COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2023FA0009

Date: 03 November 2023

Urgent Field Safety Notice
Product Removal: Quantum TTC Biliary Balloon Dilator

For Attention of: **Chief Executive / Risk Management / Purchasing / Recall Coordinator**

Contact details of local representative (name, e-mail, telephone, address etc.)*
Cook Medical Europe Ltd. O'Halloran Road National Technology Park Limerick, Ireland E-mail: European.FieldAction@CookMedical.com Phone: Please refer to the attached Country Contacts List For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.

COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2023FA0009

Urgent Field Safety Notice (FSN)
Quantum TTC® Biliary Balloon Dilator
Risk addressed by FSN

1. **Information on Affected Devices**	
1.	1. Device Type(s)
	Quantum TTC Biliary Balloon Dilators are intended to be used to dilate strictures of the biliary tree.
1.	2. Commercial name(s)
	Quantum TTC Biliary Balloon Dilator
1.	3. Unique Device Identifier(s) (UDI-DI)
	00827002227675 10827002227672 00827002226579 10827002226576 00827002226548 10827002226545 00827002227651 10827002227658 00827002226555 10827002226552 00827002227668 10827002227665 00827002226562 10827002226569
1.	4. Primary clinical purpose of device(s)
	The intended use for Quantum TTC Biliary Balloon Dilator is to dilate strictures of the biliary tree.
1.	5. Device Model/Catalogue/part number(s)
	QBD-10X3, QBD-10X3-E, QBD-4X3, QBD-6X3, QBD-6X3-E, QBD-8X3, QBD-8X3-E
1.	6. Affected serial or lot number range
	See Attached Affected Lots List

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	Cook Endoscopy/Wilson-Cook Medical, Inc. is initiating a voluntary removal of affected QBD devices from the market because they are nonconforming. They are manufactured correctly, but do not comply the design requirements. Although only 2 incidents have occurred, the likelihood of further incidents is probable to frequent, and Cook is taking a proactive approach to remove the devices from the field and stop production until a root cause and corrective action is found.

COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2023FA0009

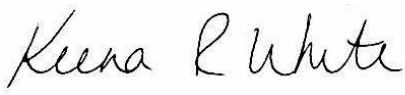
2.	2. Hazard giving rise to the FSCA
	If the balloon fails to fully inflate, will not hold inflation, or leaks, the device could be replaced with an insignificant delay in procedure. In that situation, the potential for injury is unlikely. However, the worst-case scenario if balloon leaks during sphincteroplasty is pancreatitis, and if the balloon detaches in the patient, it could potentially result in bleeding from device retrieval.
2.	3. Probability of problem arising
	There have been two (2) complaints received worldwide associated with the devices and these associated failures. This is 0.0410% of the affected devices.
2.	4. Predicted risk to patient/users
	The worst-case risk identified is moderate. The following are the potential health consequences: If the balloon detaches from the catheter, it can lead to a foreign object in the patient. The potential harms associated with balloon detachment are endoscopic retrieval of an impacted or non-impacted object, bleeding caused by the retrieval device, or the incident can occur without injury and the object is left to pass naturally. If the balloon is being used for sphincteroplasty, leakage of fluid from the inflated balloon at the papilla may occur which can lead to pancreatitis. Leakage during use for sphincteroplasty can also occur without incident to the patient, resulting in the device being replaced and an insignificant delay in the procedure. Other events of the balloon failing to inflate or balloon leakage during non-sphincteroplasty will most likely result without incident to the patient, resulting in the device being replaced and an insignificant delay in the procedure.
2.	5. Background on Issue
	It has been determined that nonconforming Quantum TTC Biliary Balloon Dilators (QBD) were distributed. A sampling of device manufactured after April 2023 identified the devices were not able to inflate to the clinical working pressure without leakage. The failures were across all QBD sizes. EU MDR 2017/745 defines a field safety corrective action as a corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident. This field action is a removal of devices to reduce the risk of a serious incident. Since the affected devices were distributed in the EU, this is considered an FSCA in the affected EU member states.

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device Please complete the enclosed Customer Reply Form. Since devices are to be returned, our Customer Services department will contact you to organize the return and issue the relevant Returns Authorization number. **Please include contact details on the Customer Reply Form so they can contact you.** Returned Devices should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler, Germany Credit will be provided for the returned affected devices where applicable.

COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2023FA0009

3.	2. By when should the action be completed?	Within five (5) business days of receipt.
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes, within five (5) business days of receipt.
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal	
3	5. By when should the action be completed?	Within five (5) business days of receipt.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Cook Endoscopy/Wilson-Cook Medical, Inc.
	b. Address	4900 Bethania Station Road, Winston-Salem, NC USA
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	**Country Contact List, Affected Lot List**
4.	6. Name/Signature	 Keena White Regulatory Reporting Specialist

	Transmission of this Field Safety Notice
	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. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.

COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2023FA0009
FSN Date	03 November 2023
Product/ Device name	Quantum TTC Biliary Balloon Dilator
Product Code(s)	QBD-10X3 QBD-10X3-E QBD-4X3 QBD-6X3 QBD-6X3-E QBD-8X3 QBD-8X3-E
Batch/Serial Number (s)	See attached Affected Lot Numbers List

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
Please mark boxes below to indicate actions have been completed. If action is not applicable, please enter N/A.

☐	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*
☐	I have affected devices to return - enter Lot number and quantities in table below.	*Customer to complete or enter N/A*
☐	No affected devices are available for return.	*Customer to complete or enter N/A*

Print Name	
Signature	
Date	

COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt, even if you do not have any of the affected product(s).
Customer Helpline	Please refer to the attached Country Contacts List

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

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.