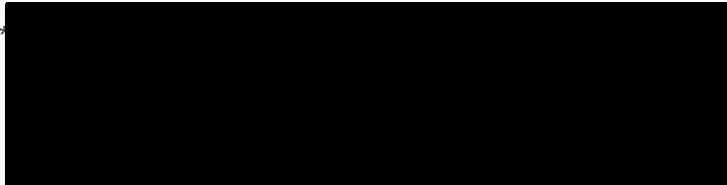


Date: 10 January 2019

Urgent Field Safety Notice
NSE PTA Balloon Catheter GDM01

For Attention of



B. Braun Medical Inc.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Name: David L. Mackie

E-mail: dmackie@GoodmanMedical.ie

Tel: + 353-91-783335

Address: Goodman Medical Ireland Limited.

Mervue Business Park, Galway, H91 H9CK Ireland.

Urgent Field Safety Notice (FSN)
NSE PTA Balloon Catheter GDM01
Risk addressed by FSN

Brief description of the device(s) in plain language, including whether supplied sterile. Consider including a photo (here or in an Annex) where this would help with identification

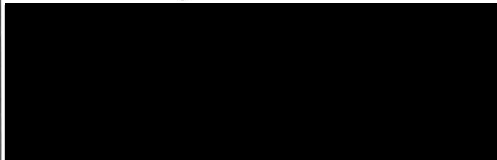

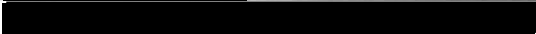
1. Information on Affected Devices*									
1	1. Device Type(s)*								
.	The product is an RX/OTW PTA balloon catheter used for the purpose of dilatation of stenotic lesions during percutaneous transluminal angioplasty. The balloon expands to the specific OD and length at nominal pressure and has three elements on the outside of balloon in order to dilate stenosis that is traditionally considered difficult to expand. This product has a hydrophilic coating applied to the surface.								
1	2. Commercial name(s)								
.	NSE PTA Balloon Catheter GDM01								
1	3. Unique Device Identifier(s) (UDI-DI)								
.	Complete when this becomes available.								
1	4. Primary clinical purpose of device(s)*								
.	This device is used for percutaneous dilatation of a stenotic lesion or post-dilatation of stent in percutaneous transluminal angioplasty(PTA) whereby it is considered that dilatation of a conventional balloon would result in inadequate lesion expansion within an artery, vein or shunt (excluding coronary and intracranial vessels including carotid arteries)								
1	5. Device Model/Catalogue/part number(s)*								
.	<table border="1"> <thead> <tr> <th>Product No.:</th><th>Lot No. and their quantity:</th></tr> </thead> <tbody> <tr> <td>NW18-09050040</td><td>NVHW180528A (5)</td></tr> <tr> <td>NW18-09060040</td><td>NVHW180612B (5)</td></tr> <tr> <td>NW18-14550040</td><td>NVHW180605A (5)</td></tr> </tbody> </table> <ul style="list-style-type: none"> • Total : 15units • shipped in : 9th October 2018 	Product No.:	Lot No. and their quantity:	NW18-09050040	NVHW180528A (5)	NW18-09060040	NVHW180612B (5)	NW18-14550040	NVHW180605A (5)
Product No.:	Lot No. and their quantity:								
NW18-09050040	NVHW180528A (5)								
NW18-09060040	NVHW180612B (5)								
NW18-14550040	NVHW180605A (5)								
1	6. Software version								
.	not applicable								
1	7. Affected serial or lot number range								
.	Same as 5.Device Model/Catalogue/part number(s)*								
1	8. Associated devices								
.	none								

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	A total of 13 reports from the field in Japan where there has been breakage of the element during withdrawal of the catheter at the end of the procedure. There were no cases of patient injury and in all incidents the entire catheter, including the broken element, was successfully removed from the patient .
2	2. Hazard giving rise to the FSCA*

.	In the case of a breakage where the element remains attached to the catheter, the catheter and the broken element can be safely removed from the patient. However, in the case of the element becoming fully detached, the element could be left in the body after removal of the catheter.
2	3. Probability of problem arising
.	All incidents and all testing to date have shown breakage but no complete detachment of the element. Therefore the risk of a complete detachment is considered negligible
2	4. Predicted risk to patient/users
.	If the element detached completely and remained in the body, the worst case would be the need for surgical removal of the element. However as a peripheral use device, risk is minimal
2	5. Further information to help characterise the problem
.	none
2	6. Background on Issue
.	Investigation has confirmed that the root cause of this failure mode is that the manufacture (extrusion) of the raw material used in the elements has left a residual stress within the material which results in a weakness of the element in the final product.
2	7. Other information relevant to FSCA
.	none

3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified.
3.	2. By when should the action be completed? By end January 2019
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required
3.	4. Is customer Reply Required? * No (If yes, form attached specifying deadline for return)

3.	5. Action Being Taken by the Manufacturer <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input type="checkbox"/> Other </div> <div> <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> None </div> </div> Provide further details of the action(s) identified.		
3	6. By when should the action be completed?	By end January 2019	
3.	7. Is the FSN required to be communicated to the patient /lay user?	No	
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? No Choose an item.		

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	none
4.	3. For Updated FSN, key new information as follows:	
	None	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	None	
4	6. Anticipated timescale for follow-up FSN	None
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Goodman Co.,Ltd
	b. Address	5F KDX Nagoya Sakae Building5-3-5 Chome. Sakae. Nagoya-shi Aichi Japan
	c. Website address	https://www.goodmankk.com/english/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes.	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	
		 

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.