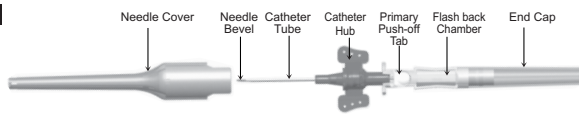


INSTRUCTIONS FOR USE

POLYSHIELD-BC ADVA Safety I.V. Catheter with Spring

BEFORE USE



INSTRUCTIONS FOR USE

These instructions contain important information for safe use of the device. Read the entire contents of these Instructions for Use, including the Warnings and Precautions, before using this product. Failure to properly follow these instructions could result in death or serious injury to the patient and/or clinician.

DESCRIPTION

The Polyshield BC Adva IV Catheter is used to administrate the i.v fluid in to body through veins. It incorporates a shielding mechanism designed to reduce accidental needle stick injuries. The catheter assembly also includes a valve which is designed to reduce blood exposure and to restrict blood flow upon initial venipuncture only.

The color of the catheter's plastic hub also identifies the gauge size, as indicated in the table. Catheter gauge size and length are identified on the product packaging.

The Polyshield BC Adva safety IV catheter is provided sterile and non-pyrogenic for single use only. The Polyshield BC Adva safety IV catheter is not made with natural rubber latex or PVC.

INDICATIONS FOR USE

The Polyshield and Polyguard Safety IV Catheters are indicated for short term use (less than 30 days) for insertion into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 18 - 24G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.

CONTRAINDICATIONS

None known

WARNINGS

- Clinical personnel using this device must be trained in the practice of venipuncture and follow the DIRECTIONS FOR USE provided back side. Failure to follow these instructions could result in death or serious injury to the patient and/or user.

To avoid the potential of an embolus:

- DO NOT CUT THE CATHETER or use sharp instruments near the catheter.
- Never reinsert the needle inside the catheter once the needle has been partially or completely withdrawn as it may pierce and/or sever the catheter. If venipuncture is not successful, discard both the needle and the catheter after engaging the safety mechanism.

Sizes	Color	Maximum Power injector Flow rate for Contrast Media Viscosity	Maximum Power injector Pressure Limit setting
		≤22.5 cP (mPa s)	
24G 0.7mmx19mm	Yellow	4ml/s	300 psi (2069 kPa)
22G 0.9mmx25mm	Blue	6ml/s	
20G 1.1mmx32mm	Pink	7ml/s	
20G 1.1mmx25mm	Pink	7ml/s	
18G 1.3mmx32mm	Green	10ml/s	

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	Cautions	ISO 15223-1:2016 Ref. 5.4.4
	Consult instructions for use	ISO 15223-1:2016 Ref. 5.4.3
REF	Catalogue No.	ISO 15223-1:2016 Ref. 5.1.6
	Do not Reuse	ISO 15223-1:2016 Ref. 5.4.2
	Do not Resterilize	ISO 15223-1:2016 Ref. 5.2.6
	Don not use if package is damaged	ISO 15223-1:2016 Ref. 5.2.8
LOT	Batch Code	ISO 15223-1:2016 Ref. 5.1.5
	Use-by-date	ISO 15223-1:2016 Ref. 5.1.4
STERILE EO	Sterilized using by Ethylene oxide	ISO 15223-1:2016 Ref. 5.2.3
EC REP	Authorized representative of european community	ISO 15223-1:2016 Ref. 5.1.2
	Manufacturer	ISO 15223-1:2016 Ref. 5.1.1
	Non Pyrogenic	ISO 15223-1:2016 Ref. 5.6.3
	Temperature limit	ISO 15223-1:2016 Ref. 5.3.7
	Keep Away from Sunlight	ISO 15223-1:2016 Ref. 5.3.2
	Keep Dry	ISO 15223-1:2016 Ref. 5.3.4
MR	MR Conditional at 1.5T and 3.0T.	
Rx ONLY		

- Exposure to blood, through either percutaneous puncture with a contaminated needle or via mucous membranes, may lead to serious illness such as hepatitis, HIV (AIDS), or other infectious diseases.

To avoid an accidental needlestick:

- Do not bend the needle prior to or during insertion, threading, or removal of the catheter assembly.
- In the unlikely event that the device does not lock out, dispose of the sharp immediately into a sharp's container.
- Do not attempt to override or defeat the safety mechanism.

- Do not reinsert a partially or completely withdrawn needle

PRECAUTIONS

- The Polyshield-BC Adva Safety IV Catheters are provided in a sterile, Non-Toxic and Non-Pyrogenic condition unless the package is open, wet, or damaged. Discard if open, wet, or damaged.
- Check the 'use by' date printed on the device label prior to use and do not use if expired.
- This device is for single use only. Do not re-sterilize and do not reuse. Polymedica Ltd. will not be responsible for any incidental or consequential damages resulting from re-sterilization, reuse or other misuse of the device.
- The valve is designed to provide blood control for typical peripheral venous pressure. Venous peripheral pressures that exceed this range may result in blood leakage from the valve. Observe the valved catheter hub carefully for any sign of leaking as the needle guard is disconnected, apply digital pressure as needed, and attach the I.V. connector securely.
- The valved catheter is intended to be attached to an I.V. connector after placement.
- Do not pull or push the catheter with excessive force and do not bend the catheter as the catheter might be damaged or separate from the hub.
- For the 18G-24G catheters, patency must be established prior to use with a power injector. Use with power injector pressure greater than 300 psi may cause product leakage and/or damage. Do not kink or obstruct the catheter while using a power injector. Ensure that the power injector is calibrated and will not function at pressures exceeding 300 psi.
- This device is designed to reduce the risk of accidental needlesticks. However, care must be exercised when using any IV catheter. In addition to these directions for use, it is recommended that health care professionals follow the recommendations of the CDC and OSHA for blood borne pathogens when inserting, maintaining or discarding any IV catheter to avoid the risk of exposure to blood.
- During catheter insertion, maintenance and removal, follow current CDC "Guidelines for the Prevention of Intravascular Catheter-Related Infections", institutional policy and procedures, and professional standard of care.
- Ensure good securement of the catheter to the patient. Improper securement may lead to loss of vascular access.
- Ensure tight connection of fluid administration to the catheter hub to prevent joint leakage.
- The catheter is shorter than the needle. Blood flashback may therefore occur before the catheter tip is fully in the vein. If necessary, slightly advance the catheter and needle together to assure the full catheter entry into the vein lumen.
- To avoid inadvertently puncturing the posterior wall of the vessel, lower the needle until it is parallel to the skin.
- If venipuncture is unsuccessful, stabilize the catheter hub and retract the needle housing unit until it locks. Listen for the "click" which tells you the needle is safely locked within the needle guard. Then remove the catheter and locked assembly together, holding the hub to the guard, if necessary, prior to disposal.
- Store between 5°C and 25°C, protect from excessive heat or direct sunlight and moisture.
- Federal law (US) restricts this device to sale by or on the order of a physician.

DIRECTIONS FOR USE

Due to the risk of bloodborne pathogen exposure, follows standard precaution during placement, use & removal of an I.V. catheter.

1. Select and prepare site per institutional policy. Apply tourniquet.
2. Remove cover in straight outward motion and inspect device. Ensure catheter hub and primary push-off tab are fully seated to the ribbed needle housing assembly.
3. Hold the device by the ribbed needle housing with thumb and fingers on opposite sides. Verify that the primary push-off tab and needle bevel are in the "up" position.
4. Anchor the vein with gentle skin traction.
5. Insert the needle into the skin and vein at an appropriate angle and check for a quick flash of blood flow in the catheter and later in flashback chamber confirms vein entry. It provides an early indication via the Adva needle technology.
6. Decrease angle and insert device slightly to assure catheter entry into the vein.
7. Holding the needle assembly stationary, advance the catheter off the needle into the vein.
8. Before withdrawing needle from catheter depress white button to retract the needle into the end cap. An audible click indicates that the safety mechanism has been activated.
9. Immediately discard the shielded needle assembly into a puncture resistant, leak proof sharp container.
10. Attach I.V. connector, stabilize device and apply dressing per institutional policy.
11. The valve will allow flow once the luer connector is attached and will remain open after initial activation. Therefore, digital pressure will be required prior to disconnecting the luer connector from the hub, in order to prevent blood leakage



MRI Safety Information

A person with the Polyshield-BC Adva IV catheter attached may be safely scanned under the following conditions. Failure to follow these instructions may result in injury.

Device name	Polyshield-BC Adva IV catheter
Static Magnetic Field Strength (Bo)	<= 3.0 T
Maximum Spatial Field Gradient	720 gauss/cm
Operating Mode	Normal
Maximum Whole Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	15 minutes
MR Image Artifact	The presence of this device may produce an image artifact if the device is relatively close to the area of interest

