Date: November 09, 2022

Urgent Field Safety Notice
Button Cannula, Button (A), 1.2mm

For the attention of*: German Competent Authority and Spanish Competent Authority,
Distributor: MediTip-Medical MTM GmbH, Health Center:**?**

Contact details of local representative (name, e-mail, telephone, address etc.)*
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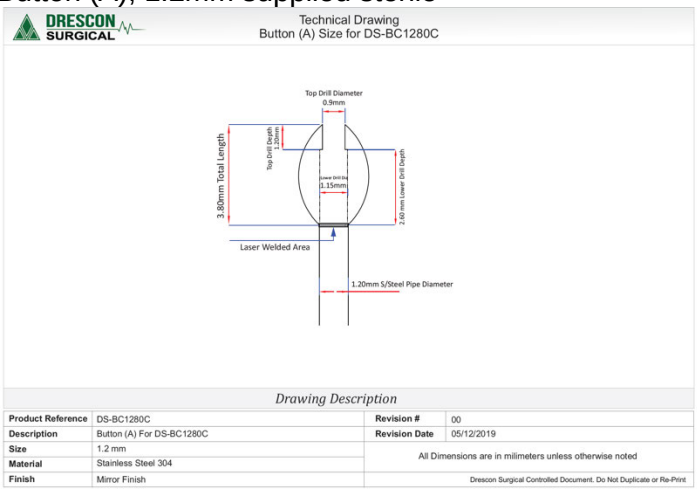
DESCON SURGICAL		DRESCON SURGICAL
FSN Ref: FSN/DS/01	FSCA Ref: CAPA2212/22	Rev.1, June 01, 2022

Urgent Field Safety Notice (FSN)
Button Cannula, Button (A), 1.2mm
Risk Addressed by FSN

1. Information on Affected Devices*	
1.	**1. Device Type(s)***
	Button Cannula, Button (A), 1.2mm supplied sterile



1.	**2. Commercial name (s)**
	Button Cannula, Button (A), 1.2mm
1.	**3. Unique Device Identifier(s) (UDI-DI)**
	Not assigned
1.	**4. Primary Clinical purpose of device (s)***
	These cannulas are used for suction and rinsing out fluids or other wastes from the body during surgical procedure.
1.	**5. Device Model/Catalogue/part number(s)***
	MT-BC1280C
1.	**6. Software version**
	Not Applicable
1.	**7. Affected serial or lot number range**
	Lot: BC12260222
1.	**8. Associated Devices**
	Not Applicable

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	The button of the button cannula separated from the shaft and went inside patient unnoticed. There was no biological impact on patient and the attendant was with the patient. Everything left as it is since there was no biological impact and implant report was filled by the hospital staff.

2.	**2. Hazard giving rise to the FSCA***
	Currently there is No product in stock with the distributor and any Health Center. So there is No risk for user or patient.
2.	**3. Probability of problem arising**
	Problem was only with one device out of 320 pieces. In the past there was no history of this type of problem. Being a responsible company, we have taken appropriate action to improve the manufacturing technique. This problem will not reoccur.
2.	**4. Predicted risk to patient/users**
	There is no possibility of button of cannula separation because it's now welded with laser technology however incase if the button is separated the Predicted risk to patient is that the patients with a steel foreign body in the brain can no longer have an MRI. To remove that, the patient should be anesthetized and operated once again. That in turn would mean that by re-opening the scalp, which has been operated on several times, to a small percentage.
2.	**5. Further information to help characterize the problem**
	None
2.	**6. Background on issue**
	Drescon Surgical become aware about the button separation from Cannula through Distributor in Germany and also through EUAR "CMC Medical Devices and Drugs SL". The problem was occurred during the use of the Button Cannula i.e the button part separated and fell inside the patient body. This is a standalone incident that button separated from Cannula. The original device involved in incident was never returned for investigation by Healthcare Center however we have taken actions to improve device from our side. In the past the button on the cannula shaft was connected through a boring joint. Cannula was aligned on shaft and then hammered to fit. After fitting, the joint was inspected to assure it is connected properly. The devices in stock were checked and passed the inspection criteria. In our capacity, we believe that the device safety can be further enhanced by use of laser welding technique to permanently connect the cannula button and the shaft. Therefore, instead of joining components with conventional hammering technique we have replace it with laser weld to mitigate any risk of component separation.
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***
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
	☐ Other ☐ None
	Currently there is No product in stock with the distributor and Health Center. There are some stocks at the manufacturing facility and conventional hammering technique was used to fix the button. During investigation process the stock was checked

	however all products passed the inspection criteria. Inspite of that, to ensure the patient safety, these stocks are quarantine for repair and to fix the button with new technique.	
3.	**2. By when should the action be completed?**	There is No risk to patient because there is No product in stock with the distributor and Health Center.
3.	**3. Particular considerations for (Implantable devices, Diagnostic imaging device, IVD**	Not Applicable
	Is follow-up of patients or review of patients' previous results recommended? **No**	
3.	**4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)**	No
3.	**5. Action Being Taken by the Manufacturer**	
	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None	
	Drescon Surgical will use laser welding technique to permanently connect the cannula button and the shaft	
3.	**6. By when should the action be completed?**	Already started on October 18, 2022
3.	**7. Is the FSN required to be communicated to the patient /lay user?**	N/A
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? **Not Applicable**	

4. General Information*		
4.	**1. FSN Type***	New
4.	**2. For updated FSN, reference number and date of previous FSN**	Not Applicable
4.	3. For Updated FSN, key new information as follows:	
	Not Applicable	
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:	
	Not Applicable	
4.	6. Anticipated timescale for follow-up FSN	Not Applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a) Company Name	Drescon Surgical

	b) Address	46-A, M.A Jinnah Road, Small Industrial Estate, Sialkot-Pakistan
	c) Website address	www.dresconsurgical.com
	d) SRN	PK-MF-000014883
4.	**8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *** **"**YES"	
4.	**9. List of attachments/appendices:**	• Field Safety Corrective Action (FSCA) • Risk Management report • A letter of Distributor • IFU
4.	**10. Name/Signature**	Muhmmad Zubair (CEO)

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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..*

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