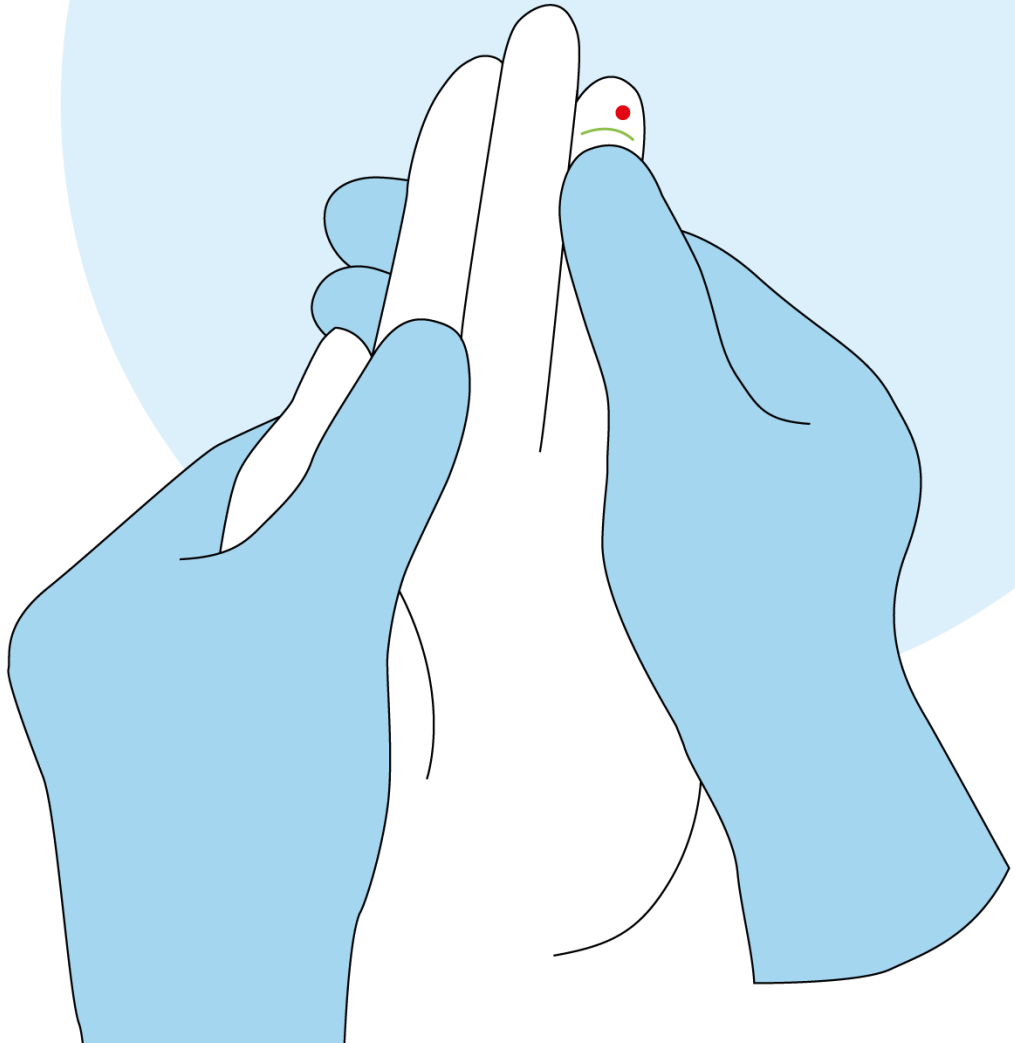
HTL-STREFA

SAFETY LANCETS LANCING TECHNIQUE & LANCING PROCEDURE FOR CAPILLARY BLOOD SAMPLING



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HTL SAFETY LANCETS
LANCING PROCEDURE FOR CAPILLARY BLOOD SAMPLING TECHNIQUE

This material presents the procedure for capillary blood lancing technique recommended by HTL-STREFA that was confirmed by the results of the Clinical Studies conducted by HTL-STREFA.[1,2]

This material also follows The World Health Organization guideline and Global recommendations for capillary blood sampling.[3,4]

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HTL SAFETY LANCETS
LANCING PROCEDURE FOR CAPILLARY BLOOD SAMPLING TECHNIQUE

HTL-STREFA developed a lancing procedure that has been clinically proven & increases the expected blood volumes by reducing pain perception at the same time.[1]

HTL SAFETY LANCETS
LANCING PROCEDURE FOR CAPILLARY BLOOD SAMPLING TECHNIQUE

CLINICAL TRIAL 01LAN2017: *A randomized, single blind, uni-centre pilot study in healthy volunteers, comparing the volume of blood obtained after the puncture of the finger with four types of lancets.*
This study aimed to select **one lancing procedure** from three different methods.

CLINICAL TRIAL 02LAN2017: *A randomized, single blind, uni-center study in healthy volunteers, to determine capillary blood volume and pain perception obtained in a process of puncturing with different safety lancets.*[2]
The selected method was evaluated in the main study, to enable to catch potential factors that may influence blood volume results [skin thickness, sex and age].

SAFETY LANCETS
LANCING TECHNIQUE CONFIRMED IN CLINICAL STUDIES

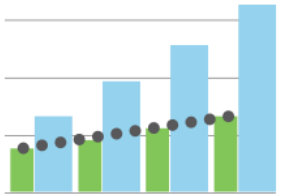
GOALS which you can achieve by using the recommended lancing technique:

EFFICACY [2]

- Adequate blood samples for chosen version of the lancet (depending on the type of the lancet - from a few µl up to 150 µl).

CONVENIENCE [2]

- May minimize pain perception during and after lancing.[1]
- Using of a smaller lancet size and obtaining the adequate blood volume may reduce pain perception at the same time.



SAFETY LANCETS
LANCING PROCEDURE CAN BE DIVIDED INTO PHASES AND STEPS:

PREPARING TO
PRE-LANCING
PROCEDURE

- [steps from 1 to 6]

PRE-LANCING

- [steps from 7 to 10]

LANCING

- [steps from 11 to 12]

POST-LANCING

- [steps from 13 to 15]

SAFETY LANCETS
PREPARING FOR PRE-LANCING PHASE

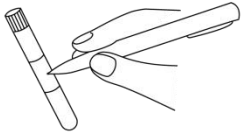
! Recommended patient position during the whole lancing procedure: **seated, with the hand placed below the elbow level.** This is HTL-STREFA recommendation based on the experience from Clinical Studies.[1]

1. Preparation of supplies for capillary blood sampling.

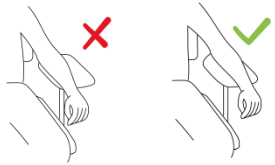
2. Hand disinfection.

3. Identifying patients.

4. Labeling the microcollection device for capillary blood collection.

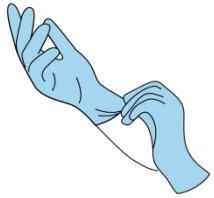


5. Positioning the patient.



Check above the recommended patient position.

6. Putting on gloves.



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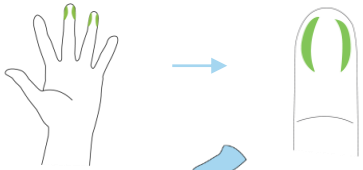
SAFETY LANCETS
PRE-LANCING PHASE

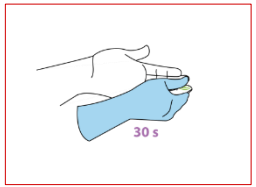
! Recommended patient position during the whole lancing procedure: **seated, with the hand placed below the elbow level.** This is HTL-STREFA recommendation based on the experience from Clinical Studies.[1]

7. Selection of hand and finger to be lanced. Area to be chosen – fingertip, palmar surface of the distal segment of the middle or ring finger.



8. Selection of the safety lancet.

9. **Massaging the test site for a full 30 seconds.**[1]



10. Disinfection of the selected site and allowing disinfectant to evaporate from the skin.

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SAFETY LANCETS
LANCING PHASE

! Recommended patient position during the whole lancing procedure: **seated, with the hand placed below the elbow level.** This is HTL-STREFA recommendation based on the experience from Clinical Studies.[1]

11. Elimination of the first drop of capillary blood from which the sample was taken - if necessary. Information on the need to wipe off the first blood drop should be included in the instructions for specific test.

12. **CAPILLARY BLOOD COLLECTION** using **LANCING TECHNIQUE.**[1]

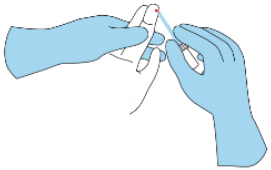
SAFETY LANCETS
LANCING TECHNIQUE:

Recommended patient position during the whole lancing procedure: **seated, with the hand placed below the elbow level.**
This is HTL-STREFA recommendation based on the experience from Clinical Studies.[1]

12 a. Prepare the safety lancet by twisting the protective safety cap and taking it out.

12 b. Place the safety lancet on the prepared test site and inform the patient of the imminent puncture. Activate the device.*

12 c. Collect the required blood sample.
For bigger volumes of blood samples gently press the fingertip during blood collection. Do not milk the site to avoid hemolysis and contamination of the sample.



* *For a contact safety lancet: activate the unblocked device by simply pushing the lancet on the finger.*
For a push-button safety lancet: activate the unblocked device by simply pressing the push-button on the top of the device.

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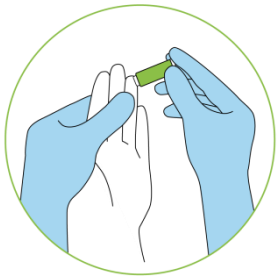
SAFETY LANCETS
LANCING TECHNIQUE

- The type of lancing procedure applied to capillary blood sampling has a significant impact on blood volume results.
- **The lancing procedure based on instructions for use** available for most safety lancets **is limitied** to **2 STEPS:**

press the push-button on the top of the device



push the lancet on the finger

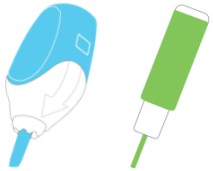
Position the unblocked safety lancet on the test site and activate the device by

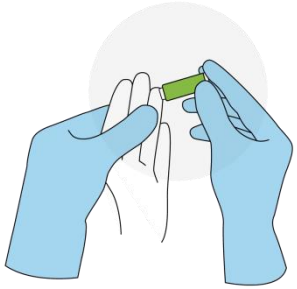
Collect the blood sample.

HTL-STREFA SAFETY LANCETS USER MANUAL

SAFETY LANCETS are single-use devices intended for capillary blood sampling from fingertip of patients for most common blood tests.

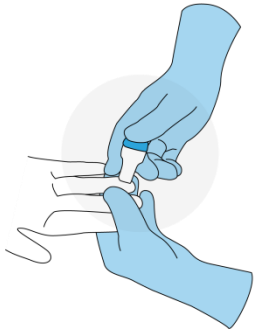
CONTACT ACTIVATION
SAFETY LANCETS





1. Twist off the protective cap and pull it straight out.
2. Press the safety lancet body firmly against the test site to activate the device.

PUSH BUTTON
SAFETY LANCETS



1. Twist off the protective cap and pull it straight out.
2. Press the safety lancet push-button to activate the device.

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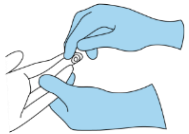
SAFETY LANCETS
POST-LANCING PHASE

! Recommended patient position during the whole lancing procedure: **seated, with the hand placed below the elbow level.** This is HTL-STREFA recommendation based on the experience from Clinical Studies.[1]

13. Disposal of all sharps.
After puncture, the device should be placed into an appropriate sharps container.

14. Protect the test site with a sterile gauze pad.



15. Glove removal.

HTL-STREFA SAFETY LANCETS

TYPE	BRAND	SIZE
push button	**Acti-Lance® Lite**	28G x 1.5 mm
push button	**Acti-Lance® Universal**	23G x 1.8 mm
push button	**Acti-Lance® Special**	17G x 2.0 mm
contact activation	**ergoLance Micro Flow**	30G x 1.5 mm
contact activation	**ergoLance Normal Flow**	25G x 1.8 mm
contact activation	**ergoLance High Flow**	21G x 2.0 mm
push button	**Haemolance® Micro Flow**	28G x 1.6 mm
push button	**Haemolance® Low Flow**	25G x 1.4 mm
push button	**Haemolance® Normal Flow**	21G x 1.8 mm
push button	**Haemolance® High Flow**	18G x 1.8 mm
push button	**Haemolance® Pediatric**	1.5 mm x 1.2 mm
push button	**Haemolance® Max Flow**	1.5 mm x 1.6 mm
push button	**MediSafe® Solo**	29G x 1.5 mm
push button	**MediSafe® Solo**	23G x 2.0 mm

TYPE	BRAND	SIZE
push button	**Medlance®**	23G x 1.8 mm
push button	**Medlance®**	21G x 1.8 mm
push button	**Medlance®**	21G x 2.4 mm
push button	**Medlance®**	1.5 mm x 1.0 mm
push button	**Medlance®**	1.5 mm x 1.5 mm
push button	**Medlance®**	1.5 mm x 2.0 mm
contact activation	**Medlance® Plus Super Lite**	30G x 1.2 mm
contact activation	**Medlance® Plus Lite**	25G x 1.5 mm
contact activation	**Medlance® Plus Universal**	21G x 1.8 mm
contact activation	**Medlance® Plus Extra**	21G x 2.4 mm
contact activation	**Medlance® Plus Special**	0.8 mm x 2.0 mm
push button	**Prolance® Micro Flow**	28G x 1.6 mm
push button	**Prolance® Low Flow**	25G x 1.4 mm
push button	**Prolance® Normal Flow**	21G x 1.8 mm
push button	**Prolance® High Flow**	18G x 1.8 mm
push button	**Prolance® Pediatric**	1.5 mm x 1.2 mm
push button	**Prolance® Max Flow**	1.5 mm x 1.6 mm

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11. Simulated Clinical Use Testing to Evaluate Sharps Injury Prevention Features of HTL-STREFA's safety lancet Prolance type 430. Study report; dated 2019-02-12.

APPENDIX - SAFETY LANCETS LANCING PROCEDURE FOR CAPILLARY BLOOD SAMPLING

Recommended patient position during the whole lancing procedure: **seated, with the hand placed below the elbow level.**
This is HTL-STREFA recommendation based on the experience from Clinical Studies.[1]

PRE-LANCING

- Select the hand and finger to be lanced. Area to be chosen – fingertip, palmar surface of the distal segment of the middle or ring finger.
- **Massage the test site for a full 30 seconds.**
- Disinfect the selected site and allow disinfectant to evaporate from the skin.

LANCING

- Prepare the safety lancet by twisting the protective safety cap and taking it out.
- Place the safety lancet on the prepared test site and inform the patient of the imminent puncture. Activate the device*.
- Collect the required blood sample.
  For bigger blood samples gently press the fingertip during blood collection. Do not milk the site to avoid hemolysis and contamination of sample.

*1. For a contact safety lancet: activate the unblocked device by simply pushing the lancet on the finger.
2. For a push-button safety lancet: activate the unblocked device by simply pressing the push-button on the top of the device.

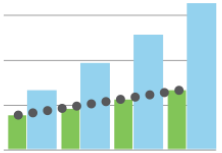
POST-LANCING

- After puncture, the device should be placed into an appropriate sharps container.
- Protect the test site with a sterile gauze pad.

GOALS

EFFICACY
CONVENIENCE

- Adequate blood samples for chosen version of the lancet (depending on the type of the lancet - from a few µl up to 150 µl).
- Minimized pain perception during and after lancing.[1]
- Using of a smaller lancet size and obtaining adequate blood volume reduces pain perception at the same time.



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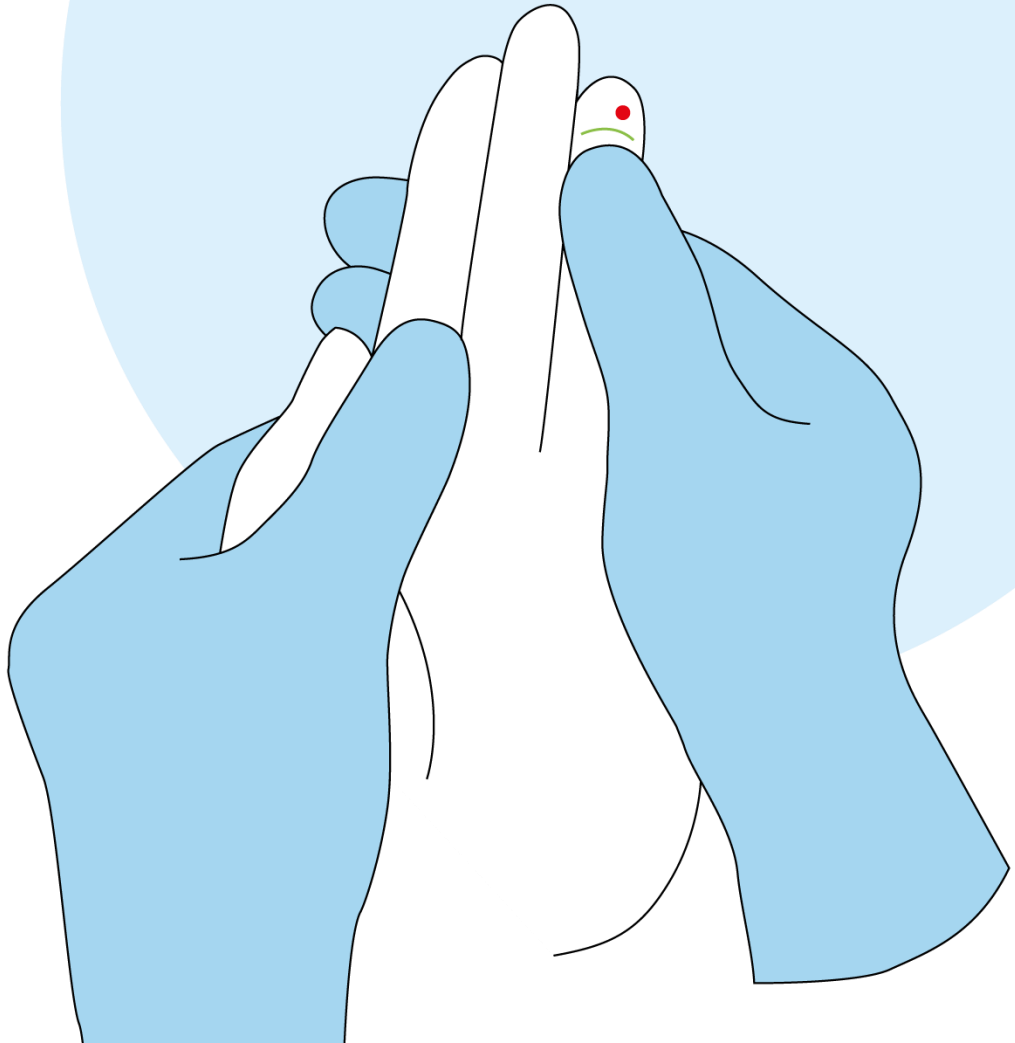

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