

MiniCollect® PIXIE Heel Incision Safety Lancet Instructions for Use

Intended Use

MiniCollect® PIXIE Heel Incision Safety Lancet is used for blood sampling from heels of infants during blood test.

Product Description

MiniCollect® PIXIE Heel Incision Safety Lancet are sterile, single-use devices for heel incision. The device consists of a stainless steel blade in a plastic housing and retracts automatically and permanently after incision. The device penetrates the skin with a pendular swing to cut capillaries.

Precautions/Cautions

- Please refer to the policies and procedures of your facility with regard to handling of **MiniCollect®** PIXIE Heel Incision Safety Lancets.
- HBV, HCV, HIV and other infectious diseases can be transmitted through contact with biological samples. In the event of exposure to biological samples, ensure that appropriate medical attention is obtained.
- Discard all **MiniCollect®** PIXIE Heel Incision Safety Lancets in biohazard containers approved for their disposal.
- Wear disposable gloves during heel incision and when handling capillary blood samples to minimize exposure hazard.
- Do not use **MiniCollect®** PIXIE Heel Incision Safety Lancets after their expiry date.
- Do not use **MiniCollect®** PIXIE Heel Incision Safety Lancets if the trigger lock mechanism has been released before unpacking.
- Do not use **MiniCollect®** PIXIE Heel Incision Safety Lancets if the shield blister packaging has been damaged.
- **MiniCollect®** PIXIE Heel Incision Safety Lancets are only recommended for infant's heel incisions.
- The product is for single use only, do not reuse.


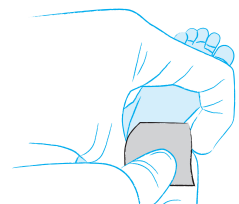
Storage

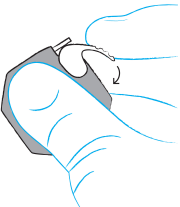
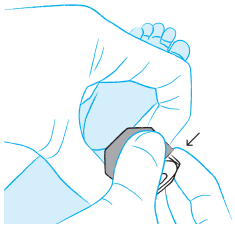

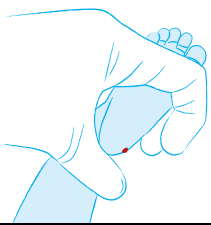
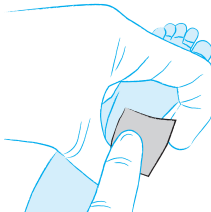
Store in a dry and well ventilated room. The product shall not come into contact with toxic, poisonous and corrosive substances.

Handling












Please refer to the recommendations of CLSI GP42-Ed7 regarding the selection of the adequate device, considering age and weight of the baby.

Colour Code	Depth/incision length	Application
Green	0.65 mm Depth / 1.40 mm Incision Length	Micro-Preemie
Orange	0.85 mm Depth / 1.75 mm Incision Length	Preemie
Yellow	1.00 mm Depth / 2.50 mm Incision Length	Newborn

1		<p>Select a site within the marked area.</p> <p>Prewarm or massage the site. A warm, moist towel (or other warming devices) at a temperature not higher than 42°C (108°F) may be used to cover the site for 3 to 5 minutes.</p>
2		<p>Clean the incision site of the heel with an antiseptic swab (70% Isopropyl) and allow skin to air dry. Residual alcohol may cause discomfort to the patient when the incision is performed and may affect the blood specimen, e.g. due to haemolysis.</p>

4		Release trigger lock mechanism by pushing down the safety tab.
5		Raise the foot above the baby's heart level. Place the incision device on the heel, ensuring that the blade side of the device is in full contact with the skin. Then push the button to release the blade.
6		After triggering, immediately remove the device from infant's heel and discard it into a biohazard sharps container.
7		It is recommended to wipe away the first drop of blood with a sterile gauze pad, since it most likely contains excess tissue fluid. Gently apply intermittent pressure to the surrounding tissue. Strong repetitive pressure (milking) must be avoided, as it may result in haemolysis or tissue-fluid contamination of the specimen. According to CLSI GP42, 7 th edition, it is recommended to position the infant's foot slightly lower than the rest of the body, if possible.
8		Following blood collection, gently press a dry sterile gauze pad to the incision site until bleeding has ceased.

Label Information

	Manufacturer		Sterilized using irradiation
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		Medical Device
	Caution		Authorized representative in the European Community
	Date of manufacture		

Literature:

CLSI. *Collection of Capillary Blood Specimens*. 7th ed. CLSI standard GP 4. Clinical and Laboratory Standards Institute; 2020.



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