

Conventional Pen Needles

Trade names:

- Base-Fine
- embecta
- Micro-Fine
- Micro-Fine PRO
- Micro-Fine Ultra
- Nano
- Nano 2nd Gen
- Ultra-Fine
- Ultra-Fine PRO
- Viva

Intended Purpose:

Pen needles are sterile, single-use devices intended for use with pen injectors for subcutaneous injection of drugs by caregivers, laypersons, or health care professionals.

Indications:

Indicated to be used with compatible pen injector devices per ISO 11608-1 for subcutaneous injection of drugs. The list of widely used pen injectors compatible with embecta pen needles is included on the packaging.

Basic UDI-Device Identifier, EMDN and GMDN Codes:

Basic UDI-DI: 0383017LGPNNDLSCPVK

EMDN Code: A0101010202

EMDN Category: Devices for Administration, Withdrawal and Collection

EMDN Description: HYPODERMIC PEN NEEDLES, W/O SAFETY SYSTEMS

GMDN Code: 44127

GMDN Description: Autoinjector needle

Risk Classification and Classification Rule:

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

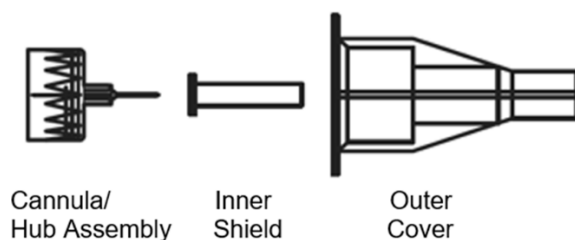
Description of Key Functional Elements:

Pen needles are single use, sterile, medical devices designed to be used in conjunction with pen injectors and pen cartridges. Pen needles come in various sizes but the structure among the varying sizes is the same.

Conventional pen needles have a base (hub and cannula), inner shield, and outer cover. They are designed to reduce occurrence of accidental needle sticks by providing an inner shield, which is assembled over the patient-end of the cannula.



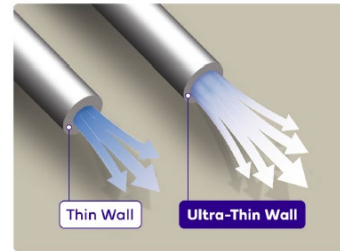
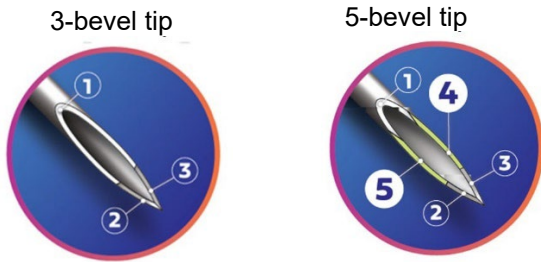
Picture of Pen Needle



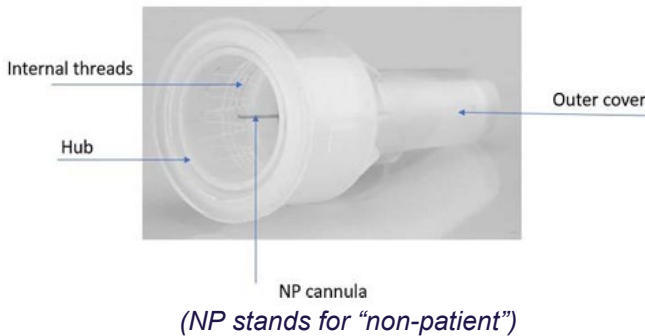
The conventional pen needle consists of a double-ended lubricated stainless-steel cannula fixed into a polypropylene hub using adhesive. The hub has internal threads, which allows it to be screwed onto the pen injector device. This allows the Non-Patient (NP) end of the cannula to penetrate through the rubber septum of the pen cartridge. The cannula is lubricated with medical grade silicone. The patient penetrating end of the cannula is protected by means of an inner polyethylene or polypropylene shield. The needle and hub assembly is contained in a protective polyethylene or polypropylene cover, which is covered by a heat sealed, peel-away sterile barrier (not shown in figure). The needle is provided sterile.

The cannula tip on patient-end side exists in either 3 or 5 bevels.

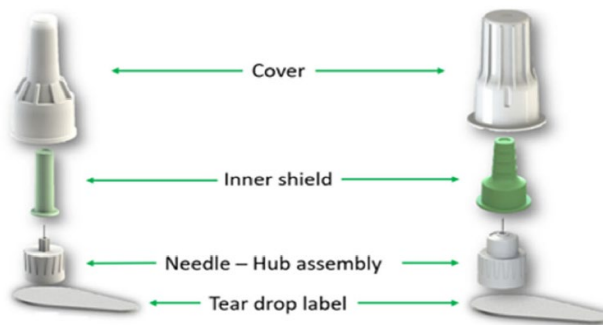
The cannula inner wall diameter can either be thin wall or ultra-thin wall.



The following image demonstrates an example of the internal hub threads and cannula as well as the outer cover.



PRO Pen Needle: The PRO pen needle is only available in 32Gx4mm, 5-bevel tip, with an ultra-thin wall. PRO pen needles differ from other pen needles in hub design, inner needle shield, and outer cover. While standard pen needles have a posted hub design with traditional inner shield and outer cover, the PRO pen needles have a contoured base (to increase injection surface area), an inner shield with flats and grips, and larger grips on the outer cover.



Standard Pen Needle

PRO Pen Needle

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.

SKUs	Family	Base	Needle Length	Gauge Size	Bevel	Wall
320824 320825 320938 320940	Base-Fine	Posted	4mm 6mm 8mm 5mm	30G 31G 32G	3	Thin
321105 321107 321109 321110 321106 321108	embecta	Posted	4mm 8mm 5mm 12,7mm 6mm	29G 30G 31G 32G	3	Thin
320190 320499 320697 321116 320207 320519 320736 321117 320433 320520 320737 321118 320434 320590 320952 321119 320470 320592 320953 321120 320471 320594 320954 321121 320472 320595 321098 321122 320473 320650 321099 321123 320497 320651 321100 324841 320498	Micro-Fine	Posted	4mm 8mm 5mm 12,7mm 6mm	29G 30G 31G 32G	3 5	Thin Ultra-Thin
320562 320564	Micro-Fine PRO	Contoured	4mm	32G	5	Ultra-Thin
320500 320649 321115 325108 320585 321097 325107 325115 320587 325118	Micro-Fine Ultra	Posted	4mm 8mm 5mm 12,7mm	29G 31G 32G	3 5	Thin Ultra-Thin
320157 320179	Nano	Posted	4mm	32G	3	Thin
320575	Nano 2nd Gen	Contoured	4mm	32G	5	Ultra-Thin
320120 320477 320524 320698 320123 320522 320545 320405 320523 320569	Ultra-Fine	Posted	4mm 8mm 5mm 12,7mm 6mm	29G 31G 32G	3 5	Thin Ultra-Thin
321125 320561 320566 320571	Ultra-Fine PRO	Contoured	4mm	32G	5	Ultra-Thin
321101 321102 321103 321104 320426	Viva		4mm 6mm 8mm 5mm	31G 32G	3	Thin

Packaging Configurations:

SKU	Description	Units per shelf carton	Shelf cartons per case carton	Units per case carton
320120	Ultra-Fine Pen Needles 5mm 31G 3bevel TW 6000ct	---	---	6000
320123	Ultra-Fine Pen Needles 5mm 31G 3bevel TW 50ct	10 bags of 5 ea	10	500
320157	Nano Pen Needles 4mm 32G 3bevel TW 6000ct	---	---	6000
320179	Nano Pen Needles 4mm 32G 3bevel TW 50ct	10 bags of 5 ea	10	500
320190	Micro-Fine Pen Needles 8mm 30G 3bevel RW 100ct	100	12	1200

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TECHNICAL DATA SHEET
Conventional Pen Needles



320207	Micro-Fine Ultra Pen Needles 12,7mm 29G 3bevel TW 100ct	100	12	1200
320405	Ultra-Fine Pen Needles 4mm 32G 5bevel UTW 100ct Sample	20 bags of 5 ea	5	500
320426	Viva Pen Needles 4mm 32G 3bevel TW 100ct Sample	20 bags of 5 ea	5	500
320433	Micro-Fine Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
320434	Micro-Fine Pen Needles 4mm 32G 3bevel TW 100ct	100	12	1200
320470	Micro-Fine Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
320471	Micro-Fine Pen Needles 8mm 31G 3bevel TW 100ct	100	12	1200
320472	Micro-Fine Pen Needles 4mm 32G 3bevel TW 100ct	100	12	1200
320473	Micro-Fine Pen Needles 12,7mm 29G 3bevel TW 100ct	100	12	1200
320477	Ultra-Fine Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
320497	Micro-Fine Pen Needles 4mm 32G 5bevel TW 100ct	100	12	1200
320498	Micro-Fine Pen Needles 5mm 31G 5bevel TW 100ct	100	12	1200
320499	Micro-Fine Pen Needles 8mm 31G 5bevel TW 100ct	100	12	1200
320500	Micro-Fine Ultra Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
320519	Micro-Fine Pen Needles 8mm 30G 3bevel TW 100ct	100	12	1200
320520	Micro-Fine Pen Needles 4mm 32G 3bevel TW 100ct	100	12	1200
320522	Ultra-Fine Pen Needles 5mm 31G 5bevel UTW 105ct	105	12	1260
320523	Ultra-Fine Pen Needles 6mm 31G 3bevel TW 105ct	105	12	1260
320524	Ultra-Fine Pen Needles 8mm 31G 5bevel TW 105ct	105	12	1260
320545	Ultra-Fine Pen Needles 5mm 31G 5bevel UTW 140ct	20 packs of 7 ea	10	1400
320561	Ultra-Fine PRO Pen Needles 4mm 32G 5bevel UTW 105ct	105	12	1260
320562	Micro-Fine PRO Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
320564	Micro-Fine PRO Pen Needles 4mm 32G 5bevel UTW 100ct Sample	20 bags of 5 ea	5	500
320566	Ultra-Fine PRO Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
320569	Ultra-Fine Pen Needles 5mm 31G 5bevel UTW 100ct	100	12	1200
320571	Ultra-Fine PRO Pen Needles 4mm 32G 5bevel UTW 100ct Sample	20 bags of 5 ea	5	500
320575	Nano 2nd Gen Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
320585	Micro-Fine Ultra Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
320587	Micro-Fine Ultra Pen Needles 5mm 31G 5bevel UTW 100ct	100	12	1200
320590	Micro-Fine Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
320594	Micro-Fine Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
320595	Micro-Fine Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
320649	Micro-Fine Ultra Pen Needles 4mm 32G 5bevel UTW 100ct Sample	20 bags of 5 ea	5	500
320650	Micro-Fine Pen Needles 5mm 31G 5bevel UTW 100ct Sample	20 bags of 5 ea	5	500

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320651	Micro-Fine Pen Needles 8mm 31G 5bevel TW 100ct Sample	20 bags of 5 ea	5	500
320697	Micro-Fine Pen Needles 6mm 32G 5bevel TW 100ct	100	12	1200
320698	Ultra-Fine Pen Needles 6mm 32G 5bevel TW 105ct	105	12	1260
320736	Micro-Fine Pen Needles 6mm 31G 3bevel TW 100ct	100	12	1200
320737	Micro-Fine Pen Needles 6mm 31G 3bevel TW 100ct	100	12	1200
320824	Base-Fine Pen Needles 4mm 32G 3bevel TW 100ct	100	12	1200
320825	Base-Fine Pen Needles 6mm 31G 3bevel TW 100ct	100	12	1200
320938	Base-Fine Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
320940	Base-Fine Pen Needles 8mm 30G 3bevel TW 100ct	100	12	1200
320952	Micro-Fine Pen Needles 6mm 31G 3bevel TW 100ct Sample	100	5	500
320953	Micro-Fine Pen Needles 6mm 32G 5bevel TW 100ct Sample	20 bags of 5 ea	5	500
320954	Micro-Fine Pen Needles 6mm 32G 5bevel TW 90ct	90	12	1080
321097	Micro-Fine Ultra Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
321098	Micro-Fine Pen Needles 5mm 31G 5bevel UTW 100ct	100	12	1200
321099	Micro-Fine Pen Needles 6mm 32G 5bevel TW 100ct	100	12	1200
321100	Micro-Fine Pen Needles 8mm 31G 5bevel TW 100ct	100	12	1200
321101	Viva Pen Needles 4mm 32G 3bevel TW 90ct	90	12	1080
321102	Viva Pen Needles 5mm 31G 3bevel TW 90ct	90	12	1080
321103	Viva Pen Needles 6mm 31G 3bevel TW 90ct	90	12	1080
321104	Viva Pen Needles 8mm 31G 3bevel TW 90ct	90	12	1080
321105	embecta Pen Needles 4mm 32G 3bevel TW 100ct	100	12	1200
321106	embecta Pen Needles 5mm 31G 3bevel TW 100ct	100	12	1200
321107	embecta Pen Needles 6mm 31G 3bevel TW 100ct	100	12	1200
321108	embecta Pen Needles 8mm 30G 3bevel TW 100ct	100	12	1200
321109	embecta Pen Needles 8mm 31G 3bevel TW 100ct	100	12	1200
321110	embecta Pen Needles 12,7mm 29G 3bevel TW 100ct	100	12	1200
321115	Micro-Fine Ultra Pen Needles 4mm 32G 5bevel UTW 100ct	100	12	1200
321116	Micro-Fine Pen Needles 5mm 31G 5bevel UTW 100ct	100	12	1200
321117	Micro-Fine Pen Needles 6mm 31G 3bevel TW 100ct	100	12	1200
321118	Micro-Fine Pen Needles 8mm 31G 5bevel TW 100ct	100	12	1200
321119	Micro-Fine Pen Needles 4mm 32G 5bevel TW 90ct	90	12	1080
321120	Micro-Fine Pen Needles 5mm 31G 5bevel UTW 90ct	90	12	1080
321121	Micro-Fine Pen Needles 6mm 31G 3bevel TW 90ct	90	12	1080
321122	Micro-Fine Pen Needles 8mm 31G 5bevel TW 90ct	90	12	1080
321123	Micro-Fine Pen Needles 12,7mm 29G 3bevel TW 100ct	100	12	1200
321125	Ultra-Fine PRO Pen Needles 4mm 32G 5bevel UTW 14ct	14	100	1400
324841	Micro-Fine Pen Needles 12,7mm 29G 3bevel TW 90ct	90	12	1080
325107	Micro-Fine Ultra Pen Needles 5mm 31G 5bevel UTW 100ct	100	12	1200

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325115	Micro-Fine Ultra Pen Needles 4mm 32G 5bevel UTW 100ct Sample	20 bags of 5 5 ea	5	500
325118	Micro-Fine Ultra Pen Needles 12,7mm 29G 3bevel TW 100ct	100	12	1200

Description of Raw Materials:

Component	Component Raw Material
Adhesive	Ultraviolet Curing Adhesive
Cannula	Stainless Steel 304
Cannula lubricant (patient end)	Silicone (medical grade)
Cannula lubricant (non- patient end)	Silicone (medical grade)
Cover	Polyethylene or Polypropylene
Inner shield	Polyethylene or Polypropylene and colour concentrate
Needle hub	Polypropylene
Shelf carton	Paperboard
Shipping carton	Corrugated paperboard
Unit label (sterile barrier)	Paper with metallized PET (polyester film) and peelable PE (polyethylene film)

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 pen needles were tested for biocompatibility to demonstrate the biological safety of the pen needles 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 pen needles 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:

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

Storage Conditions:

The pen needles have been tested at different aging temperatures to ensure the extreme conditions during transport and storage does not impact shelf life.
 The pen needles have no special storage or handling conditions outside of what is explained in the instructions for use.

Standards:

The pen needles 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
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 11608-2	Needle-based injection systems for medical use - Requirements and test methods – Part 2: Needles
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 14155	Clinical investigation of medical devices for human subjects – Good clinical practice

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
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 11608-2)</i>
EN ISO 9626	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

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			
embecta Penel Limited Pottery Road, Dún Laoghaire Co. Dublin, A96 P59, Ireland SRN: IE-AR-000040945		X	X	X
embecta Medical Devices (Suzhou) Co., Ltd. No. 1 Liangpu Street, Suzhou Industrial Park, Jiangsu P.R. China		X		
<i>(for products manufactured by embecta Medical Devices (Suzhou) Co., Ltd.)</i> Shanghai JPY Ion-Tech. Co., Ltd. No. 1168, Huijin Rd., Shanghai, Qingpu Industrial Zone, Shanghai 201707, P.R. China			X	

* embecta conventional pen needles are manufactured either by embecta Penel Limited or embecta Medical Devices (Suzhou) Co., Ltd. For more details, please refer to the EC Declaration of Conformity.

CE Certification Information:

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The Pen Needles 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

Revision	Description	By
A	Creation of the document	Laura Deslandes-Azaiez
B	<ul style="list-style-type: none">- Update of the Basic UDI-DI number.- Removed SKUs 320177, 320517, 320518 and 320631 to align with final EU MDR scope for Brand Transition program.- Corrected and rearranged SKUs characteristics.- Added standards ISO 11737-3 and EN ISO 14155. Added	Laura Deslandes-Azaiez

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