VACUETTE®

greiner BIO-ONE

CE 0123

VACUETTE® VISIO PLUS Blood Collection Needles

EN

Instructions for Use

Intended Use / Indications for Use

VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognise successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with the Instructions for Use.

The product is a sterile medical device intended to be used in healthcare settings such as hospitals, clinics, and laboratories. The device is suitable for use in pediatric, adult and elderly patients requiring venous blood collection. In combination with tube holders and one or multiple blood collection tubes the needle is inserted into a peripheral vein suitable for venipuncture to establish venous access, allowing for blood collection for in vitro diagnostic testing.

Product Description

VACUETTE® VISIO PLUS Blood Collection Needles are manufactured from stainless steel and are fitted with a safety valve at one end. The perforated label not only serves to simplify identification but also acts as a seal of integrity. The product is not made with natural rubber latex or DEHP.

Precautions / Cautions

- This device is specifically designed and intended for use in combination with other Greiner Bio-One products. Its safety and performance have not been confirmed when used with devices from other manufacturers.
- Do not use if seal is broken, packaging is damaged or unintentionally opened before use.
- Check the device for visible damage before use; do not proceed if any damage is found.
- Do not use the product after the expiration date.
- Do not use if storage conditions were exceeded.
- Practice standard precautions. Key elements include hand hygiene, use of personal protective equipment and maintaining a thorough and clean work environment.
- Do not bend or recap the needle.
- Always keep hands behind the needle to prevent needlestick injuries.
- Do not reuse. A reuse of the product may cause a severe infection.
- Do not resterilize the product.
- Angled threading of the needle into the holder can result in damage to the thread of the holder and needle and can cause the needle to loosen during venipuncture.
- Caution must be taken when collecting blood samples from immobilized, haemophilic or epileptic patients, for example.
- Obtain appropriate medical attention in the case of any exposure to biological samples (for example, through a puncture injury), since they may transmit HIV (AIDS), viral hepatitis, or other infectious disease.
- Handle all biological samples and blood collection “sharps“ (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility.
- Any used needle is considered contaminated. Discard all sets immediately after use in biohazard containers approved for their disposal.
- This device contains the following substance classified as CMR 1B, in a concentration exceeding 0.1 % by weight: Cobalt, CAS Number 7440-48-4 and EC Number 231-158-0. Current scientific evidence indicates that medical devices made from cobalt alloys or stainless steel alloys containing cobalt do not pose an increased risk of cancer or adverse reproductive effects.

Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.

Only applicable for Saudi Arabia: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the Saudi Food and Drug Authority (SFDA).

Needle gauge selection

Selecting the correct needle gauge is essential for patient comfort, minimizes complications, and preserves specimen integrity. Following best practices should be followed:

- Assess vein size and condition before needle selection.
- Use the largest gauge suitable for the patient's vein to ensure optimal flow and sample integrity.
- Follow institutional and healthcare protocols for safe blood collection.

Gauge Recommendations

- **21G:** Suitable for adults and preferred for healthy veins. Preferred for optimal flow and minimal hemolysis risk. [1, 2]
- **22G:** Suitable for adults and patients with smaller or fragile veins, including elderly and pediatric patients. [3]
- If vein conditions require smaller gauges (23G or 25G) other Greiner Bio-One winged products can be used (VACUETTE® EVOPROTECT SAFETY Blood Collection/Infusion Set or SAFETY Blood Collection/Infusion Set).

[1] CLSI GP41, 7th Edition (2017), Collection of Diagnostic Venous Blood Specimens
[2] CLSI PRE02, 8th Edition (2025), Collection of Diagnostic Venous Blood Specimens
[3] World Health Organization (2010). WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy

Storage conditions

Store at 4–36 °C (40–97 °F).
***NOTE**: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the product.*

Handling

1. Grasp both ends of the needle cover and carefully twist. The perforation of the label will now break.
2. Remove the shorter end of the cover. (Fig. 1)
3. Thread the needle into the holder. Make sure the needle is securely seated. (Fig. 2)
4. Select the venipuncture site, apply a tourniquet (max. 1 minute), and prepare the site with an antiseptic. Do not touch the site after cleaning. Place the patient's arm in a downward position, remove the longer end of the cover and perform the venipuncture. (Fig. 3)
5. Check the transparent part of the cannula hub. Flashback will confirm successful venipuncture, blood indication time depends on patient's venous pressure. In some cases, no flashback will appear even if venipuncture was successful. (Fig. 4)
6. Collect blood according to your facility's procedure. Remove tourniquet as soon as blood appears in tube.
7. Always hold tubes in place by pressing the tube with the thumb into the holder to ensure complete vacuum draw. (Fig. 5). ***NOTE**: When making tests that are sensitive to underfilling, a discard tube (no-additive) shall be drawn prior.*
8. Place succeeding tubes into the holder. Ensure that the contents of the tube do not come into contact with the cap or the needle tip during blood collection.
9. As soon as blood stops flowing into the last tube, carefully remove the needle from the vein and then apply pressure to the puncture site with a clean gauze pad until bleeding stops.
10. Promptly dispose of the device in an approved disposal container in accordance with the procedures of your facility.

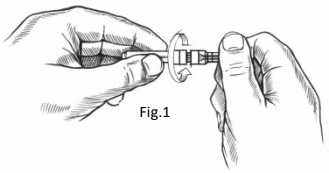
Fig.1

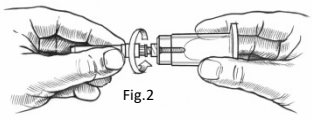
Fig.2

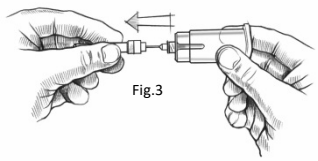
Fig.3

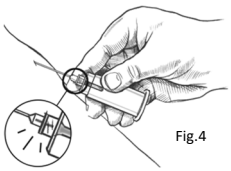
Fig.4

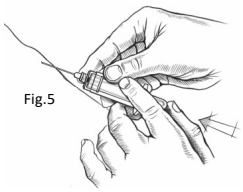
Fig.5

Label Information

	Manufacturer		Temperature limit	Rx Only (USA)	Prescription device
	Use-by date		Do not re-use	MD	Medical device
LOT	Batch code		Do not use if package is damaged		Keep away from sunlight
REF	Catalogue number		Consult instructions for use		Date of manufacture
STERILE EO	Sterilized using ethylene oxide		Single sterile barrier system	CH REP	Authorized representative in Switzerland
	Do not resterilize		Contains hazardous substances: Cobalt		Non-pyrogenic
UDI	Unique device identifier	CE	CE marking: Signifies European technical conformity	JP	Made in Japan
	Fragile		This way up		Keep dry

This only applies to US: Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Production location:
NIPRO MEDICAL INDUSTRIES LTD. Tatebayashi Plant
2-19-64, Matsubara
Tatebayashi-shi, Gunma
374-8518
Japan
Made in Japan
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