MICROCUFF® ADULT ENDOTRACHEAL TUBE

REVOLUTIONARY CUFF MATERIAL DESIGNED TO REDUCE MICRO-ASPIRATION

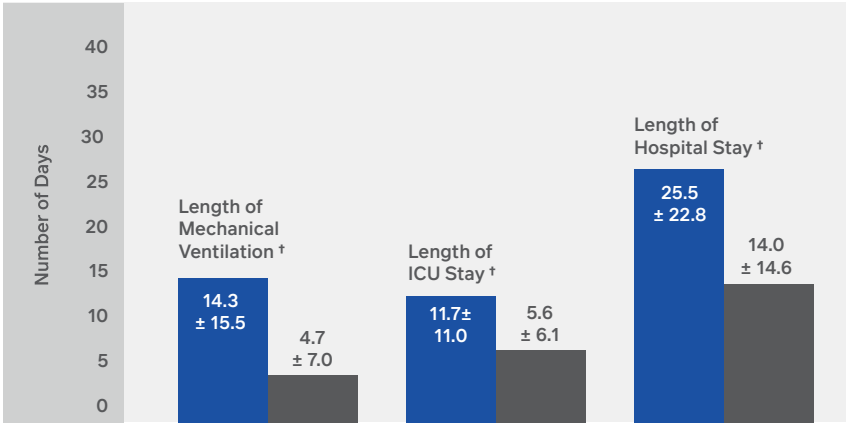
VAP/VAE IS A MAJOR CLINICAL CONCERN ASSOCIATED WITH HIGH INCIDENCE RATES, MORTALITY, AND COSTS[9,10,11]

- Pneumonia is the #1 Health Care Associated Infection[11]
- VAP is responsible for 38% of all Hospital Associated Infections[10,11]
- Approximately 8 – 28% of critical care patients develop VAP[2,13,14]
- Ventilator-associated pneumonia patients have a mortality rate of ~14% – 26%[12]
- VAP/VAE may increase patient time in the ICU up to 4 – 9 days depending on the patient population[6,12,13,14]
- Each incidence of VAP is estimated to generate an increased cost of ~$47,000[12]

"The pathogenesis of VAP... is linked to two separate but related processes: colonization of the aerodigestive tract with pathogenic bacteria, and aspiration of contaminated secretions." [8] — Kollef, et al. Respiratory Care, 2005

COMPARISONS OF PATIENTS WITH AND WITHOUT VAP[7]

A retrospective matched cohort study of patients admitted to an ICU between January 1998 and June 1999 who received mechanical ventilation for > 24 hours.



VENTILATOR-ASSOCIATED PNEUMONIA (VAP) IS A FREQUENT NOSOCOMIAL INFECTION IN THE INTENSIVE CARE UNIT[1]

MICRO-ASPIRATION IS A MAJOR CAUSE OF VAP[2]

- Micro-aspiration of potentially infectious secretions through gaps in the endotracheal tube cuff is known to be a leading cause of VAP[2]
- The cuff seal is the final barrier that protects the lungs from aspiration of potentially infectious pharyngeal secretions
- When intubated, conventional high volume, low pressure (HVLP) PVC cuffs create channels that permit fluid to leak through the cuff and into the lungs

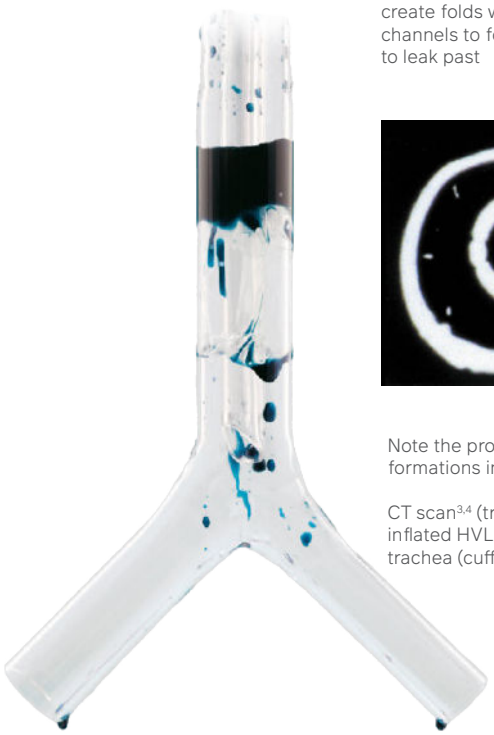
THE BETTER THE SEAL, THE LESS MICRO- ASPIRATION, THE LOWER THE RISK OF VAP

- Cuff length and cylindrical shape of Microcuff tubes are optimized for increased protection against fluid leakage

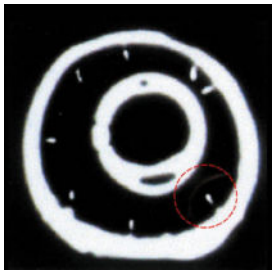
Microcuff

MICROCUFF® ADULT ENDOTRACHEAL TUBE

CONVENTIONAL ENDOTRACHEAL TUBE



Conventional HVLP PVC cuffs create folds when inflated, causing channels to form and allowing fluid to leak past

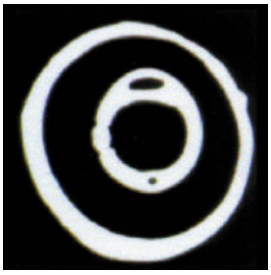


Note the prominent channel formations in the PVC cuff

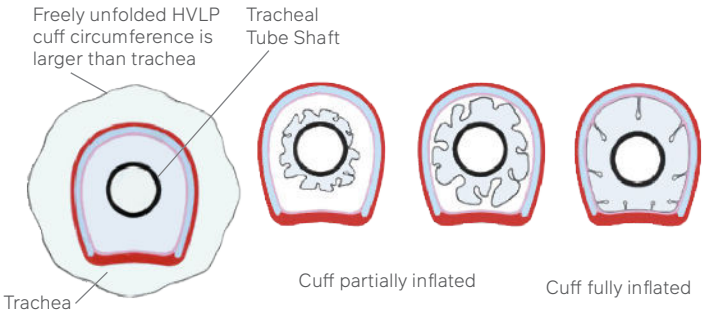
CT scan[3,4] (transversal) of an inflated HVLP-cuff in excised animal trachea (cuff-pressure: 20 cm H_2O)

MICROCUFF® ENDOTRACHEAL TUBE

Note the absence of visible channel openings in the Microcuff tube CT scan[3,4] (transversal) of an inflated Microcuff Tube in excised animal trachea (cuff pressure: 20 cm H_2O)



The Microcuff tube has advanced microthin polyurethane cuff material that allows the channels to "self seal," reducing the possibility of leakage



"In conclusion, our in-vitro experiments show the recently introduced Microcuff tube cuff to be the only one of the tested HVLP endotracheal tube cuffs that effectively prevents fluid leakage around the tracheal tube when cuff pressure was set to 30 cm H_2O or less." [3] — Dullenkopf, et al. Intensive Care Medicine, 2003

MICROCUFF® ENDOTRACHEAL TUBE PROVIDES A SUPERIOR TRACHEAL SEAL[6,7]

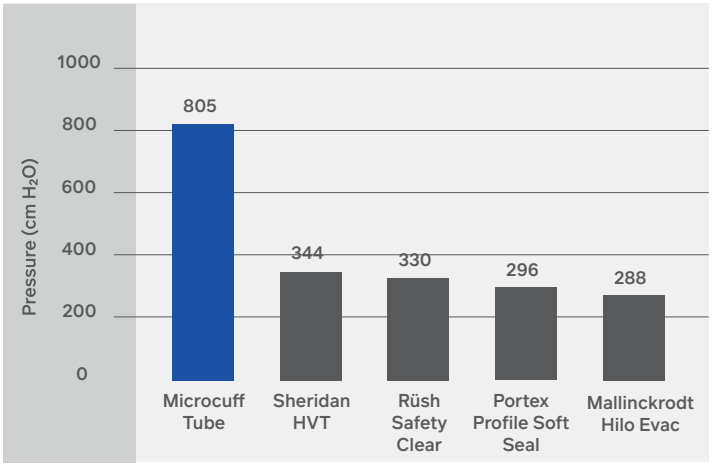
THE MICROCUFF TUBE FEATURES AN ADVANCED MICRO-THIN POLYURETHANE CUFF MATERIAL

- Provides an effective seal at low cuff pressure
- May reduce micro-aspiration of potentially infectious pharyngeal secretions
- Potentially lowers risk of VAP in prolonged ventilation
- Designed for better contact with tracheal contour
- Thinner material allows for greater visualization of vocal cords when cuff is deflated

POLYURETHANE CAN BE MADE THINNER AND STILL MAINTAIN ITS STRENGTH[4]

- Polyurethane (10 microns) cuff membranes are substantially thinner than conventional PVC cuffs (50 – 80 microns)
- Puncture strength of Microcuff tube is almost double compared to conventional cuffs[4]
- Burst pressure of Microcuff tube is more than double compared to conventional cuffs[4]

CUFF BURST PRESSURE[4]



1. Richards MJ, Edwards JR, Culver DH, Gaynes RP. Nosocomial infections in medical intensive care units in the United States. National Nosocomial Infections Surveillance System. Crit Care Med. 1999 May;27(5):887-92.
2. Chastre J, Fagon J. Ventilator-associated pneumonia. Crit Care Med. 2002; 165: 867-903.
3. Dullenkopf A, Gerber AC, Weiss M. Fluid leakage past tracheal tube cuffs: evaluation of the new MICROCUFF® endotracheal tube. Intensive Care Medicine.2003; 29:1849-1853.
4. Data on file. Roswell, GA, KCWW.
5. Safdar N, Dezfulian C, Collard HR, Saint S. Clinical and economic consequences of ventilator-associated pneumonia: a systematic review. Crit Care Med. 2005; 33:2184-2193.
6. CDC. Guidelines for Preventing Health-Care-Associated Pneumonia, 2003. Recommendations of the CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2004;53 (No. RR-3).
7. Rello J, Ollendorf DA, Oster G, Vera-Llonch M, Bellm L, Redman R, et al. Epidemiology and outcomes of ventilator-associated pneumonia in a large US database. Chest. 2002;122(6):2115-21.
8. Kollef MH. What is ventilator-associated pneumonia and why is it important? Respiratory Care. 2005 June; 50(6): 714-724.
9. Kollef, M., Hamilton, C., Ernst, F. Economic impact of ventilator-associated pneumonia in a large matched cohort. Infect Control Hosp Epidemiol (2012 Mar) 33(3):250-6
10. Baker, D., Quinn, B. Hospital Acquired Pneumonia Prevention Initiative-2: Incidence of nonventilator hospital-acquired pneumonia in the United States. American Journal of Infection Control 46 (2008) 2-7
11. Magill, S., et al. Multistate point-prevalence survey of health care-associated infections. N EnglJ Med 2014;370:1198-208.
12. Estimating the Additional Hospital Inpatient Cost and Mortality Associated With Selected Hospital Acquired Conditions, Agency for Healthcare Research and Quality, November 2017
13. Fang, W. Risk factors and associated outcomes of ventilator-associated events developed in 28 days among sepsis patients admitted to intensive care unit. Scientific Reports 10, Article number: 12702 (2020)
14. Kalanuria, A. et al. Ventilator-associated pneumonia in the ICU. Crit Care. 2014; 18(2): 208.

PS-20056-C1 Rev1