The Shiley™ Flexible Tracheostomy Tube

This white paper reviews the primary benefits and features of the Covidien Shiley™ Flexible tracheostomy tube. As compared to previous Shiley™ tubes, the Shiley™ Flexible tracheostomy tube includes:

- Improved material construction: The flange, the tube and the cuff components are made with a different material and are designed to be soft and compliant for better patient comfort.
- Increased safety: A taper-shaped cuff that uses lower intracuff pressures to provide a more effective air and fluid seal.
- Ease of insertion: A thinner, less bulky cuff that requires less force to insert.

Improved Material Construction

Product Material

Shiley™ tracheostomy tube products are constructed from a polyvinylchloride (PVC) composite. Pure PVC is a rigid material and must be combined with a plasticizer to become flexible and easy to process. A widely used plasticizer, di-(2-ethylhexyl)-phthalate, commonly referred to as DEHP, is used in tracheostomy tubes and many other medical devices, such as nasogastric tubes, extracorporeal membrane oxygenation (ECMO) circuits and respiratory tubing systems.¹

The Food and Drug Administration,² the Ministry of Health, Labor and Welfare, Health Canada³ and the European Commission⁴ recommend periodic health-risk assessments for DEHP-exposed hospitalized patients because DEHP is known to be released into biological fluids or tissues and its effect on human health has been questioned since the 1970s². Potential adverse effects can include bronchopulmonary dysplasia, deep venous thrombosis and cholestasis.¹ DEHP has been used in medical devices for many years without reports of adverse effects. Further research is needed to determine conclusively if DEHP poses any risks to health. As a precaution, it is a mandatory requirement that products containing DEHP must list it on the label. Exposure to DEHP is not recommended for vulnerable patient populations, including long-term transfusion patients, newborn boys and pregnant women.⁵

For these reasons the Shiley™ Flexible tracheostomy tube product line is manufactured with a plasticizer obtained from citric acid, a metabolite of plants and animals. Citric-based plasticizers are used in produce food packaging material, medical products, soft toys for children and cosmetics.⁶
The Flange

The Shiley™ Flexible tracheostomy tube flange is a transparent, soft, and flexible PVC composite designed to conform to a patient’s clavicle. (Figure 1) The central portion of the flange has symmetrical windows and is offset to help reduce contact with the patient’s skin. (Figure 2)

The Tube

The outer cannula of the Shiley™ Flexible tracheostomy tube is made from soft thermo-sensitive PVC with a low friction surface. The tube is flexible enough to conform to the patient’s airway, but rigid enough to maintain airway patency. The Shiley™ Flexible tracheostomy tube outer cannula is made from flexible material whereas the Shiley™ Disposable Cannula Low Pressure Cuffed Tracheostomy Tube (DCT) is made from rigid material. The cuffed version of the tube has the inflation lumen within the wall of the cannula to provide a smooth tube outer surface.

The Cuff

The cuff is designed with a more effective geometry and an improved compliant material.

Geometry

Existing tracheostomy tube cuffs use a cylindrical-shaped high-volume, low pressure (HVLP) cuff. Research has demonstrated that a cylindrical-shaped cuff, when inflated, forms longitudinal folds with microchannels that allow the direct passage of air and fluid.\(^7\,^9\)

The unique TaperGuard™ cuff provides a more effective seal of the trachea\(^10\) with a smaller tracheal contact area.\(^11\) The TaperGuard cuff forms a small band in the trachea where the inflated cuff has a diameter equal to the trachea between the oversized proximal and undersized distal portion of the cuff. The smaller band helps reduce the number of microchannels and the associated passage of air and fluid.\(^7\)
In a bench study using a model of the trachea, Madjdpour et al. demonstrated that a taper-shaped cuff made from PVC significantly improved air-sealing compared to standard cylindrical-shaped cuffs. The cylindrical-shaped PVC cuff did not effectively seal the trachea at the higher end of the clinically accepted safe intracuff pressure of 30 cm H$_2$O when measured by both Sevoflurane concentration passing the cuff and ratio of expired tidal volume to inspired tidal volume. In a clinical study examining the performance of endotracheal tubes fitted with a similar taper-shaped cuff (Mallinckrodt™ TaperGuard™ endotracheal tube), a barrel-shaped and taper-shaped cuff were compared during short-term use in the operating room on surgical patients. The authors report that, in this clinical situation, the endotracheal tube with the taper-shaped cuff demonstrated a “protective role against aspiration.”

**Material**

The Shiley™ Flexible tracheostomy tube has a taper-shaped TaperGuard™ cuff constructed with material that has a low friction surface and is thinner than traditional Shiley™ tracheostomy tubes. (See Figures 3 and 4). A lower friction surface may promote a more effective seal because friction between the cuff and tracheal wall has been identified as an additional potential source of fold formation.

![Figure 3: Shiley™ DCT with cylindrical cuff (left) next to the Shiley™ Flexible tube with TaperGuard™ cuff (right)](image)

![Figure 4: Close up of Shiley™ DCT cuff (left) and TaperGuard™ cuff (right)](image)
Safety Features

Patient complications that can occur from the use of tracheal tube cuffs include excessive mucosal pressures, tidal volume loss, and aspiration. To address these concerns, three bench tests were performed to compare the performance of the Shiley™ Flexible tube with TaperGuard™ cuff to the Shiley™ DCT cuff: lateral wall pressure, air seal, and fluid seal.

Lateral Wall Pressure

To investigate this further a bench test was performed to compare the average pressure and pressure profile exerted on the contacted area of the lateral wall of a model trachea by these two types of cuffs.

Test Procedure

The smallest (6.5 mm), medium (7.5 mm) and largest (10.0 mm) internal diameter (ID) of tracheostomy tubes were tested to ensure the extremes as well as the most commonly used size were included. The specific product tubes tested are listed in Table 1. The Shiley™ DCT tubes Jackson size was matched to the Shiley™ Flexible tubes. Testing used a polycarbonate model trachea with pressure sensors on the inner surface of the model trachea. (Figure 5)

Figure 5: Model trachea with pressure sensors placed around the circumference of the cylinder at 90 degree offsets

†The pressure sensors were supplied by Pressure Profile Systems (Los Angeles, CA, USA).
A model trachea was constructed for each size tube: 18 mm, 20.5 mm and 22.5 mm. Each pressure-sensing strip contains individual pressure sensor elements that independently measure pressure. Table 1 lists the dimensions of the tested tubes in relation to the model trachea.

<table>
<thead>
<tr>
<th>Tube Inner Diameter (mm)</th>
<th>Model Trachea I.D. (mm)</th>
<th>Product Type</th>
<th>Product Code</th>
<th>Product Cuff O.D. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.5</td>
<td>18</td>
<td>Shiley™ Flexible tube with TaperGuard™ cuff</td>
<td>4CN65A</td>
<td>20.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shiley™ DCT tube with cuff</td>
<td>4DCT</td>
<td>20</td>
</tr>
<tr>
<td>7.5</td>
<td>20.5</td>
<td>Shiley™ Flexible tube with TaperGuard™ cuff</td>
<td>6CN75A</td>
<td>25.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shiley™ DCT tube with cuff</td>
<td>6DCT</td>
<td>24</td>
</tr>
<tr>
<td>10.0</td>
<td>22.5</td>
<td>Shiley™ Flexible tube with TaperGuard™ cuff</td>
<td>10CN10A</td>
<td>28.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shiley™ DCT tube with cuff</td>
<td>10DCT</td>
<td>29</td>
</tr>
</tbody>
</table>

Table 1: Dimensions of the tubes tested in relation to the model tracheas

Each tube was inserted into the corresponding model trachea and the average pressure was measured at contact points between the cuff and the model trachea wall along the cuff profile in axial segments from the distal to the proximal end. The tracheal wall pressure was mapped for each size tracheostomy tube in a stepwise inflation of the cuff using 0, 10, 20 and 30 cm H₂O pressure. Each test was performed once on 10 samples of each product type.
Average Lateral Wall Pressure Test Results

The correlation of the intracuff pressure to the pressure applied by the cuff on the wall of the model trachea is shown in Figures 6, 7 and 8 for each size of the tracheostomy tubes.

As shown in the graphs:

- In each test with each size tube, the average pressure exerted on the lateral wall of the model trachea was less for the Shiley™ Flexible tube with TaperGuard™ cuff than the Shiley™ DCT tube with cuff.
- The larger the tube, the greater the difference in pressures.
- Intracuff pressure did not equal lateral wall pressure at every contact point.
- The lateral wall pressure measured was higher on some points of the cuff contact area than intracuff pressure.

At an intracuff pressure of zero, pressure was transmitted to the lateral wall of the model trachea because of the large size of the cuff in relation to the diameter of the model trachea. HVLP cuffs have a resting cuff diameter 120% to 150% of the internal tracheal diameter. Even when the cuff is deflated to a subatmospheric pressure, portions of the cuff could still contact the tracheal wall and transmit pressure as was observed during this test.

Higher pressure points on a lateral tracheal model wall than the intracuff pressure were also observed by an independent group of investigators. These investigators suggested that this finding could be due to the formation of folds pressing on the trachea; and “the tracheal wall adjacent to a fold could endure a higher transmitted pressure because of the tangential force against a smaller contact area.”12 This effect is common to all HVLP cuffs and is an artifact of the core design principle of the type of cuff as the cuff resting diameter is larger than the internal tracheal diameter.
Evaluation of the Lateral Wall Pressure Applied by the Cuff along the Longitudinal Axis

Although the Shiley™ Flexible tube with TaperGuard™ cuff demonstrated an overall lower average lateral wall pressure than the Shiley™ DCT cuff, of equal importance is the pressure profile at the lower contact area as compared to the larger contact area of the HVLP cuff. To investigate this further, a pressure array system that was not available during the previous testing was placed into a model trachea. See Figure 9.

The pressure array contains a number of elements that generate an electrical response relative to the pressure applied to that element. This pressure mapping system contains the electronic hardware necessary to condition the signal from the array and allow input into a computer for further processing and analysis by the Chameleon TVR™ software. Figures 10-14 are images of a graphical representation of the pressures exerted by the cuff on the lateral wall of the model trachea by the 7.5 size tracheostomy tubes cuffs starting with a vacuum in the cuffs and then sequentially inflated from 0 to 10, 20 and 30 cm H2O pressure.17
Figure 11: Pressure applied to the model tracheal wall at an intra-cuff pressure of 0 cm H2O, Shiley™ DCT tube with cuff (left) versus Shiley™ Flexible tube with TaperGuard™ (TG) cuff (right)

Figure 12: Pressure applied to the model tracheal wall at an intra-cuff pressure of 10 cm H2O, Shiley™ DCT tube with cuff (left) versus Shiley™ Flexible tube with TaperGuard™ (TG) cuff (right)

Figure 13: Pressure applied to the model tracheal wall at an intracuff pressure of 20 cm H2O, Shiley™ DCT tube with cuff (left) versus Shiley™ Flexible tube with TaperGuard™ (TG) cuff (right)
Figure 14: Pressure applied to the model tracheal wall at an intracuff pressure of 30 cm H2O, Shiley™ DCT tube with cuff (left) versus Shiley™ Flexible tube with TaperGuard™ (TG) cuff (right)

Points of interest:

- The height of the grid and the color changes illustrate the pressure values measured as per the scale bar shown on the left side of the image.
- Images on the left represent the cylindrical-shaped Shiley™ DCT cuff and those on the right the taper-shaped Shiley™ Flexible tube with TaperGuard™ cuff.
- Each image is viewed as if the circular lateral wall pressure measurements were cut longitudinally and laid flat on a grid.
- When a vacuum is applied to the cuff there is no cuff contact with the tracheal model wall and no pressure is measured as seen in Figure 10.
- As the cuff is not in contact with the full length of the model trachea no pressure is recorded at the distal end and therefore the graphical representation of the pressure remains flat as represented by the bottom portion of the grid (dark blue).
- As viewed from distal to proximal end of the model trachea approximately half way along the pressure grid values start to be observed by the pressure elements. “Mountains” start to form and the colors change accordingly.
- Comparison of the Shiley™ DCT cuff to the Shiley™ Flexible tube with TaperGuard™ cuff:
  - The pressure distribution of the Shiley™ DCT cuff on the lateral wall of the model trachea is erratic as seen by the number of red-tipped green spikes that indicate high pressure points.
  - The TaperGuard™ cuff demonstrates a more even and lower pressure distribution. The center portion of the cuff exhibits much lower pressure points as compared to the Shiley™ DCT cuff.
Cuff Sealing Performance

Cuff Air Seal Test

The purpose of this test was to determine the efficacy of the tracheostomy tubes cuffs to adequately seal air between the cuff and the trachea when used with a ventilator.

Test procedure:

- Each size of the tested tracheostomy tubes was placed into an acrylic tracheal model attached to a Michigan Instruments* Test Lung and ventilated using a Puritan Bennett™ 760 ventilator with the settings listed in Table 2.
- The cuff was inflated to 25 cm H$_2$O and the compliance of the test lung was adjusted to obtain an exhaled tidal volume of 330-338 ml for the size 6.5 tubes and 495-505 ml for the others.
- After allowing the system to stabilize for 60 seconds, five breaths were recorded and the average exhaled volume (AEV) was subtracted from the average delivered volume (ADV) as measured by the ventilator.
- Thirty samples of each tube type were tested.

Test Results

The average volume of air leak past the cuff for the Shiley™ DCT tube with cuff as compared to the Shiley™ Flexible tube with TaperGuard™ cuff is shown in Table 3.

The formula used to calculate the % improvement in ventilator air seal performance was (Mean DCT Leak) – (Mean Flexible Leak)*100/ (Mean DCT Air Leak) = % Improvement in air seal performance.

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Shiley™ DCT tube with cuff</th>
<th>Mean Volume Leak (mL)</th>
<th>Shiley™ Flexible tube with TaperGuard™ cuff</th>
<th>Mean Volume Leak (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>4 DCT</td>
<td>120.3</td>
<td>4CN65</td>
<td>11.4</td>
</tr>
<tr>
<td>7.5</td>
<td>6 DCT</td>
<td>119.4</td>
<td>6CN75</td>
<td>11.3</td>
</tr>
<tr>
<td>10.0</td>
<td>10 DCT</td>
<td>163.8</td>
<td>10CN10</td>
<td>16.2</td>
</tr>
<tr>
<td>Average Mean Volume Leak</td>
<td>134.5</td>
<td>13.0</td>
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</table>

Table 3: Cuff Air Seal Performance Results

Table 2: Ventilator Settings

<table>
<thead>
<tr>
<th>Mode</th>
<th>Pressure Control</th>
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<tbody>
<tr>
<td>Inspiratory Pressure</td>
<td>15</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>20</td>
</tr>
<tr>
<td>I:E Ratio</td>
<td>1:2</td>
</tr>
<tr>
<td>Rise Time</td>
<td>70</td>
</tr>
<tr>
<td>PEEP</td>
<td>5</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>15.2</td>
</tr>
<tr>
<td>Oxygen</td>
<td>21%</td>
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</table>
Cuff Fluid Seal Test

The purpose of this test was to determine the efficacy of the tracheostomy tubes cuffs to adequately seal fluid between the cuff and the tracheal wall.

Test Procedure:

- A straightening rod was used to insert the tracheostomy tube concentric into an acrylic model trachea.
- The cuff was inflated to 25 cm H$_2$O and the trachea model was maintained in a 37-39 degree water bath for 15 to 30 minutes.
- A water reservoir filled with distilled water at 37-39 degrees centigrade maintained 2.0-2.4 cm of water above the proximal cuff via a siphon tube for 10 minutes. (Figure 15)
- Water was collected in a beaker under the model trachea distal to the cuff seal.
- The water weight value was used to calculate the leak value.

Cuff Fluid Seal Test Results

Table 4 details the average amount of water leakage for the Shiley™ DCT tube with cuff and the Shiley™ Flexible tube with TaperGuard™ cuff. The formula used to calculate the % improvement in ventilator fluid seal performance was (Mean DCT Leak) – (Mean Flexible Leak)*100/ (Mean DCT Leak) = % Improvement in Cuff Fluid Seal performance.

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Shiley™ DCT tube with cuff</th>
<th>Mean Fluid Leak (mL/hr)</th>
<th>Shiley™ Flexible tube with TaperGuard™ cuff</th>
<th>Mean Fluid Leak (mL/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>4 DCT</td>
<td>828.9</td>
<td>4CN65</td>
<td>4.4</td>
</tr>
<tr>
<td>7.5</td>
<td>6 DCT</td>
<td>928.9</td>
<td>6CN75</td>
<td>2.8</td>
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<tr>
<td>10.0</td>
<td>10 DCT</td>
<td>1,070.9</td>
<td>10CN10</td>
<td>2.1</td>
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<tr>
<td>Average Fluid Leak using DCT Cuff</td>
<td>942.9</td>
<td>Average Fluid Leak using TaperGuard™ cuff</td>
<td>3.1</td>
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</tr>
</tbody>
</table>

Average Fluid Seal Performance Improvement – 99.67%

Table 4: Cuff fluid seal test summary, Shiley™ DCT tube with cuff compared to Shiley™ Flexible tube with TaperGuard™ cuff
Ease of Insertion

Changing a patient’s cuffed tracheostomy tube may cause irritation to the stoma due to the deflated cuff bulk. The taper-shaped cuff with a smaller volume and thinner material than the Shiley™ DCT tube with cuff should require less force when inserting the Shiley™ Flexible tracheostomy tube into the patient’s stoma, which was validated by a bench test.18

Insertion Force Test

The insertion force bench test assessed the maximum force required to insert a deflated cuffed tracheostomy tube through a simulated stoma opening (opening in a sample of latex, Figure 16). The validated comparative test method used compares data generated under the same test conditions (e.g., both the subject and control products are tested by the same operator on the same day using the same equipment). An Instron®** Tensile Test Machine measured and recorded force during the testing. (Figure 17)

Insertion Force Test Results

Table 5 lists the average Insertion force for the Shiley™ DCT tube with cuff and the Shiley™ Flexible tracheostomy tube with TaperGuard™ cuff. The force to insert the Shiley™ Flexible tube with TaperGuard™ cuff was 40% less.

The percentage performance difference was calculated as follows: (Mean DCT Insertion Force) – (Mean Flexible Insertion Force)*100/ (Mean DCT Insertion Force) = % Reduction in Insertion Force.

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Shiley™ DCT tube with cuff</th>
<th>Mean Shiley™ DCT tube with cuff Insertion Force (kgf)</th>
<th>Shiley™ Flexible tube with TaperGuard™ cuff</th>
<th>Mean Shiley™ Flexible tube with TaperGuard™ cuff Insertion Force (kgf)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>4 DCT</td>
<td>0.250</td>
<td>4CN65</td>
<td>0.119</td>
</tr>
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<td>7.5</td>
<td>6 DCT</td>
<td>0.683</td>
<td>6CN75</td>
<td>0.370</td>
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<tr>
<td>10.0</td>
<td>10 DCT</td>
<td>0.496</td>
<td>10CN10</td>
<td>0.374</td>
</tr>
<tr>
<td>Average Insertion Force for the DCT Cuff</td>
<td>0.476</td>
<td>Average Insertion Force for the TaperGuard™ cuff</td>
<td>0.288</td>
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</tr>
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</table>

Table 5: Results of cuff insertion force test
Limitations of the Studies

Bench testing is limited to a comparison of the products tested. In actual clinical practice, the trachea is not a rigid circular tube but is non-circular and distensible. In addition, the products are used continuously at body temperature not room temperature.

Conclusion

As compared to the Shiley™ DCT tube with cuff, the Shiley™ Flexible tracheostomy tube with TaperGuard™ cuff has a softer flange, a more compliant tube, and a taper-shaped thinner cuff that seals more effectively at lower intracuff pressures and requires less force to insert.
References