OsteoCentric OsteoGuard Drill Bit
Instructions for Use

Non-Sterile | Prescription Use Only | Do Not Reuse

Description:

OsteoCentric Trauma drill bits are designed specifically to prepare bone to receive a tap, screw, or other implant. The drill bit is to be used in trauma and orthopedic cases involving bone screw, pins, or other implants that require pre-drilling of bone.

The OsteoCentric Trauma drill bits are manufactured from Stainless Steel and are available in the following sizes; 2.0mm x 100mm, 2.5mm x 110mm, 2.5mm x 145mm, 2.5mm x 180mm, 2.7mm x 100mm, 2.8mm x 165mm, 3.2mm x 145mm, 3.5mm x 110mm, and 4.5mm x 145mm.

Warnings and Precautions:

For safe effective use of this system the surgeon must be thoroughly familiar with these types of instruments, and the recommended surgical technique.

Take care while drilling as to not damage, entrap, or tear the patient's soft tissue or critical structures. Be sure to keep drill or tap clear of loose surgical materials.

Handle devices with care and dispose worn bone cutting instruments in a sharps container.

These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend whenever possible and practical for the patient, the broken part should be removed.

Drill bits have sharp edges that may pinch or tear the user's glove or skin.

Do not use dull drill bits. Dull drill bits could lead to thermal necrosis of the bone and are more prone to breaking.

Possible Adverse Events:

- Thermal necrosis of bone
- Burns to soft tissue

Indications for Use:

OsteoCentric Trauma recommends single use for all drill bits.

Visual Inspection:

OsteoGuard Drill bits are shipped with a protective cap. This cap should be removed prior to placing into the set and/or prior to sterilization.

It is necessary to carefully inspect the following areas to ensure proper drill function: center tip and tip undercuts must be sharp. Drill bits should be void of any corrosion.

Any bent or damaged drill bits should be discarded. Dull or damaged cutting instruments should not be refurbished or re-sharpened. Even though they may appear undamaged, the devices may have small defects and internal stress patterns that may cause material fatigue.

Sterilization:

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specified in this package insert.

- If the protective cap is present on the devices, remove before sterilization or re-sterilization.
- Due to the variations in steam sterilization systems, sterilization parameters should be determined and validated by reference to current ANSI/AAMI standards in addition to your facility's own procedures.
- The following parameters have been validated to a sterility assurance level (SAL) of ≤ 10^{-6}:

Method	Steam
Cycle Type	Pre-Vacuum
Temperature	132ºC
Full Cycle Time	4 minutes
Minimum Dry Time	30 minutes

- Other sterilization methods have not been validated and may damage the product resulting in malfunction, injury to the patient, or both.
- OsteoCentric Trauma recommends a minimum dry time of 30 minutes for this device when sterilized using the parameters recommended above. However, because dry time can be influenced by various factors such as autoclave performance, sterilization load, sterilization wrap/package materials, steam quality, varying cool-down time, and environmental conditions, adequate drying of this device should be verified by visual inspection.

Storage:

Products that are supplied non-sterile must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an FDA approved wrap or container.

Do not store in a damp environment. Keep devices covered until needed. Prior to use, inspect product for signs of damage or contamination. In the operating room and during transport, keep devices separate from contaminated instruments or implants.

Disposal:

Dispose of implants according to facility protocol.

Symbols Glossary

Symbol	Symbol Title	Reference Number	Explanatory Text
	Catalogue number	5.1.6.(1)	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Batch Code	5.1.5.(1)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Prescription only	N/A	Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Consult instructions for use	5.4.3(1)	Indicates the need for the user to consult the instructions for use.
	Do not reuse	5.4.2(1)	Indicates a medical device that is not to be re-sterilized.
	Manufacturer	5.1.1.(1)	Indicates the medical device manufacturer.
	Date of Manufacture	5.1.3.(1)	Indicates the date when the medical device was manufactured.
	Non-Sterile	5.2.7(1)	Indicates a medical device that has not been subjected to a sterilization process.

(1) ISO 15223-1:2021(E) Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Note:

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice.

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