



Cardinal Health  
1500 Waukegan Road  
McGaw Park, IL 60085  
800.292.9332

## URGENT: FIELD SAFETY NOTICE [cardinalhealth.com](http://cardinalhealth.com)

April 21, 2017

Event-2017-00659

Dear International Distributor:

Cardinal Health has become aware of a potential breach of sterility in the packaging of certain Jackson-Pratt Perforated and Hemaduct Wound Drainage Systems. In a small percentage of product (approximately 1.6%), the inner packaging (polybag) is caught in the seal area of the outer Tyvek pouch, potentially compromising the sterility of the package contents. While sterility is only impacted if the polybag fully breaches the seal (approximately 0.23% of product), as a precautionary measure, Cardinal Health is taking this action to ensure that product is not used if any portion of the polybag is caught in the seal area. The affected lots are listed on Attachment 1. Use of impacted products could result in an increased risk of infection. There have been no complaints or reports of infection associated with this issue.

**Please inspect the packaging of impacted lots by referring to the illustrations included with this letter (Attachment 2).** Product where the inner packaging (polybag) is caught in **any portion of the seal area** of the outer Tyvek pouch should be quarantined immediately and not used (see illustrations in Attachment 2). If you determine your facility has affected unit(s), you may either discard the specific unit(s) at your facility or return it to Cardinal Health (see option 5, below).

### **Please immediately take the following action:**

1. **INSPECT** any affected lots in your possession.
2. **DO NOT USE** units where the inner packaging (polybag) is caught in any portion of the seal area of the outer Tyvek pouch. If no portion of the inner packaging is caught in the seal area of the Tyvek pouch the product may be used.
3. **NOTIFY** any customers to whom you have distributed product affected by this recall.
4. **RETURN** the enclosed acknowledgment form to [GMB-FieldCorrectiveAction@cardinalhealth.com](mailto:GMB-FieldCorrectiveAction@cardinalhealth.com), as Cardinal Health is required to confirm receipt of this notification from you.
5. **CONTACT** the appropriate Customer Service team listed below for credit of any affected product.
  - Asia—847-887-6307 or [AsiaPac@cardinalhealth.com](mailto:AsiaPac@cardinalhealth.com)
  - LATAM—847-887-6703 or [LatAm@cardinalhealth.com](mailto:LatAm@cardinalhealth.com)
  - Middle East, Europe, Australia—847-887-2033 or [MiddleEast@cardinalhealth.com](mailto:MiddleEast@cardinalhealth.com)  
[Europe@cardinalhealth.com](mailto:Europe@cardinalhealth.com)

Cardinal Health is not aware of any reports of injury attributed to this issue. The appropriate Competent Authorities have been made aware.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, or desire special assistance relating to this recall, please feel free to contact Cardinal Health Customer Advocacy at 800.292.9332 or [GMB-FieldCorrectiveAction@cardinalhealth.com](mailto:GMB-FieldCorrectiveAction@cardinalhealth.com).

Sincerely,

*Michele B. Donatich RN*

Michele B. Donatich, RN  
Director, Product Quality and Regulatory Compliance

# Attachment 1

Lots affected by this Field Action

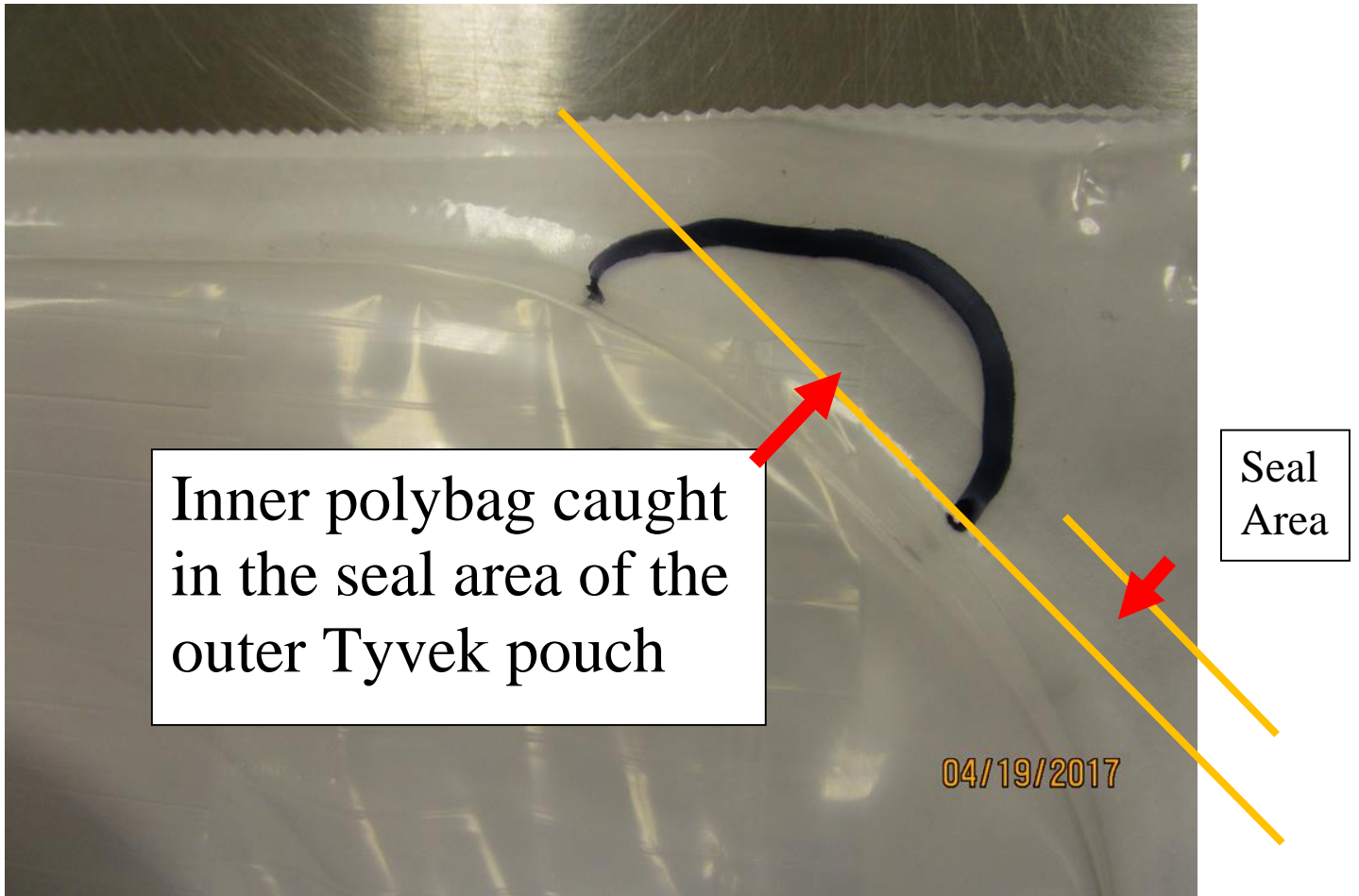
Catalog Number	Product Description	Lot Numbers	
CT-HU1900	CT HEMADUCT SIL RND DRN 19FR	1161200 1161362	1161455 1161599
JP-HUF100	J-P HEMADUCT SIL FLT DRN, 10MM, FULL DUCTS	1161357 1161466 1170015	
JP-HUF101	J-P HEMADUCT SIL FLT DRN, 10MM, FULL DUCTS W/15FR TROCAR	1161358	
JP-HUR101	J-P HEMADUCT SIL RND DRN, 10FR W/10FR TROCAR	1161193 1161194 1161359 1161467	1161468 1161591 1161592
JP-HUR151	J-P HEMADUCT SIL RND DRN, 15FR W/15FR TROCAR	1161195 1161196 1161360 1161456	1161593 1170021 1170022
JP-HUR190	J-P HEMADUCT SIL RND DRN, 19FR	1161197 1161198	1161457 1161597
JP-HUR195	J-P HEMADUCT SIL RND DRN, 19FR W/15FR TROCAR	1161199 1161361 1161458 1161459	1161594 1161595 1161596
SU130-0321	J-P SIL RND DRN 10FR W/TROCAR	1161202 1161203 1161364 1161365 1161471	1161472 1161601 1161602 1170030 1170031
SU130-0323	J-P SIL RND DRN 15FR W/TROCAR	1161366 1161473 1161603	1161604 1161605 1170033
SU130-0521	J-P PVC DRN 10FR W/TROCAR	1161481 1170193 1170194	
SU130-1308	J-P SIL FLAT DRN 7MM, ¾ DUCTS	1161228 1161229 1161396	1161397 1161490 1161491

SU130-1309	J-P SIL FLAT DRN 10MM, ¾ DUCTS	1161246 1161412 1161413 1161460 1161461	1161619 1161620 1161621 1170083 1170084
SU130-1310	J-P SIL FLAT DRN 7MM, FULL DUCTS	1161230 1161231 1161232	1161233 1161234 1161398
SU130-1310	J-P SIL FLAT DRN 7MM, FULL DUCTS	1161399 1161400 1161401 1161402 1161403 1161404 1161492 1161493 1161494 1161495 1161496	1161497 1161498 1161499 1161614 1161615 1161616 1161617 1170076 1170077 1170080
SU130-1311	J-P SIL FLAT DRN 10MM, FULL DUCTS	1161247 1161248 1161249 1161250 1161251 1161252 1161414 1161415 1161416 1161417 1161418 1161419 1161420 1161421 1161509 1161510 1161511 1161512	1161513 1161514 1161515 1161622 1161623 1161624 1161625 1161626 1161627 1161628 1170089 1170094 1170095 1170096 1170353 1170354 1170356
SU130-1320	J-P SIL RND DRN 7FR	1161205 1161368	1161369 1161475
SU130-1321	J-P SIL RND DRN 10FR	1161206 1161207 1161370 1161371 1161372 1161476	1161477 1161478 1161606 1161607 1161608 1170036

SU130-1323	J-P SIL RND DRN 15FR	1161373 1161374 1161375 1161610	1161611 1170038 1170039
SU130-1325	J-P SIL RND DRN 19FR	1161208 1161209 1161376 1161479	1161480 1161612 1161613 1170040
SU130-1410	J-P 7MM FULL W/TROCAR	1161405 1161584 1161618	
SU130-1411	J-P 10MM FULL W/TROCAR	1161253 1161516 1161692	

Attachment 2

**DO NOT USE IF ANY PORTION OF THE  
INNER POLYBAG IS CAUGHT IN THE OUTER SEAL**



Inner  
polybag  
caught in the  
seal area of  
the outer  
Tyvek pouch



**CARDINAL HEALTH**  
**DATE:** 4/21/2017  
**FILE#:** Event-2017-00659

**URGENT—RESPONSE REQUIRED**

**FAX COMPLETED FORM TO 847-689-9101 or email to [gmb-fieldcorrectiveaction@cardinalhealth.com](mailto:gmb-fieldcorrectiveaction@cardinalhealth.com)**

1. Do you have any of the recalled product in your current inventory?  
\_\_\_\_\_ YES \_\_\_\_\_ NO \_\_\_\_\_ QTY On Hand
2. Confirm you will notify customers to whom you've shipped product  
\_\_\_\_ We will notify our customers

Company Name: \_\_\_\_\_

Printed Name and Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Email address: \_\_\_\_\_

Phone number: \_\_\_\_\_