PRODUCT DATA SHEET



SUREFUSER™+ PCA

VARIABLE OR CONTINUOUS PATIENT-CONTROLLED ANALGESIA (PCA) ELASTOMERIC INFUSION SYSTEM

NIPRO

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A lightweight ambulatory balloon infusion for continuous and variable continuous infusion for several types of therapy (e.g. post-operative pain control, carcinomatous pain control, etc.). All variants have the patient-controlled analgesia (PCA) infuser.

- **Transparent material allows for detection of air bubbles and particles**
- **Protection against UV light up to 400 nm**
- **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**
- **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**
- **Available in 50 ml, 100 ml, and 300 ml in continuous and variable continuous infusion**

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
  - ISO 594-2
  - 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

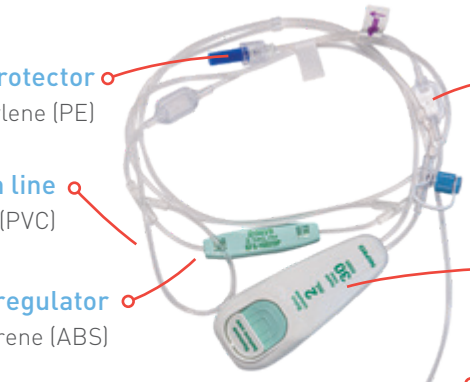
Legal manufacturer: **Nipro Corporation**

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 yellow sticker that turns red when sterilized.	3 years

MATERIALS USED



Port protector
Material: Polyethylene (PE)

Infusion line
Material: Polyvinylchloride (PVC)

Flow regulator
Material: Acrylonitrile Butadiene Styrene (ABS)

Air membrane
Material: Polyethersulfone (PES)

Balloon
Material: Isoprene rubber

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

PCA Unit
Material: Acrylonitrile Butadiene Styrene (ABS)

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

Back-check valve
Material: Silicone rubber

Not made with
Latex, BPA, or DEHP

PRODUCT RANGE OVERVIEW

Continuous Infusion

Reference code (EU)	Reference code (Japan)	Nominal volume	MEAN flow rate*	Infusion time	PCA bolus volume	Refill time	Flow regulator color
SFS-PCA-5030-EJ	P0530/S0504DP	50 ml	0,5 ml/hr	4 days	0,5 ml	30 min	Pink
SFS-PCA-1030-EJ	P2030/S1002DP	100 ml	2,1 ml/hr	2 days	2,0 ml	30 min	Green
SFS-PCA-3030-EJ	P3030/S4-30P	300 ml	4 ml/hr	3 days	3,0 ml	30 min	Blue
SFS-PCA-3060-EJ	P3060/S4-30P	300 ml	4 ml/hr	3 days	3,0 ml	60 min	Blue

*flow rate has a margin of accuracy of 10%

Variable Continuous Infusion

Reference code (EU)	Reference code (Japan)	Nominal volume	MEAN flow rate*	Infusion time	PCA bolus volume	Refill time	Flow regulator color
SMA-PCA-3030-EJ	P3030/M2345-30P	300 ml	2-3-4-5 ml/hr	2 days	3,0 ml	30 min	Green

*flow rate has a margin of accuracy of 15%

PACKAGING DETAILS

Volume	Quantity (pcs)	Quantity (pcs)	Gross Weight	INNER BOX (cm)			OUTER BOX (cm)		
(ml)	Inner box	Outer box	Outer box (kg)	L	W	H	L	W	H
50	10	30	3,7	365	260	137	425	380	284
100	10	30	3,7	365	260	137	425	380	284
300	5	15	3,7	365	260	137	425	380	284

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)

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	✓	✓	✓
	—	✓	✓
	✓	✓	✓
	—	✓	✓
	✓	✓	✓

NIPRO Live Longer. Live Better.

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