INTRAOSSEOUS Vascular Access System

Needle Set Kit

Instructions for use

Indications for Use

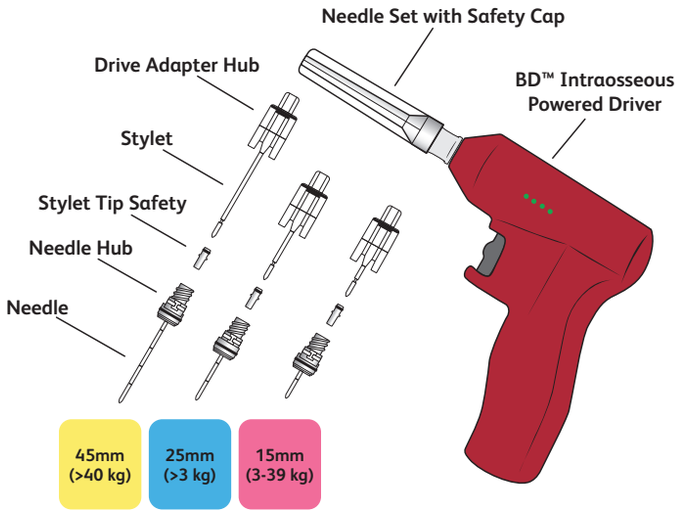
The BD™ Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent,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

Description of the BD™ Intraosseous Needle Sets

The BD™ Intraosseous Needle Set Kit consists of the following components:

- Needle with needle hub, stylet with drive adapter hub, stylet tip safety and safety cap.
- 15 gauge, 304 stainless steel needles in 15mm, 25mm, or 45mm lengths. Needle Set REF numbers: DO15151NK, DO15251NK, DO15451NK.
- Needle Set Kits are sterile, non-pyrogenic, and in protective packaging.
- BD™ Intraosseous Powered Driver is non-sterile and sold separately.
- 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 with a stylet connected to a drive adapter hub. The drive adapter hub connects to the BD™ Intraosseous Powered Driver. The BD™ Intraosseous Powered Driver is used to insert the needle by penetrating the cortex of the bone to the desired depth. Alternatively, the needle can be inserted manually, by rotating the needle set clockwise and counterclockwise. After the needle is inserted, the user separates the stylet from the needle and needle hub, leaving the needle in the bone. Upon separation of the hub assembly, 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

2 (continued)

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.

The BD™ Intraosseous Needle Set 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

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:** Use only the BD™ Intraosseous Powered 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 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.

Insertion Instructions

Preparation

1. Take barrier precautions.
   CAUTION: Use aseptic techniques.
2. Prepare supplies

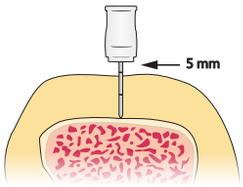
3 (continued)

4 (continued)

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. Attach the BD™ Intraosseous Needle Set to the BD™ Intraosseous Powered Driver.
7. Twist and remove the safety cap.
   Note: The stylet is to remain in the needle during insertion.
   Note: Only handle the needle set by the plastic hub.

Insertion

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



9. Squeeze the trigger and apply moderate, steady pressure to penetrate the bone cortex.
   Note: Important: Do not use excessive force. Use moderate steady downward pressure and allow needle to rotate to penetrate the bone.
   Note: In case of a powered driver failure, the needle may be advanced manually through the bone cortex by rotating the drive adapter hub clockwise and counterclockwise while applying gentle, steady, downward pressure. Do not rock or bend needle during insertion.
10. Advance BD™ Intraosseous Needle Set and release the trigger.
    - Maintain 90° angle.

    Pediatrics: Release trigger when sudden "pop" or "give" is felt, indicating entry into the medullary space.
    Adults: Advance needle set 1-2 cm into medullary space upon entry; for proximal humerus access, advance needle set 2 cm or until needle

5 (continued)

hub is flush with skin.

11. Remove the stylet by pulling straight back with the powered driver.
    Note: The stylet tip safety will automatically attach to the stylet tip as the stylet exits the needle hub.
    Note: If the powered driver separates from the drive adapter hub, or if the needle was inserted manually, remove the stylet by pulling straight back on the drive adapter hub.
    Note: Pull the drive adapter hub (or needle) out from powered driver by hand as needed.
12. Place the drive adapter hub assembly in a sharps container.

Infusion

13. Remove the protective cover and attach the primed extension set to the needle hub.
    Note: Firmly secure the extension set by twisting clockwise.
14. 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.
15. 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.
16. 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.
17. Administer fluids or medications as indicated.
    CAUTION: Monitor insertion site for extravasation.

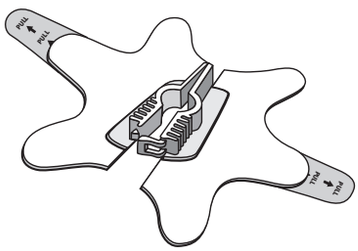
Stabilization

18. Use of the securement dressing is strongly recommended for all BD™ Intraosseous needle set insertions.

6 (continued)

CAUTION: Do not use on breached or compromised skin.

19. Properly clean and dry the insertion area for optimal adhesion.
20. Open the center snap feature of the securement dressing.
21. Snap the feature closed around the needle hub.
22. Attach the adhesive of the securement dressing by pulling the tabs.
23. Press adhesive against the skin for proper stabilization.
    CAUTION: Do not leave needle inserted for more than 24 hours.



Removal

24. 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.
25. 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 regulations.
26. 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.

7 (continued)

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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