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FSN Ref: FSN2026012201

FSCA Ref: FSCA2026012201

Date: 05:Feb:2026

Urgent Field Safety Notice
Extra-corporeal circuit tube

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

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

Deluxe Medicrafts SRL , Rodica Tomescu , E-Mail:comenzi@zentrum.ro Tel +40 728 804 390 , 65 A Street Nicolae Balcescu, Dobroesti, Ilfov County, 077085, Romania



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

1. Information on Affected Devices*				
1.	2.Device Type(s)*		Extra-corporeal Circuit Tube (ECCT) is composed of tube and connector. Use for extracorporeal circulation of cardiac operation, as a blood pathway. This product is non-toxic, transparent, appropriate hardness, smooth inner wall. This product sterilized by ETO, and it is using period of validity is two years.	
	3.Primary clinical purpose of device(s)*		Extra-corporeal Circuit Tube is intended for use during surgery requiring cardiopulmonary bypass, including coronary artery bypass grafting, valve replacement, repair, or plasty, operation for congenital heart disease, operation of great arteries, pulmonary embolectomy, etc. It is intended for use together with such device as blood pumps, centrifugal pump consoles, oxygenators, reservoirs, filters, heat exchangers and cannula. The device should not be used longer than 6 hours.	
1.	4.Commercial name(s)	5.Device Model	6.Catalogue(UDI-DI)	7.Affected serial or lot number range
	Extra-Corporeal Circuit Tube	Extra-Corporeal Circuit Tube	69448036	2401XXXX—2512XXXX
1.	8.Software version		N.A.	
1.	9.Associated devices		N.A.	

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>Our company has recently received an external complaint letter alleging compliance issues during the transition period for the EU Medical Device Regulation (MDR) upgrade.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>The doctor (user) has no instruments to use, and the patient (patient) cannot have the surgery arranged in a timely manner. There is only a risk of stockout, not a risk to the safety or efficacy of the product itself.</p>
2.	<p>3. Probability of problem arising</p> <p>The risk of users lacking appropriate medical devices for use is significant, with virtually no risk of product safety or efficacy.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>Based on the company's internal quality control for product development and manufacturing, combined with historical customer complaint data and adverse event statistics, the product poses virtually no safety or efficacy risks to patients.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>The number of complaints from historical customers regarding product quality issues is 0, and the number of historical adverse events is 0.</p>
2.	<p>6. Background on Issue</p> <p>Stop sales immediately: All affected products have been stopped immediately. All distribution channels have been closed and inventories frozen to prevent further distribution of non-compliant products. Initiate Recall: We have initiated the recall procedure for the affected products. Our traceability system is currently conducting a detailed analysis of all supply chains.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>N/A</p>

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" 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 </p>
3.	<p>2. By when should the action be completed? Within 4 weeks</p>
3.	<p>Particular considerations for: Sterile Medical Consumables</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p>
3.	<p>3. Is customer Reply Required? * (If yes, form attached specifying deadline for return) No</p>

4. General Information*	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN N/A
4.	3. For Updated FSN, key new information as follows: N/A
4.	4. Further advice or information already expected in follow-up FSN? * Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to: No
4	6. Anticipated timescale for follow-up FSN N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Tianjin Plastics Research Institute Co., Ltd.
	b. Address No.24-1,Keda 1 Road, TEDA(Jinnan) Microelectronics Park, Jinnan District, 300350, Tianjin, PEOPLE'S REPUBLIC OF CHINA
	c. Website address www.medplastic.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No
4.	9. List of attachments/appendices: N/A
4.	10. Name/Signature Liu Ning
	GM

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.