



## Evidence Review of the TaperGuard™ Cuff Technology

### Microaspiration past endotracheal tube cuffs

When inflated outside of the trachea, a fully inflated high-volume, low-pressure (HVLP) endotracheal cuff reaches a diameter that is about 1.5 to 2 times larger than an average adult trachea. Given this, when the cuff is inflated inside a trachea, the excess cuff material forms folds and channels that can allow for secretions to leak into the trachea.<sup>1</sup> The problem of fluid leakage along the cuff has been addressed by varying the cuff material or altering the cuff shape.

As compared to the thicker (~50-80 microns) polyvinyl chloride (PVC) cuffs, thinner (~10 micron) polyurethane (PU) cuffs have been shown to reduce leakage past the cuff due to smaller channels.<sup>2-6</sup> Other evidence suggests that because of their unique design, Covidien tapered cuffs also help reduce leakage. Covidien tapered cuffs include variations in cuff thickness, as well as an area along the taper that effectively matches tracheal diameter, reducing the incidence of folds or channels in that region.<sup>6</sup> In fact, the studies described in this document indicate that use of the PVC TaperGuard™ cuff can effectively reduce fluid leak past the cuff, improve the cuff seal within the trachea, provide a more uniform tracheal pressure with reduced incidence of “hot spots”.<sup>5-19</sup>

**Table 1. Fluid and Air Leak Studies**

Benchtop studies	
<b>Zanella et al<sup>5</sup> 2011</b>	<ul style="list-style-type: none"> <li>• Compared fluid leakage across Mallinckrodt™ Hi-Lo ETT, Mallinckrodt™ Hi-Contour ETT, Portex™* Ivory ETT, Mallinckrodt™ ETT with TaperGuard™ cuff, Mallinckrodt™ Oral/Nasal ETT with Seal Guard™ cuff, Kimberly-Clark* MICROCUFF* ETT and a prototype guayule latex cuff.</li> <li>• PU cuffs showed limited leakage, TaperGuard cuff performed best of the PVC cuffs, the prototype latex cuff showed no leakage.</li> <li>• Increased PEEP reduced fluid leakage, no cuffs leaked at 15 cm H<sub>2</sub>O.</li> </ul>
<b>Lau et al<sup>6</sup> 2014</b>	<ul style="list-style-type: none"> <li>• Compared leakage across the cuff for the KIMVENT* MICROCUFF* ETT (cylindrical PU), Portex™* ETT (globular PVC) and Mallinckrodt ETT with TaperGuard cuff (tapered PVC) under 10 simulated scenarios with varying cuff pressure/PEEP levels.</li> <li>• KIMVENT* MICROCUFF* ETT consistently provided the best protection against cuff leakage, followed by Mallinckrodt ETT with TaperGuard cuff.</li> <li>• Portex™* ETT demonstrated significant leakage whenever there was a loss of positive airway pressure, even with the recommended P<sub>cuff</sub> (20-30 cm H<sub>2</sub>O).</li> <li>• PEEP protected against leakage independently of peak inspiratory pressure.</li> <li>• Circuit disconnect and suctioning increased leakage.</li> </ul>
<b>Harayama et al<sup>7</sup> 2012</b>	<ul style="list-style-type: none"> <li>• Compared five sizes of Mallinckrodt ETT with TaperGuard cuff, Mallinckrodt Hi-Lo ETT, Ruesch™* Safety Clear™* Soft ETT, Portex™* Profile Soft Seal™* ETT, Parker Flex-Tip™* ETT, Sheridan™*HVT™* ETT, and JSS Entrasoft™* Murphy ETT for fluid leak with an intracuff pressure of 25 cm H<sub>2</sub>O.</li> <li>• Each ETT type and material has an optimal size at which leak is minimized.</li> <li>• For cuff sizes 7-8.5, the TaperGuard cuff demonstrated the lowest leak volumes.</li> </ul>
<b>Frey et al<sup>8</sup> 2011</b>	<ul style="list-style-type: none"> <li>• Compared Mallinckrodt™ Hi-Lo ETT, Portex™* SoftSeal™*ETT, Hudson Sheridan™* HVT™* ETT, Kimberly-Clark* MICROCUFF* ETT, Mallinckrodt™ Hi-Lo Evac Oral/Nasal ETT and Mallinckrodt™ TaperGuard Evac Oral ETT in a model.</li> <li>• There was wide variability and significant standard deviation in the study results.</li> <li>• KIMVENT* MICROCUFF* cuff demonstrated the best seal for the longest time.</li> </ul>
<b>Madjdpour et al<sup>9</sup> 2011</b>	<ul style="list-style-type: none"> <li>• Compared tapered PU (Mallinckrodt Oral/Nasal ETT with Seal Guard) or PVC (Mallinckrodt ETT with TaperGuard cuff) cuffs with the corresponding cylindrical cuffs (Mallinckrodt™ Oral/Nasal ETT with Seal Guard and Mallinckrodt Hi-Lo ETT).</li> <li>• The taper-shaped cuff improves air seal for PVC but not for PU.</li> <li>• Mallinckrodt ETT with TaperGuard cuff was similar to either PU cuff in terms of air seal.</li> </ul>
<b>Shiotsuka et al<sup>10</sup> 2012</b>	<ul style="list-style-type: none"> <li>• Compared five types of PVC ETTs (Mallinckrodt ETT with TaperGuard cuff, Portex™* Sacett™* ETT, Portex™* Profile Soft Seal™* ETT, Sheridan™* HVT™* ETT and Sheridan™* CF™* ETT) for fluid leakage with either water or a viscous fluid.</li> <li>• TaperGuard cuff showed no leakage of water in five minutes while other cuffs leaked between 46.5 and 95.4 mLs.</li> <li>• The TaperGuard cuff maintained an effective seal for up to eight hours, with water leakage of 0.2 mL at either four or eight hours.</li> <li>• For the viscous fluid, the TaperGuard cuff leaked 0.2 mL in four hours while the other cuffs leaked between 5.5 and 57.6 mLs.</li> </ul>
Animal Studies	
<b>Lichtenthal et al<sup>11</sup> 2011</b>	<ul style="list-style-type: none"> <li>• 14 pigs between 65 and 75 kg were randomly intubated with either Mallinckrodt Hi-Lo ETT or Mallinckrodt ETT with TaperGuard cuff.</li> <li>• Tube sizes were 7.0 or 8.5 depending on weight; cuff pressure was maintained between 24 and 27 cm H<sub>2</sub>O.</li> <li>• 0.3 mL/kg acidic blue dye (pH 2.5) was placed on top of the cuff and animals were ventilated for three hours.</li> <li>• After sacrifice, the tracheobronchial tree and lungs were examined for aspiration.</li> <li>• Aspiration was significantly less for TaperGuard cuff compared to Mallinckrodt Hi-Lo cuff. <ul style="list-style-type: none"> <li>– Dye leak: 7/7 for Mallinckrodt Hi-Lo cuff ; 1/6 for TaperGuard cuff (p=0.005)</li> <li>– Ulceration/erosion: 5/7 for Mallinckrodt Hi-Lo cuff; 1/6 for TaperGuard cuff (p=0.07)</li> <li>– Hemorrhagic pneumonia: 5/7 for Mallinckrodt Hi-Lo cuff ; 1/6 for TaperGuard cuff (p=0.07)</li> <li>– Bronchitis/bronchiolitis: 5/7 for Mallinckrodt Hi-Lo cuff ; 0/6 for TaperGuard cuff (p=0.016)</li> </ul> </li> </ul>

## Human Studies

**Mulier et al<sup>12</sup>  
2010**

- 85 patients with a BMI >40 were randomly intubated with Mallinckrodt™ Hi-Lo ETT (n=34), Mallinckrodt™ Hi-Lo ETT plus gel (n=15) or Mallinckrodt™ ETT with TaperGuard™ cuff (n=33).
- Methylene blue diluted in water was used to perform a leak test after the gastric bypass.
- No dye leakage past the cuff was observed with Mallinckrodt endotracheal tube with TaperGuard cuff; leakage was observed in 44% of Mallinckrodt Hi-Lo ETT patients and 20% of Mallinckrodt Hi-Lo Evac ETT plus gel patients.
- The Mallinckrodt ETT with TaperGuard cuff provides complete protection against silent aspiration.

**Iwakiri et al<sup>13</sup>  
2011**

- 49 abdominal surgery patients were randomly assigned to intubation with Mallinckrodt ETT with TaperGuard cuff, Mallinckrodt™ TaperGuard™ Evac ETT, Mallinckrodt™ Hi-Lo Evac Oral/Nasal ETT, Rusch™\* ETT, Parker Flex-Tip™\* ETT, Portex™\* Profile SoftSeal™\* ETT or Mallinckrodt™ Lo-Contour Oral/ Nasal ETT cuffed.
- Cuff pressures were fixed to 20 cm H<sub>2</sub>O.
- Indocyanine green (ICG) was used for evaluation of leakage past the cuff.
- No cuff leakage was seen in Mallinckrodt ETT with TaperGuard cuff or Mallinckrodt TaperGuard Evac Oral ETT patients; leakage was seen in 29% of patients with HPLV-type cuffs (6/7 for Mallinckrodt Lo-Contour Oral/ Nasal ETT cuffed and 2/7 for Rusch™\* ETT and Portex™\* Profile SoftSeal™\* ETT; no leakage was seen with Mallinckrodt Hi-Lo Evac Oral/ Nasal ETT or Parker Flex-Tip™\* ETT.
- Mallinckrodt ETT with TaperGuard cuff and Mallinckrodt TaperGuard Evac Oral/ Nasal ETT tubes successfully prevented dye leakage into the trachea.

**D'Haese et al<sup>14</sup>  
2013**

- 60 patients scheduled for back surgery were intubated with either Mallinckrodt Hi-Lo ETTs (n=30) or Mallinckrodt ETT with TaperGuard cuff (n=30).
- After instillation with methylene blue, bronchoscopy was performed at 10, 30, 60, 90 and 120 minutes to determine leakage along the cuff.
- No dye leakage into the trachea was observed with Mallinckrodt ETT with TaperGuard cuff; Mallinckrodt Hi-Lo ETT allowed leakage in 20% of patients.
- Use of the tapered cuff had a protective role against aspiration (OR 3.0; p=0.001).
- Dye leakage along the cuff was observed in 67% of barrel-shaped cuff patients at 30 minutes and in 87% of barrel-shaped cuff patients at 60 minutes.
- The tapered cuff provided better sealing and protection against aspiration.
- Mallinckrodt ETT with TaperGuard cuff may protect against and prevent aspiration during short-term surgical procedures.

**Table 2. Tracheal Pressure, Seal and Injury Studies**

Benchtop studies	
<b>Lichtenthal et al<sup>15</sup> 2011</b>	<ul style="list-style-type: none"> <li>• Mapped the pressure profiles of the Mallinckrodt™ Hi-Lo Evac Oral/ Nasal ETT cuff and the Mallinckrodt™ TaperGuard™ Evac ETT cuff using a pressure sensitive array inside an acrylic cylinder.</li> <li>• The TaperGuard™ cuff showed a more uniform pressure distribution and smaller contact area than the Mallinckrodt™ Hi-Lo cuff.</li> <li>• The Mallinckrodt Hi-Lo cuff demonstrated a greater range of pressures with a higher frequency of low-pressure and high-pressure regions.</li> <li>• The average force exerted on the cylinder wall was 527 gram-force for Mallinckrodt Hi-Lo cuff and 373 gram-force for the TaperGuard cuff.</li> </ul>
<b>Li Bassi et al<sup>16</sup> 2012</b>	<ul style="list-style-type: none"> <li>• Eight endotracheal tube cuffs (Ruschelit™* Safety Clear Plus™* ETT, Mallinckrodt™ Hi-Lo ETT, Portex™* Profile Soft Seal™* ETT, Portex™* Sacett™* ETT, Mallinckrodt ETT with TaperGuard cuff, Sheridan™*/HVT™* ETT, KIMVENT* MICROCUFF* ETT and Mallinckrodt™ Oral/Nasal ETT with Seal Guard) were tested for one hour leakage and then the best four cuffs were evaluated for 24 hours.</li> <li>• PU cuffs performed the best; among PVC cuffs, the TaperGuard cuff had the lowest leak rate.</li> <li>• For the 24-hour test, the leak rates (mL/hr) were: Mallinckrodt Hi-Lo cuff, 114.7; TaperGuard cuff, 2.02; KIMVENT* MICROCUFF* cuff, 0.69; Mallinckrodt™ Oral/Nasal ETT with Seal Guard, 0.00.</li> <li>• Cuff OD, length, and internal pressure were predictors of leakage rate. Lower cuff OD-length ratios were associated with reduced leakage.</li> </ul>
<b>Tsuboi et al<sup>17</sup> 2013</b>	<ul style="list-style-type: none"> <li>• N<sub>2</sub>O diffusion into an ETT cuff during general anesthesia can increase cuff pressures and cause tracheal barotrauma.</li> <li>• Intracuff pressures during the first 15 minutes of N<sub>2</sub>O exposure were significantly higher with Mallinckrodt Hi-Lo cuff than with Mallinckrodt ETT with TaperGuard cuff.</li> <li>• Intracuff pressures increased more rapidly during N<sub>2</sub>O exposure with the Mallinckrodt Hi-Lo cuff than with the TaperGuard cuff.</li> <li>• Since both Mallinckrodt Hi-Lo ETT and Mallinckrodt ETT with TaperGuard cuff are PVC with the same diffusion rate for N<sub>2</sub>O, these observed differences must be due to the increased surface area of the Mallinckrodt Hi-Lo cuff as compared to the TaperGuard cuff.</li> </ul>
Animal Studies	
<b>Lichtenthal et al<sup>18</sup> 2011</b>	<ul style="list-style-type: none"> <li>• Excised canine tracheas (18, 20, 23 and 26 mm) were intubated with Mallinckrodt Hi-Lo ETT, Mallinckrodt ETT with TaperGuard cuff, Mallinckrodt Hi-Lo Oral/ Nasal ETT cuffed, Portex™* Sacett™* ETT, Teleflex ISIS™* HVT™* or KIMVENT* MICROCUFF* ETT.</li> <li>• Cuff pressure was determined with a pressure transducer at the same level as the cuff.</li> <li>• Cuff pressure was found to be multifactorial, depending on volume, material and tracheal diameter.</li> <li>• With low-volume cuffs, small changes in volume may cause steep increase in pressure.</li> </ul>
<b>Li Bassi et al<sup>19</sup> 2013</b>	<ul style="list-style-type: none"> <li>• 23 pigs were intubated with Ruschelit™* Safety Clear Plus™* ETT (n=4), Mallinckrodt Hi-Lo ETT (n=3), KIMVENT* MICROCUFF* ETT (n=3), Portex™* Sacett™* ETT (n=3), Mallinckrodt ETT with TaperGuard cuff (n=4), Sheridan™* HVT™* ETT (n=3) or Mallinckrodt™ Oral/ Nasal ETT with Seal Guard ETT (n=3).</li> <li>• Animals were ventilated for 72 hours with cuff pressure maintained at 28 cm H<sub>2</sub>O.</li> <li>• Tracheal wall images were recorded using a fluorescence bronchoscope. PU cuffs appear to reduce risk of post-extubation tracheal injury, though among the PVC cuffs, the TaperGuard cuff tended to show a reduced incidence of injury.</li> </ul>

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6135 GUNBARREL AVENUE  
BOULDER, CO 80301  
800-635-5267

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