INTRAOSSEOUS Vascular Access System

Manual Driver Kit

Instructions for use

Indications for Use

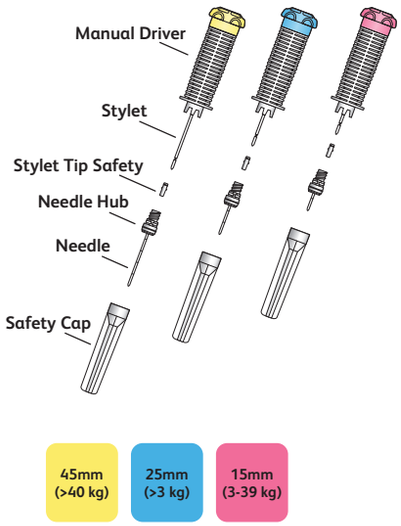
The BD™ Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia, and humeral head (proximal humerus) of adult and pediatric patients and the distal femur in pediatrics patients when intravenous access is difficult or impossible to obtain in emergent, urgent,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

Description of the BD™ Intraosseous Manual Driver Kit

The BD™ Intraosseous Manual Driver Kit consists of the following components:

- Needle with needle hub, stylet with manual driver and color cap, stylet tip safety, and safety cap
- 15 gauge, 304 stainless steel needles in 15mm, 25mm, or 45mm lengths. (DO15151MK, DO15251MK, DO15451MK).
- Manual Driver Kits are sterile and non-pyrogenic in protective packaging.
- Extension set with needle-free valve.
- Securement dressing.

1 (continued)



General Product Description

The BD™ Intraosseous Vascular Access System provides clinicians and emergency personnel with access to the intraosseous space for resuscitation and lifesaving fluid delivery.

The BD™ Intraosseous Vascular Access System consists of a single-use disposable hypodermic needle connected to a needle hub and a stylet connected to a manual driver. The needle penetrates the cortex of the bone to the desired depth by manually rotating the device clockwise and counterclockwise. After the needle is inserted, the user separates the stylet from the needle hub, leaving the needle in the bone. Upon separation, a passive stylet tip safety is released to protect the user from the tip of the stylet. A securement dressing may be placed around the needle hub and secured to the patient with an adhesive backed dressing. An extension set is available with the device kits for access to the needle hub for fluid exchange.

2 (continued)

The BD™ Intraosseous Manual Driver Kit is supplied sterile and designed to provide access to the intraosseous space. Access to bone marrow is achieved by inserting a 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 contains blood and can be used for blood draws.

Patient size (i.e. pediatric, adult) may vary; therefore, three different needle lengths are available to select from for obtaining access. This device is indicated for only the following access sites

Adults

- Proximal humerus
- Proximal tibia
- Distal tibia

Pediatrics

- Proximal humerus
- Proximal tibia
- Distal tibia
- Distal femur

Contraindications

This device is contraindicated when the following exist or are suspected to exist:

- Fracture in target bone
- Excessive tissue (i.e. severe obesity)
- Absence of adequate anatomical landmarks
- Bone Disease (i.e. Osteoporosis, etc.)
- Infection at the insertion site
- Previous significant orthopedic procedure at the insertion site
- Prosthetic limb or joint near the insertion site
- Intraosseous access at the same insertion site in the past 48 hours
- Sternal use

3 (continued)

Warnings and Precautions

- **Warning:** Intended for single use. Do not reuse. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device which may lead to device failure, and/or lead to injury, illness or death of the patient.
- **Caution:** Modification of this equipment is prohibited.
- **Caution:** Do not use if packaging is damaged or opened.
- **Caution:** Do not use the manual driver kit with power drill.
- **Caution:** Use only the BD™ Intraosseous Power Driver with the BD™ Intraosseous Needle Set.
- **Caution:** Not for sternal use.
- **Caution:** Do not use device for access other than intraosseous access.
- **Caution:** Check skin/tissue thickness prior to insertion.
- **Caution:** Use aseptic technique.
- **Caution:** Before infusing, check device placement and patency.
- **Caution:** Do not re-cap or reassemble components.
- **Caution:** Do not rock or bend the BD™ Intraosseous needle during removal.
- **Caution:** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- **Caution:** Do not use the securement dressing on breached or compromised skin.
- **Caution:** Monitor insertion site for extravasation.
- **Caution:** Do not leave needle in for more than 24 hours.
- **Caution:** The needle and manual driver set is not MRI compatible.
- **Caution:** Federal Law (USA) restricts this device to sale by or on order of a physician.
- **Caution:** Luer slip connections should not be left unattended due to potential disconnection.
- **Caution:** To prevent valve damage, do not use needles, blunt cannula, luer connections with visible defects, or non-standard syringes/luer connections. Doing so may result in leakage and/or failure of the valve.

4 (continued)

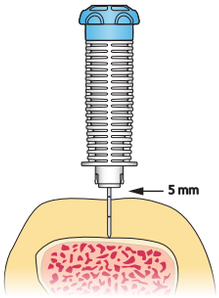
Insertion Instructions

Preparation

1. Take barrier precautions.
   CAUTION: Use aseptic techniques.
2. Prepare supplies
3. Prime the extension set.
4. Locate and prepare insertion site per institutional policy.
   CAUTION: Not for sternal use.
   CAUTION: Check skin/tissue thickness prior to insertion.
5. Select proper needle length.
   CAUTION: Do not use if packaging is damaged or opened.
6. Twist and remove the safety cap.
   Note: The stylet is to remain in the needle during insertion.
   Note: Do not touch needle.

Insertion

7. Position the manual driver at the insertion site with the needle at a 90-degree angle to the skin
   Note: Important: Control patient movement prior to and during procedure.
   - Insert the needle assembly until the needle tip touches bone.
   - 5 mm of the BD™ Intraosseous needle (at least one black line) must be visible outside the skin.



8. Penetrate bone cortex by rotating clockwise and counterclockwise while applying gentle, steady, downward pressure.
   - Maintain 90° angle.
   - Do not rock or bend manual driver and/or needle during insertion.
   - Stop insertion process when a desired depth is obtained or needle hub is flush with the skin.

   Pediatrics: Entry into the medullary space can be indicated when a "pop" or "give" is felt.
   Adults: Advance needle set 1-2 cm into medullary space upon entry; for proximal humerus access, advance needle set 2 cm or until needle hub is flush with skin.

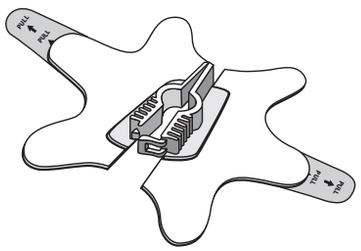
9. Remove the stylet by pulling straight back with the manual driver.
   Note: The stylet tip safety will automatically attach to the stylet tip as the stylet exits the needle hub.
10. Place the stylet assembly in a sharps container.

Infusion

11. Remove the protective cover and attach the primed extension set to the needle hub.
    Note: Firmly secure the extension set by twisting clockwise.
12. Prior to infusion, clean extension set valve with a sterile 70% IPA pad by wiping in a circular motion for 5 seconds and allow to dry for approximately 60 seconds:
    CAUTION: To prevent valve damage, do not use needles, blunt cannula, luer connections with visible defects, or non-standard syringes/luer connections. Doing so may result in leakage and/or failure of the valve.
13. Flush the extension set with normal saline (0.9% Sodium Chloride, 5-10 mL for adults; 2-5 mL infant/child).
    Note: Prior to flush, confirm needle placement by aspirating the extension set for visual confirmation of blood/bone marrow.
    CAUTION: Luer slip connections should not be left unattended due to potential disconnection.
14. For patients responsive to pain, consider infusing 2% preservative and epinephrine-free lidocaine (intravenous lidocaine) per institutional protocol/policy.
    CAUTION: Before infusing, confirm device placement and patency.
15. Administer fluids or medications as indicated.
    CAUTION: Monitor insertion site for extravasation.

Stabilization

16. Use of the securement dressing is strongly recommended for all BD™ Intraosseous insertions.
    CAUTION: Do not use on breached or compromised skin.
17. Properly clean and dry the insertion area for optimal adhesion.
18. Open the center snap feature of the securement dressing.
19. Snap the feature closed around the needle hub.
20. Attach the adhesive of the securement dressing by pulling the tabs.
21. Press adhesive against the skin for proper stabilization.
    CAUTION: Do not leave needle inserted for more than 24 hours.



Removal

22. Remove the extension set and the securement dressing. To remove the BD™ Intraosseous needle from the patient, twist clockwise while slowly applying traction to the BD™ Intraosseous needle. Alternatively, attach Luer-Lock syringe to hub of needle and withdraw the needle by applying traction while rotating the syringe and needle clockwise. Maintain axial alignment during removal.
    CAUTION: Do not rock or bend the BD™ Intraosseous needle during removal.
23. Once removed, place the needle in appropriate sharps container.
    CAUTION: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulation.
24. Dress site per institutional protocol/policy.

Storage and Transport Conditions

-29°C to -60°C (-20°F to -140°F)
Condition of Use: Transportable road, or rotary wing ambulance.

Symbols

Consult instructions for use	Quantity
Do not re-sterilize	LOT Lot number
Do not re-use	REF Reorder number
Do not use if package is damaged	Use by
Non-pyrogenic	STERILE EO Sterilized using ethylene oxide
Manufacturer	Not made with natural rubber latex.

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

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