

## TECHNICAL DATA SHEET

### **BD Micro-Fine™ +, BD Micro-Fine™ Plus, BD Ultra-Fine™, BD Ultra-Fine™ II and BD Insulin Syringes** Sterile, Single use, Latex Free

#### GENERAL INFORMATION

BD insulin syringes are a sterile, single use device designed for the parenteral administration of pharmaceuticals.

**U40 insulin syringes – Self-contained (sterile interior) with red color needle shield and printed scale mark:**

Reference	Volume	External Diameter	Needle Length	Polybag (units)	Shelf box (units)	Shipping box (units)
320801	1ml	29G	12,7mm	10	100	500
320910	1ml	29G	12,7mm	10	100	500
320911	1ml	30G	8mm	10	100	500
324876	0,5ml	30G	8mm	10	100	500

**U-100 Insulin syringes – Self-contained (sterile interior) with orange color needle shield and black printed scale mark:**

Reference	Volume	External Diameter	Needle Length	Polybag (units)	Shelf box (units)	Shipping box (units)
320829	0,3ml	30G	8mm	10	100	500
320839	0,3ml	30G	8 mm	10	100	500
320840	0,3ml	30G	8 mm	10	30	420
320841	1ml	29G	12,7mm	10	100	500
320843	0,5ml	30G	8mm	10	100	500
320909	1ml	29G	12,7mm	10	100	500
320921	0,5ml	29G	12,7mm	10	100	500
320924	1ml	29 G	12,7 mm	10	-	300
320926	0,5ml	29G	12,7 mm	10	-	300
320927	0,5ml	30G	8mm	10	-	300
320929	1ml	30G	8mm	10	100	500
320930	0,5ml	30G	8mm	10	100	500
320931	1ml	29G	12,7mm	10	100	500
320933	0,5ml	30G	8mm	10	100	500
320935	1ml	30G	8mm	10	100	500
324824	0,5ml	29G	12,7mm	10	100	500
324825	0,5ml	30G	8mm	10	100	500
324826	0,3ml	30G	8mm	10	100	500
324827	1ml	29G	12,7mm	10	100	500
324881	0,5ml	30G	8mm	10	30	420
324882	0,5ml	29G	12,7mm	10	30	420
324883	1ml	29G	12,7mm	10	30	420

Reference	Volume	External Diameter	Needle Length	Polybag (units)	Shelf box (units)	Shipping box (units)
324900	0,3ml	31G	6mm	10	100	500
324901	0,5ml	31G	6mm	10	100	500
324903	1ml	31G	6mm	10	100	500
324904	0,5ml	31G	6mm	10	100	500
324905	1ml	31G	6mm	10	100	500
324922	0,3ml	31G	6mm	10	100	500
326103	0,3ml	29G	8mm	10	100	500
326105	0,5ml	29G	12,7mm	10	100	500
326110	1ml	29G	12,7mm	10	100	500
328820	1ml	31G	8mm	10	100	500
328821	0,5ml	31G	8mm	10	100	500
328822	0,3ml	31G	8mm	10	100	500

**U-100 Insulin syringes – Blister Pack with orange color needle shield and black printed scale mark:**

Reference	Volume	External Diameter	Needle Length	Blisters in Shipping box
324891	1ml	29G	12,7mm	200
324892	0,5ml	29G	12,7mm	200
324893	0,5ml	30G	8mm	200
324899	1ml	30G	8mm	200
326674	1ml	31G	6mm	500
326675	0,5ml	31G	6mm	500
326702	1ml	30G	8mm	500
326719	1ml	29G	12,7mm	500
326725	0,5ml	30G	8mm	500
326769	0,5ml	29G	12,7mm	500
328415	1ml	27G	12,7mm	500

The insulin syringes are designed for administering insulin in the treatment of diabetes mellitus. The treatment may be carried out by a patient or by a healthcare professional, either in the home setting, in a hospital, or a clinical setting.

**GENERAL INFORMATION AND STANDARD**

✦ **MATERIALS**

Component	Material
Cannula	Stainless Steel
Lubricant - Cannula	Silicone Based
Barrel	Polypropylene
Lubricant - Barrel	Silicone Oil
Hub (0,3ml and 0,5ml syringes only)	Polypropylene
Adhesive	- Ultraviolet Curing Adhesive (0,3ml and 0,5ml syringes) - Ultraviolet Curing Adhesive or Oven Cure Epoxy (1ml syringes)
Plunger Rod	Polystyrene
Stopper	- Polyisoprene (0,3ml and 0,5ml syringes) - Polyisoprene or Styrene Butadiene Rubber (1ml syringes)
Shield	Polyethylene and Colorant

Plunger Cap (self-contained syringes only)	Polyethylene
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The products do not contain natural latex.

✧ **LABELING:** according to European Medical Device Directive

✧ **STERILIZATION:** Radiation (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 – Microbiological 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 CONTROL:**

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. There is also a 100% vision system that checks different parameters from the in-process controls.

The manufacturing sites perform final inspections and data review of each lot before release is performed.

✧ **STANDARDS:**

ISO 8537	Sterile single-use syringes with or without needle, for insulin
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## SITES IDENTIFICATION AND ADDRESSES

	<b>Name and Address</b>	<b>Certification</b>
<b>Manufacturer:</b>	Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 USA	Registered to ISO 13485, with BSI under file number FM 513512.
<b>Authorized Representative:</b>	BD Medical – Diabetes Care Becton Dickinson France S.A.S. 11, rue Aristide Bergès BP 4 38801 Le Pont-de-Claix Cedex France	
<b>Manufacturing Site:</b>	BD Medical – Diabetes Care 1329 West Highway 6 Holdrege, Nebraska 68949 USA	EN ISO 13485 with NSAI under file number MD19.1436.
<b>Sterilisation Site:</b>	BD Medical – Diabetes Care 1329 West highway 6 Holdrege, Nebraska 68949 USA	EN ISO 13485 with NSAI under file number MD19.1436.

## CE CERTIFICATION INFORMATION

### ✧ NOTIFIED BODY NAME AND ADDRESS:

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

✧ **CE CERTIFICATE NUMBER:** 252.140