Safety Pen Needles

Trade names:

- AutoShield Duo
- SafeAssist

Intended Purpose:

Safety Pen Needles are sterile, single use devices intended for use with pen injector devices for the injection of drugs by health care professionals or laypersons, in a hospital or home setting.

AutoShield Duo is needle designed to reduce occurrence of accidental needle sticks.the reduction in from both ends of the needle by providing two safety shields, which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connection-end).

SafeAssist is needle designed to reduce occurrence of accidental needle sticks from the patient end of the needle by providing a safety shield that locks over the needle after use.

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:

- AutoShield Duo - 0383017SFPNASDNERYU
- SafeAssist - 0383017SFPNNLSAH43J

EMDN Code: A0101010201
EMDN Category: Devices for Administration, Withdrawal and Collection
EMDN Description: HYPODERMIC PEN NEEDLES, WITH SAFETY SYSTEMS

GMDN Code: 44127
GMDN Description: Autoinjector needle

Risk Classification and Classification Rule:

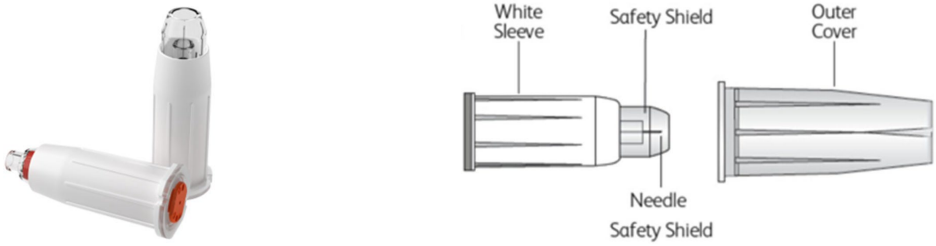
The safety pen needles are Class IIa under Rule 6 of the Regulation (EU) 2017/745.

Description of Key Functional Elements:

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

AutoShield Duo:

AutoShield Duo are safety pen needles with dual automatic protective shields, sleeve, needle assembly and outer cover. The needle assembly consists of a double-ended cannula that is assembled into an injection molded hub. The internal threads allow the safety pen needle to be screwed onto the pen injector device. This allows the non-patient end of the cannula to penetrate through the septum of the cartridge.



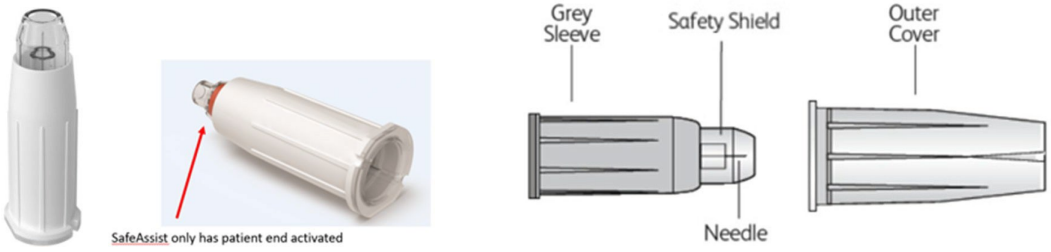
Picture of AutoShield Duo Safety Pen Needle

The patient and pen connection-ends of the cannula are visible prior to attachment to the injector pen. The patient end of the device has a mechanism that allows the needle to be shielded and locked after use and is designed to reduce the occurrence of accidental needle-stick injuries. Following removal of device from the pen injector, the pen connection-end needle is also shielded with a mechanism that is designed to reduce the occurrence of accidental needle-stick injuries.

An injection molded outer cover is assembled over the patient end of the cannula. This needle assembly is sealed with a peel-away label to provide a sterile barrier (not shown in figure). The needle is only distributed in sterilized form. AutoShield Duo safety pen needles are intended for single use only and should be properly disposed of after use.

SafeAssist:

SafeAssist™ are safety pen needles with one automatic protective shield, sleeve, needle assembly and outer cover. The needle assembly consists of a double-ended cannula that is assembled into an injection molded hub. The internal threads allow the safety pen needle to be screwed onto the pen injector device. This allows the non-patient end of the cannula to penetrate through the septum of the cartridge.



Picture of SafeAssist Safety Pen Needle

The patient and non-patient ends of the cannula are visible prior to attachment to the injector pen. The patient end of the device has a mechanism that allows the needle to be shielded and locked after use and is designed to reduce the occurrence of accidental needle-stick injuries.

An injection molded outer cover is assembled over the patient end of the cannula. This needle assembly is sealed with a peel-away label to provide a sterile barrier (not shown in figure). The needle is only distributed in sterilized form. SafeAssist™ safety pen needles are intended for single use only and should be properly disposed of after use.

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	Shield	Needle Length	Gauge Size	Bevel	Wall
329505 329535 329605 329608	AutoShield Duo	Dual safety shields	5mm 8mm	30G	3	Thin
329916 329917	SafeAssist	Single safety shield	5mm 8mm	30G	3	Thin

Packaging Configurations:

SKU	Description	Units per shelf carton	Shelf cartons per case carton	Units per case carton
329505	AutoShield Duo Pen Needles 5mm 30G 3bevel TW 100ct	100	8	800
329535	AutoShield Duo Pen Needles 5mm 30G 3bevel TW 100ct	100	8	800
329605	AutoShield Duo Pen Needles 5mm 30G 3bevel TW 100ct	100	8	800
329608	AutoShield Duo Pen Needles 8mm 30G 3bevel TW 100ct	100	8	800
329916	SafeAssist Pen Needles 5mm 30G 3bevel TW 100ct	100	8	800
329917	SafeAssist Pen Needles 8mm 30G 3bevel TW 100ct	100	8	800

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	Polycarbonate, ink for visual indicator band
Lubricant between inner shield and hub	Silicone grease
Needle hub	Polypropylene
Non-Patient end shield *(AutoShield Duo only)*	Polycarbonate, colourant (orange)
Non-Patient end spring *(AutoShield Duo only)*	Stainless Steel type 302
Outer shield	Polycarbonate (clear)
Patient end spring	Stainless Steel type 302
Sleeve	Polycarbonate, colourant *(white for AutoShield Duo), gray for SafeAssist)*
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 safety 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 safety 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:

Stability testing has been conducted to validate the sterility and performance of the safety pen needles through product aging to support the shelf-life claims of 3 years.

Storage Conditions:

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

The safety pen needles have no special storage or handling conditions outside of what is explained in the instructions for use.

Standards:

The safety 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
EN ISO 23908	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 7864	Sterile hypodermic needles for single use. Requirements and test methods *(Partially applied for specific technical design inputs including cannula point quality as per ISO 11608-2)*
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

CE Certification Information:

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

REVISION HISTORY

Revision	Description	By
A	Creation of the document	Laura Deslandes-Azaiez
B	- Update of the Basic UDI-DI number. - Added standards ISO 11737-3 and EN ISO 14155. Added	Laura Deslandes-Azaiez