

Medtronic

Clinical Evidence Guide

Your partner in reducing ventilator-associated pneumonia

Shiley™ Evac Oral Endotracheal Tube with TaperGuard™ Cuff Technology

Shiley™ Flexible Tracheostomy Tube with Evac Technology

Globally, ventilator-associated pneumonia (VAP) occurs in 15.6% of patients who are mechanically ventilated.¹ Routine use of Shiley™ evac technology has been shown to reduce the risk of VAP by 44%.² Similarly, TaperGuard™ cuff technology has been shown to improve sealing, reduce pressure on the trachea, and decrease microaspiration.³⁻⁸ Together, Shiley™ endotracheal and tracheostomy tubes with evac technology and TaperGuard™ cuff technology can reduce the risk of VAP by reducing the silent aspiration of oral and/or gastric secretions that promote the development of VAP.^{2,6}



Ventilator-associated Pneumonia (VAP)

Background

Definition²	Hospital-acquired pneumonia developed in intubated patients receiving mechanical ventilation for ≥ 48 hours.	
Prevalence¹	Globally: 15.6%	United States: 13.5% Europe: 19.4% LATAM: 13.8% APAC: 16.0%
COVID-19⁹	COVID-19 patients may have a higher risk of developing VAP (OR = 3.24, 95% CI: 2.2 to 4.7, P = 0.015).	
Patient Consequences¹⁰	<ul style="list-style-type: none">• Longer mean (\pm SD) durations of mechanical ventilation (28.8 ± 25.0 vs 10.3 ± 10.5 days, P < 0.0001)• Higher mean cost of hospitalization (\$99,598 vs \$59,770, P < 0.0001)	
Current Strategies	Care bundles to reduce the incidence of VAP infections have been studied and documented, yet the burden continues. <i>"VAP prevention bundles, including the utilization of endotracheal tube secretion drainage (ETT-SD), monitoring cuff pressure, and oral care with chlorhexidine were efficient in reducing the rate of VAP."¹¹</i>	

Review the evidence of benefits associated with Shiley™ evac technology

Background

- ▶ [Ventilator-associated pneumonia \(VAP\)](#)
- ▶ [Shiley™ technology](#)

SSD Meta-analysis

- ▶ [Pozuelo-Carrascosa et al.](#)

TPG Evac

- ▶ [Nam et al.](#)

QI Program Summary

- ▶ [Weston Smith et al.](#)

Shiley™ Evac Endotracheal & Tracheostomy Tubes with TaperGuard™ Cuff

Technologies to Help Reduce VAP RISK

TaperGuard™ Cuff Technology

The TaperGuard™ cuff has an elongation of the cuff that gives a greater seal between cuff and trachea with documented benefits including:

- Low-volume, low-pressure tapered cuffs have **significantly lower cuff pressure** vs high-volume, low-pressure cuffs,³ and have **significantly lower cuff pressure changes with positional changes** in the head and neck.⁴
- Tapered cuffs show **improved sealing** and **less microaspiration** with 0% patients experiencing leakage into the trachea, whereas traditional cuffs had dye leakage in 20-40% of patients.^{5,6}
- Tapered cuffs have a **40% lower insertion force** than cylindrical-shaped cuffs and have a **significantly lower average pressure exerted on the lateral wall of the trachea**.⁷
- Tapered cuffs have a **significantly lower incidence of sore throat** (32% vs 54%, RR = 0.60, 95% CI: 0.43 - 0.85; P = 0.003).⁸

Shiley™ Evac Technology

Subglottic secretion drainage (SSD) helps **remove oral and/or gastric secretions** from above the endotracheal tube cuff before they can be aspirated.

- SSD usage results in a **44% reduction in risk for VAP²**

Guidelines that support SSD usage:

- SHEA Guidelines¹²
- American Thoracic Society/ Infectious Diseases Society of America (ATS/IDSA) - Level I¹³
- Centers for Disease Control (CDC) - Category II¹⁴
- American Association of Critical Care Nurses (AACN)¹⁵
- Agency for Healthcare Research and Quality (AHRQ)¹⁶
- Difficult Airway Society/Royal College of Anaesthetists^{17,18}

Review the evidence of benefits associated with Shiley™ evac technology

Background

- ▶ [Ventilator-associated pneumonia \(VAP\)](#)
- ▶ [Shiley™ technology](#)

SSD Meta-analysis

- ▶ [Pozuelo-Carrascosa et al.](#)

TPG Evac

- ▶ [Nam et al.](#)

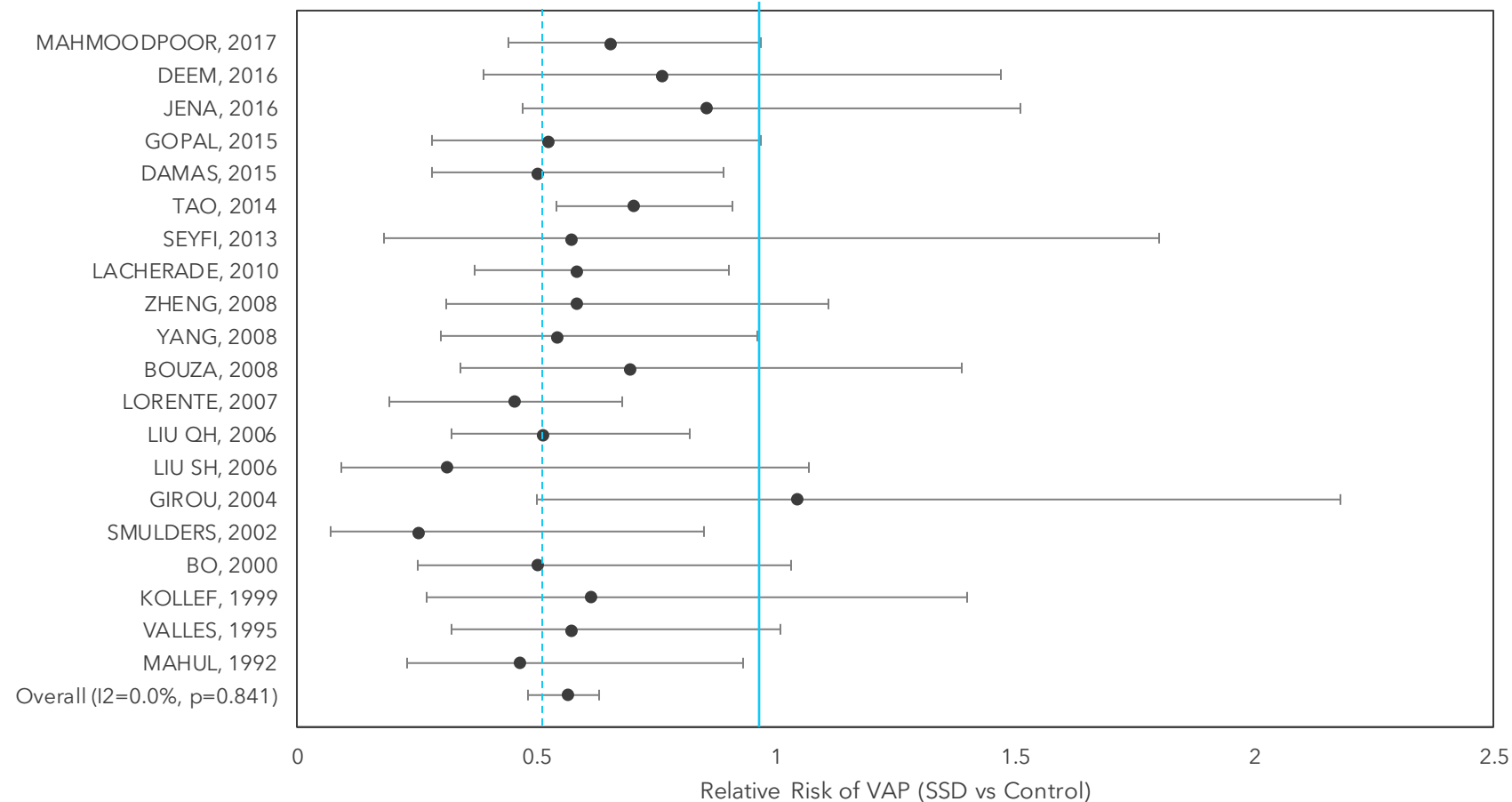
QI Program Summary

- ▶ [Weston Smith et al.](#)

Subglottic secretion drainage for preventing ventilator-associated pneumonia: an overview of systematic reviews and an updated meta-analysis

European Respiratory Review. Mar 2020, 29 (155) 190107; DOI: 10.1183/16000617.0107-2019

Adapted from Pozuelo-Carrascosa, Figure 2



Review the evidence of benefits associated with Shiley™ evac technology

Background

- ▶ [Ventilator-associated pneumonia \(VAP\)](#)
- ▶ [Shiley™ technology](#)

SSD Meta-analysis

- ▶ [Pozuelo-Carrascosa et al.](#)

TPG Evac

- ▶ [Nam et al.](#)

QI Program Summary

- ▶ [Weston Smith et al.](#)

Study information

Study design International, systematic review and meta-analysis

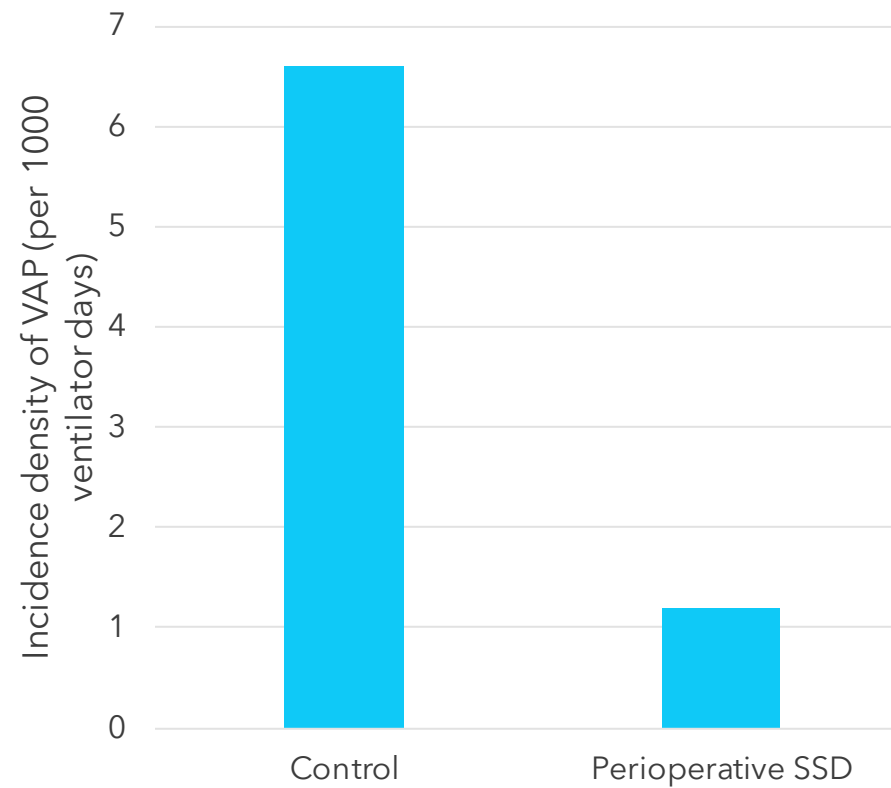
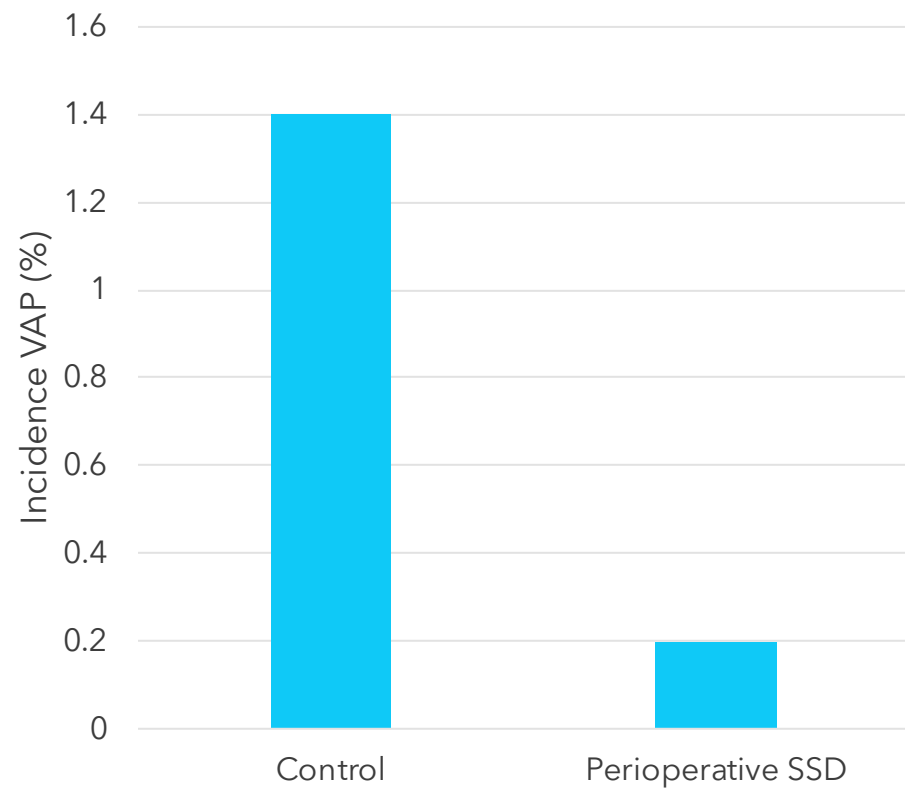
- Methods**
- 20 RCT were identified from 1992 to 2017 that included 3684 adults that received mechanical ventilation and admitted to ICU
 - Primary outcome was VAP incidence with or without subglottic secretion draining (SSD).

- Results**
- SSD significantly reduced VAP incidence (RR: 0.56, 95% CI: 0.48 - 0.63; I²=0%, p = 0.841) when pooled across all RCT.
 - SSD significantly reduced mortality in patients with VAP (RR: 0.88, 95% CI: 0.80 - 0.97; I²=0%; p = 0.888).

Nam K, Park JB, Park WB, et al.

Effect of Perioperative Subglottic Secretion Drainage on Ventilator-Associated Pneumonia After Cardiac Surgery: A Retrospective, Before-and-After Study.

J Cardiothorac Vasc Anesth. 2021;35(8):2377-2384. doi:10.1053/j.jvca.2020.09.126



Study information

Study design Single-center, retrospective, before-and-after, cohort

- Methods**
- 2,576 adult cardiac surgery patients from Jan 2013 to dec 2018 were assessed.
 - Routine use of subglottic secretion drainage (SSD) during surgery began in dec 2017 (interventional group, n = 468)
 - Risk of VAP was primary outcome

- Results**
- Risk of VAP after cardiac surgery was significantly lower in patients with perioperative SSD (adjusted OR= 0.29; 95% CI: 0.14 - 0.5; p < 0.001)
 - Duration of mechanical ventilation, rates of reintubation, tracheostomy, and all-cause in-hospital mortality were similar between groups

Review the evidence of benefits associated with Shiley™ evac technology

Background

- ▶ [Ventilator-associated pneumonia \(VAP\)](#)
- ▶ [Shiley™ technology](#)

SSD Meta-analysis

- ▶ [Pozuelo-Carrascosa et al.](#)

TPG Evac

- ▶ [Nam et al.](#)

QI Program Summary

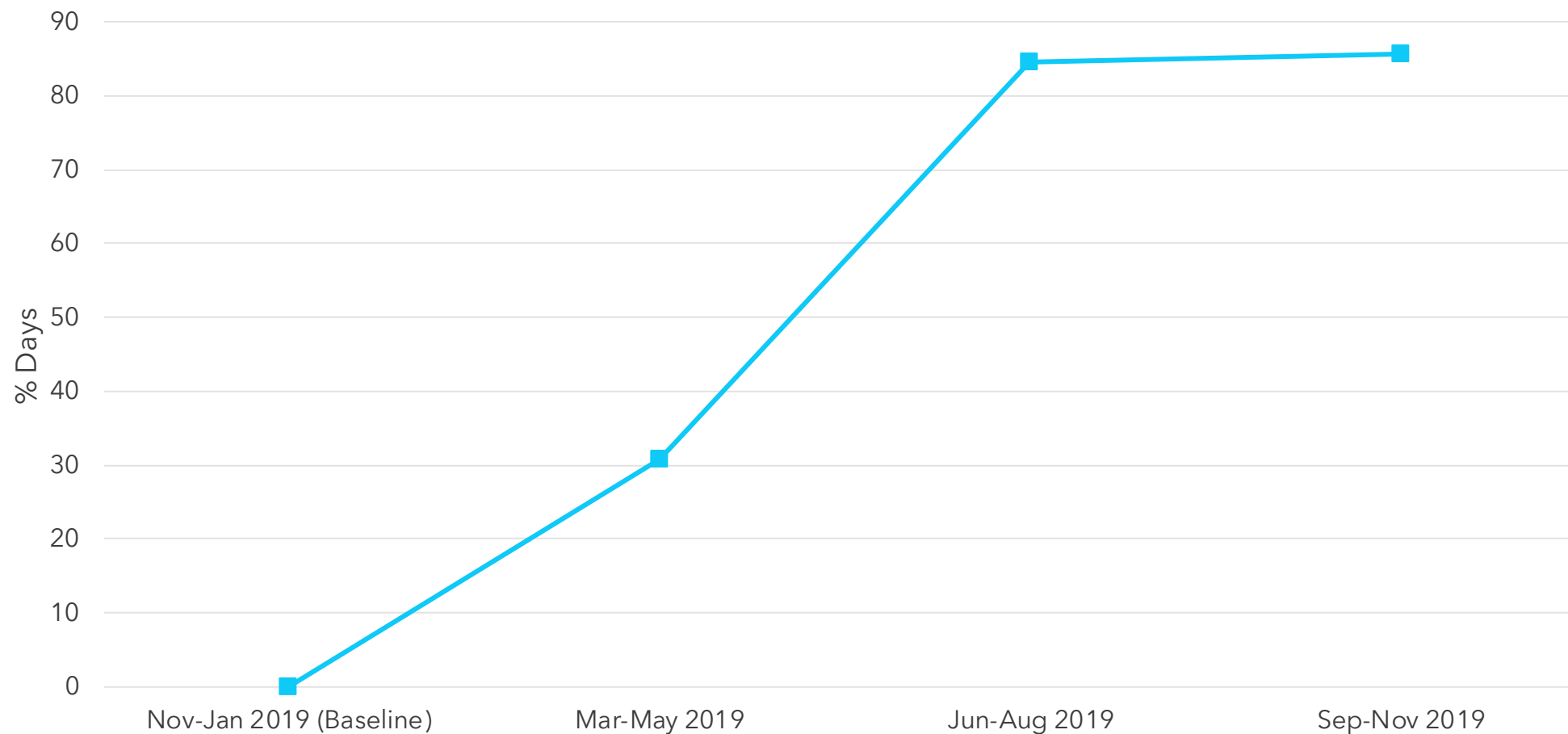
- ▶ [Weston Smith et al.](#)

Weston Smith N, Spivey M.

Promoting subglottic secretion drainage: a quality improvement project in a UK critical care unit.

BMJ Open Qual. May 2021;10(2)doi:10.1136/bmjopen-2020-001269

A Run Chart Displaying the Percentage of Days on which Regular SSD Occurred



Study information

Study design Quality improvement, Plan-Do-Study-Act methodology

- Methods**
- Subglottic secretion drainage (SSD) was prescribed every 6 hours within the clinical information system incorporated into tracheostomy care bundle
 - 24 patients were included that accumulated 353 ventilator days

- Results**
- At baseline, there was no documented evidence of SSD use
 - By implementing the care bundle, over the next 6 months there was a marked increase in SSD use

Review the evidence of benefits associated with Shiley™ evac technology

Background

- [Ventilator-associated pneumonia \(VAP\)](#)
- [Shiley™ technology](#)

SSD Meta-analysis

- [Pozuelo-Carrascosa et al.](#)

TPG Evac

- [Nam et al.](#)

QI Program Summary

- [Weston Smith et al.](#)

References

1. Kollef, M. Ventilator-associated Pneumonia Prevention. Is it Worth It? *AJRCCM*. Vol 192. Jul 1, 2015
2. Pozuelo-Carrascosa DP, et al Subglottic secretion drainage for preventing ventilator-associated pneumonia: an overview of systematic reviews and an updated meta-analysis. *European Respiratory Review*. Mar 2020, 29 (155) 190107; DOI: 10.1183/16000617.0107-2019
3. Tsuboi S, Miyashita T, Yamaguchi Y, Yamamoto Y, Sakamaki K, Goto T. The TaperGuard™ endotracheal tube intracuff pressure increase is less than that of the Hi-Lo™ tube during nitrous oxide exposure: a model trachea study. *Anesth Analg*. 2013;116(3):609-612. doi:10.1213/ANE.0b013e318279b399
4. Komasa N, Mihara R, Imagawa K, Hattori K, Minami T. Comparison of Pressure Changes by Head and Neck Position between High-Volume Low-Pressure and Taper-Shaped Cuffs: A Randomized Controlled Trial. *Biomed Res Int*. 2015;2015:386080. doi:10.1155/2015/386080
5. D'Haese J, De Keukeleire T, Remory I, Van Rompaey K, Umbra in V, Poelaert J. Assessment of intraoperative microaspiration: does a modified cuff shape improve sealing?. *Acta Anaesthesiol Scand*. 2013;57(7):873-880. doi:10.1111/aas.12119
6. Gaszyńska E, Ratajczyk P, Wiecek A, Sze wczyk T, Gaszyński T. Comparison of microaspiration around TaperGuard tube cuffs and standard tracheal tubes in obese patients subjected to surgery under general anesthesia. *Pol Przegl Chir*. 2014;86(3):107-110. doi:10.2478/pjs-2014-0020
7. Maguire S, Haury F, Jew K. An in vitro comparison of tracheostomy tube cuffs. *Med Devices (Auckl)*. 2015;8:185-192. Published 2015 Apr 21. doi:10.2147/MDER.S76960
8. Chang JE, Kim H, Han SH, Lee JM, Ji S, Hwang JY. Effect of Endotracheal Tube Cuff Shape on Postoperative Sore Throat After Endotracheal Intubation. *Anesth Analg*. 2017;125(4):1240-1245. doi:10.1213/ANE.0000000000001933
9. Ippolito M, Misseri G, Catalisano G, et al. Ventilator-Associated Pneumonia in Patients with COVID-19: A Systematic Review and Meta-Analysis. *Antibiotics (Basel)*. 2021;10(5):545. Published 2021 May 7. doi:10.3390/antibiotics10050545
10. Kollef MH, Hamilton CW, Ernst FR. Economic impact of ventilator-associated pneumonia in a large matched cohort. *Infect Control Hosp Epidemiol* 2012; 33: 250–256.
11. Akdogan O, Ersoy Y, Kuzucu C, Gedik E, Tugal T, Yetkin F. Assessment of the effectiveness of a ventilator associated pneumonia prevention bundle that contains endotracheal tube with subglottic drainage and cuff pressure monitorization. *The Brazilian Journal Of Infectious Diseases: An Official Publication Of The Brazilian Society Of Infectious Diseases [serial online]*. May 2017;21(3):276-281.
12. Klompas M, Branson R, Eichenwald EC, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals: 2014 update. *Infect Control Hosp Epidemiol*. 2014;35 Suppl 2:S133-S154.
13. American Thoracic Society; Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. *Am J Respir Crit Care Med*. 2005;171: 388-416.
14. Tablan OC, Anderson LJ, Besser R, Bridges C, Hajjeh R; CDC; Healthcare Infection Control Practices Advisory Committee. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *MMWR Recomm Rep*. 2004;53(RR-3):1-36.
15. American Association of Critical-Care Nurses (AACN) practice alert: ventilator associated pneumonia. AACN Website. http://www.aacn.org/Wd/Practice/Docs/PracticeAlerts/Ventilator_Associated_Pneumonia_1-2008.pdf. Published 2008.
16. Shojaania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: a critical analysis of patient safety practices. *Evid Rep Technol Assess (Summ)*. 2001;(43):i-668.
17. Cook TM, El-Boghdadly K, McGuire B, McNarry AF, Patel A, Higgs A. Consensus guidelines for managing the airway in patients with COVID-19: Guidelines from the Difficult Airway Society, the Association of Anaesthetists the Intensive Care Society, the Faculty of Intensive Care Medicine and the Royal College of Anaesthetists. *Anaesthesia*. 2020;75(6):785-799.
18. Higgs A, McGrath BA, Goddard C, et al. Guidelines for the management of tracheal intubation in critically ill adults. *Br J Anaesth*. 2018;120(2):323-352. doi:10.1016/j.bja.2017.10.021

Medtronic

©2022 Medtronic. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. EMEA-RE-2200043-shiley-trach-evac-evidence-guide-en-we-7130553

medtronic.co.uk/pmri

Review the evidence of benefits associated with Shiley™ EVAC Technology

Background

- ▶ [Ventilator-associated pneumonia \(VAP\)](#)
- ▶ [Shiley™ Technology](#)

SSD Meta-analysis

- ▶ [Pozuelo-Carrascosa et al.](#)

TPG Evac

- ▶ [Nam et al.](#)

QI Program Summary

- ▶ [Weston Smith et al.](#)