

# We are excited to announce the return of the BD® Intraosseous Vascular Access System

The BD® IO System is back, providing you with all the essential details you need about its features and benefits. Our commitment to transparency ensures that our actions reflect our dedication to keeping you well-informed and confident in your choice. Whether you are a new or returning customer, you can trust the reliability and quality of our system.



## Why were the BD® IO device systems recalled?

BD mandated a voluntary recall of our BD® IO device in June 2022.

### What is a “voluntary” product recall?

A “voluntary” recall is voluntarily initiated by the manufacturer of the product versus a recall that is mandated by the Food & Drug Administration (FDA) or another regulatory agency. Recalls are usually conducted voluntarily by the manufacturer to carry out its responsibility to address situations where a product may present an increased risk of patient or caregiver injury or may otherwise be potentially defective.

### Why did BD voluntarily recall this product?

We confirmed that some of our BD® Intraosseous Needle Set Kits, BD® Intraosseous Manual Driver Kits, and BD® Intraosseous Powered Drivers had issues related to adhesive misplacement:

- 1 Difficulty separating the stylet from the needle which may have resulted in functional loss of intraosseous access.
- 2 The needle safety mechanism may not have been deployed.
- 3 The metal disc may have detached from the needle assembly and retained inside the powered driver preventing future needle set connections with the drill from happening per the intended use.



The cause of the issues was related to adhesive misplacement and low adhesive bond forces. The affected lots were distributed between 29 Jan 2020 to 28 April 2022.

**BD made the decision to voluntarily recall the product and address these issues.**

## What did BD improve?

BD implemented corrective action for the issues listed above. Subsequent verification has demonstrated effectiveness in resolving the identified concerns. Note that improvements may not be visible to the end user.

Additionally, BD took advantage of this opportunity to make other continuous (non-critical) improvements to the device and its accessories:

### Extension Set

- Improvements were made to the extension set to help ensure better connection between a syringe and the needleless infusion port.

### Powered Driver

- BD qualified an updated charger cable with design changes that allow for a more reliable connection.



### What quality assurance testing did BD perform?

BD completed verification testing that demonstrated resolution of the issues related to the adhesive misplacement and low adhesive bond force. This has provided assurance that efforts have been sufficiently effective in addressing the failures that led to the recall.

### What has not changed with the BD® IO System?

**There has been no change in the use or intended function of the BD® IO Powered Driver and the BD® IO needle set (including the securement dressing).**

There has been no change to packaging or biocompatibility.

The ergonomically designed BD Powered Driver has a rechargeable Lithium-Ion battery and incorporates a multi-light battery indicator that provides visual indication of battery state of charge.

BD continues to offer a comprehensive selection of 5 needle lengths to accommodate a broad range of patients:

15 mm    25 mm    35 mm    45 mm    55 mm

Additionally, BD® IO needles continue to incorporate a passive safety design that activates automatically as the stylet exits the needle hub.

The BD® IO kits include an extension set with two needleless infusion ports and integrates BD MaxZero™ valve technology at the distal port.

Additionally, the proprietary IO securement dressing included in the BD® IO kits incorporates a patented clamp design that allows the clinician to place it before or after the extension set has been attached.

For more information, please refer to the Instructions for Use (IFU).

### What is the warranty on the BD® IO Drills?

**The BD® Intraosseous Powered Driver warranty covers defects in material and workmanship under normal use for a period of two (2) years\* from the date of delivery by BD to the original purchaser.**

\*Please refer to the Instructions for Use (IFU) for additional warranty information.

### What resources are available?

- > [Brochure](#)
- > [Pocket Guide](#)

#### > [IO Web](#)



#### > [Article](#)



### To learn more, contact your BD territory manager.

Thank you for your trust and support. We are committed to providing you with the best possible products and services. Welcome back to the BD experience!