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.

<table>
<thead>
<tr>
<th>Colour Code</th>
<th>Depth/incision length</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>0.65 mm Depth / 1.40 mm Incision Length</td>
<td>Micro-Preemie</td>
</tr>
<tr>
<td>Orange</td>
<td>0.85 mm Depth / 1.75 mm Incision Length</td>
<td>Preemie</td>
</tr>
<tr>
<td>Yellow</td>
<td>1.00 mm Depth / 2.50 mm Incision Length</td>
<td>Newborn</td>
</tr>
</tbody>
</table>

1

Select a site within the marked area. 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.

2

Clean the incision site of the heel with an antiseptic swab (70% Isopropy!) 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.
Release trigger lock mechanism by pushing down the safety tab.

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.

After triggering, immediately remove the device from infant's heel and discard it into a biohazard sharps container.

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, 7th edition, it is recommended to position the infant's foot slightly lower than the rest of the body, if possible.

Following blood collection, gently press a dry sterile gauze pad to the incision site until bleeding has ceased.

**Label Information**

<table>
<thead>
<tr>
<th>Icon</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="Sterile.png" alt="Sterilized" /></td>
<td>Sterilized using irradiation</td>
</tr>
<tr>
<td><img src="Use-by-date.png" alt="Use-by date" /></td>
<td>Do not re-use</td>
</tr>
<tr>
<td><img src="Lot.png" alt="Batch code" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="Ref.png" alt="Catalogue number" /></td>
<td>Medical Device</td>
</tr>
<tr>
<td><img src="Caution.png" alt="Caution" /></td>
<td>Authorized representative in the European Community</td>
</tr>
<tr>
<td><img src="Date-of-manufacture.png" alt="Date of manufacture" /></td>
<td></td>
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</tbody>
</table>

**Literature:**


SteriLance Medical (Suzhou) Inc.
No.168 PuTuoShan Road, New District
215153 Suzhou, Jiangsu, P.R.China

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Distributed by:
Greiner Bio-One GmbH
Bad Haller Str. 32
4550 Kremsmünster
Austria

www.gbo.com/preanalytics
office@at.gbo.com
Phone +43 7583 6791