

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



A Summary of babyLance™ Features:  
Design and Validation

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This white paper summarizes key design features—and the processes with which they were validated—for the all-new babyLance™ safety heelstick, which include its:

- + Easy activation
- + Smooth and consistent incisions
- + Ergonomics
- + Safety



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 babyLance’s 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 a fully redesigned babyLance safety heelstick that was launched worldwide in 2012.

In 2011, the babyLance design team was tasked with the goal of producing the “ideal heelstick,” which could only be fully defined and validated by the end-users: neonatal nurses. The team used the original babyLance as a basis for which it could compare and contrast its features with competing brands so that it could better understand end-users’ unique needs, expectations and requirements.

The babyLance design team translated that research into a design requirement matrix that outlined specific challenges to be solved, the design elements related to those challenges, and specifications to solve them. This white paper summarizes several key features from that matrix and how MediPurpose validated their designs before bringing the redesigned babyLance to market.

+ In 2011, the babyLance design team was tasked with the goal of producing the “ideal heelstick”

+ research was translated into a design requirement matrix

+ the matrix outlined specific challenges to be solved, the design elements related to those challenges, and specifications to solve them

Using a babyLance™ safety heelstick is, by design, a very simple process: After selecting the appropriate model for the preferred penetration depth (Preemie for an 0.85 mm incision, or Newborn for 1.0 mm), the user simply needs to locate and clean the incision target area, remove the trigger lock, and then perform actual heelstick procedure.

However, a significant amount of research, design and validation was required before MediPurpose™ was confident that the new babyLance would satisfy end-users' clearly defined preferences—which, among others, emphasized ease of activation. More can be learned about how MediPurpose was able to solicit and process those preferences into design specifications in the white paper, *Understanding the Needs of End-Users*.<sup>1</sup>

### Challenges and Solutions

MediPurpose conducted additional research, revealing that users had two primary issues with the original babyLance's trigger: the trigger's activation method and the amount of force required to activate it. This process is explained in more depth in the white paper, *Translating User Requirements into Design Specifications: Optimizing Ease of Activation*.<sup>2</sup>

#### Activation Method

The original babyLance was designed to be activated with a push-forward trigger—a departure from the pullback or pushdown styles used by competing brands.

To determine the activation styles preferred by most end-users, MediPurpose conducted a survey at the National Association of Neonatal Nurses' national convention in Orlando, Florida in September 2011.

<sup>1</sup> MediPurpose. "Understanding the Needs of End-Users." 23 August 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/75-understanding-the-needs-of-heelstick-end-users](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/75-understanding-the-needs-of-heelstick-end-users)>

<sup>2</sup> MediPurpose. "Translating User Requirements into Design Specifications: Optimizing Ease of Activation." 3 October 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/86-optimizing-heelstick-ease-of-activation](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/86-optimizing-heelstick-ease-of-activation)>

+ users had two primary issues with the original babyLance's trigger: the trigger's activation method and the amount of force required to activate it

+ neonatal nurses' survey indicated a majority preference for the new design's pull trigger

+ users' experiences with competitive devices influenced their preferences for trigger activation *force* and *distance*

The survey gauged NANN members' preferences between the original babyLance's push-forward trigger activation mechanism, a newly designed prototype's pull trigger, and the devices currently in-use at their facilities.

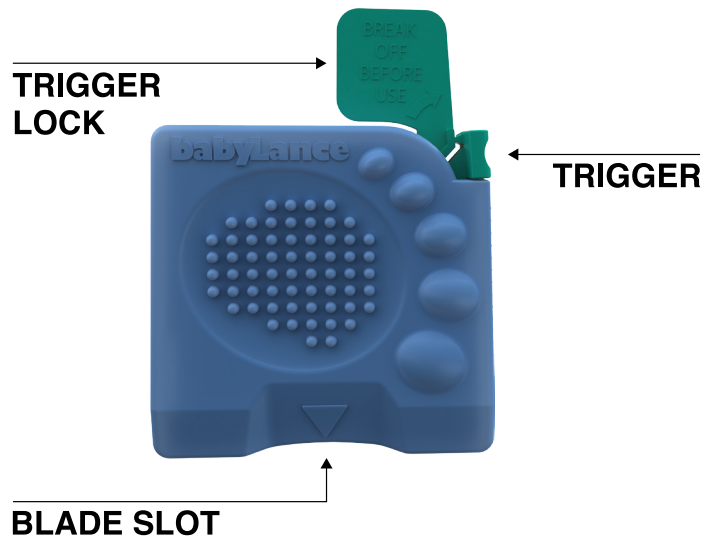
The survey indicated a majority preference for the new design's pull trigger, validating the company's decision to move forward with optimizing that trigger style. This process is explained in more depth in the white paper, *Activation Survey at the 2011 NANN Conference*.<sup>3</sup>

#### Activation Force

The babyLance design team also reviewed the necessary *force* to be applied to a heelstick device's trigger and the distance the trigger must travel to activate the device.

The design team considered user preferences for a trigger that requires minimal effort so that *stability* is not affected while applying force to the trigger, but also while avoiding accidental activation if it is *too* sensitive.

Users' experiences with competitive devices had also influenced their expectations for the amount of force a finger needed to apply to a trigger to activate it—as well as the distance the trigger needed to travel.



<sup>3</sup> MediPurpose. "Activation Survey at the 2011 NANN Conference." 11 August 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/73-heelstick-trigger-activation-survey-at-the-2011-nann-conference](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/73-heelstick-trigger-activation-survey-at-the-2011-nann-conference)>

MediPurpose carefully measured the trigger force and activation distance of existing heelstick devices so that its babyLance would be as easy (or easier) to use, but not at the risk of making the device overly sensitive so that it would have a “hair trigger” risking premature/accidental activation.

Additionally, as will be discussed in the next section (“Smooth Incision”), MediPurpose replaced the original babyLance’s internal incision mechanism with a new spring-based design, which not only improved ease of activation, but also improved the consistency of the incision.

## Validations

To validate that the new trigger and internal incision mechanism improved babyLance’s ease of activation, MediPurpose conducted a series of simulated use<sup>4</sup> and clinical use studies<sup>5</sup> in 2012 with pre-production versions of the newly designed device. These studies demonstrated significant user preferences for the new babyLance.

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<sup>4</sup> MediPurpose. “Simulated Use Study to Validate Heelstick.” 20 September 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/77-simulated-use-study-to-validate-heelstick-design)>

<sup>5</sup> MediPurpose. “Clinical Use Study to Validate Heelstick.” 16 October 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/89-clinical-use-study-to-validate-heelstick-design](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/89-clinical-use-study-to-validate-heelstick-design)>

+ trigger force and distance measurements—and a new spring-based internal incision mechanism—improved ease of activation and the consistency of the incision

## Smooth and Consistent Incisions

**b**abyLance™ safety heelsticks deliver a “smooth” incision that is unparalleled—a crucial feature that may help to minimize bruising and trauma to an infant’s delicate heel tissues and nerve endings.

The notion of “smoothness” relates to both the incision’s vertical and horizontal “profiles,” with the ideal incision’s profile being a gentle arc and less angular.

### Challenges

MediPurpose™ identified several issues related to a heelstick device’s ability to deliver the smoothest possible incision, which are explained in more depth in the white paper, *Heelstick Cut Profile Comparative Study*.<sup>1</sup> Those issues included:

#### CLSI Guidelines for Incision Depth and Width

Clinical Laboratory Standards Institute (CLSI) guidelines<sup>2</sup> specify that an infant heelstick device should create a vertical incision that is deep enough to provide blood flow for collection, but not so deep that it damages subcutaneous tissues.

Further, it proscribes that an ideal horizontal incision must be wide enough to allow enough blood for collection. More specifically, CLSI recommends an incision depth never to exceed 2.0 mm.

#### Integration with Ease-of-Activation Requirements

As illustrated in the previous section (“Ease of Activation”), MediPurpose recognized the need to design the internal incision mechanism to complement the redesigned trigger activation method.

Along with delivering a smooth incision, the trigger, mechanism and housing all needed to provide intuitive positioning and stability, which will be discussed in the next section (“Ergonomics”).

<sup>1</sup> MediPurpose. “Heelstick Cut Profile Comparative Study.” 30 August 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/76-heelstick-cut-profile-comparative-study](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/76-heelstick-cut-profile-comparative-study)>

<sup>2</sup> Clinical and Laboratory Institute. CLSI LA4-A5: Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition 23.21 (2007). Print.

+ the ideal heelstick’s incision profile is smooth, less angular, and gently arced

+ CLSI recommends an incision depth never to exceed 2.0 mm

+ a new spring mechanism activated by the trigger provides a swifter incision, and a controlled and consistently smooth incision

+ compared to competitive brands, babyLance™ consistently delivered the smoothest, cleanest incision

### Frequency of Heelstick Procedures Performed by Neonatal Nurses

Within 96 hours after birth, neonatal nurses perform an average of four infant heelstick incisions. That frequency incrementally reduces the area of an infant's very delicate subcutaneous tissues where additional incisions may be performed.

## Solutions

Collectively, these issues were resolved through two key design elements:

### New Spring Mechanism

The actual force of the user's finger drove the original babyLance's blade via the trigger. The new babyLance introduced a new spring mechanism activated by the trigger. Along with providing a swifter incision, it was designed to deliver a controlled and consistently smooth incision.

### Optimized Incision Profile

Along with ensuring a consistent incision profile that both provided sufficient blood for collection (and thus, minimizing the need for additional incisions) and met CLSI guidelines, MediPurpose's design team precisely engineered the new incision mechanism to deliver a gently-arc'd incision—as opposed to a severely-angled puncture that could result in greater tissue trauma.

## Validations

Along with the simulated use<sup>3</sup> and clinical use studies<sup>4</sup> mentioned in the previous section to validate that its new device would consistently deliver smooth and efficient incisions, MediPurpose also conducted a comparative cut profile study of its new device and several competitive products.

Although each company's heelstick device statistically met CLSI guidelines for maximum incision depth, visual examination of each device's cut profile strongly suggested that babyLance consistently delivered the smoothest, cleanest incision (all of which are illustrated in more detail in the *Heelstick Cut Profile Comparative Study* white paper<sup>5</sup>).

<sup>3</sup> "Simulated Use Study to Validate Heelstick."

<sup>4</sup> "Clinical Use Study to Validate Heelstick."

<sup>5</sup> "Heelstick Cut Profile Comparative Study."



The new babyLance™ safety heelstick’s design carefully heeds OSHA’s definition of *ergonomics* to assure “high productivity, avoidance of illness and injury risks, and increased satisfaction among the workforce.”<sup>1</sup>

+ ergonomics assures “high productivity, avoidance of illness and injury risks, and increased satisfaction among the workforce”

+ neonatal nurses are challenged by workplace environments when identifying, opening and using heelsticks

## Challenges

Both “ease of activation” and “smooth and consistent incisions” relate to that definition’s objectives. However, other end-user preferences entered into the ergonomics equation. This process is explained in more depth in the white paper, *Defining, Translating and Validating Ergonomic Design Specifications*.<sup>2</sup>

### Workplace Environment

Along with the frequency of incisions (illustrated in the previous section, “Smooth and Consistent Incisions”), MediPurpose™ was acutely aware of another unique challenge faced by neonatal nurses: performing neonatal blood collection while wearing gloves and working in dimly lit environments.

### Ease of Identifying and Opening the Device

Those workplace environment factors further emphasized end-users’ needs for heelstick devices (and packaging) that can be easily identified and intuitively opened.

For instance, in such conditions, some neonatal nurses said it was sometimes difficult to accurately identify which of the earlier babyLance’s two models had been selected for use.

<sup>1</sup> Occupational Safety and Health Administration (OSHA). “Safety and Health Topics: Ergonomics.” Web. 1 July 2013. <[www.osha.gov/SLTC/ergonomics/](http://www.osha.gov/SLTC/ergonomics/)>

<sup>2</sup> MediPurpose. “Defining, Translating and Validating Ergonomic Design Specifications.” 6 December 2012. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/90-defining-translating-and-validating-heelstick-ergonomics](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/90-defining-translating-and-validating-heelstick-ergonomics)>

### Ease of Locating and Maintaining Stable Incision Positioning

Finally, along with the other factors, nurses expressed the another challenge: accurately identifying and maintaining the device's positioning for incisions—especially while handling an infant's tiny, squirming feet.

### Solutions

MediPurpose responded to those challenges with:

#### Unique Device Housing Colors and Optimized Packaging

To make it easier to identify the appropriate heelstick device model in dimly-lit conditions, MediPurpose retained the blue-and-green color scheme for its Newborn model, but it also introduced a new contrasting color scheme (pink and white) for the Premie model.

The team also optimized the device's packaging so that its blister pack label was easier to open and prominently displayed the model's ID: "BLP" for Premie and "BLN" for Newborn.

#### Easier Trigger Lock Removal

Although the device is intended to be used with one hand, trigger lock removal typically required two hands. The babyLance team designed the trigger's lock to be easier to remove—with either a one-handed or two-handed technique, twisting in any direction.



+ new device colors and optimized packaging make babyLance™ easier to identify and open in dimly-lit conditions

+ redesigned trigger enables one-handed or two-handed safety lock techniques

+ redesigned  
device housing  
provides  
enhanced  
tactility, visual  
guidance cues  
and stability

### Tactile Enhancements to the Housing

To improve tactile feel—particularly when wearing gloves—the babyLance team revised the housing’s sides to feature grooves and convex dimples.

### Visual Guidance Cues

To advance the device’s ease of positioning, the team integrated a convex “foot imprint” on the side of the housing and a visible arrow and indentation at the bottom of the housing.

### Flat-Bottomed Housing

The original babyLance’s housing was designed with a slightly concave case at the bottom. To both improve ease of positioning and to increase stability, the new device’s housing was designed with a flat bottom.

### Validations

As with its many other new and improved features, MediPurpose validated the new babyLance’s housing and ergonomics with simulated use<sup>3</sup> and clinical use studies.<sup>4</sup>

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<sup>3</sup> “Simulated Use Study to Validate Heelstick.”

<sup>4</sup> “Clinical Use Study to Validate Heelstick.”

babyLance™ safety heelsticks are the only infant heelstick to have U.S. FDA 510(k) clearance with sharps prevention injury features.<sup>1</sup>

## Challenges

MediPurpose™ faced two core sets of challenges in regards to babyLance's safety features: Along with the ambition to produce the ideal heelstick device that satisfied its end-users' many unique requirements and preferences, it also wanted to satisfy the FDA's expectations for a safety device.

This process is explained in more depth in the white papers, *Defining, Translating and Validating Safety Features*<sup>2</sup> and *Obtaining babyLance's U.S. FDA 510(k) Clearance for Sharps Prevention Indications*.<sup>3</sup>

There are numerous features that contribute to babyLance's overall safety. In terms of its general functionality, they relate to its:

### Trigger Lock

The trigger lock needs to prevent activation before removal, but require less than four 45° bends to remove it (with either a one-handed or two-handed technique).

### Single-Use Blade Exposure

The internal incision blade must not be exposed prior to use or after activation.

### Tactile and Audible Feedback

The device needs to provide users with feedback that the device was activated.

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

<sup>2</sup> MediPurpose. "Defining, Translating and Validating Safety Features." 7 June 2013. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/154-defining-translating-and-validating-safety-features](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/154-defining-translating-and-validating-safety-features)>

<sup>3</sup> MediPurpose. "Obtaining babyLance's U.S. FDA 510(k) Clearance for Sharps Prevention Indications." 7 June 2013. Web. 1 July 2013. <[www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/146-obtaining-a-us-fda-510k-with-sharps-prevention-features](http://www.medipurpose.com/babylance/babylance-white-papers/viewdownload/22-white-papers/146-obtaining-a-us-fda-510k-with-sharps-prevention-features)>

+ *heelstick safety relates to both user requirements and U.S. FDA expectations*

+ babyLance™ is designed to be a *single-use safety needlestick device*

## Solutions

### Trigger Lock

As illustrated in the previous section (“Ergonomics”), MediPurpose optimized babyLance’s trigger lock so it would continue to provide its safety capabilities, but without affecting ease of use.

### Single-Use Blade Exposure

Although the original babyLance was designed as a single-use device that prevented the blade from exposure before and after activation, MediPurpose had to similarly engineer the new babyLance’s spring-activated internal incision mechanism to do the same.

### Tactile and Audible Feedback

Similarly, the new spring-activated internal mechanism was engineered to provide a tactile sensation and audible click during activation.

## Validations

Once again, MediPurpose validated these features with the overwhelmingly positive feedback it received from simulated use<sup>4</sup> and clinical use studies<sup>5</sup> of the new babyLance.

Further, those features were validated by the FDA’s 510(k) clearance of babyLance’s as a device with sharps injury prevention indications.<sup>6</sup>

<sup>4</sup> “Simulated Use Study to Validate Heelstick.”

<sup>5</sup> “Clinical Use Study to Validate Heelstick.”

<sup>6</sup> “MediPurpose Receives U.S. FDA 510(k) Clearance for Redesigned babyLance Safety Heelstick.”

**M**ediPurpose™ knows of no other heelstick manufacturer that has committed as much time and effort into discovering, implementing and validating the features that result in an “ideal” heelstick.

Coupled with being the only known infant heelstick to have U.S. FDA 510(k) clearance with sharps prevention indications, MediPurpose believes its babyLance™ safety heelstick meets end-users’ expectations and requirements for an ideal heelstick device.

### Business Benefits of Partnering with MediPurpose™

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)
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- 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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