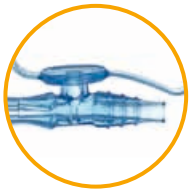
RÜSCH

Teleflex Subglottic Suctioning Solutions

A new level of safety and efficiency in subglottic secretion removal



Teleflex

Sophisticated design for a relevant reduction of ventilator associated pneumonia (VAP)

Our Pursuit

We at Teleflex believe advanced sophisticated manufacturing technology can have a significant, positive impact on patient care and the hospital's bottom line. That is why we constantly seek improvement and create products that are better by design to help eliminate airway related complications, such as ventilator associated pneumonia (VAP), and increase procedural efficiencies.

The facts

Ventilator associated pneumonia is a nosocomial disease that develops more than 48 hours after endotracheal intubation.[1] It is the most common infection acquired by adults and children in intensive care units (ICUs) and is a cause of significant patient morbidity and mortality, increased utilisation of healthcare resources and excess cost.[2]

KISS, a hospital infection surveillance system, determined 4.25 cases of VAP per 1000 invasive ventilation days.[3] Studies document a prolongation of intensive care unit stay by six to nine days[4] and a mortality rate of 13%.[5]

The Strategy

Effective subglottic secretion removal as part of a protocol provides a confident strategy to help protect against VAP. During mechanical ventilation, secretions from the upper respiratory tract accumulate above the endotracheal tube cuff. Studies have shown that these secretions can seep past the cuff into the lower tract, causing pneumonia.[6]

Drainage of the subglottic secretions has been proven as an effective strategy in helping to prevent early-onset VAP.[7]

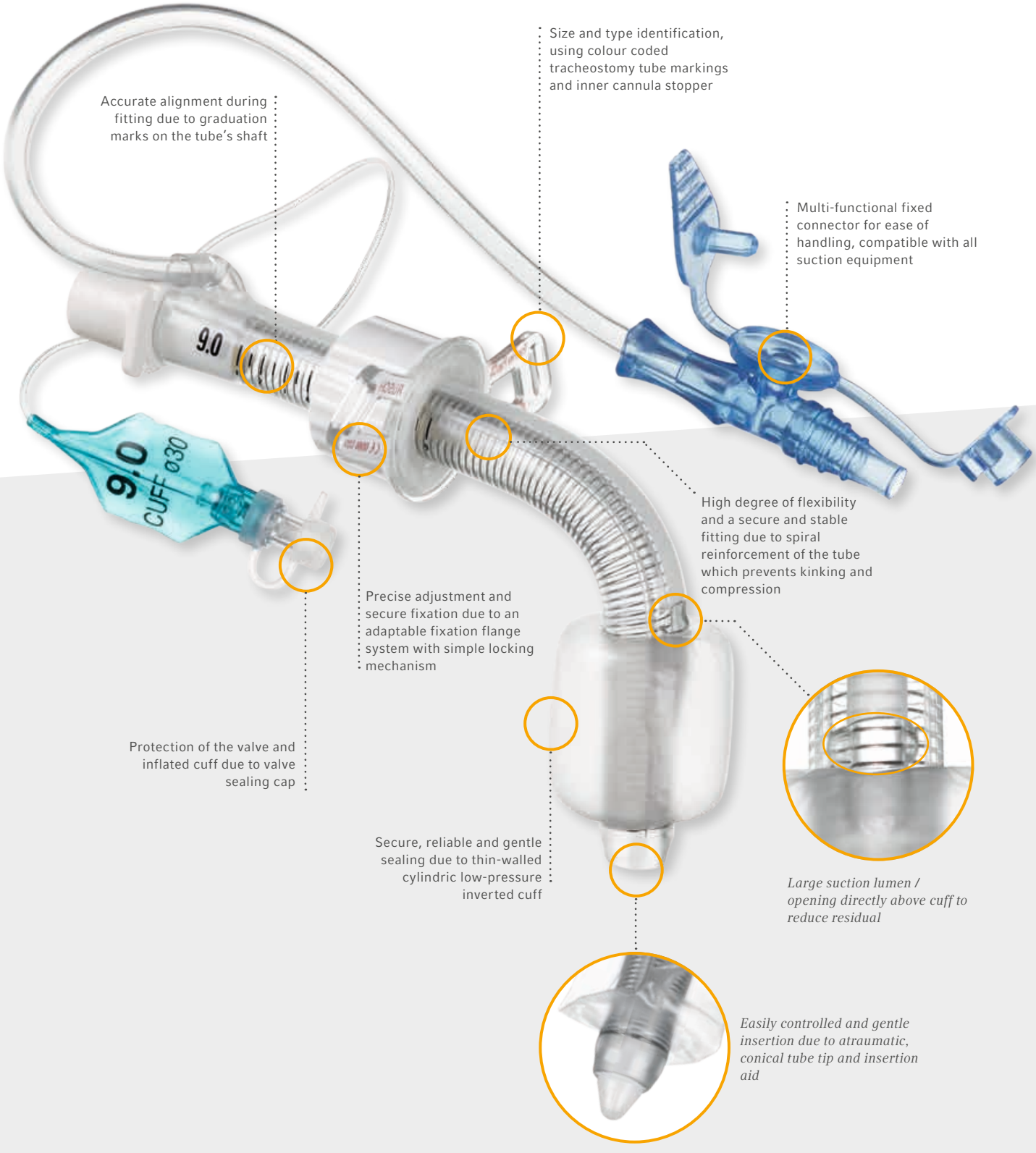
Our Solution

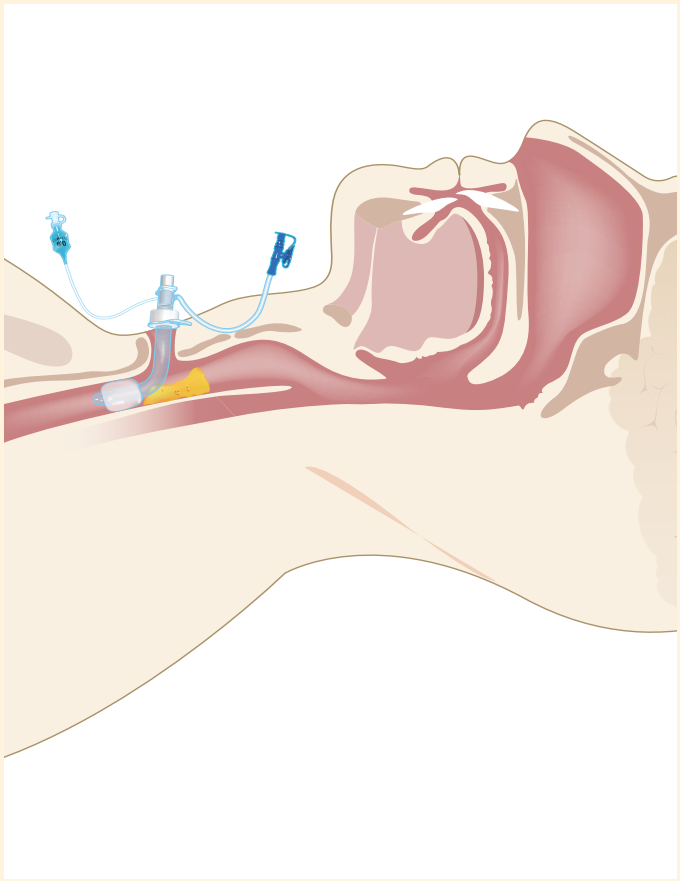
Teleflex now ushers in a new era in the fight against VAP with the new TracFlex Plus Subglottic Tracheostomy Tube.

This tracheostomy tube with integrated suction line is characterized by features of fine manufacturing technology that can make a big difference in the successful reduction of VAP. At the same time, the performance of the TracFlex Plus Subglottic Tracheostomy Tube meets all applicable medical guidelines demands and recommendations.

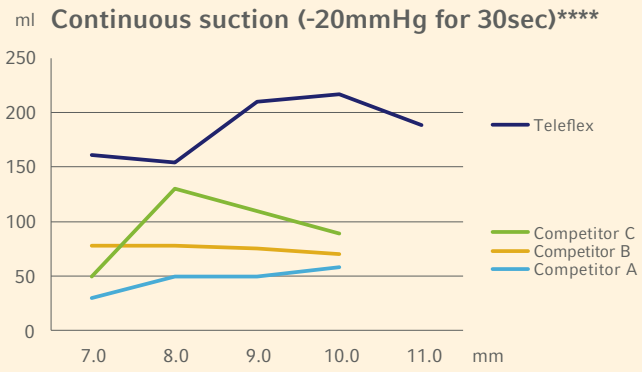
The TracFlex Plus Subglottic Tracheostomy Tube completes our Teleflex Subglottic Product Range consisting of an Ohio Push-To-Set Intermittent Suction Unit (PTS-ISU) and accessories – providing excellent support in the fight to reduce the risk of VAP.

New: TracFlex Plus Subglottic Tracheostomy Tube

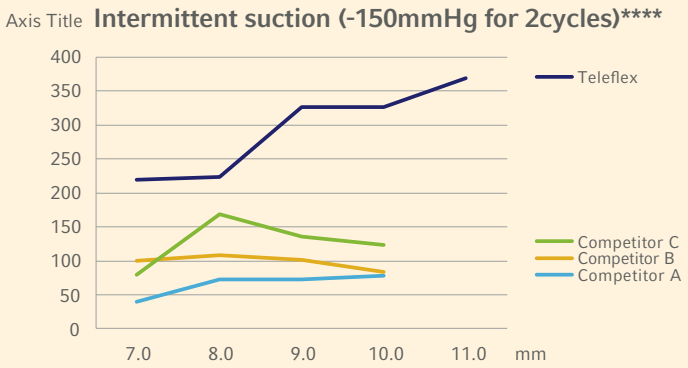




Localization of subglottic secretions



Removed test secretions in ml after 30 seconds continuous suction with -20mmHg



Removed test secretions in ml after 2 cycles at 10 seconds intermittend suction with 5 sec. interruption -150mmHg

TracFlex Plus Subglottic Set Ref. 121905

RÜSCH

ORDER SIZE / I. D.	O.D. IN MM	CLL* IN MM	DIM. A IN MM	DIM. B IN MM	DIM. C IN MM	ANGLE θ (APPROX.)	CUFF Ø IN MM **	QTY
7.0	11.1	102.5	37.0	42.7	22.8	100	23	2
8.0	12.6	122.5	40.0	57.1	25.4	100	27	2
9.0	13.8	152.5	44.0	82.1	26.4	100	30	2
10.0	15.4	157.5	44.0	79.5	34.0	100	32	2
11.0	16.7	163.5	47.0	83.4	33.1	100	34	2

* Total length (CLL=A+B+C)
** Only cuffed versions
*** When ordering, please also indicate tube size

**** Engineering Study Title: Tracheostomy Tube with Subglottic Suction Line Performance. Reference Nr.: ES-17-035. 15.July 2017

The TracFlex Plus Subglottic Tracheostomy Tube Advantages

Minimal residual volume after subglottic secretion removal

In comparison to the main market players in this field, the TracFlex Plus Subglottic Tracheostomy Tube achieved a lower residual volume after subglottic suctioning. Thus only a minimal residual volume remains.**** The positioning of the suction eye directly above the cuff allows removal of the secretion very close to the cuff, which is made possible by a special inverted cuff manufacturing process.

High extraction efficiency

Tests showed that the TracFlex Plus Subglottic Tracheostomy Tube delivers a higher extraction performance than the main market players due to its large suction lumen and large suction eye size and because of the placement.****

KISS, a hospital infection surveillance system, determined 4.25 cases of VAP per 1000 invasive ventilation days.[3] Actual studies document a prolongation of intensive care unit stay by six to nine days[4] and a mortality rate of 13%.[5]

- **Lumen of suction channel in mm²**

TracFlex Plus Subglottic Tracheostomy Tube — RÜSCH

SIZE	AREA
7.0	5.53 mm²
8.0	6.65 mm²
9.0	8.58 mm²
10.0	9.85 mm²
11.0	11.69 mm²

Conforms to guidelines

All Teleflex endotracheal and tracheostomy tubes with subglottic suction line meet applicable recommendations and guidelines for the prevention of VAP of medical organisations such as Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO), Respiratory Information for Spinal Cord Injury (RISCI), SARI Working Group, Deutsche Sepsis Gesellschaft.

Controlled and gentle insertion

Contributed to by a smooth, conical tube tip and a rounded insertion aid.

Multi-functional fingertip

The connector at the end of the suction line is fixed to help reduce the risk of contamination and offers a multifunctional fingertip for ease of handling. This one-fits-all fingertip is compatible with suction equipment such as intermittent and continuous vacuum regulators or syringe. The suction line closing cap helps prevent contaminants from syringes entering the lumen when suction is suspended.

Secure and precise fixation

The adjustable fixation flange system with its handy locking mechanism enables accurate adjustment and secure positioning of the tube to the patient's neck without putting pressure on the trachea. In addition, fine graduation marks on the tube's shaft facilitate the proper alignment, a pre-adjustment and documentation of the fixation flange.

High quality material for increased safety, flexibility and stability

The soft thermosensitive material of the tube ensures a high degree of freedom of movement for the user with maximum comfort and safety. The spiral reinforcement of the tube prevents kinking and compression, and offers a secure and stable fitting.

More comfort, less trauma

Compared to glued on suction lines, the integrated suction line of the TracFlex Plus Subglottic Tracheostoma Tube is designed to preserve the tracheostoma by reducing pressure to the patient's tracheostoma.

**** Engineering Study Title: Tracheostomy Tube with Subglottic Suction Line Performance. Reference Nr.: ES-17-035. 15.July 2017

Ohio Medical Push-To-Set™ Intermittent Suction Unit

Purchasing Specifications

The Ohio Medical Push-To-Set™ Intermittent Suction Unit (PTS-ISU) is a dual-mode intermittent and continuous vacuum regulator. It provides increased patient safety during all suctioning procedures. The Push-To-Set™ device will automatically set a vacuum limit when selecting or changing the vacuum levels preventing unintended, unregulated suction. The dual-spring regulator module will allow precise vacuum level settings in the critical-care range (0-27 kPa/0-200 mmHg) while providing fast adjustment up to full available wall vacuum for emergency resuscitation. Only two (2) turns of the control knob are needed to go from 0 to full available wall vacuum. The intermittent cycle starts in the ON mode. Both ON and OFF timing cycles will be adjustable from 1 to 30 seconds independently without removing the cover or the gauge. The intermittent ON/OFF switch cycling is nearly silent. Intermittent flow rate is adjustable from 0 to 16 L/min and is preset to 8 L/min. The gauge features glow-in-the dark increments and needle. The is fully welded and sealed back plate with no gasket. The manufacturer's warranty covers both parts and labor for three (3) years.

Push-To-Set™ Intermittent Suction Unit (PTS-ISU)

Specifications*

Safety Features
Push-To-Set™ Automatic occlusion device Quick-to-Max (2 turns to full available wall vacuum)

Flow Rate
Intermittent: 0-16 L/min (preset at 8 L/min per ASTM)
Continuous: 0-80 L/min (not adjustable) without fittings at full increase

Timing
Easily adjustable without cover or gauge removal Silent ON/OFF Preset 15 seconds ON; 8 seconds OFF begins in the "ON" mode

Vacuum Range
0-27 kPa (0 to 200 mmHg) and full available wall vacuum

Gauge Accuracy
± 5% Full Scale Deflection or ± 1.3 kPa (10 mmHg)

Dimensions
16.51 x 7.1 x 12.19 cm (6.5" H X 2.8" W X 4.8" D)

Weight
0.57 Kg (1 lb 4oz)

Warranty
Three years on parts and labor

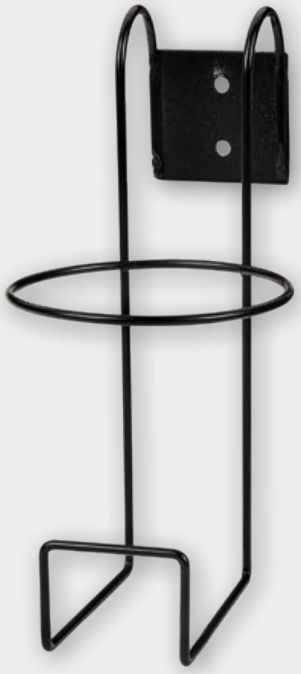
Standards
Conforms to ISO 10079-3 and ASTM F960

* Specifications are nominal, subject to change without notice.

Ohio Medical Push-To-Set™

REF.	VERSION
8732-1253-901	DIN
8731-1253-901	BS
8733-1253-901	Afnor
8732-2253-901	DIN with Venturi Backpack

Suction canister 250ml.
Ref. MI361
QTY. 40



Wall bracket for Ref. MI361
Ref. HC053
QTY. 1

Disposable Hydrophobic Suction Filter
Ref. 6730-0572-800
QTY. 50

Silkomed Vacuum Tubing

REF.	ORDER SIZE LENGTH	I.D. MM		O.D. MM	QTY 1 COIL
471800	approx. 10 m	7.0	x	13.0	1
		8.0	x	14.0	1
		10.0	x	16.0	1

Silkomed Vacuum Tubing
made of silicone

- pyrogen-free
- autoclavable
- latex-free
- non-sterile

American Association of Critical Care Nurses. Practice Alert: Ventilator Associated Pneumonia. January 2008. http://www.aacn.org/WD/Practice/Docs/Ventilator_Associated_Pneumonia_1-2008.pdf.Accessed October 21, 2013.

"American Journal of Infection Control 2016: International Nosocomial Infection Control Consortium (INICC) resources: INICC multidimensional approach and INICC surveillance online system Victor Daniel Rosenthal MD, CIC, MSc"

American Journal of Infection Control 2016: International Nosocomial Infection Control Consortium report, data summary of 50 countries for 2010 - 2015: Device-associated module

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(4):388-416.

Bekaert M, Timsit JF, Vansteelandt S, et al. Attributable mortality of ventilator-associated pneumonia: a reappraisal using causal analysis. Am J Respir Crit Care Med. 2011;184(10):1133-1139.

Bercault N, Boulain T. Mortality rate attributable to ventilator-associated nosocomial pneumonia in an adult intensive care unit: a prospective case-control study. Crit Care Med. 2001;29(12):2303-2309.

Blunt MC, Young PJ, Patil A, Haddock A. Gel lubrication of the tracheal tube cuff reduces pulmonary aspiration. Anesthesiology. 2001;95(2):377-381.

Bo H. Influence of the subglottic secretion drainage on the morbidity of ventilator associated pneumonia in mechanically ventilated patients. . Chinese J Tuberc Respir Dis. 2000(23):472-4.

Cocanour CS, Ostrosky-Zeichner L, Peninger M, et al. Cost of a ventilator-associated pneumonia in a shock trauma intensive care unit. Surg Infect (Larchmt). 2005;6(1):65-72.

Coffin S, MD, Klompas M, MD, Classen D, MD, et al. Strategies to prevent Ventilator-Associated pneumonia in acute care hospitals. Infection Control and Hospital Epidemiology. 2008;29(S1, A Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals):pp. S31-S40. Available from: http://www.jstor.org/stable/10.1086/591062.

Deem S, Treggiari MM. New endotracheal tubes designed to prevent ventilator-associated pneumonia: do they make a difference? Respir Care. 2010;55(8):1046-1055.

Dezfulian C, Shojania K, Collard HR, Kim HM, Matthay MA, Saint S. Subglottic secretion drainage for preventing ventilator-associated pneumonia:A meta-analysis. American Journal of Medicine. 2005;11-18(118).

Dodek P, Keenan S, Cook D, et al. Evidence-based clinical practice guideline for the prevention of ventilator-associated pneumonia. Ann Intern Med. Aug 17 2004;141(4):305-313.

Effectiveness Of subglottic suctioning in the prevention of ventilator associated pneumonia by Cody Winston Amato a thesis submitted in partial fulfillment of the requirements for the Honors in the Major Program in Nursing in the College of Nursing and in The Burnett Honors College at the University of Central Florida Orlando, Florida Spring Term 2011 Thesis Chair: Dr. Mary Lou Sole

Guidelines for preventing health-care-associated pneumonia, 2003 recommendations of the CDC and the Healthcare Infection Control Practices Advisory Committee. Respir Care. 2004;49(8):926-939.

Hugonnet S, Eggimann P, Borst F, Maricot P, Chevrolet JC, Pittet D. Impact of ventilator-associated pneumonia on resource utilization and patient outcome. Infect Control Hosp Epidemiol. 2004;25(12):1090-1096.

"Karla I. Mujica-Lopez , MD ; Melissa A. Pearce , BS ; Kyle A. Narron ; Jorge Perez , BS ;and Bruce K. Rubin , MD , FCCP In Vitro Evaluation of Endotracheal Tubes With Intrinsic Suction CHEST 2010; 138(4):863–869"

Köberich, S. (2006). Die subglottische Sekretabsaugung – ein Update. In: intensiv, 14(3), 123-124.

Leasure A, Stirlen J, Lu S. Prention of ventilator- associated penyumonia through aspiration of subglottic secreations: A systematic review and meta-analysis. Dimensions of Crital Care Nursing. 2012;31(2):102-117.

Ledgerwood LG, Salgado MD, Black H, Yoneda K, Sievers A, Belafsky PC. Ann Otol Rhinol Laryngol. 2013;122(1):3-8.

Metheny NA, Clouse RE, Chang YH, Stewart BJ, Oliver DA, Kollef MH. Tracheobronchial aspiration of gastric contents in critically ill tube-fed patients: frequency, outcomes, and risk factors. Crit Care Med. 2006;34(4):1007-1015.

Nseir S, Zerimech F, Fournier C, et al. Continuous control of tracheal cuff pressure and microaspiration of gastric contents in critically ill patients. Am J Respir Crit Care Med. 2011;184(9):1041-1047.

Prevent Ventilator-Associated Pneumonia. Institute for Healthcare Improvement. 100,000 Lives Campaign. Available at: http://www.ihi. org/IHI/Programs/Campaign/VAP.htm. Accessed October 21, 2013.

Smulders K, van der Hoeven H, Weers-Pothoff I, Vandenbroucke-Grauls C. A randomized clinical trial of intermittent subglottic secretion drainage in patients receiving mechanical ventilation. Chest. 2002;121(3):858-862.

Scott RD. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention. Centers for Disease Control and Prevention. March 2009. Available at: http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf. Accessed October 21, 2013.

Valles J, Artigas A, Rello J, et al. Continuous aspiration of subglottic secretions in preventing ventilator-associated pneumonia. Annals of Internal Medicine. 1995(122):179–186.

Wang F, Bo L, Tang L, et al. Subglottic secretion drainage for preventing ventilator-associated pneumonia: an updated metaanalysis of randomized controlled trials. J Trauma Acute Care Surg. 2012;72(5):1276-1285.

References

1. American Thoracic Society; Infectious Diseases Society of America. Guidelines for the management of adults withhospital-acquired, ventilatorassociated and healthcare-associated pneumonia.
   Am J Respir Crit Care Med 2005; 171(4):388.
2. Coffin S MD, MPH, Klompas M MD, Classen D MD, et al. Strategies to Prevent Ventilator-Associated Pneumonia in Acute Care Hospitals. *Infect Control Hosp Epidemiol.* 2008; 29:S31-S40.
3. Krankenhaus-Infektions-Surveillance-System KISS http://www.nrz-hygiene.de/surveillance/ kiss/
4. Beyersmann J, Gastmeier P, Grundmann H et al (2006) Use of multistate models to assess prolongation of intensive care unit stay due to no-socomial infection. *Infect Control Hosp Epidelol.*
   (2006(5);27:493–499
   Eber MR, Laxminarayan R, Perencevich EN, Mal-ani A (2010) Clinical and economic outcomes attributable to healthcare-associated sepsis and pneumonia. *Arch Intern Med.* 2010;170:347–353
5. Melsen WG, Rovers MM, Groenwold RH et al (2013) Attributable mortality of ventilator-associated pneumonia: a meta-analysis of individual patient data from randomised prevention studies.
   Lancet Infect Dis. 2013;13:665–671
6. American Thoracic Society. Consensus Statement: Hospital Acquired Pneumonia in Adults: diagnosis, assessment of severity, initial antimicrobial therapy and preventative strategies. *Am J Respir Crit Care Med.* 1996;151:1711-1725. Coffman, H.M.S., Rees, C.J., Sievers, A.E.F. & Belafsky, P.C. (2008). Proximal suction tracheotomy tube reduces aspiration volume. In: *Otolaryngology-Head and Neck Surgery.* 2008; 138(4), 441-445.
7. Dezfulian C, Shojania K, Collard HR, Kim HM, Matthay MA, Saint S. Subglottic secretion drainage for preventing ventilator-associated pneumonia: a meta-analysis. *Am J Med* 2005; 118:11-18. Pearce M, Mujica Lopez KI, Rubin BK. In vitro evaluation of endotracheal tubes with intrinsic suction. CHEST Journal. 2010;138(4):863-869.
8. Engineering Study Title: *Tracheostomy Tube with Subglottic Suction Line Performance*. Reference Nr.: ES-17-035. 15.July 2017

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose-driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow, Deknatel, Hudson RCI, LMA, Pilling, Rüsch, UroLift, and Weck – trusted brands united by a common sense of purpose.

Corporate Office

Phone +1 610 225 6800, 550 E. Swedesford Road, Suite 400, Wayne, PA 19087, USA

Regional Offices

United States: Phone +1 919 544 8000, Toll Free 866 246 6990, cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

Latin America: Phone +1 919 433 4999, la.cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

International: Phone +353 (0)9 06 46 08 00, orders.intl@teleflex.com, Teleflex Medical Europe Ltd., IDA Business and Technology Park, Dublin Road, Athlone, Co Westmeath, Ireland

Australia 1300 360 226
Austria +43 (0)1 402 47 72
Belgium +32 (0)2 333 24 60
Canada +1 (0)800 387 9699
China (Shanghai) +86 (0)21 6060 7000
China (Beijing) +86 (0)10 6418 5699
Czech Republic +420 (0)495 759 111
France +33 (0)5 62 18 79 40
Germany +49 (0)7151 691 3004
Greece +30 210 67 77 717
India +91 (0)80 4093 4790
Italy +39 0362 58911
Japan +81 (0)3 6632 3600
Korea +82 2 536 7550
Mexico +52 55 5002 3500
Netherlands +31 (0)88 00 215 00
New Zealand 0800 601 100
Poland +48 22 4624032
Portugal +351 225 491 051
Singapore (SEA non-direct sales countries) +65 6439 3000
Slovak Republic +421 (0)3377 254 28
South Africa +27 (0)11 807 4887
Spain +34 91 198 84 31
Switzerland +41 (0)31 818 40 90
United Kingdom +44 (0)1494 53 27 61
For more information, please visit teleflex.com

MCI-2018-0331-EN · REV A · MC · 06 18 PDF

94 08 55

Teleflex