Part No. 030-1786
Rev. F

OSTEOMED
OsteoDriver 2
Battery Powered Screwdriver
REF 450-0700

Description
The OsteoMed OsteoDriver2 is a single-use disposable battery powered screwdriver. Sterile-packaged, this driver comes ready-to-use in the operating room. It accepts the driver stems with the hex shank design used to rotationally drive Auto-Drive™ screws into bone.

Material
The OsteoDriver2 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 in conjunction with dental, craniofacial, craniotomies, orthognathic, mandibular, hand, foot, wrist and extremity reconstructive surgical procedures. OsteoMed OsteoDriver2 is a single use device that 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. 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.

Warnings:
- Do not attempt to re-sterilize the OsteoDriver2. Attempting to re-sterilize will render the device as inoperable.
- Do not immerse the OsteoDriver2. Immersing will render the device inoperable.
- Do not remove OsteoDriver2 from sterile packaging until ready for use.
- No modification of the OsteoDriver2 is allowed.
- If the device becomes objectionably warm during normal operation, discontinue use of the device.
- Soft tissue contact with rotating driver stem should be avoided to prevent soft tissue damage.

Maintaining Device Effectiveness
- OsteoMed OsteoDriver2 accessories must be used with the OsteoDriver2.
- 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.
- OsteoDriver2 requires no maintenance as the internal battery is not user serviceable. The OsteoDriver2's internal battery is not rechargeable or accessible.
- OsteoDriver2 should only be used in ambient environments at or below 100.4°F (38°C) and relative humidity at or below 80% non-condensing.

OsteoDriver™ 2 Accessories (APPLIED PARTS)
The OsteoDriver2 driver stems are packaged non-sterile and are reusable.
The Driver Stems are to be sterilized per the sterilization instructions included in this document. Driver Stems currently available for the OsteoDriver2 is as follows:

Part No.	Description
114-1215	1.2mm Driver Stem, Short, Hex Shank
114-1221	1.2mm Driver Stem, Med, Hex Shank
114-1233	1.2mm Driver Stem, Long, Hex Shank
114-1615	1.6mm Driver Stem, Short, Hex Shank
114-1621	1.6mm Driver Stem, Med, Hex Shank
114-1633	1.6mm Driver Stem, Long, Hex Shank
220-0263	Profile Zero, 1.6mm Screwdriver Shaft
220-0264	1.6mm OsteoDriver2 Stem, Hex Shank, Short

Always review the instructions for use and caution/warning notices. The surgeon should be thoroughly familiar with the proper operation of the power surgical instruments and accessories prior to use.
- Only use recommended OsteoMed accessories with the OsteoDriver2.
- Check for any signs of damage to the OsteoDriver2 and driver stems before use.
- Verify the driver stem is properly inserted and secured before activating the instrument.
- Eye protection should be worn when using the OsteoDriver2.
- Do not use any driver stem that exhibits excessive wobble
- Accessories may reach temperatures up to 44°C.
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Operating Instructions
- The OsteoDriver2 features a locking collet system. To insert the OsteoDriver2 driver stem shaft, insert the accessory and push into the OsteoDriver2 until it is fully seated. To release, grasp the accessory shaft and pull until it is released from the OsteoDriver2.
- OsteoDriver2 Controls: Actuation and direction are controlled by depressing either the forward or reverse control buttons.
- OsteoDriver2 is non-continuous operating device, that has a maximum operation time of 15 seconds and a minimum duty off time of 15 seconds for up to 80 screws.

Operation	Button/Symbology	Maximum Operation Time (seconds)
Forward (Insert Screws)		15
Reverse(Remove Screws)		15

- In the event the OsteoDriver2 battery becomes depleted during the procedure, another OsteoDriver2 or manual driver may be used.

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
- OsteoDriver2
  - The OsteoDriver2 is packaged STERILE (gamma sterilized)
  - DO NOT USE IF STERILE PACKAGE IS DAMAGED
  - DO NOT USE AFTER EXPIRATION DATE
  - DO NOT RESTERILIZE
- OsteoDriver2 Accessories
  - 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 accessories prior to sterilization per standard hospital procedures
  - Non-sterile accessories are sterilizable by steam sterilization (autoclaving). For sterilization of OsteoMed OsteoDriver2 Accessories, the following parameters should be used:

Pre-Vacuum Steam Sterilization	
Minimum Temperature:	270°F (132°C)
Full Cycle Time:	4 minutes
Minimum Dry Time:	40 minutes
Configuration:	Individually wrapped 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.	
Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.	

OsteoDriver2 Disposal / Transport / Storage and Operating Conditions
- Observe the general environmental regulations applicable to battery disposal.
- Transport, Storage and Operating Conditions

Atmospheric Pressure Range: 76kPa – 106kPa

Storage
Sterile packaged products should be stored at ambient temperature ran (-10°C to 70°C) out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering. The OsteoDriver2 has a shelf-life of 2 years.

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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CE 0086

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Use By (Date)		Do not use if sterile package is damaged
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture (MFG Date)		Manufacturer (MFR)
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
SN	Serial Number	STERILE R	Sterile, Method of Sterilization Using Irradiation
10°C 38°C	Operating Temperature: 10°C to 38°C		Type B Applied Part
10 95	Storage Relative Humidity Range: 10% to 95% w/o condensation	-10°C 70°C	Storage Temperature -10°C to 70°C
76kPa 106kPa	Atmosphere Pressure Range: 76kPa-106kPa	Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.

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Guidance and manufacturer's declaration – electromagnetic emissions		
The OsteoDriver2, Model 450-0700, is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoDriver2, Model 450-0700, should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions (EN 55011)	Group 1	The OsteoDriver2 Model 450-0700 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (EN 55011)	Class B	The OsteoDriver2 Model 450-0700 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable[1]	[1]The OsteoDriver2 Model 450-0700 is internally powered by a non-rechargeable $3V_{DC}$ CR123A Lithium battery.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable[1]	

Guidance and manufacturer's declaration – electromagnetic immunity (for all ME equipment and ME systems)			
The OsteoDriver2, Model 450-0700, is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoDriver2, Model 450-0700, should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) (EN 61000-4-2)	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fasts transient/burst (EN 61000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable[1 and 2]	
Surge (EN 61000-4-5)	±2 kV differential mode ±1 kV common mode	Not applicable[1]	
Voltage dips, short interruptions and voltage variations on power supply input lines (EN 61000-4-11)	<5% *U*T (<95% dip in *U*T) for 0,5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Not applicable[1]	
Power frequency (50/60 Hz) magnetic field (EN 61000-4-8)	3 A/m	Not applicable[1]	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Notes: [1]The OsteoDriver2 Model 450-0700 is internally powered by a non-rechargeable $3V_{DC}$ CR123A Lithium battery.
[2]The OsteoDriver2 Model 450-0700 does not contain any interconnection cables.
[3]The OsteoDriver2 Model 450-0700 does not contain any magnetically sensitive devices.

Guidance and manufacturer's declaration – electromagnetic immunity (for ME equipment and ME systems that are not Life-Supporting)			
The OsteoDriver2, Model 450-0700, is intended for use in the electromagnetic environment specified below. The customer or the user of the OsteoDriver2, Model 450-0700, should assure that it is used in such an environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the OsteoDriver2 Model 450-0700 including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF (EN 61000-4-6)	3 Vrms 150 kHz to 80 MHz outside ISM bands[(a)]	Not applicable[1 and 2]	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF (EN 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}\ 80\ MHz\ to\ 800\ MHz$ $d = \left[\frac{7}{E_1}\right]\sqrt{P}\ 800\ MHz\ to\ 2.5\ GHz$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey,[(a)] should be less than the compliance level in each frequency range.[(b)] Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes: [(a)]Field strengths from fixed transmitter, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AutoDriver is used exceeds the applicable RF compliance level above, the OstseoDriver 2 Model 450-0700 should be observed to verify normal operation. If abnormal performance is observed, additional measured may be necessary, such as reorienting or relocating the OsteoDriver2 Model 450-0700.
[(b)]Over the frequency range 150 kHz to 80 Mhz, field strengths should be less than 3V/m.
[1]The OsteoDriver2 Model 450-0700 is internally powered by a non-rechargeable $3V_{DC}$ CR123A Lithium battery.
[2]The OsteoDriver2 Model 450-0700 does not contain any interconnection cables.

Recommended separation distances between portable and mobile RF communications equipment and the OsteoDriver2 Model 450-0700			
The OsteoDriver2 Model 450-0700 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OsetoDriver2 Model 450-0700 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OseteoDriver2 Model 450-0700 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.35	0.35	0.70
1	1.17	1.17	2.34
10	3.70	3.70	7.40
100	11.67	11.67	23.34

Notes: For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 – At 80 MHz and 800MHz, the higher frequency range applies.
NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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