

“BD AutoShield Duo™ Safety Pen Needle”

Becton Dickinson Ireland Ltd.
Donore Road
Drogheda Co. Louth
A92 YW26
Ireland



TECHNICAL DATA SHEET

BD AutoShield Duo™ Safety Pen Needle with Dual Automatic Protective Shields

Sterile, Single use, Latex Free

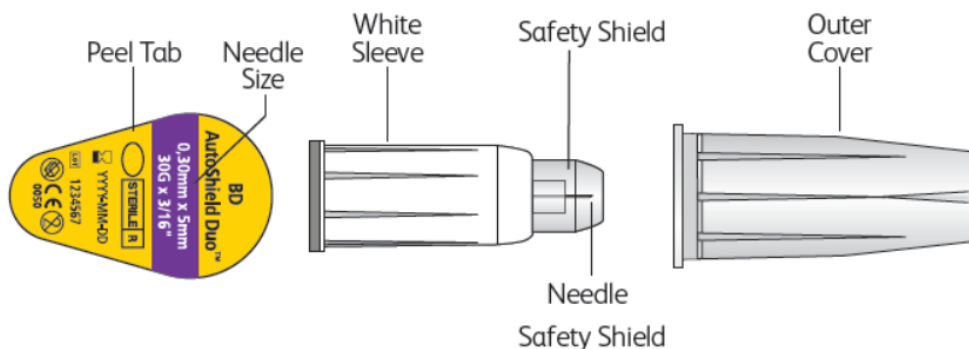
GENERAL INFORMATION

Intended Purpose: BD AutoShield Duo™ Safety Pen Needles with are intended for use with pen injector devices for the injection of drugs by health care professionals or laypersons, in a hospital or home setting. The device is a single use sterile needle designed to reduce occurrence of accidental needle sticks 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).

Description: BD AutoShield Duo™ are safety pen needles with dual automatic protective shields. They are designed to reduce occurrence of accidental needle sticks by providing two safety shields, which lock in place after use (patient-end) and upon removal of the needle from the pen injector device (pen connection-end). 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. 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 sterility barrier and tamper evidence. The needle is only distributed in sterilized form. BD AutoShield Duo™ safety pen needles are intended for single use only and should be properly disposed of after use.

Each unit consists of the following different parts illustrated below:



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Method of use: Prior to injection, the user will attach the BD AutoShield Duo™ Safety Pen Needle to the pen. As the user proceeds with inserting the needle into the skin at 90° angle, the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place. The pen needle should then be removed from the pen. When removed for the pen, the pen connection-end is shielded. The used pen needle will be discarded into a sharp collector.



Product references:

References	Outside diameter	Needle Length	Quantity per Box (units)	Quantity per Shipper (units)
329505	0,30 mm (30G)	5mm	100	800
329535	0,30 mm (30G)	5mm	100	800
329605	0,30 mm (30G)	5mm	100	800
329608	0,30 mm (30G)	8mm	100	800

GENERAL INFORMATION AND STANDARD

✦ **Materials:**

The follow is a listing of the various materials used in the composition of the product.

Components	Materials
Cover	Polyethylene
Sleeve	Polycarbonate, colorant ink for BD logo
Outer Shield	Polycarbonate (clear)
Inner Shield	Polycarbonate, ink for visual indicator band
Cannula	Stainless Steel 304 and lubricant
Cannula Lubricant	Silicone
Patient-end Spring	Stainless Steel type 302
Hub	Polypropylene
Between Inner Shield and Hub	Silicone grease
Non-patient-end Spring	Stainless Steel type 302
Non-patient-end Shield	Polycarbonate, colorant (orange)
Unit label (sterility barrier)	Paper / copolymer foil

The products do not contain natural rubber latex, nor Bisphenol A (BPA), nor phthalates classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC.

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✦ **Labeling:** according to European Medical Device Regulation (2017/745).

✦ **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 – Microbial 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:** 3 years.

✦ **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:**

BD AutoShield Duo™ safety pen needles comply with

- ISO 9626: "Stainless steel tubing for the manufacture of medical devices"
- ISO 11608-2: "Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles"
- EN ISO 23908: "Sharp injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling "

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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 EN ISO 13485, with BSI under file number FM 513512.
Authorized Representative:	Becton Dickinson Ireland Ltd. Donore Road Co. Louth A92 YW26 Ireland	
Manufacturing Site(s):	Becton Dickinson and Company, Pottery Road Dun Laoghaire Co. Dublin, Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1385.
Sterilisation Site(s):	Becton Dickinson and Company, Pottery Road Dun Laoghaire Co. Dublin, Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1385.

CE CERTIFICATION INFORMATION

✦ **Notified body name and address:**

BD AutoShield Duo™ safety pen needles are CE 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 AutoShield Duo™ pen needles are Class IIa medical devices as defined in the Medical Devices Regulation (2017/745).

✦ **CE certificate number:** 745.021

Certificate Expiration Date: 12.22.2027