

June 22, 2022

BD Announces Voluntary Recall on Intraosseous Products

FRANKLIN LAKES, N.J., June 22, 2022 /PRNewswire/ -- BD (Becton, Dickinson and Company), a leading global medical technology company, announced a voluntary recall on the BD™ Intraosseous Needle Set Kits, BD™ Intraosseous Manual Driver Kits and BD™ Intraosseous Powered Drivers.



Certain lots within the expiration date of these intraosseous products may result in the following:

- Difficulty separating the stylet from the intraosseous needle, where increased force required to remove the stylet from the intraosseous needle results in inadvertent removal of the entire needle assembly during placement or inability to remove the stylet from an indwelling intraosseous needle, both resulting in functional loss of intraosseous access.
- Needle safety mechanism on the stylet not deploying post placement of the intraosseous needle and removal of the stylet from the needle.
- Metal discs intended to connect the needle assembly to the magnet in the powered driver sticking unexpectedly to the magnet, rendering the driver unable to be used.

These issues may result in delays in care due to limited or non-functioning intraosseous access or could also lead to needlestick injuries.

Impacted products include:

Product Name	Catalog No.	UDI	Lot No.	Expiration Date	Product Package Size
Needle Kit for PoweredDriver 15mm x 15Ga	D015151NK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Manual Driver NeedleKit 15mm x 15Ga	D015151MK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Needle Kit for PoweredDriver 25mm x 15Ga	D015251NK	See appendix 1	See appendix 1	See appendix 1	1 device per package

Manual Driver NeedleKit 25mm x 15Ga	D015251MK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Needle Kit for Powered Driver 35mm x 15Ga	D015351NK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Manual Driver Needle Kit 35mm x 15Ga	D015351MK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Needle Kit for Powered Driver 45mm x 15Ga	D015451NK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Manual Driver Needle Kit 45mm x 15Ga	D015451MK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Needle Kit for Powered Driver 55mm x 15Ga	D015551NK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Manual Driver Needle Kit 55mm x 15Ga	D015551MK	See appendix 1	See appendix 1	See appendix 1	1 device per package
Intraosseous Powered Driver (drill)	D001001	00801741163579	All	All	1 device per package

Customers should immediately review their inventory for the catalog and lot numbers listed above. Affected needle kits should be destroyed in compliance with the health care institution's process for disposal. The use of affected intraosseous powered drivers should be paused until a BD representative provides instruction that it is safe for use. BD representatives will be reaching out to customers for inspection and will repair the devices if required.

There are no replacement products currently. BD recommends that customers evaluate their clinical needs and consider obtaining and using an alternative intraosseous product. BD will notify customers when replacement products become available.

Full customer and distributor letters can be found on the [recall notification section of BD.com](#).

BD remains fully committed to ensuring patient and user safety. Customers requiring additional assistance or guidance may contact a service representative at 1-844-823-5433 Monday through Friday between 8 a.m. and 5 p.m. Central Time by saying "Recall" when prompted or via email at productcomplaints@bd.com.

Any adverse health consequences experienced with the use of these products should be reported immediately. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program via:

Web: MedWatch website at www.fda.gov/medwatch

Phone: 1-800-FDA-1088 (1-800-332-1088)

Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

Appendix 1

Catalog Number	Lot / Serial Number	UDI (GTIN, DI + PI), if applicable	Date of Manufacture	Expiration Date
D015151NK	121460	801741163586	09/10/2019	09/10/2022
D015251NK	121496	801741163678	09/13/2019	09/13/2022
D015451NK	121593	801741163609	09/26/2019	09/26/2022
D015251NK	122096	801741163678	12/06/2019	01/01/2023
D015151NK	122145	801741163586	12/11/2019	01/01/2023

D015451NK	122169	801741163609	12/17/2019	01/01/2023
D015251MK	122193	801741163630	12/30/2019	01/02/2023
D015151MK	122359	801741163623	01/21/2020	01/21/2023
D015451MK	122375	801741163654	01/22/2020	01/22/2023
D015451NK	123305	801741163609	05/18/2020	05/18/2023
D015251NK	123306	801741163678	05/18/2020	05/18/2023
D015151NK	123307	801741163586	05/18/2020	05/18/2023
D015451MK	123433	801741163654	06/02/2020	06/02/2023
D015451NK	125016	801741163609	12/07/2020	12/07/2023
D015151NK	125298	801741163586	01/22/2021	01/22/2024
D015251NK	125299	801741163678	01/22/2021	01/22/2024
D015451NK	125517	801741163609	02/09/2021	02/09/2024
D015251NK	125533	801741163678	02/10/2021	02/10/2024
D015151NK	125534	801741163586	02/10/2021	02/10/2024
D015251NK	125535	801741163678	02/10/2021	02/10/2024
D015151NK	125662	801741163586	02/25/2021	02/25/2024
D015351NK	125721	801741163593	03/02/2021	03/30/2024
D015451NK	125770	801741163609	03/05/2021	03/05/2024
D015551NK	125841	801741163616	03/10/2021	03/10/2024
D015351MK	125842	801741163647	03/10/2021	03/10/2024
D015551MK	125843	801741163661	03/10/2021	03/10/2024
D015451NK	125977	801741163609	03/22/2021	03/22/2024
D015251NK	126075	801741163678	03/30/2021	03/30/2024
D015151NK	126095	801741163586	04/05/2021	04/08/2024
D015251NK	126149	801741163678	04/06/2021	04/06/2024
D015251NK	126178	801741163678	04/12/2021	04/12/2024
D015451NK	126299	801741163609	04/20/2021	04/20/2024
D015451NK	126300	801741163609	04/20/2021	04/20/2024
D015451NK	126340	801741163609	04/27/2021	04/27/2024
D015151NK	126467	801741163586	05/10/2021	05/10/2024
D015251NK	126569	801741163678	05/17/2021	05/17/2024
D015451NK	126575	801741163609	05/17/2021	05/17/2024
D015151NK	126677	801741163586	05/25/2021	05/25/2024
D015251NK	126686	801741163678	05/26/2021	05/26/2024
D015551MK	126834	801741163661	06/07/2021	06/07/2024
D015351NK	126901	801741163593	06/11/2021	06/11/2024
D015351NK	126939	801741163593	06/16/2021	06/16/2024
D015551NK	126951	801741163616	06/17/2021	06/17/2024
D015551NK	127003	801741163616	06/22/2021	06/22/2024
D015151NK	127040	801741163586	06/24/2021	06/24/2024
D015451NK	127092	801741163609	06/28/2021	06/28/2024
D015251NK	127118	801741163678	07/01/2021	07/01/2024
D015451NK	127119	801741163609	07/01/2021	07/01/2024
D015251NK	127170	801741163678	07/07/2021	07/07/2024
D015451NK	127300	801741163609	07/22/2021	07/22/2024
D015251NK	127417	801741163678	08/04/2021	08/04/2024
D015551NK	127496	801741163616	08/11/2021	08/11/2024
D015451NK	127516	801741163609	08/12/2021	08/12/2024
D015151NK	127711	801741163586	08/27/2021	08/27/2024

D015251NK	127756	801741163678	09/01/2021	09/01/2024
D015451NK	127808	801741163609	09/07/2021	09/07/2024
D015251NK	128001	801741163678	09/21/2021	09/21/2024
D015151NK	128002	801741163586	09/21/2021	09/21/2024
D015451NK	128120	801741163609	10/01/2021	10/01/2024
D015151NK	128208	801741163586	10/12/2021	10/12/2024
D015351NK	128385	801741163593	10/27/2021	10/27/2024
D015251NK	128482	801741163678	11/03/2021	11/03/2024
D015451NK	128487	801741163609	11/03/2021	11/03/2024
D015551NK	128724	801741163616	12/01/2021	12/01/2024
D015451NK	128725	801741163609	12/01/2021	12/01/2024
D015151NK	128778	801741163586	12/06/2021	12/06/2024
D015251NK	128829	801741163678	12/07/2021	12/07/2024

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 75,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit [bd.com](https://www.bd.com) or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter [@BDandCo](https://twitter.com/BDandCo).

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