PRODUCT DATA SHEET



SUREFUSER™+

VARIABLE OR CONTINUOUS ELASTOMERIC INFUSION SYSTEM

NIPRO

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.

- **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 at skin temperature)**
- **Single-use**
- **No need for batteries or electricity**
- **Optional carrying bag accessory sold separately**
- **Optional Surefuser+ Compounding Assist Device to facilitate filling process**

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/EEC, UMDNS 13192
- 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 10993-10
  - ISO 10993-11
  - ISO 28620
- Labels contain 27 languages

MANUFACTURING DETAILS

Legal manufacturer: **Nipro Corporation**

Country of origin: **Japan**

STERILIZATION AND SHELF LIFE

Sterilization	Single-use only	Indicator sticker	Shelf life
EtO (Ethylene oxide) STERILE EO		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.	3-5 years

* filter is 1,2 µm for short-term continuous infusion, 5 µm for viscous medication.

MATERIALS USED



Balloon
Material: Isoprene rubber

Back-check valve
Material: Silicone rubber

Port cap, protective housing, and cover
Material: Polypropylene (PP)

Air membrane
Material: Polyethersulfone (PES)

Not made with
latex, DEHP or BPA

Infusion line
Material: Polyvinylchloride (PVC)

Robert clamp
Material: Polyoxymethylene (POM)

Hydrophobic filter (0,2 µm)†
Material: Polyethersulfone (PES)

Flow regulator
Material: Acrylonitrile Butadiene Styrene (ABS)

Port protector on Luer-lock connector
Material: Polyethylene (PE)

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 hr	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	Green
SFS-0503DP-EJ	50 ml	0,7	3 days	Cream
SFS-0505DP-EJ	50 ml	0,4	5 days	Yellow
SFS-0501WP-EJ	50 ml	0,3	1 week	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	3 days	Cream
SFS-1005DP-EJ	100 ml	0,8	5 days	Yellow
SFS-1001WP-EJ	100 ml	0,6	1 week	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	Green
SFS-2-15P EJ	150 ml	2	3 days	Cream
SFS-1-15P EJ	150 ml	1	6 days	Leaf Green
SFS-12.5-25P-AUSC	250 ml	12,5	20 hours	Turquoise
SFS-10-25P-AUSC	250 ml	10	1 day	Blue
SFS-10-25P-EJ	250 ml	10	1 day	Blue
SFS-5-25P-EJ	250 ml	5	2 days	Green
SFS-3.5-25P-EJ	250 ml	3,5	3 days	Cream
SFS-2-25P-EJ	250 ml	2	5 days 5 hrs	Yellow
SFS-1.5-25P-EJ	250 ml	1,5	1 week	Orange
SFS-8-30P EJ	300 ml	8	1 day 14 hrs	Blue
SFS-6-30P EJ	300 ml	6	2 days	Green
SFS-5-30P EJ	300 ml	5	2 days 12 hrs	Navy
SFS-4-30P EJ	300 ml	4	3 days	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
† filter is 1,2 µm for short-term continuous infusion. Reference ending at AUSC are equipped with a filter of 5µm
*flow rate has a 10% accuracy margin for a drug solution with a viscosity equivalent to nacl 0,9% at 32°C
** 5 years shelf-life

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
		3	1 day 9 hrs
		4	1 day
		5	20 hrs
SMA-123-10P-EJ	100 ml	1	4 days 4 hrs
		2	2 days
		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
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-681012-25P-EJ	250 ml	6	1 day 18 hrs
		8	1 day 7 hrs
		10	1 day
		12	21 hrs
SMA-3456-25P-EJ	250 ml	3	3 days 11 hrs
		4	2 days 15 hrs
		5	2 days
		6	1 day 18 hrs
SMA-2345-30P-EJ	300 ml	2	6 days 6 hrs
		3	4 days 4 hrs
		4	3 days
		5	2 days 12 hrs
SMA-3456-30P-EJ	300 ml	3	4 days 4 hrs
		4	3 days
		5	2 days 12 hrs
		6	2 days
SMA-2468-30P-EJ	300 ml	2	6 days 6 hrs
		4	3 days
		6	2 days
		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 for a drug solution with a viscosity equivalent to NaCl 0,9% at 32°C

** 3 years shelf-life

Minimum volume	Nominal volume	Maximum volume
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

Continuous infusion

Volume	Quantity (pcs)	Quantity (pcs)	Net Weight	Gross Weight	INNER BOX (mm)			OUTER BOX (mm)			
(ml)	Inner box	Outer box	Unit (g)	Outer box (kg)	L	W	H	L	W	H	m³
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	Quantity (pcs)	Quantity (pcs)	Net Weight	Gross Weight	INNER BOX (mm)			OUTER BOX (mm)			
(ml)	Inner box	Outer box	Unit (g)	Outer box (kg)	L	W	H	L	W	H	m³
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 EO	✓	✓	✓
CE	✓	✓	✓

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

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