Part No. 030-1106
Rev. W

OSTEOMED
OsteoPower™ Handpiece System
Product Information and Instructions For Use

Description
The OsteoMed Osteopower system is comprised of a control console, a modular handpiece and cord, modular handpiece attachments and accessories.

Material
The motor unit (handpiece), handpiece modules, control console, attachments and accessories are made from various grades of medical grade stainless steel, medical grade high temperature plastics, carbide steel, diamond coated steel, titanium and aluminum.

Indications for Use
The OsteoMed OsteoPower System and Accessories are indicated for drilling or cutting bone or teeth, and driving screws and/or pins and wires into bone, in conjunction with dental, craniofacial, craniotomies, orthognathic, spinal, mandibular, hand, foot, wrist and extremity reconstruction surgical procedures.

Maintaining Device Effectiveness
1. The operating instructions and maintenance manual should be read prior to operating any component of the OsteoMed OsteoPower Handpiece system. The manual is enclosed with shipment of systems and can be obtained from customer service. Refer to part number 030-1179. Bulletins are provided with each module.
2. All OsteoMed implants and instrumentation 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.
3. Carefully inspect the OsteoMed implants and instruments 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.
4. OsteoMed recommends the use of OsteoMed products in a sterile environment.

Cutting Accessories
OsteoMed cutting accessories, drills, burs, and blades, 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 cutting accessory before use
- Verify the cutting accessory is properly inserted and secured before activating the instrument
- Do not exceed the recommended cutting speed as detailed in the operating manual
- Eye protection should be worn when using cutting accessories
- Do not use any cutting accessories that exhibit excessive wobble or vibration
- Forceful side loading of the cutting accessories may cause the cutting accessories to break
- Monitor the temperature of the module and handpiece during use
- Autoclave no more than 24 hours prior to use
- Irrigation at the surgical site during operation of the cutting accessory is recommended to reduce the possibility of thermal necrosis

Storage
Sterile packaged devices should be stored at controlled room temperature out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering. Sterile burs and blades have a limited shelf life. Refer to Use By date on package labeling for expiration.

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.
- Refer to the OsteoPower manual (030-1179) for specific OsteoPower Product Cleaning Instructions.

Sterility
- Product is supplied NON-STERILE unless expressly labeled as STERILE.
- Steam sterilization is recommended for the Motor Unit/Cord, Handpiece modules, tubing sets, irrigation nozzles and clips, burs, blades, drills and accessories. DO NOT AUTOCLAVE PCC OR FOOTSWITCH. DO NOT USE ETHYLENE OXIDE STERILIZATION OF THE HANDPIECE OR CONNECTOR CORD.
- Accessories such as drills, burs, and blades may be provided sterile packaged (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.
- Refer to the OsteoPower manual (030-1179) for specific OsteoPower Product Cleaning Instructions.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED* OsteoPower Products, the following parameters should be used.

Aluminum Tray (450-0555)

Pre-vacuum sterilizer

Temperature:	270°F(132°C)
Time:	4 minutes
Dry Time:	30 mnutes
Configuration:	Wrapped Tray

Wrapping Technique: Individually wrap in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques with a surgical towel placed between the wraps and the bottom of the tray.

Gravity sterilizer

Temperature:	270°F(132°C)
Time:	50 minutes
Dry Time:	45 mnutes
Configuration:	Wrapped Tray

Wrapping Technique: Individually wrap in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques.

Gravity sterilizer

Temperature:	250°F(121°C)
Time:	80 minutes
Dry Time:	45 mnutes
Configuration:	Wrapped Tray

Wrapping Technique: Individually wrap in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques.

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

Plastic Tray (450-0505)

Pre-vacuum sterilizer

Preconditioning Pulses:	3
Temperature:	270°F(132°C)
Time:	10 minutes
Dry Time:	70 minutes
Configuration:	Wrapped Tray
Wrapping Technique:	Individually wrap in two layers of

1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques.

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

The following sterilization recommendation offers a reduced cycle time for a minimal amount of equipment including no more than one straight drill module and the irrigation accessories for each.

"Flash" Autoclave Sterilization:

Prevacuum Sterilizer	
Temperature;	270-272 °F (132-134 °C)
Time:	5 minutes
Dry Time:	0 minutes
Configuration:	Wrapped or Unwrapped

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.

Read manual prior to use

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CE 0086

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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