DALIAN CREATE MEDICAL PRODUCTS CO., LTD.
II B-31, Dalian Export Processing Zone, 116600 Dalian, People's Republic of China
Tel: +86- 411-8732-2561, Fax: +86- 411-8732-2563

FSN Ref: G22-001-FSN01 FSCA Ref: G22-001-FSCA01

Date: February 9, 2022

Urgent Field Safety Notice

Type of action: Reminder notice of information on the instructions for use

Cliny Port System T070-19 Lot No.: D18042003

For Attention of*: Patients, doctors and hospitals

Contact details of local representative (name, e-mail, telephone, address etc.)*
[redacted]

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile implantable medical device
1.	2. Commercial name(s)
	Vollständig Implantierbares Kathetersystem (PUR 6Fr Katheter, für intravenös)
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The device is implanted in the body and used as an access port to inject medicine for a long time.
1.	5. Device Model/Catalogue/part number(s)*
	T070-19
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot No.D18042003
1.	8. Associated devices
	Unknown

DALIAN CREATE MEDICAL PRODUCTS CO., LTD.
II B-31, Dalian Export Processing Zone, 116600 Dalian, People's Republic of China
Tel: +86- 411-8732-2561, Fax: +86- 411-8732-2563

FSN Ref: G22-001-FSN01 FSCA Ref: G22-001-FSCA01

	2. Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	According to the user's report, the catheter was ruptured/broken after three and a half years from implantation.
2.	2. Hazard giving rise to the FSCA*
	Any problems such as outlier detection on record and reduction in product function and so on were not found as the result of the examination on the production record of the lot no.D18042003 of the device in question, the device in question, the same lot device and the equivalent another lot device. The dimensions and strength of each part of the device meet the standard values. Based on these examination results, Dalian Create Medical doesn't think at this stage that the incident resulted from the device itself. In addition, though the importer already provided the hospitals and users with the primary information on the incident, Dalian Create Medical, as the manufacturer of the device in question, also thinks that the manufacturer needs to consider providing the information and provides them with the information on the precaution for use given in the instructions for use of the device for their review again. ※All the hospitals who purchased the same lot device in question have already been identified. According to this incident information, if there is any unused device, please make sure to return it to the importer. Regarding the devices that you have been using, please check the implanting condition appropriately as usual. If you find any abnormality, please inform the importer of it. In addition, please check if the same incident occurred in the past or not.
2.	3. Probability of problem arising
	If the device is used appropriately, Dalian Create Medical never think that the same event as the reported incident will occur. As stated in the above section 2.2, however, Dalian Create Medical will provide the hospitals with the information on the precautions for use given in the instructions for use and request them to inform if the same incident occurred in the past or not and if they still have unused same lot devices or not.
2.	4. Background on Issue
	Any problems such as outlier detection on record and reduction in product function and so on were not found as the result of the examination on the production record of the lot no.D18042003 of the device in question, the device in question, the same lot device and the equivalent another lot device. The dimensions and strength of each part of the device meet the standard values. Based on these examination results, Dalian Create Medical doesn't think at this stage that the incident resulted from the device itself. In addition, though the importer already provided the hospitals and users with the primary information on the incident, Dalian Create Medical, as the manufacturer of the device in question, also thinks that the manufacturer needs to consider providing the information and then provides them with the information on the precaution for use given in the instructions for use of the device for their review again.

DALIAN CREATE MEDICAL PRODUCTS CO., LTD.
II B-31, Dalian Export Processing Zone, 116600 Dalian, People's Republic of China
Tel: +86- 411-8732-2561, Fax: +86- 411-8732-2563

FSN Ref: G22-001-FSN01 FSCA Ref: G22-001-FSCA01

	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		
3.	2. By when should the action be completed?	March 14, 2022	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, will be attached later.	
3.	4. **Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Examination on the device in question, the same lot device and so on.		
3.	5. Is the FSN required to be communicated to the patient /lay user?	Yes, To hospitals	
3	6. 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 Not appended to this FSN		

DALIAN CREATE MEDICAL PRODUCTS CO., LTD.
II B-31, Dalian Export Processing Zone, 116600 Dalian, People's Republic of China
Tel: +86- 411-8732-2561, Fax: +86- 411-8732-2563

FSN Ref: G22-001-FSN01 FSCA Ref: G22-001-FSCA01

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Dalian Create Medical Products Co., Ltd.
	b. Address	No. IIB-31, Dalian Export Processing Zone, 116600 Dalian, People's Republic of China
	c. Website address	Non
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	N/A.
4.	4. List of attachments/appendices:	IFU:Cliny Port System DC61064 (Patient) IFU:Cliny Port System DC61063 (Physician)
4.	5. Name/Signature	[redacted]

	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.