4700 Ashwood Dr. Suite 445
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Tel: 513-874-7326
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www.TyTekMedical.com

Rev 1: Jun 2021
FSN Ref: TM303_310-20210218

FSCA Ref: TM303_310-20210218

Date: 09:Jun:2021.

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:All users of TPAK and TPAK10

Contact details of local representative (name, e-mail, telephone, address etc.)*
Emergo Europe **Prinsessegracht 20** **The Hague** **2514 AP** **NL – Netherlands** **Evangeline Loh** **+31 70 345 8570** **EmergoVigilance@ul.com**

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

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	TPAK. A tension pneumothorax needle, which is a compact, sterile device that allows for secure placement of catheter for continuous relief during needle thoracostomy.
1.	2. Commercial name(s)
	TPAK and TPAK10
1.	3. Unique Device Identifier(s) (UDI-DI)
	00855204008006
1.	4. Primary clinical purpose of device(s)*
	TPAK. A tension pneumothorax needle, which is a compact, sterile device that allows for secure placement of catheter for continuous relief during needle thoracostomy.
1.	5. Device Model/Catalogue/part number(s)*
	TM-303 and TM-310
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	All
1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Revisions to Instructions for Use to identify the potential hazards of needle decompression with use of the TPAK.
2.	2. Hazard giving rise to the FSCA*
	As noted in the revised IFU, potential hazards of needle decompression include cardiac tamponade, life-threatening bleeding due to pulmonary artery, aorta or intercostal vessel injury, non-therapeutic insertion and potential nerve injury at insertion site. Hazards can be avoided by adhering to approved protocols, training and site placement.
2.	3. Probability of problem arising
	Unlikely if TPAK is administered according to approved protocols, training and site placement.
2.	4. Predicted risk to patient/users
	Cardiac tamponade, life-threatening bleeding due to pulmonary artery, aorta or

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	intercostal vessel injury, non-therapeutic insertion and potential nerve injury at insertion site.
2.	5. Further information to help characterise the problem
	Changes to the IFU were made as part of continuous review and updates and not as the result of any particular incident.
2.	6. Background on Issue
	See #5 above.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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?	Immediately
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. 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

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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.	
3	6. By when should the action be completed?	Immediately
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.	

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	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	**TyTek Medical, Inc.**
	b. Address	**4700 Ashwood Drive, Cincinnati, OH 45241**
	c. Website address	**www.tytekmedical.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Mark Sweatman, Technical Director**

	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.

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	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.