

Instructions for Use - Multi-Sample Blood Collection Needle



REF	Model
26500	Multi-Sample Blood Collection Needle 18G X 1"
26501	Multi-Sample Blood Collection Needle 20G X 1"
26502	Multi-Sample Blood Collection Needle 20G X 1½"
26503	Multi-Sample Blood Collection Needle 21G X 1"
26504	Multi-Sample Blood Collection Needle 21G X 1½"
26505	Multi-Sample Blood Collection Needle 22G X 1"
26506	Multi-Sample Blood Collection Needle 22G X 1½"

1 Device Description

- 1.1 The Multi-Sample Blood Collection Needle is a double-ended, sterile, sharp, bevel-edged, hollow tubular device assembled from a protective cap, needle tube, needle hub, rubber sheath, and inner conical fitting with luer lock connectors. It is used for venipuncture and the collection of multiple blood samples from a single puncture site during diagnostic testing or clinical laboratory procedures.
- 1.2 Materials:
 - 1.2.1 Needle tube: SUS304 Stainless Steel
 - 1.2.2 Needle hub: Acrylonitrile-butadiene-methyl methacrylate-styrene copolymer.
 - 1.2.3 Rubber sheath: Synthetic Polyisoprene
 - 1.2.4 Protective Cap: Polypropylene Copolymer

2 Indications for Use

- 2.1 These devices are intended to be used for diagnostic venous blood specimen collection.

3 Intended Users / Patient Population

- 3.1 These devices are intended for use by qualified healthcare professionals in a professional healthcare environment.
- 3.2 These devices are intended for use in the general population for patients requiring venous blood collection.

4 Clinical Benefits

- 4.1 Safe and precise blood collection.
- 4.2 Maintain integrity of blood samples.
- 4.3 Allows multiple samples to be drawn from a single puncture.

5 Warnings / Precautions

- 5.1 Handle with care to avoid needlestick injuries.
- 5.2 Do not replace original needle cover after use.
- 5.3 Single use only – Use once and discard immediately in accordance with local safety regulations. Reuse of needle can result in contamination or transmit disease.
- 5.4 Examine individual needle cartridge for integrity of seal prior to use. Do not use if the tamper proof seal is broken.
- 5.5 Dispose of the needle in a designated sharps container in accordance with guidelines set by OSHA, CDC, and/or other local safety regulations.

- 5.6 Bending the needle can lead to needle breakage. The needle bend angle should not exceed 20°.
- 5.7 If needle is bent or damaged, no attempt should be made to straighten the needle or use the product.
- 5.8 Do not resterilize or reprocess.
- 5.9 Use of infected needles can expose patients or healthcare professionals to infection or bloodborne pathogens. Do not use the product if the sterile packaging has been compromised. Use the device immediately after removing from the packaging.
- 5.10 U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

6 Contraindications

- 6.1 There are no recognized contraindications for the use of these devices.

7 Risks / Side Effects

- 7.1 Use of these devices for venipuncture and collection of blood samples may lead to the following risks and/or side effects:
 - 7.1.1 Bruising or hematoma at the puncture site
 - 7.1.2 Pain or discomfort at the puncture site
 - 7.1.3 Lightheadedness or dizziness
 - 7.1.4 Minor skin irritation at the puncture site
- 7.2 Rare but serious risks or side effects may include:
 - 7.2.1 Infection at the puncture site (if sterile technique fails)
 - 7.2.2 Phlebitis (inflammation of the vein)
 - 7.2.3 Nerve injury
 - 7.2.4 Prolonged bleeding, especially for patients taking anticoagulant medication
 - 7.2.5 Severe vasovagal syncope

8 Sterility

- 8.1 These devices are sterilized by EO gas sterilization.
- 8.2 Single use only. Do not reuse.
- 8.3 Do not resterilize.
- 8.4 Inspect each package prior to use. Do not use the device if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened the device must be used or discarded.

9 Operating Instructions

- 9.1 Clean the target puncture site according to standard clinical practice.
- 9.2 Hold the clear needle cap and twist in order to separate and break off the tamper proof seal. Pull the cap off of the sheath.
- 9.3 Holding the clear needle cap firmly, thread the rear needle (the needle in the rubber sheath) securely into a luer holder. Push an empty vacuum tube up to the guideline inside the luer holder.
- 9.4 Remove the sheath and insert the needle into the patient's vein using proper technique.
- 9.5 Push the vacuum tube further into the luer holder until it punctures the rubber stopper. Allow blood to flow into the tube via vacuum pressure.
- 9.6 Once the required volume is collected, remove the filled tube carefully. Ensure the rubber sleeve prevents any blood leakage during tube changes.
- 9.7 Insert a new tube for additional samples as needed.
- 9.8 After the required number of samples have been collected, carefully withdraw the needle from the vein. Apply pressure to the puncture site and dress it appropriately.
- 9.9 After the procedure, discard of the needle safely in a designated sharps container according to applicable local regulations.

10 Storage

- 10.1 Keep away from direct sunlight.
- 10.2 Keep dry.

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Graphic Symbol Legend for Medical Device Labeling

	Medical Device
	Catalog number
	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Consult instructions for use
	Caution
	Sterilized by Ethylene Oxide. Sterility guaranteed if package unopened and undamaged.
	Manufacturer's Lot Number
	Unique Device Identifier
	Use by date
	For single-patient-use only. Do not reuse.
	Do not reesterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep Dry
	Non-Pyrogenic
	Single Sterile Barrier
	Protective Packaging Outside of Sterile Barrier System
	Manufacturer
	Country of Manufacture
	European Conformity marking
	European Representative
	Australian Sponsor