

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

 **babyLance™**

Translating User Requirements Into  
Design Specifications

*Optimizing Ease-of-Activation*



During the redesign process for the new babyLance™ infant heel incision device launched in August 2012, MediPurpose™ collected feedback from end-users about features they wanted in an ideal heelstick device. Among those features was a device that would be easy to activate.

This white paper describes how MediPurpose gathered users' preferred requirements for a device that was easy to activate and translated them into design specifications so its engineers could develop a babyLance that met end-user requirements.

## 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 its production and marketing programs for babyLance. The company then initiated a year-plus period of intensive research, redesign and testing, with particular emphasis on collecting input from end-users to gauge their preferences and requirements.

This white paper describes how MediPurpose gathered users' preferred requirements for a device that would be easy to activate and then translated them into design specifications so its engineers could develop a babyLance that met end-user requirements.



## Defining End-Users' Requirements for Activation

From its extensive research with infant heelstick end-users, ease of activation was among the features that MediPurpose™ identified as a priority for its new babyLance™ design.

Generally, the infant heelstick needed to:

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

Along with end-users' feedback, MediPurpose evaluated the parameters that influenced how and why end-users felt ease-of-activation was a significant requirement:

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

Further, as the devices are intended for users that wear gloves, a textured surface that ensures a reliable grip was also determined to be an important feature.

### Multiple Positions for Holding Heelstick Device

Although babyLance's instructions for use (IFU) illustrate one position for holding the device, some end-users preferred alternative positions.

MediPurpose evaluated the size of competing heelstick devices and the position of their triggers to devise a new design that could accommodate end-users' preferences 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 features 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.

As the result of conducting user preference studies and a trigger activation survey of neonatal nurses at the 2011 NANN conference<sup>1</sup>, MediPurpose decided on a pull-back trigger for its new babyLance design.

### 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.

MediPurpose carefully measured the trigger force and activation distance of predicate heelstick devices so that its babyLance would be as easy (or easier) to use than other brands, but not at the risk of making the device overly sensitive so that it would have a “hair trigger” that could be prematurely activated.



The new, reinvented “pull trigger” babyLance heel incision device.

<sup>1</sup> Read more in the white paper, *Heelstick Trigger Activation Trigger Survey at the 2011 NANN Conference*.

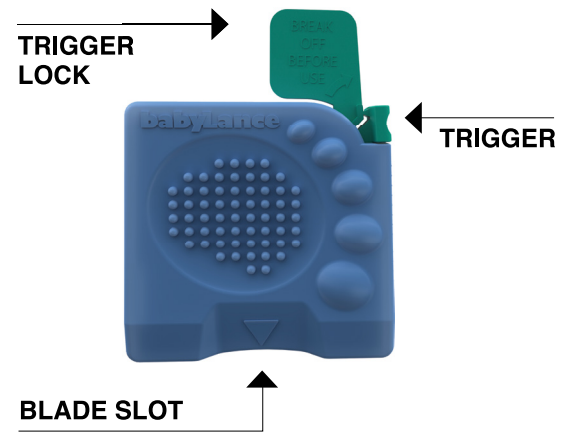
## Defining Design Specifications That Support End-User Requirements for Ease-of-Activation

After defining end-users' requirements for heelstick device ease-of-activation—and further integrating parameters informed by end-users experiences with predicate products—MediPurpose™ next defined design specifications for its new babyLance's development team.

These specifications were divided into two sets: general requirements and activation trigger requirements.

### General Requirements

- Size of device should be similar to existing devices
- Trigger lock that prevents accidental activation and can be removed with one hand
- Device can be activated with one hand
- Device needs to provide tactile feedback and an audible click when activated
- Dimples on the grip surfaces to ensure good grip with gloves



### Trigger

- Heelstick device shall be activated by pulling back the trigger
- Trigger shall be in the same position as existing devices
- Trigger pull force shall be less than existing devices
- Trigger distance shall be slightly less than existing devices

End-users of infant heelstick devices are neither product designers nor engineers—and thus, they cannot be expected to provide the exacting design details that satisfy their subjective preferences for an ideal device. However, their clinical experience makes them very knowledgeable about what they like and don't like about a device.

Throughout MediPurpose's redesign of its babyLance™ infant heelstick, the company was keenly aware that it owned the burden of developing processes that competently gather end-users' preferences and to translate that information into design specifications that would drive the redesign of its new device.

MediPurpose, which is continuously refining its processes and best practices in all aspects of medical device manufacturing and distribution, applied this proficiency to design a heelstick device that meets its end-users' requirements.

## Business Benefits of Partnering with MediPurpose™

In August 2012, MediPurpose™ launched an all-new 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](http://www.medipurpose.com/babylance)
- [Request no-cost samples and pricing](#)  
Please visit [medipurpose.wufoo.com/forms/q7x3s5/](http://medipurpose.wufoo.com/forms/q7x3s5/)
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## 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<sup>1</sup>.

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

[medipurpose.com/babylance](https://www.medipurpose.com/babylance)

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

