



**Product Name SINGLEFIX**

**Producer**  
FRA Production S.p.A.

**Expiry Date**  
5 years

**Product Description**  
Sterile ready-to-use medication for finger, characterized by a soft inner padding. Available in three different sizes: A (large), B (medium), C (small). Sterile class I medical device - CND M03030201.

**Intended use**  
Single-packed medication for finger. This device is sterile and ready to be used.

**Reference Regulations**  
European Directives 93/42/EC and 2007/47/EC and successive amendments.

**Certification**  
UNI EN ISO 9001:2015. ISO 13485:2016. CE MARKING - NOTIFIED BODY N. 0373

**Warnings**  
Clean the wound before wearing this medical device on your finger. It is advisable to put a sterile gauze between the wound and this product in case of bleeding. Do not fasten the straps too tightly around the wrist. Do not use if the pack is not intact.  
This product does not contain latex.  
Do not put in contact with flames. Do not swallow. Avoid improper use. Keep away from the reach of children.

**Instructions for use**

After cleaning the wound, choose the appropriate size and wear this product; then fasten the straps around the wrist without tightening them too much. It is advisable to put a sterile gauze between the wound and the product in case of bleeding.

**Product storage**

Keep away from heat, humidity and light sources.

**Related enclosed documents**

Declaration of conformity to the reference regulations of each batch. Bill of lading.

**Packaging information**

The device is packed in single bags.  
For each product version, the details about the different sales packs are written in the related product specifications.

**Disposal information**

Disposal must be carried out in compliance with related regulations.  
In Italy, this product is disposable as "waste from processed textile fibers".

**Guaranteed performances**

this product undergoes ionized ray sterilization.  
biocompatibility tests have been carried out on the product, in order to prove its use suitability.

**Composition**

EXT: CO 100%; INT: PU 100%



PRODUCTION S.p.A.

**SP000Q02**  
**SINGLEFIX -Sterile medication for finger**

Revision **004**  
Date **4/10/18**

Product available versions			
Item code	Item description	Sales pack	Number of packs per export carton
00570019	SURGIFIX SINGLEFIX TYPE C STZD PZ.100/SC	N. 100,00	10

Product technical data													
Item description	Textile composition	Width mm unstretched			Length mm unstretched			Length Laces mm unstretched			Weight g		
		STD	MIN	MAX	STD	MIN	MAX	STD	MIN	MAX	STD	MIN	MAX
SURGIFIX SINGLEFIX TYPE C STZD	EXT: CO 100%; INT: PU 100%	28,0	25,0	31,0	66	63	69	100	80	0	4,00	3,50	4,50

Product available versions			
Item code	Item description	Sales pack	Number of packs per export carton
00570012	SURGIFIX SINGLEFIX TYPE B STZD PZ.100/SC	N. 100,00	10

Product technical data													
Item description	Textile composition	Width mm unstretched			Length mm unstretched			Length Laces mm unstretched			Weight g		
		STD	MIN	MAX	STD	MIN	MAX	STD	MIN	MAX	STD	MIN	MAX
SURGIFIX SINGLEFIX TYPE B STZD	ESTERNO: CO 100%; INTERNO: PU 100%	30,0	27,0	33,0	85	82	88	120	90	0	4,90	4,40	5,40

Product available versions			
Item code	Item description	Sales pack	Number of packs per export carton
00570004	SURGIFIX SINGLEFIX TYPE A STZD PZ.100/SC	N. 100,00	10

Product technical data													
Item description	Textile composition	Width mm unstretched			Length mm unstretched			Length Laces mm unstretched			Weight g		
		STD	MIN	MAX	STD	MIN	MAX	STD	MIN	MAX	STD	MIN	MAX
SURGIFIX SINGLEFIX TYPE A STZD	EXT: CO 100%; INT: PU 100%	36,0	33,0	39,0	95	92	98	130	00	0	5,90	5,40	6,40

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