

URGENT MEDICAL DEVICE RECALL
on Certain Cuffed Shiley™ Tracheostomy Products

April 13, 2010

Dear Valued Customer,

We have received customer reports of serious adverse health consequences that may be linked to certain cuffed Shiley™ tracheostomy tubes, in which the cuff does not hold air as a result of leaks in the pilot balloon inflation assembly. If a cuff does not hold air, ventilation will be adversely affected and the tracheostomy tube might require immediate replacement. Accordingly, we have voluntarily determined that Shiley Tracheostomy Products from affected lot numbers should be returned.

We are requesting your assistance in conducting this activity. Please review your inventory and segregate any product with the affected lot numbers. Unused affected product should be returned according to the directions below.

If a cuffed Shiley tracheostomy tube from an affected lot is already in use in a patient, we recommend that the tube be replaced with a tube that is not included in the affected lots as soon as the patient's physician determines it is clinically appropriate. If the physician advises leaving the tracheostomy tube in place until a more acceptable replacement opportunity occurs, we strongly advise that the frequency and intensity of monitoring the cuff inflation system be increased.

The recall applies to the 62 product codes and associated lot numbers listed in the Tables 1 and 2 below. Lot numbers are configured as follows – YYMMXXXXXX where YY is the year, MM is the month, XXXXXX is a sequential number. Please note the additional information following each table.

Table 1 - Shiley™ Tracheostomy Products

Item	Starting Lot Number	Ending Lot Number
4DCT	0810002426	0908000766
6DCT	0810002428	0908000773
8DCT	0810002433	0908000787
10DCT	0811000171	0908000765
4FEN	0811001522	0908000767
6FEN	0810002445	0908000776
8FEN	0810002447	0908000256
10FEN	0811001364	0908000233
4DFEN	0811001526	0908000235
6DFEN	0810002448	0908000774
8DFEN	0811000185	0908000789
10DFEN	0812000028	0908000232
6PERC	0810002450	0908000782
8PERC	0810002453	0908000797
6FEN-S	0811000211	0907001570
8FEN-S	0811001529	0908000791
4LPC	0810002441	0908000768
6LPC	0810002442	0908000780
8LPC	0810000069	0908000792
10LPC	0811001521	0907001560
5SCT	0906000823	0907001067
6SCT	0903001835	0908000124
7SCT	0903000809	0908002300
8SCT	0903000810	0908001215
9SCT	0905001770	0907001068
10SCT	0907002007	0908001339
4LPC-S	0905000105	n/a
6LPC-S	0810002449	0906000342
8LPC-S	0901002066	0907002156
10LPC-S	0812000912	0907000367
4.0PDC	0903000859	0908001790
4.5PDC	0903000861	0908000693
5.0PDC	0903000862	0908001208
5.5PDC	0903000863	0908001211
5.0PLC	0903000865	0907001065
5.5PLC	0903001839	0907001066
6.0PLC	0903000866	0908001213
6.5PLC	0903000867	0907001525

For the products listed in Table 1 above: Products with lot codes where the first four numbers are in the range from 0810 to 0908 may be affected; consult Table 1 for specific lot code ranges for each product code. Products in the above Table 1 with lot code numbers starting with 0809 or lower, and those with lot code numbers starting with 0909 or higher, are not affected.

Table 2 – Custom Shiley™ Tracheostomy Products

MSCT	0904000093	0912001647	MPDC	0904001545	0905000593	MLPC	0908001982	0912000321
M5SCT	0907000415	0908002263	M4.0PDC	0904001545	0905000593	M6LPC	0908001982	0912000321
M5.5SCT	0907000880	0907002499	M5.5PDC	0905000552	n/a	M8LPC	0909000673	0911001672
M6SCT	0904000093	0908002249						
M6.5.SCT	0904000511	0908000714	MPLC	0905000553	n/a	MDCT	0911000199	0911000221
M7SCT	0904000118	0908001971	M5.5PLC	0905000553	n/a	M6DCT	0911000221	n/a
M7.5SCT	0904000602	0908001068				M8DCT	0911000199	n/a
M8SCT	0904000132	0910001376	MFEN	0908001420	0912000048			
M9SCT	0904001119	0912001647	M6FEN	0908001420	0910000004			
M10SCT	0905001247	0908000752	M8FEN	0909000850	0912000048			

For the products listed in Table 2 above: Products with lot codes where the first four numbers are in the range from 0904 to 0912 may be affected; consult Table 2 for specific lot code ranges for each product code. Products in the above Table 2 with lot code numbers starting with 0903 or lower, and those with lot code numbers starting with 1001 or higher, are not affected.

The lot number for all Shiley dual cannula tracheostomy tubes is clearly printed on the left side of the Soft Swivel Flange and on the carton and pouch in which the product was shipped. The lot number for all single cannula Shiley tracheostomy tubes is clearly printed on the carton and on the package tray lid. The lot number of Custom/Specialty Tracheostomy tubes is printed on the pouch or tray lid, depending upon the product configuration. If you need assistance locating the lot number, please contact our Technical Services group at 1-800-635-5267, option 3, then option 1. If you are unable to determine the lot number of the cuffed Shiley tracheostomy tube, these products should be treated as if they are within the affected lot numbers and you should proceed as directed below.

To return the affected product for credit, please contact our Technical Services group at 1-800-635-5267, option 3, then option 1, and reference the Return Goods Authorization Number (RGA) noted at the top of this page. If product was purchased from a distributor, please contact your provider for their return process. Alternatively, you may complete the enclosed Verification Form and fax it to us at 925-463-4600 to initiate the return of your device(s).

If you or your company has distributed the product codes listed above to other persons or facilities, please promptly forward those persons or facilities a copy of this letter and include the RGA provided at the top of this page as a reference.

If you are a patient or non-clinician caregiver receiving this letter, it is because you *may* have received a cuffed Shiley tracheostomy tube from one of the affected lot numbers. Check your tracheostomy tube(s) as described above to identify the lot number(s) to determine if any of your Shiley cuffed tracheostomy tubes are in the affected lots. If you cannot find any of your lot number(s), or are unsure if your lot numbers are in the affected lots, please contact your home care provider or medical equipment provider for assistance. If you determine that the Shiley tracheostomy tube being used by you or the patient you are caring for is or may be in one of the affected lot numbers, then call your physician (or the patient's physician, as applicable) for advice. If you determine that you have any unused, cuffed Shiley tracheostomy tubes from the affected lot numbers, please contact your home care provider or medical equipment provider to arrange return of the product.

Please report any issues with Shiley Tracheostomy Products to our Technical Services group to ensure proper device reporting procedures are followed. Please call 1-800-635-5267, option 3, then option 1, and you will be given further instructions.

This letter is being sent with the knowledge of the U.S. FDA.

While we do not expect that availability of usable product will be significantly impacted, please be assured that we will work diligently to resolve any supply challenges that customers may experience as a result of this action. We sincerely apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

Sincerely,



Frances E. Harrison
 Vice President, Regulatory Affairs
 Respiratory and Monitoring Solutions
 Covidien, formerly known as Tyco Healthcare