Bonree Medical Co., Ltd.
Add: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451,
Zhongshan, Guangdong, China.
Tel: +86 760 8520 7588 Fax: +86 760 8520 7568
Http: //www.bonreemed.com

To our customers of the suction catheter

2023, September 26

Field Safety Notice

Dear customer,
You are receiving this letter because our records indicate that you are using GenCath Suction Catheter that is subject to the Field Safety Notice and your organisation have received the impacted product in **table 1.**

Device Group Name	Lot Number	REF	Description	Manufacturer
Suction catheter	230418	GXM-786OSCC06	1. Suction catheter 06FR	Bonree Medical Co.,Ltd
		GXM-786OSCC08	2. Suction catheter 08FR	
		GXM-786OSCC10	3. Suction catheter 10FR	
		GXM-786OSCC12	4. Suction catheter 12FR	

Table 1: Impacted product

(This advisory is limited to the product code /lot numbers listed in Table 1.)

What is the reason for this Field Safety Notice?

The length mark on the product is an integral part of the product, and we have taken action to improve the accuracy of the length mark used.

Description of the issue

Since the product shrinks after extrusion during production, this can lead to incorrect marking on the product. Therefore, the length of the suction tube is different from that indicated on the product, and the "centimeter" mark on each tube is located at a different location on each tube, which will cause the user to enter too far or not enough during the suction process.

Immediate actions required for customer

1) It is recommended that you are aware of the potential inaccuracies of the product and conduct the necessary risk assessment of the product before using it.
2) Due to the potential inaccuracy of this product length marking, users should not rely solely on the length marking for clinical care.

3) If the user does not wish to continue using these products, they can quarantine and return the affected products.
4) Please confirm receipt of the Customer Feedback Form in the attachment A

Some suggestions for distributor

1.If the customer requests to return the product, the distributor should always pay attention to the recycling, disposal, etc., of the equipment
2.Requires that filed safety notices be communicated to all persons within the organization who need to be aware of field safety notices and remain aware for an appropriate prescribed period of time.
3.Request that the manufacturer be provided with details of any affected devices that have been transferred to other organizations and that a copy of the field safety notice be provided to the organization to which the device has been transferred.

Potential Harm:

If the suction catheter is longer than indicated by the markings this may cause unintended contact with the patients airway and overtime this can lead to granuloma.

Bonree Action:

As a manufacturer, We will actively cooperate with customers to rectify the problem of printing scale tolerance. We will control the tube drawing process, reduce the tube drawing speed, and try to control the printing tolerance within ±5mm.
We appreciate your time and attention in reading this important notification. If you have further questions or need assistance, please contact Bonree Customer support: info@bonreemed.com/he@bonreemed.com.

Sincerely,

Bonree Quality Team

BONREE MEDICAL CO., LTD. 中山博睿医疗器械有限公司

See Appendix A for more details on Bonree Medical Co., Ltd and Customer Feedback Form

Annex A

Feedback to Bonreemed.com
To the safety information, safety information 230418 Suction catheter 06fr, Suction catheter 08fr, Suction catheter 10fr, Suction catheter 12fr.
Please fill the form:

Bonree Medical Co., Ltd.
Add: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451,
Zhongshan, Guangdong, China.
Tel: +86 760 8520 7588 Fax: +86 760 8520 7568
Http: //www.bonreemed.com

Customer Feedback Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	BR230418
FSN Date*	2023.06.08
Product/ Device name*	Suction catheter
Product size(s)	06FR,08FR,10FR,12FR
Batch/Serial Number (s)	230418

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		

Bonree Medical Co., Ltd.
Add: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong, China.
Tel: +86 760 8520 7588 Fax: +86 760 8520 7568
Http: //www.bonreemed.com

☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	info@bonreemed.com/he@bonreemed.com.
Customer Helpline	+86 760 8520 7588
Postal Address	No.4 Long zhu Garden, Wan mu Industrial Estate, Nanlang 528451Zhongshan, Guangdong, China
Web Portal	www.bonreemed.com
Fax	+86 760 8520 7568

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.