Rev 1: September 2018
FSN Ref: CCAR0209011 FSCA Ref: CCAR0209011

Date: 28/12/2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Apgar A/S

Contact details of local representative (name, e-mail, telephone, address etc.)*
Name: Stig Pieler, email: SP@apgar.dk, telephone: +45 43 43 66 15, address: Ringager 24, Brøndby, 2605, Denmark

Company Name/Logo

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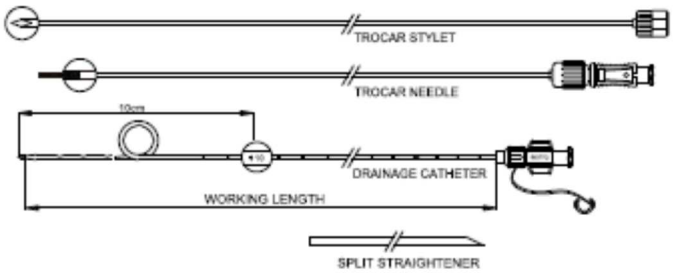
Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

The Percutaneous Drainage Catheter with hydrophilic coating ,BT-PD0, BT-PD1, BT-PD2, BT-PDS, BT-PD3, BT-PD4, is used for drainage of abscess and fluid collections. The catheter is made from a soft, biocompatible radiopaque polyurethane (TPU). The distal end of catheter contains a "J" or a pigtail and drainage holes. The catheter comes with a variety of operational acceossories. Accessories include: connecting tube. The connecting tube is made of PVC contain DEHP.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The device is a drainage catheter set which is used for drainage of abscesses and fluid collections. The catheter is mad from a soft, biocompatible plastic, a material that is radiopaque for X-rays. It is supplied sterile in a sealed pouch.  BT-PD1-series
1.	2. Commercial name(s)
	Drainage Catheter Set
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Drainage Catheter Set is designed for percutaneous drainage of abscesses fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collections.
1.	5. Device Model/Catalogue/part number(s)*
	BT-PD1-series
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	The lots manufactured before Oct. 31, 2020.
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Currently admitted to SUH Roskilde intensive care unit with i.a. vascular pleural effusion. When constructing pigtail cat can trocar not retract despite proper placement in the pleural cavity. Drains and trocar must discontinued and new drains are installed with new inserts. Both procedures without complications.
2.	2. Hazard giving rise to the FSCA*
	If the string is not fully tightened during operation, it may cause the string jam. this step is wrote on the IFU in English version but is not wrote on the IFU in Danish version.

2.	3. Probability of problem arising
	less than 1/1000000
2.	4. Predicted risk to patient/users
	The suture might be cut by the stylet. Patient might need to re-puncture a new catheter.* Drainage catheter and trocar must discontinued and new drainage catheter are installed. with new inserts. Both procedures without complications.
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	We got an incident report from Danish Authority and the incident information is as follow.According to the incident report, trocar could not be retracted. We have attached a copy of the incident report, which is in Danish. From the report it will appear whom to contact in order to collect further information about the incident. Currently admitted to SUH Roskilde intensive care unit with i.a. vascular pleural effusion. When constructing pigtail cat can trocar not retract despite proper placement in the pleural cavity. Drains and trocar must discontinued and new drains are installed with new inserts. Both procedures without complications. After our internal investigation and the reply the authority the conclusion as follow.1.Checked the returned defective device and confirmed that the trocar stylet cannot be withdrawn. After the catheter is damaged, it is found that the string and the trocar stylet are tangled.2.During the operation, the string must be tightened first, and then the trocar stylet and the trocar needle are inserted to prevent the string from being caught by the trocar stylet.3.Because there is a 100% inspection at the full inspection station before shipment, any abnormal operation should be found and eliminated.4.If the string is not fully tightened during operation, it may cause the string jam. this step is wrote on the IFU in English version but is not wrote on the IFU in Danish version. If the string is not fully tightened during operation, it may cause the string jam. this step is wrote on the IFU in English version but is not wrote on the IFU in Danish version.We revised the operation instructions of the pulling string are added to the IFU in Danish so that customers can operate correctly to avoid abnormal problems. And we have noticed our customer the revised IFU will be accompanied with devices starting from Nov.We sold this device with the old Danish IFU about 12,000pcs per year more than ten years(total more than 120,000pcs), this kind of incident(due to insufficient information in the IFU) happened 1 time only until now. The rating is less than 1/1000000, so we did not replace the IFUs on the market.
2.	7. Other information relevant to FSCA
	Revised IFU as attached

	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 ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	The revised IFU was shipped from Nov. 2020.

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? * (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 Provide further details of the action(s) identified. As attached IFU	
3	6. By when should the action be completed?	The revised IFU was shipped from Nov. 2020.
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?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**BIOTEQUE CORPORATION**
	b. Address	**5F-6, No. 23, Chang-An E. Road, Taipei 104, Taiwan**
	c. Website address	**www.bioteq.com.tw**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * N/A. The competent Authority of our country is Taiwan FDA. No affected products have been provided to Taiwan.	
4.	9. List of attachments/appendices:	**IFU**
4.	10. Name/Signature	**Stella Hsu** 

	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.