

## Product Recall

July 22, 2008

Attn:

Subject: Argyle™ Suction Catheter

Dear Tyco Healthcare Customer:

Through internal testing, Tyco Healthcare has determined that certain lots of Argyle™ Suction Catheters may have pinholes in the packaging potentially compromising sterility of the device.

This recall extends to specific lots only, manufactured within a specific timeframe.

Please be assured that we have identified the root cause of this problem and have taken the necessary steps to prevent recurrence.

Our records indicate that you may have received product affected by this recall.

Please examine your inventory and in-use stock immediately to determine if you have any of the item codes or lot numbers shown on the attached list. The attached diagram shows where the lot number can be found on the package. **Should any recalled product be found, please remove it from inventory.**

Please return a completed "Customer Returns Form" even if you have none of the products in stock at this time. Your response is vital to our ability to monitor the effectiveness of this voluntary recall.

If you are a distributor, we request that you notify your accounts of this letter.

This recall has been notified to *[insert name of competent authority (e.g. MHRA).]*

Your patience and cooperation on this matter are greatly appreciated. If you have any questions, please contact \_\_\_\_\_ at \_\_\_\_\_

Sincerely,

## Argyle™ Suction Catheter Product Recall List

<u>Product Description</u>	<u>Item Code</u>	<u>Lot Number(s)</u>
Argyle™ Suction Catheter	1180851089	08D916E, 08E581E
Argyle™ Suction Catheter	1180851105	08D822E
Argyle™ Suction Catheter	2141	08D880E
Argyle™ Suction Catheter	2101	08D328E, 08D331E
Argyle™ Suction Catheter	1180851121	08E622E
Argyle™ Suction Catheter	1180853184	08D867E
Argyle™ Suction Catheter	1180851147	08E600E, 08D228E, 08E621E

# CUSTOMER RETURNS FORM

## Argyle™ Suction Catheter Recall

Form completed by: \_\_\_\_\_

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

Title: \_\_\_\_\_

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

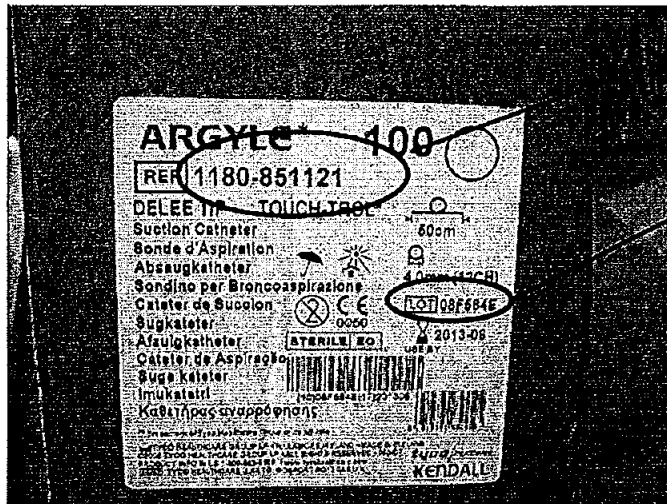
Date: \_\_\_\_\_

Item Code	Lot	QTY Returned
1180851089	08D916E	
	08E581E	
1180851105	08D822E	
2141	08D880E	
2101	08D328E	
	08D331E	
1180851121	08E622E	
1180853184	08D867E	
1180851147	08E600E	
	08D228E	
	08E621E	

I have none of the above affected product

All affected product has been removed from service and will be returned to:

Return form to: \_\_\_\_\_ FAX: \_\_\_\_\_

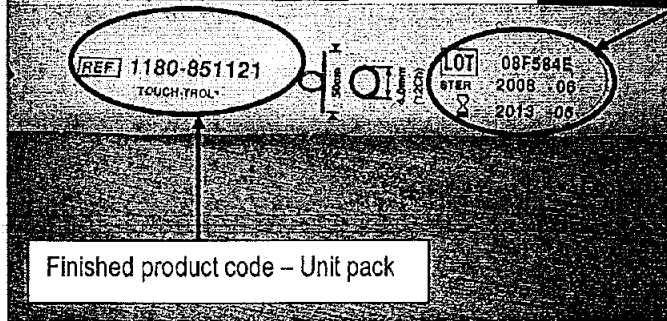


Finished Product code

Carton label Lot number location



Unit Pack Lot number location



Finished product code – Unit pack