

SUREFUSER™ + AMBER

CONTINUOUS ELASTOMERIC INFUSION SYSTEM WITH
VISIBLE LIGHT PROTECTION



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A lightweight ambulatory balloon infuser with continuous infusion for several types of therapy (e.g. chemotherapy and pain management).

- Protection against visible light up to 520 nm
- Distinct orange color for easy recognition
- Transparent material allows for detection of air bubbles and particles
- Not made with latex, BPA, or DEHP
- Discreet, ergonomic design, for single use
- Strong, lightweight housing
- Efficient particle and self-venting 0,2 µm filter with UV light protection
- Accuracy of infusion thanks to flow regulator (calibrated at skin temperature)
- No need for batteries or electricity
- Optional carrying bag accessory sold separately
- Optional Surefuser+ compounding assist device to facilitate filling process
- Tubing of 900 mm with UV light protection

CE 0123

Class IIb Medical Devices
Rule 11
MDD 93/42/EEC
UMDNS 13192

PRODUCT COMPLIANCE

- CE-marked, Class IIb Medical Devices, Rule 11, MDD 93/42/ECC, UMDNS 13192
- Complies with the following norms, directives, and regulations:
 - ISO 594-1
 - EN ISO 13485
 - EN ISO 10993-4
 - EN ISO 10993-10
 - ISO 594-2
 - EN ISO 15223-1
 - EN ISO 10993-5
 - EN ISO 10993-11
 - EN 1041: 2008+A1: 2013
 - EN ISO 10993-1
 - EN ISO 10993-7
 - ISO 28620
- Labels contain 27 languages

MANUFACTURING DETAILS

Legal manufacturer: Nipro Corporation

Country of origin: Japan

STERILIZATION AND SHELF LIFE

Sterilization

EtO (Ethylene oxide)



Single-use only



Indicator sticker

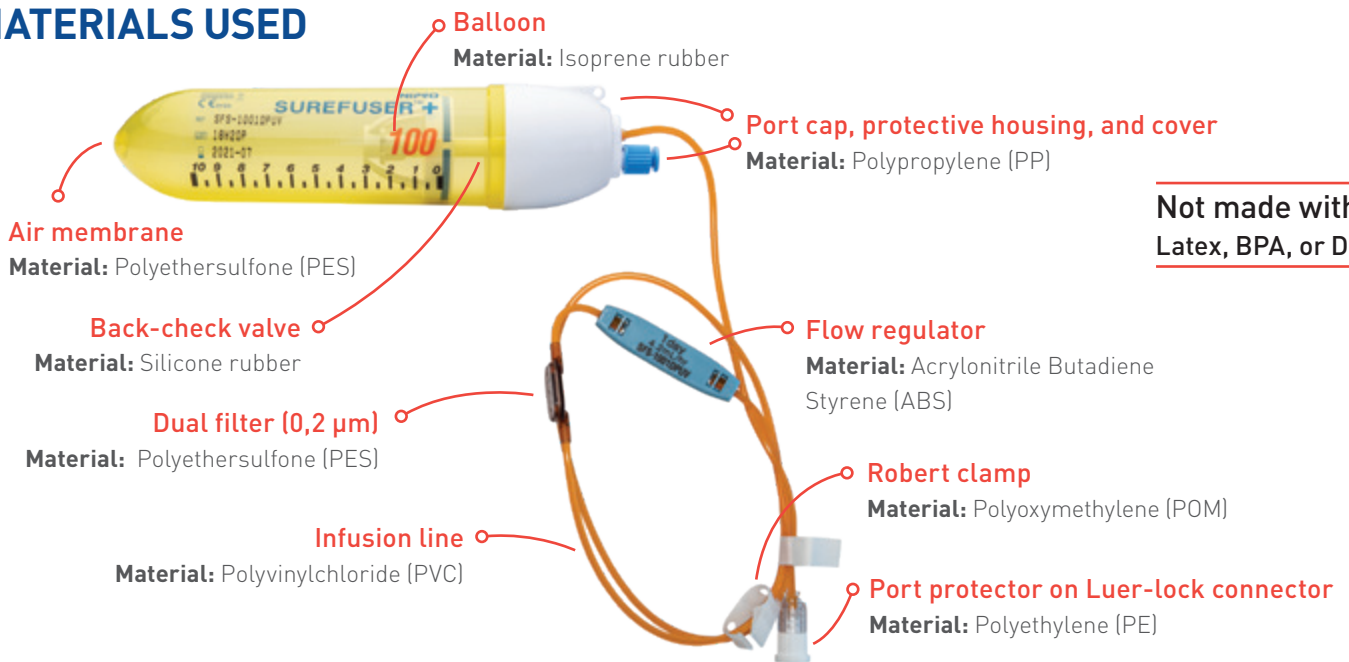
Each outer box (or shipping carton) contains a chemical indicator that ensures sterility. This indicator comes in the form of a blue sticker that turns red when sterilized.

Shelf life

5 years



MATERIALS USED



PRODUCT RANGE OVERVIEW

Reference code	Nominal volume	MEAN flow rate* (ml/hr)	Infusion time	Flow regulator color
SFS-1001DP-UV-EJ	100 ml	4,2	1 day	Blue
SFS-1002DP-UV-EJ	100 ml	2,1	2 days	Green
SFS-10-25P-UV-EJ	250 ml	10	1 day	Blue
SFS-5-25P-UV-EJ	250 ml	5	2 days	Green

*flow rate has a margin of accuracy of 10%

PACKAGING DETAILS

Volume	Weight	Quantity (pcs)	Quantity (pcs)	Gross Weight	INNER BOX (mm)			OUTER BOX (mm)		
(ml)	(g)	Inner box	Outer box	Outer box (kg)	L	W	H	L	W	H
100	56,8	10	30	3,7	365	260	137	425	380	284
250	112	5	15	3,55	365	260	137	425	380	284

Languages

2 languages available on IFU:

English (EN), Spanish (ES)

27 languages available on inner box and outer box:

English (EN), French (FR), Dutch (NL), German (DE), Spanish (ES), Italian (IT), Portuguese (PT), Greek (EL), Swedish (SV), Danish (DA), Norwegian (NO), Russian (RU), Polish (PL), Romanian (RO), Bulgarian (BG), Finnish (FI), Czech (CS), Hungarian (HU), Croatian (HR), Lithuanian (LT), Latvian (LV), Slovenian (SL), Slovakian (SK), Estonian (ET), Turkish (TR), Serbian (SR), and Ukrainian (UK)

5 languages available on individual unit packaging:

English (EN), French (FR), German (DE), Spanish (ES), Italian (IT)

Transport conditions

Closed and dry

Storage conditions

Open packaging only immediately before use to guarantee sterility. Store in a dry place away from direct heat and sunlight.

Label details

	Individual unit	Inner box	Outer box
Product name	✓	✓	✓
Product size	—	✓	✓
Quantity (pieces)	—	✓	✓
REF	✓	✓	✓
LOT	✓	✓	✓
	✓	✓	✓
STERILE EO	✓	✓	✓
CE	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
EC REP	✓	✓	✓
	—	✓	✓
	—	✓	✓
	✓	✓	✓

