Discussion Guide Comparing Cutting Characteristics of a Standard Oscillating Dermatome versus a Rotary Dermatome with an Emphasis on Efficacy of the Excision Ring™ Blade Throughout Surgical Procedures

Introduction
Exsurco® Medical, Inc has introduced the Amalgatome® SD (ASD) into the operating room environment. This device is registered with the FDA and classified (Class I/ 510(k) exempt) similarly to a dermatome as its intended use is designed to excise soft tissue in varying widths and thicknesses for skin grafting and wound debridement. It is indicated for open wounds, including wound site preparation (debridement and sharp debridement), removal of necrotic tissue and eschar, and tissue harvesting (autograft harvesting).

A similar rotary dermatome product produced by Exsurco Medical, the Amalgatome MD, is utilized by tissue bank professionals in the harvesting of allografts from cadaveric donors. Through thousands of recoveries over the last 5 years, this product has helped maximize the gift of tissue donation for those in need.

Excision Ring Blade
The intended use and general mechanism of action of the ASD device (powered excision ring blade edge used to excise soft tissue) are similar to what has been on the market for decades. However, the design of the ASD provides unique mechanical differences from that of the oscillating dermatomes and their respective blades. This document is intended to examine the device characteristics that would impact the efficacy of the blade during the duration of a procedure.

Hypothesis
The rotary cutting action of the Amalgatome SD provides advantages over the oscillating cutting action used by traditional dermatomes. These advantages, driven by the circular design of the ASD device and excision ring blade consumable, lead to an increased duration of "cutting efficacy" for the disposable components during a procedure. User perception as well as blade/excision ring characteristics lead to replacements of "dull" disposables during a procedure. The design and characteristics of the ASD lead to a significant decrease in disposable replacements during a procedure.

Excision Ring Blade Shape
When comparing the two styles of dermatomes, the most apparent difference is the shape of the excision ring blade. Oscillating dermatomes utilize a straight, thin razor blade while the rotary dermatome utilizes a ring-shaped blade that has the sharpened edge on the interior diameter. This shape is the basis from which the operational differences originate between the two styles.
Figure 1: Oscillating dermatome blade (left) and a rotary dermatome excision ring (right)

**Sharpened Surface Length**
Rotary dermatome blades are ring shaped and continuously rotating as opposed to flat and oscillating. The surface length of the blade utilized for a graft of width $L$ is increased by a factor of $\pi$ when using a rotary blade. In other words, the total sharpened blade length on a rotary blade used for a 4-inch grafting procedure would be 12.56 inches. An oscillating dermatome would use a blade that is roughly 4 inches in length.

The rotary blade has 3.14 times the sharpened surface length of a standard oscillating blade.

![4 inches vs 12.5 inches]

Figure 2: Oscillating dermatome blade sharpened surface length (left) and a rotary dermatome excision ring™ sharpened surface length (right)

**Excision Ring Blade Velocity**
Velocity is defined by the blade surface speed and direction. When comparing oscillating and rotary dermatomes, the designation between speed and velocity is important. For oscillating dermatomes, the blade must stop and change direction with each oscillation. This change in direction adds a limitation in the potential average surface speed of the blade, thus lowering its potential cutting efficiency. A lower cutting efficiency can lead to the perception of having a dull blade.
Below is a graph showing the surface speeds of four brands of electric dermatomes and two pneumatic rotary dermatome blade sizes (ASD 2in & ASD 4in) that would produce comparable excision widths. The pneumatic device speeds were calculated at load.

![Graph showing surface speeds](image)

**Figure 3**: Blade surface speeds of four brands of electric dermatomes and two sizes of Amalgatome® SD blades

The oscillating blade surface speeds were calculated using the following:

\[
\text{Speed} = 2 \times \text{frequency} \times \text{amplitude}
\]

Where

\[
\begin{align*}
\text{frequency} & = \text{Number of oscillations per minute} \\
\text{amplitude} & = \text{Amplitude of oscillation}
\end{align*}
\]

These speeds calculated were used as average values and plotted using an absolute value sinusoidal curve and the formula:

\[
\text{Speed} = \frac{0.637}{\text{frequency}} \times \sin(\text{time})
\]

Note speeds were represented with "one full oscillation" and the frequency on the graph is not representative of the frequency used in the surface speed calculation.
The rotary dermatome blade surface speed was calculated using:

\[
\frac{\text{blade speed}}{\text{motor force}} = \frac{\text{speed}}{\text{force}} = \frac{\text{speed}}{\text{force}} = \frac{\text{speed}}{\text{force}} = \frac{\text{speed}}{\text{force}}
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Where

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\]

It was observed that a much higher blade surface speed allows the device to cut with a much lower blade force by design. This is not the force required to use the device, but rather the designed output of the motor to drive the blades:

<table>
<thead>
<tr>
<th>Device</th>
<th>Motor force applied to blade [oz]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatome 1</td>
<td>175</td>
</tr>
<tr>
<td>Dermatome 2</td>
<td>877.6</td>
</tr>
<tr>
<td>Dermatome 3</td>
<td>170.3</td>
</tr>
<tr>
<td>Dermatome 4</td>
<td>106.4</td>
</tr>
<tr>
<td>Amalgatome® SD</td>
<td>57</td>
</tr>
</tbody>
</table>

*Figure 4: Motor force used to drive the blade*

The reduced force required to drive the blade allows Exsurco® ASD to use a direct drive motor (no gearbox). For this reason, during use of Exsurco® ASD there is a noticeable audible slowdown of the device - less force applied to the blade and a much higher speed which leads to a more dramatic reduction in speed during use.

**Excision Ring Blade Materials and Construction**

Both oscillating and rotary dermatomes use blades made with a "surgical" grade stainless steel in the 420 series. This grade of stainless steel allows for an optimal combination of manufacturing processing characteristics and corrosion resistance.

420 Stainless steel is hardenable (sharpenable) and is available in many different forms. Elements can be varied to provide different characteristics (i.e. harder, more corrosion resistant, etc.). Exsurco® excision ring is manufactured using a proprietary wash to maximize corrosion resistance while maintaining sharpened edge quality.
Excision Ring Edge Design
ASD excision ring blades and oscillating blade edges differ in two main ways; blade angle and method of creating the angle.

Excision Ring Blade Angle:
Oscillating dermatome blades are typically ground to 15-17 degrees with a 28-33-degree hone on the edge. The intent of the hone is to clean up burrs created during the manufacturing process and provide the blade with longevity. It is somewhat counterintuitive in stating “the sharper the blade, more quickly it will have to be replaced,” but this holds true. The more acute the blade angle, the faster it will lose its edge due to lack of rigidity. Material does not have to be worn away for a blade to become dull, but rather the edge will be deformed in some manner.

ASD excision ring blades are 28-33 degrees throughout the entire cutting profile. This design provides the blade with rigidity and a long life.

Excision Ring Blade Angle creation:
Oscillating blades are created with a compound edge, meaning they are ground and honed from both sides using varying angles. This leaves a microscopically smooth edge.

Rotary dermatome blades are created using a chisel grind, meaning they are ground and sharpened from one side. This leaves a microscopic serration on the blade edge.

Figure 5: ASD excision ring blade (top left), oscillating dermatome blade (top right), and the two blade images superimposed (bottom).