

Product Portfolio & Company Information



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Over

20

years of
experience

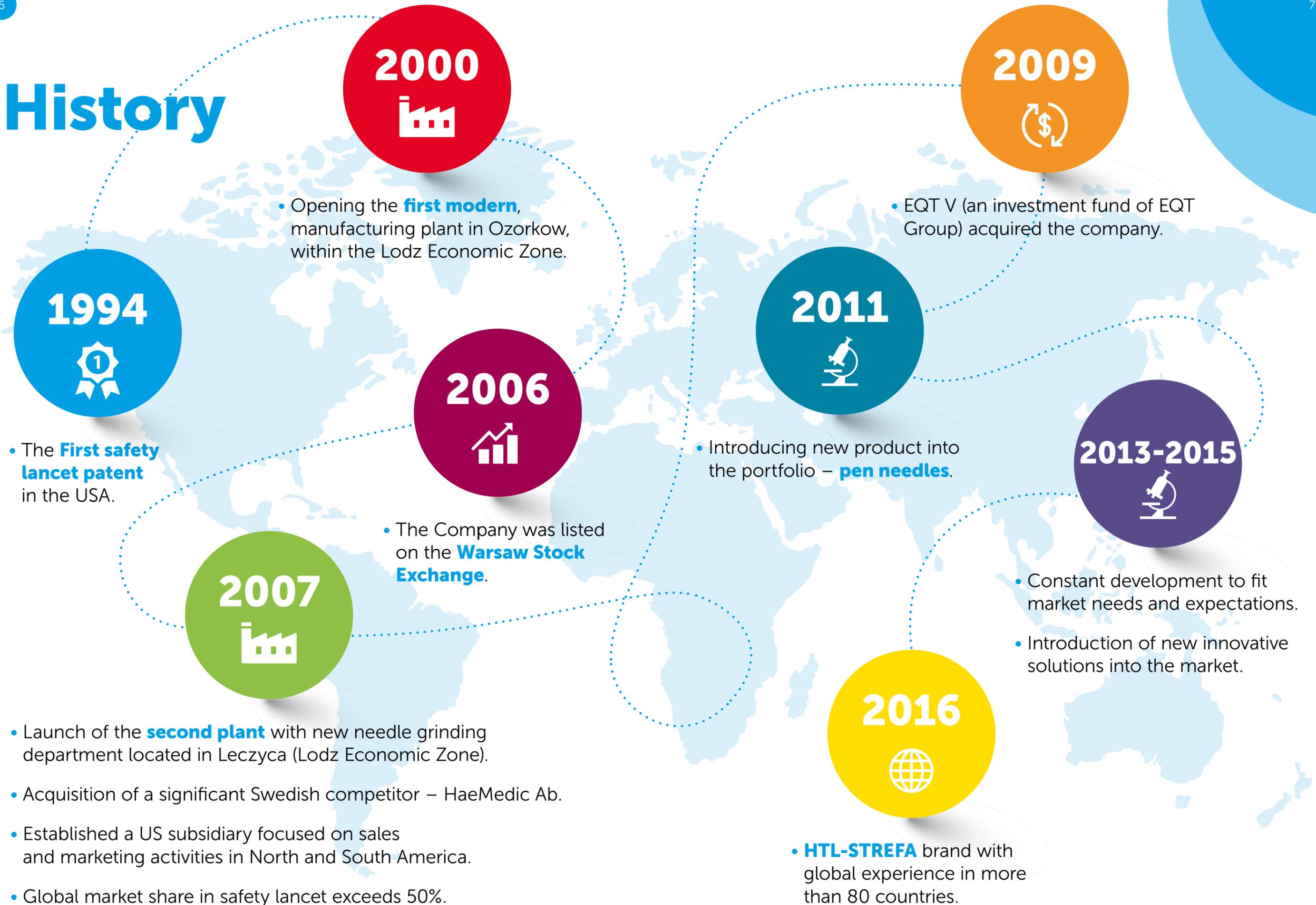
Company profile

HTL-STREFA S.A. (HTL-STREFA) is a world-leading medical device company that develops, manufactures and sells safety lancets, personal lancets, lancing devices, pen needles and safety pen needles. Our modern manufacturing process and 20 years of experience in the global market allows us to successfully ensure top quality, safety, convenience and reliability.

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



Production

At the moment, HTL-STREFA has two modern production facilities in Poland (Lodz Special Economic Zone), and a sales and marketing office located in Warsaw, Poland. HTL-STREFA, Inc. a distribution facility in Marietta, Georgia 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.

2

two modern
production
facilities





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.



5

Categories of products with different versions



Close to **10 million** products shipped every day

12

Experienced in-house R&D Team has developed **12 new** products over the past 3 years **3 new** products in 2015

55

Growing portfolio with more than **55 patents**

60

Around 60 products in portfolio

20

years of experience

2

2 sales and marketing offices in Poland (Warsaw) and in USA (Marietta/GA), ensuring excellent customer service for more than **500 customers** around the globe.



High-tech production facilities located in **Lodz** Special Economic Zone (Poland) with more than **1.200 highly qualified employees**

Market

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 has maintained and improved the quality management system in accordance with the requirements of **EN ISO 13485:2012**, **CAN /ISO 13485:2003**. All our products are CE marked. We also comply with the regulations of FDA 21 CFR, Part 820, Part 806, Part 803, Part 11.

We are **DEKRA** certified (<http://www.dekra-certification.com>) in compliance with MDD 93/42/EEC as amended in 2007 (2007/47/EC).

HTL-STREFA products are sold in over 80 countries.

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 quality certifications:

- EN ISO 13485:2012,
- CAN/CSA ISO 13485:2003,
- EC certificate for all products.



Sustainable Development Policy



HTL-STREFA by promoting unique and effective solutions related to public health, focuses on business development considering the values of social, ethical and environmental responsibility.

HTL-STREFA develops its products in a responsible and sustainable way.

Sustainable development is an integral part of our activity – now and in the future. By supplying patients and healthcare professionals with innovative products, **HTL-STREFA** contributes to the protection of life and health.

We are aware that success of a company depends on the condition of the surroundings in which it operates, thus we aspire to maintain balance with regard to three goals: business, community, and the environment.



3

Three goals:
business, community,
and the environment



1



2



4



3

Corporate Social Responsibility

HTL-STREFA has been involved in supporting the health service sector for many years. We strongly believe in social responsibility to the communities in which we live and work and to the environment around us. We are committed to corporate social responsibility (CSR) and we encourage all our employees to support HTL-STREFA CSR initiatives.

1. Polish Nationwide Project "Ciuch W Ruch"
2. HTL-STREFA In The 37th Warsaw Marathon
3. "Szlachetna Paczka" – The Noble Box Project
4. World Hepatitis Day

We Care™

We Care™ is HTL-STREFA contribution to simplify the prevention, diagnosis and treatment of diseases.

PREVENTION

Single use lancets and needles protect humans from infection by preventing the transmission of blood borne pathogens.

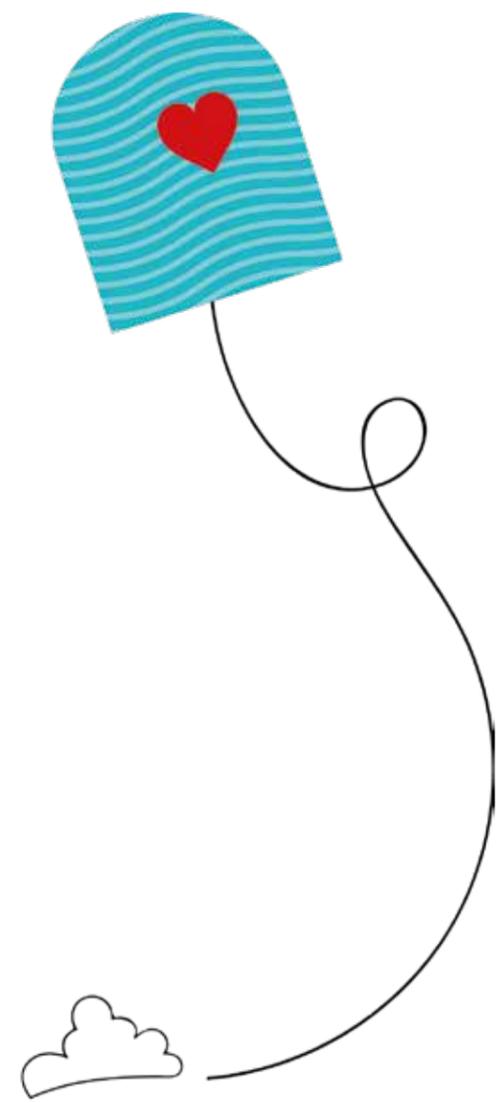
DIAGNOSIS

Safety lancets in a range of sizes allow quick sample collection while ensuring maximum patient comfort.

TREATMENT

Personal lancets allow diabetics to easily monitor blood levels; pen needles and safety pen needles are dedicated for injectable drug delivery.

It is our job to be always one step ahead, to think innovative, to give our customers the best possible solutions. We demand perfection from ourselves and from our products. Caring is what we do and what defines all our actions, because our customers satisfaction is our mission.



WE CARE™

 PREVENTION  DIAGNOSIS  TREATMENT



Products

SAFETY LANCETS

Medlance®	27
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ergoLance®	29
Acti-Lance®	30
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PEN NEEDLES

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SAFETY PEN NEEDLES

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LANCING DEVICE

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Safety Lancets

SAFETY LANCETS are single-use devices for capillary blood sampling dedicated to healthcare professionals. 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.

While exposure to bloodborne pathogens is one of the most deadly hazards that nurses face on a daily basis, it is also one of the most preventable. Over 80% of needlestick injuries can be prevented with the use of safer needle devices (CDC, 1997), which, in conjunction with worker education and work practice controls, can reduce injuries by over 90% (Jagger, 1996)*



Medlance®
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Medlance Plus®
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ergoLance®
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Acti-Lance®
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Prolance®
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MediSafe Solo®
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*Source:
http://www.who.int/occupational_health/activities/1anaism.pdf
<http://www.cdc.gov/niosh/stopsticks/safersharpdevices.html>

Key features for HTL-STREFA safety lancets:

Safe:

- All needles are gamma-sterilized and protected with a safety cap
- Fully enclosed needle housing ensuring that the needle is hidden before and after use to prevent sharps injuries
- Auto-disabling 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:

- 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 safety cap
- Precise designs for convenient finger positioning and ideal blood sample collection



Safety Lancets

Contact activated safety lancets:

Contact activated safety lancets have a unique design solution, which enables lancet activation by simply pushing the lancet on the finger.

- Medlance Plus®
- ergoLance®

Push-button activated safety lancets:

Push button activated safety lancets offer unique design solution, which enables the lancets activation by simply pressing the activation button on the top of the device.

- Medlance®
- Acti-Lance®
- Prolance®
- Haemolance Plus®
- MediSafe Solo®

Intuitive Handling and Smooth Activation

Medlance®



Key features:

- T-shape body provides a stable grip within the hand.
- Easy and smooth activation. Simple and intuitive push-button activation allows easy operation.
- Lightweight lancet with ideal body dimensions.
- Optimum contact area for accurate placement on the puncture site.

	NAME	GAUGE	PENETRATION DEPTH
	Medlance®	21G needle	1.8 mm
	Medlance®	21G needle	2.4 mm
	Medlance®	1.5 mm blade	1.0 mm
	Medlance®	1.5 mm blade	1.5 mm
	Medlance®	1.5 mm blade	2.0 mm

*Wide-Range,
Closed Compact
Body*

Medlance Plus[®]



Key features:

- Contact activation, no pre-loading required
- Closed compact body design, helps prevent accidental punctures before and after use
- Double spring mechanism to eliminate needle vibrations
- Reliable safety cap completely covers the needle
- Product size makes it easy to handle
- Largest variety of versions available to meet all patient and health care professionals needs

	NAME	GAUGE	PENETRATION DEPTH
	Medlance Plus[®] SuperLite	30G needle	1.2 mm
	Medlance Plus[®] Lite	25G needle	1.5 mm
	Medlance Plus[®] Universal	21G needle	1.8 mm
	Medlance Plus[®] Extra	21G needle	2.4 mm
	Medlance Plus[®] Special	0.8 mm blade	2.0 mm

ergoLance[®]



Key features:

- Concave housing for comfortable finger recess maximizes ergonomics of a contact activated lancet
- Precise placement on the test site is guaranteed by visual guiding and transparent shield
- Special shield distracts attention from the needle stick
- Ribbed safety cap guarantees needle sterility and gives a secure grip for easy twist-off removal

*Ergonomics
and
Precision*

	NAME	GAUGE	PENETRATION DEPTH
	ergoLance[®] Micro Flow	30G needle	1.5 mm
	ergoLance[®] Normal Flow	25G needle	1.8 mm
	ergoLance[®] High Flow	21G needle	2.0 mm

Acti-Lance®

Key features:

- Comfortable finger recess for push-button activation
- T-shape for firm and intuitive grip
- Wide lancet end enables a secure and precise positioning on the test site

*Comfort
and Security*

	NAME	GAUGE	PENETRATION DEPTH
	Acti-Lance® Lite	28G needle	1.5 mm
	Acti-Lance® Universal	23G needle	1.8 mm
	Acti-Lance® Special	1.5 mm blade (17G)	2.0 mm



Prolance®

Key features:

- Comfortable finger recess for push-button activation
- Ergonomic t-shape with extra ribs for a firm grip
- Transparent lancet body enables to see the spring action for ensured puncture
- Ribbed safety tab guarantees needle sterility and gives a secure grip for easy twist-off removal
- Wide range of sizes to meet different user and diagnostic needs

*Transparency
and Accuracy*



	NAME	GAUGE	PENETRATION DEPTH
	Prolance® Micro Flow	28G needle	1.6 mm
	Prolance® Low Flow	25G needle	1.4 mm
	Prolance® Normal Flow	21G needle	1.8 mm
	Prolance® High Flow	18G needle	1.8 mm
	Prolance® Max Flow	1.5 mm blade	1.6 mm
	Prolance® paediatric	1.5 mm blade	1.2 mm

*Premium Product,
Handy Rounded
Shape*



Haemolance Plus[®]

Key features:

- Comfortable finger recess for push-button activation
- Ergonomic rounded shape with extra ribs for a firm and non-slip grip
- Guide marks denote sample point for adequate placement on the test site
- Ribbed safety tab guarantees needle sterility and gives a secure grip for easy twist-off removal
- Premium materials and product appearance
- Widest product range – 6 different sizes

	NAME	GAUGE	PENETRATION DEPTH
	Haemolance Plus[®] Micro Flow	28G needle	1.6 mm
	Haemolance Plus[®] Low Flow	25G needle	1.4 mm
	Haemolance Plus[®] Normal Flow	21G needle	1.8 mm
	Haemolance Plus[®] High Flow	18G needle	1.8 mm
	Haemolance Plus[®] Max Flow	1.5 mm blade	1.6 mm
	Haemolance Plus[®] paediatric	1.5 mm blade	1.2 mm

MediSafe Solo[®]



Key features:

- Flattened push-button activation with extra ribs for comfortable finger recess
- Ergonomic shape with extra side wings for a firm grip
- Extended safety tab guarantees needle sterility and gives a secure grip for easy twist off removal

*Economy,
Lite and Simple*

	NAME	GAUGE	PENETRATION DEPTH
	MediSafe Solo[®]	29G needle	1.5 mm
	MediSafe Solo[®]	23G needle	2.0 mm

Droplet[®] Pen Needles

DROPLET[®] PEN NEEDLES are sterile, single use needles intended for use with pen injector device for the subcutaneous injection of insulin. Pen needles are used by consumers, caregivers and healthcare professionals.

HTL-STREFA pen needles are designed for the safety and convenience of people with diabetes!

Droplet[®] Pen Needles:

	NAME	GAUGE	PENETRATION DEPTH
	Droplet[®] pen needles	32G needle	4 mm
	Droplet[®] pen needles	32G needle	5 mm
	Droplet[®] pen needles	32G needle	6 mm
	Droplet[®] pen needles	32G needle	8 mm
	Droplet[®] pen needles	31G needle	5 mm
	Droplet[®] pen needles	31G needle	6 mm
	Droplet[®] pen needles	31G needle	8 mm
	Droplet[®] pen needles	29G needle	10 mm
	Droplet[®] pen needles	29G needle	12 mm

Key features:

- Simple:**
 - Simple as walking. Just change Droplet[®] pen needles after each injection.
 - Easy adjustable. Droplet[®] pen needles fit all major injector brands.
 - Easy to learn. Easy to educate everyone at every age.
 - Just twist, inject and dispose.
- Soft:**
 - Unique "in-house" lubrication method - DROPLICON[™] makes insulin injection smooth.
 - Accurate silicon coating provides gentle injection – needles are fully covered, no lumps.
 - Precise 3-bevel grinding ensures soft and gentle injection.
- Smart:**
 - Fast and accurate insulin delivery, thanks to thin wall, to meet your treatment requirements.
 - Thread design to prevent insulin leaking.
 - Wide range of pen needle sizes to meet your individual expectations.

Viewing window
and Needle
Locking System



DropSafe® Safety Pen Needles

DROPSAFE® SAFETY PEN NEEDLES are sterile, single use needles intended for use with pen injector devices for the injection of drugs. Safety pen needles are intended for professional health care users and non-clinical pen users.

DropSafe® Safety Pen Needles:

	NAME	GAUGE	PENETRATION DEPTH
	DropSafe® safety pen needles	31G needle	6 mm
	DropSafe® safety pen needles	31G needle	8 mm

Key features:

Safe:

- 100% safety. Protective sliding shield surrounds the needle at all times preventing accidental needlestick.
- Lock-out confirmation. Red stripe appears when needle is locked out.
- Needle locking system. Needle is automatically blocked after use.

Simple:

- Easy adjustment. DropSafe® safety pen needles, work with most of the available pen injectors on the market.
- Intuitive use. Just twist on, inject and dispose.
- Personalized Size. Two most popular needle sizes for patients comfort.

Soft:

- Gentle touch. Stable sliding shield surface may diffuse and may reduce pressure on the injection site.
- Comfort in use. Special and unique „in house“ lubrication method - Droplicon™ may guarantee smoother and less painful injection.
- Hidden Needle. The needle remains hidden from view, which can increase patient comfort.

Smart:

- Needle viewing window. An exclusive window for easy confirmation of insulin flow (priming).
- Exceptional quality. Thin wall ensures smooth injection of insulin (or other medication).
- Ergonomy. DropSafe® safety pen needles, design features with a wing shape for comfortable, secure grip.

Droplet[®] Personal Lancets

*Gentle
and
Sharp*



DROPLET PERSONAL LANCETS are sterile, single use devices intended to be used by non-clinical users to perform finger stick punctures for the purpose of collecting capillary blood sample. The lancets are usually included in kits for diabetics together with a lancing device and a glucometer.

Key features:

Comfort:

- Electro-polished, silicone coated needle ensures smooth penetration with reduced patient discomfort
- Tri-beveled needle tip guarantees superior sharpness providing an adequate blood sample
- Three gauges for individual comfort of the patient

Safety:

- Droplet personal lancets are sterilized with Gamma radiation
- Needles are protected by the safety cap
- All personal lancets are single-use to prevent infection

Universal:

- Droplet[®] personal lancets are designed for use with the Droplet[®] lancing devices, the Droplet[®] personal lancet housing is universal and can be used with the most popular lancing devices
- Recommended for patients with different skin types

	NAME	GAUGE
	Droplet[®] personal lancets	28G needle
	Droplet[®] personal lancets	30G needle
	Droplet[®] personal lancets	33G needle

Droplet[®] Lancing Device

*Smooth
and
Stable*



DROPLET LANCING DEVICES are reusable medical devices for use by a single user with sterile, single use lancets in order to collect capillary blood samples from the fingertip or alternate site for self-testing of blood glucose. Lancing devices are dedicated for home use. The lancing devices are usually included in kits for diabetics together with sterile personal lancets and a glucometer. The personal lancets to be used with a lancing device are not intended for multiple uses by a single person.

Key features:

Safe:

- Smooth and precise puncture with no vibration
- Specially designed ejection system to remove used lancets

Universal:

- Applicable with most popular lancets
- Additional transparent cap for AST (Alternative Site Testing)

Personalized:

- Adjustable cap offers 5 levels of skin penetration for individual user's comfort
- Specially profiled non-slip grip for comfortable handling
- Clear visual indications on the device

Diabetes Pandemic

Diabetes is a global epidemic affecting an estimated **415 million people worldwide**. The WHO projects that diabetes will be the **7th leading cause of death by 2030**. An estimated 4 million people die annually from diabetes complications.

Why is diabetes such a dangerous disease? Diabetes is one of the most common non-communicable diseases. 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:

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

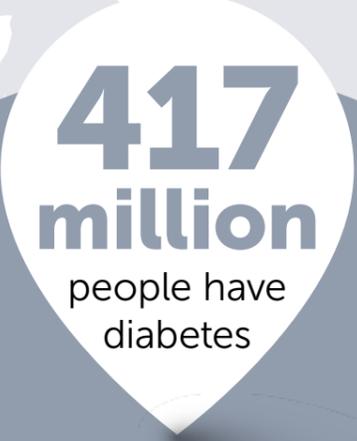
Who is affected by diabetes? This disease affects all ages, genders and races. In 2015, 415 million adults had diabetes. By 2045 this number will rise to 629 million. Every 6 seconds a person dies from diabetes (5.0 million deaths).*

Daily impact: Dietary restrictions, physical activity, blood glucose testing, regular self-injections of insulin and even insulin pumps can be required for disease management.



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

People with type 2 diabetes can remain undiagnosed for many years, unaware of the long-term damage being caused by the disease.



By **2045** this number will rise to **629** million.

Majority of people with diabetes are between **40** and **59** years of age.

212 million people with diabetes are undiagnosed.



People with **type 1 diabetes** will die without insulin.

* 2017 Diabetes Atlas IDF 8th edition

Sharps Injury Prevention

The World Health Organization estimates that there are over **35 million health care workers** globally. These workers face **an increased risk of infection** from blood-borne pathogens simply because of their exposure to blood and other bodily fluids. This risk increases substantially for the tens of thousands of health care workers who experience a **sharps-related injury**. These injuries are associated with the **highest risk of disease transmission**. Globally, the sharps injury rates vary dramatically—between 0.2 and 4.7 sharps injuries per year. At the same time, there is a stark difference in infections rates attributable to sharps injuries based on location in a developed or undeveloped country.

Regions where programs have been put in place to reduce and treat sharps injuries have successfully reduced both exposure rates and infections rates, protecting their health care workers.

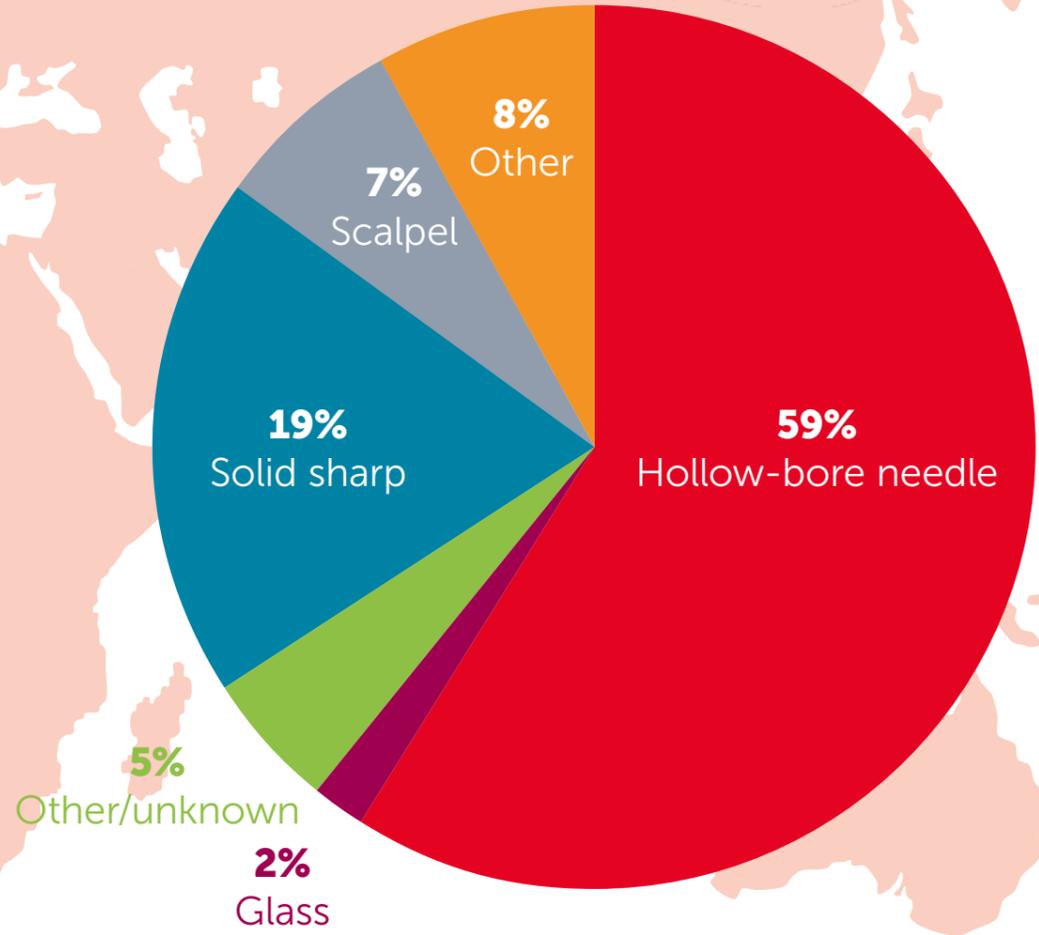
Prevention: Reduction in the number of sharps injuries and infection prevention has been successfully achieved in regions that implement:

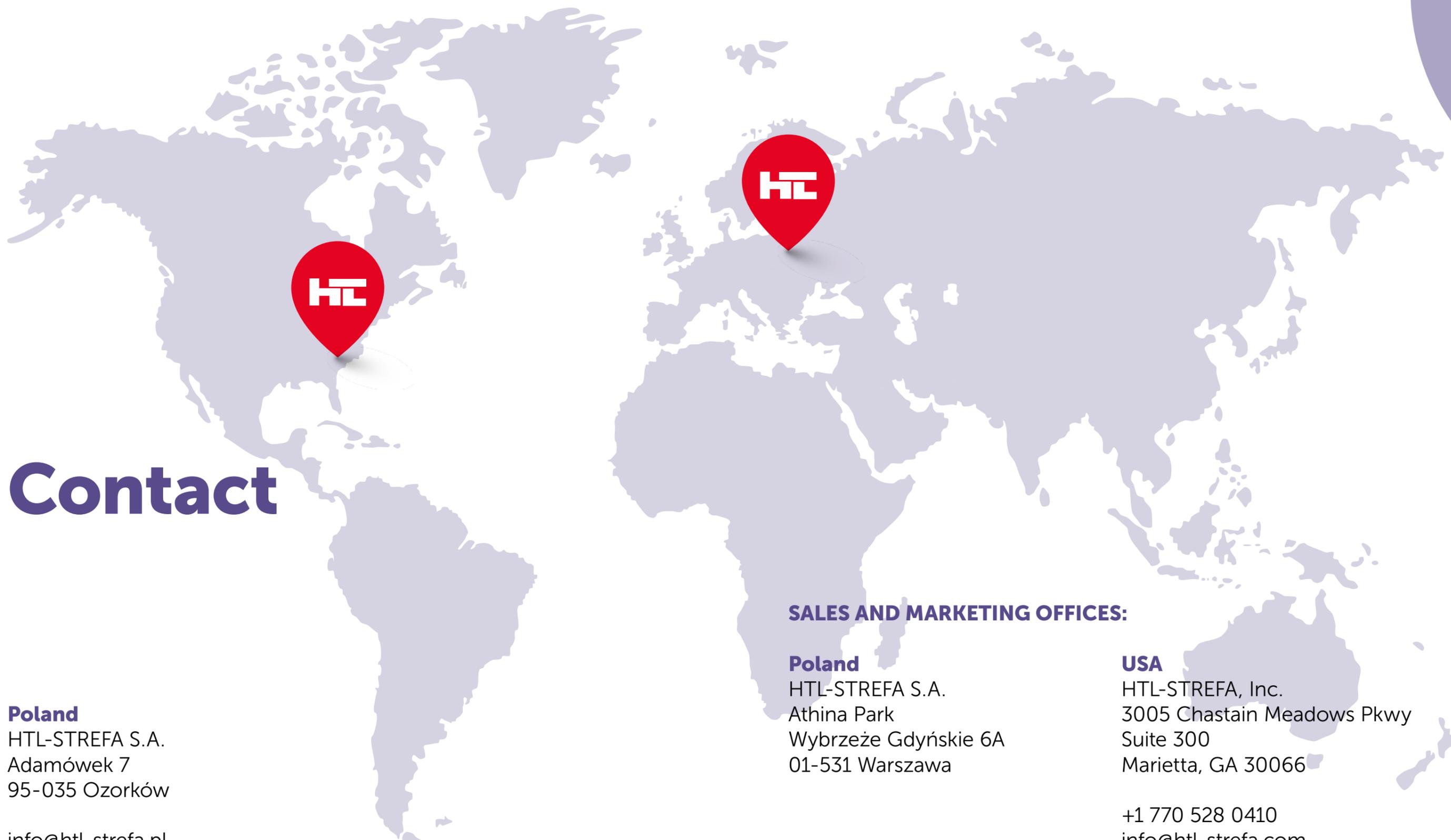
- Safe sharps handling and disposal programs
- Immunization of health care workers
- Use of safety products like safety lancets
- Post exposure prophylaxis (PEP)

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 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

Devices involved in percutaneous injuries:





Contact

Poland

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