Medtronic

Acute Care and Monitoring

Perioperative Complications 6135 Gunbarrel Ave Boulder, CO 80301 USA

www.medtronic.com

Dear Distributor Partner,

We are contacting you as our records show that you purchased Shiley Basic Cuffed Products. After careful consideration, Medtronic has decided to discontinue future commercialization of: ShileyTM Lo Pro Murphy (860XX), ShileyTM Lo Pro Magill (860XX), and ShileyTM Hi-Lo Oral/Nasal (861XX) Endotracheal Tubes. In this letter Medtronic has provided information regarding similar products that will remain available on the market as product alternatives. These alternatives were chosen based on similar intended uses but do include design differences that should be considered when choosing the right device to meet your patients' needs. Medtronic will stop manufacturing these products effective 05/17/2025. A limited supply will be available for purchase until 06/30/2025 or while supplies last whichever occurs first.

Below individual product reference codes associated with these lines have been included for review in Table 1 - Shiley™ Lo Pro Murphy (860XX), Shiley™ Lo Pro Magill (860XX) and Shiley™ Hi-Lo Oral Nasal (861XX).

Table 1. Products to be discontinued (860XX), and (861XX)					
Proprietary Name	Product Code	Product Code	Product Code	Inner Diameter (I.D.) (mm)	
Shiley™ Lo Pro Murphy Shiley™ Lo Pro Magill Shiley™ Hi-Lo Oral/Nasal Endotracheal Tube	86043	86003	N/A	3	
	86045	86005	N/A	4	
	86046	N/A	N/A	4.5	
	86047	86007	86107	5	
	86048	N/A	86108	5.5	
	86049	86009	86109	6	
	86050	86010	86110	6.5	
	86051	86011	86111	7	
	86052	86012	86112	7.5	
	86053	86013	86113	8	
	86054	86014	86114	8.5	
	86055	86015	86115	9	
	86056	86016	N/A	9.5	
	86057	86017	86117	10	

Alternative devices from Medtronic with similar intended uses will remain available. Table 2a (860XX) and Table 2b (861XX) summarize two clinically similar Shiley™ Endotracheal Tubes. Design differences are summarized but not limited to this table. Clinicians should refer to the associated labeling with each device for a full description of the products when considering for patient use.

Table 2a. Summary of Device Use and Features between Target Device (860XX) and Potential Alternative Devices.				
Device	Shiley™ Lo Pro Portfolio (860xx)		Shiley™ Intermediate	Shiley™ TaperGuard
Intended Use	Tracheal intubation oral and nasal	Devices	Tracheal intubation oral and nasal	Tracheal intubation oral and nasal
Sizing	3.0-10.0		3.0-10.0*	5.0-10.0*
Population	Ped - Adult	Ę	Ped - Adult	Adult
Cuff	High volume, Low pressure, barrel shape	Alternative	High volume, Low pressure, barrel shape	Low volume, Low pressure, tapered shape
Murphy Eye	Dependent of tube	Available	Present	Present
Tip	Hooded tip	/ai	Hooded tip	Hooded tip
Other design features	No glottic markers; Made with DEHP	A	Glottic markers; Non- DEHP	Glottic markers; Non- DEHP

Table 2b. Summary of Device Use and Features Between Target Device (861XX) and Potential Alternative Devices.				
Device	Shiley™ Hi-Lo (861XX)		Shiley™ Intermediate	Shiley™ TaperGuard™
Intended use	Tracheal intubation, oral and nasal	Devices	Tracheal intubation, oral and nasal	Tracheal intubation, oral and nasal
Sizing	5.0-10.0	ď	3.0-10.0*	5.0-10.0*
Population	Ped - Adult	V	Ped - Adult	Adult
Cuff	High volume, low pressure, barrel shape	Alternative	High volume, low pressure, barrel shape	Low volume, low pressure, tapered shape
Murphy eye	Present	7	Present	Present
Tip	Hooded tip	P	Hooded tip	Hooded tip
Other design features	No glottic markers; made with DEHP	Available	Glottic markers; non- DEHP	Glottic markers; non- DEHP
Major market availability			CE marked; FDA cleared	CE marked; FDA cleared

Table 3 includes a full list of reference codes for the potential alternative products offered by Medtronic.

Table 3. Alternative Products for Consideration.		
Proprietary Name	Product Code	Inner Diameter (I.D.) (mm)
	86442	3.0
	86443	3.5
	86444	4.0
	86445	4.5
	86446	5.0
	86447	5.5
	86448	6.0
Shiley™ Intermediate Endotracheal Tube	86449	6.5
	86450	7.0
	86451	7.5
	86452	8.0
	86453	8.5
	86454	9.0
	86455	9.5
	86456	10.0
	18750	5.0
	18755	5.5
	18760	6.0
	18765	6.5
	18770	7.0
Shiley™ TaperGuard™ Endotracheal Tube	18775	7.5
	18780	8.0
	18785	8.5
	18790	9.0
	18795	9.5
	18710	10.0

In summary, the Shiley™ Hi-Lo and Lo Pro Endotracheal Tubes (861XX) and (860xxx) [Detailed in Table 1] are planned for discontinuation. Clinicians will continue to have a choice of available Shiley™ endotracheal tubes with similar intended use, in Table 2a/b and 3, though design features may vary. Clinicians should refer to packaged device labeling for detailed information on products, features, and design when choosing a device for patient use.

Respectfully,

Peter Villani

Senior Core Airways Product Manager, Respiratory Interventions Acute Care and Monitoring, Medtronic