BD Medical – Diabetes Care
Becton Dickinson France S.A.S.
11, rue Aristide Bergès, BP 4
38801 Le Pont-de-Claix Cedex
France

Helping all people live healthy lives

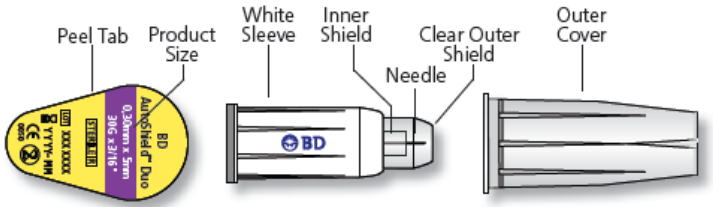
TECHNICAL DATA SHEET
BD AutoShield™ Duo Safety Pen Needle with Dual Automatic Protective Shields
Sterile, Single use, Latex Free

GENERAL INFORMATION

Intended use: BD AutoShield™ Duo Pen Needles are intended for use with pen injector devices for the injection of drugs either by a health care professional on a patient or for self-injection by a patient at home or in a hospital 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: 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 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. The non-patient end of the cannula is visible prior to attachment to the injector pen. Following removal of device from the pen injector, the 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 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:



Method of use: Prior to injection, the user will attach the BD AutoShield™ Duo 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.

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BD AutoShield™ Duo – before use

BD AutoShield™ Duo – after use

Product references:

References	Outside diameter	Needle Length	Quantity per Box (units)	Quantity per Shipper (units)
329605	0,30 mm (30G)	5mm	100	800
329608	0,30 mm (30G)	8mm	100	800
329615	0,30 mm (30G)	5mm	100	800
329618	0,30 mm (30G)	8mm	100	800
329715	0,30 mm (30G)	5mm	100	800
329718	0,30 mm (30G)	8mm	100	800

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GENERAL INFORMATION AND STANDARD

✧ **Materials:**

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

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

The products do not contain natural latex.

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

✧ **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.

✧ **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.

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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 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 "

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 13485:2003, 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):	Becton Dickinson and Company, Pottery Road Dun Laoghaire Co. Dublin, Ireland	Registered to EN ISO 13485, with NSAI under file number MD19.1385.
	Becton Dickinson Infusion Therapy Systems Inc. SA de C.V. Medical Systems Periferico Luis Donaldo Colosio#579 Nogales Sonora C.P. 84048 Mexico	Registered to EN ISO 13485 with BSI under file numbers FM 71665. Registered to EN ISO 9001 with BSI under file numbers FM 504587.

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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.
	BD Medical Diabetes Care 1329 West highway 6 Holdrege, Nebraska 68949-0860 USA	Registered to EN ISO 9001 and EN ISO 13485, with NSAI under file number MD19.1436.

CE CERTIFICATION INFORMATION

✧ **Notified body name and address:**
BD AutoShield™ Duo 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 Directive (93/42/EEC).

✧ **CE certificate number**: 252.783