

**MediPurpose™**

Lancing Devices



# White Paper: Reinventing a Better **babyLance™** Safety Heelstick



Defining, Translating and Validating Safety Features



This white paper describes the redesigned babyLance™ safety heelstick's safety features—and the processes with which they were integrated and validated:

- Gathering end-users' expectations for a safety neonatal heel incision device
- Reviewing the U.S. FDA's *Guidance Document on Medical Devices with Sharps Prevention Features*
- Translating product requirements into design specifications
- Validating safety features before launching the new device in August 2012
- Applying for U.S. FDA 510(k) with sharps safety indications in January 2013



After launching the highly successful and innovative SurgiLance™ safety lancet in 1999, medical product manufacturer and master distributor MediPurpose™ introduced a complementary product in 2010, the babyLance™ safety heelstick.

However, within a few months of launch, MediPurpose realized that the babyLance's innovative design was not fully meeting the preferences and expectations of users in the U.S. market.

Although a number of U.S. healthcare facilities expressed a desire to continue use of the product, feedback indicated that the device needed some modifications in order to fully satisfy customer demands. This included reports that some users preferred a “pull” trigger rather than the babyLance's “push forward” trigger.

MediPurpose elected not to withdraw the product from the market, but rather, it reduced its production and marketing programs for babyLance. The company then initiated a year-plus period of intensive research, redesign and testing, which resulted in its fully redesigned babyLance safety heelstick that was launched worldwide in 2012.

Safety is a crucial aspect of the device and is required to meet the needs of an increasingly safety-conscious and safety-regulated market. Further, without babyLance's safety features, MediPurpose could not submit for a U.S. Food and Drug Administration 510(k) with sharps prevention indications—which enables MediPurpose to legally market babyLance as a “safety heelstick.”

This white paper therefore describes babyLance's key safety features and how MediPurpose validated them with end-users before bringing the device to market and applying for a 510(k) with sharps prevention indications.

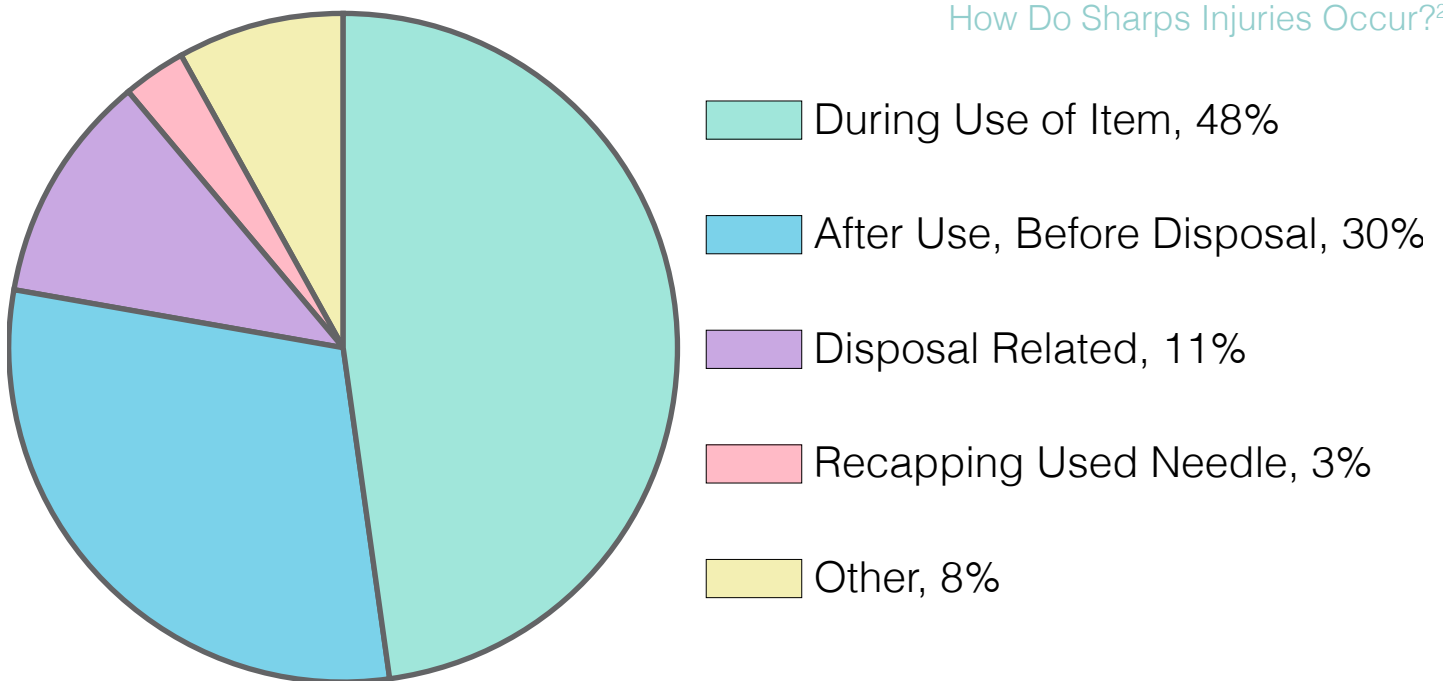
## Defining a “Safety” Heelstick

### 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*,<sup>1</sup> “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?<sup>2</sup>



<sup>1</sup> 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. <[fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071663.htm](http://fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071663.htm)>

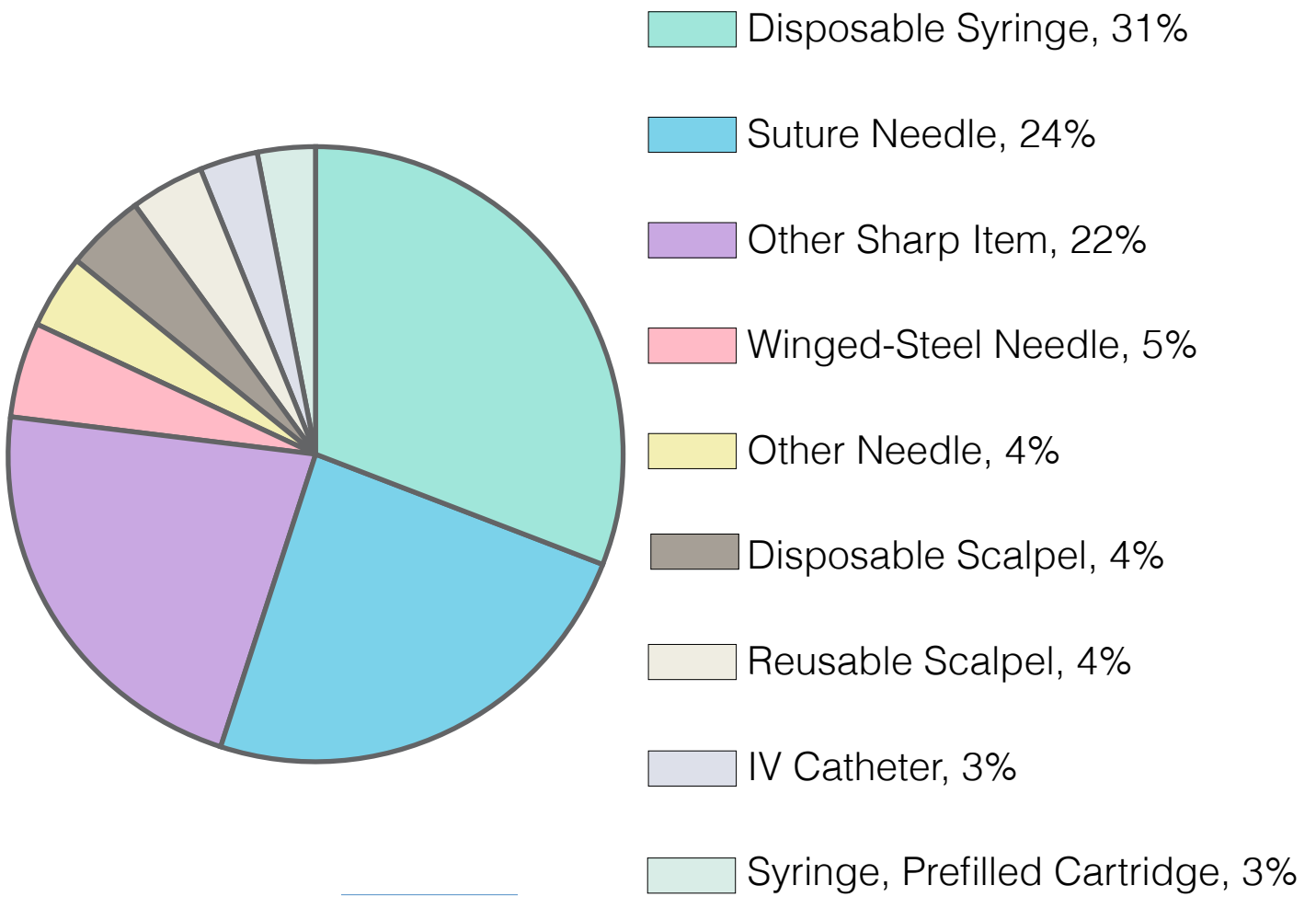
<sup>2</sup> U.S. Food and Drug Administration. “Premarket Notification (510(k)).” 3 September 2010. Web. 1 May 2013. <[fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketnotifications/premarketnotification510k/default.htm](http://fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketnotifications/premarketnotification510k/default.htm)>



The FDA has identified the 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)<sup>3</sup> 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?<sup>4</sup>



<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

## 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*<sup>5</sup> 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 Needlestick and Safety Prevention Act of 2000.<sup>6</sup>

<sup>5</sup> MediPurpose. “Simulated Use Study to Validate Heelstick Design.” 20 September 2012. Web. 1 May 2013. <[medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design](http://medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design)>

<sup>6</sup> Centers for Disease Control and Infection. “The STOP STICKS Campaign: Sharps Injuries.” 24 June 2011. Web. 1 May 2013. <[cdc.gov/niosh/stopsticks/sharpsinjuries.html](http://cdc.gov/niosh/stopsticks/sharpsinjuries.html)>

## Translating babyLance’s Safety Requirements into Design Specifications

To capture all the user requirements and FDA recommendations—and then to translate them into design specifications—MediPurpose created a “safety requirement and design specifications matrix” that included:

- **Safety requirements:** The safety features and characteristics that the users required and/or are recommended by FDA.
- **Design elements:** Design concepts created by the design team.
- **Design specifications:** The specific solutions and details in the final babyLance design.

Safety Requirements	Design Elements	Design Specifications
The use of color should achieve a specific purpose (e.g., differentiate device models or sizes) and conform with user conventions	Different colors for the Newborn and Preemie models with enough contrast to distinguish them in dimly lit environments	Blue housing with green trigger for Newborn, and pink housing with white trigger for Preemie
The sharp should remain completely in the housing before use	Initial position of blade should be completely within the housing (tolerance analysis)	Tolerance analysis required to fix position of blade. Production controls to include visual inspection.
A safety lock is preferred to prevent accidental activation of the heelstick	Removable safety lock on trigger to prevent accidental activation	Safety lock on trigger should be removable by one hand with less than four twists in any direction

Safety Requirements	Design Elements	Design Specifications
The user should be able to easily tell whether the sharps injury prevention feature is activated	Audible and tactile feedback upon activation	Sufficient spring force and stop to enable audible and tactile feedback
Once activated, the sharps injury prevention feature cannot be deactivated	Blocking mechanism to maintain sharp within housing and prevent reuse of device	Stop feature that constrains the trigger arm after activation
The sharp should be fully retracted within the housing of the device	Final position of blade should be completely within the housing	Tolerance analysis required to fix position of blade. Production controls to include visual inspection.
Once activated, the sharps injury prevention feature should remain protective through disposal	Housing should remain intact and protect sharps—even if device is accidentally dropped on a concrete floor	Snap-fit feature to hold two halves of housing together. Production controls to include drop test of device onto concrete floor.
The activation of the safety feature should preferably be automatic (e.g., passive, rather than active device) and will not interfere with normal operating procedures	Mechanism to automatically retract blade into housing at the end of the incision	Spring to retract blade into housing at the end of the incision



Safety Requirements	Design Elements	Design Specifications
The safety heelstick is intuitive to use and requires no additional steps for use than standard device	The safety heelstick design should include obvious, prominent visual cues for opening of blister packaging, removal of trigger lock and use of device	<i>See “Ergonomics” white paper for detailed design specifications<sup>1</sup></i>
The safety heelstick should be ergonomically designed for comfort	See Ergonomics white paper for identification of ergonomic requirements and design elements	<i>See “Ergonomics” white paper for detailed design specifications<sup>2</sup></i>
The safety heelstick should allow for automatic one handed use during all stages of the procedure	Trigger lock should be easily removed by one hand. Safety heelstick should be easily triggered by one hand.	Trigger lock should be easily removed by one hand with only 1–2 twists in any direction. A pullback trigger was integrated into the design, per the preferences of user surveys and research.

<sup>1</sup>“MediPurpose. “Defining, Translating and Validating Heelstick Ergonomics.” 6 December 2012. Web. 1 May 2013. <medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/90-defining-translating-and-validating-heelstick-ergonomics>

<sup>2</sup> Ibid.

# Validating babyLance's Safety Features

## Bench Testing

The following tests were conducted using samples from the first production runs:

Test	Description	Result
Blade Exposure Before Use	Attempt to expose blade prior to removal of trigger lock	Blade was not exposed
Trigger Lock	Attempt to activate device without removing the trigger lock	Device could not be activated
Removal of Activation Lock	Count the number of 45° bends required to remove the trigger lock	Less than four bends to remove trigger lock
Tactile & Audible Feedback	Activate device and determine that activation causes tactile and audible feedback	There was tactile sensation and audible feedback upon activation
Blade Exposure After Use	Attempt to expose blade prior after activation	Blade was not exposed
Blade Attachment	Apply a force of about 3 lb. when attempting to loosen the blade	Blade remained immobile
Re-Use	Attempt to reuse the device after activation	The device could not be reactivated
Drop Test	Drop devices three times from a height of 1.5 m	No damage visible. Blade remained within housing. device was not activated, and activated properly after the drops.

## Biocompatibility Testing

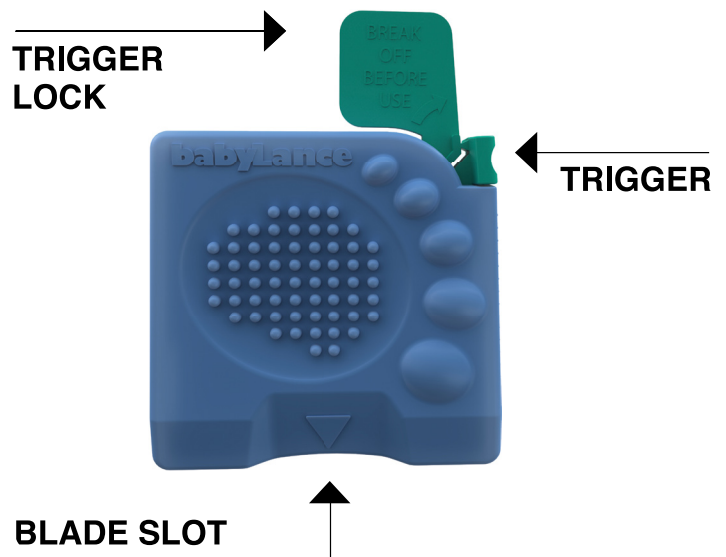
The FDA recommends biocompatibility testing as described in its guidance document.<sup>1</sup> Biological evaluation of medical devices is performed to determine the potential toxicity that might result from contact of the component materials of the device with the body.

Per *ISO 10993 Table A.1*, the babyLance plastic housing would be considered as “Surface device, Skin contact, A-limited duration.” The required testing for this is:

- Cytotoxicity,
- Sensitization, and
- Irritation or Intracutaneous Reactivity

The above tests were conducted on the plastic material used for the babyLance housing, and the results were negative.

Testing of the blade is not required as the blade material is 304 Stainless Steel, which is an approved material for use in medical instruments and is widely used in many predicate devices for the same intended use.



## Sterility Validation

The babyLance safety heelstick is sterilized by gamma radiation. The sterilization process was validated in accordance with *ISO 11137—Sterilization of Healthcare Products—Radiation*.

<sup>1</sup> U.S. Food and Drug Administration. “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.’” 3 May 2009. Web. 1 May 2013. <[fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm](http://fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm)>

## Simulated Use Tests

The FDA recommends simulated clinical-use testing for devices that include sharps injury prevention features. Simulated-use testing mimics actual clinical use by using patient substitutes (e.g., replica infant heels) rather than actual patients. Simulated use testing helps:

- Isolate problems with the device
- Optimize the device design
- Identify deficiencies in labeling
- Evaluate the type of training needed for device users

There are no standardized, validated methods to simulate clinical use of sharps injury prevention features. MediPurpose developed its own protocol following the FDA guidance document.

The FDA recommends that for many devices with sharps safety features, it is feasible to test 500 devices, which will enable detection of grossly defective devices at a one-percent level. If there were no failures observed in a test run of 500 devices, we would be 97.5 percent confident that the true failure rate was no higher than 0.7 percent, and 99.5 percent confident that it was no higher than 1.1 percent.

MediPurpose conducted a simulated clinical use test in early 2012:<sup>2</sup>

- Test Facilities: 5
- Test Users: 33
- Test Units: 501

The results were as follows:

- The trigger lock prevents 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%

<sup>2</sup> MediPurpose. "Simulated Use Study to Validate Heelstick Design." 20 September 2012. Web. 1 May 2013. <[medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design](http://medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design)>

## Clinical Use Tests

Informed by feedback from the simulated use tests, MediPurpose modified the babyLance IFU (instructions for use) and enlarged the device's trigger before next conducting a clinical use test in mid-2012:<sup>3</sup>

- Test Facilities: 5
- Test Users: 37
- Test Units: 610

The results were as follows:

- The trigger lock prevents 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%



<sup>3</sup> MediPurpose. "Clinical Use Study to Validate Heelstick Design." 16 October 2012. Web. 1 May 2013. <[medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design](http://medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design)>

## U.S. FDA 510(k) Application for Safety Indications

With the babyLance safety features tested and validated, MediPurpose submitted its 510(k) application in January 2013 and received an FDA 510(k) with sharps prevention indication in February 2013,<sup>1</sup> permitting the company to market its product as the babyLance *safety* heelstick.

MediPurpose later published a white paper<sup>2</sup> that summarized its process for obtaining the 510(k) clearance.

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<sup>1</sup> MediPurpose. "MediPurpose Receives U.S. FDA 510(k) Clearance for Redesigned babyLance Safety Heelstick." 19 February 2013. Web. 1 May 2013. <[medipurpose.com/news/462-medipurpose-receives-us-fda-510k-clearance-for-redesigned-babylance-safety-heelstick](http://medipurpose.com/news/462-medipurpose-receives-us-fda-510k-clearance-for-redesigned-babylance-safety-heelstick)>

<sup>2</sup> MediPurpose. "Obtaining a U.S. FDA 510(k) with Sharps Prevention Features." 3 April 2013. Web. 1 May 2013. <[medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/146-obtaining-a-us-fda-510k-with-sharps-prevention-features](http://medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/146-obtaining-a-us-fda-510k-with-sharps-prevention-features)>



## Business Benefits of Partnering with MediPurpose™

In August 2012, MediPurpose™ launched a redesigned babyLance™ heelstick that will satisfy the unique needs of both its end-user customers and distribution partners.

The company's confidence is supported by the knowledge that the new babyLance:

- 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](http://www.medipurpose.com/babylance)
- Download babyLance™ product and reference guides  
Please visit [www.medipurpose.com/downloads](http://www.medipurpose.com/downloads)
- Download other babyLance™ white papers and case studies  
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- Request no-cost samples and pricing  
Please visit [medipurpose.wufoo.com/forms/q7x3s5/](http://medipurpose.wufoo.com/forms/q7x3s5/)
- Participate in clinical evaluations  
Please e-mail [sales@medipurpose.com](mailto:sales@medipurpose.com)
- Arrange for in-servicing from an approved distributor  
Please e-mail [sales@medipurpose.com](mailto: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 guidelines<sup>1</sup>.

### 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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