

COVIDIEN

positive results for life

New Shiley<sup>™</sup> neonatal and pediatric tracheostomy solutions, a clinician-inspired solution



CONTENT

Shiley<sup>™</sup> tracheostomy products enhance the patient experience through clinician-inspired solutions that meet patient-specific needs.

### CONTENTS

- I. Supporting Patient Comfort
- II. Improved Seal
- III. Infection Control Support
- IV. Significant Expansion of Styles



### Design enhancements based on extensive clinician input



Flange variations for neonatal or pediatric patients.



Trach tie recess facilitates the placement of securing devices without pinching the patient's skin.



Comfort recess behind the connector to help reduce inferior stoma irritation.



Clear flange allows visualization of skin below.

### IMPROVED SEAL

# A new tool to help manage ventilator-dependent patients

The low-profile, low-pressure TaperGuard™ cuff

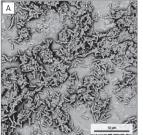
- Significantly improves management of airway leak at pressures below 25 cm H<sub>2</sub>O<sup>1</sup>
- Reduces fluid leak by an avg of 77% at intra cuff pressures of 20 cm H<sub>2</sub>O<sup>2</sup>
- Reduces removal force by 30% thereby reducing the potential for stoma damage during removal<sup>3</sup>



# Can you be sure that a cleaned tracheostomy tube isn't still carrying bacteria or biofilm?

Bacterial colonization of airway devices is implicated in the development of ventilation-associated pneumonia,<sup>4</sup> the main source of morbidity and mortality in patients receiving ventilator support.<sup>5</sup>

Recent studies have suggested that colonization of tracheostomy tubes with bacterial biofilms may be implicated in the local wound complications frequently observed in patients with tracheostomies.<sup>6</sup>



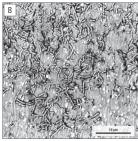


Figure 1. Scanning electron micropraphs of a polyvinyl chloride tracheostomy tube after exposure to human plasma and culture with *Pseudomonas aeruginosa* for 7 days. A, Before cleaning; B, after cleaning.<sup>a</sup>

(The following permission statement is not part of the above Figure 1.) Data from Silva RC, Ojano-Dirain CP, Antonelli PJ. Effectiveness of pediatric tracheostomy tube cleaning. (Arch Otolaryngol Head Neck Surg. 2012;138(3):251-256. Copyright © 2013 American Medical Association. All rights reserved.)

<sup>&</sup>lt;sup>a</sup> Figure from Silva, Ojano-Dirain, Antonelli<sup>6</sup>

INFECTION CONTROL

## Convenient, sterile packaging for bedside tracheostomy tube changes

Recent research has demonstrated the presence of persistent bacterial biofilms on tracheostomy tubes, which could put patient health and safety at risk.<sup>4</sup>

### The solution: Use a new sterile tube

The cuffless Shiley neonatal and pediatric tracheostomy tubes are now available in a convenient four-pack, disposable bedside tray. This enhanced tray design provides a sterile product in each pack to make it easy for the clinician to access a new tube and give the patient a "clean start" with every tracheostomy tube change.



### **Pediatric Tracheostomy Tubes**

| Product SKU | 4-Pack<br>Product SKU* | Description  | I.D.   | O.D.   | Length |
|-------------|------------------------|--|--------|--------|--------|
| 2.5PEF      | N/A                    | Pediatric<br>Tracheostomy Tube<br>Cuffless                         | 2.5 mm | 4.2 mm | 39 mm  |
| 3.0PEF      | 3.0PEF-P               |  | 3.0 mm | 4.8 mm | 39 mm  |
| 3.5PEF      | 3.5PEF-P               |  | 3.5 mm | 5.4 mm | 40 mm  |
| 4.0PEF      | 4.0PEF-P               |  | 4.0 mm | 6.0 mm | 41 mm  |
| 4.5PEF      | 4.5PEF-P               |  | 4.5 mm | 6.7 mm | 42 mm  |
| 5.0PEF      | 5.0PEF-P               |  | 5.0 mm | 7.3 mm | 44 mm  |
| 5.5PEF      | 5.5PEF-P               |  | 5.5 mm | 7.9 mm | 46 mm  |
| 5.0PELF     | N/A                    | Extra Long Pediatric<br>Tracheostomy Tube<br>Cuffless              | 5.0 mm | 7.3 mm | 50 mm  |
| 5.5PELF     | N/A                    |  | 5.5 mm | 7.9 mm | 52 mm  |
| 6.0PELF     | N/A                    |  | 6.0 mm | 8.5 mm | 54 mm  |
| 6.5PELF     | N/A                    |  | 6.5 mm | 9.0 mm | 56 mm  |
| 2.5PCF      | N/A                    | Pediatric Tracheostomy<br>Tube with<br>TaperGuard™ Cuff            | 2.5 mm | 4.2 mm | 39 mm  |
| 3.0PCF      | N/A                    |  | 3.0 mm | 4.8 mm | 39 mm  |
| 3.5PCF      | N/A                    |  | 3.5 mm | 5.4 mm | 40 mm  |
| 4.0PCF      | N/A                    |  | 4.0 mm | 6.0 mm | 41 mm  |
| 4.5PCF      | N/A                    |  | 4.5 mm | 6.7 mm | 42 mm  |
| 5.0PCF      | N/A                    |  | 5.0 mm | 7.3 mm | 44 mm  |
| 5.5PCF      | N/A                    |  | 5.5 mm | 7.9 mm | 46 mm  |
| 5.0PLCF     | N/A                    | Extra Long Pediatric<br>Tracheostomy Tube<br>with TaperGuard™ Cuff | 5.0 mm | 7.3 mm | 50 mm  |
| 5.5PLCF     | N/A                    |  | 5.5 mm | 7.9 mm | 52 mm  |
| 6.0PLCF     | N/A                    |  | 6.0 mm | 8.5 mm | 54 mm  |
| 6.5PLCF     | N/A                    |  | 6.5 mm | 9.0 mm | 56 mm  |

#### **Neonatal Tracheostomy Tubes**

| Product SKU | 4-Pack<br>Product SKU* | Description                  | I.D.   | 0.D.   | Length |
|-------------|------------------------|------------------------------|--------|--------|--------|
| 2.5NEF      | N/A                    |                              | 2.5 mm | 4.2 mm | 30 mm  |
| 3.0NEF      | 3.0NEF-P               | Neonatal                     | 3.0 mm | 4.8 mm | 30 mm  |
| 3.5NEF      | 3.5NEF-P               | Tracheostomy Tube            | 3.5 mm | 5.4 mm | 32 mm  |
| 4.0NEF      | 4.0NEF-P               | Cuffless                     | 4.0 mm | 6.0 mm | 34 mm  |
| 4.5NEF      | 4.5NEF-P               |                              | 4.5 mm | 6.7 mm | 36 mm  |
| 2.5NCF      | N/A                    |                              | 2.5 mm | 4.2 mm | 30 mm  |
| 3.0NCF      | N/A                    | Neonatal Tracheostomy        | 3.0 mm | 4.8 mm | 30 mm  |
| 3.5NCF      | N/A                    | Tube with                    | 3.5 mm | 5.4 mm | 32 mm  |
| 4.0NCF      | N/A                    | TaperGuard <sup>™</sup> Cuff | 4.0 mm | 6.0 mm | 34 mm  |
| 4.5NCF      | N/A                    |                              | 4.5 mm | 6.7 mm | 36 mm  |

#### References

- Internal bench testing. Comparative ventilator air leak test performed using the Shiley™ 4.0PCF and 6.5PLCF pediatric tracheostomy tubes with taper-shaped cuff vs. predicate Shiley™ 4.0PDC and 6.5PLC pediatric tracheostomy tubes with barrel-shaped cuff.
- Internal bench testing. Comparative fluid seal test performed using the Shiley™ 4.0PCF and 6.5PLCF pediatric tracheostomy tubes with taper-shaped cuff vs. predicate Shiley™ 4.0PDC and 6.5PLC pediatric tracheostomy tubes with barrel-shaped cuff.
- Internal bench testing. Comparative removal force test performed using the Shiley™ 4.0PCF and 6.5PLCF pediatric tracheostomy tubes with taper-shaped cuff vs. the predicate Shiley™ 4.0PDC and 6.5PLC pediatric tracheostomy tubes with barrel-shaped cuff.
- Adair CG, Gorman SP, Feron BM, et al. Implications of endotracheal tube biofilm for ventilator-associated pneumonia. *Intensive Care Med*. 1999;25(10):1072-1076.
- Warren DK, Shukla SJ, Olsen MA, et al. Outcome and attributable cost of ventilator-associated pneumonia among intensive care unit patients in a suburban medical center. Crit Care Med. 2003;31(5):1312-7.
- Silva R, Ojano-Dirain C, Antonelli P. Effectiveness of Pediatric Tracheostomy Tube Cleaining. Arch Otolaryngol Head Neck Surg. 2012; 138(3):251-6.
- \*4-pack only available in the U.S.

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