Tytek Medical Recalls TM-317 PneumoDart-Pneumothorax Needle Due to Fully and Partially Blocked Needles

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

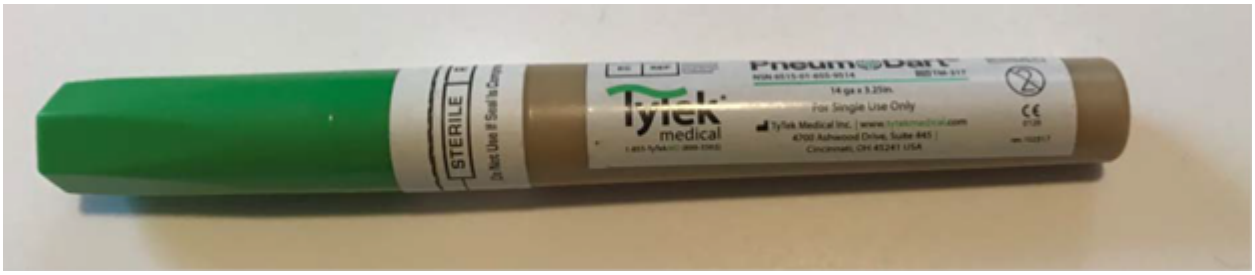
Recalled Product

- Name and Version: PneumoDart, TM-317
- Product Code: NSN 6515-01-655-9514 Lot Number:190524J69
- Manufacturing Dates: June 03, 2019 to September 17, 2019
- Distribution Dates: June 03, 2019 to September 17, 2019
- Devices Recalled in the U.S.: 920
- Date Initiated by Firm: November 18, 2019

Device Use

The TM-317 PneumoDart-Pneumothorax Needle is used to remove air that has become trapped in the pleural cavity (https://medlineplus.gov/ency/imagepages/9749.htm) during a life threatening situation such as trauma to the lung or a collapsed lung. The needle is used in emergency pre-hospital or hospital settings.

PneumoDart Product Photo:



Reason for Recall

Tytek Medical is recalling its PneumoDart-Pneumothorax Needle due to the risk of blocked needles. The blockage in the needles is caused by the presence of adhesive from the assembly process. If the needle is blocked, emergency treatment is delayed which can lead to heart or lung

failure, or death. An affected device may cause additional injury since the diagnosis of lung injury may be complicated. If treatment is unsuccessful with the first needle, health care providers may attempt to place another needle and could cause further lung collapse.

There has been one complaint and no reported injuries or deaths.

Who May be Affected

- Health care providers using the PneumoDart-Pneumothorax Needle
- All patient groups having procedures using the PneumoDart-Pneumothorax Needle

What to Do

On November 15, 2019, Tytek Medical sent an Urgent Medical Device Recall Notice to customers and distributors informing them of the affected model and provided the following instructions:

- Do not use any of the affected product.
- Recall the product from points of distribution and return it right away by UPS Account #R5513V or DHL Account #958855282 to:
    - Tytek Medical
      4700 Ashwood Drive Ste 445
      Cincinnati, OH 45241
- Complete the Acknowledgement and Receipt Form as soon as possible and return the form by fax to 1-513-874-7294.

Contact Information

Customers who have questions or need additional information about this recall should call 1-513- 872-7326, Monday through Friday between 8:00am and 5:00pm (Eastern Time).

Additional Resources

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177975)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) theyexperienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.