

Instructions for Use

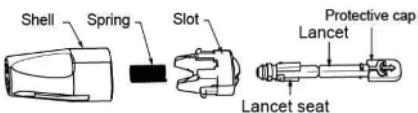
Pressure Activated Safety Lancet

21G, 2.0mm Depth

REF DIALAN001

Product components

The safety lancet is made up of a needle core, a spring device, a launching device and a casing.



Intended use

The safety lancet is intended for capillary blood sampling in order to obtain a small blood sample for various tests. It is designed for use by both healthcare professionals and lay users, providing a safe and convenient method for blood specimen collection in clinical and home healthcare settings.

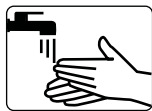
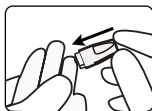
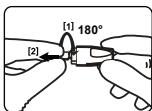
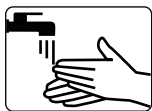
Contraindication

Use with caution in individuals with coagulation mechanism disorders.

Operating procedure

- Please read the instructions before use.
- Wash hands before use. Dry thoroughly.
- Healthcare professionals must wear gloves prior to disinfecting the lancing site and completing the lancing procedure. Scrub and disinfect the complete skin surface of the blood collection site with medical disinfectants such as iodine or alcohol.
- Use the safety lancet immediately after opening the primary package.
- Follow the instructions to use the safety lancet to draw blood.
- Dispose of used safety lancet in a biohazard waste container. Wash hands after use.

Instructions



1. Wash hands before use. Healthcare professionals must wear gloves prior to disinfecting the lancing site and completing the lancing procedure. Scrub and disinfect the complete skin surface of the blood collection site with medical disinfectants such as iodine or alcohol.
2. Twist off the protective cap.
3. Hold the safety lancet against the patient's fingertip and press down gently to draw blood. After use, dispose of the used device into a sharps container in accordance with your local regulations.
4. Wash hands after use.
5. For pediatric patients, first immobilize the child by asking the parent to:
 - Sit on the phlebotomy chair and place the child on their lap
 - Position their legs around the child in a cross legged pattern to immobilize the child's lower extremities
 - Extend an arm across the child's chest and firmly over the child's free arm to secure it
 - Grasp the child's elbow and hold it securely
 - Use his or her other arm to firmly grasp the child's wrist, holding the hand palm up.
 - If instructed to use this 2.0mm lancet on a neonatal patient, we recommend to only use it on the foot. Always seek guidance from clinical staff.

Continued on next page →

Indications for use

- The safety lancet is a single use device indicated for capillary blood sampling.
- For single use only. Not intended for use on more than one patient. The device is deactivated after single use.

Warning

- For single use only. Not intended for more than one use. Not intended for use on more than one patient. The device is deactivated after single use and cannot be used more than once.
- Improper use of safety lancets can increase the risk of inadvertent transmission of blood borne pathogens, particularly in settings where multiple patients are tested.
- Unused product expires five years after the manufacture date, and using the product beyond expiration is strictly prohibited.
- The product has no therapeutic or diagnostic function.
- Do not use if the lancet protective cap is damaged or lost.
- Use with caution on those with coagulation mechanism disorders.
- For obese users or individuals who require larger blood volumes, it is recommended to choose products with small "G" value or large puncture depth for blood collection.

Storage and transportation

1. The device should be stored at an environment where the temperature is between -4° F and 104° F / -20° C and 40° C and the relative humidity less than 80%. The storage environment should be free of corrosive gases, dry, away from sunlight, well-ventilated conditions, and clean.
2. The device should be carefully transported and handled.

Shelf life

Shelf life of product is 5 years.

Clinical benefits

Safety lancets help medical staff and patients complete capillary blood sampling in order to obtain a small blood sample for various tests.
















Adverse events

We conducted a search for adverse events and reviewed up-to-date published information on equivalent and similar devices in the market. No adverse events were found for equivalent and similar products, indicating compliance with the current technical standards. If any adverse events occur during the use of the product, please contact us and we will resolve the relevant issues as soon as possible. Additionally, note that any serious incidents related to the device should be reported to the manufacturer and the appropriate regulatory authority where the user and/or patient is established.

Disposal

- The product must be disposed of after use.
- Products contaminated with blood must be disposed of in accordance with the local regulations for hazardous materials.
- The product must not be used after the expiration date.
- Safe disposal must be carried out in accordance with current local regulations.

Symbols

 Do not re-use	 Single sterile barrier system	 Unique device identifier
 Sterilized using irradiation	 Consult instructions for use	
 Non-pyrogenic	 Temperature limit -20°C 40°C	 Humidity limitation 0% 80%
 Caution	 Keep dry	 Do not use if package is damaged
 Keep away from sunlight	 Use-by date	 Batch code
 Date of manufacture	Manufactured for Sunset Healthcare Solutions 141 W Jackson Blvd Ste 1950 Chicago IL 60604 www.SunsetHCS.com	