MediPurpose™
Lancing Devices

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

babyLance™

Listening to End-Users

Simulated Use Design Validation Study

Abstract

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

The company actively involved end-users throughout the development process to learn more about their requirements and to validate that its new babyLance was meeting those expectations.

In early 2012, MediPurpose conducted a series of simulated use studies (SUS) 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 a survey and report their experiences to MediPurpose.

The SUS results indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements, enabling the company to proceed with the babyLance development project.

+ simulated use study conducted to validate new babyLance™ design was meeting end-user expectations

+ positive results enabled continued development

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 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 preferences and expectations of end-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. For example, 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 to learn more about end-users' requirements and to validate that its new babyLance was meeting those expectations.

In early 2012, MediPurpose conducted a series of simulated use studies (SUS) to validate its latest babyLance design.

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End-User Requirements for a New babyLance™ Design

Throughout the redesign process for its babyLance™ heelstick device, MediPurpose™ actively involved end-users to learn more about their requirements[1] and to validate that its new device was meeting their expectations.

The company's research indicated that end-users wanted a heelstick device with a series of new features, while retaining a number of features from its original babyLance.

New Features

End-users wanted the following new features and characteristics:

- 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

Additionally, end-users wanted the new device to maintain the following existing features and characteristics:

- 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

1 Learn about how MediPurpose engaged end-users to determine their heelstick device preferences, expectations and requirements in the white papers, *Understanding the Needs of End-Users* and *Heelstick Trigger Activation Survey at the 2011 NANN Conference*.

Developing the babyLance™ Simulated Use Study

To validate that its new babyLance™ heelstick device was meeting end-users' requirements, MediPurpose™ conducted a series of simulated use studies (SUS) in early 2012.

As compared to a clinical use study where a device is used on living infants, the SUS gave end-users an opportunity to test the new babyLance on an artificial foot that simulates an infant's heel.

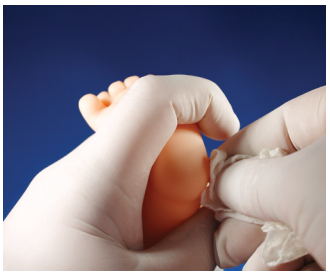
To accomplish its goal, MediPurpose carefully planned the SUS, which involved creating the following:

Instructions for Use

Using the instructions for use (IFU) from its original device as a starting point, MediPurpose revised the new device's IFU to provide both written and visual instructions.

Along with providing the IFU so end-users would know how to properly use the device, the company used the SUS as an opportunity to evaluate its new IFU.

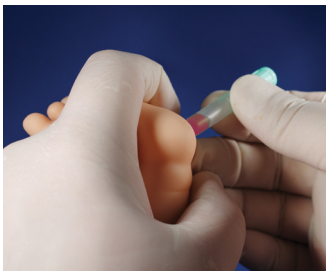
babyLance™ Instructions for Use



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.

Simulated 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 unuable 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

Simulated Use Protocol

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

Test User Population

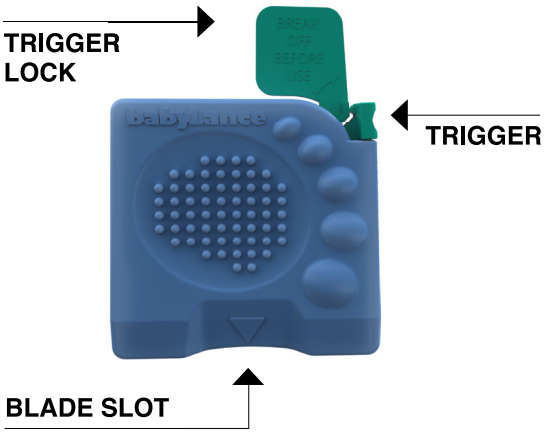
The test user population needed to include a minimum of 20 health care professionals from at least three different facilities that routinely use heelstick devices.

Test Sample Size

Test users needed to evaluate a minimum cumulative total of 500 units, using artificial baby heels as test patients.

Trainer Responsibilities

Prior to beginning the simulated 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

Along with performing the simulated use tests and completing the evaluation form, test users 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.

Simulated Use Participant Groups

After announcing the SUS opportunity to its extensive network of relationships within the healthcare industry, MediPurpose was invited to five neonatal healthcare facilities in California and Georgia to conduct its study.

babyLance™ Simulated Use Study Results

In April–May 2012, MediPurpose™ launched a series of simulated use studies (SUS) to validate its latest babyLance™ design. In those studies, end-users were given pre-production babyLance devices to use on an artificial infant heel so they could complete a survey and report their experiences to MediPurpose.

The SUS results indicated that the new babyLance consistently met or exceeded end-users' expectations and requirements, enabling the company to proceed with the babyLance development project.

Results At a Glance

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

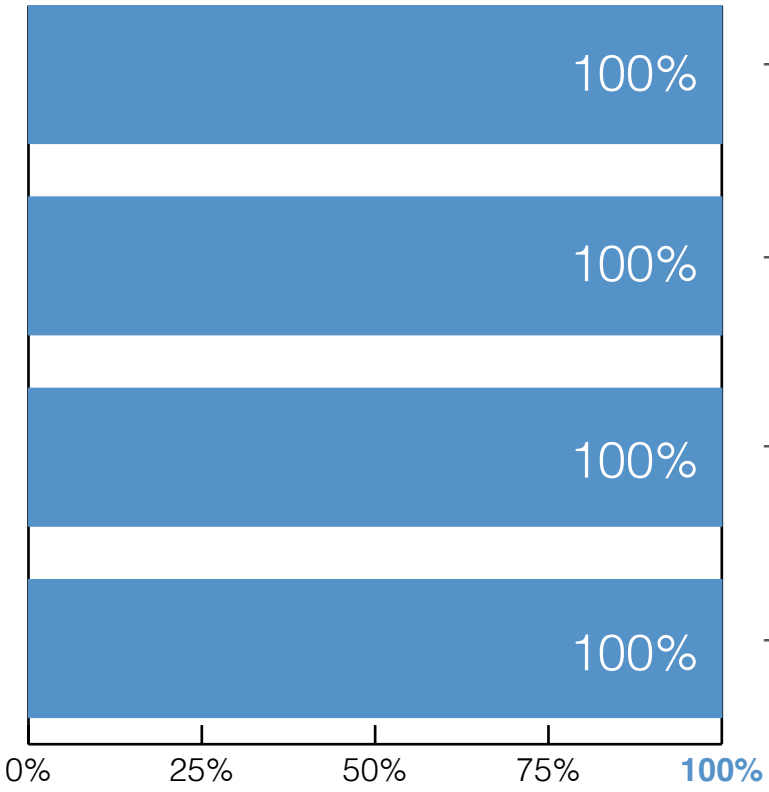
- Test Facilities: 5 (minimum needed: 3)
- Test Users: 33 (minimum needed: 30)
- Test Units: 501 (minimum needed: 500)
- Average Safety Score: 100 percent (minimum needed: 100%)
- Average Usage Score: 4.9 (minimum needed: 4.0)

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



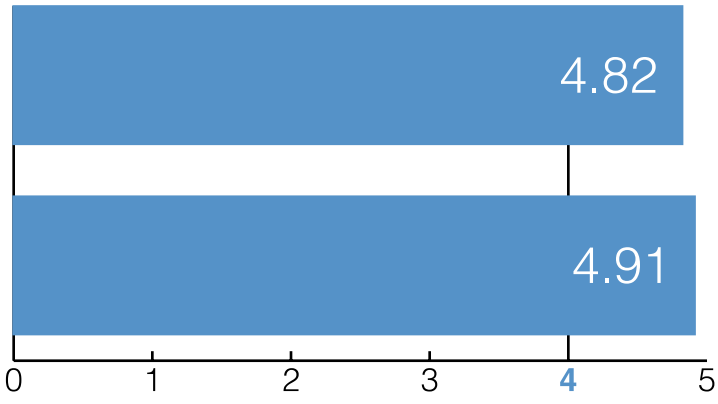
The trigger lock prevents accidental activation

The blade was shielded prior to activation

The blade was shielded after activation

The device cannot be reused after activation

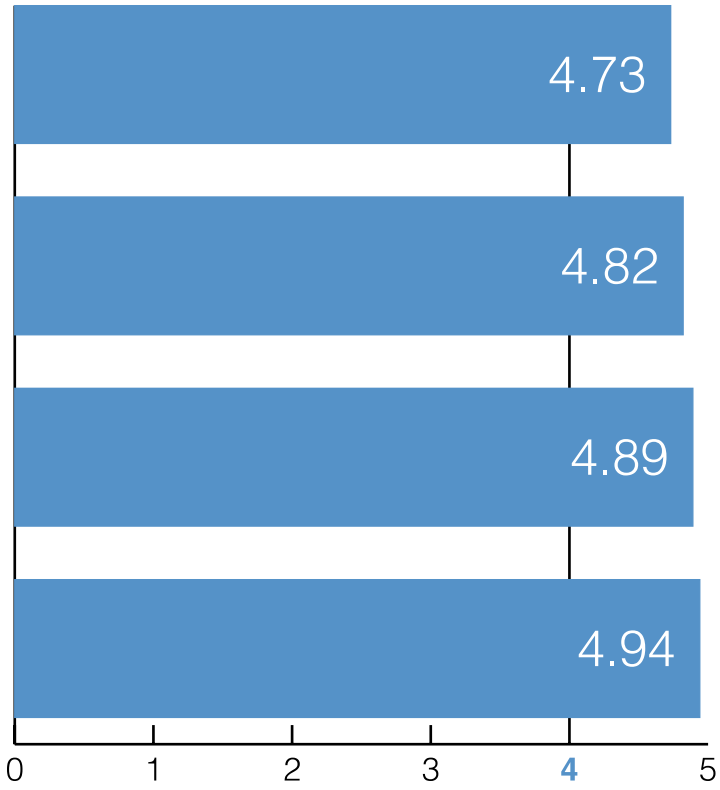
Training



The Instructions for Use are clear and easy to understand

It is easy to learn how to use the device

Ergonomics



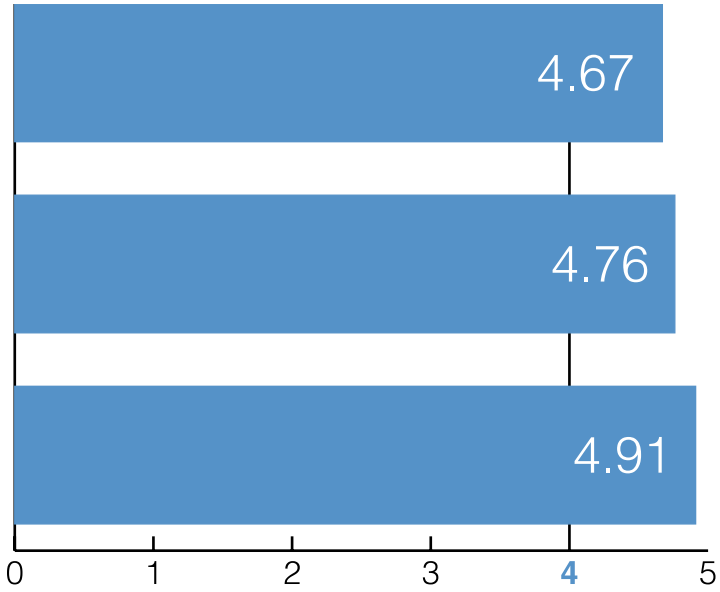
The device felt comfortable and stable in your hand

The blade was shielded prior to activation

The blade was shielded after activation

The device cannot be reused after activation

Trigger

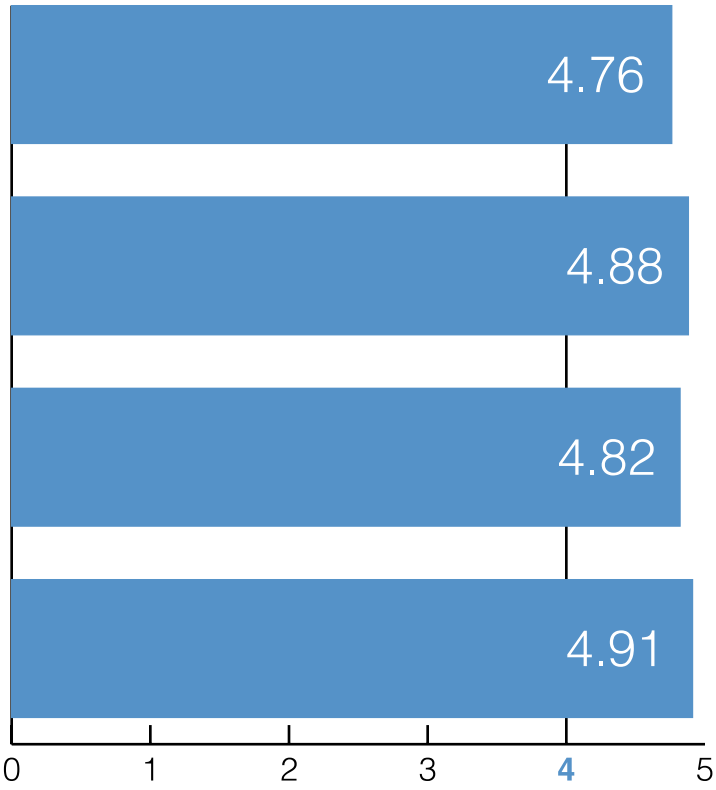


The trigger mechanism feels comfortable

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

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.

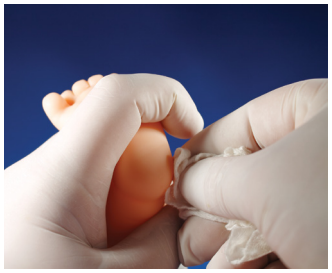
Fits Your Hand Like a Glove

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



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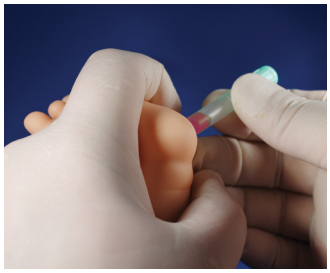

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Product	Code	Incision Depth	Color	Packaging
Preemie	BLP	0.85mm	Pink	50/box | 200/case
Newborn	BLN	1.00mm	Blue	50/box | 200/case

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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.

Americas
3883 Rogers Bridge Road NW
Suite 501
Duluth, GA 30097
Tel: +1 770 448 9493

Asia
15 Hoe Chiang Road #12-02
Tower Fifteen
Singapore 089316
Tel: +65 63451588

Europe
3 College Gardens
New Malden, Surrey KT3 6NT
England, UK
Tel: +44 208 213 5859

MediPurpose™