Company Information
PenBlade, Inc.
Address: 2180 S 1300 E, Salt Lake City, UT 84106
Phone: 801-903-1113
Website: www.penblade.net
E-Mail: info@penblade.net
What is PenBlade?
PenBlade is a new, FDA-approved, innovative safety scalpel that was engineered with the physician in mind. PenBlade safety scalpel’s retractable blade activates like a click pen and retracts with a simple press of a button without the need to change hand position. The “Pen-Style” activation is intuitive, using existing muscle memory and is gaining widespread physician approval. PenBlade will reduce scalpel injuries and make the workplace safer for health care workers. (HCW)

PenBlade Answers the Call for Innovation
- Sharps injuries due to scalpels remain a persistent and growing problem.
- Leading organizations such as OSHA, CDC, and ACS recommend safety scalpels to reduce injuries.
- Safety engineered scalpels have failed to achieve widespread adoption. (<15% use currently)
- Physicians have resisted adoption citing several issues to show the devices are inadequate for use.
- PenBlade was designed to address these issues and is gaining widespread approval.
- PenBlade costs are outweighed by savings in injury expenses, fines, and wasted product.

Unique Features of PenBlade
- **Semi-Passive, Complete Safety Activation**
  - Complete blade retraction occurs without repositioning the user's grip.
  - The CDC reported that failure of complete activation of the safety mechanism occurred 86% of the time with other products.²
- **Decreased Blade Exposures**
  - The incidence of scalpel injuries increases with each blade exposure.
  - Safe-trimming Groove for suture trimming decreases blade exposure up to 66%.
- **Intuitive Mechanism**
  - Extending the blade for use employs the familiar action of a click pen.
  - Extending and retracting the blade eliminates the need to look at the device.
- **Improved Ergonomics**
  - Increased weight over previous “flimsy” products.
  - Non-slip grip
  - Tapered for improved blade visibility.

PenBlade® Finally Delivers Intuitive Safety and Market-leading Performance

Safety stop to prevent accidental blade exposure
Scalpel Safety

• Scalpels present an occupational risk to health care workers. (HCW)
  o Approximately 30,800 scalpel injuries are reported each year and represent a significant occupational risk for health care workers.⁴
  o Over 84% of injuries occur to perioperative personnel other than the surgeon.¹
  o 38% of general surgery patients carry a potentially transmittable blood borne infection.⁵

• All organizations are required to reduce risk to HCWs
  o In 2001, Congress passed the Needlestick Safety and Prevention Act mandating the use of safety engineered products wherever possible.⁶
  o The CDC requires facilities to document annual consideration, evaluation of safer sharp products. ²
  o AORN recommends use of safety scalpels in the operating room as best practice.³

• To date, success has not been achieved with safety scalpels
  o Safety needles have decreased injury rate by 31.6% but scalpel injuries have increased by 6.5%.⁷
  o The lack of reduction in scalpel injuries is due to the <15% adoption rate of safety scalpels.¹
  o Poor adoption rates are attributed to inadequate products previously available.

Why Have Previous “Safety” Scalpels Failed?

Until now, adoption of safety scalpel products has lagged due to poor ergonomics, cumbersome safety activation mechanisms, perceived quality issues and surgeon opinions on fitness for use. To date, only about 15% of operating rooms use safety scalpels routinely.¹ The products previously available were deemed unfit for use based on several factors:

• Lack of Safety
• Not User Friendly
• Looking at the device is required
• Requires two hands to operate
• Not ambidextrous

• Low weight compared to traditional scalpels / flimsy
• Uncomfortable
• Line of site obstruction
• Blade dullness

Current Recommendations:

• National Institution of Occupational Safety and Health (NIOSH)
  o Recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries

• American College of Surgeons (ACS)
  o The use of engineered sharps injury prevention (ESIP) devices as an adjunctive safety measure to reduce sharps injuries during surgery...¹⁷

• Centers for Disease Control (CDC)
  o Requires documentation of annual consideration and evaluation of safer sharps devices.
<table>
<thead>
<tr>
<th>Reported Safety Scalpel Issues</th>
<th>PenBlade Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of Safety(^7,8)</td>
<td>PenBlade employs several measures to improve safety:</td>
</tr>
<tr>
<td></td>
<td>1. Integrated groove for trimming sutures</td>
</tr>
<tr>
<td></td>
<td>2. Ensure no hand repositioning</td>
</tr>
<tr>
<td></td>
<td>3. Uses existing muscle memory</td>
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<tr>
<td></td>
<td>4. Textured surface improves grip.</td>
</tr>
<tr>
<td>Not user friendly(^9)</td>
<td>Intuitive click-pen action uses existing muscle memory.</td>
</tr>
<tr>
<td>Looking at the Device is Required to Activate the Safety Mechanism</td>
<td>Front-positioned release button retracts blade without hand movement. (Semi-Passive Retraction).</td>
</tr>
<tr>
<td>Requires Two Hands to Operate(^7)</td>
<td>Familiar click-pen action allows one-handed use.</td>
</tr>
<tr>
<td>Not Ambidextrous(^10)</td>
<td>Left- or right-handed users can easily use PenBlade.</td>
</tr>
<tr>
<td>Low Weight(^7,10,11) (unfamiliar feel)</td>
<td>PenBlade is 50% heavier than the leading safety scalpel. The pen-like design addresses the predominate sense that current products <em>don’t feel familiar</em> or comfortable in the hand.</td>
</tr>
<tr>
<td>Uncomfortable(^8,9,10,11)</td>
<td>PenBlade’s size and semi-triangular-cross-section design was developed for optimal ergonomic comfort.</td>
</tr>
<tr>
<td>Flimsy(^9)</td>
<td>PenBlade’s beam-like cross section and ABS polymer provide a design that is significantly more resistant to bending than other safety scalpel designs.</td>
</tr>
<tr>
<td>Line-of-Site Obstruction(^7,12)</td>
<td>PenBlade has a tapered tip for improved visibility.</td>
</tr>
<tr>
<td>Bladedullness(^10)</td>
<td>PenBlade’s high quality stainless-steel blade has superior sharpness, minimizing pressure and improving blade control.</td>
</tr>
</tbody>
</table>

**Physician Adoption**

- Adoption of safety scalpels by physicians is currently estimated to be less than 15\(^1\).  
- Physicians typically have the option to opt out of safety scalpel use if they deem the device impairs patient care, decreases safety, or is clumsy or awkward to use.  
- PenBlade’s award winning innovative design addresses these common complaints and results in a significant increase in physician acceptance.  
- Currently PenBlade is used in leading institutions across the country.
Cost Benefit Analysis

Estimated costs of 30,800\textsuperscript{4} scalp injuries each year are $5,689\textsuperscript{13,14} per injury with a total expense of $175,221,200 nationally. According to the WHO, 435 health care workers (HCW) will test positive for HCV, HBV, or HIV with thirty-five resulting from scalpel injuries.\textsuperscript{4,15} The average cost for a seropositive HCW is estimated at $1.1 million\textsuperscript{16} adding an additional $38,500,000 for a total cost of $213,721,200.\textsuperscript{16} The risk premium of $1.42 per blade (figure 5) is an additional cost to the existing cost of each scalpel. PenBlade is designed to prevent scalpel injuries to healthcare workers and thus significantly reduces overall cost and morbidity.

Direct Cost Savings
- Risk premium due to injury
- Non-compliance penalties re: OSHA
- Reduced anxiety and mental health treatment related to injuries

Indirect Cost Savings
- Legal fees and lawsuits
- Reduced waste from improved utilization of safety products
- Improved morale

| Risk Premium |  
|----------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Reported Scalpel Injuries | 30,800 | Number of Scalpel Blades used | 150,000,000 | Average cost per injury, inflation adjusted | $5,689 | Average cost for seropositive HCWs | $38,500,000 | Cost due to scalpel injuries | $213,721,200 |
| Risk premium per scalpel | $1.42 |

Current Product Comparison

<table>
<thead>
<tr>
<th>Scalpel Features</th>
<th>PenBlade</th>
<th>Sheath-Type</th>
<th>Box-Cutter</th>
<th>Blade Cartridge</th>
<th>Traditional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Features</td>
<td>Auto retractable blade, Intuitive use</td>
<td>Protective sliding hood</td>
<td>Manual blade retraction</td>
<td>Protective sliding hood</td>
<td>None</td>
</tr>
<tr>
<td>User Friendly</td>
<td>Uses familiar muscle memory as click-pen</td>
<td>Change grip to expose and protect blade</td>
<td>Require changing grip to extend and retract blade</td>
<td>Requires releasing grip to expose and protect blade</td>
<td>Traditional feel and weight</td>
</tr>
<tr>
<td>Activation of safety feature</td>
<td>Semi-passive, no-look activation</td>
<td>Requires active activation</td>
<td>Requires active activation</td>
<td>Requires active activation</td>
<td>None</td>
</tr>
<tr>
<td>Ambidextrous</td>
<td>Ambidextrous</td>
<td>Inconsistently ambidextrous</td>
<td>Not ambidextrous</td>
<td>Inconsistently ambidextrous</td>
<td>Ambidextrous</td>
</tr>
<tr>
<td>Ergonomics</td>
<td>Pen-style grip Better weight and balance. Non-slip</td>
<td>Confusing, clumsy Too lightweight</td>
<td>Confusing, clumsy Too lightweight</td>
<td>Confusing, clumsy Too lightweight</td>
<td>Familiar</td>
</tr>
<tr>
<td>Clear line of sight</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Blade sharpness</td>
<td>High quality British surgical blade.</td>
<td>Poor reviews</td>
<td>Poor reviews</td>
<td>Poor reviews</td>
<td>Sharp blade, dulls quickly</td>
</tr>
</tbody>
</table>
PenBlade represents a unique platform for safety scalpel standardization throughout the healthcare system. We also work closely with most kit vendors to provide PenBlade in trays and packs such as Arrow/Teleflex, Merit Medical, Centurion, Cardinal, and others.

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*PenBlade is currently available through GPOs including Premier, Vizient, Intalere, Partners, HealthTrust, Partners Healthcare MA, Capstone, Yankee Alliance, and Partners Coop GA.*

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### How to use:

**SINGLE HAND USE!**

1. Holding the scalpel in the hand like a ballpoint pen, the thumb is used to extend the blade.

2. The scalpel is then rotated in the hand exactly like a pen would be. This natural and familiar feel allows the operator to focus on the field rather than the scalpel to deploy the blade.

3. Blade retraction does not require repositioning of the hand. The index finger is used to simply depress the retraction button as the scalpel is held. This activates the blade retraction which is an all or none movement eliminating the risk of partial activation of the safety mechanism.

4. With the blade retracted, the suture groove can be used to trim suture or small diameter catheters.
REFERENCES


9. OR Manager. 2005. *OSHA is pressing ORs to adopt safety scalpels but surgeons resist*. OR Manager 21, no. 12 (December).


