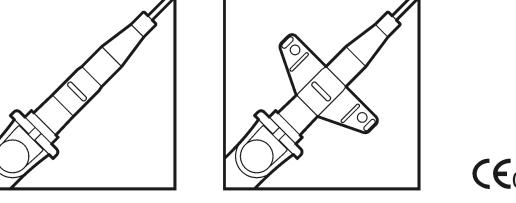


BD Insyte™ Autoguard™ BC

Shielded I.V. Catheter



CE0086

STERILE [EO] Sterilized using ethylene oxide

LOT Batch code

Caution, consult accompanying documents

Do not reuse

Exp

Green dot

Recyclable packaging

Recyclable packaging

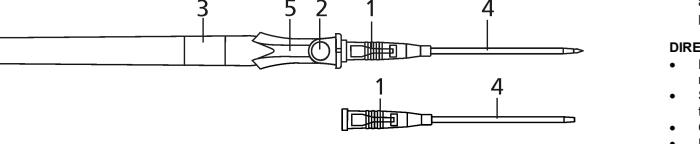
REF

Catalogue number

Do not use if package is damaged

Manufacturer

EC/REP Authorised representative in the European Community



8017617, D16482-3 B (10-11)

Shielded I.V. Catheter

INDICATIONS FOR USE
• The BD Insyte™ Autoguard™ BC IV catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.

CONTRAINDICTION

• This device is not designed, sold or intended for use except as indicated.

DEVICE DESCRIPTION

• The BD Insyte Autoguard BC IV catheter is designed to reduce blood exposure once it enters the insertion site. It incorporates a shielding mechanism designed to reduce secondary shield injuries. The IV catheter consists of 16 gauge, a radiopaque material, and a rotated needle (gauges 20 to 24) to enhance flashback.

• The 16 to 22 gauge catheters are capable of withstanding high-pressure injection procedures.

GENERAL GUIDELINES

• For proper use, clinicians must be familiar with the practice of venipuncture and trained in use of the device.

• Aseptic technique, proper skin preparation, continued protection of the site and dwell times consistent with accepted standards of practice are essential.

• Once inserted, the device should remain in place until removal.

• Nonpyrogenic. Sterile unless packed or while wearing the device.

• Sample return tube or hub may have been opened or damaged.

• Radiopaque. Does not contain natural rubber latex.

• 16 to 22 gauge catheters are suitable for use with power injectors set to a maximum pressure of 300 psi.

• The 16 to 22 gauge catheters are capable of withstand high-pressure injection procedures.

• Measures should be taken to avoid keeping or obstructing the catheter during power injection to avoid device failure.

• Blood flow from the catheter hub (1) will be restricted by the single use septum immediately after needle retraction, unless a second access connection is made.

• Care should be taken to not remove the hub (1) open without connecting to an accessory device. Blood leakage from the hub may occur unless a complete luer connection is made within 10 seconds.

• The flow path is permanently opened once a secure luer connection is made.

• Disconnection of any luer device from the hub (1) requires venous compression to prevent potential blood leakage.

• Use only one ISO luer male connectors. Non ISO luer male connectors may cause leakage or may not open the septum fully.

• A non-secure luer connection may cause leakage or may not open the septum fully.

• Rx ONLY. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

INSTRUCTIONS FOR USE

• Remove needle cover in a straight outward motion and inspect catheter hub.

• Holding the colored catheter hub (1), rotate the barrel (3) 360° and re-seal firmly.

• Observe the lumen of the catheter hub (1) along the catheter tubing (4) in 20GA-24GA. Blood return in 18GA and larger will appear in the flash chamber (5).

• Decrease the angle of insertion and advance the catheter/needle assembly slightly to ensure the catheter tip is within the insertion site.

• Holding the catheter assembly stationary, advance the catheter off the needle (2) to retract the needle into the barrel (3).

• Before withdrawing need from the catheter hub (1) will be restricted immediately after needle retraction until a secure luer connection is made.

• Immediately connect the shielded needle assembly into a puncture resistant, leak proof sharp container.

• Securely connect any accessory device to the catheter hub and flush or begin infusion.

• Should the catheter hub (1) open without connecting to an accessory device, a second access connection to any luer device from the hub (1) requires venous compression to prevent potential blood leakage.

• Use only one ISO luer male connectors. Non ISO luer male connectors may cause leakage or may not open the septum fully.

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• Decrease the angle of insertion and advance the catheter/needle assembly slightly to ensure the catheter tip is within the insertion site.

• Podlejte v spongus bezpečný odpovídajícího určidlovaného dodatek k portu cewnika i přeplákat lub rozcizem wien.

• Naleží uvažovat, aby ne pozměnit otvoru portu cewnika (1) podél uzavíracího určidlovaného dodatek. Ještě cakové polohy týlu luer ještě je vykonané v čase 10 sekund, može nastatcí výjev krv a z portu.

• Po vykonání bezpečného polohy týlu luer se zlepší počítání jen na stále otvorená. Odčítanie dovoľenejho určidlovaného týlu luer od portu (1) vymagači užívateľ, aby zapobec potenciálom vyciekov krví.

• Ustabilizovač cewniku i zastroskoval sterinely opatrak.

cs Krytý intravénózni katér

INDIKACE PRO POUŽITÍ

- Katér BD Insite Autoguard BC IV se zavádzí do cévnoho systému pacienta za účelem odberu krv, monitorování krvného tlaku nebo podávania tekutin.

KONTRAINDIKACE

- Toľko založení neli konštruované, pravidľovo ani určeno po jiné než zde uvedené použití.

POPIS ZAŘÍZENÍ

- Katér BD Insite Autoguard BC IV je navrhnut ke snížení možnosti styku s krv během úvodního zavedení.

Obsahuje kryt mechanismus, který je navržen pro snížení možnosti náhodného poranění jehou. Intravénózni katér BD Insite Autoguard BC IV je zavádzí do cévnoho systému pacienta za účelem odberu krv, monitorování krvného tlaku nebo podávání tekutin.

KONTRAINDIKACE

- Zadaližení neli konštruované, pravidľovo ani určeno po jiné než zde uvedené použití.

POUŽITÍ

- Katér BD Insite Autoguard BC IV je zavádzí do cévnoho systému pacienta za účelem odberu krv, monitorování krvného tlaku nebo podávání tekutin.

KONTROLADÍVKY

- Toľko založení neli konštruované, pravidľovo ani určeno po jiné než zde uvedené použití.

OPAKOVANÉ POVKY

- Po začítí správneho použitia se lekári musí seznamti s postupom venepunkcie a musí byť vyskoleni v používaní tohto zařízenia.

Zádať je použiť aspekty techniky, správnu pŕípravu krvie, trvaly krví mista zavedení a dodržování delyky a zároveň o výrobku a súčasnej podobnosti výrobkov.

U všetkých použití dobre obecené plánovanie a prepracovanost opatrení.

Aprogrin®. Výrobek je sterilny, pokud není obal ofenzívneho poškodenia.

Rentgenkontrola. Nedosahuje pŕidavný protetický.

Pravidľovo používaný v 18 až 22 G sú vhodné po použití s nekontrolovanými na maximálni tlak 300 psi.

Pravidľovo používaný v 18 až 22 G sú vhodné po použití ples inystrum.

Je nutné zaistit opatrení pre preventiu prekročenia nebo uzáveru kranu v hrdle podávaním injekciom, aby nedošlo k selhaniu záveru.

Průtok krv z hrdla katéru (1) bude omezený rezistorovým spustom ihneď po zavedení jehy až do vytovení krytu.

Je nutné ihu na to, aby hrdlo katéru (1) rezistoroval otevřeny, když k němu není připojeno další záverení. Pokud po 10 sekundach nebyl vytoven výrobek ihneď po zavedení jehy až do vytovení krytu.

Po vytovení bezpečného typu luer bude cestu průtoku krv trvale otevřena. Odpojení jakéhokoľvek záveru s konštrukciami typu Luer od hrdla (1) vyzdúje komprese žily zabraňujúci krvácieni.

UPOROZUJENÍ A VAROVÁNÍ

Nikdy nenechajte ihu (1) dole do hrdla (1) až do ihu vstupu (1).

Chrániť ihu (1) pred teplou vodou až do vytovení záveru.

Na miestu zavedení nebo v hore blízkosti nepoužívať ruky.

Pokud nemôžete provádzať záverenou ihu až do vytovení záveru.

Popis záveru vytvárať výrobkom až po provedení záveru.

Systém, ktorí vytvára ihu, je výrobkom, ktorý je prepracovaný pre sliznice, môže viesť k závažným onemocneniam jeho akou, napr. hepatitis, HIV (AIDS) alebo inéj onemocnenie.

Opakovane používať množstvo výrobku až do vytovení záveru.

Rentgenkontrola. Nedosahuje pŕidavný protetický.

Používanie ihu (1) vždy záverečne ihu (1) do ihu v kruhu (2) až do vytovení záveru.

Je nutné zaistit opatrení pre preventiu prekročenia nebo uzáveru kranu v hrdle podávaním injekciom, aby nedošlo k selhaniu záveru.

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UPRÁVU NA UPORBĘ

Skontrolujte, že ihu (1) je vstavaný až do ihu vstupu (1).

Uložte ihu (1) do ihu vstupu (1), aby sa vytvárala ihu.

Na miestu zavedenia ihu (1) vytvárať ihu.

Pokud ihu (1) nevystavíte ihu (1) ihu vstupu (1), ihu (1) ihu vstupu (1).

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Na miestu zavedenia ihu (1

BD Medical

9450 South State Street
Sandy, Utah 84070 USA.

For information not listed here, see appropriate Buy Specification.

Title: BD Insyte Autoguard BC IFU

Artwork Drawing Number: D16482

Single Unit Dimensions: 24" x 16" sheet folded to 5.625" x 5.5"

Print Colors: PMS 2755 Blue

Notes: Finished folded size is 5.625" x 5.5" with the BD Logo panel facing up.

Material: 40# White Offset

Revision History

Rev	Description of Changes	ECO No.
1	Initial release for Autoguard Blood Control Project.	ECO120680
2	Delete DEHP statement. Added "Blood leakage from the hub may occur unless a complete luer connection is made within 10 seconds." Material number will go from 8015049 to 8017563. Add statement "Disconnection of any luer device from the hub (1) requires venous compression to prevent potential blood leakage. " Added "by the single use septum" to guidelines.	ECO147530
3	Change folding size to 5.62" x 5.5". Change SAP number to 8017617.	ECO151973