



TECHNICAL DATA SHEET

BD™ Pen Needles

BD Micro-Fine™ + Pen Needles

BD Micro-Fine™ *Plus* Pen Needles

BD Micro-Fine Ultra™ Pen Needles

BD Micro-Fine Ultra™ PRO Pen Needles

BD Ultra-Fine™ Pen Needles

BD Ultra-Fine™ PRO Pen Needles

BD Ultra-Fine™ 2nd Gen

BD Nano™

BD Viva™ Pen Needles

Sterile, Single use, Latex Free

GENERAL INFORMATION

The pen needles are single use sterile device designed for the parenteral administration of a drug from a cartridge contained in a drug pen injector. The pen injectors are themselves designed for the self-administration of a drug by a patient in the home setting. They may equally be used in a hospital but drug cartridges must not be shared between patients.

The first and major application is the subcutaneous administration of insulin.

Reference	Polybag (units)	Box (units)	Shipper (units)
0,33 mm (29G) x 12,7 mm			
320188	-	100	1200
320189	-	100	1200
320207	-	100	1200
320216	-	100	1200
320304	5	100	500
325118	-	100	1200
0,30 mm (30G) x 8 mm			
320214	-	100	1200
320305	5	100	500
320517	-	100	1200
320519	-	100	1200
320591	-	100	1200
320940	-	100	1200
0,25 mm (31G) x 8 mm			
320213	-	100	1200
320423	-	90	1080
320499	-	100	1200
320524	-	105	1260
320592	-	100	1200
320593	-	100	1200
320631	-	100	1200
320648	-	100	1200
320651	5	100	500



Reference	Polybag (units)	Box (units)	Shipper (units)
320792	-	100	1200
324836	-	90	1080
324839	-	100	1200
325108	-	100	1200
0,25 mm (31G) x 6 mm			
320523	-	105	1260
320733	-	100	1200
320734	-	100	1200
320736	-	100	1200
320737	-	100	1200
320739	-	90	1080
320743	-	100	1200
320824	-	100	1200
320952	5	100	500
324837	-	90	1080
0,25 mm (31G) x 5 mm			
320212	-	100	1200
320408	-	90	1080
320424	-	90	1080
320433	-	100	1200
320498	-	100	1200
320518	-	100	1200
320522	-	105	1260
320535	-	100	1200
320569	-	100	1200
320586	-	100	1200
320587	-	100	1200
320590	-	100	1200
320594	-	100	1200
320595	-	100	1200
320632	-	100	1200
320647	-	100	1200
320650	5	100	500
320794	-	100	1200
320795	-	100	1200
320938	-	100	1200
324835	-	90	1080
324840	-	100	1200
325107	-	100	1200
0,23 mm (32G) x 6mm			
320696	-	100	1200
320697	-	100	1200
320698	-	105	1260
320953	-	100	1200
320954	-	90	1080
0,23 mm (32G) x 4mm			
320137	-	100	1200
320139	-	100	1200
320140	-	100	1200
320141	-	100	1200
320143	5	100	500

Reference	Polybag (units)	Box (units)	Shipper (units)
320211	-	100	1200
320407	-	90	1080
320425	-	90	1080
320426	5	100	500
320434	-	100	1200
320435	-	100	1200
320497	-	100	1200
320500	-	100	1200
320520	-	100	1200
320561	-	105	1260
320562	-	100	1200
320564	5	100	500
320566	-	100	1200
320571	5	100	500
320575	-	100	1200
320584	-	100	1200
320585	-	100	1200
320646	-	100	1200
320649	5	100	500
320824	-	100	1200
324838	-	100	1200
325103	-	100	1200
325106	-	100	1200
325115	5	100	500

❖ **GMDN:**

- GMDN code: 44127
- GMDN term: Autoinjector needle

❖ **MATERIALS:**

Component	Material
Cannula	Stainless steel (Medical Grade)
Cannula lubricant	Silicone, Catalysed – Patient end Silicone, Uncatalysed – Non-Patient end
Cannula adhesive	Ultraviolet Curing Adhesive
Hub	Polypropylene
Needle shield	Polyethylene or Polypropylene + Colour Concentrate
Cover	Polyethylene or Polypropylene
Unit label – sterility barrier	Paper / Copolymer Foil
Packaging components	Polybag – Polyethylene or PET Shelf-box – Paperboard Shipping carton – Corrugated Paperboard

The products do not contain natural rubber latex.



✧ **LABELING:** according to European Medical Device Directive 93/42/EEC

✧ **STERILIZATION:** Irradiation (gamma)

Validation studies were carried out in compliance with the following international standards:

- EN 556-1 Sterilization of medical devices – Requirements for medical devices to be designated ‘STERILE’ – Part 1: Requirements for terminally sterilized medical devices
- EN ISO 11137-1 Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11137-2 Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose
- EN ISO 11737-1 Sterilization of medical devices – Microbial methods- Part 1: Determination of a population of microorganisms on products
- EN ISO 11737-2 Sterilization of medical devices – Microbiological methods –Part 2: Tests of sterility performed in the validation of a sterilization process

✧ **SHELF LIFE:** 5 years after sterilization

✧ **STORAGE CONDITIONS:** There is no specific storage conditions required for this product.

✧ **QUALITY CONTROLS:**

Incoming materials inspections are performed as per internal procedures. Where required, raw materials are inspected against the appropriate certificate of compliance for conformance prior to their use in manufacture.

During in-process inspection, individual components are inspected for appropriate dimensional requirements as well as conformance to performance specifications. Also a 100% vision system checks different parameters from the in-process controls.

Final inspections are performed. The pen needles are inspected for dimensional and functional attributes.

✧ **STANDARDS:**

The BD Pen Needles comply with:

- ISO 9626: “Stainless steel needle tubing for the manufacture of medical devices”
- ISO 11608-2: “Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles ”

SITES IDENTIFICATION AND ADDRESSES

	Name and Address
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Technical Data Sheet – BD Pen Needles (BD™, BD Micro-Fine™ +, BD Micro-Fine™ Plus, BD Micro-Fine Ultra™, BD Micro-Fine Ultra™ PRO, BD Ultra-Fine™, BD Ultra-Fine™ PRO, BD Ultra-Fine™ 2nd Gen, BD Nano™ and BD Viva™)	
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Legal Manufacturer:	Becton Dickinson and Company 1 Becton Drive, Franklin Lakes, New Jersey 07417 USA
EU Authorized Representative:	BD Medical – Diabetes Care, Becton Dickinson France S.A.S. 11, rue Aristide Bergès, BP 4, 38801 Le Pont-de-Claix Cedex France
Manufacturing and Assembly Site(s):	Becton Dickinson and Company, Pottery Road, Dun Laoghaire, Co. Dublin Ireland embecta Medical Devices (Suzhou) Co., Ltd. No.1 Liangpu Street, Suzhou Industrial Park, China (Jiangsu), Pilot Free Trade Zone Suzhou Area, Suzhou, Jiangsu 215126 China
Sterilization Site(s):	Becton Dickinson and Company, Pottery Road, Dun Laoghaire, Co. Dublin Ireland Subcontractor of BD Suzhou: Shanghai JPY Ion-Tech. Co., Ltd No. 1168, Huijin Rd Shanghai Qingpu Industrial Zone Shanghai 201707, P. R. China

CE CERTIFICATION INFORMATION

✦ NOTIFIED BODY NEAM AND ADDRESS:

The BD Pen Needles are certified by:

National Standards Authority of Ireland (NSAI)
1 Swift Square, Northwood, Santry
Dublin 9
Ireland

Notified body number: 0050

✦ MEDICAL DEVICE CLASSIFICATION:

The BD Pen Needles are Class IIa medical devices as defined in the Medical Devices Directive (93/42/EEC).

✦ CE CERTIFICATE NUMBER: 252.128

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