Document Number: EMEA-SOP039-F1	**Rev. Lev.:** 02
Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

BD® Insyte™ IV Catheters
Sterile, Single-use
Product codes: 381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267

Becton Dickinson Infusion Therapy Systems Inc.,
9450 South State Street, Sandy,
Utah 84070, USA

BD® Insyte-N™ IV Catheters
Sterile, Single-use
Product codes: 381211, 381311

BD® Insyte-W™ IV Catheters with wings
Sterile, Single-use
Product codes: 381312, 381323, 381334, 381337, 381344, 381347, 381357

BD® Angiocath™ IV Catheters
Sterile, Single-use
Product codes: 381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164, 381167, 382258, 382259, 382268, 382269, 382277, 382287

TDS number: V201-192 Rev. 01
Veeva Vault number: BD-154670
2025-September

General product name "Insyte™ IV Catheters" is used throughout this technical documentation.

Product Family Name	Trade Name
Insyte™ IV Catheters	Insyte™ IV Catheter
	Insyte-N™ IV Catheter
	Insyte-W™ IV Catheter with wings

1. General Information

1.1 Intended purpose

Insyte™ IV Catheters (381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357)	An intravascular (IV) catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure
Angiocath™ IV Catheters (381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164 and 381167)	
Angiocath™ IV Catheters (382258, 382259, 382268, 382269, 382277 and 382287)	These intravascular (IV) catheters are inserted into a patient's vascular system to administer fluids, medications or blood products, to obtain blood samples, and to monitor blood pressure.

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1.2 Intended User

Insyte™ IV Catheters (381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357)	Intended to be used by clinicians trained in vascular access.
Angiocath™ IV Catheters (381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164 and 381167)	
Angiocath™ IV Catheters (382258, 382259, 382268, 382269, 382277 and 382287)	These products are CE certified under the Medical Device Directive (MDD). BD is transitioning to the Medical Device Regulation (MDR), and as the information in this section is the requirement of MDR, it is still not available. The TDS will be updated once the transition to MDR is completed.

1.3 General Medical Devices description

Insyte™ IV Catheters (381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357):

Insyte™ IV Catheters are conventional (non-safety) over-the-needle intravascular catheters. Insyte™ IV Catheters have a radiopaque BD® Vialon™ Catheter Material. Insyte™ IV Catheters include a needle and a flash chamber with removable flow control plug / vent plug. The needle and the catheter are protected by a needle cover. The flash chamber on Insyte™ IV Catheters provides confirmation that the device has entered the vessel. In addition, Insyte-N™ IV Catheters (381211, 381311) have BD® Instaflash™ Needle Technology allowing for immediate visualisation of blood along the catheter.Instaflash™ Needle Technology is clinically demonstrated to significantly improve first-attempt insertion success*.

Insyte™ IV Catheters are available without wings; Insyte-W™ IV Catheters with wings are only available with wings and Insyte-N™ IV Catheters are available with or without wings. The catheter hub and wings are color coded to indicate catheter gauge size.
The 22-18G (0.9-1.3 mm) Insyte™ IV Catheters are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa).



Figure 1: Unit Package of Insyte™ IV Catheter (14G)

*Compared to a non-notched needle.[1,2]

1. Van Loon FH, Timmerman R, den Brok GP, et al. The impact of a notched peripheral intravenous catheter on the first attempt success rate in hospitalized adults: Block-randomized trial. J Vasc Access. 2021. DOI: 10.1177/1129729821990217.
2. Seetharam AM, Raju U, Suresh K. A randomized controlled study to compare first stick success with Instaflash technology: The FIRSST study. J Vasc Access. 2022:11297298221080369.

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Angiocath™ IV Catheters (381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164, 381167, 382258, 382259 , 382268, 382269, 382277 and 382287):

Angiocath™ IV Catheters are conventional (non-safety) over-the-needle intravascular (IV) catheters.

Angiocath™ IV Catheters have a radiopaque fluorinated ethylene propylene (FEP) catheter. These devices include a needle and a flash chamber with removable vent plug. The needle and the catheter are protected by a needle cover.
The flash chamber provides confirmation that the device has entered the vessel.

Angiocath™ IV Catheters are available without wings. The catheter hub is color coded to indicate catheter gauge size (24 G (0.7 mm) = Yellow, 22G (0.8 mm) = Blue, 20G (1.1 mm) = Pink, 18G (1.3 mm) = Green, 16G (1.7 mm) = Grey, 14G (2.1 mm) = Orange, 12G (2.8 mm) = Light Blue, 10G (3.4 mm) = Brown).



Figure 2: Primary or Unit Package Configuration of BD Angiocath™ IV Catheter

BD Catalogue Number	BD Product Description	Gauge	Size (mm)	Inner Diameter - ID (mm)	Outer Diameter - OD (mm)	Gravity Flow Rate	Priming Volume (mL)	Maximum Power Injector Pressure Limit Setting
381311	Insyte-N™ IV Catheter 24G x 0.56in (14mm)	24G	0.7 x 14	0.52	0.70	25 mL/min (1500 mL/hr)	0.1	Not for use with power injectors
381211	Insyte-N™ IV Catheter with wings 24G x 0.56in (14mm)	24G	0.7 x 14	0.52	0.70	25 mL/min (1500 mL/hr)	0.1	Not for use with power injectors
381212	Insyte™ IV Catheter 24G x 0.75in (19mm)	24G	0.7 x 19	0.52	0.70	25 mL/min (1500 mL/hr)	0.1	Not for use with power injectors
381223	Insyte™ IV Catheter 22G x 1.00in (25mm)	22G	0.9 x 25	0.65	0.88	35 mL/min (2100 mL/hr)	0.1	300 psi (2068 kPa)

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BD Catalogue Number	BD Product Description	Gauge	Size (mm)	Inner Diameter - ID (mm)	Outer Diameter - OD (mm)	Gravity Flow Rate	Priming Volume (mL)	Maximum Power Injector Pressure Limit Setting
381234	Insyte™ IV Catheter 20G x 1.16in (30mm)	20G	1.1 x 30	0.80	1.09	60 mL/min (3600 mL/hr)	0.1	300 psi (2068 kPa)
381237	Insyte™ IV Catheter 20G x 1.88in (48mm)	20G	1.1 x 48	0.80	1.09	55 mL/min (3300 mL/hr)	0.15	300 psi (2068 kPa)
381244	Insyte™ IV Catheter 18G x 1.16in (30mm)	18G	1.3 x 30	0.98	1.31	105 mL/min (6300 mL/hr)	0.15	300 psi (2068 kPa)
381247	Insyte™ IV Catheter 18G x 1.88in (48mm)	18G	1.3 x 48	0-98	1.31	95 mL/min (5700 mL/hr)	0.15	300 psi (2068 kPa)
381257	Insyte™ IV Catheter 16G x 1.77in (45mm)	16G	1.7 x 45	1.36	1.74	205 mL/min (12300 mL/hr)	0.15	Not for use with power injectors
381267	Insyte™ IV Catheter 14G x 1.75in (45mm)	14G	2.1 x 45	1.74	2.15	330 mL/min (19800 mL/hr)	0.2	Not for use with power injectors
381312	Insyte-W™ IV Catheter with wings 24G x 0.75in (19mm)	24G	0.7 x 19	0.52	0.70	25 mL/min (1500 mL/hr)	0.1	Not for use with power injectors
381323	Insyte-W™ IV Catheter with wings 22G x 1.00in (25mm)	22G	0.9 x 25	0.65	0.88	35 mL/min (2100 mL/hr)	0.1	300 psi (2068 kPa)
381334	Insyte-W™ IV Catheter with wings 20G x 1.16in (30mm)	20G	1.1 x 30	0.80	1.09	60 mL/min (3600 mL/hr)	0.1	300 psi (2068 kPa)
381337	Insyte-W™ IV Catheter with wings 20G x 1.88 in (48mm)	20G	1.1 x 48	0.80	1.09	55 mL/min (3300 mL/hr)	0.15	300 psi (2068 kPa)
381344	Insyte-W™ IV Catheter with wings 18G x 1.16in (30mm)	18G	1.3 x 30	0.98	1.31	105 mL/min (6300 mL/hr)	0.15	300 psi (2068 kPa)
381347	Insyte-W™ IV Catheter with wings 18G x 1.88in (48mm)	18G	1.3 x 48	0.98	1.31	95 mL/min (5700 mL/hr)	0.15	300 psi (2068 kPa)
381357	Insyte-W™ IV Catheter with wings 16G x 1.77in (45mm)	16G	1.7 x 45	1.36	1.74	205 mL/min (12300 mL/hr)	0.15	Not for use with power injectors

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BD Catalogue Number	BD Product Description	Gauge	Size (mm)	Inner Diameter - ID (mm)	Outer Diameter - OD (mm)	Gravity Flow Rate	Priming Volume (mL)	Maximum Power Injector Pressure Limit Setting
381112	Angiocath™ IV Catheter 24G x 0.75in (19mm)	24G	0.7 x 19	0.48	0.71	17 mL/min (1020 mL/hr)	0.1	Not for use with power injectors
381123	Angiocath™ IV Catheter 22G x 1.00in (25mm)	22G	0.8 x 25	0.60	0.84	28 mL/min (1680 mL/hr)	0.1	Not for use with power injectors
381134	Angiocath™ IV Catheter 20G x 1.16in (30mm)	20G	1.1 x 30	0.75	1.09	49 mL/min (2940 mL/hr)	0.1	Not for use with power injectors
381137	Angiocath™ IV Catheter 20G x 1.88in (48mm)	20G	1.1 x 48	0.75	1.09	42 mL/min (2520 mL/hr)	0.1	Not for use with power injectors
381144	Angiocath™ IV Catheter 18G x 1.16in (30mm)	18G	1.3 x 30	0.93	1.32	86 mL/min (5160 mL/hr)	0.1	Not for use with power injectors
381147	Angiocath™ IV Catheter 18G x 1.88in (48mm)	18G	1.3 x 48	0.93	1.32	79 mL/min (4740 mL/hr)	0.15	Not for use with power injectors
381154	Angiocath™ IV Catheter 16G x 1.16in (30mm)	16G	1.7 x 30	0.05	0.07	156 mL/min (9360 mL/hr)	0.15	Not for use with power injectors
381157	Angiocath™ IV Catheter 16G x 1.88in (48mm)	16G	1.7 x 48	1.18	1.70	147 mL/min (8820 mL/hr)	0.15	Not for use with power injectors
381164	Angiocath™ IV Catheter 14G x 1.16in (30mm)	14G	2.1 x 30	1.59	2.11	295 mL/min (17700 mL/hr)	0.15	Not for use with power injectors
381167	Angiocath™ IV Catheter 14G x 1.88in (48mm)	14G	2.1 x 48	1.59	2.11	277 mL/min (16620 mL/hr)	0.2	Not for use with power injectors
382258	Angiocath™ IV Catheter for Special Placement 16G x 3.25in (83mm)	16G	1.7 x 83	1.18	1.70	127 mL/min (7620 mL/hr)	0.15	Not for use with power injectors
382259	Angiocath™ IV Catheter for Special Placement 16G x 5.25in (133mm)	16G	1.7 x 133	1.18	1.70	108 mL/min (6480 mL/hr)	0.15	Not for use with power injectors
382268	Angiocath™ IV Catheter for Special Placement 14G x 3.25in (83mm)	14G	2.1 x 83	1.59	2.11	249 mL/min (14940 mL/hr)	0.2	Not for use with power injectors
382269	Angiocath™ IV Catheter for Special Placement 14G x 5.25in (133mm)	14G	2.1 x 133	1.59	2.11	219 mL/min (13140 mL/hr)	0.2	Not for use with power injectors

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382277	Angiocath™ IV Catheter for SpecialPlacement 12G x 3.00in (76mm)	12G	2.8 x 76	2.29	2.80	449 mL/min (26940 mL/hr)	0.25	Not for use with power injectors
382287	Angiocath™ IV Catheter for Special Placement 10G x 3.00in (76mm)	10G	3.4 x 76	2.70	3.40	609 mL/min (36540 mL/hr)	0.25	Not for use with power injectors

Note: Please check BD catalogue number availability in your country.
The BD Product Description can slightly differ from the Declaration of Conformity; please always refer to the BD Catalogue Number.

1.4 Certification

BD Catalogue Number	BD Legal Manufacturer And ISO 13485 Certification	CE/UKCA Certificate Number and Notified Body Acronym and Number	BD Manufacturing Site (Country of Origin) And ISO 13485 Certification	EC Representative/ CH Representative (if applicable)
381311 381211 381212 381223 381234 381237 381244 381247 381257 381267 381312 381323 381334 381337 381344 381347 381357	Name and Address: Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, Utah 84070, USA ISO 13485 Certificate No.: FM71665	CE certified with BSI (2797) MDR Certificate No.: 731353 UKCA certified: N/A	Name and Address: Becton Dickinson Industrias Cirurgicas Ltda. Avenida Juscelino Kubitschek, 273 Francisco Bernardino - Juiz de Fora - MG / Brazil, 36081-000 ISO 13485 Certificate No.: TNBR-31216 Name and Address: Becton Dickinson Medical (s) Pte Ltd. 30 Tuas Avenue 2 Singapore 639461 ISO 13485 Certificate No.: MD81426	Name and Address: EC Representative: Becton Dickinson Ireland Ltd. Donore Road, Drogheda, Co. Louth A92 YW26, Ireland Name and Address: CH Representative: BD Switzerland Sarl Terre Bonne Park – A4, Route de Crassier 17, 1262 Eysins, Switzerland

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BD Catalogue Number	BD Legal Manufacturer And ISO 13485 Certification	CE/UKCA Certificate Number and Notified Body Acronym and Number	BD Manufacturing Site (Country of Origin) And ISO 13485 Certification	EC Representative/ CH Representative (if applicable)
381112 381123 381134 381137 381144 381147 381154 381157 381164 381167	Name and Address: Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, Utah 84070, USA ISO 13485 Certificate No.: FM71665	CE certified with BSI (2797) MDR Certificate No.: 731353 UKCA certified: N/A	Name and Address: Becton Dickinson Infusion Therapy Systems Inc., S.A.de C.V. Periferico Luis Donaldo Colosio #579, Nogales, Sonora, C.P. 84048, Mexico ISO 13485 Certificate No.: FM673986 Name and Address: Becton Dickinson Industrias Cirurgicas Ltda. Avenida Juscelino Kubitschek, 273 Francisco Bernardino - Juiz de Fora - MG / Brazil, 36081-000 ISO 13485 Certificate No.: TNBR-31216	Name and Address: EC Representative: Becton Dickinson Ireland Ltd. Donore Road, Drogheda, Co. Louth A92 YW26, Ireland Name and Address: CH Representative: BD Switzerland Sarl Terre Bonne Park – A4, Route de Crassier 17, 1262 Eysins, Switzerland
382258 382259 382268 382269 382277 382287	Name and Address: Becton Dickinson Infusion Therapy Systems Inc., 9450 South State Street, Sandy, Utah 84070, USA ISO 13485 Certificate No.: FM71665	CE certified with BSI (2797) MDD Certificate No.: CE 01738 UKCA certified: N/A	Name and Address: Becton Dickinson Medical (s) Pte Ltd 30 Tuas Avenue 2, Singapore 639461 ISO 13485 Certificate No.: MD81426 Name and Address: Becton Dickinson Industrias Cirurgicas Ltda. Avenida Juscelino Kubitschek, 273 Francisco Bernardino - Juiz de Fora - MG / Brazil, 36081-000 ISO 13485 Certificate No.: TNBR-31216 Name and Address: Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales Sonora, C.P.84048, Mexico ISO 13485 Certificate No.: FM673986	Name and Address: EC Representative: Becton Dickinson Distribution Center NV Laagstraat 57 B-9140 Temse Belgium Name and Address: CH Representative: BD Switzerland Sarl Terre Bonne Park – A4, Route de Crassier 17, 1262 Eysins, Switzerland

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1.5 UDI-DI and Basic UDI-DI

BD Catalogue Number	UDI-DI		Basic UDI-DI
381311	Primary Packaging	00382903813117	038290FVWUNBPFM4
	Shipping Case	50382903813112	
	Shelf Box	30382903813118	
381211	Primary Packaging	00382903812110	038290FVWUNBPFM4
	Shipping Case	50382903812115	
	Shelf Box	30382903812111	
381212	Primary Packaging	00382903812127	038290FVWUNBPFM4
	Shipping Case	50382903812122	
	Shelf Box	30382903812128	
381223	Primary Packaging	00382903812233	038290FVWUNBPFM4
	Shipping Case	50382903812238	
	Shelf Box	30382903812234	
381234	Primary Packaging	00382903812349	038290FVWUNBPFM4
	Shipping Case	50382903812344	
	Shelf Box	30382903812340	
381237	Primary Packaging	00382903812370	038290FVWUNBPFM4
	Shipping Case	50382903812375	
	Shelf Box	30382903812371	
381244	Primary Packaging	00382903812448	038290FVWUNBPFM4
	Shipping Case	50382903812443	
	Shelf Box	30382903812449	
381247	Primary Packaging	00382903812479	038290FVWUNBPFM4
	Shipping Case	50382903812474	
	Shelf Box	30382903812470	
381257	Primary Packaging	00382903812578	038290FVWUNBPFM4
	Shipping Case	50382903812573	
	Shelf Box	30382903812579	
381267	Primary Packaging	00382903812677	038290FVWUNBPFM4
	Shipping Case	50382903812672	
	Shelf Box	30382903812678	
381312	Primary Packaging	00382903813124	038290FVWUNBPFM4
	Shipping Case	50382903813129	
	Shelf Box	30382903813125	
381323	Primary Packaging	00382903813230	038290FVWUNBPFM4
	Shipping Case	50382903813235	
	Shelf Box	30382903813231	
381334	Primary Packaging	00382903813346	038290FVWUNBPFM4
	Shipping Case	50382903813341	
	Shelf Box	30382903813347	
381337	Primary Packaging	00382903813377	038290FVWUNBPFM4
	Shipping Case	50382903813372	
	Shelf Box	30382903813378	
381344	Primary Packaging	00382903813445	038290FVWUNBPFM4
	Shipping Case	50382903813440	
	Shelf Box	30382903813446	
381347	Primary Packaging	00382903813476	038290FVWUNBPFM4
	Shipping Case	50382903813471	
	Shelf Box	30382903813477	

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BD Catalogue Number	UDI-DI		Basic UDI-DI
381357	Primary Packaging	00382903813575	038290FVWUNBPFM4
	Shipping Case	50382903813570	
	Shelf Box	30382903813576	
381112	Primary Packaging	00382903811120	038290PLUSQXZORT
	Shipping Case	50382903811125	
	Shelf Box	30382903811121	
381123	Primary Packaging	00382903811236	038290PLUSQXZORT
	Shipping Case	50382903811231	
	Shelf Box	30382903811237	
381134	Primary Packaging	00382903811342	038290PLUSQXZORT
	Shipping Case	50382903811347	
	Shelf Box	30382903811343	
381137	Primary Packaging	00382903811373	038290PLUSQXZORT
	Shipping Case	50382903811378	
	Shelf Box	30382903811374	
381144	Primary Packaging	00382903811441	038290PLUSQXZORT
	Shipping Case	50382903811446	
	Shelf Box	30382903811442	
381147	Primary Packaging	00382903811472	038290PLUSQXZORT
	Shipping Case	50382903811477	
	Shelf Box	30382903811473	
381154	Primary Packaging	00382903811540	038290PLUSQXZORT
	Shipping Case	50382903811545	
	Shelf Box	30382903811541	
381157	Primary Packaging	00382903811571	038290PLUSQXZORT
	Shipping Case	50382903811576	
	Shelf Box	30382903811572	
381164	Primary Packaging	00382903811649	038290PLUSQXZORT
	Shipping Case	50382903811644	
	Shelf Box	30382903811640	
381167	Primary Packaging	00382903811670	038290PLUSQXZORT
	Shipping Case	50382903811675	
	Shelf Box	30382903811671	
382258, 382259, 382268, 382269, 382277, 382287	These products are CE-certified under the Medical Device Directive (MDD). BD is transitioning to the Medical Device Regulation (MDR) and, as the information in this section is a MDR requirement, it is still not available. The Technical Data Sheet will be updated once the transition to MDR is completed.		

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1.6 Materials

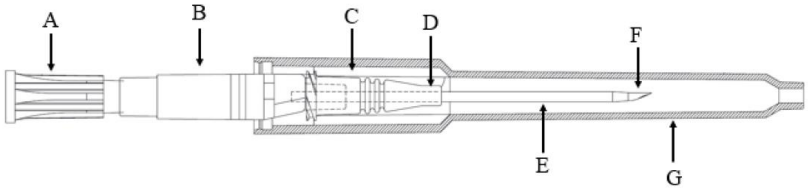


Figure 3: Key Functional Components of Insyte™ IV Catheters

BD Catalogue Number	Component Identifier	Component	Material
381212 381223 381234 381237 381244 381247 381257 381267 381211 381311 381312 381323 381334 381337 381344 381347 381357	A	Plug Flow Control	Plug: Polypropylene (PP)
			Acrylic copolymer membrane cast on a nonwoven nylon support
	B	Needle hub	Cellulosic plastics (Cellulose Acetate Propionate) with high toughness, hardness, strength, surface gloss, and clarity
	C	Catheter Adapter	PP homopolymer
	Not Shown	Catheter Adapter Colorant	Yellow
			Blue
			Pink
			Green
			Gray
			Orange
	D	Metal wedge	Stainless steel
	E	Catheter	Polyurethane (PU)
	F	Needle/Cannula	Stainless steel
	G	Needle cover	PP homopolymer
	Not Shown	Catheter Lube	Polydimethylsiloxane (PDMS)
	Not Shown	Catheter Tipping Lube	Aminopropyl terminatedPDMS
	Not Shown	Needle Lube	PDMS
	Not Shown	Wedge Lube	PDMS
	Not Shown	Adhesive	Epoxy resin
			Curing agent

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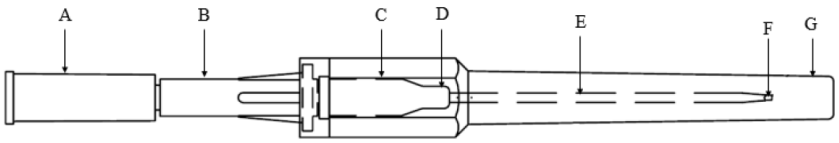


Figure 4: Key Functional Components of Angiocath™ IV Catheter

BD Catalogue Number	Component Identifier	Component	Material
381112 381123 381134 381137 381144 381147 381154 381157 381164 381167	A	Flashback Plug	Low Density Polyethylene
	B	Needle Hub	Cellulosic plastics (Cellulose Acetate Propionate) with high toughness, hardness, strength, surface gloss, and clarity
	C	Catheter Adapter	Polypropylene (PP) homopolymer
	D	Metal Wedge	Stainless steel
	E	Catheter	Fluorinated Ethylene Propylene
	F	Needle/Cannula	Stainless steel
	G	Needle cover	PP homopolymer
	Not Shown	Catheter Adapter Colorant	Yellow
			Blue
			Pink
			Green
			Gray
			Orange
	Not Shown	Catheter Lube	Polydimethylsiloxane (PDMS)
	Not Shown	Needle Lube	PDMS
	Not Shown	Catheter Tipping Lube	Aminopropyl terminated PDMS
	Not Shown	Wedge Lube	PDMS
	Not Shown	Adhesive	Epoxy resin
			Curing agent

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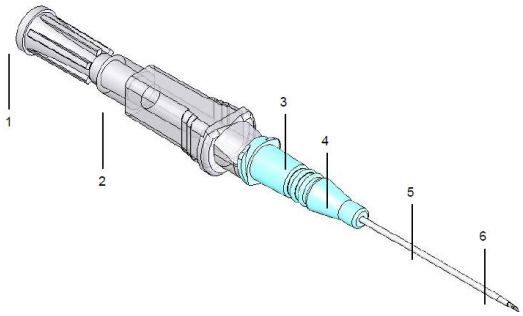


Figure 5: Main parts of the Angiocath™ IV Catheter (non-winged shown)

BD Catalogue Number	Component Identifier	Component	Material
382258 382259 382268 382269 382277 382287	1	Vent Plug	Polyethylene
	2	Needle Hub	Propionate
	3	Catheter Hub	Polypropylene
	4	Metal Wedge (not shown, inside catheter hub)	Stainless Steel
	5	Catheter Tubing	Fluorinated ethylene propylene with radiopaque barium sulfate
	6	Needle	Stainless Steel
	Not Shown	Needle Cover	Polypropylene

1.7 Materials of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment
Phthalates	Based on our ongoing data collection efforts and/or information received from our suppliers as per 05 August 2025, BD has not identified any 1,2-Benzenedicarboxylic acid, dihexyl ester (branched & linear) (CAS# 68515-50-4), 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters (CAS# 71888-89-6), 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (CAS# 68515-42-4), 1,2-Benzenedicarboxylic acid, di-C6-10 alkyl esters (CAS# 68515-51-5), 1,2-Benzenedicarboxylic acid, mixed decyl, hexyl, and octyl diesters (CAS# 68648-93-1), Benzyl butyl phthalate (BBP) (CAS# 85-68-7), Bis (2-ethylhexyl) phthalate (DEHP) (CAS# 117-81-7), Bis (2-methoxyethyl) phthalate (DMEP) (CAS# 117-82-8), Di-n-hexyl phthalate (DnHP) (CAS# 84-75-3), Dibutyl phthalate (DBP) (CAS# 84-74-2), Diisobutyl phthalate (DIBP) (CAS# 84-69-5),

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Material	Comment
	Diisopentyl phthalate (DIPP) (CAS# 605-50-5), Dipentyl phthalate (DPP) (CAS# 131-18-0), N-pentyl-isopentyl phthalate (CAS# 776297-69-9), or Dicyclohexyl phthalate (DCHP) (CAS# 84-61-7) in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% w/w.
Latex (euMDR Annex I Sections 13.3 and 23.4(s))	Based on our ongoing data collection efforts and/or information received from our suppliers as per 05 August 2025, natural rubber latex and latex are not part of the material formulation for the articles with the product numbers referenced above.
Bisphenol A (BPA)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 05 August 2025, BD has not identified any 4,4'-isopropylidenediphenol (BPA) (CAS# 80-05-7) in the article and packaging with the product numbers as referenced above, in an individual concentration above 0.1% (w/w). Bisphenol A (BPA), CAS# 80-05-7, is a component in a raw material used in the adhesive. Based on information from our suppliers and BD test results, the BPA level is less than 0.1% w/w (<1000 ppm). These levels are below a de minimis concentration with no demonstrable clinically significant exposure nor toxicity. No labeling for California Prop 65 is needed. No REACH SVHC declaration is required.
Animal Derivatives	The raw materials used in the manufacture of these devices do not contain any animal tissue but may contain very small amounts of chemicals that are derived from animal-derived raw materials. This product is manufactured using polymer resins which may contain very small amounts of stearic acid and related substances derived from tallow derivatives. Our resin suppliers have confirmed that these chemicals have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN ISO 22442-1:2020 and Section 6 of EMA 410/01 Rev. 3. Therefore, these raw materials meet or exceed the requirements of EN ISO 22442-1 and EMA 410/01 Rev. 3. Based on this information, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases. Furthermore, such derivative chemicals produced in accordance with the aforementioned standards and guidelines are considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC, MDR 2017/745, and EU No 722/2012).
Polyvinyl chloride (PVC)	Based on our ongoing data collection efforts and/or information received from our suppliers as per 20 April 2025, the medical devices referenced above have not been designed nor intentionally manufactured with any additives or raw materials that contain PVC. No PVC is intentionally added to these medical devices.
Heavy Metals in Packaging, according to TPCH/CONEG and EU 94/62/EC (2004)	Based on our ongoing data collection efforts and/or information received by our suppliers as per 05 August 2025, the product (devices & packaging) listed above conform with the requirements of TPCH/CONEG and Section 1.2 of RL 94/62/EC (2004).
RoHS directive, heavy metals and brominated flame retardants	It is BD's view that the above-referenced products do not meet the definition of electrical and electronic equipment as stated in Art. 3(1) of Directive 2011/65/EU ("EU RoHS") and, therefore, do not fall within the scope of the EU RoHS Directive. Based on our ongoing data collection efforts and/or information received from our suppliers as of 05 August 2025, there is no intentionally added lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, or polybrominated diphenyl ether in the above-listed products.

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1.8 REACH information

Based on our ongoing data collection efforts and/or information received from our suppliers as per 05 August 2025, BD has not identified any chemicals in the articles and packaging with the product numbers as referenced above, in an individual concentration above 0.1% weight by weight (w/w), which have been listed as SVHC and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 14 June 2023 according to Art. 59 (1,10) of the Regulation (EC) No 1907/2006 (REACH).

1.9 Biocompatibility

BD Medical products comply with the requirements of the standard for toxicity, pyrogenicity and biocompatibility of medical devices, ISO 10993 series - Biological Evaluation of Medical Devices.

1.10 Sterilisation method

All products included in this document are provided sterile and they are sterilised via Ethylene Oxide (EO).

1.11 Shelf life and storage conditions

The Insyte™ IV Catheters and Angiocath™ IV Catheters shelf life has been assessed by stability studies in order to verify the functionality, physico-chemical and microbial properties over time.
Insyte™ IV Catheters and Angiocath™ IV Catheters have a shelf life of **5 years**.
BD recommends to store in a dry and warm place, not exposed to strong light.

1.12 Applied Standards

As per the Technical Documentation of **Insyte™ IV Catheters (381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357)**:

Standard reference number	Title	Standard applied (Full or Partial)
Quality Standards		
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes	Full
Risk Management Standards		
ISO 14971: 2019	Medical devices - Application of risk management to medical devices	Full
Biocompatibility Standards		
EN ISO 10993-1:2020 / ISO 10993-1:2018, Corrected Version 10/2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-3:2014 / ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full
EN ISO 10993-4:2017 / ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	Full

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Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 10993-5:2009 / ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity	Full
EN ISO 10993-6:2016 / ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	Full
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation	Full
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitisation	Full
EN ISO 10993-11:2018/ ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Full
EN ISO 10993-12:2021/ ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Full
EN ISO 10993-17:2009/ ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	Full
EN ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterisation of medical device materials within a risk management process	Full
ISO 10993-18:2020/ AM 1:2022	Biological evaluation of medical devices — Part 18: Chemical characterisation of medical device materials within a risk management process — Amendment 1: Determination of the uncertainty factor	Full
Labeling Standards		
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	Full
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Full
Packaging/Distribution Standards		
ISO 11607-1:2019	Packaging for terminally sterilised medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
ISO 11607-2:2019	Packaging for terminally sterilised medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Full
Sterilisation Standards		
BS EN 556-1:2001	Sterilisation of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilised medical devices	Full
ISO 11135:2014	Sterilisation of health care products – Ethylene oxide: Requirements for the development, validation and routine control of a sterilisation process for medical devices	Full
EN ISO 10993- 7:2008/ AC:2009/AM 1:2022 / ISO 10993- 7:2008/ COR 1:2009/ AM 1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilisation residuals	Full
EN ISO 11737-1:2018/ A1:2021	Sterilisation of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1	Full

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Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 11737-2:2020	Sterilisation of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process	Full
Device Specific Standards		
ISO 594-1:1986*	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	Partial**
ISO 594-2:1998*	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings	Full
ISO 10555-1:2013	Sterile, single-use intravascular catheters - Part 1: General requirements	Full
ISO 10555-5:2013	Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters	Partial***
Other Standards		
EN ISO 22442-1:2020	Medical devices utilising animal tissues and their derivatives - Part 1: Application of risk management	Full
IEC/EN 62366-1:2015+AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices	Full
EN ISO 14644-1:2015 / ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	Full
EN ISO 14644-2:2015 / ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
ISO14001:2015	Environmental Management System	Full
Other Guidelines		
EMA 410/01	Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Full
MEDDEV 2.7/1 Rev 4	Clinical Evaluation: A guide for manufacturers and notified bodies Under directives 93/42/EEC and 90/385/EEC	Full
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC – A guide for manufacturers and notified bodies April 2020	Full
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies April 2020	Full
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies April 2020	Full
MDCG 2021-24	Guidance on classification of medical devices - October 2021	Full
Other Regulations		
(EU) No 207/2012	Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices	Full
(EU) 2021/2226	Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	Full

* Luer connector for the device is compliant to ISO 594 -1 and ISO 594-2. Test activities for evaluating compliance to ISO 80369-7 are ongoing.

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** Insyte™ products are designed with a female conical fitting but do not meet ISO 594-1 Section 4.1.2 Gauging (Female Conical Fitting) requirements.
*** ISO 10555-5, Section 4.3.3.1: product meets ISO 9626 with exception to stiffness, and resistance to breakage.

As per the Technical Documentation of **Angiocath™ IV Catheters (381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164 and 381167)**:

Standard reference number	Title	Standard applied (Full or Partial)
Quality Standards		
ISO 13485:2016 / NS-EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes	Full
Risk Management Standards		
ISO 14971: 2019	Medical devices - Application of risk management to medical devices	Full
Biocompatibility Standards		
EN ISO 10993-1:2020 / ISO 10993-1:2018, Corrected Version 10/2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-2:2006 / ISO 10993-2:2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements	Full
EN ISO 10993-3:2014 / ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full
EN ISO 10993-4:2017 / ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	Full
EN ISO 10993-5:2009 / ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity	Full
EN ISO 10993-6:2016 / ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	Full
EN ISO 10993-9:2021 / ISO 10993-9:2019	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products	Full
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation	Full
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitisation	Full
EN ISO 10993-11:2018/ ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Full
EN ISO 10993-12:2021/ ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Full
EN ISO 10993-13:2010/ ISO 10993-13:2010	Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices	Full
EN ISO 10993-15:2009	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys	Full
ISO 10993-15:2019	Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys	Full

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Standard reference number	Title	Standard applied (Full or Partial)
EN ISO 10993-17:2009/ ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	Full
EN ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterisation of medical device materials within a risk management process	Full
ISO 10993-18:2020/AM 1:2022	Biological evaluation of medical devices — Part 18: Chemical characterisation of medical device materials within a risk management process — Amendment 1: Determination of the uncertainty factor	Full
EN ISO 10993-23:2021/ ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation	Full
Labeling Standards		
ISO 15223-1:2016, Corrected version 2017-03	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Full
BS EN 1041:2008	Information supplied by the manufacturer of medical devices	Full
Packaging/Distribution Standards		
ISO 11607-1:2019	Packaging for terminally sterilised medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Full
Sterilization Standards		
BS EN 556-1:2001	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilised medical devices	Full
ISO 11135:2014	Sterilization of health care products – Ethylene oxide: Requirements for the development, validation and routine control of a sterilisation process for medical devices	Full
EN ISO 10993- 7:2008/ AC:2009/AM 1:2022 / ISO 10993- 7:2008/ COR 1:2009/ AM 1:2019	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilisation residuals	Full
EN ISO 11737-1:2018/A1:2021	Sterilisation of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products – Amendment 1	Full
EN ISO 11737-2:2020	Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process	Full
Device Specific Standards		
ISO 594-1:1986*	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	Partial
ISO 594-2:1998*	Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings	Partial
ISO 10555-1: AMD 1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements – Amendment 1	Partial
ISO 10555-5:2013	Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters	Partial

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Standard reference number	Title	Standard applied (Full or Partial)
Other Standards		
EN ISO 22442-1:2020	Medical devices utilising animal tissues and their derivatives - Part 1: Application of risk management	Full
IEC/EN 62366-1:2015+AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices	Full
EN ISO 14644-1:2015 / ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	Full
EN ISO 14644-2:2015 / ISO 14644-2:2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
Other Guidelines		
EMA 410/01	Minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Full (Section 6)
MEDDEV 2.7/1 Rev 4	Clinical Evaluation: A guide for manufacturers and notified bodies Under directives 93/42/EEC and 90/385/EEC	Full
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC – A guide for manufacturers and notified bodies April 2020	Full
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template – A guide for manufacturers and notified bodies April 2020	Full
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies April 2020	Full
MDCG 2021-24	Guidance on classification of medical devices - October 2021	Full
ISO14001:2015	Environmental Management System	Full
Other Regulations		
(EU) No 207/2012	Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices	Full
(EU) 2021/2226	Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	Full

*Luer connector for the device is compliant to ISO 594 -1 and ISO 594-2. Test activities for evaluating compliance to ISO 80369-7 are ongoing.

As per the Technical Documentation of **Angiocath™ IV Catheters (382258, 382259, 382268, 382269, 382277 and 382287):**

Standard reference number	Title
Harmonised Standards	
EN ISO 14971:2019 (ISO 14971:2019)	Medical devices - Application of risk management to medical devices
EN ISO 13485:2016 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 20594-1:1993 (ISO 594-1:1986*)	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements

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Standard reference number	Title
EN ISO 10555-1:2009 (ISO 10555-1:2013), except Section 4.4 (visible drops)	Sterile, single-use intravascular catheters - Part 1: General requirements
EN ISO 10993-1:2009 (ISO 10993-1:2009)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014 (ISO 10993-3:2014)	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity
EN ISO 10993-7:2008 (ISO 10993-7:2008)	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilisation residuals
EN ISO 10993-11:2018 (ISO 10993-11:2017)	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012 (ISO 10993-12:2012)	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-17:2009 (ISO 10993-17:2002)	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009 (ISO 10993-18:2005)	Biological evaluation of medical devices - Part 18: Chemical characterisation of materials
EN ISO 11607-1:2009 (ISO 11607-1:2006)	Packaging for terminally sterilised medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006 (ISO 11607-2:2006)	Packaging for terminally sterilised medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135-1:2007 (ISO 11135-1:2007)	Sterilisation of health care products — Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices
EN 556-1:2001/AC:2006	Sterilisation of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilised medical devices
EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03)	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices
EN ISO 11607-1:2020 (ISO 11607-1:2019)	Packaging for terminally sterilised medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020 (ISO 11607-2:2019)	Packaging for terminally sterilised medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO14001:2015	Environmental Management System
Non-Harmonised Standards	
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
ISO 10555-5:2013	Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters
ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitisation

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Standard reference number	Title
ISO 23908:2011	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

*Luer connector for the device is compliant to ISO 594 -1 and ISO 594-2. Test activities for evaluating compliance to ISO 80369-7 are ongoing.

Note:
The above standards reflect the status at time of document release.

1.13 Classification

- **Insyte™ IV Catheters** (381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357) and **Angiocath™ IV Catheters** (381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164, 381167) are classified as Class IIa medical devices under Rule 7 of MDR (EU) 2017/745 Annex VIII, no other rules apply.
- **Angiocath™ IV Catheters** (382258, 382259, 382268, 382269, 382277, 382287) are classified as Class IIa medical devices under Rule 7 of Annex IX of the Council Directive 93/42/EEC, as amended, based on the intended use of the device.

1.14 Medical Device Nomenclature

GMDN Code: 64574
GMDN Term: Peripheral intravenous cannula

1.15 Manufacturing practices

The entire manufacturing and testing processes are following the Manufacturing Practices as specified below:

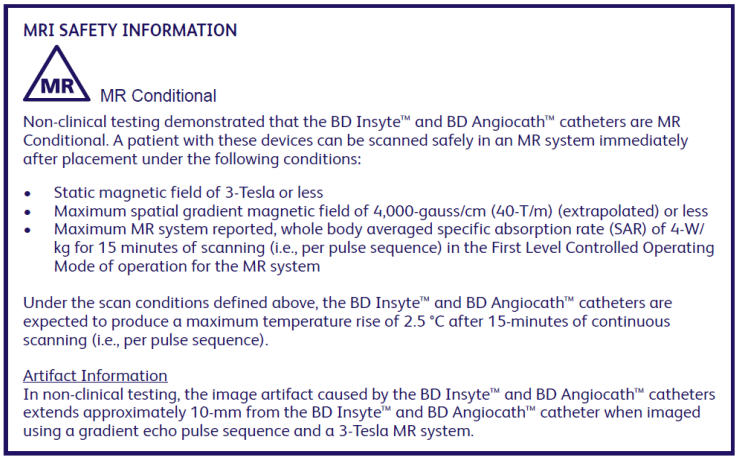
- Incoming raw materials are verified via material inspection and testing and our suppliers are approved via our vendor management system.
- In addition to the automatic on-line inspections, in-process inspections are performed in addition to final product testing to ensure compliance with approved specifications.
- The manufacturing and testing details of each batch of product are recorded on a batch record which is retained in accordance with our document control procedures.
- BD operates a system of internal and external audits to maintain compliance.
- BD confirms that it will continue to adhere to relevant international standards in designing and manufacturing its products.

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1.16 Other information

- Safety Data Sheets are not required for this product.
- Certificate of Food Contact (Commission Regulation EU 1183/2012 on "plastic materials and articles intended for contact with food" and Directive 2002/72/CE (as amended) "relating to plastic materials and articles intended to come into contact with foodstuffs") is not required as BD products are used for general purpose injection and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin.
- Good Manufacturing Practices as defined by the EU Pharmaceutical is not applicable for Medical Devices.
- All products included in this document are MRI compatible:



MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing demonstrated that the BD Insyte™ and BD Angiocath™ catheters are MR Conditional. A patient with these devices can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

Under the scan conditions defined above, the BD Insyte™ and BD Angiocath™ catheters are expected to produce a maximum temperature rise of 2.5 °C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information

In non-clinical testing, the image artifact caused by the BD Insyte™ and BD Angiocath™ catheters extends approximately 10-mm from the BD Insyte™ and BD Angiocath™ catheter when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

2. Packaging

2.1 Packaging configuration

BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
381311	Insyte-N™ IV Catheter 24G x 0.56in (14mm)	1	50	200	Yes
381211	Insyte-N™ IV Catheter with wings 24G x 0.56in (14mm)	1	50	200	Yes
381212	Insyte™ IV Catheter 24G x 0.75in (19mm)	1	50	200	Yes
381223	Insyte™ IV Catheter 22G x 1.00in (25mm)	1	50	200	Yes
381234	Insyte™ IV Catheter 20G x 1.16in (30mm)	1	50	200	Yes
381237	Insyte™ IV Catheter 20G x 1.88in (48mm)	1	50	200	Yes
381244	Insyte™ IV Catheter 18G x 1.16in (30mm)	1	50	200	Yes
381247	Insyte™ IV Catheter 18GA x 1.88in (48mm)	1	50	200	Yes
381257	Insyte™ IV Catheter 16G x 1.77in (45mm)	1	50	200	Yes
381267	Insyte™ IV Catheter 14G x 1.75in (45mm)	1	50	200	Yes
381312	Insyte-W™ IV Catheter with wings 24G x 0.75in (19mm)	1	50	200	Yes
381323	Insyte-W™ IV Catheter with wings 22G x 1.00in (25mm)	1	50	200	Yes
381334	Insyte-W™ IV Catheter with wings 20G x 1.16in (30mm)	1	50	200	Yes

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BD Catalogue Number	BD Product Description	Primary Packaging (Qty)	Shelf Box (Qty)	Shipping Case (Qty)	IFU Insert N/A / Yes / No*
381337	Insyte-W™ IV Catheter with wings 20G x 1.88in (48mm)	1	50	200	Yes
381344	Insyte-W™ IV Catheter with wings 18G x 1.16in (30mm)	1	50	200	Yes
381347	Insyte-W™ IV Catheter with wings 18G x 1.88in (48mm)	1	50	200	Yes
381357	Insyte-W™ IV Catheter with wings 16G x 1.77in (45mm)	1	50	200	Yes
381112	Angiocath™ IV Catheter 24G x 0.75in (19mm)	1	50	200	Yes
381123	Angiocath™ IV Catheter 22G x 1.00in (25mm)	1	50	200	Yes
381134	Angiocath™ IV Catheter 20G x 1.16in (30mm)	1	50	200	Yes
381137	Angiocath™ IV Catheter 20G x 1.88in (48mm)	1	50	200	Yes
381144	Angiocath™ IV Catheter 18G x 1.16in (30mm)	1	50	200	Yes
381147	Angiocath™ IV Catheter 18G x 1.88in (48mm)	1	50	200	Yes
381154	Angiocath™ IV Catheter 16G x 1.16in (30mm)	1	50	200	Yes
381157	Angiocath™ IV Catheter 16G x 1.88in (48mm)	1	50	200	Yes
381164	Angiocath™ IV Catheter 14G x 1.16in (30mm)	1	50	200	Yes
381167	Angiocath™ IV Catheter 14G x 1.88in (48mm)	1	50	200	Yes
382258	Angiocath™ IV Catheter for Special Placement 16G x 3.25in (83mm)	1	10	50	Yes
382259	Angiocath™ IV Catheter for Special Placement 16G x 5.25in (133mm)	1	10	50	Yes
382268	Angiocath™ IV Catheter for Special Placement 14G x 3.25in (83mm)	1	10	50	Yes
382269	Angiocath™ IV Catheter for Special Placement 14G x 5.25in (133mm)	1	10	50	Yes
382277	Angiocath™ IV Catheter for Special Placement 12G x 3.00in (76mm)	1	10	50	Yes
382287	Angiocath™ IV Catheter IV Catheter for Special Placement 10G x 3.00in (76mm)	1	10	50	Yes

*"No": IFU may be available but not as an insert.

2.2 Packaging materials

BD Catalogue Numbers	Component	Material
381212, 381223, 381234, 381237, 381244, 381247, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357, 381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164, 381167	Top Web	Tyvek or Medical grade paper
	Bottom Web	Thermoformable Nylon based film
	Shelf Pack	Clay coated news white printing surface, gray liner or Solid unbleached sulphate, white printing surface, brown liner
	Shipping Case	Natural Kraft
382258, 382259, 382268, 382269, 382277, 382287	Top Web	Medical grade paper
	Bottom Web	Thermoformable Nylon based film
	Shelf Pack	Clay coated news white printing surface, gray liner or Solid unbleached sulphate, white printing surface, brown liner
	Shipping Case	Natural Kraft

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2.3 Recycled materials in packaging

-Recyclability of Packaging: The secondary and tertiary portions of the packaging are recyclable. Some portions of the primary packaging may only be recyclable in the communities that have appropriate recycling facilities, and some portions of the package may not be recyclable.

BD Catalogue Number	Packaging Type	Recyclability
381212, 381223, 381234, 381237, 381244, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357, 381112, 381123 381134, 381137, 381144, 381147, 381154, 381157, 381164, 381167, 382258, 382259, 382268, 382269, 382277, 382287	Primary Packaging: Multilayer laminate plastic and paper	Two materials – designed to be peeled apart
		This grade of paper is not suitable for current mechanical recycling processes. It may be disposed in other non-regulated mixed waste streams, as permitted by local regulation.
		Multilayer laminate is recyclable through monomer recovery recycling methods
	Secondary Packaging: Dispenser Box	Cardboard is recyclable
	Tertiary Packaging: Shipper Box	Cardboard is recyclable

-Recycled Content:

BD Catalogue Number	Secondary Packaging Recycled Content (Shelf Box)	Tertiary Packaging Recycled Content (Case Carton)
381311	100%	100%
381211	100%	100%
381212	100%	100%
381223	100%	100%
381234	100%	100%
381237	100%	100%
381244	100%	100%
381247	100%	100%
381257	100%	100%
381267	100%	100%
381312	100%	100%
381323	100%	100%
381334	100%	100%
381337	100%	100%
381344	100%	100%
381347	100%	100%
381357	100%	100%
381112	Unknown	Unknown
381123	Unknown	100%
381134	Unknown	100%
381137	Unknown	100%
381144	Unknown	100%
381147	Unknown	100%
381154	Unknown	55%
381157	100%	55%
381164	Unknown	55%
381167	100%	55%
382258	100%	55%

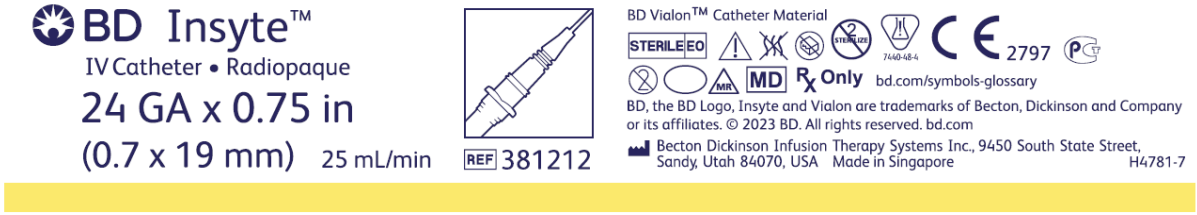
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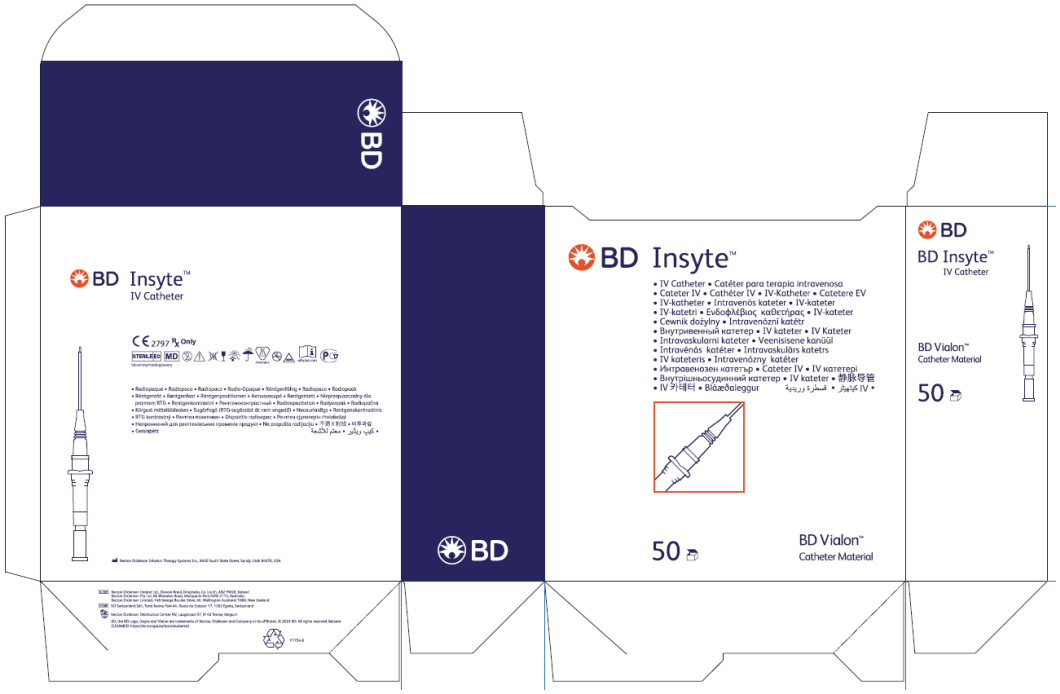
BD Catalogue Number	Secondary Packaging Recycled Content (Shelf Box)	Tertiary Packaging Recycled Content (Case Carton)
382259	100%	55%
382268	100%	55%
382269	100%	55%
382277	100%	55%
382287	100%	55%

2.4 Examples of labelling

Unit Label extracted from document H4781 rev. 07 / version G related to reference 381212:



Shelf Box (Secondary Packaging) extracted from document F1754 rev. 08 / version E related to reference 381212:



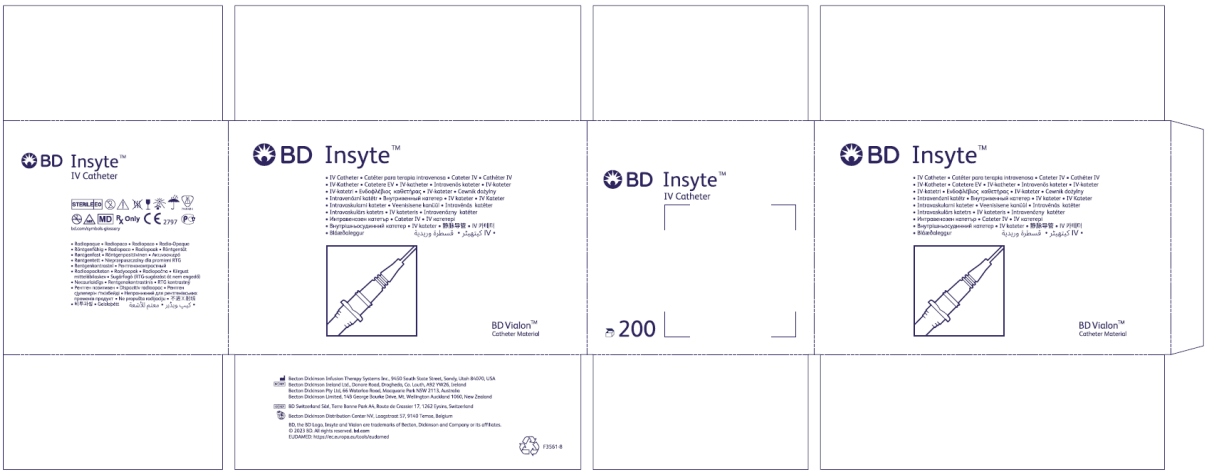
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Shelf Box label extracted from document D13598 rev. 05 / version C related to reference 381212:



Case Box (Tertiary Packaging) extracted from document F3561 rev. 08 / version E related to reference 381212:



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Case Box label extracted from document D13599 rev. 05 / version C related to reference 381212:

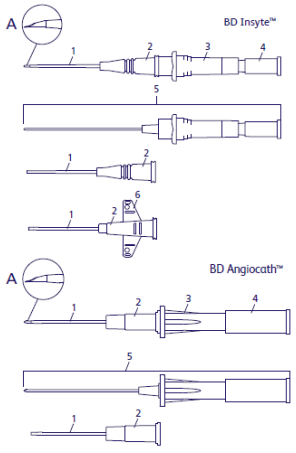


IFU insert (English part only) extracted from document D17949 rev. 03 / version C related to reference 381212:
For the whole document, where other languages are included, please refer to: eifu.bd.com

BD

BD Insyte™ BD Insyte-N™ BD Angiocath™ IV Catheter

D17949-3 REV. 2023-06



		Gravity Flow Rate	Maximum Power Injector Pressure Limit Setting
BD Insyte-N™	24 GA x 0.56 in (0.7 x 14 mm)	25 mL/min (1500 mL/hr)	Not for use with power injectors
BD Insyte™ BD Insyte-W™	24 GA x 0.75 in (0.7 x 19 mm)	25 mL/min (1500 mL/hr)	
	22 GA x 1.00 in (0.9 x 25 mm)	35 mL/min (2100 mL/hr)	300 psi (2068 kPa)
	20 GA x 1.00 in (1.1 x 25 mm)	65 mL/min (3900 mL/hr)	
	20 GA x 1.16 in (1.1 x 30 mm)	60 mL/min (3600 mL/hr)	
	20 GA x 1.88 in (1.1 x 48 mm)	55 mL/min (3300 mL/hr)	
	18 GA x 1.16 in (1.3 x 30 mm)	105 mL/min (6300 mL/hr)	
	18 GA x 1.88 in (1.3 x 48 mm)	95 mL/min (5700 mL/hr)	
	16 GA x 1.16 in (1.7 x 30 mm)	220 mL/min (13200 mL/hr)	Not for use with power injectors
	16 GA x 1.77 in (1.7 x 45 mm)	205 mL/min (12300 mL/hr)	
BD Insyte™	14 GA x 1.75 in (2.1 x 45 mm)	330 mL/min (19800 mL/hr)	
BD Angiocath™	24 GA x 0.75 in (0.7 x 19 mm)	17 mL/min (1020 mL/hr)	
	22 GA x 1.00 in (0.8 x 25 mm)	28 mL/min (1680 mL/hr)	
	20 GA x 1.16 in (1.1 x 30 mm)	49 mL/min (2940 mL/hr)	
	20 GA x 1.88 in (1.1 x 48 mm)	42 mL/min (2520 mL/hr)	
	18 GA x 1.16 in (1.3 x 30 mm)	86 mL/min (5160 mL/hr)	
	18 GA x 1.88 in (1.3 x 48 mm)	79 mL/min (4740 mL/hr)	
	16 GA x 1.16 in (1.7 x 30 mm)	156 mL/min (9360 mL/hr)	
	16 GA x 1.88 in (1.7 x 48 mm)	147 mL/min (8820 mL/hr)	
	14 GA x 1.16 in (2.1 x 30 mm)	295 mL/min (17700 mL/hr)	
	14 GA x 1.88 in (2.1 x 48 mm)	277 mL/min (16620 mL/hr)	

en
Gravity Flow Rate. Maximum Power Injector Pressure Limit Setting. Not for use with power injectors.

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IV Catheter – Instructions for Use

DEVICE DESCRIPTION

BD Insyte™ and BD Angiocath™ IV catheters are conventional (non-safety) over-the-needle intravascular catheters. BD Insyte™ devices have a radiopaque BD Vialon™ catheter. BD Angiocath™ devices have a radiopaque fluorinated ethylene propylene (FEP) catheter. Both devices include a needle and flash chamber with removable vent plug. The needle and catheter are protected by a needle cover.

The flash chamber on both devices provides confirmation that the device has entered the vessel. In addition, BD Insyte-N™ devices have BD Instaflash™ Needle Technology allowing for immediate visualization of blood along the catheter.

BD Insyte™ and BD Angiocath™ devices are available without wings; BD Insyte-W™ devices are only available with wings (3); and BD Insyte-N™ devices are available with or without wings. The catheter hub and wings are color coded to indicate catheter gauge size.

The 22-18GA (0.9-1.3 mm) BD Insyte™ devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa).

INDICATIONS FOR USE (USA) / INTENDED PURPOSE

An intravascular catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

CLINICAL BENEFITS

- Provides short term vascular access to facilitate blood sampling to aid in patient treatment, management, and diagnosis.
- Provides short term vascular access to facilitate blood pressure monitoring to aid in patient treatment, management, and diagnosis.
- Provides short term vascular access to facilitate the administration of IV fluids (e.g., fluids, medication, blood product) to aid in patient treatment/management.
- For BD Insyte™ IV Catheter and BD Insyte-W™ IV Catheter gauges 22-18 (0.9-1.3mm) only:
  - Provides short term vascular access to facilitate power injection of contrast media set to a maximum pressure of 300 psi (2068 kPa) to aid in patient treatment, management, and diagnosis.

CONTRAINDICATIONS

- None known.

GENERAL WARNINGS

- Intended for single patient use only.
- Do not resterilize.
- DO NOT RE USE. Re use may lead to infection or other illness/injury.
- Exposure to blood, either through percutaneous puncture with a contaminated needle or via mucous membranes or non-intact skin, may lead to serious illness such as hepatitis, HIV (AIDS), or other infectious diseases.
- Do not leave Luer slip connections unattended as they may become disconnected and result in blood exposure or blood loss.
- The 24 GA (0.7 mm), 16 GA (1.7 mm), or 14 GA (2.1 mm) BD Insyte™ catheters should not be used with power injectors.
- Small parts are a potential choking hazard. After use, discard small parts according to your facility policy.
- Potential complications related to the insertion and use of PIVC include but are not limited to: abscess, air embolism, blood exposure, blood loss / leakage, blood stream infection, bruising, catheter breakage / embolization, choking, death, delay or interruption of treatment, discomfort, edema, exposure to non-hazardous / hazardous drugs, hematoma, hemolysis during blood draw, hemorrhage, inaccurate dose, infusate leakage , localized infection, needle stick injury, pain at injection site, particulate infusions, permanent ischemic damage, persistent pain, phlebitis, pseudoaneurysm, second arterial cannula insertion, slow flow rate infusion, syncope / fainting, thrombophlebitis, thrombosis, unsuccessful insertion, vessel infiltration / extravasation, and wrong medication dose / type.

GENERAL PRECAUTIONS

- Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- For proper use, clinicians should be trained in vascular access and use of these catheters.
- Use these catheters in conjunction with your facility policy.
- Ensure aseptic technique, proper skin preparation, and continued protection of the site consistent with accepted standards of practice and your facility policy.
- Replace catheter according to your facility policy, relevant guidelines, or if the integrity of the device has been compromised.
- Follow Universal/Standard Precautions when inserting, maintaining, and removing these catheters to prevent exposure to bloodborne pathogens.
- Adhere to all contraindications, warnings, precautions, and instructions for all infusates, as specified by their manufacturer.
- Do not bend the needle before or during use.
- Do not use scissors or other sharp instruments at or near the insertion site.
- Use only with ISO compliant Luer connections. Non-ISO compliant Luer connections may cause leakage
- Do not overtighten ISO Luer connections as damage may occur.
- EU Only: Users should report any serious incident related to the device to the Manufacturer and National Competent Authority.

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing demonstrated that the BD Insyte™ and BD Angiocath™ catheters are MR Conditional. A patient with these devices can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode of operation for the MR system

Under the scan conditions defined above, the BD Insyte™ and BD Angiocath™ catheters are expected to produce a maximum temperature rise of 2.5 °C after 15-minutes of continuous scanning (i.e., per pulse sequence).

Artifact Information

In non-clinical testing, the image artifact caused by the BD Insyte™ and BD Angiocath™ catheters extends approximately 10-mm from the BD Insyte™ and BD Angiocath™ catheter when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

HAZARDOUS SUBSTANCES INFORMATION

7440-48-4 Contains Hazardous Substances

This device contains the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

INSTRUCTIONS

Catheter Insertion and Removal

1. Examine unit package before opening to confirm its integrity. **PRECAUTION:** Do not use if package is damaged or opened or if the expiration date has passed.
2. Prepare insertion site according to your facility policy.
3. Open package and remove device by grasping the grip (3).
4. Inspect device for damage before insertion. Ensure vent plug (4) is secure. **PRECAUTION:** Do not use if device is damaged.
5. Hold grip (3) and remove needle cover in a straight, outward motion. Discard needle cover according to your facility policy.
6. Hold grip (3) and rotate catheter hub (3) to loosen the catheter tubing (1) from the needle. Ensure the catheter tip is positioned behind the needle bevel and the needle bevel is oriented upward.
7. Access vessel. **WARNING:** If the needle is partially or completely withdrawn from the catheter tubing (1) during insertion, do not re-insert the needle into the catheter tubing (1) as damage may occur.
8. Observe blood return in flash chamber within the grip (3).
9. Decrease angle of insertion and advance catheter slightly to ensure the catheter tip is within the vessel.
10. Advance catheter off the needle into the vessel.
11. Stabilize catheter by gently pressing the catheter hub (2) to the skin. Apply venous compression while pulling needle (5) out of the catheter. Discard needle (5) into a puncture-resistant, leak-proof sharps container.
12. Maintain venous compression and securely connect a Luer device to the catheter hub (2).
13. Flush or begin infusion. **WARNING:** Apply venous compression before disconnecting Luer device from the catheter hub (2) to prevent blood leakage.
14. Stabilize catheter and apply a sterile dressing according to your facility policy.
15. Upon catheter removal, examine catheter tubing (1) to ensure it is intact and discard entire device according to your facility policy.

Power Injection for 22–18GA (0.9-1.3mm) BD Insyte™ catheters only

NOTE: If power injecting through an access port, ensure access port is capable of power injection.

1. Ensure catheter patency according to your facility policy immediately before power injection. **WARNING:** Failure to ensure patency of the catheter immediately before power injection may result in catheter failure and/or extravasation.
2. Avoid kinking or obstructing catheter during power injection. **WARNING:** In the event of an occlusion, power injector pressure-limiting features may not prevent catheter failure.

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Бектон Дикинсон Инфьюжн Терапи Системс Инк. Санди, Юта 84070 США

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Becton Dickinson İth. İhr. Ltd. Şti., Rüzgarlıbahçe Mahallesi, Ş. Sinan Eroğlu Cad. No:6, Akel İş Merkezi, A Blok, 3. Kat, 34805 Kavacık Beykoz – İstanbul, Türkiye

EUDAMED: https://ec.europa.eu/tools/eudamed

7440-48-4 Contains hazardous substances
Contient des substances dangereuses

elfu.bd.com Consult instructions for use or consult electronic instructions for use
Consulter la notice d'utilisation ou consulter la notice d'utilisation électronique

Do not resterilize
Ne doit pas être restérilisé

MR Conditional
Compatible avec l'IRM sous conditions

CH REP Authorized representative in Switzerland
Représentant autorisé en Suisse

Packaging unit
Emballage

Importer
Importador

Declaration of conformity GOST R
Déclaration de conformité GOST R

CE 2797

STERILE EO Sterilized using ethylene oxide
Stérilisé à l'oxyde d'éthylène

LOT Batch code
Code de lot

REF Catalogue number
Numéro de référence

Use-by date
Utiliser avant

Non-pyrogenic
Apyrogène

Do not use if package is damaged
Ne pas utiliser si l'emballage est endommagé

Do not re-use
Ne pas réutiliser

Caution, consult instructions for use
Attention, consulter les instructions d'utilisation

Fragile, handle with care
Fragile, manipuler avec soin

Keep away from sunlight
Conserver à l'abri de la lumière du soleil

Keep dry
Conserver au sec

Manufacturer
Fabricant

Date of manufacture
Date de fabrication

EC REP Authorized representative in the European Community
Représentant autorisé dans la Communauté européenne

MD Medical device
Dispositif médical

Single sterile barrier system
Système à barrière stérile unique

℞ Only
- Prescription use only • Uso exclusivamente bajo prescripción
- Sujeito a receita médica • Exclusivement sur ordonnance
- Verschreibungspflichtig • Usare solo dietro prescrizione
- Uitsluitend op voorschrift gebruiken • Endast receptbelagda
- Receptpligtig • Käyttö vain lääkärin määräyksestä
- Χρήση μόνο με ιατρική συνταγή • Brukes kun på resept
- Wyłącznie na receptę • Použití pouze na lékařský předpis
- Применять только по назначению врача
- Samo na liječnički recept • Sadece Reçeteli Olarak Kullanılır
- Uporaba samo na naročilnico • Kasutamine ainult retsepti alusel
- Kizárólag orvosi rendelvényre használható • Tik pagal receptą
- Len na písomný lekársky poukaz • Само за употреба по предписание
- Utilizare numai pe bază de rețetă medicală
- Upotreba samo uz recept lekara • 仅限处方用 • 처방 전용
- للاستخدام بناءً على وصفة طبية فقط •

- Recyclable packaging • Embalaje reciclable • Embalagem reciclável
- Emballage recyclable • Wiederverwendbare Verpackung
- Materiali di confezionamento riciclabili • Recyclebare verpakking
- Återanvändbar förpackning • Genanvendelig emballage
- Kierrätettävä pakkaus • Ανακυκλώσιμη συσκευασία
- Resirkulerbar pakning • Opakowanie nadające się do recyklingu
- Recyklovatelný obal • Упаковка пригодна для вторичной переработки • Pakiranje se može reciklirati • Geri dönüşümlü ambalaj
- Embalaža, ki jo je mogoče reciklirati • Taasringluspakend
- Újrahasznosítható csomagolás • Perdirbamoji pakuotė
- Recyklovateľný obal • Рециклируема опаковка • Ambalaj reciclabil
- Reciklirajuće pakovanje • 可回收包装 • 재활용 포장
- عبوة قابلة لإعادة التدوير •

bd.com/symbols-glossary

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Title: EMEA - EEA, UK and CH -Technical Data Sheet (TDS) Form	

REVISION	CHANGE SUMMARY
01	Initial release according to TDS template EMEA-SOP-F1 Rev02 based on Technical Documentation: - PIV-STED-007 Rev.03/Ver.C – September 2024 o Insyte™ IV Catheters (381212, 381223, 381234, 381237, 381244, 381257, 381267, 381211, 381311, 381312, 381323, 381334, 381337, 381344, 381347, 381357) - PIV-STED-013 Rev.04/Ver.D– February 2025 o Angiocath™ IV Catheters (381112, 381123, 381134, 381137, 381144, 381147, 381154, 381157, 381164 and 381167) - TFCE-42 Ver.V– March 2025 o Angiocath™ IV Catheters (382258, 382259, 382268, 382269, 382277 and 382287)

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