OSTEOMED Pinnacle Battery Powered Driver

Product Information and Instructions for Use

Description

The OSTEOMED Pinnacle Driver is a handheld, cordless, software driven, battery operated driver for high speed drilling of bone screws and drill pilot holes. The software is capable of driving 1.6mm bone screws in lengths from 3mm to 6mm. It is solely supplied by OSTEOMED 2.0mm bone screws in lengths from 4mm to 18mm, 2.0mm MMF screws in lengths from 8mm to 11mm, and 1.2mm cortical bone screws in lengths from 3mm to 10mm. The device operates in the forward and reverse directions. A single, universal battery powers the device and is intended for use solely with the Pinnacle Driver.

Material

The Pinnacle Driver (p/n 110-1000) is made from various grades of stainless steel, aluminum, silicone, PEEK, gold plated brass, and plastic. Accessory sets are made from various grades of stainless steel. The driver uses a lithium ion replacement battery pack (p/n 110-1000). The battery housing containing the battery is made from various grades of plastic and gold plated brass, is sterilized sterile packaged via gamma irradiation in 1-pack (p/n 110-1000-SP) or 2-pack (110-1000-SP-02) configurations, and is solely supplied by OSTEOMED.

Clinical Indications

The Pinnacle Driver is intended for driving screws and for drilling into bone, in conjunction with dental, orthognathic, mandibular, cranial and orthopedic surgical procedures.

Contraindications

• The Pinnacle Driver is contraindicated in patients where there is insufficient bone or poor bone quality.

Warnings

• BATTERY MUST BE REMOVED FROM THE PINNACLE DRIVER BEFORE CLEANING AND STERILIZING THE HANDPIECE. DO NOT ATTEMPT TO RE-STEROILIZE THE BATTERY.
• The STERILE PACKAGED BATTERY IS SINGLE-USE ONLY. DO NOT REUSE.
• The DRILL BITS ARE SINGLE-USE ONLY AND SHOULD BE DISCARDED AFTER USE.
• Do not immerse the Pinnacle Driver in any solution. Immersing will render the device inoperable.
• Do not modify the Pinnacle Driver.
• If the device becomes too warm to comfortably handle during normal operation, discontinue use of the device.
• Do not use the Pinnacle Driver for any purpose other than the intended use. Use of the Pinnacle Driver to insert screws in soft bone or diseased bone may result in stripping of the screw threads in bone after full insertion.
• Do not use the Pinnacle Driver to remove screws. Failure to do so may result in damage to the device or accessories. Do not attempt to use the Pinnacle Driver to apply power to a bone screw or to remove it.
• Do not attempt to advance a fully seated screw using the Pinnacle Driver, as it can result in stripping of the screw crosscut driving feature. Use an alternative (e.g., manual driving mechanism for adjusting or fully seating screw or a mechanical driver does not function as desired). When using a mechanical driver, torque limiting software may prevent full insertion of the screw as the screw tip approaches the second screw collet. In this situation, after the motor operation delay concludes, the Pinnacle Driver can be used to then fully seat the screw.
• When driving bi-cortical screws, the torque limiting software may prevent full insertion of the screw as the screw tip approaches the second screw collet. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation methods should be available intraoperatively to assist in seating screws if the Pinnacle Driver does not function as desired. When the torque limiting software indicates that torque limiting has been reached, the surgeon should carefully inspect the Pinnacle Driver and battery prior to use. Devices which are faulty, leaking, emitting malodor or discoloration, damaged, or suspect should not be used. Immediately contact your local OSTEOMED representative.

Cautions

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

Maintaining Device Effectiveness

• The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation methods to assist in seating screws if the Pinnacle Driver does not function as desired.
• Carefully inspect the Pinnacle Driver and battery prior to use. Devices which are faulty, leaking, emitting malodor or discoloration, damaged, or suspect should not be used. Immediately contact your local OSTEOMED representative for replacement.
• The Pinnacle Driver will illuminate a flashing red light indicating the device is in a FAULT mode if the device is no longer functioning or if the motor operation delay concludes. Contact your local OSTEOMED representative for maintenance of the Pinnacle Driver.
• OsteoMed recommends utilizing the device in a sterile environment.
• Eye protection should be worn when using the Pinnacle Driver.
• Carefully inspect the hand piece by visually inspecting the area. Failure to do so may result in damage to the hand piece or the battery.

Instructions for Use

1. If mode switch immediately illuminates a flashing red, remove the battery and replace with a new, unused battery and repeat battery insertion. If the mode switch again illuminates a flashing red, this indicates the battery is dead. Contact your local OSTEOMED representative.
2. After activating the appropriate size driver stem or drill bit, pull the collet towards the hand piece, insert the driver stem or drill bit until it is fully inserted into the collet, and then fully seat it in the collet. Release the collet to allow it to spring forward into a locked position, and ensure the driver stem or drill bit is fully inserted into the collet, and then fully seat it in the collet. Use caution when inserting or changing accessories to avoid activation of the buttons.
3. For OSTEOMED Hex Shank Accessories may be inserted either before or after battery insertion.
4. To drive screws, ensure the mode switch is illuminated green, indicating DRIVE mode, and confirm a driver stem is locked into position in the collet.
5. To drive the screw, ensure the mode switch is illuminated green, indicating DRIVE mode, and confirm a driver stem is locked into position in the collet.
6. To remove a driver stem or drill bit, pull the collet towards the hand piece and remove it from the collet.
7. To remove the battery, firmly grip the sides of the battery housing and pull it away from the hand piece.
8. To change the hand piece back to DRIVE mode from DRILL mode, pull down on the center of the hand piece at the outline button for at least 2 seconds until the mode switch illuminates green. Alternatively, the hand piece can be changed to DRIVE mode by removing and then re-inserting the battery.

Pitfalls

• After patient use, remove the battery and dispose. Also, remove and dispose of the single patient use OsteoMed Hex Shank Drills (if applicable). Clean the exterior of the driver and OsteoMed Hex Shank Driver Stems after each use to remove any noticeable debris. If available, use a soft nylon brush to assist in the removal of superficial debris.

Cleaning

• The Pinnacle Driver and OsteoMed Hex Shank Accessories are supplied NON-STERILE and must be cleaned and sterilized by the facility prior to use with the appropriate method.
• After patient use, ensure the OsteoMed Hex Shank Accessories are removed from the collet and the battery is removed from the hand piece. Fully immerse the battery, squeeze the tabs on either side of the battery and pull away from the hand piece while holding the driver stationary with the other hand. To remove the OsteoMed Hex Shank Accessory, pull back on the collet and hold depressed while pulling the accessory away from the hand piece.
• To clean the OsteoMedHex Shank Driver Stems, rinse under running cool tap water (40ºC) to remove visible soil until visibly clean. Prepare an enzymatic cleaner (such as Kleenzyne®) per manufacturer’s recommendations. Use a soft bristle brush, clean the entire accessory paying close attention to hard to reach areas until all evidence of soil is removed. A spray may be used to clean the hard to reach areas. Prepare a mild detergent (such as Reenu-Kleen®) per the manufacturer’s recommendations. Fully immerse the accessories in the prepared solution and sonicate the accessories for a minimum of 10 minutes. Following sonication, rinse the accessories under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
• Inspect re-usable Hex Shank Driver Stem for any signs of damage, wear, or other defects which may render the device unsuitable or unfit to fit the Pinnacle Driver. Do not use damaged accessories. If the accessories are damaged, contact OsteoMed.
• Complete the device cleaning per either the Manual Cleaning Method or Automated Cleaning Method as outlined below.

Manual Cleaning Method

Step | Time | Instructions
--- | --- | ---
1 | 2 minutes | Remove pressure from the forward button and gently rock the hand piece from side to side to disengage the driver stem from the collet. Release the collet to allow it to spring forward into a locked position, and ensure the driver stem is fully seated in the collet.
2 | 2 minutes | Prepare a mild detergent such as PolyPlus® 2X Concentrated (PolyPlus®) or other manufacturer’s recommendations using lukewarm tap water. Soak a lint-free cloth in the prepared detergent and use to wipe the article. Carefully wipe the article using a soft brush or microfiber cloth. 
3 | 2 minutes | Rinse all articles under running RO/DI water until all evidence of detergent is removed. A syringe, Bernie or spray or jet may be used to aid in rinsing.
4 | 45 minutes to 1 hour | Dry the article using a clean lint-free cloth. Please allow at 2 hours to 6 hours for drying.
5 | N/A | Visually examine each article for visible soil with stained eye and adequate lighting. If visible soil or cleaning residue remains, repeat cleaning.

Manual Cleaning Method

Color | Mode | Comment
--- | --- | ---
Green | DRIVE | Indicates Pinnacle Driver is powered, operational, and in DRIVE mode
Red | FAULT | Indicates Pinnacle Driver is powered, but not functioning properly

N/A: Not applicable

OsteoMed Hex Shank Accessories are single-use only. All replacement stems are reusable, while drill bits are single use. Always review the instructions for use and caution/warnings for these devices prior to use. The single use battery is packaged sterile.
Automated Cleaning Method

Automated Cleaning may be performed with Pinnacle Driver and OSTEOMED Hex Shank Accessories inside the Pinnacle Sterilization Organizational Case. Place the Hex Shank Accessories in the silicone brackets and the Pinnacle Driver in the larger holding brackets as depicted by the graphics located on the bottom sterilization organizational tray. Only load the devices in the retaining slots as noted by the graphics. DO NOT OVERFILL the sterilization organizational tray. The number of accessories placed in the sterilization organizational tray should not exceed the number of slots available (6). Place 1 or 2 drivers in the sterilization organizational tray, depending on the tray available, as noted in the graphics. Follow the washer/disinfector instructions for placing the sterilization trays inside the washer/disinfector.

Automated Cleaning Method

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Duration</th>
<th>Water/Temperature</th>
<th>Detergent Type and concentration (or equivalent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash 1</td>
<td>3 minutes</td>
<td>Cold tap water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash 1</td>
<td>5 minutes</td>
<td>Hot tap water (55°C)</td>
<td>TecWash III (pH 7.0-9.5) 1 oz/gallon</td>
</tr>
<tr>
<td>Wash 2</td>
<td>10 minutes</td>
<td>Hot tap water (60°C)</td>
<td>TecWash III (pH 7.0-9.5) 1 oz/gallon</td>
</tr>
<tr>
<td>PURW Rinse</td>
<td>1 minute</td>
<td>DI water (45°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>PURW Rinse</td>
<td>10 minutes</td>
<td>DI water (93°C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Visually inspect the device after cleaning is performed. If the device does not appear clean, or there is noticeable debris, repeat the automated cleaning method.

Sterility

- The Pinnacle Driver battery is provided STERILE by exposure to gamma irradiation. DO NOT RESTERILIZE. The battery is for one-time, single-patient use only. DO NOT USE IF STERILE PACKAGE IS OPENED OR DAMAGED. The expiration date of the battery is provided on the individual battery packaging label. DO NOT USE PAST THE EXPIRATION DATE TO AVOID RISK OF INFECTION.
- The Pinnacle Driver and OSTEOMED Hex Shank Accessories are provided NON-STERILE and are sterilizable by steam sterilization (autoclaving).
- Sterilization of the Pinnacle Driver can be achieved wrapped by itself (no case), or inside the Pinnacle Sterilization Organizational Case (p/n 110-1011 or 110-1012) inside an Aesculap tray. Sterilization of the OSTEOMED Hex Shank Accessories can only be achieved inside the Pinnacle Sterilization organizational tray. If the sterilization organizational trays are used, load according to the graphics located on the sterilization organizational tray. If an Aesculap tray is used, place the sterilization organizational tray inside the rigid container and secure the lid.

- 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.
- OsteoMed recommends wiping down the Pinnacle Driver with a soft cloth to insure thorough drying prior to sterilization.

The following sterilization parameters must be used:

<table>
<thead>
<tr>
<th>Pre-Vacuum Steam Sterilization</th>
<th>1 Driver Case (110-1011)</th>
<th>2 Driver Case (110-1012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Case</td>
<td>Hot piece Only (No Case)</td>
<td>Hot piece Only (No Case)</td>
</tr>
<tr>
<td>Minimum Temperature:</td>
<td>270°F (132°C)</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>Full Cycle Time:</td>
<td>4 minutes</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Minimum Dry Time:</td>
<td>30 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Configuration:</td>
<td>Individually wrapped in two layers of 1-ply polypropylene wrap (Kimgard KC600 – 510(k) K082554) using sequential wrapping techniques.</td>
<td>Unwrapped using a rigid sterilization container (Aesculap – 510(k) K053389 or equivalent)</td>
</tr>
</tbody>
</table>

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.

Note: If the specified wrap is not available, only FDA cleared wraps and labeled for the validated sterilization parameters in this IFU should be used to wrap the subject device.

Note: If using the sterilization organizational trays (part number 110-1011 or 110-1012), place the device in one of the trays and place the tray inside the FDA cleared rigid container.

After cleaning and sterilization, and prior to re-use, conduct a visual inspection of the device, specifically looking for any signs of material degradation, corrosion, worn parts, surface coating damage, etc. If the device does not appear to be in proper condition, please notify OsteoMed. Do not use a suspect device.
**Pinnacle Driver Technical Specifications**

**Classification:**
- Part No. 9461.

**Electromagnetic Environmental Guidelines**

<table>
<thead>
<tr>
<th>EN Standard</th>
<th>Guideline</th>
<th>Notes or Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>(EN 61000-4-2)</td>
<td>Radiated RF magnetic field</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(EN 61000-4-3)</td>
<td>Radiated RF electric field</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(EN 61000-4-8)</td>
<td>Magnetic field power frequency</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(EN 61000-4-5)</td>
<td>Surge</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(IEC 61000-4-4)</td>
<td>Emissions</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(CISPR 11)</td>
<td>Emissions</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(IEC 61000-3-2)</td>
<td>谐波</td>
<td>Not applicable</td>
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**Note:**
- The Pinnacle Driver is intended for use in an electromagnetic environment which satisfies the above referenced IEC 61000-4-5, electromagnetic immunity requirements.
- The Pinnacle Driver is internally powered by a non-rechargeable Lithium-Polymer battery.
- This device is intended to be used in an operating room of a Professional Healthcare Facility. It is not intended to be operated at the same time that HF surgical equipment is active.
- Verify operating mode (Driver or Drill) of the device prior to use.
- Verify electromagnetic immunity prior to use.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. In such a case, the Pinnacle Driver equipment should be observed to verify that it is operating normally.
- WARNING: Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decrease electromagnetic immunity of the equipment and result in improper operation.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pinnacle Driver. Otherwise, degradation of the performance of the equipment could result.

**Recommended operation distances between portable and mobile RF communications equipment and the Pinnacle Driver**

<table>
<thead>
<tr>
<th>Distance (m)</th>
<th>Power Level (W)</th>
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<tbody>
<tr>
<td>1</td>
<td>0.01</td>
<td>0.1</td>
</tr>
<tr>
<td>0.1</td>
<td>0.12</td>
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</tr>
<tr>
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