INSTRUCTIONS FOR USE

hemaPEN® opening tool

Description

The opening tool can only be used in conjunction with Trajan’s hemaPEN®.

The hemaPEN opening tool has been designed to assist in the retrieval of the dried blood spot samples from internal body of hemaPEN.

The tool functions by first piercing the main body of the hemaPEN then cutting around the plastic housing. The housing can be safely removed to expose the dried blood spot cartridge which contains four discrete DBS paper substrates for use in an analytical workflow.

The contaminated capillaries are contained within the front housing and hemaPEN base and can be discarded as medical waste in accordance with laboratory procedures.

Important

Please read these instructions before attempting to open the hemaPEN.

The opening tool is for use with hemaPEN only.

Components:
1. Handle with guard
2. Cradle with blade

Components:
1. Top
2. Main body
3. Green tab
4. Data matrix label, front
5. Capillaries
6. Base
**Important**

**Warning**
With the blade guard removed from the opening tool, a sharp blade is exposed within the cradle. Use caution when handling the opening tool.

**Warning**
Opening the hemaPEN may expose glass capillaries which may contain residual dried blood. Wear personal protective equipment as directed by your institutional biohazard procedures.

**Caution**
Opening the hemaPEN is a repetitive action. Take frequent breaks whilst using the opening tool. Plan to open no more than 30 hemaPEN in any one session.

**Precaution**
The hemaPEN is designed to collect and transport dried blood within the DBS cartridge. It is recommended that the hemaPEN remain in the bag for at least two hours before attempting to open the hemaPEN. Gloves are recommended when handling potential biohazard materials.

**Instructions**
Before opening a hemaPEN ensure you have:

1. hemaPEN opening tool (P/N 49811001).
2. Personal protective equipment including nitrile gloves or equivalent, laboratory eye protection and laboratory coat.
3. A clean flat work surface.

**Step 1 – Removing opening tool handle**
1. Using the index finger remove handle from the cutting head to expose cutting blade (Figure 1).

**Step 2 – Attaching to the cradle**
1. Place hemaPEN in the opening of the opening tool, positioning the base above the opening tool cradle (Figure 2).

2. Gently push hemaPEN into the opening tool until the hemaPEN engages the V notch of the cradle. Inspect and ensure that the cutting blade has engaged the main body (Figure 3).

3. Next place the handle onto the main body of the hemaPEN (Figure 4).
Step 3 - Cutting the main body
1. While holding the opening tool, use the thumb to apply pressure to the base. Slowly rotate the handle until the upper portion of the hemaPEN main body is separated from the base (Figure 5). This may take one or two turns and is normally accompanied by an audible click or when the rotating handle rotates freely with no tension.

2. Remove the handle from the hemaPEN main body.

Step 4 - Removing the main housing
1. Invert the hemaPEN, cradle side down (Figure 6).

2. Remove the separated main body section to expose the moulded spring assembly.

3. Re-invert the assembly into a vertical position with the base and cradle uppermost (Figure 7).
4. Take hold of the moulded spring assembly and gently pull out to remove it. Both the moulded spring assembly with the DBS cartridge attached will come out as one unit (Figure 7).

5. Place the assembly on a flat surface with the DBS cartridge facing up (Figure 8).
Step 5 – Removing remaining hemaPEN parts

1. While holding the opening tool firmly, grip the hemaPEN base utilizing the scalloped sections of the opening tool cradle (Figure 9).

2. Gently disengage the hemaPEN base away from the opening tool.

△ Precaution
When disengaging the remaining hemaPEN parts be aware that the blade will be exposed.

3. Once removed, the remaining hemaPEN parts can be disposed.

△ Precaution
Dispose of any waste materials and biological samples in accordance with local waste management policies and procedures.

4. Always secure the handle after opening tool use to protect the blade in the cradle.

Care and maintenance

The opening tool blade will become blunt over time. Estimate approximately 150-200 hemaPEN per opening tool. Contact your Trajan representative or customer service for a replacement opening tool.

Cleaning

For decontaminating the opening tool use 70% ethanol or isopropyl alcohol to wipe the surfaces. Be careful not to touch the exposed blade. Wipe the blade with a cotton bud soaked with 70% ethanol or isopropyl alcohol.

Information and support

Visit www.hemapen.com or contact techsupport@trajanscimed.com

Specifications are subject to change without notice.