

MediPurpose™

Lancing Devices

White Paper: Reinventing a Better babyLance™ Infant Heel Incision Device

babyLance™

Defining, Translating and Validating
Ergonomic Design Specifications



Abstract

This white paper describes how MediPurpose™ successfully:

- + Gathered end-users' expectations for an ergonomic neonatal heel incision device.
- + Translated those expectations into design specifications.
- + Validated the design ergonomics before launching its all-new babyLance™ infant heelstick in August 2012.



Introduction

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™ infant heelstick.

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

MediPurpose elected not to withdraw the product from the market, but rather, it reduced babyLance's production and marketing programs as it initiated a reinvention process that lasted for more than a year.

Throughout the reinvention process, the company painstakingly evaluated virtually every component and feature of its device as it engaged with end-users to better understand their expectations and requirements for the ideal heelstick.¹ Along with their performance needs, MediPurpose recognized ergonomics as equally important.



The original, “push-forward trigger” babyLance heel incision devices.

¹ Learn more in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Understanding the Needs of End Users*.

Defining Ideal Heelstick Device Ergonomics

Definition of Ergonomics

OSHA defines ergonomics as:

“...the science of fitting workplace conditions and job demands to the capabilities of the working population. Effective and successful ‘fits’ assure high productivity, avoidance of illness and injury risks, and increased satisfaction among the workforce.”¹

Obtaining End-User Input on Heelstick Ergonomics

MediPurpose spent considerable effort on understanding and validating its end-users' expectations for an ergonomic device. It achieved this via:



“Voice of the Customer” (VOC) Input

Throughout the entire reinvention process, MediPurpose talked to end-users about their requirements for the ideal heelstick. Along with getting feedback about its original babyLance, MediPurpose also wanted to better understand users' perspectives about other heelstick brands being used at their healthcare facilities.

Interdepartmental Effort

MediPurpose's close relationships with neonatal nurses and medical product distributors enabled its sales, marketing and customer service teams to engage in many conversations with the market. The information gleaned from that discourse was routinely shared with the babyLance design team.

¹ To view the entire definition, please visit <http://www.osha.gov/SLTC/ergonomics/>.

The Definition of babyLance Ergonomics

MediPurpose ultimately defined babyLance's ergonomics as a heelstick device that provided unparalleled ease-of-use without any reduction to its productivity or safety. More specifically, this meant a heelstick that would:

- Be easy to activate with one hand
- Be as easy to activate as user's current device²
- Feel comfortable and stable during activation
- Provide an audible click when activated

The babyLance ergonomics definition was informed by research and feedback about:

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 the devices are often used under dimly lit conditions, devices that offer tactile and audible feedback of activation is advantageous.

Multiple Positions for Holding Heelstick Devices

Although babyLance's instructions for use illustrate one position for holding the device, some end-users indicated a preference for alternative positions.

Trigger Preferences Influenced by Predicate Products

MediPurpose's research indicated that heelstick users' expectations of activation trigger features were in no small part influenced by their experience with a relatively small range of market-leading devices. Those characteristics included:

- **Trigger activation style:** MediPurpose had already learned from experience about the issues created by deviating too far from end-users' expectations. For instance, the original babyLance featured an innovative "push-forward" trigger that did not meet the expectations of end-users.
- **Trigger activation force and distance:** Predicate heelstick devices had also influenced 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.

² Learn more in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Translating User Requirements Into Design Specifications—Optimizing Ease of Activation*.

Translating Ergonomic Requirements into Design Specifications

To capture all the end-users' requirements and translate them into design specifications, MediPurpose created "ergonomics requirement and design specifications matrices" that included:

- **End-user requirements:** The features and characteristics that the users required.
- **Design elements:** Design concepts created by the design team.
- **Design specifications:** The specific solutions and details in the final babyLance design.

Matrix 1: Device Identification

End-User Requirement	Design Element	Design Specification
How can the correct model be located in dimly lit conditions?	Each model should have distinctive colors and contrasts that enhance visibility in dimly lit conditions.	The preemie (BLP) is constructed with pink/white parts, while the newborn (BLN) is constructed with blue and green parts.
	Device packaging labeling should have optimized typography that enhances visibility in dimly lit conditions.	The font for the model IDs (BLP and BLN) was significantly enlarged and offset on the blister pack label.



Early babyLance prototypes for housing color study. Along with brand identity, colors were carefully selected to ensure proper identification in dimly-lit environments.

Matrix 2: Packaging

End-User Requirement	Design Element	Design Specification
How can opening the device package be more intuitive?	Package should have a visual mark that indicates the correct corner to peel open.	A highly visible, bold arrow that points to correct corner was added to the back label of the blister pack.
How can the device package be easier to open?	Paper backing should be easily separated at the correct corner.	A step/dimple was added to the upper corner of the packaging to separate the paper backing from the plastic case.
	Minimal effort should be required to remove the paper backing from the plastic case, but still ensure a sterile barrier and durability.	Various package-sealing techniques were tested to determine an optimum of reduced seal force with maximum sterility/durability.
	Package should use a paper backing material that can be removed easily without tearing.	DuPont Tyvek® was identified as an optimal paper backing material.



“Blister pack” labeling typography was optimized to enhance identification in dimly-lit conditions.



The paper backing was designed to be easy to open while wearing gloves, but without sacrificing sterility or durability.

Matrix 3 Trigger Lock Removal

End-User Requirement	Design Element	Design Specification
How can removing the trigger lock be more intuitive?	Trigger lock should include obvious, prominent visual cues for removal.	A highly visible directional arrow and "BREAK OFF BEFORE USE" text was added to the trigger lock.
How can removing the trigger lock be easier?	Trigger lock should be removable by one hand with only 1–2 twists.	The size of the plastic connector between the lock and trigger was modified to achieve result.
	Trigger lock should be removable by either twisting side-to-side or forward-and-backward.	The plastic connector between the lock and trigger was modified to have a square or round profile.



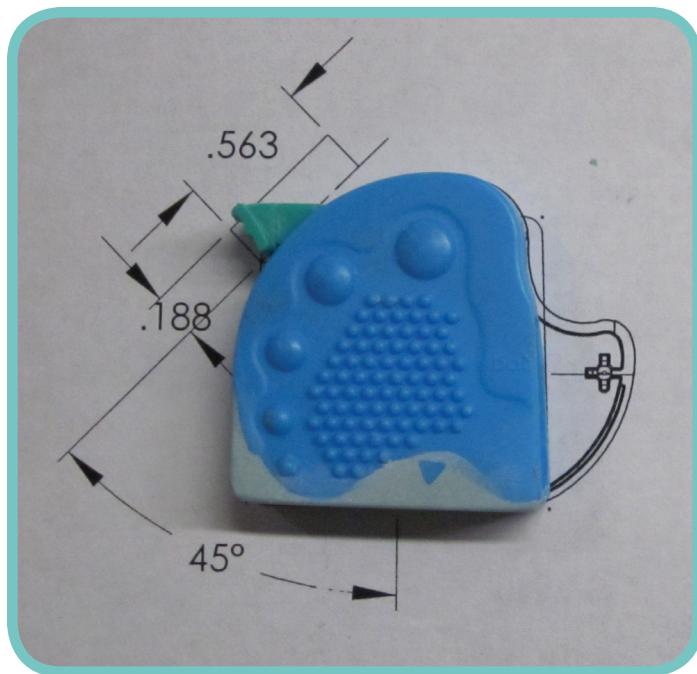
More babyLance prototypes for housing color study (translucent). Note the optimized trigger lock and housing with visual and tactile cues for proper usage.

Matrix 4: Device Handling

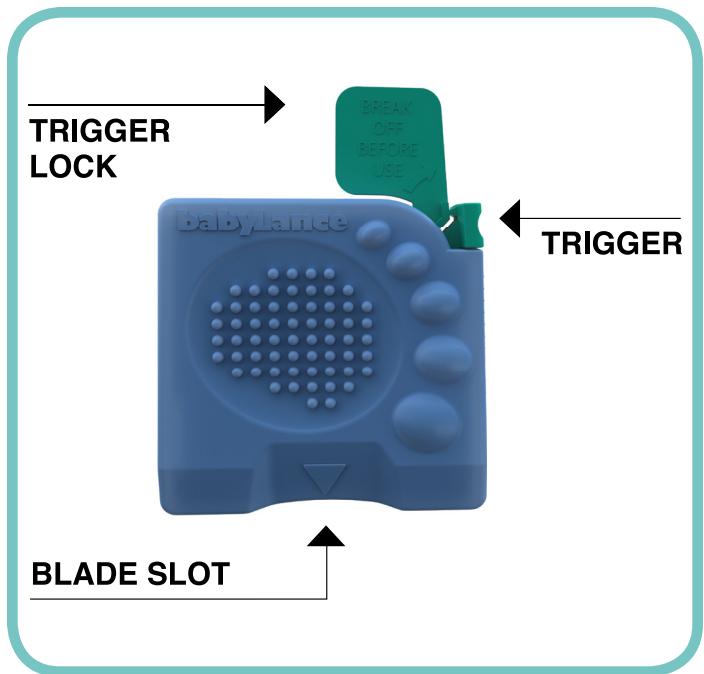
End-User Requirement	Design Element	Design Specification
How can correctly holding the device be more intuitive?	Device housing should have an obvious, prominent visual cue to guide user to the correct holding position.	A convex "foot imprint" on the side of the device's housing provides tactile and visual cues for the correct position to hold the device.
How can the device be more stable to hold, especially when wearing gloves?	Device housing should have a textured surface that enhances grip stability.	Grooves and convex dimples on the sides of the device's housing enhance tactile feel and stability.

Matrix 5: Target Incision Site

End-User Requirement	Design Element	Design Specification
How can the user know where the blade comes out of the device?	Device housing should have a visual indicator of blade slot.	The housing features a highly visible arrow and indentation that indicates the location of the blade slot.
How can precise positioning of the device on the baby's heel be easier?	Blade slot should be thinner to allow greater visibility of incision site.	The housing features an indentation at blade slot.
	Blade slot should follow curve of baby's heel.	The housing features a curve at bottom of blade slot.



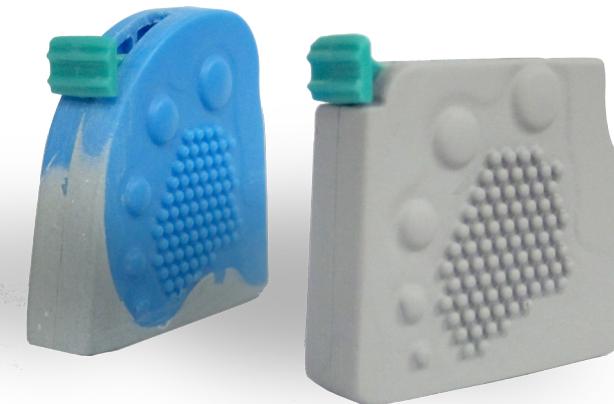
An early prototype with a flat housing bottom.



The final design with a curve at the bottom of the blade slot.

Matrix 6: Activation

End-User Requirement	Design Element	Design Specification
How can the device be easier to activate?	Trigger activation style should follow users' most preferred style, i.e., pullback, pushdown or push-forward.	A pullback trigger was integrated into the design, per the preferences of user surveys and research.
How can trigger activation force enhance ease of use?	Trigger activation force should be slightly less than required by competing products.	The trigger activation force was reduced to an average of 6.3 N.
How can trigger activation distance enhance ease of use?	Trigger activation distance should be slightly less than required by competing products.	The trigger activation distance was reduced to an average of 2.0 cm.
How can device be easier to keep stable during activation?	Bottom of housing device should be flat (as compared to curved bottom of original babyLance) to minimize rocking.	Except for slight curve at blade slot, the housing was designed to be mostly flat.
How can user easily know that the device was activated?	A tactile and audible click when device is activated.	A "stop" at the end of the trigger arm to provide both a tactile and audible click.



Two early prototypes from babyLance's evolution into a pullback trigger design.

Validating babyLance's Ergonomics

Comparative Product Studies

To further ensure that its new babyLance was exceeding both ergonomic and performance standards, MediPurpose conducted comparative product studies—such as for incision depths¹ and trigger activation force.

Simulated Use Studies (SUS)

MediPurpose conducted a series of simulated use studies² to validate its latest babyLance design. In those studies, end-users were given pre-production babyLance devices to use on a replica infant heel so they could complete an evaluation survey and report their experiences.

A simple, one-page evaluation form was designed to provide end-users with babyLance characteristics to evaluate with a Likert scale (1–5, indicating a response of no/poor to yes/excellent). Ergonomics-related results were as follows:

Trigger Lock Removal

- The trigger lock is easily identified and easy to remove: 4.9

Device Handling

- The device felt comfortable and stable in your hand: 4.7
- The device is easy to handle while wearing gloves: 4.9

Target Incision Site

- The incision location was easily identified: 4.8
- It is easy to target the incision site: 4.9

Activation

- The trigger mechanism feels comfortable: 4.7
- The trigger is easy to activate: 4.8
- There is an audible click when the device is activated: 4.9
- The device was easily activated using one hand: 4.8
- The device is as convenient to use as my existing device: 4.8
- The device does not require more time to use than the device I am currently using: 4.9

Although the SUS results were overwhelmingly positive, they compelled MediPurpose to make additional modifications to the new babyLance—such as increasing the size of the activation trigger button.

¹ Learn more in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Heelstick Cut Profile Comparative Study*.

² Learn more in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Simulated Use Design Validation Study*.

Clinical Use Studies

In mid-2012, MediPurpose next conducted a series of clinical use studies to further validate the final babyLance product.³

Unlike the SUS where neonatal nurses evaluated babyLance by using them on replica infant heels, nurses used the first batch of babyLance production units on infants in a clinical setting. Ergonomics-related results were as follows:

Packaging

- The package was easy to open: 4.8

Trigger Lock Removal

- The trigger lock is easily identified and easy to remove: 4.6

Device Handling

- The device felt comfortable and stable in your hand: 4.8
- The device is easy to handle while wearing gloves: 4.7

Target Incision Site

- The incision location was easily identified: 4.7
- It is easy to target the incision site: 4.5

Activation

- The trigger mechanism feels comfortable: 4.6
- The trigger is easy to activate: 4.7
- There is an audible click when the device is activated: 4.9
- The device was easily activated using one hand: 4.6
- The device is as easy to use as my existing device: 4.7
- The device does not require more time to use than the device I am currently using: 4.8

As with the SUS, the CUS results also indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements. Meanwhile, the CUS validated the device's ability to satisfy ergonomic requirements while providing an incision that yielded an adequate volume of blood.

³ Learn more in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Clinical Use Design Validation Study*.

Summary

When MediPurpose initiated the redesign of its babyLance infant heelstick, it took an extremely thoughtful and meticulous approach to developing a device that had superior form and function. It wasn't enough to have a properly functioning device; it was paramount for user acceptance that the device was also ergonomically easy to use.

Therefore MediPurpose's routinely included end-users throughout the redesign process. The company was keenly aware that success would require more than just collecting user input and feeding it to the design team. Instead, it would demand a very interactive, reciprocal process that ensured harmony between what its users wanted and what the design team produced.

When MediPurpose launched its all-new babyLance in August 2012, it didn't just introduce an improved heelstick device. Rather, it raised the bar for all manufacturers that seek to provide neonatal caregivers with a heelstick solution that looks and feels as well as it works.

Business Benefits of Partnering with MediPurpose™

In August 2012, MediPurpose™ launched a redesigned babyLance™ infant heel incision device 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
- Download the babyLance™ Heelstick Cross-Reference Guide
Please visit www.medipurpose.com/downloads
- Download other babyLance™ white papers
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



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
Preemie	BLP	0.85mm	Pink	50/box 200/case
Newborn	BLN	1.00mm	Blue	50/box 200/case

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.

Advanced Heel Incisions

Our babyLance™ device was developed with over ten years of proven product development expertise, and leveraging the advanced thinking behind our SurgiLance™ 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.

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