HTL-STREFA

SAFETY LANCETS LANCING TECHNIQUE & LANCING PROCEDURE FOR CAPILLARY BLOOD SAMPLING







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}





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



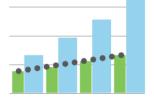
GOALS which you can achieve by using the recommended lancing technique:

EFFICACY ²

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

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 PRE-LANCING** [steps from 1 to 6] [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





Hand disinfection.



Identifying patients.



4. Labeling the microcollection device for capillary blood collection.



Positioning the patient.



6. Putting on gloves.



Check above the recommended patient position.



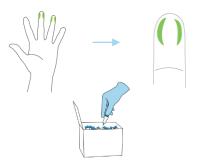




****** SAFETY LANCETS **PRE-LANCING PHASE**

- 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.
- Selection of the safety lancet.
- Massaging the test site for a full 30 seconds.1
- Disinfection of the selected site and allowing disinfectant to evaporate from the skin.















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

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



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CAPILLARY BLOOD COLLECTION Using 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
- 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 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.





SAFETY LANCETS LANCING TECHNIQUE

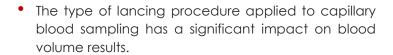


press the push-button on the top of the device



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

push the lancet on the finger



The lancing procedure based on instructions for use available for most safety lancets is limitied to 2 STEPS:



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.











- 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.



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







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

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
50	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
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





REFERENCES

- 1. 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.
- 2. Janus-Dziedzic K, Zurawska G, Banyś K, Morozowska J. The impact of needle diameter and penetration depth of safety lancets on blood volume and pain perception in 300 volunteers: A randomized controlled trial. J Med Lab Diagn 2019 Jan Vol 10(1), pp. 1-12.
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- 4. Krleza J, Dorotic A, Grzunov A, Mradin M. Capillary blood sampling: national recommendations on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine. Bioch Med 2015 Oct 15;25(3):335-58.
- 5. Serafin, M. Malinowski & A. Prażmowska-Wilanowska (2020): Blood volume and pain perception during finger prick capillary blood sampling: are all safety lancets equal?, Postgraduate Medicine, DOI: 10.1080/00325481.2020.1717160.
- 6. Simulated Clinical Use Study to Evaluate Sharps Injury Prevention Feature of HTL-STREFA's Mediance Plus safety lancet, type 553-556. Study report; dated 2019-10-22.
- 7. Simulated Clinical Use Testing to Evaluate Sharps Injury Prevention Features of HTL-STREFA's safety lancet Haemolance Plus type 420. Study report; dated 2019-02-12.
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- 10. Simulated Clinical Use Testing to Evaluate Sharps Injury Prevention Features of HTL-STREFA's safety lancet MediSafe Solo type 520. Study report; dated 2019-02-12.
- 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.



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



20 S sampling

2 MIN samplin



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.









THANK YOU





