

# PRODUCT DATA SHEET

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## SUREFUSER™+ NRFit

CONTINUOUS OR VARIABLE ELASTOMERIC INFUSION SYSTEM  
COMPATIBLE WITH NRFit ISO 80369-6



# SUREFUSER™+ NRFit

Continuous or variable elastomeric infusion system compatible with NRFit ISO 80369-6 system

The Surefuser+ NRFit pump is designed for the precise and controlled delivery of medications over a specified period. Compatible exclusively with NRFit connectors, this ensures enhanced safety by eliminating the risk of misconnections. Ideal for use in various clinical settings, the Surefuser+ pump is suitable for continuous infusion therapies, including pain management and neuraxial anesthesia. Its user-friendly design and reliable performance make it a trusted choice for healthcare professionals.

- Compatible with NRFit ISO 80369-6
- Discreet, ergonomic design
- Strong, lightweight housing
- Protection against UV light up to 400 nm
- Efficient particle and self-venting 0.2 µm\* filter
- Not made with DEHP, latex, or BPA
- Accuracy of infusion thanks to flow regulator (calibrated to skin temperature)
- Single-use
- No need for batteries or electricity
- Optional carrying bag accessory sold separately

CE 0123

Class IIb Medical Devices

## Product Compliance

- CE-marked, Class IIb Medical Devices
- Complies with the following norms, directives, and regulations:
  - ISO80369-7
  - EN 868-5
  - EN 1041: 2008
  - ISO 13485
  - ISO 15223-1
  - ISO 10993-1
  - ISO 10993-4
  - ISO 10993-5
  - ISO 10993-7
  - ISO 10993-11
  - 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.

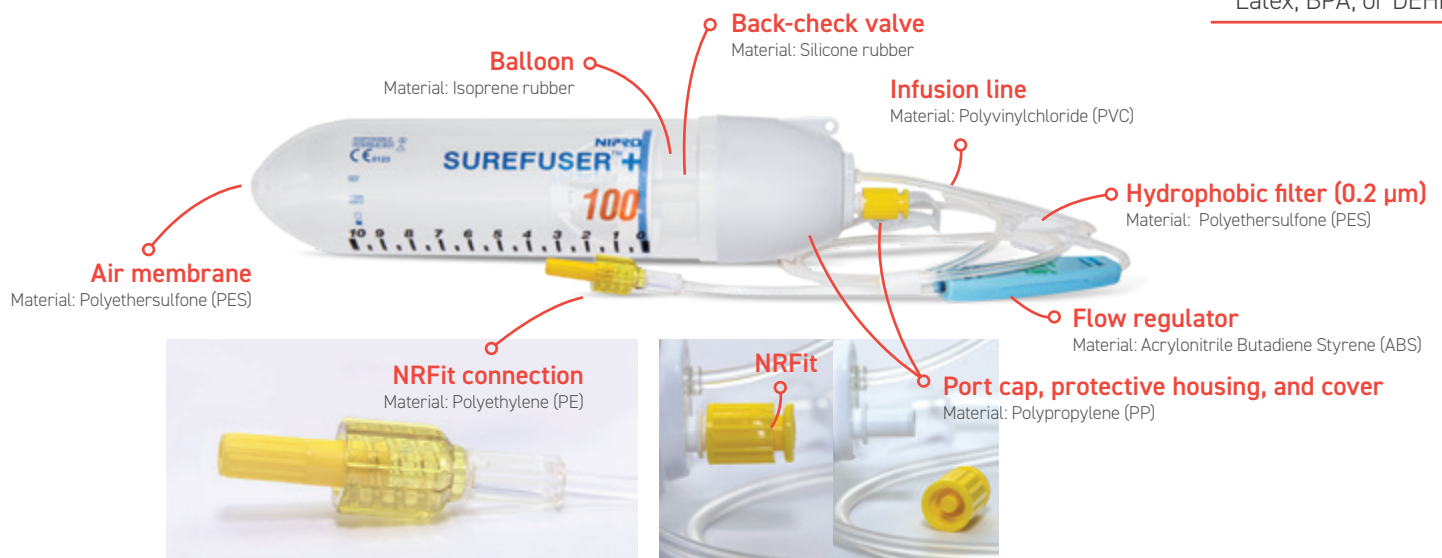
### Shelf life

5 years



## Materials Used

Not made with  
Latex, BPA, or DEHP



## PRODUCT RANGE OVERVIEW

### Long-term Continuous Infusion

Reference code (EU)	Nominal volume	MEAN flow rate*	Infusion time	Flow regulator color
SFS-1012HRP-NR-EJ	100 mL	8.3 mL/hr	12 hrs	Pink
SFS-1001DP-NR-EJ	100 mL	4.2 mL/hr	1 day	Blue
SFS-1002DP-NR-EJ	100 mL	2.1 mL/hr	2 days	Green
SFS-3-5-15P-NR-EJ	150 mL	3.5 mL/hr	1 day 19 hrs	Blue
SFS-3-15P-NR-EJ	150 mL	3 mL/hr	2 days	Green
SFS-2-15P-NR-EJ	150 mL	2 mL/hr	3 days	Cream
SFS-10-25P-NR-EJ	250 mL	10 mL/hr	1 day	Blue
SFS-5-25P-NR-EJ	250 mL	5 mL/hr	2 days	Green
SFS-3-5-25P-NR-EJ	250 mL	3.5 mL/hr	3 days	Cream
SFS-8-30P-NR-EJ	300 mL	8 mL/hr	1 day 14 hrs	Blue
SFS-6-30P-NR-EJ	300 mL	6 mL/hr	2 days	Green
SFS-5-30P-NR-EJ	300 mL	5 mL/hr	2 days 12 hrs	Navy
SFS-4-30P-NR-EJ	300 mL	4 mL/hr	3 days	Cream

\*flow rate has a margin of accuracy of 10%

### Variable Continuous Infusion

Reference code (EU)	Nominal volume	MEAN flow rate*	Infusion time	Flow regulator color
SMA-2468-25P-NR-EJ	250 mL	2 mL/hr	5 days 5 hrs	Green
		4 mL/hr	2 days 15 hrs	
		6 mL/hr	1 day 18 hrs	
		8 mL/hr	1 day 7 hrs	
SMA681012-25PNR-EJ	250 mL	6 mL/hr	1 day 18 hrs	
		8 mL/hr	1 day 7 hrs	
		10 mL/hr	1 day	
		12 mL/hr	21 hrs	
SMA-2468-30P-NR-EJ	300 mL	2 mL/hr	6 days 6 hrs	
		4 mL/hr	3 days	
		6 mL/hr	2 days	
		8 mL/hr	1 day 14 hrs	

\*flow rate has a margin of accuracy of 15%

## Volume

Minimum	Nominal	Maximum
40 mL	50 mL	55 mL
80 mL	100 mL	110 mL
120 mL	150 mL	165 mL
200 mL	250 mL	275 mL
240 mL	300 mL	330 mL

## Packaging Details

Volume (mL)	Quantity (pcs) Inner box	Quantity (pcs) Outer box
100	10	30
150	5	15
250	5	15
300	5	15

## Languages

27 languages available on IFU, 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)


## Transport conditions








Closed and dry

## Storage conditions

Only for immediate use once package has been opened. 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	✓	✓	✓

	Individual unit	Inner box	Outer box
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
EC REP	✓	✓	✓
	—	✓	✓
	✓	✓	✓
	—	✓	✓
	✓	✓	✓

