


MediPurpose™

Lancing Devices



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



Heelstick Cut Profile Comparative Study

August 2012 (Rev.1)



Throughout the redesign process for its new babyLance™ safety heelstick 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.

+ comparison of leading heelstick devices' cut profiles

+ babyLance™ most consistently delivered superior incisions

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™ safety 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,



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

redesign and testing.¹ 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" trigger²), 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.



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

¹ Learn more about MediPurpose's process in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Understanding End-Users Requirements*.

² Learn more about this study in the white paper, *Reinventing a Better babyLance™ Infant Heel Incision Device: Listening to End-Users—Trigger Activation Survey at the 2011 NANN Conference*.

Defining the Ideal Infant Heel Incision

In its process of redesigning the babyLance™ safety heelstick 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.



¹ CLSI LA4-A5. *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition*, Vol. 23, No. 21, 2007

Conducting the Comparative Infant Heelstick Device Cut Profile Study

After redesigning the babyLance™ safety heelstick, MediPurpose™ validated its improvements and 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.

¹ Trademark of International Technidyne Corporation.

² Trademark of Becton, Dickinson and Company.

³ Trademark of Cardinal Health, Inc.

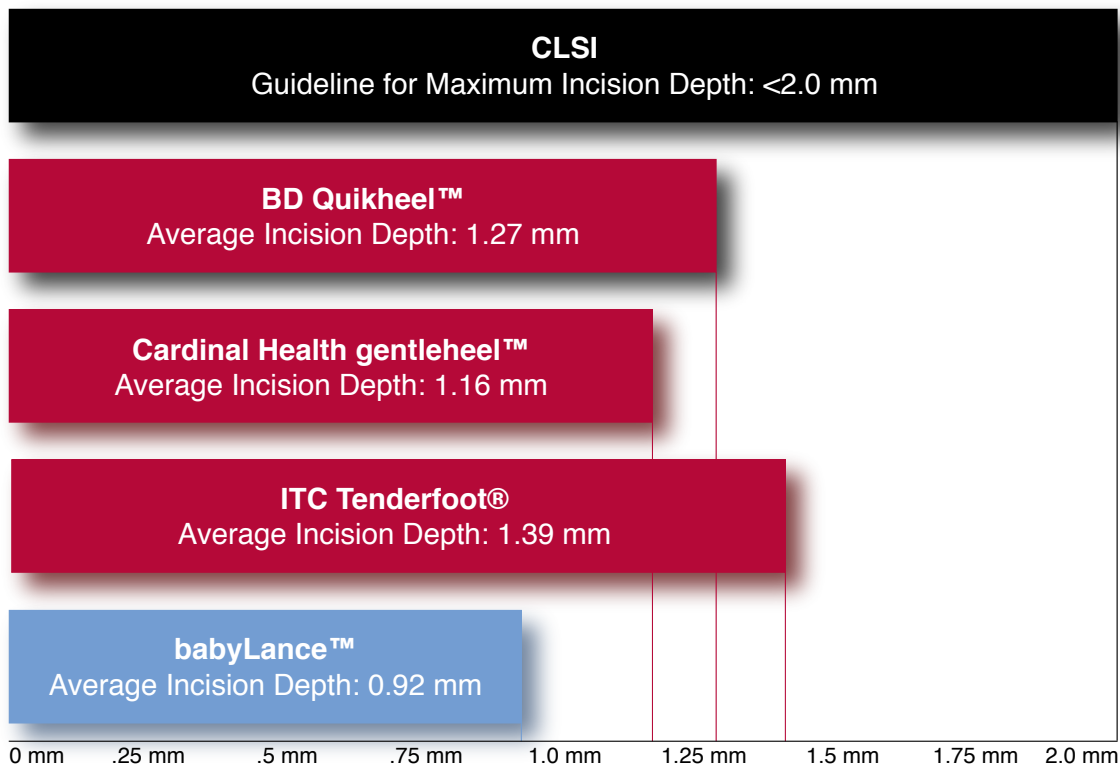
Comparative Cut Profile Study Results

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

Although there is no industry standard that defines an ideal heelstick incisions depth, Clinical Laboratory Standards Institute (CLSI) guidelines¹ do recommend that an incision for newborns should not exceed two millimeters deep.

All of the devices in the study yielded incision depths that were less than two millimeters, and therefore, satisfied CLSI guidelines.



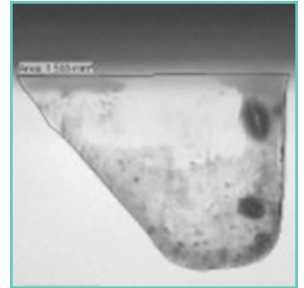
¹ CLSI LA4-A5. *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition*, Vol. 23, No. 21, 2007

Visual Results

Microscopic evaluation of each device's cut profile indicated substantial differences. MediPurpose™ observed the following results:

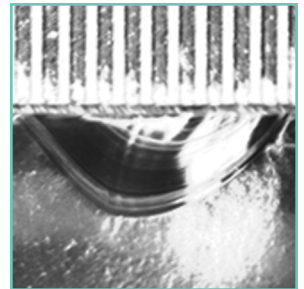
BD Quikheel™

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



Cardinal Health gentleheel™

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



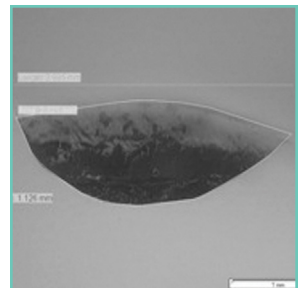
ITC Tenderfoot®

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.

Business Benefits of Partnering with MediPurpose™

In August 2012, MediPurpose™ launched a redesigned babyLance™ safety heelstick 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](#)
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Please visit medipurpose.babylance/samples
- [Participate in clinical evaluations](#)
Please e-mail sales@medipurpose.com
- [Arrange for in-servicing from an approved distributor](#)
Please e-mail sales@medipurpose.com



Designed for Neonatal Nurses ...with Neonatal Nurses

Designed with more than 10 years of MediPurpose's proven product development expertise and with extensive input and validation from neonatal nurses, babyLance™ safety heelsticks are **reliable, consistent, safe and easy to use!**

Reliability: Ultra-Smooth Incisions Minimizes Trauma to Infants' Heels

babyLance's proprietary internal spring design activates its blade's swift pendulum action, which delivers an **ultra-smooth incision** that complies with CLSI LA4-A5 guidelines to **reduce trauma** to an infant's delicate subcutaneous tissues.

Consistency: Accurate Incisions Reduce Need for Multiple Heelsticks

babyLance's ultra-smooth and accurate incisions **consistently produce preferred blood flow volumes**...which reduces the need for multiple heelstick procedures.

Ergonomics: Numerous Features Promote Safety and Ease of Use

babyLance's **intuitive single-use design** makes it one of the safest and easiest heelsticks to use. Featuring the industry's most **effortless activation trigger**, its unique housing provides visual guides for **accuracy** and dimples for a **secure grip**.



Four 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's visual marking with the incision site 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!

babyLance™	Product Code	Depth	Body/Trigger Colors
Micropremie	BLM	.60 mm	Yellow/Lime Green
Premie	BLP	.85 mm	Pink/White
Newborn	BLN	1.0 mm	Blue/Green
Toddler	BLT	1.4 mm	Orange/Gray

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