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www.TyTekMedical.com

Rev 1: Jun 2021
FSN Ref: TM317-20210218

FSCA Ref: TM317-20210218

Date: 09:Jun:2021

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: All users of PneumoDart

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

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

1. Information on Affected Devices*	
1.	<p style="text-align: center;">1. Device Type(s)*</p> <p>PneumoDart. A pneumothorax needle, which is a compact, sterile, device intended for the introduction into the body to facilitate the removal of air from the pleural cavity as a result of a pneumothorax condition.</p>
1.	<p style="text-align: center;">2. Commercial name(s)</p> <p>PneumoDart</p>
1.	<p style="text-align: center;">3. Unique Device Identifier(s) (UDI-DI)</p> <p>00855204008167</p>
1.	<p style="text-align: center;">4. Primary clinical purpose of device(s)*</p> <p>PneumoDart. A pneumothorax needle, which is a compact, sterile, device intended for the introduction into the body to facilitate the removal of air from the pleural cavity as a result of a pneumothorax condition.</p>
1.	<p style="text-align: center;">5. Device Model/Catalogue/part number(s)*</p> <p>TM 317</p>
1.	<p style="text-align: center;">6. Software version</p> <p>Only where relevant.</p>
1.	<p style="text-align: center;">7. Affected serial or lot number range</p> <p>All</p>
1.	<p style="text-align: center;">8. Associated devices</p> <p>NA</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	<p style="text-align: center;">1. Description of the product problem*</p> <p>Revisions to Instructions for Use to instruct users not to place PneumoDart during active chest compressions and to identify the potential hazards of needle decompression with use of the PneumoDart.</p>
2.	<p style="text-align: center;">2. Hazard giving rise to the FSCA*</p> <p>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.</p>
2.	<p style="text-align: center;">3. Probability of problem arising</p> <p>Following its revisions to the IFU, TyTek was made aware of one potential incident involving a cardiac tamponade that occurred while using the PneumoDart. However, if the user adheres to approved protocols, training, and site placement, the hazard is completely avoidable.</p>
2.	<p style="text-align: center;">4. Predicted risk to patient/users</p> <p>Cardiac tamponade, life-threatening bleeding due to pulmonary artery, aorta or intercostal vessel</p>



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	injury, non-therapeutic insertion and potential nerve injury at insertion site.
2.	<p>5. Further information to help characterise the problem</p> <p>The potential hazards of needle decompression were added as part of TyTek's periodic review and update to its IFU. TyTek had received a question from a user on whether it was safe to use the PneumoDart while performing CPR chest compressions. As a result of this inquiry, TyTek felt it was appropriate to add the specific instruction not to place PneumoDart during active chest compressions.</p>
2.	<p>6. Background on Issue</p> <p>See #5 above.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.</p>

	3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input 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 checked="" type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Provide further details of the action(s) identified.</p>	
3.	2. By when should the action be completed?	Immediately
3.	<p>3. Particular considerations for: Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended? Choose an item.</p> <p>Provide further details of patient-level follow-up if required or a justification why none is required</p>	
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	
	<input type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input type="checkbox"/> Other	<input type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> 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.

	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
4.	10. Name/Signature	



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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.