



TECHNICAL DATA SHEET

BD Insyte™ Autoguard™ shielded IV catheter

Sterile, single use; these products do not contain natural rubber latex and are DEHP free.

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GENERAL INFORMATION

The BD Insyte™ Autoguard™ shielded IV catheter is a single use, natural rubber latex free intravascular device for infusion of fluids and medications and/or withdrawal of blood. Catheter gauges 18-22 may be used with power injectors for which maximum rated pressure is 300 psi.

The BD Insyte Autoguard shielded IV catheter comes in a wide variety of gauges and lengths to accommodate a variety of infusion therapies. Multiple clinical investigations have proven that IV catheters made of BD Vialon™ biomaterial are easier to insert, while providing longer dwell times with improved patient outcomes.^{1,2,3,4} The BD Insyte Autoguard needle-shielding technology works with the push of a button to retract the needle, reducing the risk of accidental needlestick injuries by 95%.⁵ BD Instaflash™ needle technology is designed to help improve first-stick effectiveness by confirming vessel entry quickly through a unique notch in the needle shaft. BD Instaflash needle technology is available on gauges 24, 22 and 20.

BD Insyte™ Autoguard™ shielded IV catheter with BD Vialon™ biomaterial

Reference number Non-winged	Reference number Winged	Catheter gauge/length (inches)	Catheter gauge/length (mm)	Catheter hub color	Gravity flow rate*	Catheter inside diameter	Catheter outside diameter
381811	381911	24 G x 0.56 in.	0.7 x 14 mm	Yellow	20 mL/min	0.021 in.; 0.521 mm	0.028 in.; 0.699 mm
381812	381912	24 G x 0.75 in.	0.7 x 19 mm	Yellow	20 mL/min	0.021 in.; 0.521 mm	0.028 in.; 0.699 mm
381823	381923	22 G x 1.00 in.	0.9 x 25 mm	Blue	35 mL/min	0.026 in.; 0.648 mm	0.035 in.; 0.876 mm
381833	381933	20 G x 1.00 in.	1.1 x 25 mm	Pink	65 mL/min	0.032 in.; 0.800 mm	0.043 in.; 1.080 mm
381834	381934	20 G x 1.16 in.	1.1 x 30 mm	Pink	60 mL/min	0.032 in.; 0.800 mm	0.043 in.; 1.080 mm
381837	381937	20 G x 1.88 in.	1.1 x 48 mm	Pink	55 mL/min	0.032 in.; 0.800 mm	0.043 in.; 1.080 mm
381844	381944	18 G x 1.16 in.	1.3 x 30 mm	Green	105 mL/min	0.039 in.; 0.978 mm	0.052 in.; 1.308 mm
381847	381947	18 G x 1.88 in.	1.3 x 48 mm	Green	95 mL/min	0.039 in.; 0.978 mm	0.052 in.; 1.308 mm
381854	381954	16 G x 1.16 in.	1.7 x 30 mm	Gray	220 mL/min	0.054 in.; 1.359 mm	0.069 in.; 1.740 mm

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Reference number Non-winged	Reference number Winged	Catheter gauge/length (inches)	Catheter gauge/length (mm)	Catheter hub color	Gravity flow rate*	Catheter inside diameter	Catheter outside diameter
381857	381957	16 G x 1.77 in.	1.7 x 45 mm	Gray	205 mL/min	0.054 in.; 1.359 mm	0.069 in.; 1.740 mm
381867	N/A	14 G x 1.75 in.	2.1 x 45 mm	Orange	330 mL/min	0.069 in.; 1.740 mm	0.085 in.; 2.146 mm

Shipping case contains 200 units – 4 boxes of 50

* ISO 10555-5:1996, annex B test method is a head height of 1000±5 mm water at 22° ±2°C with an open flow rate of 525±25 mL/min.

MATERIALS

Needle	Stainless steel, “B” bevel, (contains chromium, nickel, manganese)
Catheter material.....	BD Vialon™ Polyurethane (radiopaque)
Catheter adapter	Polypropylene and colorant
Metal wedge.....	Stainless steel
Needle hub.....	Polycarbonate
Needle cover	Polypropylene
Barrel.....	Polycarbonate
Vent plug	Polyethylene with CMC polymer
Activation button.....	Polycarbonate and colorant
Spring.....	Stainless steel
Lubricant	Medical grade silicone (needle, catheter, metal wedge)
Gel.....	Silicone grease
Top web unit packaging	Paper (Reinforced polymer \ 50# white paper stock)
Bottom web unit packaging.....	Polymer film (Ethylene Vinyl Acetate \ K-Resin \ Ethylene Vinyl Acetate)
Dispenser box	Cardboard (Clay coated Newsback liner board)
Shipper box	Corrugated (Liner/medium singlewall board)
Instructions for Use (IFU).....	Paper (43#)
Unit package dimensions (non-winged).....	8.27 in. x 1.18 in. (short); 9.65 in. x 1.18 in. (long)
Unit package dimensions (winged).....	8.27 in. x 1.40 in. (short); 9.65 in. x 1.40 in. (long)

These products do not contain any phthalates (DEHP, DBP, BBP)

Fluid path components do not contain BPA

PVC free

Nonpyrogenic

PRINT: PERMANENT TYPE WATER BASED BLACK INK

Resistant to detergent, water, 70% isopropyl and 70% ethyl alcohols

PERMANENT TYPE WATER BASED MULTI-COLORED INKS

Resistant to detergent, water, 70% isopropyl and 70% ethyl alcohols

LABELS AND INSTRUCTIONS FOR USE (IFU): according to European Medical Device directive, multilingual

BAR CODE ON SHELF PACK (Box) AND SHIPPER: EAN 128

STERILIZATION: ETHYLENE OXIDE in accordance with ANSI/AAMI/ISO 11135

Three years shelf life

EO residuals within applicable regulations

HIGH PRESSURE INJECTION: Products 18 through 22 Gauge are suitable for use with power injectors rated for a maximum of 300 psi.

BD Manufacturer	ISO Certification	CE Marking	BD Manufacturing Site
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070 USA Facility Certificate Number: 1710034 for FDA	BSI ISO 13485:2003 Certificate Number FM 71665 BSI ISO 9001:2008 Certificate Number FM 504587 Det Norske Veritas Certificate ISO 14001:2004	BSI Full Quality Assurance Certificate Number CE 01738	Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, UT 84070 USA Facility Certificate Number: 1710034 for FDA

STANDARDS INFORMATION

ALL BD INSYTE AUTOGUARD IV CATHETERS USE THE FOLLOWING STANDARDS:

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|-----------------------|-----------------------------|
| 21 CFR PART 801 | EN 1041 |
| 21 CFR PART 802 | EN 10555 PART 1/AMD 1/AMD 2 |
| ANSI/AAMI/ISO 10993-7 | EN 10555 PART 5/AMD 1/COR 1 |
| ANSI/AAMI/ISO 10993-1 | ISO 9001/COR 1 |
| ANSI/AAMI/ISO 11135 | EN 14001 |
| ANSI/AAMI/ISO 11607 | ISO 13485 |
| EN 594 PART 1 | ISO 14644-1 |
| EN 594 PART 2 | ISO 14971 |
| EN 908 | MDD 93/42/EEC |

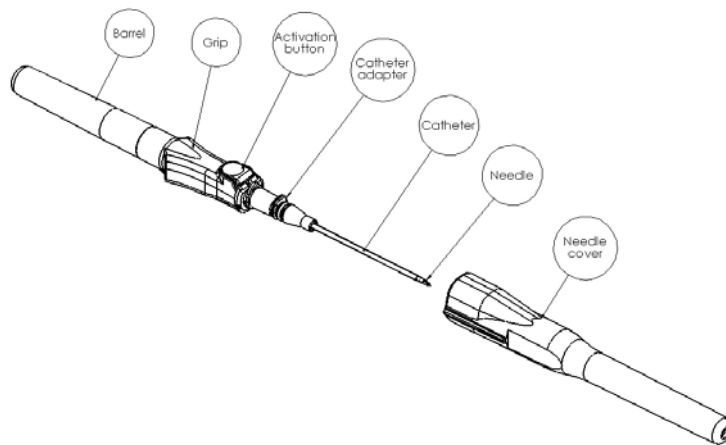
CLASSIFICATION:

- EU Class IIa
- USA Class II, 510K – K952861

CATHETER LUERS – Complies with ISO 594

QUALITY CONTROL: 21 CFR PART 801 AND 21 CFR PART 802

BD Insyte™ Autoguard™ shielded IV catheter product drawing



REFERENCES

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- ¹ Maki DG, Ringer M. Risk factors for infusion-related phlebitis with small peripheral venous catheters. *Annals of Internal Medicine*. 1991;114:845-854.
 - ² Gaukroger PB, Roberts JG, Manners TA. Infusion thrombophlebitis: a prospective comparison of 645 Vialon and Teflon cannulae in anaesthetic and postoperative use. *Anaesthesia and Intensive Care*. 1988;16:265-271.
 - ³ Stanley MD, Meister E, Fuschuber K. Infiltration during intravenous therapy in neonates: comparison of Teflon® and Vialon® catheters. *Southern Medical Journal*. 1992;85:883-886.
 - ⁴ McKee JM, et al. Complications of intravenous therapy: a randomized prospective study—Vialon vs. Teflon. *Journal of Intravenous Nursing*. 1989;12(5):288-295.
 - ⁵ Mendelson MH, Lin-Chen BY, Finkelstein-Blond L, Bailey E, Kogan G. Evaluation of a safety IV catheter (IVC) (Becton Dickinson, Insyte Autoguard): final report [abstract]. Eleventh Annual Scientific Meeting Society for Healthcare Epidemiology of America. 2001.