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Shading indicates that text has been modified, added or deleted.

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HemoHeel®



HemoHeel Preemie®

Instructions for Use

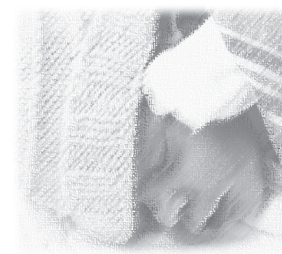
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REF	Product:	Pkg:
5781	HemoHeel	50/pkg
5784	HemoHeel Bulk Pack	8 Boxes/Case
5782	HemoHeel Preemie	50/pkg
5785	HemoHeel Preemie Bulk Pack	8 Boxes/Case

Instructions for Use

Overview



The heelstick is a widely used method for sampling blood from infants. Rather than accessing a tiny, neonatal vein during venipuncture, the heelstick procedure involves a minor puncture of the skin on the baby's heel to collect

a capillary blood sample. Generally safer and easier than venipuncture in babies, the heelstick method has proven particularly useful in obtaining samples for metabolic screening tests, as well as for measurements of bilirubin, glucose, chemistry and hematology.

Traditionally, a scalpel blade or lancet device has been used to inflict the wound to the baby's heel. These devices suffer from limitations centered around the inability to safely control the wound depth. As a result, cuts are often much deeper than needed causing undue pain to the baby. Also, the risk of injury to the deep layers of the dermis and even to the calcaneus are real, and infection can occur with long-lasting damage.

With the lancet method, blood flow from the heel is often inadequate. The stabbing method is quite painful and simply ineffective at promoting a free-flowing, adequate volume of blood. To compensate, the baby's heel is often squeezed to force out as much sample as

possible. This unfavorable practice, causes bruising of the baby's foot and likely contamination of the specimen (due to hemolysis, etc.). It then becomes difficult to obtain a later sample from a bruised heel, which can be a serious problem in sick babies who require multiple heelsticks. Further, contaminated samples or samples of insufficient volume may be rejected by the laboratory and a repeat heelstick may need to be performed.

In recent years, heelstick technologies have evolved which make an incision to the baby's heel, rather than a puncture. HemoHeel and HemoHeel Preemie fall into this category of heel incision devices, which optimize the neonatal heel blood sampling procedure. The premise behind heel incision devices is to incise the skin in a more horizontal direction, rather than a vertical (deep) direction. Because of this approach, these devices offer a significant improvement over lancet technologies by providing much better blood flow, standardizing the cut to a safer depth, and minimizing pain to the infant.

In this regard, both devices have been engineered to be as minimally invasive as possible while ensuring successful sample collection. HemoHeel provides a minor incision 1.0 mm in depth and 2.5 mm in length. A heel incision of this size has been shown to provide an optimum sample volume without excessive hemorrhage and minimizes the possibility of injury to cartilage or bone. HemoHeel Preemie provides an even shallower incision 0.85 mm in depth and 1.75 mm in length. Depending on the size of the baby and the amount of blood required for sampling, either device may be chosen.

These devices further the evolution of products for infant blood sampling from heelstick to heelnick. What they deliver is a unique combination of improved performance, safety and affordability to make this technology universally available.

Procedure

Heel Anatomy

The heel has been well established as the preferred sampling site in infants since the distance from skin to bone is greater than in other areas of the body. Anatomical studies of infants have demonstrated that in infants weighing between 1000-2000g the depth from skin to cartilage/bone is 2.4-5.7 mm at the lateral/medial plantar sites. The added unmeasured effect of skin compression during the heelstick process makes it imperative that the tip of the blade is shorter than the

actual distance from the skin surface to the underlying cartilage/bone. Thus, [with the devices,] the incision depths of 1.0 mm and 0.85 mm, are well above the level recommended for safety.

Site Selection

The recommended area for heelstick has been described as marked by a line extending posteriorly from a point between the fourth and fifth toes and running parallel to the lateral aspect of the heel, and a line extending posteriorly from the middle of the great toe running parallel to the medial aspect of the heel.



Blood Sampling

1. Once the site on the heel has been selected, clean the area with an antiseptic swab and allow it to air dry.

2. Remove the HemoHeel or HemoHeel Preemie device from its package. (Note: The device is sterile in its package. Once it is removed, do not contaminate the bottom surface that will come in contact with the baby's heel.)

3. Place the bottom surface of the device on the desired heelstick site, making sure that it is in firm contact with the skin. Use the arrow or the small notch on the device as a placement guide to the incision site. See Figure 1



Figure 1

4. Hold the device by the textured grips (colored) between the thumb and middle finger. Place the forefinger on top of the device. Press the top part toward the baby's heel in one continuous firm motion until the device clicks. (NOTE: The blade will make the incision and automatically retract. The pressure applied at the time of the cut is controlled by the device, so there should be no concern about over compression.) See Figure 2

5. Use a sterile pad to wipe away the first drop of blood prior to collecting the sample. Discard the used device as a biohazard.



Figure 2

6. Use the desired capillary tube, collection vessel, or filter paper to obtain the needed specimen.

7. Once the desired sample is obtained, gently press a sterile pad to the wound site until the bleeding stops. If desired, general wound care and bandaging techniques may be utilized.

8. Check the wound site periodically to ensure healing.

Cautions and Limitations

When performing a heelstick, avoid any areas that show evidence of prior heelstick, bruising, edema, or infection.

Medical professionals should be aware that small heelstick wounds are potential sites for local and systemic infection. General wound care practices should be followed. Potential complications of heelstick include penetration to or into bone or cartilage resulting in osteomyelitis, necrotising chondritis, or cutaneous calcification of the heel.

Use caution when handling and disposing of any sharp device and follow the recommended procedure to avoid injury. Used devices should be disposed as a biohazard.

Features and Benefits

Makes a standardized minor incision	Provides optimal length and depth for capillary blood collection in babies. Controlled, standardized skin incision technique is preferred over crude heelstick puncture methodologies.
Shallow incision depth	Incises capillaries at a safe depth. Avoids overly deep wounds that may cause trauma to the cartilage/bone. Minimizes the risk of heel injury and damage.
Micro incision length	Incises across capillary loops, not deep into larger vessels, for safer and more effective blood sampling.
Surgical-grade blade	High-quality surgical steel blade allows for heel incision with minimal skin trauma. (Skin puncture techniques can tear or rip through the skin.)
Rapid healing of the incision site without bruising	Facilitates multiple heel incisions if needed, an especially important consideration for sick babies.
Minimal discomfort to the infant	The shallow incision depth also avoids the pain fibers for kinder, gentler blood sampling.
Effective blood flow	Accomplishes blood sampling easily, safely and rapidly without re-sticks.
Ergonomic device design	Allows for easy manipulation and use by a gloved hand. The device incorporates textured gripping areas, and incision-site guides. Automatic blade retraction minimizes exposure risk.
Controlled actuation force	This device triggers at a known, controlled force which eliminates variation in compression that may lead to variables in the incision process.
Chemical and additive-free assembly	No irritants, glues, or lubricants are used in the manufacturing process. This feature improves product safety and reduces the potential for wound contamination problems.
Cost-effective	Even with improvements in performance, HemoHeel is substantially less expensive than other heel incision technologies. Its affordability makes it financially feasible even for limited budgets. Additionally, minimizing re-sticks, heel warmers, and blood collection time can make HemoHeel a cost-effective replacement for traditional lancets and other puncture devices.