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INSTRUCTIONS FOR USE AND STERILIZATION PROTOCOL

GPC Medical USA Orthopaedic Instruments and Non-Sterile Bone Screws

DISCLAIMER

Medical devices listed throughout this document are manufactured by GPC Medical USA and distributed by restor3d, inc. Reference documents Steam Sterilization Letter, Instructions for Use of Orthopaedic Instruments, Instructions for Use of Bone Screws.

DOCUMENT CONTENTS

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STEAM STERILIZATION PROTOCOL

Instruction for Steam Sterilization (Autoclave) of orthopeadic instrument set with implants.

The Orthopeadic implants, instrument, and instrument set are manufactured and supplied in non-sterile condition. Users sterilize these before use as instructed by IFU. Therefore, we have validated the steam sterilization procedure according with ISO 17665 standard for this combination, and following the sterilization validation, we recommend that the Steam sterilization (Autoclave) validated parameters for Customized Kit (Instruments and Implants).

- Temperature should be 121°C (250°F) pressure should be 106 KPA (15lbs/in^2): 15 mins for unwrapped items or GPC sterilization pouch packed item & 30 mins for wrapped items
- Or higher temperature of 132°C (270 F) pressure should be 30 lbs /in^2: 15 mins for wrapped items.

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INSTRUSTIONS FOR USE, ORTHOPAEDIC INSTRUMENTS

DESCRIPTION AND INTENDED USE
These surgical instrument sets consist of various configurations of orthopedic instruments in cases or trays. The sets are constructed from durable metal and plastic materials. The reusable surgical instruments are intended for use in orthopedic surgical procedures according to the Instructions for Use and surgical techniques that accompany Ascension implants. Instruments are to be cleaned, inspected, and sterilized between uses.

INSPECTION BEFORE USE
Reusable instruments can be used indefinitely if not damaged or worn. Instrument systems should be cleaned and then inspected between uses. **DO NOT** use broken or damaged instruments. Contact Ascension for repair or replacement of damaged items. If damage or malfunction is detected, the instrument should not be used.

MACHINE CLEANING
If possible, use automated equipment (washer-disinfectors) for instrument cleaning and disinfection, as machine processes are more consistent. Be sure to observe and follow the operating and loading instructions provided by the
machine manufacturer. In addition, only
the cleaning agents recommended by
the manufacturer should be used.

If needed, manual pre-cleaning can be done.

Please note the following:

- Jointed instruments should be processed in open position. Be sure to arrange the items so that the water can easily flow out of cannulations, blind holes, and cavities.
- Complex instruments should be disassembled as far as possible before cleaning.
- For instruments with long or narrow lumens, standard processing should be used only if the hot disinfectant can flow easily through the lumens and safe rinsing is guaranteed.
- The instrument trays used for cleaning must always be loaded correctly to ensure proper cleaning.
- After cleaning, check instruments for cleanliness (visible dirt). This especially applies to cannulated instruments or those with blind holes. If necessary, brush and pre-clean manually or repeat the cleaning cycle.
- Demineralized or distilled water should be used for the final rinse.

MANUAL CLEANING
It is best to disinfect and clean the instruments immediately after use in order to avoid instrument encrustations that make cleaning and disinfection more difficult.

The following should be observed in manual cleaning processes:

- The solutions used for manual cleaning must always be prepared

in accordance with the manufacturer's instructions.

- Use a suitable brush for cleaning lumens, cannulations, blind holes, and cavities, making sure that every part of the inner surface can be properly accessed.
- Use a soft brush and a neutral or mildly alkaline detergent for removing blood and other residues.
- Never use metal brushes or metal sponges for manual cleaning.
- To ensure proper instrument functioning, verify that all movable parts have been thoroughly cleaned.
- Clean jointed instruments in closed as well as open positions.
- Disassemble instruments as far as possible before cleaning.
- Pay special attention to slots, ratchets, joints and box locks, narrow lumens, blind holes, and other areas that are hard to access.

INSPECTION AFTER CLEANING

Following cleaning, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits. All movable parts, working tips and blades (scissors) should be inspected with particular care.

STERILIZATION

Ortho Care has completed sterilization validations for our instrument sets. The validation protocols were performed in accordance with *requirements of autoclavibility following parameters,*

In accordance with our validation results, the following cycles are recommended for wrapped goods:

- **Steam Pre-vacuum:** 4 minutes at 132°C (270°F)
- **Steam Gravity:** 15 minutes at 132°C (270°F) –

DO NOT USE THIS CYCLE FOR FILTERED STERILIZATION CONTAINERS

A vacuum drying cycle of at least 30 minutes is also recommended.

However, there is limit of number of cycles of autoclaving that is recommended based on internal verification of number of successful autoclaving cycles without any deterioration in the performance of the instruments. The instruments should be used within shelf life of 5 years from the date of manufacturing or within 50 cycles of steam sterilization method as mentioned above (whichever is earlier).

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INSTRUSTIONS FOR USE, NON-STERILE BONE SCREWS

DEVICE DESCRIPTION: Bone screws are the most common general-purpose fixation devices. It may be the only hardware used in reparative or reconstruction surgery. More commonly, they are used with other hardware devices, particularly plates, to fixate the associated device to bone.

The length of these screws varies from 10 mm to 130 mm.

The **GPC MEDICAL LIMITED** Bone plates are fixed using bone screws. The bone screws are differentiated by the manner in which they are fastened on the bone, their function, their size and the type of bone they are intended to be used for:

- Four types of screws i.e.; Cortical (Cortex), Cancellous, Malleolar and Cannulated
- Provided with locking compression thread as well as regular types
- Type of Recess: Hexagonal
- Diameter Range: 1.5mm to 7.3mm

MATERIALS

The devices can be made up of either stainless steel (316L or 316LVM alloy) or Titanium (TiAl6V4 alloy).

INDICATIONS

The Bone Screw System including Cortical Screws, Cancellous Screws, Cannulated Screws, Lag screw, Compression Screw, Locking Screws is designed to provide fixation for fractures, fusions or osteotomies.

CONTRAINDICATIONS

The implant should not be used in a patient who has a history of active infection and suspected or documented metal allergy or intolerance.

WARNING

Serious post-operative complications may occur from the use of implant in a patient who:

- Lacks good general physical condition
- Active or suspected latent infection
- Compromised vascularity
- Systemic medical or surgical co-morbities
- Demonstrates anatomical or physiological anomalies
- Do Not Re-use or Re-process. The device is not designed for re-processing. Reprocessing of the medical device intended for single use devices may lead to degraded performance or a loss of functionality. The Cleaning and disinfection/sterilization for re-processing of these single use devices has not been validated nor any authentic information is available.
- A qualified experienced surgeon who have adequate knowledge of surgical techniques, proper selection and placement of implants and post-operative patient care while performing an orthopedic surgical procedure must use the implants.

NOTE

It is the responsibility of the surgeon to discuss the precautions, possible risks, warnings, consequences, complications and adverse reactions which may occur as a result of the surgical procedure and implantation of the device(s) with the patient.

The patient should be informed that the life expectancy of the device is unpredictable and once implanted, successful results cannot be guaranteed if adequate care and precautions are not taken.

If adverse effects happen, it may necessitate re-operation, revision or removal surgery, arthrodesis or the involved joint and /or amputation of the limb.

MRI COMPATIBILITY

The material used is proven to be MRI safe as sample literature evidence is available for implantable materials. Safe use limit of 1.5 Tesla for MR imaging subject to the recommendation and supervision of the orthopaedic surgeon.

PRECAUTIONS

It is advised to the surgeon to carefully read and follow instructions as mentioned on the IFU. The precautions should be followed by the surgeons before performing any surgery.

a) **Selection of the patient:** The following factors must be considered before performing surgery i.e.;
   - Immunological intolerance: If the material sensitivity is suspected, appropriate foreign body tests should be performed for immunological intolerance.
   - Degenerative Diseases/Obesity: Any degenerative diseases or obesity can be aggravated during implantation and experienced load which will decrease the expected life of the implant or implant failure
   - Mental illness/ Drug addiction: Mental illness, schizophrenia and drug addiction may cause patients to ignore the limitations and precautions of the implanted material, leading to implants fracture and complication
   - Activity: If the patient indulges in an activity involving significant muscular strain in the implanted region, the result may be failure of the implant

b) **Selection of the implants:** The selection of the proper size, shape and design of the implant are important. The orthopaedic surgeon has to select the appropriate implant depending upon the application, which should also be free from any apparent corrosion or any manufacturing defects

c) **Handling of implants:** Care should be taken that there are no scratches, distortions, notches, sharp dents or reverse bends at the site of the hole. These may cause defects in the surface finish and result in improper bonding.

d) **Second hand implants:** Used implants, which appear un-damaged, may have internal and external defects. It is possible that individual stress analysis of each part fails to reveal the accumulated stress on the metal because of use in the body. It may lead ultimately to implant failure. Every implant must be discarded after use and should never be re-used. It should be bent & then disposed of properly so that it is unfit for re-use. While disposing it off, ensure that the discarded implant does not pose any threat to children, stray animals and environment.

e) **Implant removal:** It is recommended that an implant used as an aid for healing should be removed once its services are over, particularly in younger and more active patients. The surgeon must take the final decision on implant removal.

f) **Post-operative care:** A patient must take precautions to avoid unnecessary stress to implant. The patient must restrict his activities like partial weight bearing or full weight bearing to assist its healing.

g) **Re-use of single use implants:** The implants must be discarded after use and should never be re-used. It should be bent & then disposed of properly so that it becomes unfit for reuse. While disposing, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment.

h) **Incompatible Combinations:** Implants components from one manufacturer should not be used with those from another. Implants from each manufacturer may have metal and design differences so that the use in conjugation with different devices may lead to inadequate fixation or corrosion of the implant.

i) **Packaging Disposable:** The packaging material of this device if swallowed may cause choking hazards. Therefore, it should be disposed of in such a way that it is out of reach of children and stray animals.

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STERILTY

GPC MEDICAL LIMITED BONE SCREWS are supplied **Non-Sterile**. Check the integrity of the packing and labelling before opening the pack. Remove the device from the pack before sterilization. Implants are recommended to be sterilized by using steam autoclaving process regularly used in the hospitals and clinics.

Method which have been validated and recommended by the company is given below:

Method	Steam Sterilization (Autoclaving)-Gravity Feed
Temperature	121 Degree Centigrade
Exposure Time	15 Minutes

STORAGE

Store in a dry place away from direct sunlight

PRODUCT INFORMATION DISCLOSURE GPC MEDICAL LIMITED Warranties the products against any manufacturing defects.

INFORMATION

FOR ANY OTHER INFORMATION REGARDING THE IMPLANTS OR THEIR USE BE REQUIRED, PLEASE CONTACT OUR REPRESENTATIVE OR DISTRIBUTOR OR CONTACT THE MANUFACTURER DIRECT.

Contact Us:

EC Representative: EC REP

Head Office: GPC MEDICAL LTD. CMC Medical Devices & Drugs S.L.
DDA LSC, VIKASPURIC/ HoracioLengo N^{0} 18, CP 29006,
NEW DELHI – 110018 Malaga, Spain

Tel. +91-11-43222600 (100 Lines)
Website: https://www.indianorthopaedic.com
Website: https://www.cmcmedicaldevices.com Email- info@gpcmedical.com
Email: info@cmcmedicaldevices.com

Factory Address: Plot C-3, Sec B-1, UPSIDC, Trans Delhi Signature City, Loni, Ghaziabad, UP- 201102

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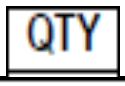
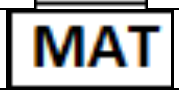
SYMBOLS FOR PRODUCT INFORMATION AND LABELING

Symbol	EN ISO 15223-1	Symbol Description
	5.1.1	Manufacturer
	5.1.3	Date of manufacture
	5.1.5	LOT Number
	5.4.2	Do-not reuse
	5.2.7	Non-sterile
	5.4.3	Consult instructions before use
	5.1.6	Catalog Number
	5.2.8	Do not use if package is damaged
	5.1.2	European Community Representative
	5.4.4	Caution
	5.3.2	Keep away from sunlight
	5.3.4	Keep dry
	N/A	Quantity in the package
	N/A	Material Grade

	5.7.7	Medical Device
	5.1.4	Use by YYYY-MM
	N/A	CE Mark

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Revision History

Revision	Reason for Change	Change by	Issue Date
00	Original Issue	Jordan Wagner	Refer to eQMS