reuse		Unique product identification
	CE marking with the number of the notified body: mdc – medical device certification GmbH Kriegerstrasse 6, D – 70191 Stuttgart		

17 PRODUCT LIST FOR THE INSTRUCTIONS FOR USE

REF

Printed on 19.03.2024

17.1 Products made of implant steel (1.4441)

M33S01D06L310	M33S01D14L150	M33S01D20L100	M33S02D09L150	M33S02D16L160
M33S01D08L100	M33S01D14L160	M33S01D20L120	M33S02D09L230	M33S02D16L180
M33S01D08L150	M33S01D14L310	M33S01D20L140	M33S02D10L070	M33S02D16L200
M33S01D08L310	M33S01D15L060	M33S01D20L150	M33S02D10L080	M33S02D16L220
M33S01D09L310	M33S01D15L100	M33S01D20L160	M33S02D10L100	M33S02D16L230
M33S01D10L060	M33S01D15L120	M33S01D20L230	M33S02D10L120	M33S02D16L245
M33S01D10L070	M33S01D15L140	M33S01D20L300	M33S02D10L130	M33S02D16L310
M33S01D10L100	M33S01D15L150	M33S01D20L310	M33S02D10L150	M33S02D16L345
M33S01D10L120	M33S01D15L160	M33S01D20L450	M33S02D10L180	M33S02D16L400
M33S01D10L140	M33S01D15L310	M33S01D22L060	M33S02D10L250	M33S02D17L180
M33S01D10L150	M33S01D16L060	M33S01D22L100	M33S02D10L310	M33S02D17L230
M33S01D10L160	M33S01D16L100	M33S01D22L120	M33S02D10L400	M33S02D17L310
M33S01D10L310	M33S01D16L120	M33S01D22L140	M33S02D11L100	M33S02D18L150



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M33S01D11L060	M33S01D16L140	M33S01D22L150	M33S02D11L150	M33S02D18L160
M33S01D11L080	M33S01D16L150	M33S01D22L160	M33S02D12L100	M33S02D18L180
M33S01D11L100	M33S01D16L160	M33S01D22L310	M33S02D12L150	M33S02D18L220
M33S01D11L120	M33S01D16L310	M33S01D24L310	M33S02D12L180	M33S02D18L230
M33S01D11L140	M33S01D17L060	M33S01D25L150	M33S02D12L300	M33S02D18L280
M33S01D11L190	M33S01D17L100	M33S01D25L160	M33S02D12L310	M33S02D18L310
M33S01D12L060	M33S01D17L120	M33S01D25L230	M33S02D12L350	M33S02D19L230
M33S01D12L080	M33S01D17L140	M33S01D25L310	M33S02D12L400	M33S02D20L150
M33S01D12L100	M33S01D17L150	M33S01D25L570	M33S02D13L150	M33S02D20L151
M33S01D12L120	M33S01D17L160	M33S01D28L310	M33S02D14L060	M33S02D20L180
M33S01D12L140	M33S01D17L310	M33S01D30L150	M33S02D14L100	M33S02D20L230
M33S01D12L150	M33S01D18L060	M33S01D30L230	M33S02D14L150	M33S02D20L280
M33S01D12L160	M33S01D18L100	M33S01D32L570	M33S02D14L180	M33S02D20L310
M33S01D12L310	M33S01D18L120	M33S02D06L070	M33S02D14L310	M33S02D20L400
M33S01D13L060	M33S01D18L140	M33S02D08L070	M33S02D14L400	M33S02D20L450
M33S01D13L100	M33S01D18L150	M33S02D08L080	M33S02D15L060	M33S02D22L150
M33S01D13L120	M33S01D18L160	M33S02D08L100	M33S02D15L070	M33S02D22L310
M33S01D13L140	M33S01D18L310	M33S02D08L130	M33S02D15L100	M33S02D22L400
M33S01D13L150	M33S01D19L060	M33S02D08L150	M33S02D15L150	M33S02D24L150
M33S01D14L060	M33S01D19L100	M33S02D08L310	M33S02D15L180	M33S02D24L151
M33S01D14L100	M33S01D19L120	M33S02D08L400	M33S02D15L310	M33S02D24L300
M33S01D14L120	M33S01D19L140	M33S02D09L100	M33S02D15L400	M33S02D24L310
M33S01D14L140	M33S01D20L060	M33S02D09L130	M33S02D16L150	M33S02D24L400
M33S02D24L430	M33S02D45L200	M33S03D15L310	M33S13D12L310	M33S25D30L300
M33S02D25L070	M33S02D45L250	M33S03D16L060	M33S13D14L150	M33S25D32L1000
M33S02D25L100	M33S02D45L300	M33S03D16L080	M33S13D14L310	M33S25D32L600
M33S02D25L150	M33S02D50L120	M33S03D16L150	M33S13D15L150	M33S25D40L310
M33S02D25L250	M33S02D50L150	M33S03D16L310	M33S13D15L310	M33S31D08L310
M33S02D25L280	M33S02D50L180	M33S03D17L150	M33S13D16L150	M33S31D10L310
M33S02D25L310	M33S02D50L200	M33S03D17L310	M33S13D16L200	M33S31D12L310
M33S02D25L400	M33S02D50L250	M33S03D18L120	M33S13D16L310	M33S31D14L150
M33S02D25L450	M33S02D50L300	M33S03D18L150	M33S13D17L150	M33S31D15L310
M33S02D30L060	M33S03D05L070	M33S03D18L285	M33S13D17L310	M33S31D16L310
M33S02D30L075	M33S03D05L080	M33S03D18L310	M33S13D18L150	M33S31D17L310
M33S02D30L150	M33S03D06L070	M33S03D19L150	M33S13D18L200	M33S31D18L310
M33S02D30L310	M33S03D06L150	M33S03D19L310	M33S13D18L225	M33S31D20L310
M33S02D30L400	M33S03D08L100	M33S03D20L120	M33S13D18L310	M33S31D22L310
M33S02D32L075	M33S03D08L150	M33S03D20L150	M33S13D20L150	M33S31D25L310
M33S02D32L090	M33S03D08L310	M33S03D20L160	M33S13D20L310	M33S31D30L310
M33S02D32L105	M33S03D09L100	M33S03D20L310	M33S13D22L150	M33S31D35L310
M33S02D32L120	M33S03D09L150	M33S03D22L150	M33S13D22L310	M33S31D40L310
M33S02D32L130	M33S03D09L310	M33S03D22L310	M33S13D24L300	M33S32D08L310
M33S02D32L150	M33S03D10L080	M33S03D24L310	M33S13D25L150	M33S32D10L310
M33S02D32L200	M33S03D10L100	M33S03D25L100	M33S13D25L310	M33S32D12L310
M33S02D32L450	M33S03D10L150	M33S03D25L150	M33S13D30L150	M33S32D14L150
M33S02D35L120	M33S03D10L160	M33S03D25L310	M33S13D30L170	M33S32D15L310



Instructions for use – please read before use 14/ 14

M33S02D35L150	M33S03D10L200	M33S03D25L800	M33S13D30L310	M33S32D20L310
M33S02D35L180	M33S03D10L285	M33S03D28L310	M33S13D30L420	M33S32D20L400
M33S02D35L200	M33S03D10L310	M33S03D30L120	M33S18D32L300	M33S32D25L310
M33S02D35L250	M33S03D11L100	M33S03D30L150	M33S19D16L200	M33S33D08L150
M33S02D35L300	M33S03D11L150	M33S03D30L310	M33S19D16L230	M33S33D12L120
M33S02D35L400	M33S03D12L100	M33S03D35L310	M33S25D08L150	M33S33D20L300
M33S02D40L080	M33S03D12L120	M33S03D40L310	M33S25D08L320	M33S33D25L150
M33S02D40L100	M33S03D12L140	M33S03D45L310	M33S25D10L300	M33S33D25L250
M33S02D40L120	M33S03D12L150	M33S03D50L310	M33S25D10L450	M33S33D25L300
M33S02D40L140	M33S03D12L230	M33S03D60L310	M33S25D12L220	M33S33D30L200
M33S02D40L150	M33S03D12L285	M33S05D20L150	M33S25D14L310	M33S33D30L250
M33S02D40L180	M33S03D12L310	M33S12D15L150	M33S25D14L350	M33S33D40L400
M33S02D40L200	M33S03D13L150	M33S12D16L200	M33S25D14L400	M33S45D17L350
M33S02D40L250	M33S03D13L310	M33S12D18L200	M33S25D16L400	M33S45D20L350
M33S02D40L300	M33S03D14L100	M33S12D20L150	M33S25D18L220	M33S45D24L430
M33S02D40L400	M33S03D14L150	M33S12D25L150	M33S25D18L400	M33S46D24L230
M33S02D45L120	M33S03D14L310	M33S12D25L250	M33S25D20L300	M33S46D24L250
M33S02D45L150	M33S03D15L150	M33S12D30L150	M33S25D20L400	M33S47D24L400
M33S02D45L180	M33S03D15L285	M33S13D12L150	M33S25D25L750	M33S47D24L430
M33S52D23L250	M33S81D12L280	M33S90D04L9999	M33S90D08L9999	M33S90D15L9999
M33S81D08L280	M33S81D12L600	M33S90D05L9999	M33S90D09L9999	M33S90D18L9999
M33S81D10L280	M33S90D02L9999	M33S90D06L9999	M33S90D10L9999	M33S90D20L9999
M33S81D10L600	M33S90D03L9999	M33S90D07L9999	M33S90D12L9999	

17.2 Products made of titanium (Ti6Al4V)

M34S01D10L150	M34S02D14L150	M34S02D20L150	M34S03D12L150	M34S32D25L150
M34S01D12L150	M34S02D16L150	M34S02D25L150	M34S03D14L150	
M34S01D14L150	M34S02D18L150	M34S02D30L150	M34S03D15L150	
M34S02D10L150	M34S02D18L310	M34S03D08L150	M34S03D16L150	
M34S02D12L150	M34S02D18L400	M34S03D10L150	M34S03D18L150	