



Product Notification

Shiley™ flexible adult tracheostomy tube with disposable inner cannula



Dear Valued Customer,

The purpose of this letter is to notify you of updates to Shiley™ flexible adult tracheostomy tubes with disposable inner cannulas. You are receiving this letter because our records indicate you previously purchased these products.

The changes outlined below are the result of an effort to streamline manufacturing and continue to meet global regulations and standards.

Please review the updates to the Shiley™ flexible adult tracheostomy tube with disposable inner cannula:

- The product reference codes indicating a disposable inner cannula will transition from ending in H (xxCNxxH, xxUNxxH) to ending in A (xxCNxxA, xxUNxxA). There are no changes to the product reference codes for the Shiley™ flexible adult tracheostomy tube with reusable inner cannula (xxCNxxR, xxUNxxR). (Table 1)
- On the flange of the tracheostomy tube, the updated product reference code ending in A (xxCNxxA, xxUNxxA) will replace the code ending in H (xxCNxxH, xxUNxxH). (Table 2)
- The outer cannula inner diameter (I.D.) and the cuff resting diameter will now be etched onto the pilot balloon as an additional reference for clinicians. (Table 3)
- Product packaging has been updated. These updates include new product reference codes and expanded labeling. (Table 4)
- Instructions for Use (IFU) will include additional languages and expanded labeling.

The planned date of the SKU transition is September 1, 2025, at which time manufacturing of xxCNxxH and xxUNxxH will cease. However, they will remain available alongside their direct replacement xxCNxxA and xxUNxxA through December 31, 2025, or until stock is depleted. We cannot guarantee stock of xxCNxxH or xxUNxxH after September 1, but xxCNxxA and xxUNxxA should be treated as direct replacements.

Updates will not impact the clinical usage of the product. Clinicians should refer to packaged device labeling for detailed information on products, features, and design when choosing a device for patient use.

Please share this important product update with your clinical teams. We appreciate your business and look forward to continuing to support your airway product needs.

Table 1. Product reference codes associated with the Shiley™ flexible adult tracheostomy tube with disposable inner cannula

Product	Obsoleted Product Code (H Code)	Updated Product Code (A Code)	Outer Cannula Inner Diameter (O.C. I.D.) (mm)
Shiley™ Flexible Adult Tracheostomy Tube with Disposable Inner Cannula	With TaperGuard™ Cuff		
	4CN65H	4CN65A	6.5
	5CN70H	5CN70A	7.0
	6CN75H	6CN75A	7.5
	7CN80H	7CN80A	8.0
	8CN85H	8CN85A	8.5
	9CN90H	9CN90A	9.0
	10CN10H	10CN10A	10.0
	Cuffless		
	4UN65H	4UN65A	6.5
	5UN70H	5UN70A	7.0
	6UN75H	6UN75A	7.5
	7UN80H	7UN80A	8.0
	8UN85H	8UN85A	8.5
	9UN90H	9UN90A	9.0
	10UN10H	10UN10A	10.0

Table 2. Previous (H code) vs. updated product reference codes (A code) etched onto the flange

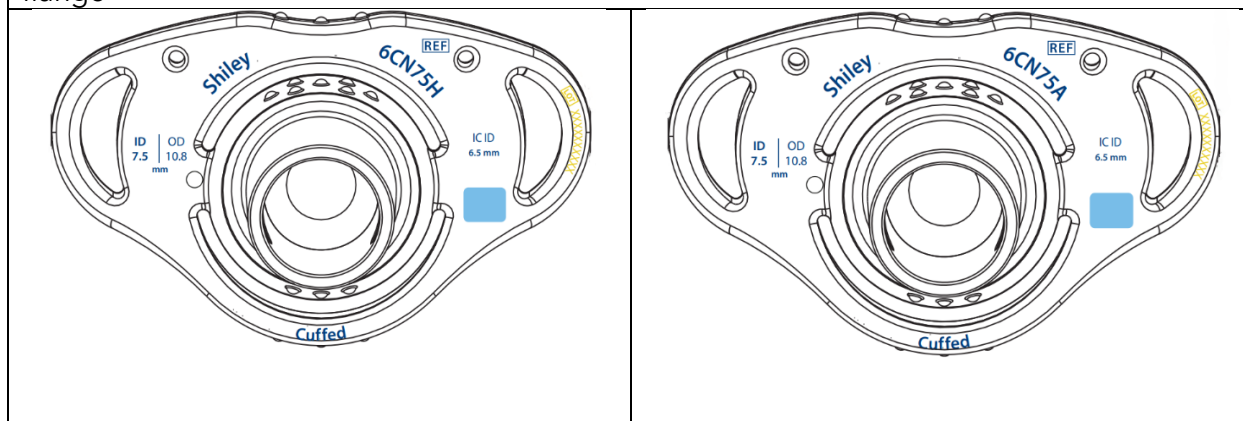


Table 3. Previous vs. updated pilot balloon, which includes the outer cannula inner diameter (I.D.) and the cuff resting diameter etched onto the pilot balloon

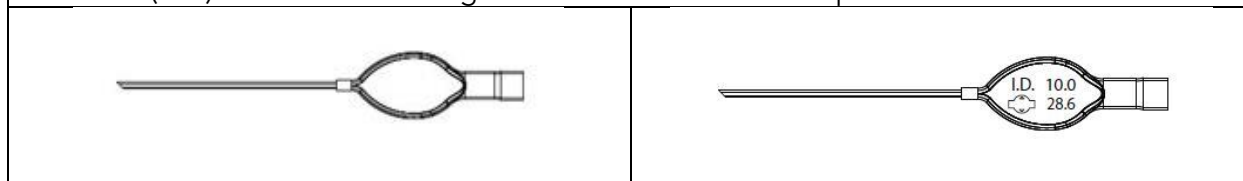
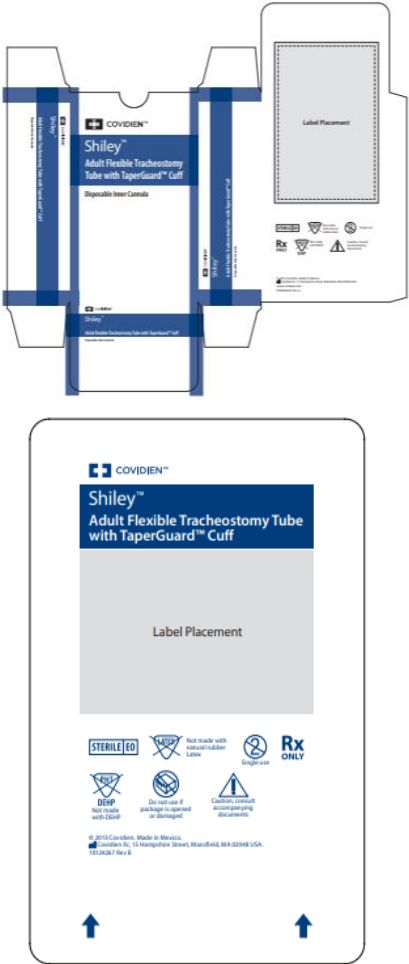


Table 4. Previous vs. updated product packaging with product references codes and more detailed labeling

 Disposable Inner Cannula 6CN75H 7.5 mm I.D. 10.8 mm O.D. 25.4 mm 74 mm 6.5 mm I.D. REF 6CN75H LOT XXXXXXXXXX Use by YYYY-MM-DD PT00090581 Rev A	 Disposable Inner Cannula 7.5 mm I.D. 10.8 mm O.D. 25.4 mm 74 mm 7.5 mm I.D. 6.5 mm I.D. REF 6CN75A LOT XXXXXXXXXX Use by YYYY-MM-DD PT00113948 Rev A
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Should you have any questions, please reach out to your local Medtronic representative.

Respectfully,

Peter Villani
U.S. Product Manager, Airway Portfolio