Scalpel Injuries

- CDC reports over 385,000 sharps injuries / year
- Approx. 8% (30,800) are due to scalpel blades
- Sharps data tracked by EPINet shows:
  - 1.2 - 1.8 scalpel injuries/100 ADC / year
    * ADC – average daily census

- More severe injury than needle stick
  - 5 times more likely to cause severe* injury
    *deep cut with profuse bleeding
  - Tendon and nerve injury
Scalpel Injury Cost

- Injury cost is spread over multiple departments
- Represents a real expense to the system

- Contributing Costs
  - Lab testing
  - Prophylactic medications
  - Repair of injury
    - May exceed $100,000
  - Treatment of acquired disease
    - Seroconversion - $1.1 million
  - Labor cost
  - Lost productivity
  - Supportive services

- Injury premium
  - Average cost $5,800 per injury
  - 38 seroconversions per year
  - $213,721,200 per year
  - 150 million scalpel blades annually
  - $1.42 per scalpel blade used

- Paid by:
  - Employee Health
  - Emergency Department
  - Workers Compensation
  - Department labor budget
Scalpel Injury Prevention

- Needlestick Safety and Prevention Act of 2000
  - Mandated use of safety-engineered sharps
  - Needlestick injury rate decreased by 35%
  - Scalpel injury rate **increased** by 6.5%
    - Poor rate of implementation
      - Reusable scalpels - <5% are safety engineered
      - Disposable scalpels - 59% are safety engineered
    - Lack of an effective safety scalpel

“Contrary to their name, these devices are actually more dangerous”

– Dr. H. Hwang
Safety Scalpel Design

- Sliding Sheath Style
  - Fixed blade
  - Slide hood over blade to protect
  - Reposition scalpel to operate

- 80% of injuries relate to failure of the safety mechanism
  - Cumbersome and awkward
  - Flimsy
Safety Scalpel Design

- Box Cutter Design
  - Sliding scalpel blade
  - Use thumb to extend and retract
  - Reposition hand to retract blade
  - Not ambidextrous

- 80% of injuries relate to failure of the safety mechanism
  - Incomplete retraction of the blade
  - Switching hands for use
The Current Safety Scalpel Issues

- Safety scalpels have failed to decrease injury rates
- Poor adoption, poor design, and poor ergonomics cited as contributing factors

- Common complaints
  - Awkward/Clumsy
  - Flimsy, cheap feel
  - Not ergonomic
  - Repositioning grip
  - Poor blade quality
  - Not ambidextrous

- Causes of failure
  - No attempt to use safety mechanism
  - Incomplete blade protection
  - Lack of standardization
  - Injury during manipulation
Call for Innovation

• Consensus Statement released in 2010 by Sharps Steering Committee

“We recommend that:

12. Manufacturers partner with surgeons and surgeon groups to develop suture and scalpel safety designs that both reduce risk and are comfortable and intuitive for surgeons to use.

Requested Features:

• Audible indicator
• Improve blade sharpness
• Ergonomic

• Stiffer / Heavier
• Retractable blade
• Standardization
PenBlade Design and Features

**BLADE**
- High-quality, stable, deep-cut blade; #10, 11P, & 15 blade availability; Exposed-blade color indicator

**TRIMMING GROOVE**
- Safe, tapered groove for sutures & PICCs

**BLADE RETRACTION**
- No-Look, no-reposition "Passive" or active blade retraction

**BLADE ACTIVATION**
- Intuitive right- or left-handed pen-style activation

**GRIP**
- Comfortable, sturdy, non-slip & ergonomic

**SAFETY STOP**
- Safety stop to prevent accidental blade exposure
Why of PenBlade

• Performance
  • Instrument-quality performance in an intuitive ergonomic design
  • Physician friendly with great satisfaction ratings
  • Universal platform for system wide use

• Safety
  • The only safety scalpel that dramatically reduces injury
  • Designed for sharps standardization as recommended by the CDC

• Economics
  • High performance, highly rated product at the same price
  • Injury reduction yields significant with improved morale
Injury Reduction

- Injury report from major academic center
  - 99 scalpel injuries over a 3 year period
  - Estimated cost $574,200
  - Cause of injuries studied
    - 17 occurred during use
    - 17 due to lack of safety mechanism
    - 29 due to un-retracted blade
    - 12 during passing
    - 11 while cutting suture
    - 9 related to confusion
  - 82/99 (82%) preventable injuries
  - Total savings of $475,600
Cost Savings

- # of licensed beds
- Est. ADC at 80% or beds
- 1.8 injuries/100 beds = injuries per year
- Estimate $injuries x $5.8K annual cost
- 82% injury reduction to per year

Annual savings of $reduced x $5.8K
Scalpel Injuries in the Operating Room

- Most frequent site for scalpel injuries
- Second most common sharps injury
- Surgeons rarely are injured:
  - Surgeon – 18%
  - Nurses – 27%
  - Scrub Techs – 36%

- When injuries occur:
  - During Use 30%
  - Passing 42%
  - Disassembly 12%
  - Before disposal 11%
  - Other 5%
<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 No grip change</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>
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<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>
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<td>Poor reviews</td>
<td>Sharp blade, dulls quickly</td>
</tr>
</tbody>
</table>
Available Blade Sizes

Three blade sizes for institution wide standardization