

Safe-T-Lance® Plus Safety Lancet

Technical Summary Sheet

DEVICE CLASSIFICATION

Medical Device Directive
Conformity Route: 93/42/EEC II
MDD Classification: Rule VI

GMDN

Code Number: 37466
Term: Blood Lancet, single-use

CE MARK

DEKRA CE 0344

CANADA

License Number: 65385
Classification: Class II

DEVICE OVERVIEW

The Safe-T-Lance Plus® push-button activated lancets are sterile, single-use safety lancets used to perform finger pricks on adults and children in order to collect micro samples of capillary blood.

INDICATIONS*

The Safe-T-Lance® Plus Safety Lancet is intended to carry out skin punctures, collecting capillary blood samples.

PRECAUTIONS*

Follow the standard infection control procedures as specified by the CDC and OSHA standards (USA) or local equivalent. Do not reuse.

*Note: Please refer to the Instructions for Use provided with the device for a full listing of the Indications and the Precautions.

DEVICE COMPONENTS

Needle/Blade: Stainless Steel AISI (302, 304, 316)

Housing: Polyethylene

Needle Holder: Polypropylene

Return and Drive Spring: Stainless Steel AISI 302- polished

Needle Support: Polypropylene

The Safe-T-Lance® Plus Safety Lancet is not made with natural rubber latex.

MANUFACTURING SITE NAME AND ADDRESS

HTL-STREFA S.A.
 ul. Adamówek 7, Ozorków, 95-035 Poland

COUNTRY OF ORIGIN

Poland

STERILIZATION METHOD

HTL-STREFA S. A. uses a validated sterilization process. Validation of the sterilization process is performed based on recognized standards. The sterilization method used is gamma irradiation.

LABELING AND PACKAGING







Two-hundred (200) units are packed per carton and ten (10) cartons are packed per shipper. Shelf box is Alaska GC2 280 IP~750g/m². The shipper is grey corrugated cardboard min. 750 g/m². The lot number and expiration date are on all levels of packaging. Instructions for Use (IFU) are provided with each shelf pack.

Container Type	Length	Width	Height	Weight
ST Box (200 Units)	115 mm	115 mm	158 mm	.525 kg
Shipper (2000)	597 mm	237 mm	174 mm	5.760 kg

STERILE DEVICES*

A 5-year expiration date is assigned to the product.

*The needle/blade remains sterile until the protective cap is removed.

Blood Volume	Code	Blade Width / Needle Gauge	Depth
 Pediatric	1028-1	1.5 mm Blade	1.2 mm
 Max Flow	1005-1	1.5 mm Blade	1.6 mm
 High Flow	1008-1	18G Needle	1.8 mm
 Normal Flow	1014-1	21G Needle	1.8 mm
 Low Flow	1020-1	25G Needle	1.4 mm
 Micro Flow	1025-1	28G Needle	1.6 mm

Ordering Quantity: 200 Units/Box, 2000 Units/Case

For more information visit our website at www.smiths-medical.com

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