PRODUCT DATA SHEET



SAFELET™ CATH

STERILE, SINGLE-USE CATHETER FOR IV INFUSION AND BLOOD COLLECTION

NIPRO

SAFELET™ CATH

STERILE, SINGLE-USE CATHETER FOR IV INFUSION AND BLOOD COLLECTION

- Radiopaque
- Ultra sharp three-beveled needle to minimize discomfort
- Siliconization of needle minimizes penetration and gliding force
- Quick blood visualization
- Hydrophobic filter prevents blood spillage
- Color-coded hub to indicate gauge
- Not made with latex, DEHP or PVC
- Available in 14-24 G
- For use by healthcare professionals only

CE 0123
Class IIa Medical Devices
Rule 7
UMDNS 10727
MDD 93/42/EEC

PRODUCT COMPLIANCE

- CE-marked, Class IIa Medical Devices, Rule 7, UMDNS 10727, MDD 93/42/EE
- Complies with the following norms, directives, and regulations:
  - MEDDEV 2.12/2 Rev.2
  - EN 556-1:2001/AC2006
  - EN 556-2:2015
  - EN1041:2008+A12013
  - EN ISO 9626:2016
  - EN ISO 10555-1:2009
  - EN ISO 10555-5:2013
  - EN 10993-1:2009
  - EN 10993-5:2009
  - EN 10993-10:2013
  - EN 10993-11:2018
  - EN 10993-4:2009
  - EN 10993-7:2008
  - EN ISO 11135:2014
  - EN ISO 11737-1: 2018
  - EN ISO 13485:2016
  - EN ISO 14971:2012
  - EN ISO 15233-1:2016
  - EN ISO 20594-1:1993
  - EN 62366-2008+A1:2015
- Labels contain 12 languages

MANUFACTURING DETAILS

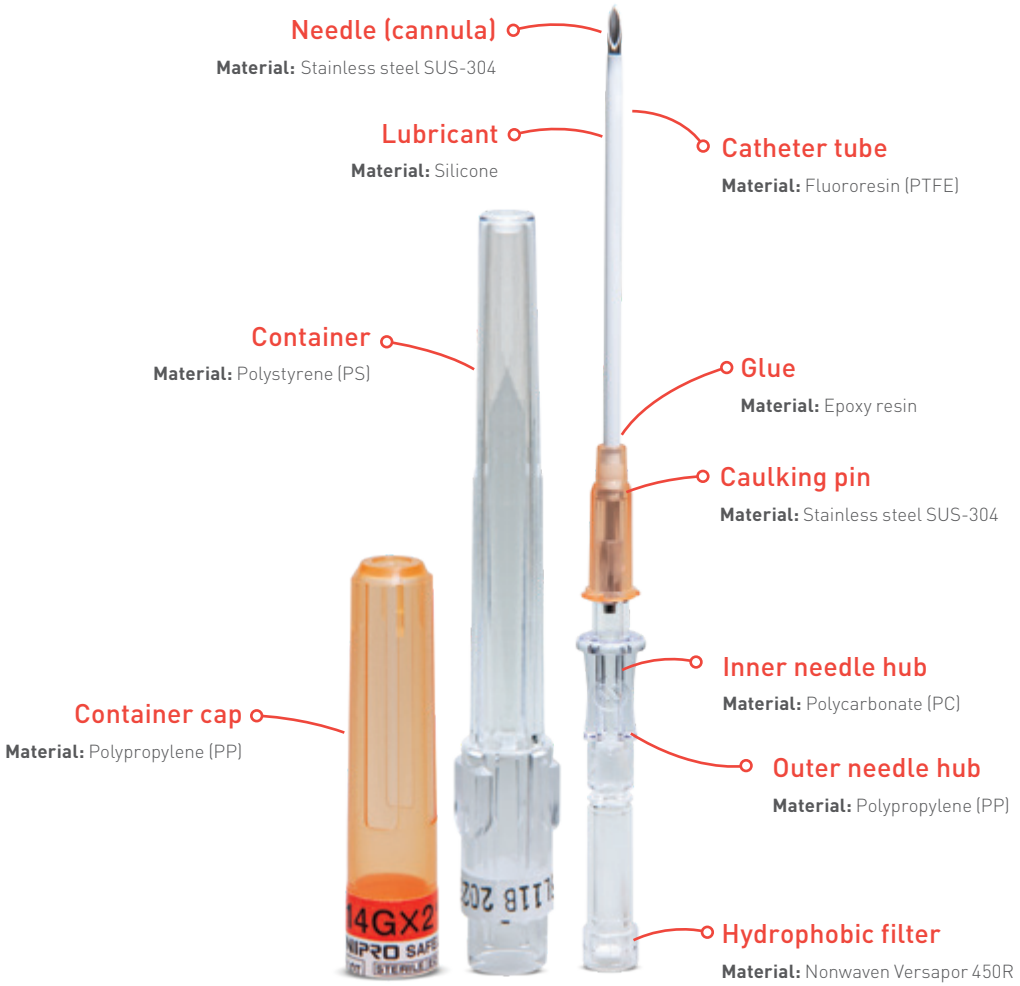
Legal manufacturer: Nipro Corporation

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 (red) sticker that turns (blue) when sterilized.	3 years

MATERIALS USED



Not made with
Latex, DEHP or PVC

PRODUCT RANGE OVERVIEW

Reference code	Description	Color
NIC-1450R-EJ	IV Cath 14 g x2 (22x50 mm) Radiopaque	
NIC-1650R-EJ	IV Cath 16 g x2 (22x50 mm) Radiopaque	
NIC-1663R EJ	IV Cath 16 g x2 1/2 (1.6x63 mm) Radiopaque	
NIC-1832R EJ	IV Cath 18 g x1 1/4 (1.4x32 mm) Radiopaque	
NIC-1850R EJ	IV Cath 18 g x2 (12x50 mm) Radiopaque	
NIC-1863R EJ	IV Cath 18 g x2 ½ (12x63 mm) Radiopaque	
NIC-2032R-EJ	IV Cath 20 g x1 1/4 (09x32 mm) Radiopaque	
NIC-2050R-EJ	IV Cath 20 g x2 (09x50 mm) Radiopaque	
NIC-2225R-EJ	IV Cath 22 g x1 (07x25 mm) Radiopaque	
NIC-2232R-EJ	IV Cath 22 g x1 1/4 (07x32 mm) Radiopaque	
NIC-2420R-EJ	IV Cath 24 g x3/4 (55x20 mm) Radiopaque	
NIC-2425R-EJ	IV Cath 24 g x1 (55x25 mm) Radiopaque	

PACKAGING DETAILS

Reference	Inner box					Intermediate box				Outer box				
	Quantity	L (mm)	W (mm)	H (mm)	Weight (g)	Quantity	L (mm)	W (mm)	H (mm)	Quantity	L (mm)	W (mm)	H (mm)	Weight (kg)
NIC-1450R-EJ	50	63	151	123	8,800	200	273	157	135	1000	825	290	180	3,20
NIC-1650R-EJ	50	63	151	123	8,700	200	273	157	135	1000	825	290	180	9,80
NIC-1663P-EJ	50	63	151	123	8,800	200	273	157	135	1000	825	290	180	9,70
NIC-1832R-EJ	50	63	123	121	7,100	200	273	129	133	1000	685	290	175	9,80
NIC-1850R-EJ	50	63	151	123	8,500	200	273	157	135	1000	825	290	180	8,10
NIC-2032R-EJ	50	63	123	121	7,000	200	273	129	133	1000	685	290	175	9,50
NIC-2050R-EJ	50	63	151	123	8,400	200	273	157	135	1000	825	290	180	8,00
NIC-2225R-EJ	50	63	123	121	6,900	200	273	129	133	1000	685	290	175	9,40
NIC-2232R-EJ	50	63	123	121	6,900	200	273	129	133	1000	685	290	175	7,90
NIC-2420R-EJ	50	63	123	121	6,900	200	273	129	133	1000	685	290	175	7,90
NIC-2425R-EJ	50	63	123	121	6,900	200	273	129	133	1000	685	290	175	7,90

Languages

12 languages on inner, intermediate, and outer boxes:

English (EN), French (FR), Dutch (NL), German (DE), Spanish (ES), Italian (IT), Portuguese (PT), Greek (EL), Swedish (SV), Danish (DA), Norwegian (NO), and Finnish (FI)

Transport conditions

Closed and dry

Storage conditions

Open the packaging only immediately before use to guarantee sterility.

Label details

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

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

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