B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
e-mail:
productcomplaints.ie@bbraun.com
http://www.bbraun.com

Date:
February 03, 2021

Ref: FSN 2020-09-21 AS;STK

FIELD SAFETY NOTICE – Redyrob® Trans Plus

To whom it may concern,

B. Braun Melsungen AG would like to inform you that they have updated the Instructions for Use for

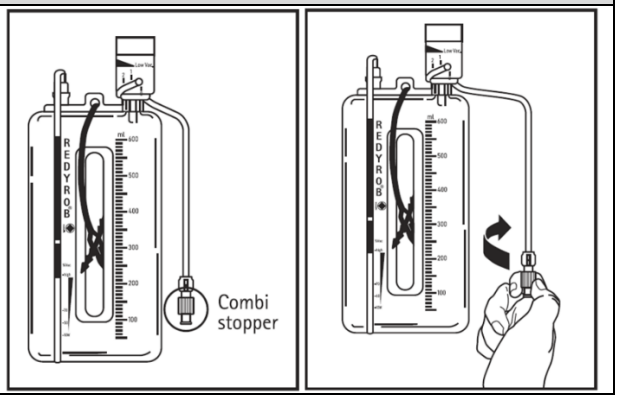
Article	Material number
Redyrob® Transplus Closed Wounddr. System	5526604

This Field Safety Notice serves only for your information.

Reason for the Field Safety Notice
By detailed evaluation of our post-market surveillance activities it has been identified that an update of the instructions for use is necessary in order to highlight the need for the removal of the red combi stopper before using the device.

The combi stopper is a component closing the tube and ensuring the vacuum tightness of the product, when the vacuum regulator is not in zero position. If not removed before usage, it prevents flow of wound secretion and therefore posing the risk for a delayed therapy.

In order to inform customers of the correct handling the Instructions for Use were updated. The updated version contains the respective instruction in writing and as picture, to ensure an adequate description.

Text	Picture
2. Remove the red combi stopper or secretion bag from Luer Lock of the Redyrob Comp. **CAUTION: Do not connect anything to the red combi stopper! The combi stopper prevents wound secretion flow.**	

The updated IfU is included in the above referenced products since 2019-11.

The IfU is provided as ANNEX1 (Redyrob® Transplus Closed Wounddr. System).

Actions to be taken by the customer:

Our records have shown that your institution has received some of the concerned products.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organisation and other concerned persons are informed about this notification. If you are a distributor, please forward this notification to your customers.
- Confirm receipt of this information.
- The Competent Authority, HPRA, has received a copy of this safety information.

If more information is needed, please contact:

Rob Egan
Business Unit Manager
Medical Technologies Division
Tel: +353 86 2606917

Declan Burke
Sales Consultant
Safe Infusion Therapy & Pain Control
Tel: +353 86 2529912

Enclosed you will find an acknowledgement of receipt. We would please request that you sign and send this back to us (email: productcomplaints.ie@bbraun.com or fax no. +353 1 7091 889) to confirm that you have received this notice.
*Please return the completed form by **Friday 12th February 2021**, or sooner if possible.*

Kindly accept our apologies for any inconveniences.

Yours sincerely,

Robert Egan
Business Unit Manager

Roberta Egan
Regulatory Affairs Manager

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February 03, 2021

Field Safety Notice CONFIRMATION FORM

Article	Material number
Redyrob® Transplus Closed Wounddr. System	5526604

Please complete this form and return by email or fax to:
Email: productcomplaints.ie@bbraun.com
or
Fax No. +353 1 7091 889

We hereby confirm that we are aware of the Field Safety Notice from February 03, 2021 concerning the IfU update of Redyrob® Transplus Closed Wounddr. System

Hospital / Organisation:	
Address:	
Contact Name:	
Position / Department:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	