PRODUCT DATA SHEET



SAFETOUCH[™] CATH (WINGED)

STERILE, SINGLE-USE CATHETER WITH SAFETY DEVICE FOR IV INFUSION





SAFETOUCH[™] CATH (WINGED)

STERILE, SINGLE-USE CATHETER WITH SAFETY DEVICE FOR IV INFUSION

- Irreversible, passive safety mechanism
- Audible click confirms locking of safety device
- Does not require a change in puncture technique
- Radiopaque
- Ultra sharp three-beveled needle to minimize discomfort
- Siliconization of needle minimizes penetration and gliding force
- Flexible wings for easy grip
- Color-coded wings and hub to indicate gauge
- Transparent PUR catheter tube for quick visualization of blood in the flashback chamber to facilitate insertion
- Flashback in hub means the needle is correctly in the vein
- Flashback in catheter means the catheter is correctly in the vein
- Not made with latex, DEHP or PVC
- Available in 16-24 G
- IV infusion duration: hours to several days
- For use by healthcare professionals only

PRODUCT COMPLIANCE

- CE-marked, Class IIa Medical Devices, Rule 7, MDD 93/42/EEC, UMDNS 18331
- Complies with the following norms, directives, and regulations:
 - ISO 594-1:1986
 - ISO 594-2:1998
- ISO 10555-5:2013

- ISO 7864:1993

- ISO 14644-4:2001
 ISO 23908:2011
- ISO 2859-1:1999 /AMD 2011 ISO 10993-10:2010
- Labels contain 26 languages

MANUFACTURING DETAILS

Legal manufacturer: Nipro Corporation

Country of origin: Thailand

STERILIZATION AND SHELF LIFE

Sterilization EtO (Ethylene oxide) Single-use only

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Indicator sticker

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

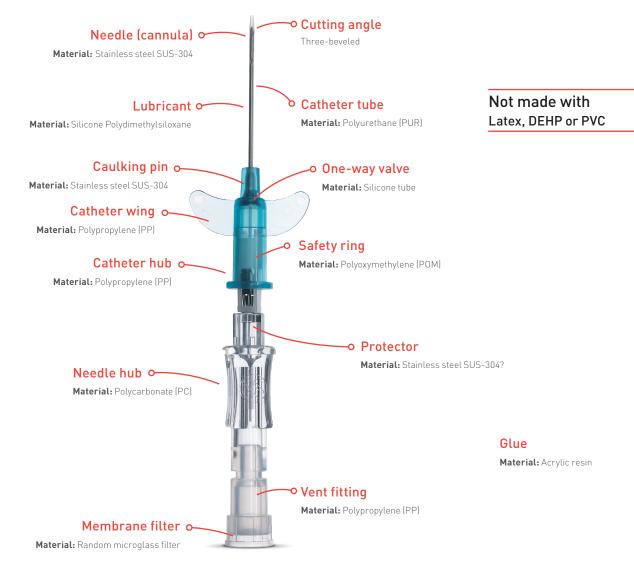
Shelf life

5 years



Class IIa Medical Devices Rule 7 MDD 93/42/EEC UMDNS 18331

MATERIALS USED



PRODUCT RANGE OVERVIEW

Reference code	Description	Color	Flow rate not less than
NIC-SF 1650PW -ET	IV Cath SF wing 16Gx2" (1,7x50mm) PUR		≥ 162 ml/min
NIC-SF 1832PW-ET	IV Cath SF wing 18Gx1 1/4" (1,3x32mm) PUR		≥ 81 ml/min
NIC-SF 1850PW-ET	IV Cath SF wing 18Gx2" (1,3x50mm) PUR		≥ 81 ml/min
NIC-SF 2032PW-ET	IV Cath SF wing 20Gx1 1/4" (1,1x32mm) PUR		≥ 49 ml/min
NIC-SF 2050PW-ET	IV Cath SF wing 20Gx2" (1,1x50mm) PUR		≥ 49 ml/min
NIC-SF 2225PW-ET	IV Cath SF wing 22Gx1" (0,8x25mm) PUR		≥ 29 ml/min
NIC-SF 2232PW-ET	IV Cath SF wing 22Gx1 1/4" (0,8x32mm) PU		≥ 29 ml/min
NIC-SF 2419PW-ET	IV Cath SF wing 24Gx3/4" (0,7x19mm) PUR		≥ 17 ml/min
NIC-SF 2425PW-ET	IV Cath SF wing 24Gx1" (0,7x25mm) PUR		≥ 17 ml/min

PACKAGING DETAILS

Reference code	Gauge	Length	Inner box			Outer box							
		(mm)	Quantity	L (mm)	W (mm)	H (mm)	Weight (g)	Quantity	L (cm)	W (cm)	H (cm)	Weight (kg)	m³
NIC-SF-xxxxPW-ET	XX	XX	50	206	63	145	6,740	2000	662	429	319	10,800	0,0906

Languages

26 languages on IFU, and all levels of packaging:

English (EN), Bulgarian (BG), Czech (CS), Danish (DA), German (DE), Greek (EL), Spanish (ES), Estonian (ET), Finnish (FI), French (FR), Croatian (HR), Hungarian (HU), Italian (IT), Lithuanian (LT), Latvian (LV), Dutch (NL), Norwegian (NO), Polish (PL), Portuguese (PT), Romanian (RO), Russian (RU), Slovakian (SK), Slovenian (SL), Serbian (SR), Swedish (SV), Turkish (TR)

Transport conditions

Closed and dry

Storage conditions

Open the packaging only immediately before use to guarantee sterility.

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			-		

	Individual unit	Inner box	Outer box
Product name	\checkmark	\checkmark	\checkmark
Product size	~	\checkmark	\checkmark
Quantity (pieces)		\checkmark	\checkmark
REF	~		
LOT	~		
2	~		
STERILE EO	~	~	~
CE	~	~	~

	Individual unit	Inner box	Outer box	
2	~	\checkmark	\checkmark	
	~	~	~	
Ж	~	~	~	
	~	~	~	
EC REP	~	\checkmark	\checkmark	
		~	~	
	~	~	~	



