MediPurpose™
Lancing Devices

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

babyLance™

Listening to End-Users

Clinical Use Design Validation Study

Abstract

MediPurpose™, a manufacturer and master distributor of medical products, launched its reinvented babyLance™ infant heel incision device in August 2012.

+ clinical use study (CUS) conducted to validate new babyLance™ design was meeting end-user expectations

+ prefaced by simulated use study (SUS)

+ positive results from SUS validated the reinvented babyLance™

Throughout the development process, the company actively involved end-users to learn more about their requirements, translate them into design specifications, and to validate that its new babyLance was meeting their expectations.

After conducting simulated use studies (SUS) to validate pre-production devices in early 2012, MediPurpose next conducted a series of clinical use studies (CUS) to further validate the final babyLance product.

But 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.

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

The validations from the SUS and CUS studies enabled the company to conclude the babyLance development project and prepare for launch.

The new, reinvented "pull trigger" babyLance heel incision device.

Introduction

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

However, within a few months of launch, MediPurpose learned that 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 modification in order to fully satisfy customer demands.[1] This included comments that some users preferred a "pull" trigger rather than the babyLance's "push forward" trigger.[2]

MediPurpose elected not to withdraw the product from the market, but rather, it reduced its production and marketing programs. The company then initiated a year-plus period of intensive research, redesign and testing.

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

[1] Learn more about how MediPurpose learned about its customers' heelstick preferences in the white paper, ***Understanding the Needs of End-Users***.

[2] Learn more about how MediPurpose learned about end-users' trigger preferences in the white paper, ***Heelstick Trigger Activation Survey at the 2011 NANN Conference***.

After conducting studies of end-users to gauge their expectations and requirements—including a simulated use study (SUS) where neonatal nurses were given pre-production babyLance devices to use on a replica infant heel[3]—MediPurpose next designed a clinical use study (CUS) for neonatal nurses to continue evaluating the new device, but this time using the first batch of babyLance production units on infants in a clinical setting.

Along with putting the device through its paces with actual babies in a "real life" clinical context, the SUS also evaluated the new device's ability to provide an incision that yielded an adequate volume of blood.

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

The validations from the SUS and CUS studies enabled the company to conclude the babyLance development project and prepare for launch.

[3] Learn more about the processes and results in the white paper, *Simulated Use Validation Study*.

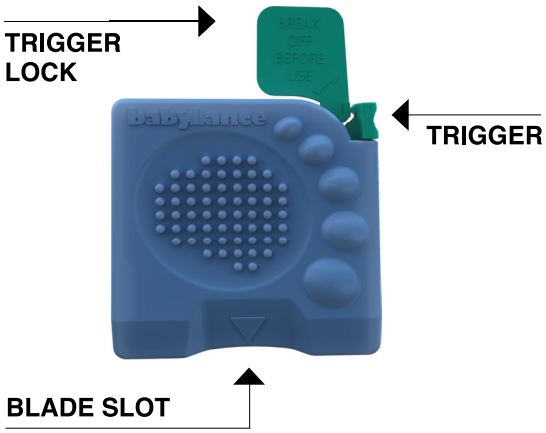
Defining End-User Heelstick Device Requirements

Throughout the redesign process for its babyLance™ heelstick device, MediPurpose™ actively involved end-users to learn more about their requirements. This information was carefully collected and translated into design specifications for the babyLance design team.

End-users wanted a series of new features in the new babyLance while retaining preferred characteristics from the original design:

New Features

- Changing the trigger activation to a "pull back" mechanism rather than "push forward"
- Reducing the device's propensity to "rock" when placed on infant's heel
- Changing the housing and trigger colors
- Enhancing the device's intuitive visual cues
- Easier removal of trigger lock



Existing Features

- Smooth cutting profile
- Dimples on the sides of the housing for good grip
- Distinctive baby footprint on the sides of the housing
- Curve and arrow indicators at the bottom of the housing

Developing the Clinical Use Study

MediPurpose's simulated use studies (SUS) for its new babyLance™ heelstick device indicated that the new design was meeting end-users' expectations and requirements.

However, since the SUS was performed in non-clinical situations and with replica infant heels, MediPurpose still needed to ensure that the new babyLance would maintain that same performance and to validate the device's ability to provide an incision that yielded an adequate volume of blood in a clinical setting.

Similar to the process that MediPurpose used to plan its SUS, the company developed a clinical use study (CUS), which involved the following:

Instructions for Use

Using the instructions for use (IFU) from the SUS, MediPurpose revised the new device's IFU to incorporate comments from the SUS.

Clinical Use Evaluation Form

A simple one-page evaluation form was designed to provide end-users with babyLance characteristics to evaluate.

The form was written so that evaluators could provide one of two types of responses: absolute (pass or fail) and Likert scale (1–5, indicating a response of no/poor to yes/excellent).

The form was structured to comprehensively validate the following:

Safety

- Trigger Lock
  - Needs to prevent accidental activation

- Blade Shield
  - Blade needs to be shielded prior to activation
  - Blade needs to be shielded after activation

Single-Use
- Device need to be unusable after activation

Training
- IFUs need to be concise and easy to understand
- Device needs to be easy to learn how to use

Ergonomics
- Device needs to be comfortable and stable
- Incision location needs to be easily identified
- Device needs to be easy to handle while wearing gloves

Trigger Activation
- Trigger needs to feel comfortable
- Trigger needs to be easy to activate
- Activation mechanism needs to provide an audible click when activated

Usage
- Device needs to be easy to activate with one hand
- Incision site needs to be easy to identify
- Device needs to be as easy to use as user's current device
- Device needs to not require more time to use than user's current device
- Device needs to deliver an incision that yields an adequate volume of blood for collection

Clinical Use Protocol

To assure that the new babyLance design was properly tested for acceptability and usability in a clinical setting, MediPurpose created a protocol that included the following:

Test User Population

The test user population needed to include a minimum of 20 health care professionals from at least three different facilities that routinely use heelstick devices.

Test Sample Size

Test users needed to evaluate a minimum cumulative total of 500 units, using the device on living infants' heels.

Trainer Responsibilities

Prior to beginning the clinical use tests, trainers were required to review the test protocol and evaluation form and to demonstrate the use of the device with each test user. Additionally, trainers needed to supervise each test user for at least one practice heelstick incision and to ensure the test user's comfort with use of the device before beginning the evaluation.

Test User Requirements

Test participants were asked to wear gloves per their institutional procedure.

Acceptance Criteria

Overall acceptance for each characteristic evaluated needed to be 80 percent or more—except for safety characteristics, which needed to be 100 percent.

Clinical Use Participant Groups

After announcing the CUS opportunity to its extensive network of relationships within the healthcare industry, MediPurpose was invited to five neonatal healthcare facilities in the United States (California and Georgia) and Austria.

babyLance™ Clinical Use Study Results

In Summer 2012, MediPurpose™ conducted a series of clinical use studies (CUS) to validate that its final babyLance™ product would meet end-user preferences and expectations and specifically provide an incision that yielded an adequate volume of blood.

The CUS results indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements, enabling the company to conclude the babyLance development project and prepare it for launch.

Results At a Glance

MediPurpose's protocol for the babyLance CUS specified minimum figures for testing and acceptance. The results indicated that it met or exceeded each:

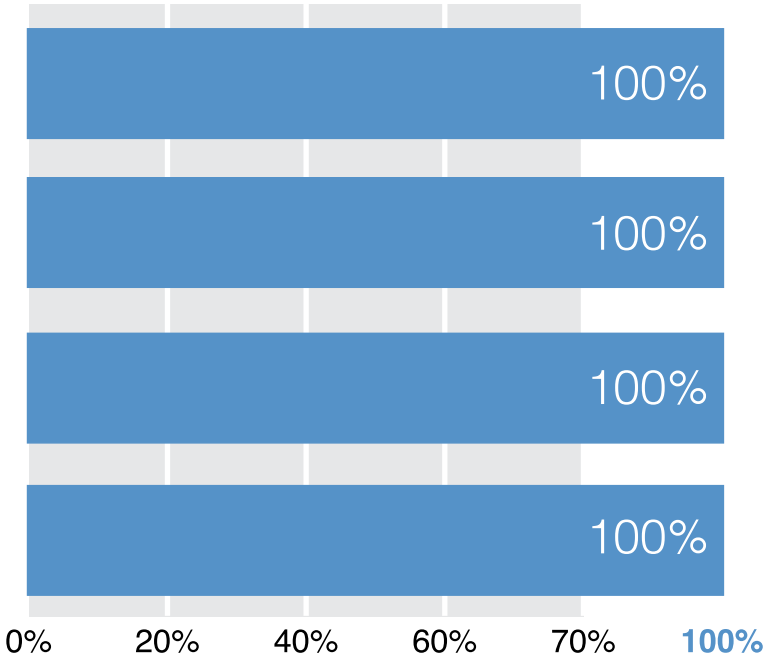
- Test Facilities: 5 (minimum: 3)
- Test Users: 37 (minimum: 20)
- Test Units: 610 (minimum: 500)
- Average Safety Score: 100 percent (minimum: 100%)
- Average Usage Score: 4.7 (minimum: 4.0)

Detailed Results

A simple, one-page evaluation form was designed to provide end-users with babyLance characteristics to evaluate.

The form was written so that evaluators could provide one of two types of responses: absolute (pass or fail) and Likert scale (1–5, indicating a response of no/poor to yes/excellent). The results were as follows:

Safety



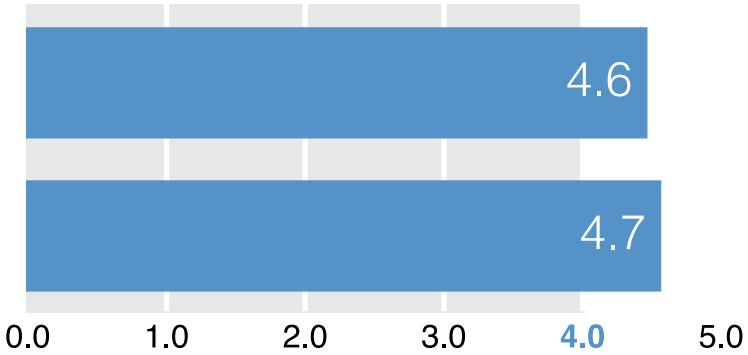
The trigger lock prevents accidental activation

The blade was shielded prior to activation

The blade was shielded after activation

The device cannot be reused after activation

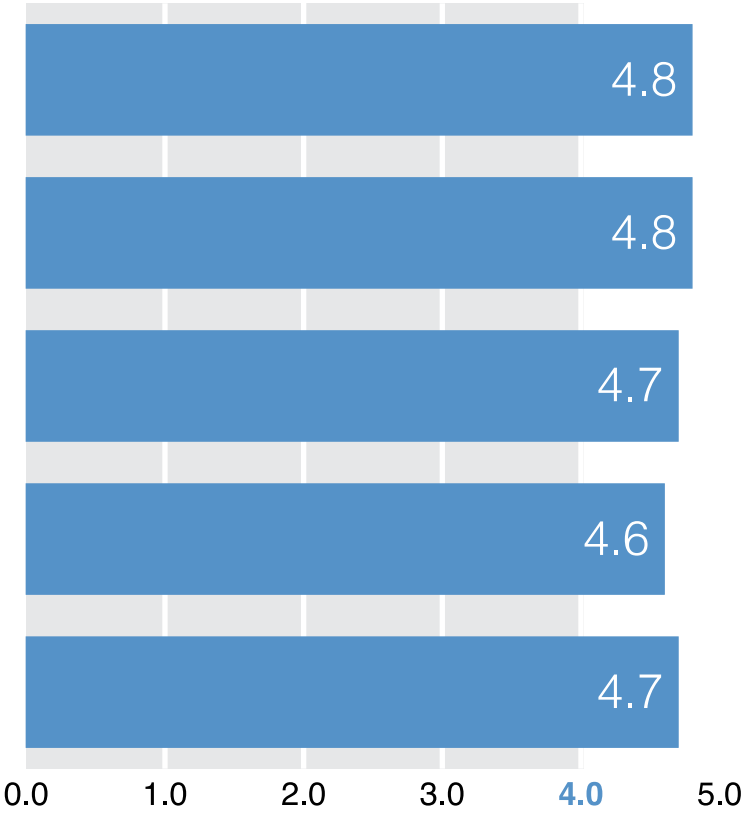
Training



The Instructions for Use are clear and easy to understand

It is easy to learn how to use the device

Ergonomics



The package was easy to open

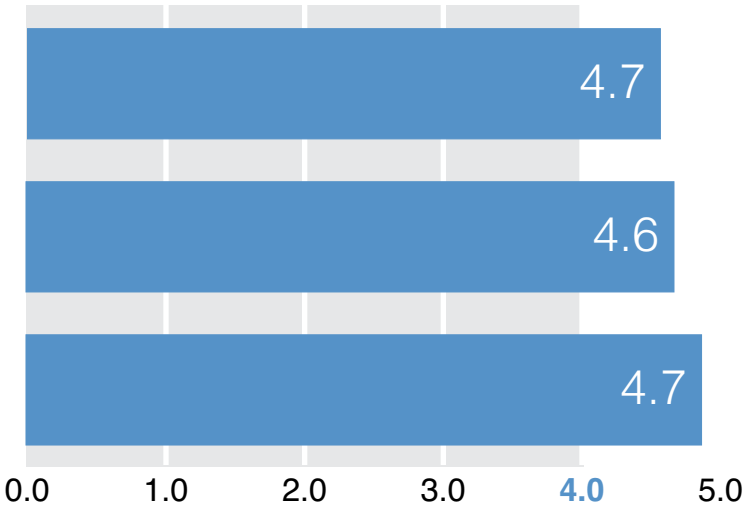
The device felt comfortable and stable in your hand

The incision location was easily identified

The trigger lock easily identified and easy to remove

The device is easy to handle while wearing gloves

Trigger

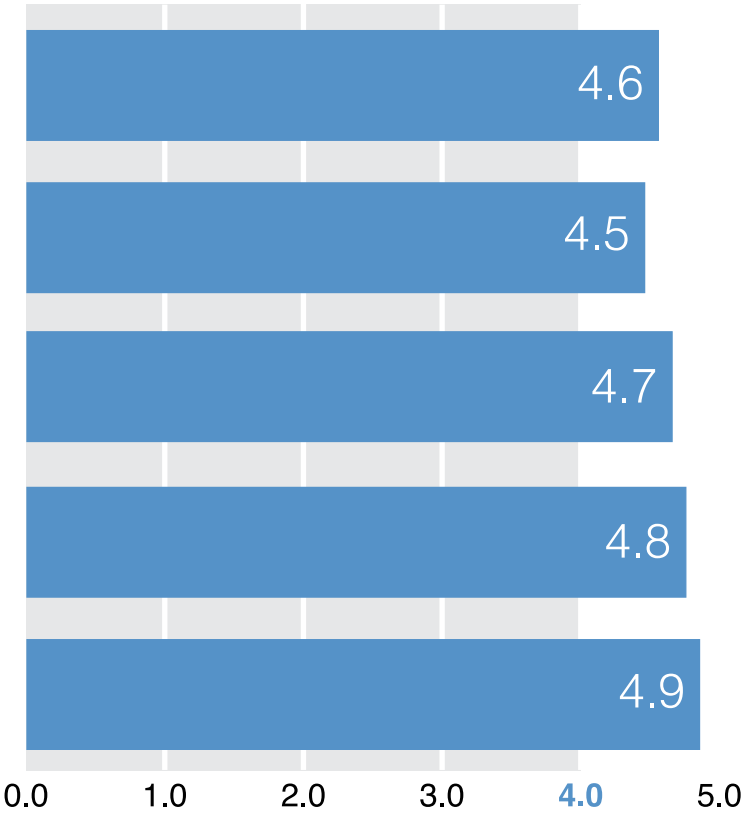


The trigger mechanism feels comfortable

The trigger is easy to activate

There is an audible click when the device is activated

Usage



The device was easily activated using one hand

It is easy to target the incision site

The device is an convenient to use as my existing device

The device does not require more time to use than the device I am currently using

I could get as much blood with the device as the one I am currently using

Summary

With 100-percent average scores for safety and 94-percent average scores for usage, the clinical use study (CUS) validated MediPurpose's new babyLance™ heelstick device.

The SUS and CUS results indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements, enabling the company to conclude the babyLance development project and prepare it for launch.

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 a preferred "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

babyLance™

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 guidelines[1].

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.

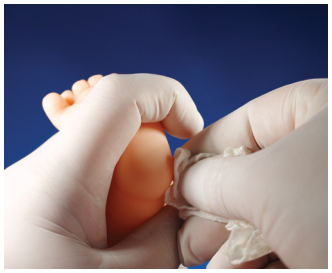
Fits Your Hand Like a Glove

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.

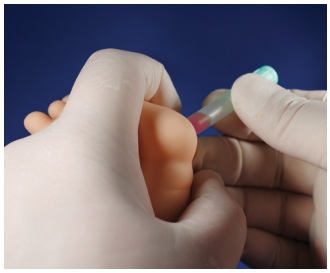
4 Easy Steps



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

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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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