



January 14, 2009

Dear Valued Covidien Customer:

URGENT DEVICE ALERT FOR SHILEY™ 3.0PED CUFFLESS PEDIATRIC TRACHEOSTOMY TUBES

We are informing you of the following urgent device alert.

We have determined that a recent modification to the Shiley 3.0PED cuffless pediatric tracheostomy tube may result in difficulty inserting the obturator into the tracheostomy tube prior to placement in the patient's stoma. This modification may also result in difficulty inserting a suction catheter into the tube after placement.

We are advising that all Shiley 3.0PED tracheostomy tubes—from the lots listed below—be evaluated prior to placement into a patient's stoma to ensure that both the obturator and an appropriately sized sterile suction catheter can be inserted into the tube. Please reference the American Thoracic Society (ATS) guidelines¹ for the correct suction catheter size for tracheostomy tube care.

If either the obturator or the desired sterile suction catheter does not fit properly, do not insert the tube into a patient. Select another Shiley 3.0PED tracheostomy tube and repeat the verification steps.

Products from the following lot numbers are the only ones affected:

0806000266	0807002502	0810000864	0811000546
0806000858	0808000387	0810000865	0811000547
0806000859	0808000431	0810001201	0811001875
0806001328	0808002285	0811000228	
0807000555	0810000288	0811000522	
0807001444	0810000289	0811000523	

To return the open and unused product for credit, please contact your local sales representative (for details please see below)

Alternatively, you may complete the enclosed Verification Form and fax it to 01329 224287 to initiate the return of your device(s).

For audit purposes please return the fax to state whether you still have inventory of the product even if you choose not to return it.

This letter is being sent with the knowledge of the MHRA.

Please be assured that new product will be available by mid February that will address this issue. In the meantime, we apologize for any inconvenience this may cause and appreciate your attention to this matter.

Sincerely,

Shelley Dale
Product Manager – Mallinckrodt/Shiley and DAR range of products
07966 117850

Kristian Howells

Lorna McGinnis

¹ American Thoracic Society. 2008. <http://www.thoracic.org/sections/education/care-of-the-child-with-a-chronic-tracheostomy/components-of-tracheostomy-care/suctioning.html>.

Date:	Fax Number: 01329 224287
To: Customer Services Department	Page(s) – including cover sheet:
From (Facility Name):	Facility Address:
Facility phone number:	Facility RGA number:

a) Please complete the above details if you have read the safety notice and have not got any product to return

b) Please complete the following table if you have read the safety notice and only if you have product that you wish to return.

Quantity	Part Number	Lot Number
	3.0 PED	

Name: (Please print):

Signature & Date:

Please contact your sales representative if you wish to return products and label goods with the RGA number prominently on the outside of the box.

Additional Comments:
