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 $\leq 10^{-6}$:

Method	Steam
Cycle Type	Pre-Vacuum
Minimum Temperature	132°C
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 and Definitions:

Symbol	Definition
	**Catalogue number**
	**Lot number**
	**Prescription only**
	**Consult instructions for use**
	**Do not reuse**
	**Manufacturer**
	**Date of Manufacture**

Manufacturer:

OsteoCentric Technologies, Inc
75 W 300 N, Suite 150
Logan UT, 84321
Phone: 1-800-969-0639

OsteoGuard
DRILL BITS