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## Insulin Syringes

### Trade names:

- Micro-Fine
  - Ultra-Fine
- 

### Intended Purpose:

Insulin Syringes are sterile, single-use devices designed for subcutaneous administration of insulin. These syringes have only been tested and validated for the intended use.

### Indications:

Insulin Syringes are intended to be used for subcutaneous administration of insulin at a concentration of 100U/ml (U-100) or 40U/mL (U-40) for the treatment of diabetes mellitus.

### Basic UDI-Device Identifier, EMDN and GMDN Codes:

Basic UDI-DI:

- Blister configuration: 0383017INLSYRNGJR8V
- Polybag configuration: 0383017INLSYRNPBJR6K

EMDN Code: A02010601

EMDN Category: Devices for Administration, Withdrawal and Collection

EMDN Description: INSULIN SYRINGES WITH FIXED NEEDLE, SINGLE-USE

GMDN Code: 38501

GMDN Description: Insulin syringe/needle, basic

### Risk Classification and Classification Rule:

The insulin syringes are Class IIa under Rule 6 of the Regulation (EU) 2017/745.

### Description of Key Functional Elements:

The Insulin Syringes are offered in three barrel size configurations (0.3, 0.5, and 1.0mL) and two different packaging types (self-contained (polybag) and blister package). The scale marking of the barrel is either designed for insulin concentrations of 100U/ml (U-100) or 40U/ml (U-40). In accordance with ISO 8537, the needle (cannula) is covered by an orange (U-100) or red (U-40) polyethylene shield which snaps onto the hub.

The volumetric configurations for Insulin Syringes with 100U/ml (U-100) graduation are 0.3mL, 0.5mL, and 1mL. There are five different needle size variants:

- 12.7mm x 27G
- 12.7mm x 29G
- 8mm x 30G
- 8mm x 31G
- 6mm x 31G

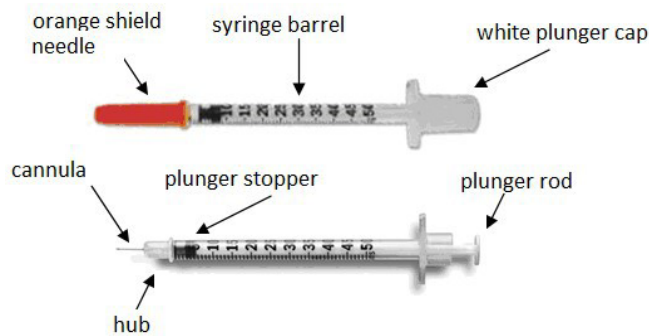
The volumetric configurations for Insulin Syringes with 40U/ml (U-40) graduation are of 1mL and 0.5mL. There are two different needle size variants:

- 12.7mm x 29G
- 8mm x 30G

### 0.3mL / 0.5mL Insulin Syringes

The 0.3mL and 0.5mL Insulin Syringes consist of a needle and hub assembly, barrel, shield, stopper, and plunger. The needle is a single ended lubricated stainless-steel cannula which is permanently attached to the hub with a UV adhesive. The needle and hub assembly is then snapped onto the barrel to form the barrel assembly. The needle is covered by an orange (U-100) or red (U-40) polyethylene shield which snaps onto the hub. The barrel is molded from polypropylene with the exterior permanently marked with the proper scale

markings. The unit markings for the 0.3mL and 0.5mL syringes are available in a 1 unit or ½ unit scale mark. The barrel's interior is lubricated and forms an airtight seal with the stopper. The stopper is attached to the plunger.

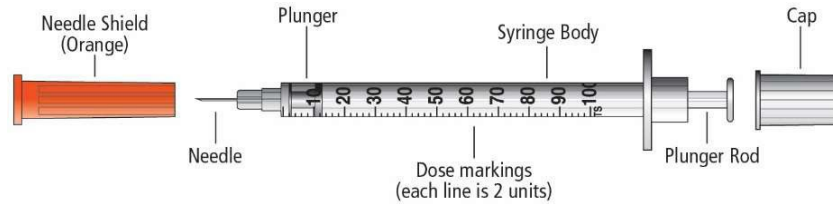


*Example of 0.5mL Insulin Syringe*

### 1mL Insulin Syringe

The 1mL Insulin syringe consists of a needle, integral barrel, shield, stopper, and plunger. Unlike the 0.3mL and 0.5mL syringes, the hub of the 1mL configuration is built into the barrel (instead of snapped onto the barrel). The needle is a single ended lubricated stainless-steel cannula which is permanently attached to the barrel with a UV adhesive. The needle is covered by an orange (U-100) or red (U-40) polyethylene shield which snaps onto the integrated hub. The barrel is molded from polypropylene with the exterior permanently marked with the proper scale markings. The unit markings for the 1mL syringe are available in a 1-unit scale mark or 2-unit scale mark. The barrel's interior is lubricated and forms an airtight seal with the stopper. The stopper is attached to the plunger.

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Example of 1mL Insulin Syringe

**Self-Contained Syringe Package**

The self-contained syringe package consists of a polyethylene cap placed over the plunger rod. The self-contained syringe may be packaged in polybags of multiple quantities. Only the fluid path of a self-contained syringe is sterile and non-pyrogenic.

**Blister Pack Syringe Package**

Syringes which are packed in blister pack are assembled without a polyethylene plunger cap. The blister pack syringes are provided sterile and non-pyrogenic.

**Products references and configurations:**

*Note: Please check SKU availability in your country. The Product Description can slightly differ from the EC Declaration of Conformity; please always refer to the SKU.*

SKU	Micro-Fine or Ultra-Fine	U-100	U-40	Needle Length	Gauge Size	Volume Capacity	Polybag/ Blister
320801	Micro-Fine		X	12,7mm	29G	1mL	Polybag
320829	Micro-Fine	X		8mm	30G	0,3mL	Polybag
320839	Micro-Fine	X		8mm	30G	0,3mL	Polybag
320840	Micro-Fine	X		8mm	30G	0,3mL	Polybag
320841	Micro-Fine	X		12,7mm	29G	1mL	Polybag
320843	Micro-Fine	X		8mm	30G	0,5mL	Polybag
320909	Micro-Fine	X		12,7mm	29G	1mL	Polybag
320910	Micro-Fine		X	12,7mm	29G	1mL	Polybag
320911	Micro-Fine		X	8mm	30G	1mL	Polybag
320921	Micro-Fine	X		12,7mm	29G	0,5mL	Polybag
320929	Micro-Fine	X		8mm	30G	1mL	Polybag
320930	Micro-Fine	X		8mm	30G	0,5mL	Polybag
320931	Micro-Fine	X		12,7mm	29G	1mL	Polybag
320933	Micro-Fine	X		8mm	30G	0,5mL	Polybag
320935	Micro-Fine	X		8mm	30G	1mL	Polybag
324824	Micro-Fine	X		12,7mm	29G	0,5mL	Polybag
324825	Micro-Fine	X		8mm	30G	0,5mL	Polybag
324826	Micro-Fine	X		8mm	30G	0,3mL	Polybag
324827	Micro-Fine	X		12,7mm	29G	1mL	Polybag
324876	Micro-Fine		X	8mm	30G	0,5mL	Polybag
324881	Micro-Fine	X		8mm	30G	0,5mL	Polybag
324882	Micro-Fine	X		12,7mm	29G	0,5mL	Polybag
324883	Micro-Fine	X		12,7mm	29G	1mL	Polybag
324891	Micro-Fine	X		12,7mm	29G	1mL	Blister
324892	Micro-Fine	X		12,7mm	29G	0,5mL	Blister
324893	Micro-Fine	X		8mm	30G	0,5mL	Blister
324899	Micro-Fine	X		8mm	30G	1mL	Blister
324900	Ultra-Fine	X		6mm	31G	0,3mL	Polybag

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**TECHNICAL DATA SHEET**  
**Insulin Syringes**



324901	Ultra-Fine	X		6mm	31G	0,5mL	Polybag
324902	Ultra-Fine		X	6mm	31G	1mL	Polybag
324903	Ultra-Fine	X		6mm	31G	1mL	Polybag
324904	Micro-Fine	X		6mm	31G	0,5mL	Polybag
324905	Micro-Fine	X		6mm	31G	1mL	Polybag
324922	Micro-Fine	X		6mm	31G	0,3mL	Polybag
324923	Micro-Fine	X		6mm	31G	0,5mL	Polybag
324924	Micro-Fine	X		6mm	31G	1mL	Polybag
326103	Ultra-Fine	X		12,7mm	29G	0,3mL	Polybag
326105	Ultra-Fine	X		12,7mm	29G	0,5mL	Polybag
326110	Ultra-Fine	X		12,7mm	29G	1mL	Polybag
326674	Ultra-Fine	X		6mm	31G	1mL	Blister
326675	Ultra-Fine	X		6mm	31G	0,5mL	Blister
326702	Ultra-Fine	X		8mm	30G	1mL	Blister
326719	Ultra-Fine	X		12,7mm	29G	1mL	Blister
326725	Ultra-Fine	X		8mm	30G	0,5mL	Blister
326769	Ultra-Fine	X		12,7mm	29G	0,5mL	Blister
328415	Ultra-Fine	X		12,7mm	27G	1mL	Blister
328457	Ultra-Fine		X	6mm	31G	1mL	Blister
328502	Ultra-Fine		X	8mm	31G	1mL	Polybag
328820	Ultra-Fine	X		8mm	31G	1mL	Polybag
328821	Ultra-Fine	X		8mm	31G	0,5mL	Polybag
328822	Ultra-Fine	X		8mm	31G	0,3mL	Polybag

**Packaging Configurations:**

SKU	Description	Units per shelf carton	Shelf cartons per case carton	Units per case carton
320801	Micro-Fine Insulin Syringes•U- 40•12.7mm• 29G•1mL•100ct	10 units/polybag 10 polybags	5	500
320829	Micro-Fine Insulin Syringes•U- 100•8mm• 30G•0.3mL•½ unit•100ct	10 units/polybag 10 polybags	5	500
320839	Micro-Fine Insulin Syringes•U- 100•8mm• 30G•0.3mL•½ unit•100ct	10 units/polybag 10 polybags	5	500
320840	Micro-Fine Insulin Syringes•U- 100•8mm• 30G•0.3mL•½ unit•30ct	10 units/polybag 3 polybags	14	420
320841	Micro-Fine Insulin Syringes•U- 100•12.7mm• 29G•1mL•100ct	10 units/polybag 10 polybags	5	500
320843	Micro-Fine Insulin Syringes•U- 100•8mm• 30G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
320909	Micro-Fine Insulin Syringes•U- 100•12.7mm• 29G•1mL•100ct	10 units/polybag 10 polybags	5	500
320910	Micro-Fine Insulin Syringes•U- 40•12.7mm• 29G•1mL•100ct	10 units/polybag 10 polybags	5	500
320911	Micro-Fine Insulin Syringes•U- 40•8mm• 30G•1mL•100ct	10 units/polybag 10 polybags	5	500
320921	Micro-Fine Insulin Syringes•U- 100•12.7mm• 29G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
320929	Micro-Fine Insulin Syringes•U- 100•8mm• 30G•1mL•100ct	10 units/polybag 10 polybags	5	500
320930	Micro-Fine Insulin Syringes•U- 100•8mm• 30G•0.5mL•100ct	10 units/polybag 10 polybags	5	500

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**TECHNICAL DATA SHEET**  
**Insulin Syringes**



320931	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•1mL•100ct	10 units/polybag 10 polybags	5	500
320933	Micro-Fine Insulin Syringes•U- 100•8mm•30G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
320935	Micro-Fine Insulin Syringes•U- 100•8mm•30G•1mL•100ct	10 units/polybag 10 polybags	5	500
324824	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
324825	Micro-Fine Insulin Syringes•U- 100•8mm•30G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
324826	Micro-Fine Insulin Syringes•U- 100•8mm•30G•0.3mL•½ unit•100ct	10 units/polybag 10 polybags	5	500
324827	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•1mL•100ct	10 units/polybag 10 polybags	5	500
324876	Micro-Fine Insulin Syringes•U- 40•8mm•30G•0.5mL•½ unit•100ct	10 units/polybag 10 polybags	5	500
324881	Micro-Fine Insulin Syringes•U- 100•8mm•30G•0.5mL•30ct	10 units/polybag 3 polybags	14	420
324882	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•0.5mL•30ct	10 units/polybag 3 polybags	14	420
324883	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•1mL•30ct	10 units/polybag 3 polybags	14	420
324891	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•1mL•200ct•Blister	1 unit per blister	N/A	200
324892	Micro-Fine Insulin Syringes•U- 100•12.7mm•29G•0.5mL•200ct•Blister	1 unit per blister	N/A	200
324893	Micro-Fine Insulin Syringes•U- 100•8mm•30G•0.5mL•200ct•Blister	1 unit per blister	N/A	200
324899	Micro-Fine Insulin Syringes•U- 100•8mm•30G•1mL•200ct•Blister	1 unit per blister	N/A	200
324900	Ultra-Fine Insulin Syringes•U- 100•6mm•31G•0.3mL•100ct	10 units/polybag 10 polybags	5	500
324901	Ultra-Fine Insulin Syringes•U- 100•6mm•31G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
324902	Ultra-Fine Insulin Syringes•U- 40•6mm•31G•1mL•100ct	10 units/polybag 10 polybags	5	500
324903	Ultra-Fine Insulin Syringes•U- 100•6mm•31G•1mL•100ct	10 units/polybag 10 polybags	5	500
324904	Micro-Fine Insulin Syringes•U- 100•6mm•31G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
324905	Micro-Fine Insulin Syringes•U- 100•6mm•31G•1mL•100ct	10 units/polybag 10 polybags	5	500
324922	Micro-Fine Insulin Syringes•U- 100•6mm•31G•0.3mL•½ unit•100ct	10 units/polybag 10 polybags	5	500
324923	Micro-Fine Insulin Syringes•U- 100•6mm•31G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
324924	Micro-Fine Insulin Syringes•U- 100•6mm•31G•1mL•100ct	10 units/polybag 10 polybags	5	500
326103	Ultra-Fine Insulin Syringes•U- 100•12.7mm•29G•0.3mL•100ct	10 units/polybag 10 polybags	5	500
326105	Ultra-Fine Insulin Syringes•U- 100•12.7mm•29G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
326110	Ultra-Fine Insulin Syringes•U- 100•12.7mm•29G•1mL•100ct	10 units/polybag 10 polybags	5	500
326674	Ultra-Fine Insulin Syringes•U- 100•6mm•31G•1mL•100ct•Blister	100 units/shelf carton	5	500

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326675	Ultra-Fine Insulin Syringes•U- 100•6mm•31G•0.5mL•100ct•Blister	100 units/shelf carton	5	500
326702	Ultra-Fine Insulin Syringes•U- 100•8mm•30G•1mL•100ct•Blister	100 units/shelf carton	5	500
326719	Ultra-Fine Insulin Syringes•U- 100•12.7mm•29G•1mL•100ct•Blister	100 units/shelf carton	5	500
326725	Ultra-Fine Insulin Syringes•U- 100•8mm•30G•0.5mL•100ct•Blister	100 units/shelf carton	5	500
326769	Ultra-Fine Insulin Syringes•U- 100•12.7mm•29G•0.5mL•100ct•Blister	100 units/shelf carton	5	500
328415	Ultra-Fine Insulin Syringes•U- 100•12.7mm•27G•1mL•100ct•Blister	100 units/shelf carton	5	500
328457	Ultra-Fine Insulin Syringes•U-40•6mm•31G•1mL•100ct•Blister	100 units/shelf carton	5	500
328502	Ultra-Fine Insulin Syringes•U-40•8mm•31G•1mL•100ct	10 units/polybag 10 polybags	5	500
328820	Ultra-Fine Insulin Syringes•U- 100•8mm•31G•1mL•100ct	10 units/polybag 10 polybags	5	500
328821	Ultra-Fine Insulin Syringes•U- 100•8mm•31G•0.5mL•100ct	10 units/polybag 10 polybags	5	500
328822	Ultra-Fine Insulin Syringes•U- 100•8mm•31G•0.3mL•100ct	10 units/polybag 10 polybags	5	500

**Description of Raw Materials:**

Syringe size, configuration	Component	Component Raw Material
All	Cannula	304 Stainless Steel
All	Cannula Lubricant	Silicone Based
All	Alternative Cannula Lubricant	Silicone Based
All	Syringe Barrel	Polypropylene
All	Barrel Lubricant	Silicone Oil
All	Ink on Barrel	Black ink, red ink, and ink thinners
0.3 ml, 0.5 ml	Hub	Polypropylene
All	Adhesive	Ultraviolet Curing Adhesive
All	Plunger Rod	High Density Polystyrene
All	Plunger Stopper	Polyisoprene
All	Orange or Red Shield	Polyethylene Orange or Red
All self-contained	Plunger Cap	High Density Polyethylene
All blister packed syringes	Blister (Bottom Web)	Nylon
All blister packed syringes	Paper label (Top Web)	Heat Seal Coated Paper Web
All self-contained	Polybag	Linear Low Density Polyethylene film
All	Shelf carton	Paperboard
All	Shipper	Corrugated Paperboard

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**Labeling:**

Information supplied by the manufacturer (i.e., labeling and instructions for use) was developed in accordance with the MDR (EU) 2017/745, Annex I General Safety and Performance Requirements, Chapter III Requirements and Article 20 (CE marking of conformity).

**Biocompatibility:**

The materials used in the manufacture of the insulin syringes were tested for biocompatibility to demonstrate the biological safety of the insulin syringes in accordance with the requirements of the MDR (EU) 2017/745 and ISO 10993.

Biocompatibility testing and the biological safety evaluation were based on the nature and degree of direct or indirect bodily contact, and concludes that the probability of any biological risk or harm to the patient or user is negligible when considering the intended clinical use.

**Sterilization:**

The Insulin Syringes are gamma irradiated and provided sterile.

Testing has been done on final finished devices using commercial line manufacturing processes. All sterile product is manufactured in a controlled environment with environmental monitoring. Sterilization procedures meet the requirements of ISO 11137-1 and ISO 11137-2.

**Shelf Life:**

Stability testing has been conducted to validate the sterility and performance of the insulin syringes through product aging to support the shelf-life claims of 5 years.

**Storage Conditions:**

The Insulin Syringes have been tested at different aging temperatures to ensure the extreme conditions during transport and storage does not impact shelf life.

The Insulin Syringes have no special storage or handling conditions outside of what is explained in the instructions for use.

**Standards:**

The insulin syringes comply with the standards listed in the table below.

EN Standard #	Standard Title
EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
EN 62366-1	Medical Devices - Application of usability engineering to medical devices
EN ISO 10993 serie	Biological evaluation of medical devices

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EN ISO 11137-1	Sterilization of health care products - Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2	Sterilization of health care products - Radiation – Part 2: Establishing the sterilization dose
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1	Sterilization of health care products - Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilization of health care products - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11737-3	Sterilization of health care products – Microbiological methods – Part 3: Bacterial endotoxin testing
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417	Medical devices – Information supplied by the manufacturer of medical devices
EN ISO 8537	Sterile single-use syringes with or without needle, for insulin
EN ISO 7864	Sterile hypodermic needles for single use. Requirements and test methods <i>(Partially applied for specific technical design inputs including cannula point quality as per ISO 8537)</i>
EN ISO 7886-1	Sterile Hypodermic Syringes For Single Use – Part 1: Syringes for Manual Use <i>(Partially applied, since applicable only to the barrel)</i>
EN ISO 9626	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
EN ISO 13004	Sterilization of health care products — Radiation — Substantiation of a selected sterilization dose: Method VDmaxSD
EN ISO 14155	Clinical investigation of medical devices for human subjects – Good clinical practice

**Sites Identification and Addresses:**

Location Name/ Address	Legal Manufacturer	Manufacturing	Sterilization	EU Authorized Representative
embecta Medical II LLC 300 Kimball Drive Parsippany, NJ 07054 USA  SRN: US-MF-000044225	X			

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embecta Penel Limited Pottery Road, Dún Laoghaire Co. Dublin, A96 P59, Ireland  SRN: IE-AR-000040945				X
embecta Medical I LLC 1329 West Highway 6, Holdrege, NE 68949 USA		X		
BD Medical 1329 West Highway 6, Suite A, Holdrege, NE 68949 USA			X	

**CE Certification Information:**

The Insulin Syringes are certified by:

BSI Group The Netherlands B.V.  
 Say Building, John M. Keynesplein 9,  
 1066 EP, Amsterdam, Netherlands

**Notified Body Number:** 2797

**CE Certificate Number:** MDR 816238

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**REVISION HISTORY**

<b>Revision</b>	<b>Description</b>	<b>By</b>
A	Creation of the document	Laura Deslandes-Azaiez
B	Update of the Basic UDI-DI numbers. Added 324902, 328457 and 328502. Added standards ISO 11737-3 and EN ISO 14155.	Laura Deslandes-Azaiez

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