

MediPurpose™

Lancing Devices

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



How Does the babyLance™ Safety
Heelstick Compare?



This white paper outlines sharps safety advocate Safe in Common's "10 Golden Rules of Safety" and evaluates how well the all-new babyLance™ safety heelstick measures to them.



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) in 2000, 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

Specifically developed for neonatal blood collection, babyLance was first introduced in 2010 as a complementary product to SurgiLance. In 2012, an all-new babyLance was launched after more than a year of intensive research, design and validation for its safety and ease of use.

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

¹ Safe in Common. “The Golden Rules of Safety.” 20 June 2013. Web. 15 August 2013. <www.safeincommon.org/blog/golden-rules-safety>

² Infection Control Today. “Needlestick Safety and Prevention Act 10-Year Anniversary.” 2 November 2010. Web. 15 August 2013. <www.infectioncontroltoday.com/articles/2010/11/needlestick-safety-and-prevention-act-10-year-anniversary.aspx>

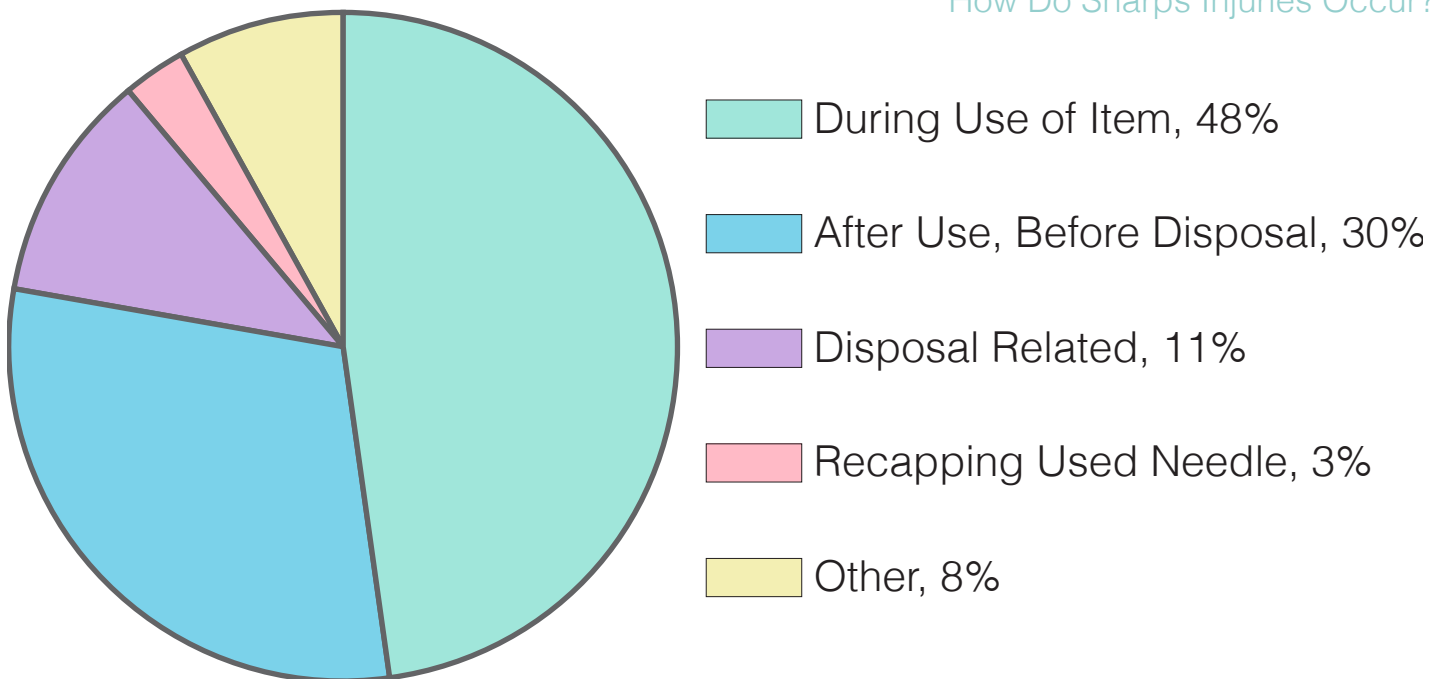
Defining a “Safety” Heelstick

What is a “Safety” Heelstick?

A heelstick is an incision device that makes a shallow cut on a baby’s heel for the purpose of obtaining a blood sample. A *safety* heelstick 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

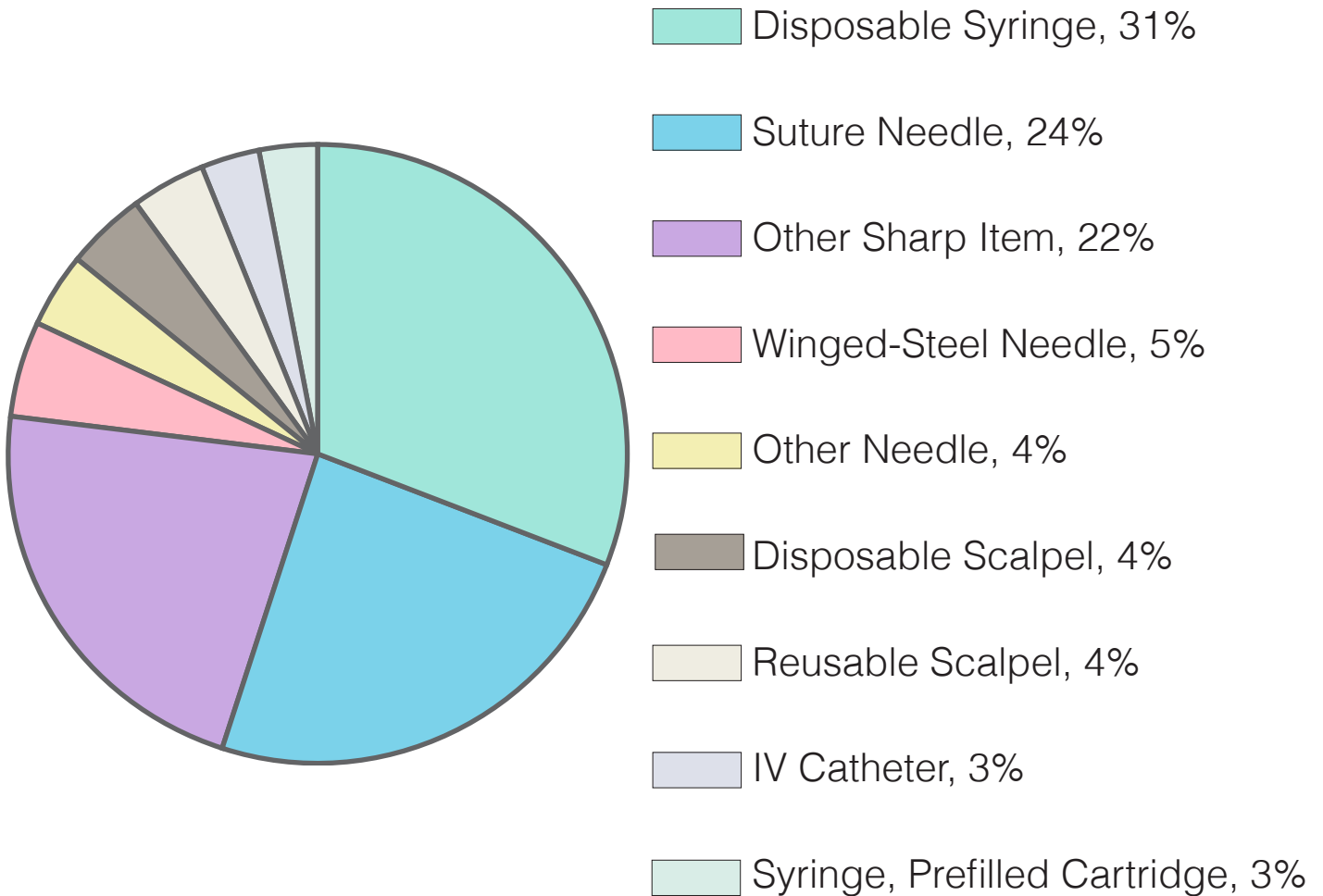


¹ U.S. Food and Drug Administration. “Guidance for Industry and for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features.” 9 August 2005. Web. 1 May 2013. <www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071663.htm>

² Centers for Disease Control and Infection. “The STOP STICKS Campaign: Sharps Injuries.” 24 June 2011. Web. 1 May 2013. <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. 1 May 2013. <www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketnotifications/premarketnotification510k/default.htm>

⁴ "The STOP STICKS Campaign: Sharps Injuries."

Why Do You Need a Safety Heelstick?

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. 1 May 2013. <www.nejm.org/doi/full/10.1056/NEJMc1110979>

⁶ “The STOP STICKS Campaign: Sharps Injuries.” .

What is a babyLance™ Safety Heelstick?

babyLance™ safety heelsticks are single-use neonatal heel incision devices, used for the collection of blood from the heels of infants.

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

babyLance™ Safety Heelstick	Penetration Depth
 <p data-bbox="792 934 998 976">Preemie (BLP)</p>	<p data-bbox="1123 934 1250 976">0.85 mm</p>
 <p data-bbox="784 1148 1006 1190">Newborn (BLN)</p>	<p data-bbox="1133 1148 1240 1190">1.0 mm</p>

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

In 2010 and 2012, MediPurpose received U.S. FDA clearances to legally market its babyLance heel incision device as a “safety” device in the United States when the FDA approved its babyLance application for a 510(k) with sharps prevention indications.¹

¹ MediPurpose. “MediPurpose Receives U.S. FDA 510(k) Clearance for Redesigned babyLance Safety Heelstick.” 19 February 2013. Web. 15 August 2013. <www.medipurpose.com/news/462-medipurpose-receives-us-fda-510k-clearance-for-redesigned-babylance-safety-heelstick>

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

More specifically, this refers to babyLance's internal incision mechanism. When activated, an internal blade is exposed momentarily before it automatically retracts into the housing. After activation, the single-use device cannot be operated again.

To validate the reliability of these safety features, MediPurpose conducted clinical use tests in early 2012 before babyLance's official launch. The tests were conducted at five facilities where 33 users tested 501 devices, with the following results:²

- The trigger lock prevented accidental activation: 100%
- The blade was shielded prior to activation: 100%
- The blade was shielded after activation: 100%
- The device cannot be reused after activation: 100%





¹ "The Golden Rules of Safety."

² MediPurpose. "Clinical Use Study to Validate Heelstick Design." 16 October 2012. Web. 1 May 2013. <www.mediurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/89-clinical-use-study-to-validate-heelstick-design>

Golden Rule of Safety #2: Intuitive Use

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

The babyLance™ safety heelstick requires only four simple steps to operate:

	1. Select and clean an incision site on the flat-bottom surface of the infant's heel.
	2. Remove the trigger lock, but do not pull back the trigger until ready for use.
	3. Align the blade slot with the incision site using the visual marking, and then pull back trigger with index finger. Discard after use.
	4. Gently wipe away the first droplet of blood and collect the desired quantity.

These written and visual instructions for use (IFU) are provided to users in each box of babyLance—including translations into several languages.

¹ "The Golden Rules of Safety."

MediPurpose™ also provides the IFU on a large, easy-to-read wall chart to customers at no additional cost,² as well as on its Website.³

Additionally, MediPurpose produced an online video that demonstrates proper and safe usage.⁴

Additional Intuitive Characteristics

babyLance's intuitive ease-of-use is the result of MediPurpose's very close interaction with neonatal nurses throughout the device's development.

MediPurpose's research determined that end users' explicit expectations for an "ideal heelstick" is a device that would:⁵

- Feel comfortable and stable during activation
- Be as easy to activate as the user's current device
- Be easy to activate with one hand
- Provide an audible click when activated

As with the safety features described in the previous section, MediPurpose validated these characteristics (which included the IFU) during a series of clinical use studies conducted in 2012, with highly positive results.⁶

² MediPurpose. "babyLance™ Instructions for Use (IFU) Quick Reference Wall Chart." 30 July 2012. Web. 15 August 2013. <www.medipurpose.com/downloads/viewdownload/3-product-guides/66-babylance-instructions-for-use-ifu-quick-reference-wall-chart>

³ MediPurpose. "How to Use babyLance™ Safety Heelsticks." Web. 15 August 2013. <www.medipurpose.com/babylance/babylance-ifu>

⁴ MediPurpose. "How to Use babyLance™ Safety Heelsticks Video." Web. 15 August 2013. <www.medipurpose.com/babylance/babylance-videos>

⁵ MediPurpose. "Translating User Requirements into Design Specifications: Optimizing Ease-of-Activation." 3 October 2012. Web. 15 August 2013. <www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/86-optimizing-heelstick-ease-of-activation>

⁶ "Clinical Use Study to Validate Heelstick Design."

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 babyLance™ safety heelstick’s blade retracts into the housing after activation. A single-use needlestick device, once activated, it cannot be operated again.

Furthermore, as also described in earlier sections, this safety feature’s reliability was validated in a series of clinical use tests with 100% positive results.²

¹ “The Golden Rules of Safety.”

² “Clinical Use Study to Validate Heelstick Design.”

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 babyLance™ safety heelstick’s passive safety mechanism automatically activates after the device is used, requiring no action on the part of the user.

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

Furthermore, as also described in earlier sections, this safety feature’s reliability was validated in a series of clinical use tests with 100% positive results.²

¹ “The Golden Rules of Safety.”

² “Clinical Use Study to Validate Heelstick Design.”

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 babyLance™ safety heelstick does not create any additional occupational hazards.

In fact, MediPurpose™ designed, engineered and tested babyLance's all-new activation trigger and internal incision mechanism to make an already safe device even safer. By precisely calibrating babyLance's trigger force and activation distance, babyLance is as easy (or easier) to use than other brands' heelstick devices, but not at the risk of making it so sensitive that it would have a "hair trigger" that could be prematurely activated.²

Once again, MediPurpose tested the safety and reliability of these safety features in a series of clinical use tests, with 100% positive results.³

¹ "The Golden Rules of Safety."

² "Translating User Requirements into Design Specifications: Optimizing Ease-of-Activation."

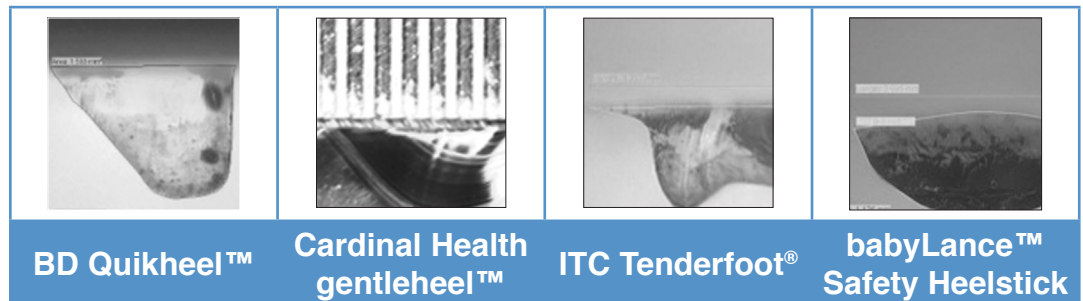
³ "Clinical Use Study to Validate Heelstick Design."

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

babyLance™ safety heelsticks were explicitly designed to deliver remarkably smooth incisions that minimize trauma to an infant’s delicate subcutaneous tissues.

babyLance heelsticks not only meet Clinical Laboratory Standard Institutes (CLSI) guidelines for incision depths, but when compared to competing brand’s heelstick devices, it visibly delivered the smoothest “cut profile,” which further minimizes pain and trauma:²



The notion of a smooth cut profile is very important when considering that neonatal nurses perform an average of four infant heelstick incisions within 96 hours after birth.³

That frequency incrementally reduces the area of an infant’s heel where additional incisions may be performed—which demands a device that delivers the smoothest possible incision that yields an appropriate volume of blood for collection. Otherwise, additional heelstick procedures may need to be performed.

¹ “The Golden Rules of Safety.”

² MediPurpose. “Heelstick Cut Profile Study.” 30 August 2012. Web. 15 August 2013. <www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/76-heelstick-cut-profile-comparative-study>

³ MediPurpose. “A Summary of babyLance™ Features: Design and Validation.” 11 July 2013. Web. 15 August 2013. <www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/157-a-summary-of-babylance-features-design-and-validation>

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

As illustrated in “Golden Rule of Safety #2,” babyLance™ safety heelsticks only require one hand to operate—leaving the user’s other hand to hold the infant’s leg/foot while he or she performs the heelstick procedure. Additionally, the safety trigger was designed to be removed with either a one- or two-handed technique, whichever the user prefers.²

Comfort and other ergonomic concerns were priorities throughout babyLance’s development.³ That is why babyLance was carefully designed to satisfy the following:

- **Heelstick usage environment:** Nursing professionals in the neonatal units of maternity hospitals—or midwives assisting deliveries at home—frequently use heelstick devices on newborn babies with very small feet, and while wearing gloves. As heelstick devices are often used under dimly lit conditions, babyLance was designed to offer tactile and audible feedback after activation.
- **Multiple positions for holding heelstick devices:** Although babyLance’s instructions for use (IFU) illustrate one position for holding the device, it was designed to be used with alternative “grips” that users might find more comfortable.
- **Trigger preferences (i.e., activation style, force and distance):** As described in “Golden Rule of Safety #5), babyLance’s precisely calibrated trigger makes it as easy (or easier) to use than other brands’ heelstick devices, but not at the risk of making it so sensitive that it would have a “hair trigger” that could be prematurely activated.⁴

¹ “The Golden Rules of Safety.”

² MediPurpose. “Defining, Translating and Validating Heelstick Ergonomics.” 6 December 2012. Web. 15 August 2013. <www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/90-defining-translating-and-validating-heelstick-ergonomics>

³ Ibid.



⁴ “Translating User Requirements into Design Specifications: Optimizing Ease-of-Activation.”

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

babyLance™ safety heelsticks are available in two models, both of which provide identical safety and reliability.²

Each are primarily identified by its blade's average penetration depth, as well as unique housing colors and packaging features for easy, accurate identification and use in dimly-lit neonatal nursing facilities:

babyLance™ Safety Heelstick	Penetration Depth
 <p data-bbox="792 1087 997 1125">Premie (BLP)</p>	<p data-bbox="1127 1087 1250 1125">0.85 mm</p>
 <p data-bbox="786 1302 1003 1339">Newborn (BLN)</p>	<p data-bbox="1136 1302 1240 1339">1.0 mm</p>

¹ "The Golden Rules of Safety."

² MediPurpose. "babyLance™ Safety Heelstick Models." Web. 15 August 2013.
<www.medipurpose.com/babylance/babylance-models>

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

babyLance™ safety heelsticks are designed to be as small as possible, but without reducing their safety or ease of use. Approximately 1-1/8th inches square, 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, babyLance™ safety heelsticks are passive single-use sharps devices that prevent blade exposure both before and after use.

And, as indicated in the last section, babyLance'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"¹ can be considered a scorecard for sharps safety devices, the babyLance™ safety heelstick arguably earns a perfect score.

This did not come by accident. MediPurpose™ invested more than a year of research, design, testing and validation into the device—much of it with close collaboration from neonatal nurses.

MediPurpose knows of no other heelstick manufacturer that has committed as much time and effort into discovering, implementing and validating the safety and ergonomic features that result in what it intended to be the "ideal" heelstick.

Coupled with being the only known infant heelstick device to have U.S. FDA 510(k) clearance with sharps prevention indications, MediPurpose believes its babyLance safety heelstick raises the bar for all heelstick device manufacturers.

¹ "The Golden Rules of Safety."

Business Benefits of Partnering with MediPurpose™

The company's confidence in its new babyLance™ safety heelstick is supported by the knowledge that it:

- Is designed with intensive input from a diverse range of highly qualified users.
- Is capable of consistently delivering the ideal heelstick incision that yields an adequate volume of blood for collection while minimizing pain, bruising and trauma to an infant's delicate tissues and nerve endings.
- Provides preferred ergonomic features—such as a “pull trigger” activation mechanism—that is comfortable and easy to use.
- Is assured to provide safety and quality from a proven and trusted manufacturer with worldwide distribution channels.

Additionally, this interactive process further validates MediPurpose's medical product innovation methodology and capabilities.

Calls to Action

- Learn more about babyLance™
Please visit www.medipurpose.com/babylance
- Download babyLance™ product and reference guides
Please visit www.medipurpose.com/downloads
- Download other babyLance™ white papers and case studies
Please visit www.medipurpose.com/downloads
- Request no-cost samples and pricing
Please visit medipurpose.wufoo.com/forms/q7x3s5/
- Participate in clinical evaluations
Please e-mail sales@medipurpose.com
- Arrange for in-servicing from an approved distributor
Please e-mail sales@medipurpose.com



Advanced Heel Incisions

Our babyLance™ safety heelstick device was developed with more than 10 years of proven product development expertise, and leveraging the advanced thinking behind our SurgiLance™ safety lancet. The result is a precise, safe and consistent device specifically designed for babies.



Performance You Will Appreciate

The proprietary spring design provides a swift pendulum action of the cutting blade that makes a gentle incision and complies with CLSI LA4-A5 guidelines¹.

Easy on You and Baby

The industry's easiest trigger reduces finger pressure and activation distance for improved stability and incision quality, which greatly minimizes the risk of bruising.

Fits Your Hand Like a Glove

Designed with you in mind. Ergonomically, the dimples give you a secure grip. While functionally, the device cradles the baby's foot for stability and reduced rock, with visual markings that enable better alignment and a more accurate incision.

The Perfect Incision Every Time

The innovative spring design controls the consistency of the depth and width of the incision for better blood flow, without touching the baby's tender nerve fibers.

4 Easy Steps



1. Select an incision site on the flat bottom surface of the heel, then clean the area.




2. Remove the Trigger Lock, but do not pull back the trigger until ready for use.



3. Align the Blade Slot with the incision site using the visual marking and pull the trigger back with your index finger. Discard.



4. Gently wipe away the first droplet of blood, then collect the desired quantity. That's it.

Product	Code	Incision Depth	Color	Packaging
 Premie	BLP	0.85mm	Pink	50/box 200/case
 Newborn	BLN	1.00mm	Blue	50/box 200/case

[medipurpose.com/babylance](https://www.medipurpose.com/babylance)

1. Clinical and Laboratory Standards Institute. Blood Collection on filter paper for newborn screening programs – Fifth Edition; Approved Standard. CLSI document LA4-A5. Wayne, PA: CLSI, 2007.

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