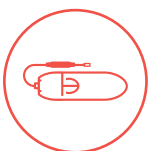




SUREFUSER™+

VARIABLE OR CONTINUOUS
ELASTOMERIC INFUSION SYSTEM



SUREFUSER™+

VARIABLE OR CONTINUOUS ELASTOMERIC INFUSION SYSTEM

A lightweight ambulatory balloon infuser with continuous or variable continuous infusion for several types of therapy, including chemotherapy, antibiotics, pain management, and thalassemia.

- Discrete, ergonomic design
- Strong, lightweight housing
- Efficient particle and self-venting 0,2 µm filter
- Latex-free, DEHP-free
- Accuracy of infusion thanks to flow regulator (calibrated at skin temperature)
- Single-use
- No need for batteries or electricity
- Optional carrying bag accessory sold separately

CE

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
 - ISO 594-2
 - EN 868-5
 - EN 1041: 2008
 - ISO 13485
 - ISO 15223-1
 - ISO 10993-1
 - ISO 10993-4
 - ISO 10993-5
 - ISO 10993-7
 - ISO 10993-10
 - 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

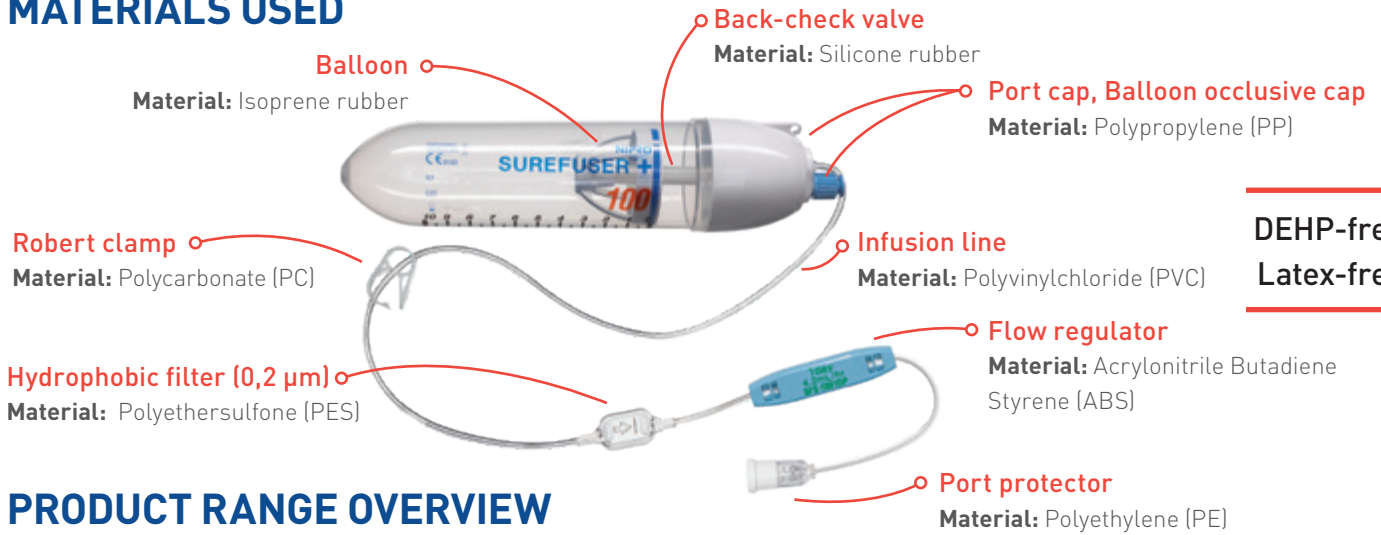
Each outer box (or shipping carton) contains a chemical indicator that ensures sterility. This indicator comes in the form of a blue sticker that turns red when sterilized.

Shelf life

3 years



MATERIALS USED



DEHP-free
Latex-free

PRODUCT RANGE OVERVIEW

Short-term Continuous Infusion

Reference code	Nominal volume	MEAN flow rate* (ml/hr)	Infusion time	Flow regulator (color code)
SFS-1030MP-EJ	100 ml	200	0,5 hrs	White
SFS-1001HRP-EJ	100 ml	100	1 hr	Pale Gray
SFS-250-25P-EJ	250 ml	250	1 hr	Pale Gray
SFS-125-25P-EJ	250 ml	125	2 hrs	Salmon Pink
SFS-62.5-25P-EJ	250 ml	62,5	4 hrs	Khaki

Long-term Continuous Infusion

Reference code	Nominal volume	MEAN flow rate* (ml/hr)	Infusion time	Flow regulator (color code)
SFS-0505HRP-EJ	50 ml	10	5 hrs	Purple
SFS-0512HRP-EJ	50 ml	4,2	12 hrs	Pink
SFS-0501DP-EJ	50 ml	2,1	1 day	Blue
SFS-0502DP-EJ	50 ml	1	2 days 2 hrs	Green
SFS-0503DP-EJ	50 ml	0,7	2 days 23 hrs	Cream
SFS-0505DP-EJ	50 ml	0,4	5 days 5 hrs	Yellow
SFS-0501WP-EJ	50 ml	0,3	6 days 23 hrs	Orange
SFS-1012HRP-EJ	100 ml	8,3	12 hrs	Pink
SFS-1001DP-EJ	100 ml	4,2	1 day	Blue
SFS-1036HRP-EJ	100 ml	2,8	36 hrs	Magenta
SFS-1002DP-EJ	100 ml	2,1	2 days	Green
SFS-1003DP-EJ	100 ml	1,4	2 days 23 hrs	Cream
SFS-1005DP-EJ	100 ml	0,8	5 days 5 hrs	Yellow
SFS-1001WP-EJ	100 ml	0,6	6 days 23 hrs	Orange
SFS-1005HRP-EJ	100 ml	20	5 hrs	Purple
SFS-3.5-15P EJ	150 ml	3,5	1 day 19 hrs	Blue
SFS-3-15P EJ	150 ml	3	2 days 2 hrs	Green
SFS-2-15P EJ	150 ml	2	3 days 3 hrs	Cream
SFS-1-15P EJ	150 ml	1	6 days 6 hrs	Leaf Green
SFS-5-25P-EJ	250 ml	5	2 days 2 hrs	Green
SFS-3.5-25P-EJ	250 ml	3,5	2 days 23 hrs	Cream
SFS-2-25P-EJ	250 ml	2	5 days 5 hrs	Yellow
SFS-1.5-25P-EJ	250 ml	1,5	6 days 23 hrs	Orange
SFS-10-25P-EJ	250 ml	10	1 day 1 hr	Blue
SFS-8-30P EJ	300 ml	8	1 day 14 hrs	Blue
SFS-6-30P EJ	300 ml	6	2 days 2 hrs	Green
SFS-5-30P EJ	300 ml	5	2 days 12 hrs	Navy
SFS-4-30P EJ	300 ml	4	3 days 3 hrs	Cream
SFS-3-30P EJ	300 ml	3	4 days 4 hrs	Red
SFS-2-30P EJ	300 ml	2	6 days 6 hrs	Leaf Green

M: Minutes, HR: hours, D: Day(s), W: Week, P: Plus model, SFS: SureFuser+, E: ETO sterilized, J: made in Japan
*flow rate has a 10% accuracy margin

Variable Infusion

Flow regulator (color code) : ■ Green

Reference code	Nominal volume	MEAN flow rate* (ml/hr)	Max. total hours of variable infusion
SMA-0123-10P-EJ	100 ml	0,5	8 days 8 hrs
		1,5	2 days 19 hrs
		2,5	1 day 16 hrs
		3,5	1 day 5 hrs
SMA-2345-10P-EJ	100 ml	2	2 days 2 hrs
		3	1 day 9 hrs
		4	1 day 1 hr
		5	20 hrs
SMA-123-10P-EJ	100 ml	1	4 days 4 hrs
		2	2 days 2 hrs
		3	1 day 9 hrs
SMA-2345-25P-EJ	250 ml	2	5 days 5 hrs
		3	3 days 11 hrs
		4	2 days 15 hrs
		5	2 days 2 hrs
SMA-2468-25P-EJ	250 ml	2	5 days 5 hrs
		4	2 days 15 hrs
		6	1 day 18 hrs
		8	1 day 7 hrs
SMA-3456-25P-EJ	250 ml	3	3 days 11 hrs
		4	2 days 15 hrs
		5	2 days 2 hrs
		6	1 day 18 hrs
SMA-2345-30P-EJ	300 ml	2	6 days 6 hrs
		3	4 days 4 hrs
		4	3 days 3 hrs
		5	2 days 12 hrs
SMA-3456-30P-EJ	300 ml	3	4 days 4 hrs
		4	3 days 3 hrs
		5	2 days 12 hrs
		6	2 days 2 hrs
SMA-2468-30P-EJ	300 ml	2	6 days 6 hrs
		4	3 days 3 hrs
		6	2 days 2 hrs
		8	1 day 14 hrs

S: SureFuser+, M: Manual, A: adjustment, P: Plus model, E: ETO sterilized, J: made in Japan

*flow rate has a 15% accuracy margin

PACKAGING DETAILS

Continuous infusion

Volume (ml)	Quantity (pcs)		Net Weight Unit (g)	Gross Weight Outer box (kg)	INNER BOX (mm)			OUTER BOX (mm)			
	Inner box	Outer box			L	W	H	L	W	H	m ³
50	10	30	49,4	3,40	365	260	137	425	380	284	0,045
100	10	30	58,6	3,70	365	260	137	425	380	284	0,045
150	5	15	96,4	3,30	365	260	137	425	380	284	0,045
250	5	15	112,4	3,55	365	260	137	425	380	284	0,045
300	5	15	114,5	3,60	365	260	137	425	380	284	0,045

Variable infusion

Volume (ml)	Quantity (pcs)		Net Weight Unit (g)	Gross Weight Outer box (kg)	INNER BOX (mm)			OUTER BOX (mm)			
	Inner box	Outer box			L	W	H	L	W	H	m ³
100	10	30	63,7	3,80	365	260	137	425	380	284	0,045
250	5	15	115,2	3,60	365	260	137	425	380	284	0,045
300	5	15	118,4	3,70	365	260	137	425	380	284	0,045

Languages

27 languages on IFU and every level of packaging:

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

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	✓	✓	✓
CE	✓	✓	✓

	Individual unit	Inner box	Outer box
	✓	✓	✓
	—	—	✓
	✓	✓	✓
EC REP	✓	✓	✓
(EAN 13)	—	✓	✓
	✓	✓	✓
	—	✓	✓

