

SAFETOUCH™ CATH WINGED WITH INJECTION PORT

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





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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
- Injection port with universal luer fitting
- 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 7864:1993

— ISO 14644-4:2001

— ISO 594-2:1998

— ISO 10555-5: 2013

- 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)

STERILE EO

Single-use only



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

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Rule 7

MDD 93/42/ECC

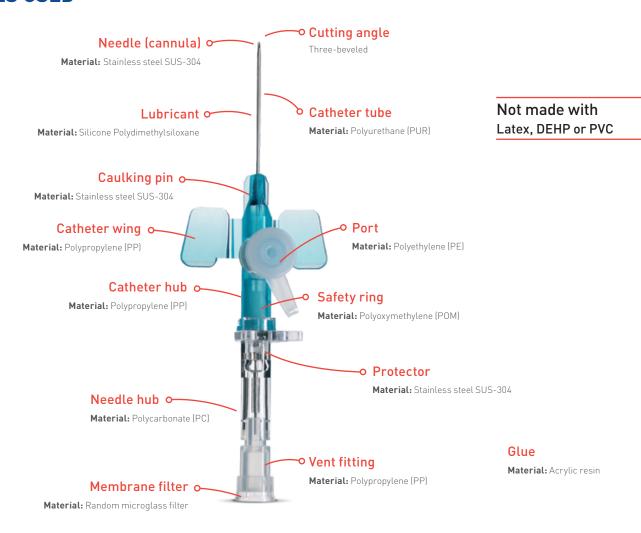
UMDNS 18331

Class IIa Medical Devices

5 years



MATERIALS USED



PRODUCT RANGE OVERVIEW

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

PACKAGING DETAILS

Reference code	Individual unit			Inner box				Outer box						
	Gauge (G)	Length (mm)	Net weight (g)	Quantity	L (mm)	W (mm)	H (mm)	Gross weight (g)	Quantity	L (mm)	W (mm)	H (mm)	Gross weight (kg)	m³
NIC-SF-xxxxPWP-ET	XX	XX	1,16	50	160	105	161	323,9	2000	1074	342	356	13,62	0,1222

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.

Label details

	Individual unit	Inner box	Outer box
Product name	/	/	/
Product size	/	/	/
Quantity (pieces)	_	/	/
REF	~	_	_
LOT	~	_	_
Σ	~	_	_
STERILE EO	/	/	/
CE	~	~	~

	Individual unit	Inner box	Outer box
2	/	/	/
	/	/	/
Ж	~	/	/
	~	~	~
EC REP	~	/	/
	_	~	/
<u> </u>	~	/	/

