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

TO WHOM IT MAY CONCERN

Date:
March 22, 2022

Ref: FSCA 2022/03/10 KJ/CC

Urgent FIELD SAFETY NOTICE – SIMPSON SHELF PESSARY

Dear Sir/Madam,

B. Braun Medical Limited UK has decided to proactively recall the below batches of Simpson Shelf Pessary in the form of a Field Safety Corrective Action (FSCA) from the market:

Product Code	Product Description	Batch Numbers
FG-895-04-M	SIMPSON SHELF PESSARY NO.5 54MM	10496
FG-895-08-V	SIMPSON SHELF PESSARY NO.9 67MM	10401 10500
FG-895-09-X	SIMPSON SHELF PESSARY NO.10 70MM	10501
FG-895-11-J	SIMPSON SHELF PESSARY NO.12 76MM	10452
FG-895-12-L	SIMPSON SHELF PESSARY NO.13 79MM	10426 10504 10555
FG-895-14-Q	SIMPSON SHELF PESSARY NO.15 86MM	10455 10471
FG-895-15-S	SIMPSON SHELF PESSARY NO.16 89MM	10507
FG-895-16-U	SIMPSON SHELF PESSARY NO.17 92MM	10457
FG-895-18-Y	SIMPSON SHELF PESSARY NO.19 98MM	10491
FG-895-19-Z	SIMPSON SHELF PESSARY NO.20 101MM	10458 10490

Reason for the Recall

B. Braun Medical Limited, UK, has identified that the labelling for specific batches of the above-mentioned products is missing the CE mark.

This labelling defect has no effect on device safety but means the marketed device is not in regulatory compliance. Based on the identified issue, we have decided to proactively recall all affected batches of the devices from the market. No additional follow-up activities are required for patients already treated with the devices.

This FSCA is limited to the batches mentioned above. The defect is due to a deviation during production. Corrective action has been implemented in March 2022.

Actions to be taken

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 Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected products.
- Do not use identified affected devices.
- Confirm receipt of this information by completing and signing the attached Confirmation Form and return this to B. Braun using the contact details provided.

*Please return the completed form by **Friday 25th March 2022**, or sooner if possible.*
A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose a copy of the Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority (HPRA) has been informed of this action.

If more information is needed, please contact salessupport.ie@bbraun.com.

We appreciate your immediate attention and apologise for any inconvenience this may cause.

Yours sincerely,

Uwe Steinau
AESCULAP Commercial Manager

Roberta Egan
Regulatory Affairs Manager

March 22, 2022

Field Safety Corrective Action CONFIRMATION FORM
FSCA 2022/03/10 KJ/CC
Simpson Shelf Pessaries

Please complete this form and return by e-mail to
productcomplaints.ie@bbraun.com

☐ We have received the Field Safety Notice and confirm that we have no remaining products in stock.

☐ We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:

Product Code	Batch	Quantity to be Returned

☐ We have not shipped any products affected by this Field Safety Notice to third parties.

☐ We have notified our customers who are affected by this recall notice, and we will contact our customers to arrange collection of any affected products for onward return to B. Braun Medical Limited.

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