

# DISCONTINUATION NOTICE

## Shiley™ Disposable and Reusable Cuffed and Cuffless Tracheostomy Tube Portfolio

Medtronic

October 13, 2020

Dear Valued Medtronic Customer:

As of September 30, 2021, Medtronic will discontinue the manufacture and distribution of the legacy Shiley™ disposable and reusable cuffed and cuffless tracheostomy tube product portfolio. You are receiving this notice because you have previously purchased these specific products. These products will be available to order through September 30, 2021 or until the supply is depleted.

These products will be replaced with the enhanced Shiley™ flexible (flex) adult tracheostomy tubes. There are multiple design enhancements with the new Shiley™ flex adult tracheostomy tube portfolio.

The Shiley™ flex adult tracheostomy tube with TaperGuard™ cuff includes:

- A flexible, transparent flange designed to conform to the patient's anatomy to help reduce the risk of skin breakdown and patient comfort.<sup>1</sup>
- Dual cannula sizing with a TaperGuard™ cuff vs. barrel-shaped cuff.
  - The TaperGuard™ cuff may help protect the lungs and reduce tracheal impact by reducing fluid leakage by 99% and exerting 18.6% less lateral wall pressure on the trachea.<sup>2</sup>
- A flexible cannula
- A beveled tip for percutaneous insertion
- An integrated, 15 mm connector

Additionally, the Shiley™ flex adult tracheostomy tube with TaperGuard™ are made of non-DEHP material.



The enhanced Shiley™ flex adult tracheostomy product portfolio offers an expanded size range as highlighted in the chart below. Please review the specifications closely when selecting a replacement product.

Discontinued SKUs		Replacement SKUs	
SKU	Name	SKU	Name
4DCT	DISP.CAN P-C 4-8.5	4CN65H	6.5MM SHILEY™ FLEX CUFFED DISP TRACH
		5CN70H	7.0MM SHILEY™ FLEX CUFFED DISP TRACH
6DCT	DISP.CAN.P-C 6-10.0	6CN75H	7.5MM SHILEY™ FLEX CUFFED DISP TRACH
		7CN80H	8.0MM SHILEY™ FLEX CUFFED DISP TRACH
8DCT	DISP.CAN. P-C 8-12.0	8CN85H	8.5MM SHILEY™ FLEX CUFFED DISP TRACH
		9CN90H	9.0MM SHILEY™ FLEX CUFFED DISP TRACH
10DCT	DISP.CAN.P-C 10-13.0	10CN10H	10.0MM SHILEY™ FLEX CUFFED DISP TRACH
6PERC	PERCUTANEOUS TRACH.TUBE 6	6CN75H	7.5MM SHILEY™ FLEX CUFFED DISP TRACH
8PERC	PERCUTANEOUS TRACH.TUBE 8	8CN85H	8.5MM SHILEY™ FLEX CUFFED DISP TRACH
4DCFS	DISP.CAN. W/O CUF 4-8.5	4UN65H	6.5MM SHILEY™ FLEX CUFFLESS DISP TRACH
		5UN70H	7.0MM SHILEY™ FLEX CUFFLESS DISPTRACH
6DCFS	DISP.CAN W/O CUF 6-10.0	6UN75H	7.5MM SHILEY™ FLEX CUFFLESS DISP TRACH
		7UN80H	8.0MM SHILEY™ FLEX CUFFLESS DISP TRACH
8DCFS	DISP.CAN W/O CUF 8-12.0	8UN85H	8.5MM SHILEY™ FLEX CUFFLESS DISP TRACH
		9UN90H	9.0MM SHILEY™ FLEX CUFFLESS DISP TRACH
10DCFS	DISP.CAN W/O CUF 8-12.0	10UN10H	10.0MM SHILEY™ FLEX CUFFLESS DISP TRACH
4CFS	TRACHEO W/O CUFF 4-8.5	4UN65R	6.5MM SHILEY™ FLEX CUFFLESS REUS TRACH
		5UN70R	7.0MM SHILEY™ FLEX CUFFLESS REUS TRACH
6CFS	TRACHEO W/O CUFF 6-10.0	6UN75R	7.5MM SHILEY™ FLEX CUFFLESS REUS TRACH
		7UN80R	8.0MM SHILEY™ FLEX CUFFLESS REUS TRACH
8CFS	TRACHEO W/O CUFF 8-12.0	8UN85R	8.5MM SHILEY™ FLEX CUFFLESS REUS TRACH
		9UN90R	9.0MM SHILEY™ FLEX CUFFLESS REUS TRACH
10CFS	TRACHEO W/O CUFF 10-13.0	10UN10R	10.0MM SHILEY™ FLEX CUFFLESS REUS TRACH
4LPC	LOW PRESSURE CUFFED 4-8.5	4CN65R	6.5MM SHILEY™ FLEX CUFFED REUS TRACH
		5CN70R	7.0 MM SHILEY™ FLEX CUFFED REUS TRACH
6LPC	LOW PRESSURE CUFFED 6-10.0	6CN75R	7.5MM SHILEY™ FLEX CUFFED REUS TRACH
		7CN80R	8.0MM SHILEY™ FLEX CUFFED REUS TRACH
8LPC	LOW PRESSURE CUFFED 8-12.0	8CN85R	8.5MM S SHILEY™ FLEX CUFFED REUS TRACH
		9CN90R	9.0MM SHILEY™ FLEX CUFFED REUS TRACH
10LPC	LOW PRESSURE CUFFED 10-13.0	10CN10R	10.0MM SHILEY™ FLEX CUFFED REUS TRACH

Inner cannulas for the disposable tracheostomy lines will require the below transition to the new Shiley™ flex inner cannula:

Legacy IC		Replacement SKUs	
SKU	Name	SKU	Name
4DIC	DISP. INNER CAN 4 BX10	4IC65	6.5MM TRACH DISPBLE INNER CANN
		5IC70	7.0MM TRACH DISPBLE INNER CANN
6DIC	DISP. INNER CAN. 6 BX10	6IC75	7.5MM TRACH DISPBLE INNER CANN
		7IC80	8.0MM TRACH DISPBLE INNER CANN
8DIC	DISP. INNER CAN. 8 BX10	8IC85	8.5MM TRACH DISPBLE INNER CANN
		9IC90	9.0MM TRACH DISPBLE INNER CANN
10DIC	DISP. INNER CAN. 10 BX10	10IC10	10.0MM TRACH DISPBL INNER CANN

To provide optimal sizing for our customers, you will find specifications related to I.D., O.D., length, and cuff resting diameter in the table below:

#### Discontinued SKUs

SKU	I.D.(MM)	O.D.(MM)	LENGTH (MM)	CUFF Ø (MM)
4DCT	5.0	9.4	62.0	20.0
6DCT	6.4	10.8	74.0	24.0
8DCT	7.6	12.2	79.0	27.0
10DCT	8.9	13.8	79.0	29.0
6PERC	6.4	10.8	74.0	24.1
8PERC	7.6	12.2	79.0	27.2
4DCFS	5.0	9.4	62.0	N/A
6DCFS	6.4	10.8	74.0	N/A
8DCFS	7.6	12.2	79.0	N/A
10DCFS	8.9	13.8	79.0	N/A
4CFS	5.0	9.4	65.0	N/A
6CFS	6.4	10.8	76.0	N/A
8CFS	7.6	12.2	81.0	N/A
10CFS	8.9	13.8	81.0	N/A
4LPC	5.0	9.4	65.0	20.0
6LPC	6.4	10.8	76.0	24.0
8LPC	7.6	12.2	81.0	27.0
10LPC	8.9	13.8	81.0	29.0

#### Replacements SKUs

SKU	I.D.(MM)	O.D.(MM)	LENGTH (MM)	CUFF Ø (MM)
4CN65H	6.5	9.4	62.0	20.6
5CN70H	7.0	10.1	68.0	23.0
6CN75H	7.5	10.8	74.0	25.4
7CN80H	8.0	11.4	77.0	25.4
8CN85H	8.5	12.2	79.0	26.6
9CN90H	9.0	12.7	79.0	27.6
10CN10H	10.0	13.8	79.0	28.6
6CN75R	7.5	10.8	74.0	25.4
8CN85R	8.5	12.2	79.0	26.6
4UN65H	6.5	9.4	62.0	N/A
5UN70H	7.0	10.1	68.0	N/A
6UN75H	7.5	10.8	74.0	N/A
7UN80H	8.0	11.4	77.0	N/A
8UN85H	8.5	12.2	79.0	N/A
9UN90H	9.0	12.7	79.0	N/A
10UN10H	10.0	13.8	79.0	N/A
4UN65R	6.5	9.4	62.0	N/A
5UN70R	7.0	10.1	68.0	N/A
6UN75R	7.5	10.8	74.0	N/A
7UN80R	8.0	11.4	77.0	N/A
8UN85R	8.5	12.2	79.0	N/A
9UN90R	9.0	12.7	79.0	N/A
10UN10R	10.0	13.8	79.0	N/A
4CN65R	6.5	9.4	62.0	20.6
5CN70R	7.0	10.1	68.0	23.0
6CN75R	7.5	10.8	74.0	25.4
7CN80R	8.0	11.4	77.0	25.4
8CN85R	8.5	12.2	79.0	26.6
9CN90R	9.0	12.7	79.0	27.6
10CN10R	10.0	13.8	79.0	28.6

For more information and a complete overview of the Shiley™ airways portfolio, please contact your local Medtronic airway sales representative.

Thank you for your continued business.

Sincerely,



Abigail Scaggs  
Global Product Manager  
Respiratory Interventions – ETT & Tracheostomy

1. Dixon LM, Mascioli S, Mixell JH, Gillin T, Upchurch CN, Bradley KM. Reducing Tracheostomy-Related Pressure Injuries. AACN Advanced Critical Care. 2018;29(4):426-431. doi:10.4037/aacnacc2018426.

2. Internal benchtop testing results. Results reflect the Shiley™ flexible adult tracheostomy tube with TaperGuard™ cuff, disposable inner cannula tubes ability to titrate / control ventilator air leak in comparison to the Shiley™ tracheostomy tube cuffed with disposable inner cannula (DCT). Benchtop test # 10122514.