

White Paper: Safe in Common's “10 Golden Rules of Safety”

How Does the SurgiLance™ Safety Lancet Compare?



This white paper outlines sharps safety advocate Safe in Common's "10 Golden Rules of Safety" and evaluates how well the SurgiLance™ safety lancet from MediPurpose™ satisfies them.



Introduction

In June 2013, sharps safety advocate Safe in Common published the *Top 10 Golden Rules of Safety*,¹ which it described as a “set of guidelines for everyone to use to fight injuries and adopt prevention techniques.”

As a manufacturer and master distributor of two safety needlestick devices—the babyLance™ safety heelstick and the SurgiLance™ safety lancet—MediPurpose™ closely follows and supports such advocacy.

In fact, MediPurpose’s flagship SurgiLance fingerstick device was introduced in the United States at approximately the same time as the passage of the U.S. Needlestick Safety and Prevention Act (NSPA) (HR.5178), which was “designed to make more specific the requirement by the Occupational Safety and Health Administration (OSHA) that employers identify, evaluate and implement safer medical devices, especially addressing occupational exposure to bloodborne pathogens from accidental sharps injuries in healthcare and other occupational settings.”²

This white paper outlines the *Top 10 Golden Rules of Safety* and evaluates how well SurgiLance satisfies them. Further, it provides references to publications and documents that provide additional background and evidence for the claims and arguments made on SurgiLance’s behalf for each rule.

¹ Safe in Common. “The Golden Rules of Safety.” 20 June 2013. Web. 30 January 2014. <www.safeincommon.org/blog/golden-rules-safety>

² Infection Control Today. “Needlestick Safety and Prevention Act 10-Year Anniversary.” 2 November 2010. Web. 30 January 2014. <www.infectioncontroltoday.com/articles/2010/11/needlestick-safety-and-prevention-act-10-year-anniversary.aspx>

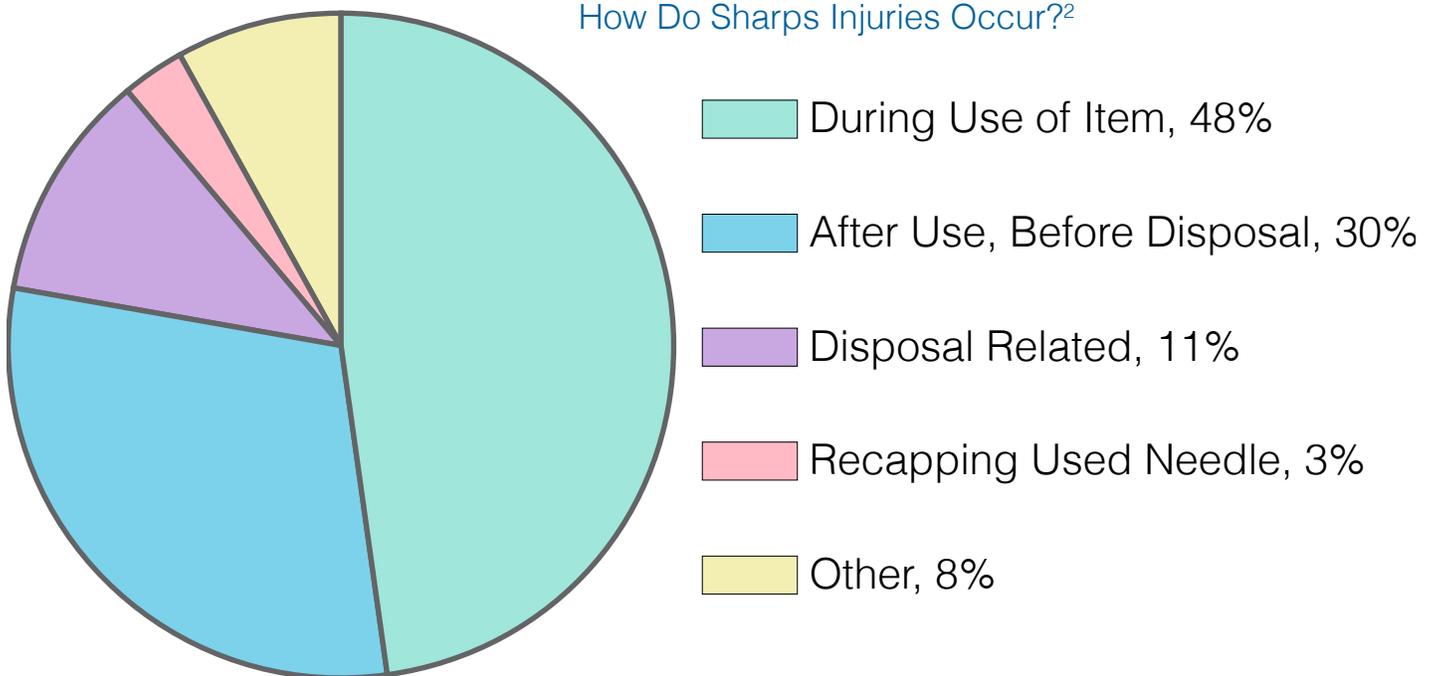
Defining a “Safety” Heelstick

What is a “Safety” Lancet?

A lancet is an incision device that makes a shallow cut on a person’s skin for the purpose of obtaining a blood sample. More commonly, lancets—or fingersticks—are used to produce a blood sample for a variety of diagnostic tests, such as blood sugar, A1c hemoglobin, Hepatitis, HbG, HIV, and many more. A safety lancet is a similar device, but with a sharps injury prevention feature.

According to the U.S. FDA’s *Guidance Document on Medical Devices with Sharps Injury Prevention Features*,¹ “a sharps injury prevention feature is designed to protect the user from a sharps injury. Some sharps injury prevention features are incorporated as integrated components of finished devices. Others are marketed separately as accessories that are attached to a device by the user at the point of use, for example, a needle shield.”

How Do Sharps Injuries Occur?²

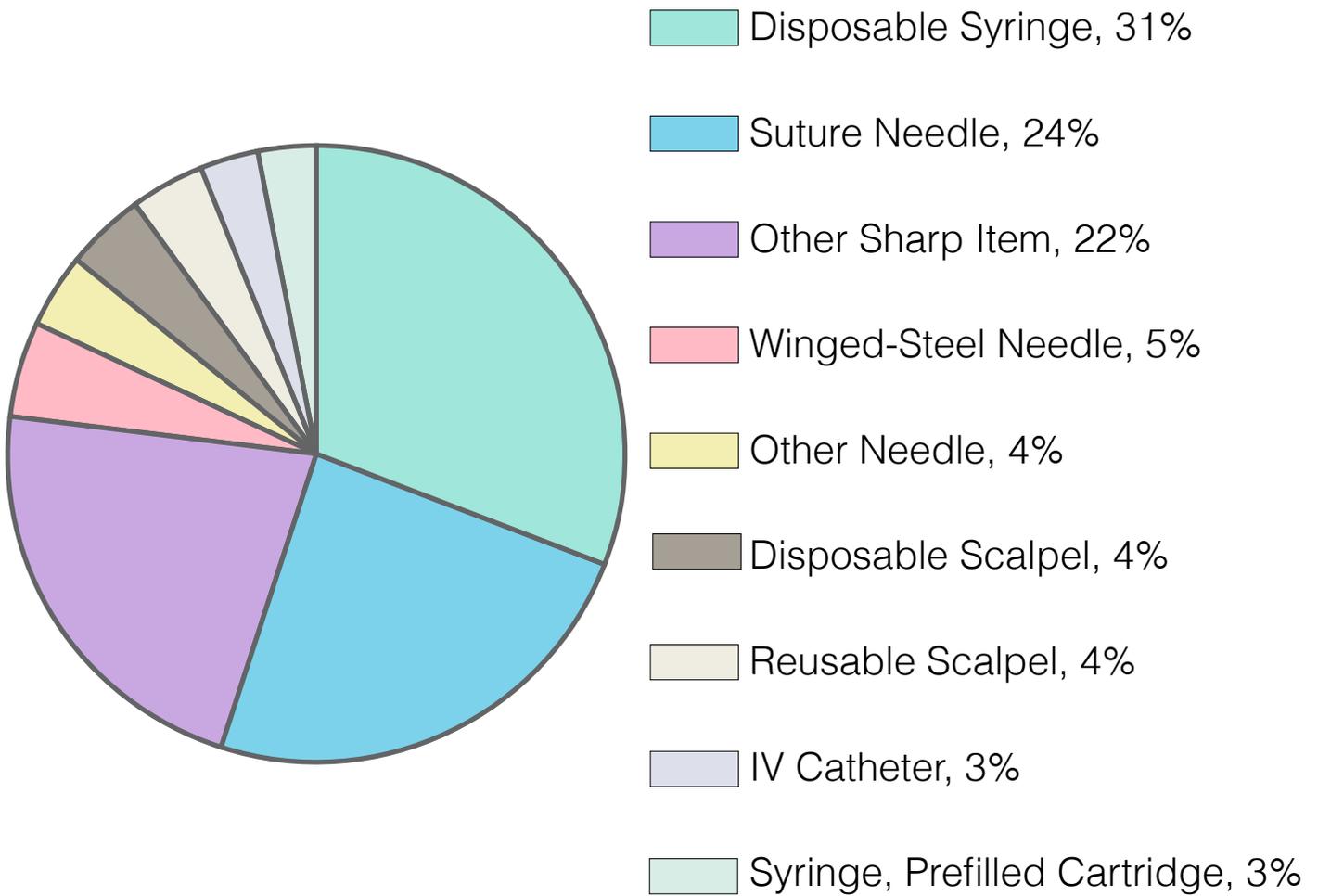


¹ U.S. Food and Drug Administration. “Guidance for Industry and for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features.” 9 August 2005. Web. 30 January 2014. <www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071663.htm>

² Centers for Disease Control and Infection. “The STOP STICKS Campaign: Sharps Injuries.” 24 June 2011. Web. 30 January 2014. <www.cdc.gov/niosh/stopsticks/sharpsinjuries.html>

The FDA has identified health risks generally associated with the use of sharps injury prevention features, and it requires manufacturers of medical devices with sharps safety features to submit a Premarket Notification (510k)³ before the device can be marketed. The FDA also provides design recommendations for Sharps Injury Prevention Features in its guidance document.

What Devices are Involved with Sharps Injuries?⁴



³ U.S. Food and Drug Administration. "Premarket Notification (510(k))." 3 September 2010. Web. 30 January 2014. <www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketnotifications/premarketnotification510k/default.htm>

⁴ "The STOP STICKS Campaign: Sharps Injuries."

Why Do You Need a Safety Lancet?

The availability of safety medical devices makes the difference between having a safe workplace and one that could be fatal.

The U.S. Needlestick Safety and Prevention Act (NSPA) (HR.5178) was signed into law on November 6, 2000 to protect healthcare workers from needlestick injuries. It required employers to provide safety-engineered devices to employees that are at-risk for exposure to bloodborne pathogens. The Act requires employers to:

- Identify, evaluate and implement safer medical devices
- Maintain a sharps injury log
- Involve healthcare workers in deciding which devices are used
- Implement engineering controls for sharps disposal containers, self-sheathing needles, safer medical devices (e.g., sharps with engineered injury protections and needle-less systems)—and requiring those engineering controls be used to eliminate or lessen employee exposure to bloodborne pathogens
- Train employees in the proper usage of the engineering and work practice controls to help keep them safe

*The New England Journal of Medicine*⁵ reported that there was “a drop [of reported sharps injuries] of about 38 percent in 2001 when the NSPA took effect. Subsequent injury rates, through 2005, remained well below pre-NSPA rates.” The Centers for Disease Control and Prevention (CDC) further reported a 31.6 percent reduction in sharps-related injuries in non-surgical hospital settings during 2001–06 following the NSPA’s passage.⁶

⁵ “Percutaneous Injuries Before and After the Needlestick Safety and Prevention Act.” *The New England Journal of Medicine* 366:670-671 (2012). 16 February 2012. Web. 30 January 2014. <www.nejm.org/doi/full/10.1056/NEJMc1110979>

⁶ “The STOP STICKS Campaign: Sharps Injuries.”

What is a SurgiLance™ Safety Lancet?

SurgiLance™ safety lancets are single-use fingerstick devices, used for the collection of blood from the fingers of adults and children.

Available in seven models, each is primarily identified by its incision's average penetration depth:

SurgiLance™ Safety Lancet		Penetration Depth
	SLN100	1.0 mm
	SLN170	1.7 mm
	SLN200	1.8 mm
	SLN240	2.2 mm
	SLN300	2.8 mm
	SLB200	1.8 mm
	SLB250	2.3 mm

As will be described in the following sections, SurgiLance was designed with several safety features to complement its ease-of-use and reliability.



Golden Rule of Safety #1: Automatic, Non-Interfering Safety Mechanisms

The design and activation of the safety mechanism is automatic and will not interfere with normal operating procedures and processes.¹

The SurgiLance™ safety lancet's passive safety mechanism automatically activates after the device is used, requiring no action on the part of the user.

This safety feature specifically refers to SurgiLance's internal spring-activated mechanism. When activated, an internal needle or blade is exposed momentarily before it automatically retracts into the housing. After activation, the single-use device cannot be used again.

¹ "The Golden Rules of Safety."

Golden Rule of Safety #2: Intuitive Use

The device is intuitive and requires no additional steps for use than equivalent standard/conventional device.¹

Unlike traditional lancets—and for that matter, some safety lancets—that requiring “arming” (inserting a needle into the device), SurgiLance™ safety lancets are “pre-armed” and only require five simple steps to operate:

	1. Clean test site according to your facility’s protocol.
	2. Remove the protective cap from a SurgiLance safety lancet.
	3. Place red raised platform end of SurgiLance safety lancet on the test site.
	4. Gently push SurgiLance safety lancet down against test site to activate the lancet mechanism.
	5. Discard used SurgiLance safety lancet into a suitable biohazard sharps container.

¹ “The Golden Rules of Safety.”

These written and visual instructions appear on each box of SurgiLance, which also include inserts that provide translated instructions for more than a dozen languages. Additionally, MediPurpose™ hosts an online demonstration video on its Website.²



² MediPurpose. "How to Use SurgiLance™ Safety Lancets Video." Web. 30 January 2014. <www.medipurpose.com/surgilance/videos/using-surgilance>

Golden Rule of Safety #3: Safe Rendering of Non-Sterile Sharp

The contaminated, non-sterile sharp will be rendered safe prior to removal or exposure to the environment.¹

As described in “Golden Rule of Safety #1,” the SurgiLance™ safety lancet’s needle or blade is automatically retracted into the housing immediately after use and remains safely in the housing. A single-use needlestick device, once activated, it cannot be used again.

¹ “The Golden Rules of Safety.”

Golden Rule of Safety #4: Simplicity of Safety Mechanism Activation

Activation of the safety mechanism does not require the healthcare worker to undertake any additional steps during normal process/protocols providing patient care.¹

As described in “Golden Rule of Safety #1,” the SurgiLance™ safety lancet’s passive safety mechanism automatically activates after the device is used, requiring no action on the part of the user.

The SurgiLance’s blade retracts into the housing automatically after activation. A single-use needlestick device, once activated, it cannot be used again.

¹ “The Golden Rules of Safety.”

Golden Rule of Safety #5: Occupational Hazards

Activation of the safety mechanism will not create additional occupational hazards (such as aerosolization, splatter, exposure to OPIM, etc.).¹

When used as directed, the SurgiLance™ safety lancet does not create any additional occupational hazards.

¹ “The Golden Rules of Safety.”

Golden Rule of Safety #6: No Additional Harm or Discomfort to Patient

Activation of the safety mechanism does not cause additional discomfort or harm to the patient.¹

SurgiLance™ safety lancets were explicitly designed to deliver remarkably smooth incisions that minimize trauma to patients' fingers. This is achieved through several innovative features, including:

- A spring-activated cutting mechanism that ensures quick puncture.
- Sharp and smooth needles/blades.
- Activation that only requires pressing the device against the finger (rather than an activation trigger).

¹ "The Golden Rules of Safety."

Golden Rule of Safety #7: One-Handed Ergonomics

The device will be ergonomically designed for comfort, allowing for automatic one handed use during all stages of patient procedure.¹

SurgiLance™ safety lancets only require one hand to operate. Further—and as described in previous sections—SurgiLance is a “pre-armed” fingerstick device that is activated by pressing the device against the finger (rather than an activation trigger).

¹ “The Golden Rules of Safety.”

Golden Rule of Safety #8: Diverse Sizes and Iterations

The safer engineering control is available in sizes and iterations appropriate for all areas of use relevant to the patient care needs.¹

SurgiLance™ safety lancets are available in seven models, all of which provide identical safety and reliability. Each is primarily identified by its needle or blade’s average penetration depth, as well as its unique housing color for easy, accurate identification.

SurgiLance™ Safety Lancet		Penetration Depth
	SLN100	1.0 mm
	SLN170	1.7 mm
	SLN200	1.8 mm
	SLN240	2.2 mm
	SLN300	2.8 mm
	SLB200	1.8 mm
	SLB250	2.3 mm

¹ “The Golden Rules of Safety.”

Golden Rule of Safety #9: Disposal of Safety Device

Disposal of safety device will not increase waste disposal volumes but should incorporate designs to reduce waste.¹

SurgiLance™ safety lancets are designed to be as small as possible, but without reducing their safety or ease of use.

Approximately 7/8-inch wide, a half-inch thick and 1–1/4 inches long, the device consumes relatively little space in approved sharps disposal containers.

¹ “The Golden Rules of Safety.”

Golden Rule of Safety #10: Convenient Disposal

The used safety device will provide convenient disposal and mitigate any risk of reuse or re-exposure of the non-sterile sharp.¹

As mentioned in earlier sections, SurgiLance™ safety lancets are passive single-use sharps devices that prevent blade exposure both before and after use.

And, as indicated in the last section, SurgiLance's compact housing makes it very convenient for disposal, taking up relatively little space when placed in an approved sharps disposal container.

¹ "The Golden Rules of Safety."

If Safe in Common’s “Top 10 Golden Rules for Safety” can be considered a scorecard for sharps safety devices, the SurgiLance™ safety lancet arguably earns a perfect score.

Likewise, consumers have given their votes of confidence for SurgiLance’s safety, comfort and ease of use—through both their purchasing power and microscopic complaint rates.

In June 2013, MediPurpose announced the sale of its billionth SurgiLance,¹ and later in the year, it announced a 10-year complaint rate of 0.00002 percent (two one-hundred thousandths), which translated into a scant 212 complaints for the nearly one billion lancets sold during that time.²

¹ MediPurpose. “Billionth SurgiLance™ Safety Lancet Sold to AOSS Medical Supply.” 5 June 2013. Web. 30 January 2014.

<medipurpose.com/news/488-billionth-surgilance-safety-lancet-sold-to-aoss-medical-supply>

² MediPurpose. “One in a Million: SurgiLance™ Safety Lancet Quality.” 31 October 2013. Web. 30 January 2014. <www.medipurpose.com/blog/entry/one-in-a-million-surgilance-safety-lancet-quality>

Business Benefits of Partnering with MediPurpose™

The company's confidence in its SurgiLance™ safety lancet is bolstered by its:

- International popularity with healthcare providers and patients for nearly two decades.
- Capability to consistently deliver a fingerstick incision that yields an adequate volume of blood for collection while minimizing pain, bruising and trauma.
- Safety and quality from a proven and trusted manufacturer with worldwide distribution channels.

Calls to Action

Learn more about SurgiLance™

- Please visit medipurpose.com/surgilance

Download SurgiLance™ product and reference guides

- Please visit medipurpose.com/downloads

Request no-cost SurgiLance™ samples and pricing

- Please visit medipurpose.com/surgilance/samples-and-pricing

Participate in SurgiLance™ clinical evaluations

- Please e-mail sales@medipurpose.com

Arrange for SurgiLance™ in-servicing from an approved distributor

- Please e-mail sales@medipurpose.com