BD Medical – Diabetes Care
Becton Dickinson France S.A.S.
11, rue Aristide Bergès, BP 4
38801 Le Pont-de-Claix Cedex
France

Advancing the world of health

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 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
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
320792	-	100	1200
325108	-	100	1200

Reference	Polybag (units)	Box (units)	Shipper (units)
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
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
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
325107	-	100	1200
0,23 mm (32G) x 4mm			
320137	-	100	1200
320139	-	100	1200
320140	-	100	1200
320141	-	100	1200
320143	5	100	500
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
320646	-	100	1200
320649	5	100	500
325103	-	100	1200
325106	-	100	1200
325115	5	100	500

GENERAL INFORMATION AND STANDARDS

✧ **MATERIALS:**

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

The products do not contain natural 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	Certification
Legal Manufacturer:	Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 USA	Registered to ISO 13485, with BSI under file number FM513512
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 Site(s):	Becton Dickinson and Company, Pottery Road Dun Laoghaire Co. Dublin Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1385
	Becton Dickinson and Company, Donore Road Drogheda, Co Louth Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1609
	Becton Dickinson Medial (S) Pte Ltd. 30 Tuas Avenue 2, Singapore 639461 Singapore	Registered to EN ISO 13485 with BSI under file number MD 81426
	Becton Dickinson Medical Devices Co, Ltd. • Suzhou 3 No. 1 Liangsu Street Suzhou Industrial Park Jiangsu, P. R. China	Registered to EN ISO 13485 with Presafe (DNV GL NEMKO) under file number 239117-2017-AQ-RGC-NA-PS 1.0

Assembly Site(s):	Becton Dickinson and Company, Pottery Road Dun Laoghaire Co. Dublin Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1385
	Becton Dickinson and Company, Donore Road Drogheda, Co Louth Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1609
	Becton Dickinson Medial (S) Pte Ltd. 30 Tuas Avenue 2, Singapore 639461 Singapore	Registered to EN ISO 13485 with BSI under file number MD 81426
	Becton Dickinson Medical Devices Co, Ltd. • Suzhou 3 No. 1 Liangsu Street Suzhou Industrial Park Jiangsu, P. R. China	Registered to EN ISO 13485 with Presafe (DNV GL NEMKO) under file number 239117-2017-AQ-RGC-NA-PS 1.0
Sterilization Site(s):	Becton Dickinson and Company, Pottery Road Dun Laoghaire Co. Dublin Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1385
	Subcontractor of BD Tuas: Baxter Healthcare S.A. Singapore Branch 2 Woodlands Industrial Park D Singapore 738750 Singapore	Registered to EN ISO 13485 and EN ISO 11137-1 with TUV under file number Q6 18 01 26437 001
	Subcontractor of BD Suzhou: Shanghai JPY Ion-Tech. Co., Ltd No. 1168, Huijin Rd Shanghai Qingpu Industrial Zone Shanghai 201707, P. R. China	Registered to EN ISO 13485 and EN ISO 11137-1 with TÜV SÜD Product Service GmbH under file Q4N 17 04 57747 006

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