

4th May 2021

URGENT: FIELD SAFETY NOTICE – MDS-21-4027

Groshong Catheter Products

REF & Lot Numbers: See Appendix 1

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is issuing an advisory Field Safety Notice for specific lots of Groshong Catheter products, as listed in Appendix 1 and according to our distribution records your organisation may have received the impacted product.

Description of the Problem

Based on customer feedback, BD has identified two issues with the Groshong connector portion (Figure 1) that impacts the product identified in Appendix 1:

Figure 1: Connector Portion- Proximal and Distal section connected



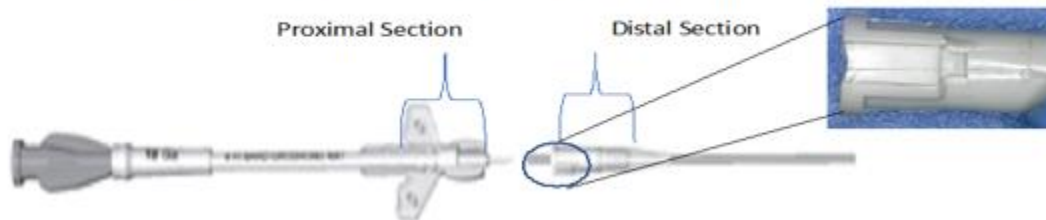
1. The inner diameter of the distal connector may be reduced resulting in the inability to pass the catheter through the connector (Figure 2).

Figure 2: Distal Connector section – catheter insertion into distal connector



2. The catch slot on the distal connector may be deformed resulting in the inability for the distal connector to properly lock onto the associated proximal connector section (Figure 3).

Figure 3: Distal and proximal section – Deformed catch slot



The complaint rate for this issue is 0.178%.

Clinical Impact

The health consequences associated with the use of a defective connector include the potential for delays in treatment, device leakage, catheter separation leading to infection and embolization requiring medical intervention.

BD has not identified any reports of serious adverse events to date that could be associated with this Field Safety Corrective Action. No specific patient follow-up activities are required if the product has already been used.

Advice for Clinical Users

As a result of this feedback and to mitigate the occurrence of the lack of locking sensation, BD is recommending:

1. For new placements, follow the current instructions for use that accompanies the product and that states:

“A tactile, locking sensation will confirm that the two pieces are properly engaged.”

Following these instructions will provide mitigation as the lack of the locking sensation will signal the clinician to obtain a replacement device.

2. If the clinician encounters the issues described in this notification, a Replacement Connector must be used.
 - a. Replacement connector kit will be provided by BD free of charge.
 - b. If the Replacement Connector is not available at your facility, then obtain the connector from a new 4Fr S/L Groshong nXt catheter kit.

Actions by BD:

1. Upon receipt of the customer notification form (page 3), BD will supply one case (containing 10 units) of the Replacement Connector (REF# 7812400CE) free of charge.

This kit will provide the same connector device for the Groshong products listed in Appendix 1 that demonstrates the issues described in this notification



Actions for Customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the Groshong Catheter devices listed in Appendix 1.
2. If you have further distributed the product, please identify those users and notify them at once of this Field Safety Notice.
3. Complete the customer response form on page 4 and return it to bdukfieldaction@bd.com **as soon as possible or no later than 22nd June 2021**. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

There is no requirement for customers to return any Groshong Catheter devices to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on +44 (0)1293 606643 or e-mail bdukfieldaction@bd.com

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Darrock'.

Lorna Darrock
Sr. Manager, Post Market Quality
EMEA Post Market Quality



Customer Response Form – MDS-21-4027

Groshong Catheter Products

REF & Lot Numbers: See Appendix 1

Please read in conjunction with Field Safety Notice MDS-21-4027 and return the completed and signed form as soon as possible or **no later than the 22nd June 2021** to bdukfieldaction@bd.com

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

If different from above, please provide a contact name of a representative from your organisation who will be the point of contact for BD to ship replacement connectors to, *free of charge*:

Name:	Tel No.:	E-mail:
Delivery Address:		

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



Appendix 1 – Impacted Product Codes / Lot numbers

Product Name	Product REF	Lot Number
PICC Catheter Groshong NXT Clearvue Single Lumen	7617405CE	REDV2537 REDV4016 REDW0837 REDW4033 REDW4035 REDW4170 REDX1340 REDZ0185 REDZ0697 REEN1982
Catheter Groshong PICC ClearVue IV 4fr with Microintroducer	7655405CE	REDT1760 REDT2909 REDU0080 REDU2186 REDU2403 REDU3073 REDU3829 REDV1285 REDV2022 REDV2095 REDV2812 REDV4092 REDW0460 REDW1019 REDW2592 REDX0982 REDX0986 REDX1002 REDY0095 REDZ0433 REDZ3691 REDZ3692 REEN1971 REEN4660 REEN4733 REEN5319 REEQ2384 REEQ2508 REEQ2519
4F Single Lumen Groshong NXT ClearVue PICC with Sherlock TLS Stylet, Bedside Kit	CK000379	REDV1069 REDV3463 REDX1384 REEP4143 REEQ1238
4F Single Lumen Groshong NXT ClearVue PICC with Sherlock TLS Stylet, basic tray	69655405	REDX4687 REES1313



Appendix 1 – Impacted Product Codes / Lot numbers Cont.

Product Name	Product REF	Lot Number
Groshong NXT Clearvue Catheter with Sherlock 4F Single Lumen	CK000516	REDX1385 REDX4726 REDY0824 REDY1206 REDZ3509 REEN4546 REEP4145 REER0944 REER2048 REES1328 REES2108 REES3222 REEU1443 REEU2740 REEU3561 REEW4312
Replacement Connector For 4 Fr. Groshong NXT ClearVue* PICC With Extension Leg	7812400CE	REDU3402 REDU4194 REDU4226 REDV2001 REDV2750 REDX3828 REDY2874 REDY3867 REDZ1927 REDZ3505 REEN1396 REEQ1509 REET2730 REET3239 REEU0563 REEX3092 REEX3917 REEY2704
4F Single Lumen Groshong NXT ClearVue PICC with Sherlock TLS Stylet and Sherlock TPS Stylet, basic tray	91660417	REDV2901 REDX0702 REDX1450 REDX2338 REDX4128 REEP0823 REEQ3588 REER3480 REES1246 REES2299 REEW1849 REEW4279 REEX0353 REEX3469