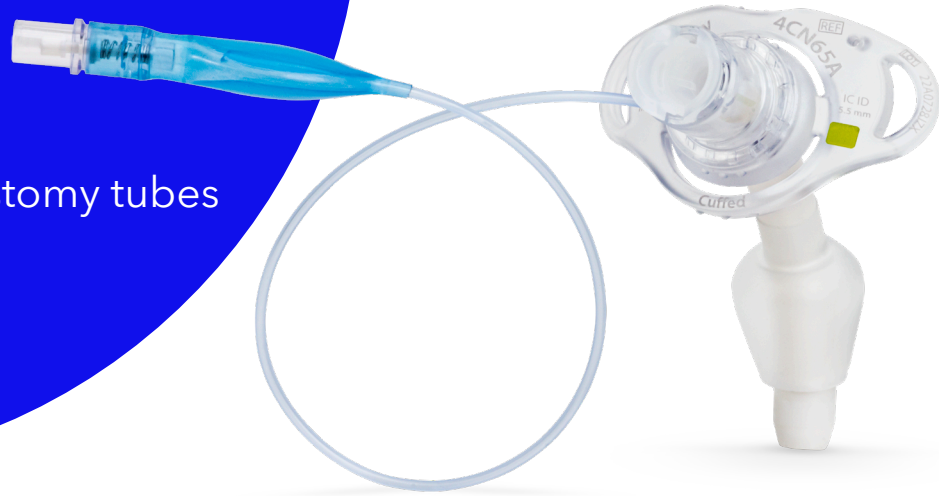


Medtronic

Sizing guide

Shiley™ flexible adult tracheostomy tubes with TaperGuard™ cuff‡



As healthcare evolves, so should the technology and design of products.

Our Shiley™ flexible (flex) adult tracheostomy tube portfolio has several beneficial design advancements compared to the legacy† product design.

One key change is the cuff. Cuffs play an important role in sealing the airway for positive-pressure ventilation and protecting against micro-aspiration.¹ The TaperGuard™ cuff on the Shiley™ flex product portfolio improves patient safety by surpassing the performance of the barrel-shaped cuff on our legacy Shiley™ tracheostomy devices in both fluid leakage and protection from mucosal injury.^{2,3}



Shiley™ DCT tracheostomy tube standard cuff† (legacy product)



Shiley™ flexible adult tracheostomy tube with TaperGuard™ cuff§

† Licensed as Shiley Disposable Cannula Tracheostomy Tube.

‡ Licensed as Shiley Adult Flexible Tracheostomy Tube Cuffless Reusable Inner Cannula, Shiley Adult Flexible Tracheostomy Tube with TaperGuard Cuff Reusable Inner Cannula, Shiley Adult Flexible Evac Tracheostomy Tube with TaperGuard Cuff, Shiley Adult Flexible Tracheostomy Tube XLT.

§ Licensed as Shiley Tracheostomy Tube with TaperGuard, Shiley Adult Flexible Tracheostomy Tube with TaperGuard Cuff Reusable Inner Cannula.

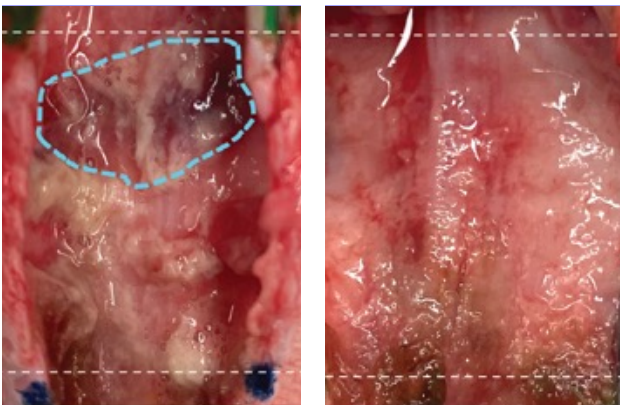
Benefits worth the change

The TaperGuard™ cuff on our Shiley™ flex tracheostomy tubes has a unique tapered shape, designed to create a sealing band along the tracheal wall and minimize wrinkles created by the excess material in a standard cuff.

The micro-channels created by wrinkles allow fluid to leak past the cuff, known as microaspiration. The TaperGuard™ cuff has demonstrated **significantly less leakage**,² compared to the bulky cuff on the legacy Shiley™ DCT tracheostomy tube.

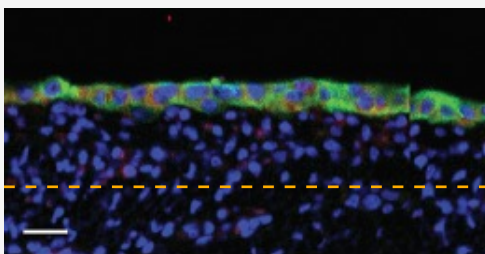
The TaperGuard™ cuff also reduces high pressure points that are found in standard cuffs through the sealing band. This creates more evenly distributed pressure on the mucosal surface. A swine model comparing Shiley™ flex† and Shiley™ DCT tracheostomy tubes found that after 24 and 48 hours, those with the Shiley™ flex tracheostomy tubes **had significantly less mucosal injury and inflammation** compared to the Shiley™ DCT tubes.³

Finally, without the extra bulk, there is **decreased force required for insertion**,² which may result in less trauma at the stoma site.

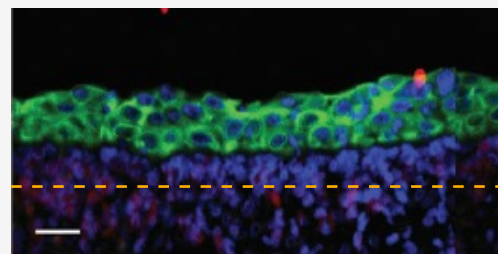


Gross tracheal specimen mucosa after tracheostomy with Shiley™ DCT (left) and Shiley™ flex (right)†. The blue line marks edematous tissue in the left image.³

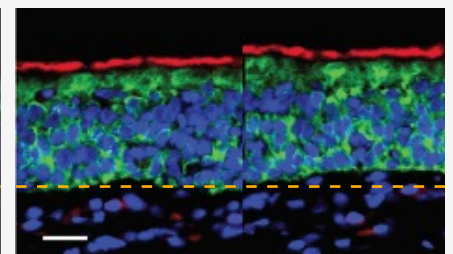
Images comparing epithelial thickness. The yellow dotted line is included for comparison across samples.



Shiley™ DCT at 48 hours after insertion



Shiley™ flex at 48 hours after insertion



Control sample

Impact to clinical practice

The Shiley™ flex tracheostomy tube portfolio maintains similar inner and outer diameter dimensions compared to the legacy product, while adding additional sizing options to offer more choice to clinicians.

The benefits of the unique TaperGuard™ cuff come from the precise fit of the sealing band.

Though the cuff resting diameter (CRD) – the maximum diameter of the cuff – is similar between portfolios, the tapered fit may require additional clinical consideration to ensure a proper seal within safe cuff pressure ranges (~25 cmH₂O).

Considerations for sizing the Shiley™ flex tracheostomy tube.

Feedback from clinicians successful in Shiley™ flex conversion

- A more precise fit without the extra bulky material may warrant an upsizing from traditional size selections. Incremental increases in ID/OD/CRD are now available with our extended size options.
- Airway edema at the insertion point may impact the tracheal diameter. Consider opting for a larger size at insertion to accommodate an expected increase in tracheal diameter after edema subsides.

Shiley™ flexible tracheostomy tubes				Shiley™ DCT tracheostomy tube			
CFN	ID	OD	CRD	CFN	ID	OD	CRD
4CN65X	5.5	9.4	20.6	4DCT	5.0	9.4	20.0
5CN70X	6.0	10.1	23.0				
6CN75X	6.5	10.8	25.4	6DCT	6.4	10.8	24.0
7CN80X	7.0	11.4	25.4				
8CN85X	7.5	12.2	26.6	8DCT	7.6	12.2	27.0
9CN95X	8.0	12.7	27.6				
10CN10	9.0	13.8	28.6	10DCT	8.9	13.8	29.0

For use by tracheostomy care personnel. The tracheostomy tube and obturator are sterile, single-use patient medical devices not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. Duration of use should not exceed twenty-nine (29) days. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

† Legacy Shiley™ tracheostomy tubes refers to Shiley™ DCT†, DCF5‡, DCFN§, DFEN¶, LPC¶, CFS#, CFN#, FEN# and Perc^Δ tracheostomy tubes.

‡ Licensed as Shiley Disposable Cannula Tracheostomy Tube.

§ Licensed as Shiley Tracheostomy Tube Cuffless with Disposable Inner Cannula.

¶ Licensed as Shiley Disposable Cannula Tracheostomy Tube.

Licensed as Shiley Tracheostomy Tube Cuffed with Inner Cannula.

Licensed as Shiley Laryngectomy Tube.

Δ Licensed as Shiley Percutaneous Tracheostomy Tube with Disposable Inner Cannula.

1. Spiegel, Joan. Endotracheal tube cuffs design and function. *Anesthesiology News*. 2010.
2. Maguire et al (2015). An invitro comparison of tracheostomy tube cuffs. *Medical Devices: Evidence and Research*
3. Berges et al (2022). Impact of low volume, low pressure tracheostomy cuffs on acute mucosal injury in swine. *Am Academy of Otolaryngology Head and Neck Surgery*. DOI: 10.1177/01945998221119160

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