1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

9th December 2020

URGENT: FIELD SAFETY NOTICE – MDS-20-3902

BD Regional Block Needle

REF: 408348

Type of Action: Advisory

Attention: Clinical Engineering Managers, Clinical Personnel, Risk Managers

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this Field Safety Notice for the **BD Regional Block Needle (REF: 408348)**. Our distribution records indicate that your organisation may have received impacted lot numbers below.

Table 1: List of impacted products

REF	Product Description	Lot Numbers
408348	BD Regional Block Needle	0127675; 9239506 5212781; 5275995 6154672; 6221838 6245502; 8108630 8240630; 8282987

Description of the Problem

BD has identified that the Instructions for Use that were shipped with the BD Regional Block Needle (REF: 408348) were missing the appropriate contraindications.

This Field Safety Notice is providing the contraindications and BD recommends they be applied when using the product.

These needles should not be used if there is:

- *infection at the intended site of entrance*
- *allergy to the intended anesthetic agent*
- *evidence of a severe coagulation disorder*
- *sepsis*
- *abnormal anatomy that would preclude successful placement of the needle*
- *the patient is uncooperative or unable to be positioned adequately*

Currently the contraindications state, "*The risks associated with the use of this device may be increased due to patient physiological characteristics and clinical needs*."

No changes have been made to the product nor has BD received any complaints regarding these contraindications over the last 5 years.

The clinicians involved in the use of this product are trained anesthesia clinicians. Prior to use of needles, these contraindications would be assessed as part of standard clinical practice. Nonetheless, the health consequences associated with a clinician not assessing the contraindications above prior to use of the needles are potentially

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life threatening. The harms include sepsis, anaphylactic reaction, complications due to severe coagulation disorder and infection and/or injury at the needle site.

Advice on actions to be taken by the user

1. Ensure the contents of this Field Safety Notice including the contraindications are read and understood by those within your organisation who may use the BD Regional Block Needles (REF: 408348).
    - If you have further distributed the product to other organisations, please identify those organisations and notify them at once of this Field Action.

2. Please complete the Customer Response form (Page 3) and return the completed form to BDUKFieldAction@bd.com no later than **January 15th, 2021**.

3. If you are no longer in possession of or no longer use the instruments listed in Appendix 1, please indicate this on the response form and return to BD so we may update our records.

Discontinuation of BD Regional Block Needle (REF: 408348)

Due to increasing costs required to maintain supply, we are no longer able to accept any orders for this product as we have ceased production and distribution, with immediate effect. Due to the specialized nature of this needle, we are unable to offer or recommend any viable BD alternative products. We regret any inconvenience this may cause.

Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact BDUKFieldAction@bd.com. We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Yours sincerely,

William David
Senior Director Quality Compliance EMEA

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Customer Response Form – MDS-20-3902

BD Regional Block Needle

Please read in conjunction with Field Safety Notice MDS-20-3902 and return the completed and signed form as soon as possible or **no later than January 15th, 2021** to BDUKFieldAction@bd.com.

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

Name of Trust *(if applicable)*			
Name of all Facilities / Hospitals covered by this response *(e.g. other hospitals within your Trust)*			
Facility / Hospital address			
Postcode			
Telephone number		**E-mail address**	
Name of your supplier / wholesaler (if not BD)			
Your Name			
Signature		**Date**	

Please return your completed and signed Customer Response Form to: BDUKFieldAction@bd.com.

This form must be returned to BD before this action can be considered closed for your account.