



4700 Ashwood Dr. Suite 445
Cincinnati, Ohio 45241
Tel: 513-247-2002
855-TyTekMD
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www.TyTekMedical.com
ISO 13485

November 15, 2019

URGENT FIELD SAFETY NOTICE
TM-317 Pneumodart

Customer Name
Company
Street Address
City, State, Zip Code

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Tytek Medical Inc is implementing a field safety corrective action on one lot of our TM-317 Pneumodart. The **only** lot under recall is **LOT # 190524J69**. The appropriate regulatory agencies have been notified.

We have no reports of deaths or of serious injuries.

We received a single customer complaint of a non-conforming product discovered in training. The non-conformance was found to be an occlusion in the inner needle caused by the presence of adhesive from the hub bonding assembly process.

Inspection of inventory has indicated that approximately 0.24% of product in this lot could contain an occlusion. No adverse events have been reported.

In the prehospital setting pneumothorax decompression is usually performed based on vague and non-specific exam findings. Failure to obtain an "air rush" from the needle after application or achieve patient improvement would often be attributed to lack of a tension pneumothorax and need to pursue alternative etiology of the patient's symptoms, rather than assuming failure to decompress and need for additional attempts with other devices. Failure to decompress tension pneumothorax in a timely manner is a critical patient can lead to death.

Please **DO NOT** use any of the product from the affected Lot #190524J69.

Please recall this product from your points of distribution and return it immediately. Product may be returned to Tytek Medical via UPS Account # R5513V or DHL Account # 958855282 to:

Tytek Medical
4700 Ashwood Drive
Ste 445
Cincinnati, OH 45241
513-874-7326

We will be shipping you 100% inspected replacement product on Wednesday, November 20, 2019.

We have identified the root cause of the non-conformance and are implementing corrective actions which will prevent this from future occurrence.

We ask that you please complete and return the Instructions for Acknowledgement form we have included with this letter. Forms may be returned to us via FAX (513)874-7294; or email stacey@tytekgroup.com.

Please see below for product information:

Product and Distribution Information Table					
Product Name / Unique Device Identifier	Manufacturer's Product #	Lot/Serial Number	Manufacturing/ Distribution Dates	Expiration Date (MM/DD/YYYY)	Quantity
Pneumodart UDI # (01)00855204008167(17)260524(10)190524J69	TM-317	190524J69	Distribution Dates 6/3/19 – 9/17/19	05/24/2026	3565

PneumoDart – Pneumothorax Needle - 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 tension pneumothorax condition.

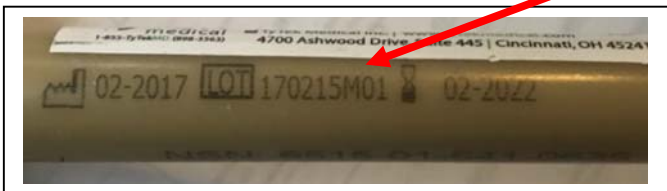
Product Label example:



PneumoDart Product Photo:



Lot # Identification Location: Affected product will be **LOT # 190524J69**



As a short-term corrective action, we have inspected all on-site inventory to ensure there are no occlusions in any remaining product.

Long term, corrective actions are underway to correct the adhesive application problem and prevent future occurrence. These corrective actions are in place for our new production and include verification of effectiveness.

Questions regarding this recall may be directed to

Mark Sweatman, Technical Director - msweatman@tytekgroup.com

Stacey Cremers, Contracts Manager – stacey@tytekgroup.com

We are available Monday – Friday, 8 am – 5 pm EST – Phone 513-872-7326

Authorized by:

Stacey Cremers
Contracts Manager



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MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:

Customer Name
Street Address
Town, State, Zip Code

Re: TM-317 PNEUMODART

LOT : 190524J69:

I have read and understand the recall instructions provided in the 11/15/19 letter. Yes _ No _

Any adverse events associated with recalled product? Yes _ No _

If yes, please explain:

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table					
Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Quantity in inventory	Quantity relabeled	Quantity destroyed/ returned
Pneumodart – UDI (01)00855204008167(17)260524(10)190524J69	TM-317	190524J69			

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Distributors:

I have checked my stock and have quarantined inventory consisting of _____ boxes

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**);

Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE FAX COMPLETED RESPONSE FORM TO: Fax # 513-874-7294,
ATTN: Stacey Cremers OR E-MAIL TO: stacey@tytekgroup.com