



COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

IMPORTANT PRODUCT INFORMATION

Dear Risk Management,

According to our records, your institution is currently using one or more of the Wayne Pneumothorax Sets or Trays as listed below:

Catalog Number (Global Product Number)

C-UTPT-1020-WAYNE	(G09922)	C-UTPT-1400-WAYNE	(G07910)
C-UTPT-1400-WAYNE-100494	(G44035)	C-UTPT-1400-WAYNE-112497	(G11182)
C-UTPT-1400-WAYNE-A-112497	(G11183)	C-UTPTY-1400-WAYNE-112497	(G12032)

We would like to thank you for choosing these devices for your patients; your confidence and support are very important to us. We would also like to notify you of some important changes we will be making to the product Instructions for Use.

We have received information indicating that in a few cases, separation of the fitting from the catheter may occur. This appears to occur when excessive force is applied to the system, specifically the connection of the catheter and fitting.

Based on this information, we will be adding instructions for catheter and line maintenance to our standard Instructions for Use booklet as soon as possible. These techniques are designed to prevent excessive force from being applied to the system, preventing catheter dislodgement, migration and / or separation. The instructions to be added are provided on the attached page, and may be placed with your stock of product or in the appropriate using department for ready availability.

Should you have any questions or concerns, please feel free to contact your local Cook representative or distributor.

Sincerely,

Vice President Quality Assurance

08 Mar 2010

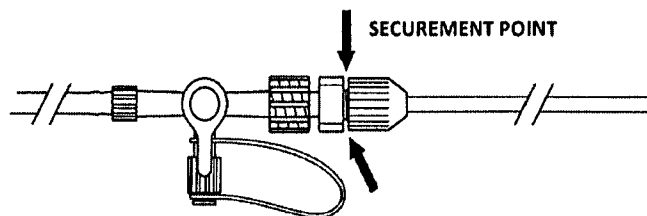


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Addendum to **IMPORTANT PRODUCT INFORMATION**
Wayne Pneumothorax Sets or Trays

- 11. Secure catheter in position at the entry site by using a bio-occlusive dressing or suturing if desired.**
- 12. The catheter and connected drain lines should be secured to the patient. Excessive tension on catheter connections (e.g., in instances of patient movement where the catheter is connected to a vacuum or drainage collection apparatus) may cause catheter/hub separation or accidental catheter dislodgement. To help prevent this from occurring, it is recommended to do one or both of the following:**
 - a. Secure the catheter hub to the patient's skin by placing tape, suture, or a catheter securement device at the location shown in the illustration below.**



- b. Form a strain relief loop in the connecting tube, as shown in the illustration below, and secure the loop to the patient's skin with tape or suture.**

