In case the driver fails, secure the needle set in hand, set aside the BD™ Intraosseous Powered Driver, and twist or rotate the needle set clockwise and counterclockwise into the medullary space.  

- Waste of electronic and electrical equipment must not be disposed as unsorted municipal waste. It must be collected separately, and disposed as per local regulations. Contact an authorized representative for information concerning the decommissioning of your equipment.  

- Keep the device clean and protected from dust and lint.

**Directions For Use**  

- See Safety and Warning Information Section  

- Consult the Instruction for Use for needle set instructions for inserting needle sets and for additional warnings.  

- Connect the appropriate needle set to the drive socket until coupled.  

- Pull trigger to display the powered driver charge status (see battery information and Indicators and Alerts section) and to rotate needle.  

- Release trigger to stop needle.  

- Pull back on the Powered Driver to disconnect the needle after the needle is inserted.  

- Connect power supply to USB charge socket for charging the powered driver (see separate section for battery information and LED indicators).  

- Clean the device after each use and prior to charging (see care and cleaning section). Store device until ready to use (see Storage and Transport Table).

**Battery Information**  

- The BD™ Intraosseous Powered Driver cannot be used while charging the battery.  

- The battery is charged with a minimum 30% charge. CAUTION: Be sure to charge the battery before first use.  

- The BD™ Intraosseous Powered Driver is sealed and should not be opened.  

- The battery is rechargeable by inserting the USB connection of the power supply (provided) into the base of the Powered Driver.  

- It is recommended to fully charge the BD™ Intraosseous Powered Driver every 3 months.  

- USB cover should be opened during charging and closed after charging.  

- Approximate charging time to fully charge the battery is 4 hours.  

- AC Power Supply should only be connected to 100-240 volt power outlet supply.  

- AC Power Supply is a Class 2, isolated AC Power Supply with Micro USB type b connector.  

- Plug of AC Power Supply is used as a means of isolation. Position the Powered Driver so that disconnection to the main plug can be easily made during an unexpected error.

---

**General Product Description**  

- Driver REF number: D001001  

- Applied Parts: BD™ Intraosseous Needle Set Kits – 15 mm; 25 mm; 45 mm; REF numbers: D015151NK, D015251NK, D015451NK, respectively sold separately  

- Needle and power supply can be detached from the power driver  

- Power Supply REF number: D001002, only use this power supply  

**Important Information For Users**  

- Use the following guidance to ensure the BD™ Intraosseous Powered Driver operates correctly. Failure to follow these instructions will result in battery damage or disconnection of the equipment.  

- Use this device in correspondence with this IFU and labeled products.  

- Alterations, modifications, technical maintenance or repairs are prohibited. The driver does not contain replaceable components inside.  

- Check battery status before each use by pushing the trigger. With a charged battery, the device is immediately ready to use. (See Indicators and Alerts section for LED indicators of battery charge)  

- Connecting this device or its components to products not provided by BD is prohibited  

- Use only the BD™ Intraosseous Needle Set Kits with this device.  

- Thoroughly check the BD™ Intraosseous Powered Driver for cracks and sharp edges before use.  

- Prevent spilling fluids on the BD™ Intraosseous Powered Driver.  

- Avoid exerting too much force while inserting the device.  

- Allow the BD™ Intraosseous Powered Driver to do the work during needle insertion.

---

**Power Supply**  

- **LED Battery Indicator**  

- **Charging Level** – (Displayed on LED Battery Indicator)  

- **Charging**  

**Battery Charge Level – (Displayed on LED Battery Indicator)**  

<table>
<thead>
<tr>
<th>Charge Level</th>
<th>LED Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% to 25%</td>
<td>Red blinking</td>
</tr>
<tr>
<td>25% to 50%</td>
<td>Red and amber blinking</td>
</tr>
<tr>
<td>50% to 75%</td>
<td>Amber blinking</td>
</tr>
<tr>
<td>75% to 100%</td>
<td>Green blinking</td>
</tr>
</tbody>
</table>

**Battery Charge Level – (Displayed on LED Battery Indicator)**

**Needle Attention**

- The LED indicator on the BD™ Intraosseous Powered Driver has 6 LED's.  

- The BD™ Intraosseous Powered Driver LED's will turn on and the drive shaft will rotate immediately when the trigger is pressed.  

- The battery is rechargeable by inserting the USB connection of the power supply (provided) into the base of the Powered Driver.  

- Fully Charged: BD™ Intraosseous Powered Driver LED's will be solid green when trigger is activated with a full charge.  

- When fully charged, the BD™ Intraosseous Powered Driver is sealed and should not be opened.  

- Charging BD™ Intraosseous Powered Driver single LED will blink when charging using the AC Power Supply connected.  

- No Charge: BD™ Intraosseous Powered Driver single LED will blink red when the trigger is activated with an insufficient battery life remaining and battery needs to be charged.  

- Needs Attention: All four flashing lights indicates a driver fault requiring one of the following actions.

If questions arise, troubleshooting, or if the information sheet is missing, immediately contact BD.

**Too Hot**

- Wait for BD™ Intraosseous Powered Driver to cool down to resume. Once cooled to a safe temperature (∼50 °C), the lights will stop blinking.

**Too Cold**

- Press trigger and hold to allow the Powered Driver to warm up. Once warm (> -5 °C), the lights will stop blinking.

**Driver Stalled**

- Let go of the trigger then resume using less insertion force.

**Trigger Stuck or runtime fault**

- Let go of the trigger then resume. If used >59 seconds the Powered Driver will shut off automatically.

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**Equipment Classification**  

- **Type of protection against electric shock**  

- **Internal powered equipment**  

- **Degree of protection against electric shock**  

- **Type B applied part**  

- **Degree of protection against ingress of water**  

- **IP33. Spraying water and solid foreign body protection (objects < 2.5mm diameter)**  

- **Suitability for use in an oxygen rich environment**  

- **Not intended for use in an oxygen rich environment**  

- **Conditions of Use**  

- **Transportable road ambulance**  

- **Mode of operation**  

- **The BD™ Intraosseous Powered Driver is designed and started to run intermittently with a duty cycle of 10 seconds on, 1 minute off for 2 consecutive cycles. Allow 1 hour cool down time.**  

- **Methods of Sterilization**  

- **Powered Driver is not intended to be sterilized**

---

**Environmental Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Temperature</th>
<th>Relative Humidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atmospheric Pressure</td>
<td>500 to 1060 hPa</td>
<td>N/A</td>
</tr>
<tr>
<td>Relative Temperature</td>
<td>-40°C to +55°C</td>
<td>Up to 90%, non-condensing</td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>500 to 1060 hPa</td>
<td>N/A</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>500 to 1060 hPa</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Safety And Warning Information**

- Infused needles/inserts, contraindications, additional warnings, precautions, and other safety information are included in the instructions for use for the BD™ Intraosseous Needle Kit  

- Consult the instructions for use for the BD™ Intraosseous Needle Kit before installing.  

- It is strongly recommended that the BD™ Intraosseous Needle Kit be used on-site.  

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the equipment should be observed to verify that they are operating normally.  

- Fully charge the battery before first use.  

- Keep the unit clean and protected from dust, dirt and sunlight.  

- Modifications of this equipment are prohibited.  

- The battery must be taken when operating this equipment around other equipment to avoid reciprocal interference.  

- Power electronic equipment or other interference could occur to this or to other equipment. Try to minimize this interference by not using other equipment in conjunction with this equipment.  

- The BD™ Intraosseous Powered Driver has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.  

- CAUTION: Use of electrical equipment requires special precautions regarding EMC and must be installed and operated (put in service) according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the system. Existence of disruption may include image degradation or distortion, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s):  

- Turn equipment in the vicinity off and on to isolate disruptive equipment.  

- Relocate or reorient interfering equipment.  

- Increase distance between interfering equipment and your system.  

- Manage use of frequencies close to the system frequencies.  

- Remove devices that are highly susceptible to EMI.  

- Lower power from internal sources within the facility control (such as paging systems).  

- Label devices susceptible to EMI.  

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• Educate clinical staff to recognize potential EMI-related problems.
• Eliminate or reduce EMI with technical solutions (such as shielding).
• Restrict use of personal communications (cell phones, computers) in areas with devices susceptible to EMI.
• Share relevant EMI information with others, particularly when evaluating new equipment purchases, and promote good behavior by which may generate EMI.
• Purchase medical devices that comply with IEC 60601-1-2 EMI Standards

This equipment is designed to comply with IEC 60601-1-2. This equipment generates, uses, and can radiate radio frequency (RF) energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If harmful interference to other devices can be determined by turning this equipment ON and OFF, try to correct the interference using one or more of the following:

• Reorient or relocate the receiving device.
• Increase the separation between the equipment.
• Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected and consult the BD service technician for help.

Consult BD for help.

Electromagnetic Compatibility (EMC) Tables For RF Emissions

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The BD™ Intraosseous Powered Driver is intended for use in the electromagnetic environment specified below. The user of the BD™ Intraosseous Powered Driver should assure that it is used in such an environment.

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The BD™ Intraosseous Powered Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the BD™ Intraosseous Powered Driver should ensure that it is used in such an environment.

Immunity Test IEC 60601 Test Level Compliance Level Electromagnetic Environment - Guidance

<table>
<thead>
<tr>
<th>Test</th>
<th>Level</th>
<th>Level</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>AC Mains 3V</td>
<td>3V</td>
<td>3V</td>
</tr>
<tr>
<td></td>
<td>DC &amp; I/O &amp; Patient Coupled (3m)</td>
<td>3V with 6V EM</td>
<td>Home: 6V Amateur radio</td>
</tr>
<tr>
<td></td>
<td>Digital EMI</td>
<td>3V with 6V EM</td>
<td>Home: 6V Amateur radio</td>
</tr>
<tr>
<td></td>
<td>Radio Frequency</td>
<td>10V/m, 80% AM at 1 kHz</td>
<td>800 MHz – 2700 MHz</td>
</tr>
<tr>
<td></td>
<td>(TE1) + 10V/m</td>
<td>10V/m, 80% AM at 1 kHz</td>
<td>800 MHz – 2700 MHz</td>
</tr>
</tbody>
</table>

NOTE 1 At 80 MHz and 800 MHz, 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.

Recommended separation distances between portable and mobile RF communications equipment and the BD™ Intraosseous Powered Driver

The BD™ Intraosseous Powered Driver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BD™ Intraosseous Powered Driver should ensure that electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BD™ Intraosseous Powered Driver as recommended below, according to the maximum output power of the communications equipment.

Warranty

BD warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be defective, purchaser may return same to BD for repair, replacement, refund, or credit at BD’s option. All returns must be authorized in advance in accordance with BD’s Returnable Goods Policy found in its then current Price List. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. The liability of BD under this limited warranty does not extend to any abuse, misuse, modification, improper storage, alteration, further manufacture, packaging or processing of the product or repair by anyone other than a BD representative. The following will also void this limited warranty:

• Opening or servicing any component of the BD™ Intraosseous Powered Driver by anyone other than BD or BD’s authorized service personnel.
• Removing system labels by anyone other than service personnel authorized by BD.
• Connecting the BD™ Intraosseous Powered Driver to any AC adapter other than the system adapter.

BAD’S COMPLETE PRODUCT WARRANTY IS IN LIEU OF ALL IMPLIED WARRANTIES, WHETHER EXPRESS OR IMPLIED (INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). THE LIABILITY OF BD REMEDIES STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BD AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT. THIS LIMITATION OF LIABILITY IS NOT DEPENDENT ON WHETHER OR NOT THE PURCHASER HAS ADVISE OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE.

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• Removing system labels by anyone other than service personnel authorized by BD.

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BD Access Systems, Inc. 605 North 56th West Salt Lake City, UT 84118 US 801.522.5505 bd.com

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