





PRODUCT PORTFOLIO















CONTENT

Company Profile	2
History	4
Production	6
Market	8
Quality Standards	10
Sustainable Development Policy	12
Education	14
Our Publications and Research	16
Diabetes Pandemic	18
Sharps Injury Prevention	20
Products	22
References	44
Contact	46



COMPANY PROFILE

HTL-STREFA S.A., a company of **MTD group**. We are one of the global leaders in the production of medical devices, particularly: safety lancets, personal lancets, pen needles, and lancing devices.

Our products are used by healthcare professionals for capillary blood collection in diagnostic tests conducted in hospitals, clinics, and laboratories, as well as by diabetics for daily blood glucose monitoring and subcutaneous drug administration, including insulin.

MTD (Medical Technology and Devices) is a leading group in med-tech that designs, develops and delivers innovation globally through a comprehensive range of safety sharps and medical devices for diabetes management and personal care. MTD is a holding company founded in 2018 by the union of two historical and leading companies in the health market: Pikdare and HTL-STREFA that together count over 80 years of experience in these areas. MTD products are designed to improve the safety, quality and comfort of use of medical equipment for both patients and healthcare professionals. Made with cutting-edge technologies and maximum precision from the three production plants in Europe, the solutions of the holding company help to reduce hospital complications and consequently promote the sustainability of the healthcare system. The group's headquarters are located in Lugano, Switzerland, but the company is present worldwide with five offices (Italy, Poland, USA, Canada, France) and a widespread distribution of its products in over 100 countries.

25 years of 55 series of experience



We employ a continuous improvement strategy to analyze and update products. We are implementing and launching new solutions to meet the changing needs of patients and health care professionals. Our internal SOPs ensure the required cleanliness of production. Additionally, the air cleanliness requirements of class ISO 8 (100.000 as per USA Federal Std 209 E) are fulfilled in clean zones. The design of our products is defined by ergonomics, simplicity and reliability.

HISTORY

1994

First patent for a **safety lancet** granted in the USA

2000

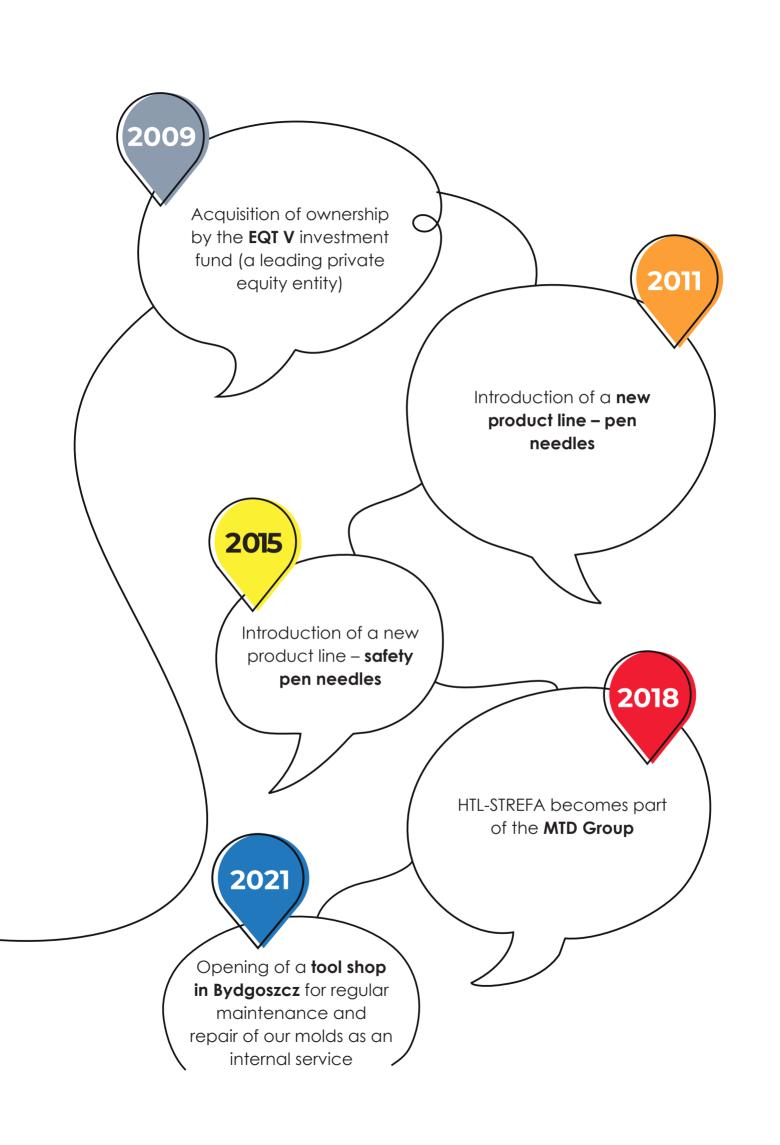
Opening of the **first modern manufacturing plant** in Ozorków,
within the Łódź Special
Economic Zone

2006

Company was listed on the Warsaw Stock Exchange

2007

- Launch of the second manufacturing plant with an in-house needle grinding facility located in Łęczyca (Łódź Special Economic Zone)
- acquisition of a major Swedish competitor Haemedic AB
- Establishing of a subsidiary in the USA dedicated to sales and marketing of HTL-STREFA products
 - Gaining over 50% market share in the safety lancet segment



PRODUCTION

At the moment, HTL-STREFA has three modern production facilities in Poland (Lodz Special Economic Zone and Bydgoszcz), and a sales and marketing office located in Warsaw, Poland. HTL-STREFA, Inc. a distribution facility **in the United States** is also responsible for Sales & Marketing in North and South America.



HTL-STREFA works in close cooperation with its customers and end users to exactly meet the market requirements. We maintain complete control over **quality and design for all aspects of each product.** Our team of committed designers and engineers constantly improve the quality of our products and processes, while also **developing new and innovative solutions.**

HTL-STREFA is focused on strategic manufacturing for top multinational medical device corporations; we also market our own products under the HTL-STREFA brand in cooperation with local distributors.

Every day, nearly 10 million products are shipped from HTL STREFA plants. Thanks to a highly developed distribution network, safety lancets, personal lancets and pen needles carrying the HTL STREFA logo, or under our Customers' brands, are available worldwide.





3 modern 9 production facilities

MARKET

The **medical technology industry** is a dynamic and essential component of the healthcare sector. **Advances in technology** improve medical devices to simplify the **prevention**, **diagnosis and treatment** of many diseases.



Prevention

Medical devices equipped with a single use protection feature allow patients to be protected from blood borne pathogens.



Diagnosis

Safety lancets of a wide variety of sizes allow quick sample collection while ensuring maximum patient comfort.



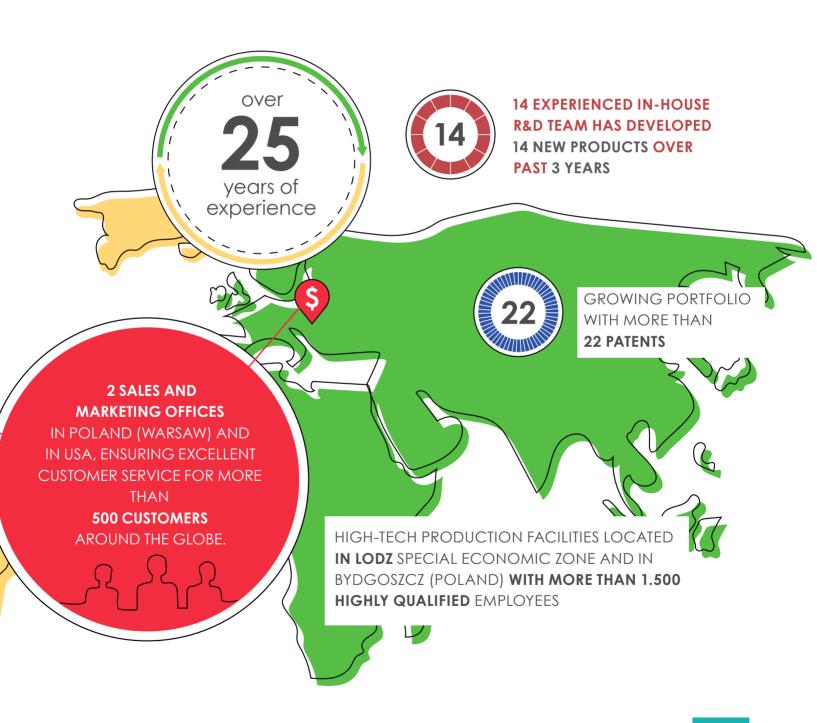
Treatment

Personal lancets allow diabetics to easily monitor blood glucose level which helps to manage diabetes in a more sufficient way; pen needles are dedicated for injectable drug delivery.





HTL-STREFA is a brand with global experience from **more than 80 countries**. We are the global leading provider of blood micro-sampling medical devices with close to 50% global market share in safety lancets (#1 position globally) and #2 provider globally of personal lancets. For many years, our brand has never failed the promises made to the patients and health care professionals.



QUALITY STANDARDS

HTL-STREFA products consistently exceed the most rigorous international safety and quality standards.

HTL-STREFA PRODUCTS ARE SOLD IN OVER 80 COUNTRIES.

Since its very foundation, HTL-STREFA has maintained and improved a quality management system. Our quality management system complies with the **EN ISO 13485:2016** standard requirements.

All HTL-STREFA products bear the CE marking, which proves compliance with the requirements for medical devices applicable in the European Union specified in **Directive 93/42/EWG** and Regulations **(EU) 2017/745, (EU) 2023/607** and relevant regulations.

The Notified Body involved in the conformity assessment process of our products is **TÜV Rheinland LGA Products GmbH**.

Since January 2019, HTL-STREFA holds Medical Device Single Audit Program Certificate (MDSAP), confirming compliance with **ISO 13485:2016**, and the regulatory requirements of five jurisdictions: Australia, Brazil, Canada, Japan, and the United States.

HTL-STREFA products are sold worldwide, primarily in **Europe**, the **USA**, **Canada**, and **South American** countries, including **Brazil**, **Mexico**, **China**, **Japan**, **Australia**, as well as in **the Middle East** and **Asia**. We hold registrations and marketing authorizations issued by competent authorities and government agencies, as well as certificates of conformity issued by accredited notified bodies, allowing us to place the medical devices on the market, among others:

- TÜV Rheinland LGA Products GmbH. (European Union)
- FDA in the Unites States
- Anvisa in Brazil
- HC in Canada

- MHLW in Japan
- MFDS in Korea
- COFEPRIS in Mexico
- UKRMEDCERT in Ukraine
- SFDA in Saudi Arabia
- CFDA in China



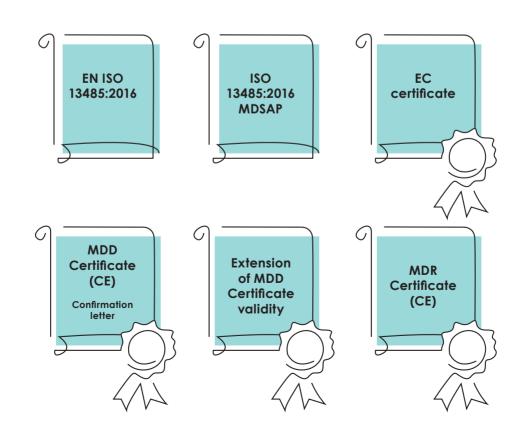
HTL-STREFA

branded devices are registered in:

- All EU countries
- the USA
- China
- Russia
- Korea
- Brasil
- Mexico
- Thailand
- Israel
- Canada
- Turkey
- United Arab Emirates
- Australia



HTL-STREFA holds multiple certifications:



SUSTAINABLE DEVELOPMENT POLICY

HTL-STREFA is part of the MTD Group with a shared sustainability strategy.

Environmental, social, and governance issues are an integral part of our corporate culture. Sustainability plays a central role in our business model, and ethical management guides all corporate decisions.

MTD's commitment is translated into a roadmap, based on a sustainability strategy. The strategy is built on four pillars, each with specific objectives aligned with the United Nations Sustainable Development Goals (SDGs).

TAKING CARE OF PEOPLE'S WELLBEING

Our actions are driven by a commitment to caring for people, patients, and consumers. This is why we pay close attention to their unmet needs, taking into account their emotional well-being, in order to design products that address those needs. This approach of listening has been key to our continuous product innovation, making our products more user-friendly, enhancing comfort, and ultimately improving compliance with medical treatments.



THE SAFETY OF HEALTHCARE PROFESSIONALS

At HTL-STREFA, along with the MTD Group, one of our key priorities is the portfolio of safety sharps. These products focus on preventing hospital infections, which not only jeopardize the health of healthcare professionals but also represent a significant financial burden on healthcare systems.

We design and provide safety solutions specifically aimed at minimizing or eliminating the risk of healthcare professionals' exposure to bloodborne pathogens. Our devices are designed to enhance the comfort and safety of medical treatments for both healthcare professionals and patients.





THE IMPACT ON PLANET AND PEOPLE

Achieving a positive impact on health also means caring for the environment. That's why, as the MTD Group, we not only focus on the well-being of people but also play an active role in preserving and improving the health of our planet.

Learn more about how HTL-STREFA, as part of MTD Group, takes care of the planet.

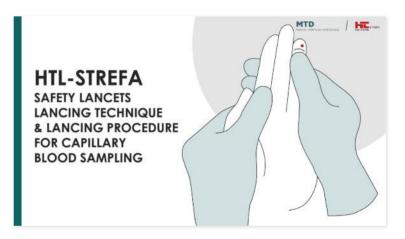
htl-strefa.com

EDUCATION

The **educational materials** have been carefully developed to provide reliable information and practical support for **diabetes monitoring**. With these resources, you can deepen your knowledge and make informed decisions on your journey to **better health**.

We are committed to improving your daily **quality of life**, which is why we offer tools that provide valuable and up-to-date information.







SAFETY LANCETS

sterile, single-use medical devices designed for capillary blood sampling from the finger.



Intended for healthcare professionals and lay users.* Clinically proven blood sample volumes.1.2.3



Safety lancets are an integral component to the sharps injury prevention programs in hospitals, clinics, Inhoratories, doctor's offices and wherever halfs patients and professionals need to feel safe.





Hi, do you know how to mesure blood sugar? Ok, I'll show you it's very easy!

DIABETES

zones can affect your blood sugar levels. How to make your travels easier?



Before you go





SEE YOUR DOCTOR BEFORE YOU GO

Before your holiday have a medical exam to make sure that your diabetes is under control. Ask your doctor for a prescription and letter with all information about your



PREPARE FOR AN EMERGENCY ABROAD

Prepare list of doctors/places where you can ask someone for help. Always wear "I have diabetes" bracelet or necklace, also learn how to say "I have diabetes" in language of the country you'll visit.



MEDICAL IDS



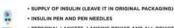
PACKING



Holiday checklist

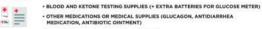










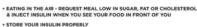


- OTHER MEDICATIONS OR MEDICAL SUPPLIES (GLUCAGON, ANTIDIARRHEA MEDICATION, ANTIBIOTIC OINTMENT)
- · MEDICAL ID AND DIABETES IDENTITY CARD
- COOLER BAG FOR INSULIN AND TEST STRIPS · CANDY OR GLUCOSE TABLETS TO TREAT LOW BLOOD SUGAR
- TREATMENT PLAN (WITH INSULIN DOSES AND CORRECTION FACTORS)
- + HEALTH INSURANCE AND AN EMERGENCY CONTACT PERSON TELEPHONE NUMBER



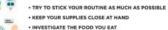
When you get there







CROSSING TIME ZONES - TALK TO YOUR DOCTOR BEFORE YOUR TRIP
 AND PLAN THE TIMING OF INSULIN INJECTION WITH YOUR TRAVEL SCHEDULE





 TEST YOUR BLOOD SUGAR OFTEN · WEAR COMFORTABLE SHOES



* TELL OTHERS THAT YOU HAVE DIABETES Take it easy & have a great holiday!



INCLUDING FINGER PRICKS ROTATION & ALTERNATE SITE TESTIN G

SELF-MONITORING OF BLOOD GLUCOSE









OUR PUBLICATIONS AND RESEARCH^{1,2,3,4,5}

We invest in research and development - always striving to create new solutions for patients and medical personnel, always putting their safety and comfort first.

We focus on people and their needs. We listen to our customers and we respond actively for their necessities and expec-

tations. Our products are created in cooperation with healthcare professionals and patients. We evaluate our portfolio in Focus Groups and Consumer Studies all over the World.

We release a variety of publications reflecting our commitment and knowl-

edge. We want to provide our customers not only with innovative and safe solutions in terms of medical devices but also give them educational support.

All our publications are available on our website in the Learning Hub section.

https://htl-strefa.com/

Journal of Diabetes Science and Technology 1 –8

Evaluation of Three Lancing Devices: What Do Blood Volume and Lancing Pain Depend On?

Beata Mianowska, MD, PhD1, Wojciech Mlynarski, MD, PhD2, Irena Szadkowska, MSc3, and Agnieszka Szadkowska, MD, PhD1

Abstrac

Background: Globally millions of people with diabetes still prick their fingers to measure blood glucose. The aim of this study was to comprehensively evaluate and to compare three lancing devices set at the minimum ("1") and at the maximum ("5") lancing depth with respect to blood volume (BV) and pain related to lancing.

Methods: Lancing devices tested were A—Glucoject Dual PLUS, B—droplet (both: HTL-Strefa S.A., Poland), and C—Microlet Next... Switzerland), all used with personal lancets of three sizes 28G, 30G, and 33G. BVs were measured with calibrated capillaries. Pain related to lancing was expressed as a derivative of pain rating with visual analog scale.





DIABETES PANDEMIC

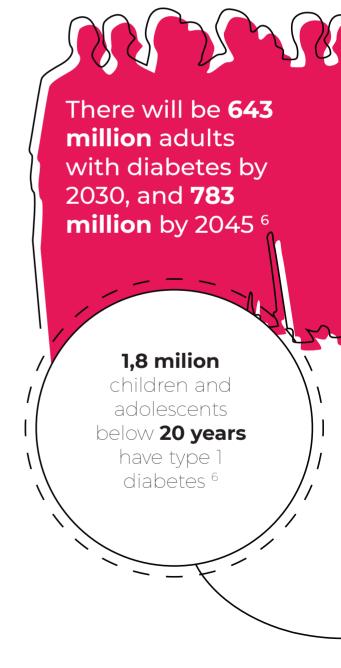
Diabetes is a **global epidemic** affecting as estimated **589 million people worldwide**. According to "Global status report on noncommunicable diseases 2010", published by World Health Organization, diabetes will be the 6th leading cause of death by 2030. An estimated **6,7 million** people die from diabetes complications in 2021.6

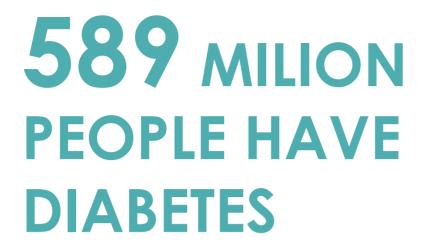
Why is diabetes such a dangerous disease?

It is a chronic disease occurring when the body's pancreas does not produce enough insulin or when the body cannot effectively use the insulin produced. Diabetes can cause chronic complications.⁷

Diabetes complications: 7

- Diabetic cardiomyopathy, damage to the heart, leading to diastolic dysfunction and eventually heart failure.
- Diabetic nephropathy, damage to the kidney which can lead to chronic renal failure, eventually requiring dialysis.
- Diabetic neuropathy, abnormal and decreased sensation which combined with damaged blood vessels can lead to diabetic foot sometimes requiring amputation.
- Diabetic retinopathy, severe vision loss or blindness.





People with **type 2** diabetes can remain undiagnosed for many years, unaware of the

LONG-TERM DAMAGE

being caused by the disease ⁶

The number of people with **type 2** diabetes is increasing in every country ⁶

almost 252 milion

people with diabetes are undiagnosed ⁶ People with

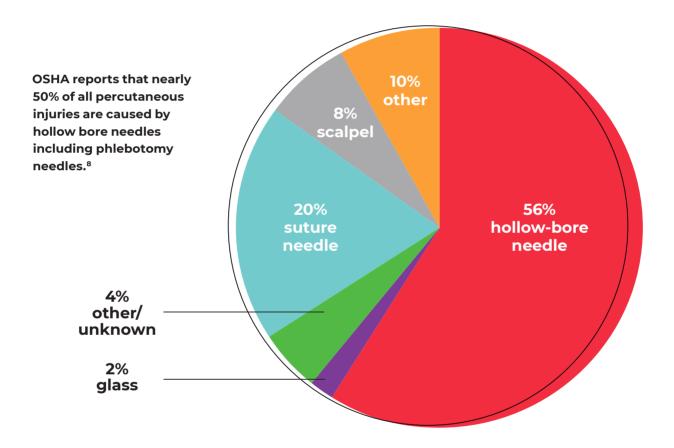
type I diabetes

will die without

insulin

SHARPS INJURY PREVENTION

Sharps injury is defined as: an incident, which causes a needle, blade (such as scalpel) or other medical instruments to penetrate the skin. This is sometimes called a percutaneous injury.



HEPATITIS B

(chances of infection from a contaminated sharps injury):

1 in 5 (if you're not vaccinated)

HEPATITIS C

(chances of infection from a contaminated sharps injury):

1 in 50

HIV

(chances of infection from a contaminated sharps injury)

= 1 in 300



Reduction in the number of sharps injuries and infection prevention has been successfully achieved in regions that implement: 9,10

- · Safe sharps handling and disposal programs
- · Immunization of health care workers
- · Use of **safety products** like safety lancets
- Post exposure prophylaxis (PEP)

Sometimes, the smallest pieces of equipment offer **the greatest protection** for both patients and health care providers.

HTL-STREFA is committed to manufacturing safety products designed to reduce or eliminate the risk of exposure to blood borne pathogens. We are the leading manufacturer of sterile single-use, safety lancets.

Our unique design features are:

- Dual-spring design to ensure complete needle retraction
- Full housing to prevent needle exposure before and after activation
- Auto-disabling mechanisms to prevent lancet re-use

SAFETY LANCETS

Safety lancets are sterile, single-use medical device intended for the capillary blood sampling. Depending on the safety lancets type intended users are healthcare professionals (Medlance® Plus; ergoLance®; Acti-Lance®; Heamolance® Plus; MediSafe® Solo; Medlance®) and lay users (Acti-Lance®; ergoLance®).

They are an integral component to the sharps-injury prevention programs in hospitals, clinics, laboratories, doctor's offices and wherever both patients and professionals need to feel safe. By using safety lancets needle-stick injuries and infections can be minimized.¹⁰

* Clinically proven safety lancets of HTL-STREFA are available in a different versions to meet specific blood sample needs and address the variety of patients' skin types.^{1,3}



Key features for HTL-STREFA safety lancets:

Safe

- All needles are sterilized using irradiation and protected with protective cap
- Fully enclosed needle housing ensuring that needle is hidden before and after use to prevent sharps injuries
- Self-destructing mechanism preventing reuse of the device

Comfortable:

- Silicone-coated, ultra-sharp needles, ideally positioned during skin penetration
- Various, color-coded product versions to meet specific blood sample applications and address the variety of patient skin types
- Wide range of designs providing simple, comfortable and secure puncture



Simple: 11, 12

- Easy to handle, intuitive activation in 2 steps only with no pre-loading, for both push button and contact activations
- Wide and long safety cap for easy removal – simply twist and pull to remove the needle cover
- Precise designs for convenient finger positioning and ideal blood sample collection

MEDLANCE® PLUS

USERS:



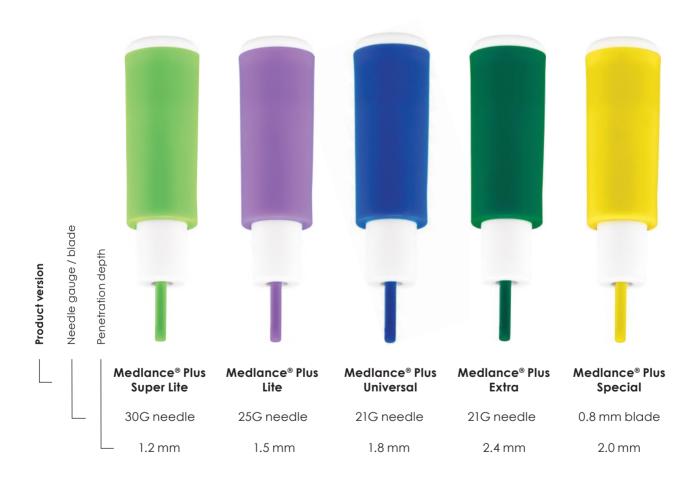




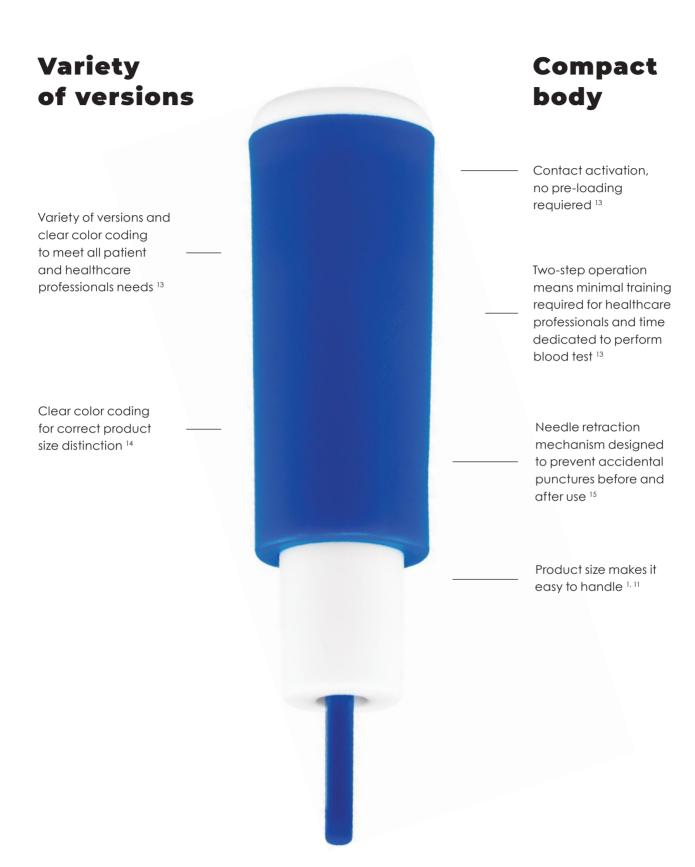
PRODUCT INTENDED USE

Medlance® Plus safety lancets are sterile, single-use medical devices intended for capillary blood sampling. Intended users are healthcare professionals.

AVAILABLE IN FIVE VERSIONS:



KEY FEATURES



ERGOLANCE®

USERS:











PRODUCT INTENDED USE

ergoLance® safety lancets are sterile, single-use medical devices intended for capillary blood sampling.

Intended users are healthcare professionals and lay users.

AVAILABLE IN THREE VERSIONS:



KEY FEATURES



ACTI-LANCE®

USERS:











PRODUCT INTENDED USE

Acti-Lance® safety lancets are sterile, single-use medical devices intended for capillary blood sampling. Intended users are healthcare professionals and lay users.

AVAILABLE IN THREE VERSIONS:



KEY FEATURES

Safety **Comfort** Comfortable finger surface for push-button activation 19 T-shape for firm and intuitive grip 11, 12 Fully enclosed needle housing to prevent sharps injuries 12, 19, 20 Wide lancet end enables precise and convenient positioning on the test site 11, 12 Long protective cap for easy removal 11, 19, 20 Protective cap ensures needle safety 19, 20

HAEMOLANCE® PLUS

USERS:



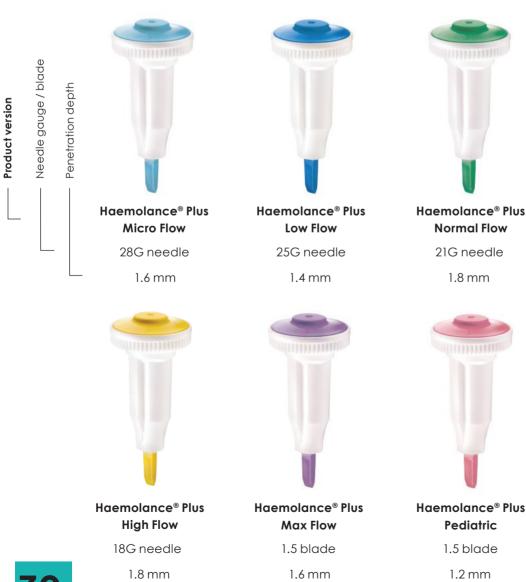




PRODUCT INTENDED USE

Haemolance® Plus safety lancets are sterile, single-use medical devices intended for capillary blood sampling. Intended users are healthcare professionals.

AVAILABLE IN SIX VERSIONS:

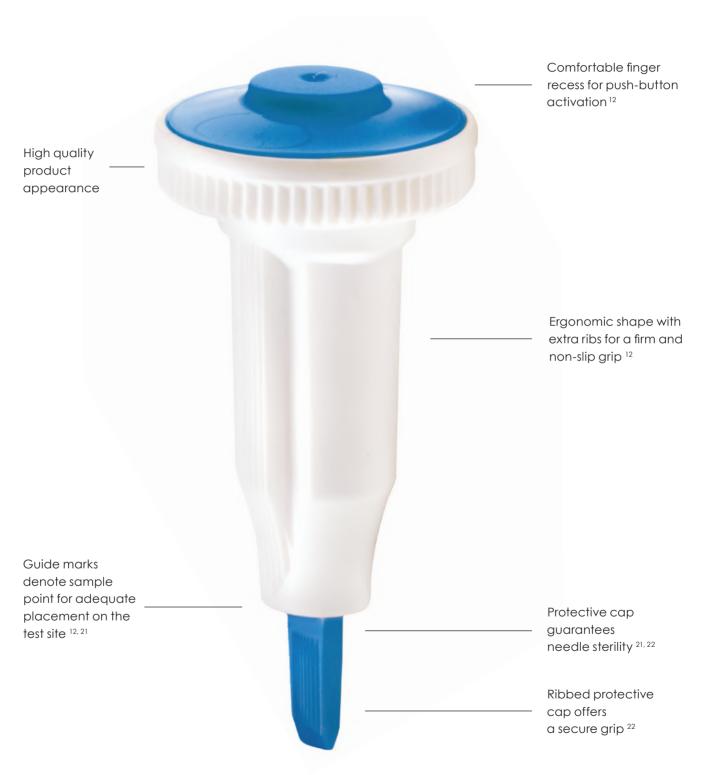


30

KEY FEATURES

Quality

Handy design



MEDISAFE® SOLO

USERS:



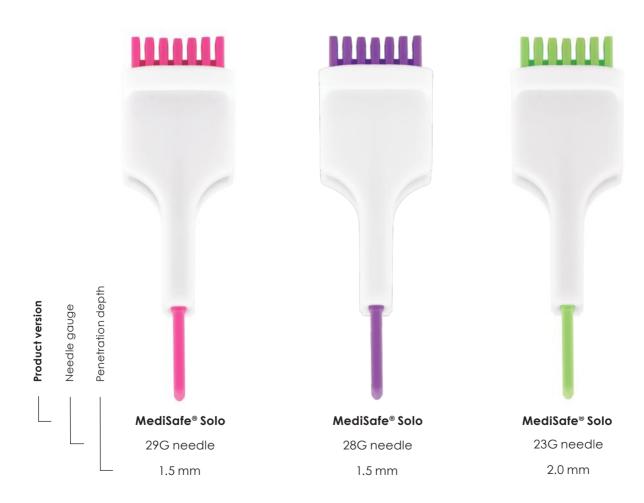




PRODUCT INTENDED USE

MediSafe® Solo safety lancets are sterile, single-use medical devices intended for capillary blood sampling. Intended users are healthcare professionals.

AVAILABLE IN THREE VERSIONS:



KEY FEATURES



DROPLET® PEN NEEDLES

USERS:





PRODUCT INTENDED USE

are sterile, single use medical devices intended for use with pen injector devices for the subcutaneous injection of drugs by healthcare professionals and lay users. droplet® pen needles are compatible with most insulin pens available on the market:

www.htl-strefa.com

AVAILABLE IN NINE VERSIONS:





droplet® pen needle 29G needle 12 mm



droplet® pen needle 31G needle 5 mm



droplet® pen needle 31G needle 6 mm



pen needle
31G needle
8 mm

droplet®



droplet® pen needle 32G needle

4 mm



droplet® pen needle 32G needle 5 mm



droplet®
pen needle
32G needle
6 mm



droplet®
pen needle
32G needle
8 mm



droplet® pen needle*

34G needle

3.5 mm

KEY FEATURES

Our pen needles proactively address: 30

- easy adjustment
- greater convenience
- quick and comfortable use



Outer cap shape with ribs to remove the protective cap 31



DROPSAFE® SAFETY PEN NEEDLES

USERS:







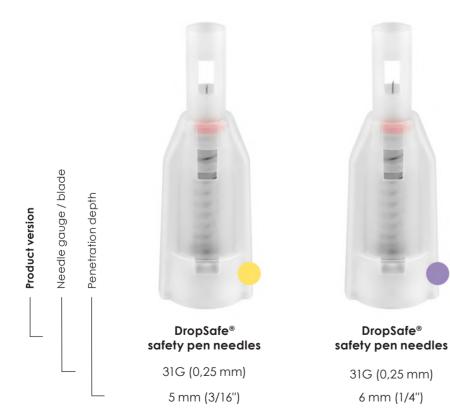


PRODUCT INTENDED USE

DropSafe® safety pen needles are sterile, single-use safety needles intended for use with pen injector devices for the injection of drugs. **DropSafe®** safety pen needles can be used by healthcare professional users and lay users.

DropSafe® safety pen needle work with most pen injectors available on the market: www.htl-strefa.com

AVAILABLE IN THREE VERSIONS:





DropSafe® safety pen needles

31G (0,25 mm) 8 mm (5/6'')

KEY FEATURES



Safety before and after injection

Needle safely contained behind shield, preventing accidental exposure

Lock-out confirmation

Red stripe appears when the needle is used and locked out

Ease of use

DropSafe® safety pen needles work with most pen injectors available on the market ³⁶

Just screw it on the pen, inject and dispose.

Comfort

Special and unique
"in-house" lubrication
method – DROPLICON™
designed for smooth
injection 33

Hidden needle

The needle remains hidden from the view, which may increase patient comfort 33

Accuracy

Needle viewing window

For easy confirmation of drug flow (priming) 34

Thin wall (31G) may allow an easier and faster injection of the drug.³⁵

DROPLET® PERSONAL LANCETS

USERS:





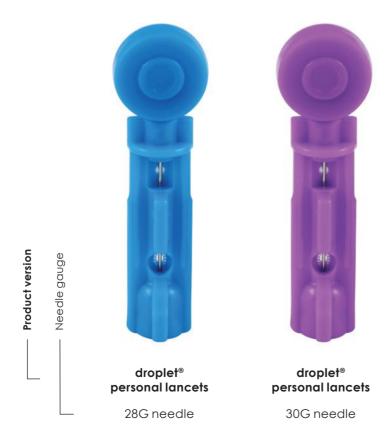


PRODUCT INTENDED USE

droplet® personal lancets are sterile, single-use medical devices intended to be used with a lancing device by lay users for capillary blood sampling.

droplet® personal lancets are recommended to be used with droplet lancing device, however they are compatible with the majority of lancing devices available on the market. See the compatibility statement for more information - **www.htl-strefa.com**

AVAILABLE IN TWO VERSIONS:



KEY FEATURES



DROPLET® LANCING DEVICE

USERS:









PRODUCT INTENDED USE

droplet® lancing device is a medical device for multiple use with sterile, single-use lancets intended for capillary blood sampling by a lay person.

KEY FEATURES

Personalized

5 levels of skin penetration for individual user's comfort ³⁹



Additional transparent cap for AST (Alternate Site Testing) ³⁹



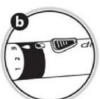


Safe

Specially designed ejection system to remove used lancets ³⁹







Visible difference between loaded (a) and unloaded (b) lancing device 39



ALL PRODUCTS

SAFETY LANCETS

		Type	Product version	Needle gauge / blade	Penetration depth		
	* INTENDED USERS: HEALTH CARE PROFESSIONALS & LAY USERS						
ERGOLANCE®		contact activation contact activation contact activation	Micro Flow Normal Flow High Flow	30G needle 25G needle 21G needle	1.5 mm 1.8 mm 2.0 mm		
ACTI-LANCE®	- 1	push button push button push button	Lite Universal Special	28G needle 23G needle 17G blade	1.5 mm 1.8 mm 2.0 mm		
	* INTENDED USERS: HEALTH CARE PROFESSIONALS						
MEDLANCE® PLUS		contact activation contact activation contact activation contact activation contact activation	Super Lite Lite Universal Extra Special	30G needle 25G needle 21G needle 21G needle 0.8 mm blade	1.2 mm 1.5 mm 1.8 mm 2.4 mm 2.0 mm		
HAEMOLANCE® PLUS		push button push button push button push button push button push button	Micro Flow Low Flow Normal Flow High Flow Max Flow Paediatric	28G needle 25G needle 21G needle 18G needle 1.5 blade	1.6 mm 1.4 mm 1.8 mm 1.8 mm 1.6 mm 1.2 mm		
MEDISAFE® SOLO		push button push button push button	MediSafe Solo® MediSafe Solo® MediSafe Solo®	29G needle 28G needle 23G needle	1.5 mm 1.5 mm 2.0 mm		

^{*} Some types of the safety lancets have different intended users.

* INTENDED USERS: LAY USERS

DROPLET® PEN NEEDLES

-	droplet® pen needle	29G needle	12 mm
	droplet® pen needle	31G needle	5 mm
-	droplet® pen needle	31G needle	6 mm
	droplet® pen needle	31G needle	8 mm
	droplet® pen needle	32G needle	4 mm
-	droplet® pen needle	32G needle	5 mm
	droplet® pen needle	32G needle	6 mm
	droplet® pen needle	32G needle	8 mm
	droplet® pen needle	34G needle	3.5 mm

* INTENDED USERS: HEALTH CARE PROFESSIONALS & LAY USERS

DROPSAFE® SAFETY PEN NEEDLES

• 6		DropSafe® safety pen needles	31G needle	5 mm
• 6	- HT-	DropSafe® safety pen needles	31G needle	6 mm
• 6	district and	DropSafe® safety pen needles	31G needle	8 mm

* INTENDED USERS: LAY USERS

DROPLET® PERSONAL LANCETS

droplet® personal lancet

28G needle

droplet® personal lancet

30G needle

* INTENDED USERS: LAY USERS

DROPLET® LANCING DEVICE



Available with additional AST cap

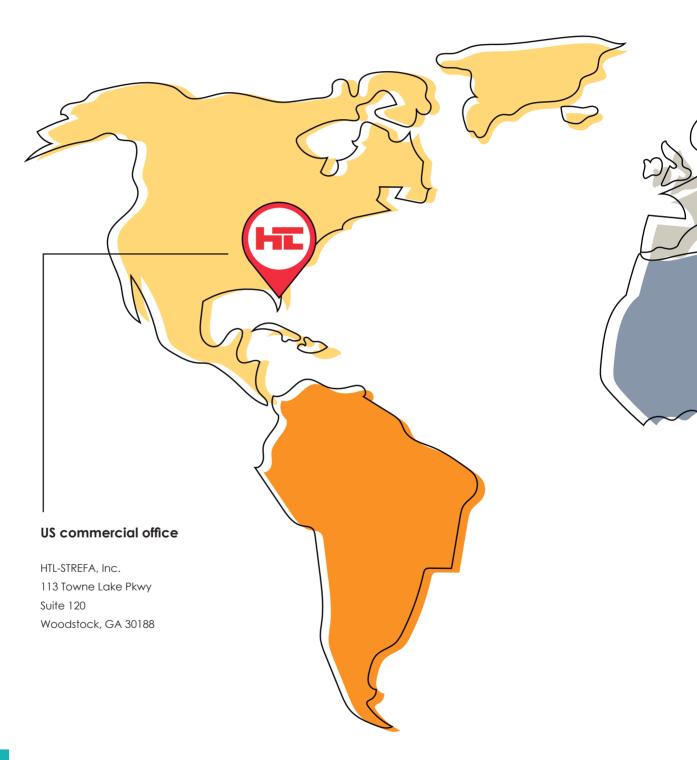
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