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

Heelstick Cut Profile Comparative Study
Abstract

Throughout the redesign process for its new babyLance® infant heel incision device launched in August 2012, MediPurpose® conducted a series of surveys, evaluations and studies, including a comparative heelstick incision profile study of its own device and its competitors.

The results indicated that the design of the new babyLance’s internal cutting mechanism consistently delivered an ideal, superior incision that may minimize pain, bruising and trauma to an infant’s delicate heel tissues and nerve endings.

+ comparision of leading heelstick devices’ cut profiles

+ babyLance® most consistently delivered superior incisons
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 users in the U.S. market.

Although a number of U.S. healthcare facilities expressed a desire to continue use of the product, feedback suggested that the device needed some modifications to fully satisfy customer demands. This included refinements to babyLance’s internal cutting mechanism so that it would create an incision that provided not only an adequate volume of blood for collection, but also delivered a “clean” incision that minimized pain, bruising and trauma to the infant’s delicate heel tissues and nerve endings.

MediPurpose elected not to withdraw the product from the market. Rather, it reduced its production and marketing programs for babyLance. The company then initiated a year-plus period of intensive research, redesign and testing. ¹

¹ Learn more about MediPurpose’s process in the white paper, Reinventing a Better babyLance® Infant Heel Incision Device: Understanding End-Users Requirements.
While some studies continued to gauge end-users’ needs and requirements (such as a study for activation trigger preferences, which resulted in the decision to proceed with an innovative “pull” trigger\(^2\)), others were conducted internally so that MediPurpose could validate improvements made to the new babyLance. Among them was a performance study of babyLance’s internal cutting mechanisms, comparing its incision profiles to competitive heelstick devices.

This white paper illustrates that study’s process and findings, which ultimately concluded that the new babyLance most frequently delivered an incision that met both industry and end-user requirements.

\(^2\) Learn more about this study in the white paper, Reinventing a Better babyLance\(^\circledast\) Infant Heel Incision Device: Listening to End-Users—Trigger Activation Survey at the 2011 NANN Conference.
In its process of redesigning the babyLance® heelstick device so that it would consistently deliver the ideal incision, MediPurpose® identified the following considerations:

CLSI Guidelines
Clinical Laboratory Standards Institute (CLSI) guidelines¹ 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 has the potential to cause bone damage. Further, it proscribes that an ideal horizontal incision must be wide enough to allow enough blood for collection. More specifically, CLSI recommends that the incision depth not exceed 2.0 mm.

Ease of Positioning and Activation
The new babyLance internal cutting mechanism needs to work in harmony with a redesigned activation trigger and housing so that it consistently provides easy, intuitive positioning and activation.

Frequency of Heelstick Procedures
Within 96 hours after birth, neonatal nurses perform an average of four infant heelstick incisions. Considering both an incrementally reduced area to perform those incisions and the infant’s very delicate subcutaneous tissues, the ideal heelstick device needs to deliver a gently arced incision—as opposed to a severely angled puncture that could result in greater tissue trauma.

After redesigning the babyLance® device, MediPurpose® validated its improvements conducted comparative cut profile studies of its own device and its competitors.

Comparative Heelstick Device Selection
MediPurpose selected three competing brands/models that are among the top-selling products in the U.S. heelstick market:

- ITC Tenderfoot® 1
- BD Quikheel™ 2
- Cardinal Health gentleheel™ 3

Comparative Cut Profile Methodology
The cut profile study was conducted internally with objective criteria and methodologies, and without anticipation of any particular result.

Each heelstick device’s cut profile was created by:

- Placing the device on a piece of clear silicone rubber, to simulate an infant’s heel.
- Activating the device so that it created an incision in the silicone block.
- Microscopically examining, measuring and photographing the incision.
- Recording a visual summary of what the technician observed.

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1 Trademark of International Technidyne Corporation.
2 Trademark of Becton, Dickinson and Company.
3 Trademark of Cardinal Health, Inc.
After creating cut profiles for both its own babyLance® device and three of its competitors, MediPurpose® evaluated the results both statistically and visually.

Statistical Results
Industry standards define ideal heelstick incisions depth for newborns to not exceed 2.0 mm.

In that perspective, virtually all of the cut profile measurements met industry standards, and by definition, fulfilled the objective of creating an incision that would not damage subcutaneous tissues.
Visual Results
Microscopic evaluation of each device's cut profile indicated substantial differences. MediPurpose® observed the following results:

**BD Quikheel™**
The BD Quikheel cut profile illustrated an incision with an initial blunt puncture followed by a slicing action.

**Cardinal Health gentleheel™**
The Cardinal Health gentleheel profile illustrated an incision with an angular initial puncture, followed by an increasingly deep arc.

**ITC Tenderfoot®**
The ITC Tenderfoot cut profile illustrated an incision with a plunging, multi-angled puncture and a jagged, lopsided “W” pattern.

**babyLance®**
The babyLance cut profile illustrated a gently arcing incision that lacks a blunt puncture mark or inconsistent, jagged cut.
MediPurpose’s comparative cut profile study of its new infant heelstick and its competitors indicated that babyLance® most consistently met the definition of what could be considered the ideal infant heel incision.

Although each company’s heelstick device statistically met CLSI guidelines for ideal incision depth, visual examination of each device’s cut profile demonstrates that babyLance consistently delivered the smoothest, cleanest incision.

In its goal of designing a device that is easy to use, meets CLSI guidelines, and delivers an incision that may minimize pain, bruising and trauma to the infant’s delicate heel tissues and nerve endings, MediPurpose believes that the new babyLance meets all the criteria of an ideal heelstick device.
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 fostered 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 heel'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
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.

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.

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