INSTRUCTIONS FOR USE

Cut Screw - Percutaneous Compression Screw

GENERAL INFORMATION

The Cut Screw - Percutaneous Compression Screw is a cannulated compression screw for bone synthesis

- Single-use product, do not reuse, even if it is in perfect condition;
- Sterile or non-sterile supplied product;
- Non-sterile implants must undergo both cleaning and sterilization prior to use, according to recommended sterilization method;
- Prohibited reprocessing for sterile implants.

INDICATIONS FOR USE

Cut Screw - Percutaneous Compression Screw are single use devices indicated for fixing and stabilizing the bones of the mid foot, metatarsal and phalanges of the foot using an appropriate relation bone-screw size.

APPLICATIONS

The success of the treatment is directly related to the appropriate surgical technique applied by the surgeon and the correct choice of implants, following their characteristics: model, shape, type, dimensions, etc. Size and anatomy of the bone structures are main factors when choosing implants to be used. The recommendations in the Table below should be followed:

Description	Specific site treated
Cut Screw - Percutaneous Compression Screw	Mid foot bones, metatarsal and phalanges of the foot.

CONTRAINDICATIONS

- Active infection or history of recent infection at or near the implantation site;

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- Osteometabolic diseases that cause weakness or reduction of bone mass;
- Insufficient/poor quality bone mass to securely anchor the implant;
- Inadequate vascularization at or near the implantation site could compromise the adequate blood supply;
- Patients with existing implants may compromise implantation and/or interfere with the product;
- Drug abuse and alcoholism;
- Fever;
- Pregnancy;
- Allergy and/or sensitivity to metal, and
- Patients who are incapacitated and/or uncooperative during all the treatment phases.

PHYSICAL PRINCIPLE AND TECHNOLOGY FUNDAMENTALS DESCRIPTION, APPLIED TO ITS WORKING AND ACTION

Cut Screw - Percutaneous Compression Screw is a cannulated compression screw and allows the use of guide wires for positioning, visualization of the implant by the surgeon, until its final fixation.

PRODUCT MATERIALS

Screws are made of Titanium Alloy (ASTM F136/ISO 5832-3)

MARKING

The implantable components are identified by marking laser with the following information:

- Batch of product;
- Product Code;
- GMReis logo.

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PRODUCT TRACEABILITY PROCEDURE

Identification and traceability of the product are ensured through a set of 05 adhesive tags contained in the package, along with the instructions for use and the implant, such as: name, model, code, allotment, product registration and manufacturer identification. In this way it is possible to make the reverse path and reach a production, raw material, suppliers, and other quality controls established in the GMReis Quality System. It is a responsibility of the medical and hospital staff (the custodians of patient information and records), the tag fixation on the surgical description sheet or a section of the medical chart. GMReis recommends that the patient receive this information, receiving a certificate stating one of the traceability adhesive tags.

PRESENTATION FORM OF THE MEDICAL PRODUCT

Non-sterile: individual plastic packages, including 5 labels and external label identification.

Sterile: individual, using blister and surgical grade paper, containing 5 labels, ETO indicator, external carton box and identification label.

GENERAL INFORMATION - REPROCESSING

Non-sterile Implants (Single-Use) and Instruments:

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- Point of Use Preparation for Reprocessing: Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on devices prior to cleaning.
- Cleaning process is the first step in effectively reprocessing devices. Adequate sterilization depends on thoroughness of cleaning.
- Cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities".
- It is recommended to rinse the device components with water that meets specifications for AAMI TIR34 "Water for the reprocessing of medical devices" for example, DI/RO water.

Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure and should be used to transportation and storage.

NOTE: Any implant that has not been used, but has become soiled, should be handled according to hospital protocols. Refer to implant product inserts for any specific processing, cleaning, and sterilization instructions for that implant.

Devices Preparation:

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Before use, medical devices must be cleaned to ensure that there is no risk to the patient from the transmission of infectious agents and other residues that could become toxic.

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Cleaning Instructions for non-sterile devices:

- Devices must be cleaned prior to sterilization.
- Disconnect all handles/knobs prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions.
- Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, replace it with a new piece.

NOTE 1: The information on concentration, temperature, quality water, exposure time and cycles used in the equipment, follow the instructions for use and labels according to products manufacturer.

Manual Cleaning

- In a sink the devices must be rinsed in running water to remove excess soil or contaminants.
- Prepare a Prolystica® Steris enzymatic detergent solution according to the label instructions using distilled water at a concentration of 4 mL of detergent per liter of water (4 mL/1L).
- Then, with a brush soaked in the prepared solution, brush the devices

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- Wash the devices with running water and repeat the brushing process as many times as necessary.
- Finally, wash the devices with distilled water and dry and protected place.

Preparation of detergent and disinfectant solutions

- Prepare a solution at a concentration of 4 mL of detergent per liter of water (4 mL/1L) of Prolystica® Steris enzymatic detergent using potable water heated between 35ºC and 65ºC.
- Prepare another solution at a concentration of 5% neutral detergent according to the label instructions (50 mL of detergent for each liter of water) using potable water heated between 35ºC and 65ºC.
- Prepare a disinfectant solution at a concentration of 29.6 mL of disinfectant to 3.78 L of water of Vesta Syde SQ disinfectant according to label instructions using potable water.

Washing

- Pre-rinse the devices in running water to remove excess of soil or contaminants.
- Then, immerse the devices were in the prepared enzymatic detergent solution for at least 10 minutes.
- After the action time, brush the items with the neutral detergent solution.
- Finally, wash them in running water and drain on absorbent paper to remove excess water.

Disinfection

- Immerse the devices in disinfectant solution in containers.
- Wait the action time of 10 minutes.
- After the time, wash the devices with running potable water.

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- With the aid of absorbent paper, dry the devices.
- The cleaning process is illustrated in Figure 03

INSPECTION, MAINTENANCE, TESTING

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
- Visually inspect for completeness, damage and/or excessive wear.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

STERILIZATION/RESTERILIZATION

Implants (non-sterile) and instruments should be autoclave sterilized using the following validated cycle parameters. The hospital is responsible for sterilization before surgery, through the method he finds more convenient and secure, while respecting the technical standards and current sanitary regulations. The sterilization procedures as well as the quality and the training of staff involved in this process is sole responsibility of the health service. GMReis recommends the following validated cycle:

STEAM STERILIZATION CYCLES - FOR NON-STERILE PRESENTATION

Type: humid heat

Cycle: gravitational

Temperature: 121°C (250°F)

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Exposure Time: 30 minutes

Minimum Drying Time: 15 – 30 min.

The product must be wrapped with an FDA-cleared wrap.

Additional information regarding sterilization is described in ISO 17665-1- “Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices”.

ETHYLENE OXIDE STERILIZATION - FOR STERILE PRESENTATION

When supplied sterile, the method used is ethylene oxide sterilization, according to ISO 11135, implants must be maintained in its original packaging until the moment of its use.

CAUTIONS

The implants are designed to support distributed loads on their surface when implanted for stabilization of a particular bone structure and may rupture until total bone healing occurs.

The correct choice of implants must be extremely rigorous. The success of bone healing is directly related to the correct choice of characteristics (model, dimension, etc.) of the implant to be used. The size and shape of bone structures are limiting factors in the choice of implants. Metal implants cannot withstand activity levels and loads equivalent to natural bones. Always follow the instructions for use of the product.

Excessive activities and/or a new trauma may affect the positioning of the implant, which may result in migration, loosening, severe wear and/or early rupture of the implant, as well as affecting the support bone structure, demanding revision surgery.

Implants allow for early patient mobility but limited to no-load movements until the surgeon confirms bone fracture consolidation.

The implants are designed structural support to the natural consolidation process but are not intended to replace anatomical structures or to support body weight before a complete bone healing.

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Smoking, diabetes , patients with metabolic disorders and/or use of anabolic steroids, or who are using any medication that may compromise consolidation, and/or who have other diseases that can lead to delayed bone consolidation, should take aware that bone healing may not occur properly and that the implants may be loosened or ruptured, and that revision surgery may be necessary in the event of a new trauma, patient must be advised that the implant may fail, loosen and/or migrate.

If any implantable component falls or shows any type of damage, it must be destroyed and discarded, according to the Disposal Procedure.

PATIENT INSTRUCTIONS

Patient should be warned about the risks of surgery, secondary effects, or undesirable side effects and that the reconstruction carried out with the implant will not present the same physical characteristics of the natural bones, and that there might be fatigue, breaks or migration of the implant, resulting from abnormal physical activities, trauma or degenerative diseases and other diseases.

The patient should be warned about the limits of its initial activities and about their rehabilitation to protect the surgery performed by the surgeon in charge.

The patient should be informed that the implant can be replaced when the surgeon deems it necessary.

The patient must be instructed by the surgeon responsible to use adequate external support until the complete fracture consolidation, as well as to restrict physical activities that put the implant at risk or that allow movements in the fracture focus, delaying bone consolidation.

The patient should be informed that, despite of the raw material used for the implant manufacturer is biocompatible, side effects may occur or adverse reactions in more sensitive patients, such as:

- Sensibility to the material;
- Allergic reactions;

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- Bone deformity in the place of the implementation;
- Incomplete bone consolidation;

Until full load is released, the patient should follow the surgeon recommendations.

FACTORS THAT MAY CAUSE THE IMPLANT TO A POSSIBLE BREACH, LOOSENING, DISPLACEMENT OR HEATING WHICH SHOULD BE INFORMED TO THE PATIENT

- Disregard with the postoperative recommendations;
- Metabolic disorders;
- Diabetes;
- Smoking;
- Use of medications that may affect the success of the surgery;
- Patients who have used or are using anabolic steroids;
- New traumas (e.g., falls, accidents);
- Pseudoarthrosis;
- Delay in bone consolidation due to any individual factor (age, weight, etc);
- Failure following product surgical technique;
- Inappropriate choice of implants;
- Early releasing of load;
- Failure or lack of use of external supports;
- Osteoporosis;
- Practice of physical activity (any level) prior to the surgeon release;

MRI SAFETY INFORMATION

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The Cut Screw - Percutaneous Compression Screw in an implantable device made in titanium alloy. This screw is Conditional for MRI (safe for a patient undergoing a Magnetic Resonance Imaging (MRI) scan), as long as the following specific conditions are present:

MRI Safety Information
A person with the Cut Screw implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury

Device Name	Cut Screw
Static Magnetic Field Strength (B_0)	3.0 T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact

The patient card can be seen in “Attachment I” at the end of this IFU.

ADVERSE EFFECTS OR UNDESIRABLE ADVERSE EFFECTS

The implantable components Cut Screw - Percutaneous Compression Screw are manufactured with raw materials of recognized biomedical uses.

The chemical, metallographic and mechanical requirements of the material standards are used as a criterion to ensure the purity of the product and its biomechanical performance, characterizing it as appropriate to be implanted in the human body.

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It should be noted, however, that no material for surgical implant is shown to be completely free of adverse reactions in the human body, and that an acceptable level of biological response can be expected when the material is used in appropriate applications. Thus, the product may generate some undesirable adverse effects due to the biomaterial:

- Sensitivity to metal or allergic reaction;
- Pain, discomfort, and abnormal sensations due to incorrect use and indication of the implant.

It is recommended that the surgeon evaluate the patient possible sensitivity to the use of the biomaterial to be used before implantation.

- Consolidation delay or pseudoarthrosis, which may lead to loosening or rupture of the implant when consolidation does not occur 60 days after surgery;
- Rupture or loosening of the implants for not following the post-operative guidelines for rehabilitation and/or overload during physiotherapy and/or incorrect implant positioning;
- Shortening of the limb due to fracture compression or bone resorption;
- Decreased bone density;
- Pain, discomfort, and abnormal sensations due to the presence of the implant;
- Nerve injuries due to surgical trauma;
- Bone necrosis; and
- Vascular changes and among others inherent to the surgical procedure.

NOTE 1: Smokers with metabolic disorders have greater difficulties in achieving the bone consolidation, consequently there is a greater chance to occur deformation, rupture or loosening of the implants and does not reach the bone and suffer more progressive degeneracy.

NOTE 2: Other interventions may be needed to repair the secondary effects;

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DETAILED INFORMATION ON THE CHARACTERISTICS OF ALL PARTS, ACCESSORIES AND MATERIALS DESTINED TO BE USED WITH THE PRODUCT

Admissible Combinations with Other Materials

The raw material used to manufacture the products is:

Ti6Al4V-ELl Titanium Alloy, according to ASTM F 136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications"

The materials in question are highly resistant to corrosion of the solution., The product cannot be used in conjunction with any product from another manufacturer, or any metallic product with different chemical composition, because this association may generate chemical incompatibilities (producing galvanic corrosion and others), physical, biological, and functional, early fatigue and possible risks to the patient.

In the event of any undue combination by the surgeon, he will be responsible for the risks associated with such combination. The product should only be implanted with GMReis instruments.

USEFUL INFORMATION TO PREVENT RISKS AT SURGERY

Implantation Risk

Although the raw material used for the manufacture of products is biocompatible and standardized, the patient may experience sensitivity to the product or allergic reaction. It is known that, even if a raw material presents the chemical requirements, mechanical and microstructural determined by rules (which ensures its purity and biomechanical performance, making it suitable for use as material for the manufacture of implants), there is no material that shows completely free of adverse reactions in the human body.

To prevent others risks of deployment, other precautions may be taken, such as:

- Total aseptic condition;
- Radiologic pre-assessment, intraoperative;

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- Follow the instructions for use;
- Proper selection of the implant based on pre-operative radiological planning.
- Others risks of implantation:
- Failure in the surgical indication,
- Failure in the surgical technique, and/or
- Lack of patient cooperation during postoperative.

Assessment of the implanted product

After implantation, the responsible professional should perform radiological control to verify the correct positioning of the product. The professional responsible must plan, and it is his/her responsibility, the clinical and radiological assessments after the surgical procedure, in the frequency stipulated by him, to check the condition of the implant and the bone healing. If the product find itself outside the correct position, or present any nonconformity, it is the responsibility of the surgeon take the more appropriate corrective action.

INSTRUCTIONS IN CASE OF PACKAGING DAMAGE

Restrictions and instructions on the damage of the packaging

In the circumstances described below, the product must be unusable and discarded.

- The sealing area of the package is violated;
- Any one of the packages present physical damage;
- The label or identification code is unreadable and
- Date of validity is expired.

Restrictions on reprocessing

Reprocessing of the product is not allowed, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, failing to perform as intended for its intended use, and may put the health of patients and professionals at risk.

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INSTRUCTIONS FOR THE CORRECT USE OF THE PRODUCT AND INDICATION OF TRAINING

1- Perform the radiological and clinical evaluation;
2- Pass the guide wire and perform radiological control, if it is well positioned, measure with the appropriate gauge;
3- Conduct the drilling with the appropriate drill to the correct depth;
4- Machining with the thread tool if necessary;
5- Place the screw with the appropriate wrench;
6- Check the positioning of the screw through radiological control
7- Provide postoperative recommendations to the patient.

HANDLING, CONSERVATION, STORAGE AND TRANSPORT

The product must be preserved, handled, and transported in order to prevent any damage or modification to its characteristics and packaging. From transportation, storage and pre use, avoid any shock, vibration, temperature extremities (high and low), humidity, solar rays. Refer to external package symbols for additional cares.

It must be preserved and stored in its original packaging or in specific surgical boxes until the moment of use, with the proper care of the medical and hospital area, in a clean, dry, ventilated environment protected from sunlight and free of contaminants (acid vapors).

Exclusively professionals in the hospital area, properly trained, empowered and familiar with the technique and the procedures involved, must do the handling of the product.

PROCEDURE FOR DISPOSAL TO ENSURE THE DESTRUCTION OF THE PRODUCT

Implants for some reason were not used during the surgery and had the package open (sterile), intentionally or accidentally or were in contact with any body fluids, may not be re-used and/or re-sterilized and should be discarded in the hospital as the medical procedure hospital and/or local law.

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The methods and procedures for product disposing should ensure the complete mischaracterization of it, preventing any possibility of reuse. The adulteration of the product is the sole responsibility of the hospital institution, as well as the methods and procedures for disposing used.

REMOVING AND HANDLING OF IMPLANTS

The implant must not be removed, except in the case of surgical revision.

If the implant should be removed and need to be subjected to analysis, it must be in accordance with ISO 12891-1 "Removal and analysis of surgical implantation - Part 1 - Removal and Handling".

The labelling of products, which will be forwarded for analysis, should ensure their accurate identification, being that the ISO 12891-1 recommends the use of labels nonremovable (that tear in the case of attempted removal).

ADVERSE EVENTS

Any adverse event that has occurred in relation to the device should be reported to the manufacturer through the GMReis Customer Service (SAC), and the respective national competent sanitary authority. To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 traceability tags, provided within the packaging, along with the instructions for use, as described in the topic "Product Traceability Procedure".

CUSTOMER COMPLAINT

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, directly notify the GMReis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address: GM Dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no.600

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TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:(5519)3765-9900; E-mail: sac@gmreis.com.br

SYMBOLS GLOSSARY

ANSI/AAMI/ISO 15223-1 and ASTM F2503-13.

Non-sterile			
Symbol	**Description**	**Symbol**	**Description**
	Date of Manufacture		Batch number
	Manufacturer and Date of Manufacture		Caution “see instructions for use”
	Use-by date		Keep away from sunlight
	Keep dry		Do not use if package damaged
	Prescription use only		Product catalogue number
	Non-sterile		MR Conditional
	Do not re-use		

Sterile			
Symbol	**Description**	**Symbol**	**Description**
	Date of Manufacture		Batch number
	Manufacturer and Date of Manufacture		Caution “see instructions for use”
	Use-by date		Keep away from sunlight
	Keep dry		Do not use if package is damaged
	Prescription use only		Do not resterilize
	Sterile by Ethylene Oxide		MR Conditional
	Do not reuse		

USER WARNING

These Instructions for Use are available on-line, through the electronic address of the manufacturer: http://www.gmreis.com.br/produtos/IFU, and can be checked in the search field by trade name, described on the label of the product packaging. The Instructions for

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use provided will always be in accordance with the current latest version. If there is interest from the user, the Instructions for Use may be available in printed format, without additional cost. Ask for free by e-mail: sac@gmreis.com.br

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

Company Name / Manufacturer Name:

GM Dos Reis Industria e Comercio Ltda.

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Email: qualidade@gmreis.com.br

Telephone number: +55 19 37659900

Revision: 0, December 28, 2022

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Attachment I - Patient Card

Figure 1 - Front of the card

GMREIS Qualidade para Vida	MRI SAFETY INFORMATION - PATIENT CARD	
Patient		
Followup Physician		
Implanting Physician		
Hospital		
Device Description	***Model Number***	***Serial Number***
Implant Date		
		Rev.: 0 (12/2022)

Figure 2 - Verse of the card

GMREIS Qualidade para Vida	MRI SAFETY INFORMATION - PATIENT CARD
This person is implanted with a ***(device name)*** *implant and can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in severe injury of device malfunction.* *Full MRI safety information is available in the MRI Safety Information section of the Instructions for Use, which can be obtained at www.gmreis.com.br, by calling +55-19-3765-9900 or by scanning the QR code in this card.* MR ***MR Conditional***	

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Product Codes

Table 1: Ø3.0 mm non-sterile devices

CODE	DESCRIPTION	LENGTH (mm)	IMPLANT
317-03-16	CUT SCREW Ø3.0 x 16.0mm	16.0	
317-03-18	CUT SCREW Ø3.0 x 18.0mm	18.0	
317-03-20	CUT SCREW Ø3.0 x 20.0mm	20.0	
317-03-22	CUT SCREW Ø3.0 x 22.0mm	22.0	
317-03-24	CUT SCREW Ø3.0 x 24.0mm	24.0	
317-03-26	CUT SCREW Ø3.0 x 26.0mm	26.0	
317-03-28	CUT SCREW Ø3.0 x 28.0mm	28.0	
317-03-30	CUT SCREW Ø3.0 x 30.0mm	30.0	
317-03-32	CUT SCREW Ø3.0 x 32.0mm	32.0	
317-03-34	CUT SCREW Ø3.0 x 34.0mm	34.0	
317-03-36	CUT SCREW Ø3.0 x 36.0mm	36.0	
317-03-38	CUT SCREW Ø3.0 x 38.0mm	38.0	
317-03-40	CUT SCREW Ø3.0 x 40.0mm	40.0	
317-03-42	CUT SCREW Ø3.0 x 42.0mm	42.0	
317-03-44	CUT SCREW Ø3.0 x 44.0mm	44.0	
317-03-46	CUT SCREW Ø3.0 x 46.0mm	46.0	
317-03-48	CUT SCREW Ø3.0 x 48.0mm	48.0	
317-03-50	CUT SCREW Ø5.0 x 50.0mm	50.0	

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Table 2: Ø4.0 mm non-sterile devices

CODE	DESCRIPTION	LENGTH (mm)	IMPLANT
317-04-16	CUT SCREW Ø4.0 x 16.0mm	16.0	
317-04-18	CUT SCREW Ø4.0 x 18.0mm	18.0	
317-04-20	CUT SCREW Ø4.0 x 20.0mm	20.0	
317-04-22	CUT SCREW Ø4.0 x 22.0mm	22.0	
317-04-24	CUT SCREW Ø4.0 x 24.0mm	24.0	
317-04-26	CUT SCREW Ø4.0 x 26.0mm	26.0	
317-04-28	CUT SCREW Ø4.0 x 28.0mm	28.0	
317-04-30	CUT SCREW Ø4.0 x 30.0mm	30.0	
317-04-32	CUT SCREW Ø4.0 x 32.0mm	32.0	
317-04-34	CUT SCREW Ø4.0 x 34.0mm	34.0	
317-04-36	CUT SCREW Ø4.0 x 36.0mm	36.0	
317-04-38	CUT SCREW Ø4.0 x 38.0mm	38.0	
317-04-40	CUT SCREW Ø4.0 x 40.0mm	40.0	
317-04-42	CUT SCREW Ø4.0 x 42.0mm	42.0	
317-04-44	CUT SCREW Ø4.0 x 44.0mm	44.0	
317-04-46	CUT SCREW Ø4.0 x 46.0mm	46.0	
317-04-48	CUT SCREW Ø4.0 x 48.0mm	48.0	
317-04-50	CUT SCREW Ø4.0 x 50.0mm	50.0	
317-04-52	CUT SCREW Ø4.0 x 52.0mm	52.0	
317-04-54	CUT SCREW Ø4.0 x 54.0mm	54.0	
317-04-56	CUT SCREW Ø4.0 x 56.0mm	56.0	
317-04-58	CUT SCREW Ø4.0 x 58.0mm	58.0	
317-04-60	CUT SCREW Ø4.0 x 60.0mm	60.0	

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Table 3: Ø3.0 mm EO sterile devices

CODE	DESCRIPTION	LENGTH (mm)	IMPLANT
317-03-16S	CUT SCREW S Ø3.0 x 16.0mm	16.0	
317-03-18S	CUT SCREW S Ø3.0 x 18.0mm	18.0	
317-03-20S	CUT SCREW S Ø3.0 x 20.0mm	20.0	
317-03-22S	CUT SCREW S Ø3.0 x 22.0mm	22.0	
317-03-24S	CUT SCREW S Ø3.0 x 24.0mm	24.0	
317-03-26S	CUT SCREW S Ø3.0 x 26.0mm	26.0	
317-03-28S	CUT SCREW S Ø3.0 x 28.0mm	28.0	
317-03-30S	CUT SCREW S Ø3.0 x 30.0mm	30.0	
317-03-32S	CUT SCREW S Ø3.0 x 32.0mm	32.0	
317-03-34S	CUT SCREW S Ø3.0 x 34.0mm	34.0	
317-03-36S	CUT SCREW S Ø3.0 x 36.0mm	36.0	
317-03-38S	CUT SCREW S Ø3.0 x 38.0mm	38.0	
317-03-40S	CUT SCREW S Ø3.0 x 40.0mm	40.0	
317-03-42S	CUT SCREW S Ø3.0 x 42.0mm	42.0	
317-03-44S	CUT SCREW S Ø3.0 x 44.0mm	44.0	
317-03-46S	CUT SCREW S Ø3.0 x 46.0mm	46.0	
317-03-48S	CUT SCREW S Ø3.0 x 48.0mm	48.0	
317-03-50S	CUT SCREW S Ø5.0 x 50.0mm	50.0	

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Table 4: Ø4.0 mm EO sterile devices

CODE	DESCRIPTION	LENGTH (mm)	IMPLANT
317-04-16S	CUT SCREW S Ø4.0 x 16.0mm	16.0	
317-04-18S	CUT SCREW S Ø4.0 x 18.0mm	18.0	
317-04-20S	CUT SCREW S Ø4.0 x 20.0mm	20.0	
317-04-22S	CUT SCREW S Ø4.0 x 22.0mm	22.0	
317-04-24S	CUT SCREW S Ø4.0 x 24.0mm	24.0	
317-04-26S	CUT SCREW S Ø4.0 x 26.0mm	26.0	
317-04-28S	CUT SCREW S Ø4.0 x 28.0mm	28.0	
317-04-30S	CUT SCREW S Ø4.0 x 30.0mm	30.0	
317-04-32S	CUT SCREW S Ø4.0 x 32.0mm	32.0	
317-04-34S	CUT SCREW S Ø4.0 x 34.0mm	34.0	
317-04-36S	CUT SCREW S Ø4.0 x 36.0mm	36.0	
317-04-38S	CUT SCREW S Ø4.0 x 38.0mm	38.0	
317-04-40S	CUT SCREW S Ø4.0 x 40.0mm	40.0	
317-04-42S	CUT SCREW S Ø4.0 x 42.0mm	42.0	
317-04-44S	CUT SCREW S Ø4.0 x 44.0mm	44.0	
317-04-46S	CUT SCREW S Ø4.0 x 46.0mm	46.0	
317-04-48S	CUT SCREW S Ø4.0 x 48.0mm	48.0	
317-04-50S	CUT SCREW S Ø4.0 x 50.0mm	50.0	
317-04-52S	CUT SCREW S Ø4.0 x 52.0mm	52.0	
317-04-54S	CUT SCREW S Ø4.0 x 54.0mm	54.0	
317-04-56S	CUT SCREW S Ø4.0 x 56.0mm	56.0	
317-04-58S	CUT SCREW S Ø4.0 x 58.0mm	58.0	
317-04-60S	CUT SCREW S Ø4.0 x 60.0mm	60.0	

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