Part No. 030-1188
Rev. P

OSTEOMED
AutoDriver™
Battery Powered Screwdriver
Product Information and Instructions for Use

Description
The OsteoMed AutoDriver™ is comprised of a screwdriver body, sterile battery pack and screw driver stem.

Material
The AutoDriver and accessories are made from various grades of stainless steel, high temperature plastics and aluminum. Batteries are lithium type.

Clinical Indications
Driving screws, in conjunction with dental, craniofacial, craniotomies, orthognathic, mandibular, hand, foot, wrist and extremity reconstruction surgical procedures.

Warnings:
- Battery must be removed and discarded before sterilizing the Autodriver.
- Do not allow open battery cartridge to come in contact with conductive materials.
- Do not autoclave battery package.
- Do not immerse.

Maintaining Device Effectiveness
- All OsteoMed AutoDriver accessories may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the OsteoMed implants and instrumentation prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating conditions. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition and repair.
- OsteoMed recommends the use of OsteoMed products in a sterile environment.

Cutting Accessories
OSTEOMED DRILLS ARE DISPOSABLE AND INTENDED FOR SINGLE PATIENT 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.

Always review the instruction manual 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 OsteoPower equipment
- Check for any signs of damage to the stem before use
- Verify the stem is properly inserted and secured before activating the instrument
- Eye protection should be worn when using cutting accessories
- Do not use any driver stem that exhibits excessive wobble
- Forceful side loading of the driver stem may cause the driver stem to break
- Irrigation at the surgical site during operation of the cutting accessory is recommended to reduce the possibility of thermal necrosis

Operating Instructions
- 450-0040 / 450-0055: Autodriver, Collet Model: These models feature a friction fit accessory locking system. To insert the driver shaft, simply insert the accessory, while turning it, until it is fully seated. This can be confirmed by ensuring that the insertion line is no longer visible on the shaft of the accessory. To release, grasp the accessory shaft and pull until it is released.
- 450-0050 / 450-0056: Autodriver, 1.6mm Fixed Model: These models feature a permanently attached driver that can only be removed by an OsteoMed Service Center.
- Battery Installation and Removal: After removing the battery pack from the sterile package, insert into the battery socket on the back end of the Autodriver. IMPORTANT: Align polarity of the battery Pack.
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- Autodriver Controls: Actuation and direction is controlled by depressing the forward or reverse control buttons.
- Maintenance and Disposal:
  - After each use, remove the battery pack from the battery socket of the Autodriver.
  - Clean the Autodriver with a soap and water solution

Cleaning
- Products 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
- Product is supplied NON-STERILE unless expressly labeled as STERILE.
- Battery packs are packaged STERILE (gamma sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- 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 devices are sterilizable by steam sterilization (autoclaving). For sterilization of OsteoMed Autodriver System, 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 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)	SN	Serial Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
	Do not use if sterile package is damaged	STERILE R	Sterile, Method of Sterilization Using Irradiation
Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.		

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