



# OsteoCentric TECHNOLOGIES

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DOCUMENT NUMBER:

DOCUMENT TITLE:

DOCUMENT NOTES:

## Document Information

Revision:

Vault:

Doc Type:

Status:

## Date Information

Effective Date:

Next Review Date:

Release Date:

Expiration Date:

## Control Information

Author:

Previous Number:

Owner:

Change Number:

All dates and times are in



## OsteoCentric Trauma - OsteoGuard Drill Bit Surgical Technique Guide

### Description:

**Single Use**, OsteoGuard drill bits are uniquely designed to provide advanced cutting features for efficient drilling into bone while minimizing thermal necrosis of bone. The OsteoGuard drill bits have been specifically designed to prepare bone to receive a tap, screw, or other implant. The OsteoGuard drill bits can 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
- 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. Care must be taken in determining the appropriate size drill bit for the proposed implant.

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

Where possible avoid drilling into metal

The use of a drill guide is recommended where appropriate, the drill guide will facilitate directional control of the drill bit and minimize bending. It is recommended that the drill be started after the insertion into the drill guide, this will prevent excessive contact between the drill bit and drill guide as well as protecting surrounding tissue.

**OsteoGuard Drill Bits are specifically designed for single use. Upon human use, do not reuse.** ②

### Possible Adverse Events:

- Thermal necrosis of bone
- Burns to soft tissue

### 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.

### Drill Bits and Caddy Catalog Numbers:

Catalog #	Description
110007	2.0mm Drill Bit, 100mm
110013	2.5mm Drill Bit, 110mm
110014	2.5mm Drill Bit, 145mm
110015	2.5mm Drill Bit, 1180mm
110016	2.7mm Drill Bit, 100mm
110037	2.8mm Drill Bit, 165mm
110025	3.2mm Drill Bit, 145mm
110028	3.5mm Drill Bit, 110mm
110034	4.5mm Drill Bit, 145mm
A-2500	OsteoGuard Drill Bit Caddy Assembly
A-2500-01	OsteoGuard Drill Bit Caddy Lid

#### **Manufacturer:**

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## Signature Manifest

**Document Number:** TR-018-SPEC-0002  
**Title:** OsteoGuard Surgical Technique Guide  
**Effective Date:** 08 Apr 2020

**Revision:** 01

All dates and times are in Central Time Zone.

### OsteoGuard Drill Bits IFU

#### Engineering Approval

Name/Signature	Title	Date	Meaning/Reason
Andy Fauth (ANDY.FAUTH)	Chief Technology Officer	08 Apr 2020, 09:07:28 AM	Approved

#### Operations Approval

Name/Signature	Title	Date	Meaning/Reason
Amy Reeves (AMY.REEVES)		08 Apr 2020, 06:57:19 AM	Approved

#### Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Todd Evans (TODD.EVANS)	Sr Dir of QA/RA	08 Apr 2020, 02:01:01 PM	Approved

#### Set Date

Name/Signature	Title	Date	Meaning/Reason
Todd Evans (TODD.EVANS)	Sr Dir of QA/RA	08 Apr 2020, 02:01:17 PM	Approved