



COOK INCORPORATED
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BLOOMINGTON, IN 47402-0489 USA
TLF: 812.339.2235
GRØNT NUMBER: 800.457.4500
WWW.COOKMEDICAL.COM

URGENT: PRODUCT RECALL

ATTENTION: Risk Management

Affected Product:

Ciaglia Blue Rhino Percutaneous Tracheostomy		Ciaglia Blue Dolphin Balloon Percutaneous Tracheostomy Introducer	
Reorder Number	Global part Number	Reorder Number	Gibal Part Number
C-PTIS-100-A-HC-PERC8	G12403	C-PTBS-2600-PERC6	G36116
C-PTISY-100-A-HC-PERC8	G12566	C-PTBSY-2600-PERC6	G36118
C-PTIS-100-HC-PERC6	G13165	C-PTBSYJC-2600-PERC6	G51971
C-PTIS-100-HC-PERC6-CA	G36037	C-PTBS-2800-PERC8	G36117
C-PTISY-100-HC-PERC6	G13166	C-PTBSY-2800-PERC8	G49507
C-PTIS-100-HC-PERC8	G12523	C-PTBSYJC-2800-PERC8	G51972
C-PTIS-100-HC-PERC8-CA	G36038		
C-PTISY-100-HC-PERC8	G12565		
C-PTISY-100-HC-G-PERC6	G53178		
C-PTIS-100-WCE-HC-G-PERC6	G53169		
C-PTIS-100-WCE-HC-G-PERC8	G53170		


Covidien, a supplier to COOK MEDICAL, has initiated a product recall involving Covidien's 6PERC and 8PERC Shiley Percutaneous Dual Cannula Tracheostomy Tubes. For full details regarding this recall, please refer to an attached copy of Covidien's recall notice.

Our records indicate that your institution has purchased one or more of the above listed devices from COOK MEDICAL that contains a recalled Shiley Percutaneous Tracheostomy Tube. Please refer to the enclosed COOK listing that contains specific part numbers and lot numbers affected by this recall. If you distribute these products, any further distribution of products with these specific lot numbers should cease and your customers should be notified immediately.

To assist Covidien in its recall, COOK MEDICAL is requesting that you examine your stock of the Ciaglia Blue Rhino and Ciaglia Blue Dolphin Percutaneous Tracheostomy Introducers to determine if you have any of the products listed on hand. If you have any inventory of this product, please complete the enclosed Recall Response Form and notify COOK MEDICAL for product return.

Thank you for your attention to these matters of mutual concern. COOK MEDICAL emphasizes the need to ensure that all persons at your facility who are affected or potentially affected by this recall are notified of its content and the attached information. If you should have any questions about this notice, please contact our Customer Relations Department at 1-800-457-4500.

Sincerely,
COOK MEDICAL

 Vice President, Quality Insurance
Vice President, Quality Assurance

Attachments