MiniCollect®





MiniCollect® Safety Lancets Instructions for Use



Intended Use

MiniCollect® Safety Lancets are designed for use in the daily capillary blood collection routine when delegated by a qualified practitioner. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with these instructions.

Product Description

MiniCollect® Safety Lancets are sterile, single-use, button activated devices for skin puncture, allowing controlled length and depth of incision. The device consists of a stainless steel needle/blade in a plastic housing and retracts automatically and permanently after puncture.

Precautions/Cautions

- Please refer to the policies and procedures of your facility with regard to handling of MiniCollect® 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® Safety Lancets in biohazard containers approved for their disposal.
- · Wear disposable gloves during skin puncture and when handling blood collection tubes to minimise exposure hazard.
- Do not use MiniCollect® Safety Lancets after their expiry date.
- The protective cap is a single sterile barrier system. Do not use if protective tab has been damaged or unintentionally removed.
- Do not reuse MiniCollect® Safety Lancets. Reuse of the product may cause harmful infections or injury.
- Lancets with a puncture depth greater than 2 mm are not recommended for the use on children less than one-year old.
- Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be
 reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.
- Only applicable for Saudi Arabia: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the Saudi Food and Drug Authority (SFDA).

Storage

Recommended storage temperature: 4-36°C (40-97°F). Store in a dry place, away from direct or excessive heat. **NOTE**: Avoid exposure to direct sunlight.

Handling

READ THIS ENTIRE DOCUMENT BEFORE PERFORMING SKIN PUNCTURE

Equipment required for specimen collection.

Be sure that the following materials are readily accessible before performing skin puncture:

- All necessary MiniCollect® tubes, identified for size, draw and additive or other necessary collection containers. NOTE: MiniCollect® 9NC Coagulation are only used for venous blood collection.
- Disposable gloves and personal protective equipment.
- Labels for positive patient identification of samples.
- Alcohol swab for cleansing site.
- Adhesive plaster or bandage.
- Sharp disposal container for safe disposal for used material.

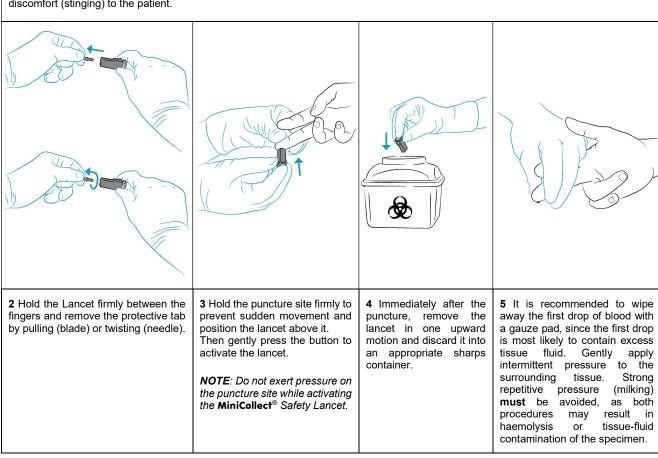
The MiniCollect® Safety Lancet version should be selected based on the patient's tissue thickness and volume of blood required.



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

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1 Prepare puncture site with appropriate antiseptic. After cleansing the skin puncture site, allow the area to air dry, so the antiseptic action of the alcohol can take effect. Residual alcohol causes rapid haemolysis, can have adverse effects on test results, and will cause discomfort (stinging) to the patient.



NOTE: Please use these instructions in conjunction with the MiniCollect® Capillary Blood Collection Tube Instructions for Use, if necessary.

Label Information

***	Manufacturer	STERILE R	Sterilized using irradiation		Single sterile barrier system with protective packaging outside
	Use-by date	\otimes	Do not re-use	MD	Medical device
LOT	Batch code	[]i	Consult instructions for use	*	Keep away from sunlight
REF	Catalogue number	\overline{M}	Date of manufacture	CH REP	Authorized representative in Switzerland
1	Temperature limit	\triangle	Caution		

Literature

CLSI. Collection of Capillary Blood Specimens. 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute; 2020.



Greiner Bio-One GmbH Bad Haller Str. 32 4550 Kremsmünster Austria Production location: ASAHI Polyslider Company, Limited 860-2 Misaki Maniwa, Okayama, 719-3226 Japan Made in Japan

Distributed by Greiner Bio-One GmbH, Austria

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



Greiner Bio-One Vacuette Schweiz GmbH St. Leonhardstraße 39 9000 St. Gallen Switzerland

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