

TECHNICAL DATA SHEET
BD Micro-Fine™ +, BD Micro-Fine™ Plus 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)
320722	1ml	30G	8mm	10	100	500
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)
320804	0,5ml	29G	12,7mm	10	100	500
320806	0,5ml	29G	12,7mm	10	100	500
320812	0,5ml	29G	12,7mm	10	10	500
320829	0,3ml	30G	8mm	10	100	500
320830	0,3ml	30G	8mm	10	100	500
320837	0,3ml	30G	8mm	10	100	500
320838	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
320842	0,5ml	29G	12,7mm	10	100	500
320843	0,5ml	30G	8mm	10	100	500
320909	1ml	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
320932	0,5ml	29G	12,7mm	10	100	500
320921	0,5ml	29G	12,7mm	10	100	500
320930	0,5ml	30G	8mm	10	100	500

320931	1ml	29G	12,7mm	10	100	500
320932	0,5ml	29G	12,7mm	10	100	500
320933	0,5ml	30G	8mm	10	100	500
320935	1ml	30G	8mm	10	100	500
324622	1ml	29G	12,7mm	10	-	300
324805	1ml	29G	12,7mm	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
324880	0,3ml	30G	8mm	10	30	420
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
324884	0,3ml	30G	8mm	10	100	500
326725	0,5ml	30G	8mm	10	100	500

U-100 Insulin syringes – Blister Pack :

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

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	304 Stainless Steel
Lubricant - Cannula	Silicone Based
Barrel	Polypropylene
Lubricant - Barrel	Silicone Oil
Hub (applicable to 0,3ml and 0.5ml syringes only)	Polypropylene
Adhesive	-Ultraviolet Adhesive (0,3ml and 0.5ml syringes) -Ultraviolet Adhesive or Oven Cure Epoxy (1ml syringes)
Plunger Rod	Polystyrene and Colorant
Stopper	Polyisoprene
Shield	Polyethylene and Colorant
Plunger Cap (self-contained syringes only)	Polyethylene

The products do not contain natural latex.

Based on information available and BD's continuous data collection efforts throughout the supply chain, 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 Substances of Very High Concern (SVHC) and included in the "Candidate List" published by the European Chemical Agency (ECHA) on 28 October 2008, according to Art. 59 (1, 10) of the Regulation (EC) N° 1907/2006 (REACH). The substances published in such list are candidates for eventual inclusion in the List of Substances Subject to Authorisation (Annex XIV of REACH). As such, these products don't contain di-(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP) or dibutyl phthalate (DBP) in concentrations above 0,1% of the total article.

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

✧ **STERILIZATION:** Radiation (gamma)

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

✧ **STORAGE CONDITIONS:** The long-term storage limitations of the product are considered to be 4 to 40°C with capability to withstand short periods of exposure (up to 2 weeks) at 60°C.

✧ **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 8537:2007	Sterile, single-use syringes with or without needle, for insulin injection
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SITES IDENTIFICATION AND ADDRESSES

	Name and Address	Certification
Manufacturer:	Becton Dickinson and Company 1 Becton Drive Franklin Lakes New Jersey 07417 USA	Registered to ISO 13485:2003, with BSI under file number FM 513512
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):	BD Medical Diabetes Care 1329 West Highway 6 Holdrege, Nebraska 68949-0860 USA	EN ISO 13485:2003 and EN 9001:2008 with NSAI under file number MD19.1436.
Sterilisation Site(s):	BD Medical Diabetes Care 1329 West highway 6 Holdrege, Nebraska 68949-0860 USA	EN ISO 13485:2003 and EN 9001:2008 with NSAI under file number MD19.1436.

CE CERTIFICATION INFORMATION

✧ NOTIFIED BODY NAME AND ADDRESS:

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

✧ CE CERTIFICATE NUMBER: 252.140