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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 077790 0060 Rev. 00

Manufacturer:

Covidien LLC

15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): Oximetry and Capnography Monitor Systems
Temperature Monitor Systems, Patient Warming
Device Systems, Disposable Airway Management
Devices, Tracheal Tubes, Tracheostomy Tubes,
Speaking Valves, and Intubating Stylets, Ventilator
Systems and Patient Interface Circuit Systems,
EEG Monitoring Systems, Breathing Therapy and
Humidification, Heated Inspiratory Line
Humidifiers, Multi-patient Physiologic Monitoring
System and Data Analytics Software,
Gastrointestinal Measurement and Dilation System,
Electrosurgical Diathermy System Electrode.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

72145607

Valid from:

2020-06-29

Valid until:

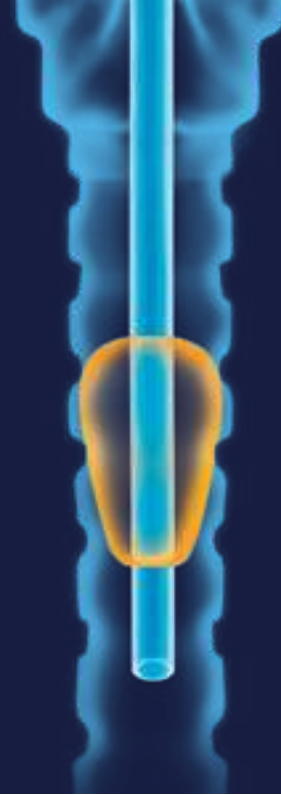
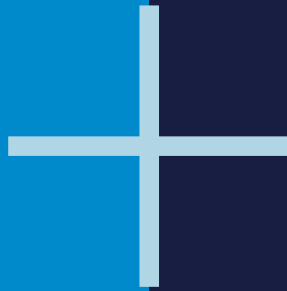
2024-05-26

Date,

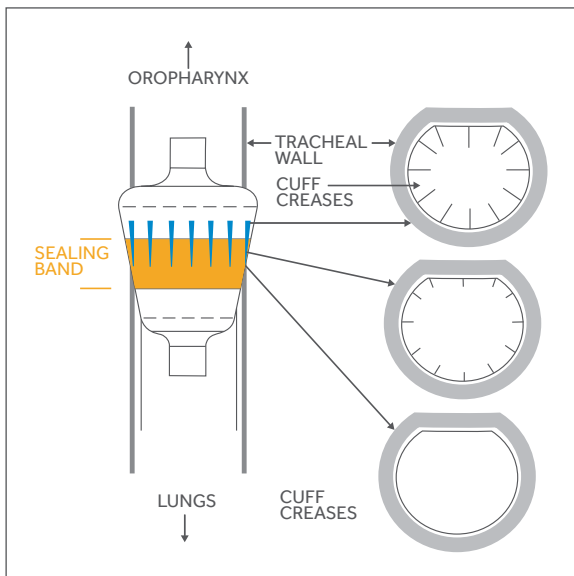
2020-06-29

Christoph Dicks
Head of Certification/Notified Body

CONFIDENCE FOR YOU. BENEFITS FOR PATIENTS.



Shiley™ Evac Endotracheal Tube with TaperGuard™ Cuff



Shiley™ Evac with
TaperGuard™ Cuff



Shiley™ Tracheal Tube
with Hi-Lo™ Cuff

The Shiley™ evac endotracheal tube incorporates the TaperGuard™ cuff, which reduces the risk of microaspiration¹ and ventilator associated pneumonia (VAP) by combining the TaperGuard™ cuff technology and the integrated subglottic secretion drainage port.²

The TaperGuard™ cuff significantly improves tracheal seal

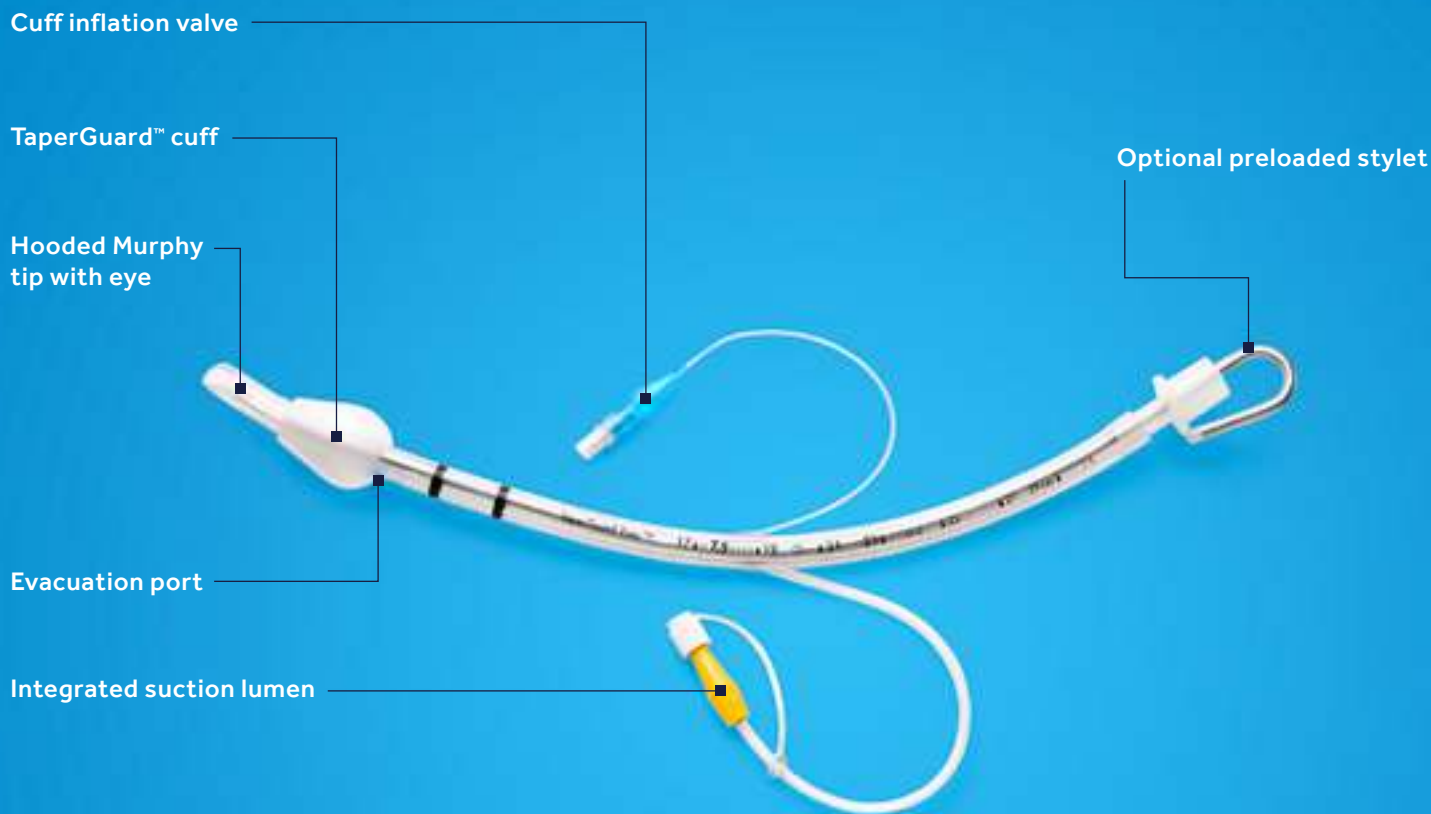
Compared to the Shiley™ endotracheal tube with Hi-Lo™ barrel-shaped cuff.¹

The tapered shape reduces microaspiration by an average of 90%¹

Compared to the Shiley™ endotracheal tube with Hi-Lo™ barrel-shaped cuff.¹ This may reduce the risk of pulmonary complications associated with microaspiration.¹

Getting the pressure right

Taper-shaped cuffs can both enhance fit and reduce pressure on the trachea.^{3, 4}



UNIQUE DESIGN. UNIVERSAL SEAL.

The Shiley™ evac tube with TaperGuard™ cuff contains the latest generation of Shiley™ technology, which has been shown — when used in conjunction with a VAP bundle — to significantly reduce the incidence of VAP⁵.

The Shiley™ evac endotracheal tube with TaperGuard™ cuff

I.D. (MM)	O.D. (MM)	PRODUCT CODES	WITH OPTIONAL STYLET
6.0	9.0	18860	18860S
6.5	9.8	18865	18865S
7.0	10.4	18870	18870S
7.5	11.2	18875	18875S
8.0	11.8	18880	18880S
8.5	12.6	18885	18885S
9.0	13.1	18890	18890S

1. Based upon internal test report #100033000, TaperGuard™ Seal Performance Summary Report, Feb 2009.
2. Pérez Granda MJ, Barrio JM, Hortal J, Muñoz P, Rincón C, Bouza E. Routine aspiration of subglottic secretions after major heart surgery: impact on the incidence of ventilator-associated pneumonia. *J Hosp Infect.* 2013;85(4):312-315.
3. Li Bassi G, Ranzani OT, Marti JD, et al. An in vitro study to assess determinant features associated with fluid sealing in the design of endotracheal tube cuffs and exerted tracheal pressures. *Crit Care Med.* 2013;41:518-526.
4. Lichtenthal PR, Wood L, Wong A, Borg U. Pressure applied to tracheal wall by barrel and taper shaped cuffs. Paper presented at: Anesthesiology 2011 American Society of Anesthesiologists Annual Meeting; October 15-19, 2011; Chicago, IL. <http://www.asaabstracts.com/strands/asaabstracts/abstract.htm?sessionid=53EABF8A93F80BAFCB5D4879AF65C145?year=2011&index=8&absnum=5240>
5. Mahmoodpoor A, Hamishehkar H, Hamidi M, et al. A prospective randomized trial of tapered-cuff endotracheal tubes with intermittent subglottic suctioning in preventing ventilator-associated pneumonia in critically ill patients. *J Crit Care.* 2017;38:152-156.

Medtronic



Use scan app to read

For more information, please visit
medtronic.eu/product-catalog

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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Intubating Stylet

FEATURES AND BENEFITS:

- Malleable aluminium with a smooth plastic sheath assists in tracheal intubation under difficult circumstances.
- Soft distal tip to reduce the possibility of intubation damage.
- Special surface for easier introduction and removal of the stylet.
- Packed clean, for single use only.
- Also available sterile.

ORDERING INFORMATION:

REF	Recommended tube I.D. (mm)	Length (mm)	
SATIN SLIP			
Intubating stylet clean packed			
116-06	2.5 to 4.5	280	PED
116-10	4.0 to 6.0	350	
116-14	> 5.0	350	
Intubating stylet sterile, single packed			
116-06-S	2.5 to 4.5	280	PED
116-10-S	4.0 to 6.0	350	
116-14-S	> 5.0	350	

Carton Quantity: 10

Tracheal Tube Restraint

FEATURES AND BENEFITS:

- Stabilises orally and nasally intubated tracheal tubes without adhesive tape.
- One size fits all tracheal tubes.
- Made from Velfoam™* to reduce skin irritation.
- Laminated with Velcro™* for easy and rapid adjustment.
- Packed clean, for single use only.

ORDERING INFORMATION:

REF tracheal tube restraint	Length (mm)
330	700

Carton Quantity: 25

