BD INTRAOSSEOUS Vascular Access System

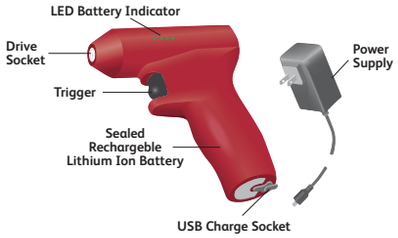
Powered Driver

Instructions for use

Description

The BD™ Intraosseous Powered Driver is an easy-grip, hand-held, powered medical device with a rechargeable lithium battery. It is part of the BD™ Intraosseous Vascular Access System and used as an aid for inserting BD™ Intraosseous needles into bone.

The BD™ Intraosseous Vascular Access System provides access to the intraosseous space for fluid and medication delivery when unable to obtain IV access, or in addition to IV access. Access to bone marrow is achieved by inserting a hypodermic needle specifically designed for tissue and bone penetration. Fluids delivered to the bone marrow are dispersed systemically through the bone vasculature. Aspiration of the bone marrow also contains blood and therefore can be used for blood draws.



Indications for Use

The BD™ Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatrics patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours

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 void any related warranties.

- 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 pulling 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 Sets 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.

- 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 electrical and electronic 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 for instructions on 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 device is shipped with a minimum 30% charge. **CAUTION:** Be sure to fully 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-DC 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.

Indicators & Alerts

Battery Charge Level – (Displayed on LED Battery Indicator)				
Charge Level	**0% to 25%**	**25% to 50%**	**50% to 75%**	**75% to 100%**
Running				
Charging				

Note: At least two green LEDs are required for an insertion

Needs Attention	

- The LED indicator on the BD™ Intraosseous Powered Driver has 4 LED's
- The BD™ Intraosseous Powered Driver LED's will turn on and the drive shaft will rotate immediately when the trigger is pressed. Releasing the trigger will stop the rotation.
- Fully Charged: BD™ Intraosseous Powered Driver LEDs will be solid green when trigger is activated with a full charge. When fully charged and connected to the AC Power Supply, the 4 LEDs are also solid green.
- 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

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.

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

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

Care And Cleaning

1. Follow BSI or PPE precautions.
2. Ensure the USB charge socket is covered so no liquid ingress can occur
3. Thoroughly wet and clean all external surfaces using gauze or wipes moistened with anti-microbial solution (i.e. QUAT based SANI-CLOTH AF3 or similar) per the manufacturer's instructions.
4. Using sterile gauze pads or wipes, moistened with anti-microbial solution (i.e. QUAT based SANI-CLOTH AF3 or similar), clean around the trigger and inside the opening of the metal drive slot.
5. When finished cleaning, examine device to confirm no debris remain and that the device is not damaged.
6. Dry the Powered Driver with a clean cloth.

Do not submerge the Powered Driver or use excessive amount of liquid during the cleaning and disinfecting process. Do not allow liquid to enter the USB charge socket.

Warranty Information

- The BD™ Intraosseous Powered Driver is free from defects in material and workmanship under normal use for a period of one (1) year from the date of delivery by BD to the original purchaser.
- Service life for the BD™ Intraosseous Powered Driver is approximately 1 year or 1500 insertions (insertion is defined as a 10 second drill run time).
- Service life expectancy is dependent on actual usage (bone density and average insertion time), storage, and frequency of testing.

Equipment Classification

Type of protection against electric shock	Internal powered equipment
Degree of protection against electric shock	Type BF 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 ambulances
Mode of operation	The BD™ Intraosseous Powered Driver is designed and tested 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

	Transient Operating[2]	Continuous Operating[2]
Atmospheric Pressure	620 to 1060 hPa	620 to 1060 hPa
Relative Humidity	15% to 90%, non-condensing	15% to 90%, non-condensing
Temperature Range	-20°C to 50°C	0 to 40C

Storage and Transport

	Temperature Range[2]		
	-40°C to +5°C	+5°C to +35°C	>35°C to +70°C[1]
Atmospheric Pressure	500 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa
Relative Humidity	N/A	Up to 90%, non-condensing	N/A

1 – Water vapor pressure up to 50 hPa
2 – Maximum altitude 3000 meters

- Allow Powered Driver 20 minutes in operating environmental conditions after removing from storage temperatures before using.

Safety And Warning Information

- Intended use/indications, contraindications, additional warnings, precautions, and other safety information are included in the instructions for use for the BD™ Intraosseous Needle Set Kit.
- Consult the instructions for use for the BD™ Intraosseous Needle Set Kit before installing.
- It is strongly advised to carry or maintain a backup BD™ Intraosseous Powered Driver 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, lint and sunlight.
- Modifications of this equipment are prohibited.
- Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the 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:** Medical 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. Evidence 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.

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

- This Equipment is designed to comply with IEC 60601-1-2. This equipment generates, uses, and can radiate radio frequency 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. 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.

Symbols


Consult instructions for use

Temperature Limitation

Humidity Limitation

Atmospheric Pressure Limitation

Serial Number

IP33 – protection from solid objects and falling water

Direct Current 5v - 1 AMP


BF Applied Part

Rx Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.


Date of Manufacturer


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


Manufacturer

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.		
Emissions Tests	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The BD™ Intraosseous Powered Driver 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 CISPR 11	Class B	The BD™ Intraosseous Powered Driver 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	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

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 assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV for Contact Discharge ±2 kV, ±4 kV , ±8 kV and ±15kV for Air Discharge	± 8 kV for Contact Discharge ±2 kV, ±4 kV, ±8 kV and ±15kV for Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Mains Line to Ground ±0.5kV, ±1kV and ±2kV AC Mains Line to Line ±0.5kV and ±1kV DC Input (>3m) Line to Line ±0.5kV and ±1kV DC Input (>3m) Line to Ground ±0.5kV, ±1kV and ±2kV I/O, Line to Ground ±2kV (Outdoor Line only)	AC Mains Line to Ground ±0.5kV, ±1kV and ±2kV AC Mains Line to Line ±0.5kV and ±1kV DC Input (>3m) Line to Line ±0.5kV and ±1kV DC Input (>3m) Line to Ground ±0.5kV, ±1kV and ±2kV I/O, Line to Ground ±2kV (Outdoor Line only)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (100% dip in UT) for 0.5 cycles 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (100% dip in UT) for 250/300 cycles	<5% UT (100% dip in UT) for 0.5 cycles 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BD™ Intraosseous Powered Driver requires continued operation during power mains interruptions, it is recommended that the BD™ Intraosseous Powered Driver be powered from an uninterrupted power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity Non-life supporting ME Equipment
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 assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	AC Mains 3V 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz DC & I/O & Patient Coupled (>3m) 3V with 6V ISM, Home: 6V Amateur radio 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz	AC Mains 3V 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz DC & I/O & Patient Coupled (>3m) 3V with 6V ISM, Home: 6V Amateur radio 80% AM at 1 kHz or risk frequency 150 kHz – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the BD™ Intraosseous Powered Driver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{3,5}{V1}]\sqrt{P}$ $d=[\frac{3,5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz to 800 MHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Radiated RF IEC 61000-4-3	10V/m, 80% AM at 1 kHz 80 MHz – 2700 MHz	(E1) = 10V/m	
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.			

a Field strengths from fixed transmitters, 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 "Product Name" is used exceeds the applicable RF compliance level above, the "Product Name" should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BD™ Intraosseous Powered Driver.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the BD™ Intraosseous Powered Driver Non-life supporting ME Equipment
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 can help prevent 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.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=[\frac{3,5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3,5}{E1}]\sqrt{P}$	800 MHz to 2,7 GHz $d=[\frac{7}{E1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 800 MHz, the separation distance for 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.			

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 so 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 Returned 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 warrantly 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 Power Driver by anyone other than BD authorized service personnel.
- Removing system labels by anyone other than service personnel authorized by BD.
- Connecting the BD™ Intraosseous Power Driver to any AC adapter other than the system adapter.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, (INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BD AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BD WILL NOT BE LIABLE TO PURCHASERS FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.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