THE MALLINCKRODT™ TAPERGUARD™ ENDOTRACHEAL TUBES

Secretion management for the operating room
"Postoperative complications are associated with higher death rates, longer hospital stays, and increased costs of care."¹

- A 2009 New England Journal of Medicine article reported 22.4% (n=520,512) of Medicare readmissions are surgical patients and pneumonia is the second most common reason for rehospitalization.⁴
  - Unplanned rehospitalization accounted for approximately $17.4 billion.
  - CMS may consider lower per-case payments for hospitals with higher rehospitalization rates.⁴

Prevalent and Impactful

Postoperative pulmonary complications (PPCs) are prevalent and associated with longer hospital stays.³

Incidence and Hospital Length of Stay

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence</th>
<th>Hospital Length of Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac complications</td>
<td>9.5%</td>
<td>10.3 Days</td>
</tr>
<tr>
<td>Pulmonary complications</td>
<td>5.7%</td>
<td>10.4 Days</td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td>22.5 Days</td>
</tr>
</tbody>
</table>

Lawrence et al. (1995)

Significant

- A 2009 New England Journal of Medicine article reported 22.4% (n=520,512) of Medicare readmissions are surgical patients and pneumonia is the second most common reason for rehospitalization.⁴
  - Unplanned rehospitalization accounted for approximately $17.4 billion.
  - CMS may consider lower per-case payments for hospitals with higher rehospitalization rates.⁴

Well Documented

Summary of studies investigating incidence of postoperative pulmonary complications by surgical site as of 2006.⁵

<table>
<thead>
<tr>
<th>Surgical Site</th>
<th>Unadjusted Pulmonary Complication Rate</th>
<th>Number of Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA Repair</td>
<td>25.5%</td>
<td>16</td>
</tr>
<tr>
<td>Esophagectomy</td>
<td>18.9%</td>
<td>11</td>
</tr>
<tr>
<td>Abdominal Surgery</td>
<td>14.2%</td>
<td>6</td>
</tr>
<tr>
<td>Head &amp; Neck Surgery</td>
<td>10.3%</td>
<td>43</td>
</tr>
<tr>
<td>Hip Surgery</td>
<td>5.1%</td>
<td>5</td>
</tr>
<tr>
<td>Gynecological/Thoracic</td>
<td>1.8%</td>
<td>2</td>
</tr>
</tbody>
</table>

Smetana et al.
Postoperative pulmonary complications are an economic burden on hospitals.4,6,7

• Patients who developed pneumonia following abdominal surgery stayed 11 days longer and cost an additional $31,000.6

• Respiratory complications, consisting of pneumonia, are the second most expensive type of complication in trauma patients, increasing hospital costs by an estimated $62,890 per affected patient.7

• Postoperative pulmonary complications may lead to unplanned admission to the ICU, longer duration of mechanical ventilation and longer stay in the ICU.3,5,6

ECONOMIC IMPACT

- Patients who developed pneumonia following abdominal surgery stayed 11 days longer and cost an additional $31,000.6
- Respiratory complications, consisting of pneumonia, are the second most expensive type of complication in trauma patients, increasing hospital costs by an estimated $62,890 per affected patient.7
- Postoperative pulmonary complications may lead to unplanned admission to the ICU, longer duration of mechanical ventilation and longer stay in the ICU.3,5,6

Average cost of a day in the ICU: $2,000 – $3,000 per day.8

Average cost of a ventilator day: approximately $1,500 per day.9
Postoperative pulmonary complications are associated with significant mortality.²³

The most commonly cited serious complications are²⁴:
- Pneumonia
- Respiratory Failure
- Acute Exacerbation of Chronic Lung Disease
- Atelectasis

Other examples include¹¹⁻¹³:
- Sore Throat
- Tracheal Stenosis
- Postoperative Fever
- Bronchospasm
- Pulmonary Edema
- Tracheobronchitis

A prospective study of 155,266 surgical patients demonstrated 30-day mortality rate to be 23% in patients with postoperative pneumonia vs. only 2% without (p < 0.001).¹⁹

### OUTCOMES

<table>
<thead>
<tr>
<th>Complication</th>
<th>30-day Mortality</th>
<th>1-year Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Cardiac*</td>
<td>22%</td>
<td>36%</td>
</tr>
<tr>
<td>Serious Pulmonary†</td>
<td>13%</td>
<td>44%</td>
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<tr>
<td>None</td>
<td>1.7%</td>
<td>12%</td>
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</tbody>
</table>

* Definite or probable MI, emergency cardioversion, pacemaker insertion, ventricular fibrillation, ventricular tachycardia, hypotension requiring vasopressors, sick sinus syndrome or other conduction defect, or CPR.
† Respiratory failure or pneumonia.

Lawrence et al. (2002)
Microaspiration is associated with postoperative pulmonary complications.\textsuperscript{9-11}

Microaspiration is surprisingly common in the OR with conventional high-volume low-pressure cuffs.\textsuperscript{14-16}

**IN VITRO**
Conventional high-volume, low-pressure cuffs have failed to demonstrate effective prevention of fluid leakage.\textsuperscript{17}

In a bench-top study, nearly 80% of tubes leaked all 20ml of fluid within 5 minutes.\textsuperscript{18}

**IN VIVO**
- Ephgrave et al. found gastric pathogens in the sputum of 28% of postoperative patients.\textsuperscript{19}
- Mortality and pneumonia rates were significantly higher in patients with evidence of microaspiration (p < 0.001).\textsuperscript{19}

Patients without evidence of microaspiration

Patients with evidence of microaspiration

- **MORTALITY**
  - 1.7%
  - 12%
- **PNEUMONIA**
  - 19.2%
  - 40%
Evidence of blue dye was found throughout the lung

Evidence of acute alveolar hemorrhage and thickened alveolar membrane was present

Classified as acute focal hemorrhagic pneumonia as a result of aspiration

No evidence of blue dye in the lungs, blue staining noticed only above the cuff

Histopathologic investigation demonstrated no change in lung parenchyma or trachea attributable to aspiration

In vivo study shows a reduction in microaspiration and lung damage with TaperGuard™ cuff.

Porcine models undergoing simulated abdominal surgery were intubated with either a barrel- or taper-shaped endotracheal tube cuff. Simulated gastric fluid stained with Methylene-blue (pH2.5, 0.3 ml/Kg) was placed above the cuff.

CONVENTIONAL CUFF
- Evidence of blue dye was found throughout the lung
- Evidence of acute alveolar hemorrhage and thickened alveolar membrane was present
- Classified as acute focal hemorrhagic pneumonia as a result of aspiration

TAPERGUARD™ CUFF
- No evidence of blue dye in the lungs, blue staining noticed only above the cuff
- Histopathologic investigation demonstrated no change in lung parenchyma or trachea attributable to aspiration
The TaperGuard™ tubes enable effective secretion management in the operating room.

• With the taper-shaped cuff, the TaperGuard™ tubes reduce microaspiration by an average of 90% compared with our own Mallinckrodt™ Hi-Lo™ cuffs (0.21 g/5 min versus 8.8 g/5 min respectively p<0.05, size 7.5). 21

• The cuff has a proximal end diameter larger than the average adult trachea, tapering to a smaller diameter at the distal end.

• The TaperGuard™ Evac tube enables clinicians to manage secretions above the cuff.
  - Remove secretions that may collect above the cuff
  - Reduce the risk of secretions moving past the cuff
  - Prepare the patient for extubation

REDUCE MICROASPIRATION

By reducing the risk of perioperative microaspiration caused by inadequately sealing cuffs, the TaperGuard™ tube may reduce the risk of postoperative pulmonary complications associated with microaspiration. 11,12
### Mallinckrodt™ TaperGuard™ Evac endotracheal Tube

#### Specifications:

<table>
<thead>
<tr>
<th>Description</th>
<th>I.D. (MM)</th>
<th>O.D. (MM)</th>
<th>Product Codes</th>
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<tbody>
<tr>
<td>Cuff Inflation Valve</td>
<td>6.5</td>
<td>9.8</td>
<td>18602</td>
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<tr>
<td>Magill Curve</td>
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<td>Tapered, Low-Pressure Cuff</td>
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<tr>
<td>Hooded Murphy Tip with Eye</td>
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<td>Suction Port</td>
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<td>Suction Lumen</td>
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### Mallinckrodt™ TaperGuard™ endotracheal Tube

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<td>Cuff Inflation Valve</td>
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<td>Magill Curve</td>
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<td>Hooded Murphy Tip with Eye</td>
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<td>Suction Port</td>
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1. Cuff Inflation Valve
2. Magill Curve
3. Tapered, Low-Pressure Cuff
4. Hooded Murphy Tip with Eye


21 FDA 510(k) clearance.
