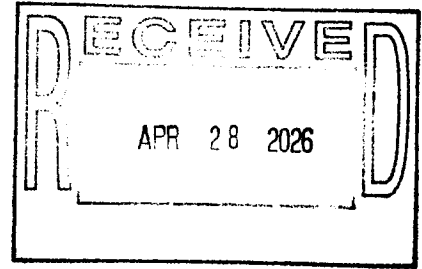


Medtronic

Medical Surgical

Acute Care and Monitoring
250 Medtronic Drive
Lafayette, CO 80026
www.medtronic.com



Urgent Medical Device Correction Covidien Shiley™ Disposable Decannulation Plug Product Code: DDCP

April 23, 2026


Dear Risk Manager:

The purpose of this letter is to inform you that Medtronic is issuing a voluntary product correction for all lots of Covidien Shiley™ disposable decannulation plugs.

This correction is being issued as the labeling for all lots of Covidien Shiley™ disposable decannulation plugs incorrectly includes the symbol indicating non-DEHP (Bis(2-ethylhexyl) phthalate). The seal of this product includes 30 to 35% DEHP. Covidien Shiley™ disposable decannulation plugs are supplied in individual pouches or included within the inner packaging of certain cuffed and cuffless Covidien Shiley™ tracheostomy tubes. Please refer to Attachment A for the list of products affected by this notice.

You are receiving this notice as Medtronic records indicate that affected product was shipped to your facility.

Issue Description:

All levels of product packaging for Covidien Shiley™ disposable decannulation plugs incorrectly display the symbol for non-DEHP:  This symbol was erroneously included during the labeling creation process. The decannulation plug seal contains DEHP.

Risk to Health:

Use of Covidien Shiley™ disposable decannulation plugs with this labeling discrepancy does not increase risk to health. This accessory is only compatible with Covidien Shiley™ tracheostomy tubes that contain DEHP.

These tracheostomy tube devices are correctly labeled as containing DEHP:  .

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Patient Management:

No additional action is required by clinicians for the care or follow-up of patients who are using or have used Covidien Shiley™ disposable decannulation plugs.

Customer Actions:

- Customers can continue to use the Covidien Shiley™ disposable decannulation plugs.
- Post this notice in all care environments where the affected products are used to maintain awareness to this labeling issue.
- Share this notice with all relevant personnel within your organization, and with any organization to which the affected product has been transferred or distributed.
- Complete and return the enclosed Customer Confirmation Form to rs.gmbmitgfca@medtronic.com even if you do not have unused inventory.

Additional Information:

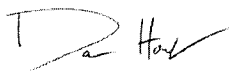
Medtronic has notified the U.S. FDA of this recall action.

Adverse reactions or quality problems experienced with this product should be reported to the FDA and Medtronic:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or
- Call FDA (800) FDA-1088
- Call Medtronic Quality Assurance at 800-255-6774 option 1, then option 1

Medtronic is committed to patient safety and appreciates your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative or Customer Service at 800-962-9888.

Sincerely,



Dan Howk
Vice President, Quality
Acute Care and Monitoring

Enclosures: Customer Confirmation Form

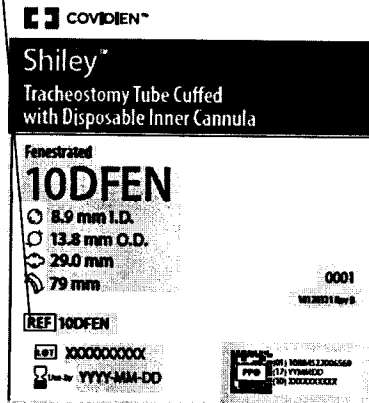
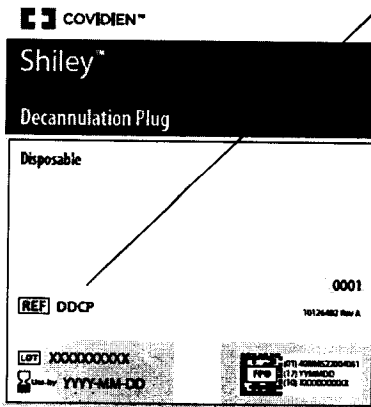
Attachment A: List of Affected Products

Product Description	Product Number	Product GTIN/MATNR	Affected Lot Numbers
Covidien Shiley™ Disposable Decannulation Plug	DDCP	10884522004060	All Lots
Products Package Includes DDCP			
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula – Fenestrated, Size 4	4DCFN	10884522006576	All Lots
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula Fenestrated Size 4	4DCFS	10884522006583	
Covidien Shiley™ Tracheostomy Tube Cuffed with Disposable Inner Cannula – Fenestrated, Size 4,	4DFEN	10884522006606	
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula – Fenestrated, Size: 6	6DCFN	10884522006613	
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula Fenestrated Size 6	6DCFS	10884522006620	
Covidien Shiley™ Tracheostomy Tube Cuffed with Disposable Inner Cannula – Fenestrated, Size: 6	6DFEN	10884522006644	
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula – Fenestrated, Size: 8	8DCFN	10884522006651	
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula Fenestrated Size 8	8DCFS	40884522006690	
Covidien Shiley™ Tracheostomy Tube Cuffed with Disposable Inner Cannula – Fenestrated, Size: 8	8DFEN	10884522006675	
Covidien Shiley™ Tracheostomy Tube – Cuffless with Disposable Inner Cannula, Fenestrated, Size: 10	10DCFN	20884522006535	
Covidien Shiley™ Tracheostomy Tube Cuffless with Disposable Inner Cannula Fenestrated, Size 10	10DCFS	10884522006545	
Covidien Shiley™ Tracheostomy Tube – Cuffed with Disposable Inner Cannula, Fenestrated, Size: 10	10DFEN	10884522006569	

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Attachment B: Identifying impacted product

Product Number



© 2011 Covidien, Made in Mexico.
 Covidien K, 15 Hampshire Street, Mansfield, MA 02048 USA
 Covidien Ireland Limited, EA
 Bannock & Technology Park, Tullamore, 10064347 Rev A



U.S. Patents 5,361,756; 5,788,872; 5,818,736; 7,647,626
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 Covidien K, 15 Hampshire Street, Mansfield, MA 02048 USA
 Covidien Ireland Limited, EA
 Bannock & Technology Park, Tullamore, 10064347 Rev B