

OSTEOMED
OsteoDriver™
Disposable Battery Powered Screwdriver
Product Information and Instructions for Use

Description

The OsteoMed OsteoDriver™ System is comprised of a sterile battery powered screwdriver, screw driver stems, taps, and drills.

Material

The OsteoDriver™ is made from various grades of steel and plastic. Accessories are made from various grades of stainless steel. Batteries are lithium type.

Clinical Indications

Driving screws, and drilling in conjunction with dental, craniofacial, craniotomies, orthognathic, mandibular, hand, foot, wrist and extremity reconstruction surgical procedures. OsteoDriver™, taps and drills are **single use only**. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient. The driver stems are re-usable.

Warnings:

- Do not attempt to re-sterilize the OsteoDriver™.
- Do not immerse the OsteoDriver™.

Maintaining Device Effectiveness

- OsteoMed OsteoDriver™ accessories must be used with the OsteoDriver™.
- Carefully inspect the OsteoMed instrumentation prior to use. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition.
- OsteoMed recommends the use of OsteoMed products in a sterile environment.

Cutting Accessories

OSTEOMED OSTEODRIVER™, DRILLS AND TAPS ARE DISPOSABLE AND INTENDED FOR **SINGLE PATIENT USE ONLY**. Always review the instructions for use and caution/warning notices. The surgeon should be thoroughly familiar with the proper operations of the powered surgical instruments and accessories prior to use.

- Only use recommended accessories with the OsteoDriver™
- Check for any signs of damage to the drill or tap before use
- Verify the drill or tap is properly inserted and secured before activating the instrument
- Eye protection should be worn when using cutting accessories
- Do not use any drill that exhibits excessive wobble
- Irrigation at the surgical site during operation of the cutting accessory is recommended to reduce the possibility of thermal necrosis

Operating Instructions

- 450-0600:** The OsteoDriver™ features a locking collet system. To Insert the driver shaft, drill, or tap, simply insert accessory and turn accessory until it slips into the keying feature and then push the accessory into the OsteoDriver™ until it snaps into place. This can be confirmed by ensuring that the insertion line on the accessory is in line with the nose of the OsteoDriver™. To release, grasp the accessory shaft and pull until it is released from the OsteoDriver™.
- OsteoDriver™ Controls:** Actuation and direction is controlled by depressing the forward or reverse control buttons.

Cleaning

- Accessories must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.

Sterility

- The OsteoDriver™ is packaged **STERILE** (gamma sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE. DO NOT ATTEMPT TO RESTERILIZE.
- Accessories are supplied **NON-STERILE** and must be sterilized prior to surgical use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.

- Non-sterile accessories are sterilizable by steam sterilization (autoclaving). For sterilization of OsteoMed OsteoDriver™ Accessories, the following parameters should be used.

Pre-Vacuum Steam Sterilization:

Temperature: **270°F (132°C)**

Time: **10 minutes**

Drying Time: **70 minutes**

Configuration: **Wrapped tray**

Wrapping Technique: **Wrapped tray in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554).**

Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

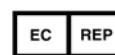
Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.

Caution

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.



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Symbols and Definitions



Single Use Only

REF

Catalogue
Number



Use By
(Date)



Do not use if
sterile package is
damaged



Batch Code
(Lot Number)



Consult
Instructions for
Use



Date of Manufacture

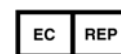


Manufacturer



Attention,
See Instructions for
Use

Caution,
Consult
Accompanying
Documents



Authorized
Representative in
the European
Community



Federal Law (U.S.A)
Restricts this device to
sale by or on the order
of a physician.



Sterile, Method of
Sterilization Using
Irradiation