VenaBLOCK©

VEIN SEALING SYSTEM

INSTRUCTION FOR USE | ENGLISH

ALL INSTRUCTIONS MUST BE READ BEFORE USE

Marketed by

Reach Medical Systems Pvt. Ltd

FAST & EFFECTIVE VARICOSE VEIN TREATMENT

INVAMED RD GLOBAL

VenaBLOCK ©

Vein Sealing System
Instructions For Use

WARNING:

Single use only. Do not reutilize or re-sterilize. Reuse or re-sterilization processes may cause structural changes, biologi-cal or chemical residuals on the device, failing to work or improper operate of the device and causing damage to the patient. Re-use or re-sterilization processes may result in infection, permanent disease / disability or death.

DEVICE DESCRIPTION

VenaBlock Vein Sealing System 93/42/EEC is a Class III Medical-Surgery product that has the qualities required by “EU Directive, (can be used in surgeries in and out of body). VenaBlock is a n-BCA-polymer structure of which was changed by adding a monomer synthesized by the producing company. It is a ready for use, blue colored, transparent liquid.
Product show polymerization effect with embolization. When contacted with living tissue and in humid environments, it very fast becomes polymerized by forming a thin, flexible membrane with high tension resistance that ensure sticking firmly to the tissues. The subject matter membrane ensures natural fit with the structure of the tissues, it is watertight, does not effects the structures of the blood and organic liquids. This formed membrane, since the polymerization of the product does not cause occurrence of glassy components, it can easily be perforated with surgical needle after it is hardened. The polymerization time changes according to the type of tissue polymer contacted, characteristics of the liquid found, and amount of the product used. When it is applied in the right conditions, VenaBlock starts polymeriza-tion after 1-2 seconds and finish the polymerization process in about 5 seconds. In the normal surgical operations, the membrane formed by it is eliminated from the body through hydrolytic deterioration process; the time of the mentioned process depends on the type of tissue and amount of the polymer used. Whereas in the embolization processes, the polymer stays for a longer time. The polymerization reaction creates a temperature of about 45oC.

INDICATIONS FOR USE

Closure of saphenous vein (vena saphena magna, valve saphenous parva) or perforator veins in endovenous treatment of incompetent varicose veins.

WARNINGS & PRECAUTIONS

- The VenaBlock system should only be used by a trained physician with experience in diagnosis and treatment of venous reflux disease through endovenous techniques.
- Physicians require training using the VenaBlock system by the manufacturer prior to performing this procedures independently.
- Due to the risk of exposure to HIV or other blood borne pathogens, health care workers should always use standard blood and body fluid precautions in the care of all patients. Sterile techniques should be strictly adhered to during any handling of the device.
- The manufacturing company shall not be responsible for the damages to be incurred from the uses other than the applications indicated in this user’s manual.
- VenaBlock is a single use product.
- VenaBlock is ready for use.
- VenaBlock, is not diluted, mixed with other materials.
- “Delivery catheter” of VenaBlock must not be washed with any other liquid
- Do not use the VenaBlock with instruments or accessories that includes silicon or polycarbonate inside them.
- For preventing early occurrence of polymerization or deterioration of the characteristic of polymer, please always check if the instruments or accessories are sterile, compromise with the polymer.
- Do not use if the product is not viscous and/or cloudy.
- Discard the remaining VenaBlock, without re-using it.
- VenaBlock cannot be re-sterilized.
- Manipulate the catheter ONLY under ultrasound imaging guidance.
- Confirm position of the catheter tip in the desired location by ultrasound imaging before activation of the device.
- Injection of the VenaBlock agent should be done by hand injection only and using the VenaBlock delivery system provided. Do not use a power injector.
- Do not kink the catheter. Do not use the catheter if kinked.
- The safety and effectiveness of the VenaBlock system in pregnant women and in pediatric patients have not been established.
- The VenaBlock system is sterile unless the package is opened or damaged. The package should be examined prior to use. If the package is damaged DO NOT USE.
- Do not use after the expiration date.

POTENTIAL ADVERSE EFFECTS

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the VenaBlock system. The adverse events associated with the device are similar to those with traditional endovenous thermal ablation procedures.

- Allergic reactions to cyanoacrylates, such as hives, asthma, hay fever and anaphylactic shock
- Arteriovenous fistula
- Bleeding from the site of access
- Deep vein thrombosis (DVT)
- Edema in the treated leg
- Embolization, including pulmonary embolism (PE)
- Hematoma
- Hyperpigmentation
- Infection at the access site
- Non-specific mild inflammation of the cutaneous and subcutaneous tissue
- Pain
- Paresthesia
- Phlebitis
- Superficial thrombophlebitis
- Urticaria or ulceration may occur at the site of injection
- Vascular rupture and perforation
- Visible scarring

SHELF LIFE

If preserved in the indicated conditions, the product has a shelf life of one (1) year after the production date of the prod-uct. It is not used after the date of expiry.

STERILITY

The VenaBlock embolization liquid provided sterile by exposure to ethylene oxide (EtO) following exposure to dry heat. The VenaBlock delivery system is provided sterile by exposure to ethylene oxide (EtO).

SUPPLIED COMPONENTS

The VenaBlock closure system is a medical device provided as a sterile two parts. VenaBlock embolization liquid can be obtained as much as necessary as one (1) cc vials. VenaBlock Delivery System comes as one sterile package. Compo-nent list is below:

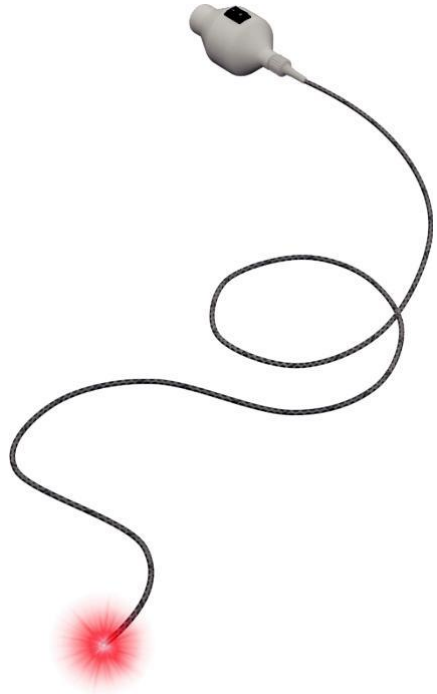
1. VenaBlock Embolization Liquid

One (1) cc of the VenaBlock adhesive (a specially formulated n-butyl-cyanoacrylate) is contained within a screwed-capped vial. Can be supplied as desired volumes. (Minimum 2 cc is required)

2. The Dispenser Gun

The dispenser gun consists of a pistol type, ergonomic handle with an integrated barrel and trigger. Each depression and hold of the trigger delivers a 0.3 cc in 5 seconds continuously.

3. Delivery Catheter



- The catheter is 6 Fr with an effective length of 100 cm.
- Catheter is fully made of PTFE in order to not give reaction with NBCA.
- Catheter is coil reinforced in order to increase kink resistance and enhogenic visibility.
- There are markers at every 2 cm in order to help with pull back rate.
- There is guidelight assist at the proximal tip of the catheter.

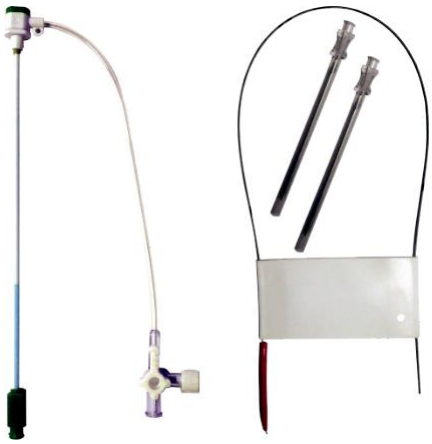
4. Guidelight Adapter

Guidelight can be turned on and off from the adapter at the distal end of the catheter. Injector also connects with the adapter.

5. 3 cc – Syringe

The 3-cc Luer Lock Syringes, can be filled by 2 cc and locked to the adapter.

6. Introducer Kit



6F Intoducer catheter with dilator, 0.035” J-Tip 45 cm guidewire and two (2) units of 18G seldinger needle is provided with kit.

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APPLICATION

1) Installation

a. Open blister package and place the materials in the set on the operation table according to the sterile techniques.

b. VenaBlock package should consist of the following materials:
   i. 2 units of 18 G seldinger needle
   ii. An intraducer set with 6F short introducer sheath, dilator and 45 cm 0,035” J-tip guidewire
   iii. 6F (2 mm), 100 cm PTFE delivery catheter and adaptor
   iv. 3 cc injector
   v. VenaBlock polymer (minimum 2 cc is required)
   vi. Dispensing Gun

c. Check the package contents and lumen openings of catheters.

d. Please be careful! Delivery catheter and injector shouldn’t be washed or contact with water / saline

2) Seldinger entry and introducer placement under USG

a. Before puncture vena saphena magna or vena saphenaparva and perforator mapping should be per formed detailed.

b. Once the entry side is determined, local anesthesia should be done.

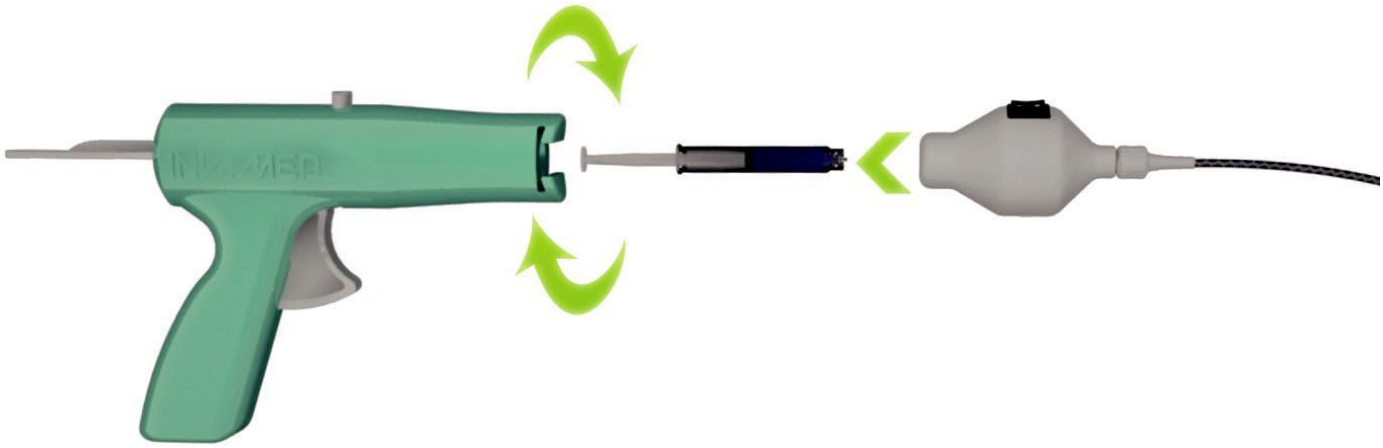
c. Once lumen access is achieved 6F introducer sheath placed into the target vein.

3) Preparation and positioning of the delivery system

a. VenaBlock polymer must be transferred into the 3 cc injector by 2 cc. Gun is adjusted to 2 cc polymer injection not more. Air inside of the injector should be released by pushing trigger of the gun. If it is needed to use more polymer, this step should be repeated.

b. Once the polymer transferred into the injector, injector should be attach to the gun adaptor and locked by twisting. Please make sure of injector is locked. Otherwise pressure of the gun can throw injector.

c. Injector and adaptor part of delivery catheter must be connected by spin-lock mechanism.



d. Priming of the delivery catheter: Delivery catheter must be primed. After connection made between delivery catheter and adaptor gun trigger must be held for one second X2 (twice). This way all the air in delivery catheter will be primed.

e. Turn on the adaptor at the distal end of delivery catheter. Light beam at the distal tip of the catheter will be turned on and it will improve traceability inside of the vessel.

f. After venous access, PTFE delivery catheter is send into the target vein and advanced into the saphe nofemoral junction or saphenopopliteal junction.

g. The distance between the tip of delivery catheter and junction should be 3 cm. So, tip of the delivery catheter must be pulled back by 3 cm from the beginning of the junction. This distance should be checked under ultrasound.

4) Application

a. Before starting inject VenaBlock polymer into the vein, constant pressure should be applied over the junction and closure of should be confirmed by ultrasound.

b. Before the first injection, specialist must pressure over the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ) in order to prevent migration of first bolus polymer in to the deep venous system. While pressuring SFJ or SPJ, first injection of polymer must be applied continuously. Right after first injection pressure must be applied for at least five (5) seconds while pressuring SPJ simultaneously. After the venous closure is obtained and second polymer injection continuously done, second pressure shall be applied in same method. Pressure technique shall continue until the targeted vein segment fully sealed.

c. Injection of polymer into the vein is a continuous procedure. Delivery gun is set up as: One slowly pull of the trigger, while pressing for five (5) seconds, gives 0.3 cc of polymer. Specialist must draw back catheter according to the diameter of the target vein. In every five (5) trigger must be pushed again and continuous draw back should be applied simultaneously. This way specialist can apply polymer in every cm.

d. For the diameters raging from 5.5 to 10 mm, delivery catheter should be pulled back ten (10) cm during five (5) seconds polymer injection (2cm/s). For the diameters of 10-20 mm, delivery catheter should be pulled 5 cm in every five seconds (1cm/s).

e. After first injection, pressure must be applied for at least five (5) seconds while pressuring SPJ simultaneously. After the venous closure is obtained and second polymer injection continuously done second pressure shall be applied in same method. Pressure technique shall continue until the targeted vein segment fully sealed.

f. Pressure areas can be traced easily by following guide light at the tip of the delivery catheter. Pressure must be applied right after following guide light by 2cm/sec.

5) Control and finish

a. After the procedure, all applied vein segment should be controlled under ultrasound.

b. All perforators should be controlled detailed in order to prevent recanalization over perforators. If there is open perforator segment or open vein segment, polymer should be applied with an entry of injector. Polymer can be applied by 0.1 cc with a small injector and pressure of five (5) seconds over the perforator or open segment would be enough to closure.

Total Amounts of VenaBlock Embolization Liquid Expected for Use in Vein Treatments

The amount of adhesive delivered is related to length of the target GSV. The VenaBlock Instructions for Use describe the application of 0.03 cc of the VenaBlock embolization liquid every cm in the target vein. The table below shows a calculation of the total expected amount of adhesive delivered as a function of target treatment length. Additional injections could be administered at sites of dilatation and junctions with tributaries. The exact application procedure and dosage is to be determined by the physician.

Table 1: Total amount of adhesive delivered as a function of planned treatment length (FOR REFERENCE ONLY)

Planned Treatment Length (cm)	Total Amount of NBCA (cc)
5	0,15
10	0,3
15	0,45
20	0,6
25	0,75
30	0,9
35	1,05
40	1,2
45	1,35
50	1,5
55	1,65
60	1,8
65	1,95
70	2,1
75	2,25
80	2,4
85	2,55
90	2,7
95	2,85
100	3

STORAGE

Store in controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet radiation.

DISPOSE

Dispose VenaBlock product according to the standard institutional processes for single use, medical waste including devices in contact with blood.

WARRANTY DISCLAIMER AND SETTLEMENT LIMITATION:

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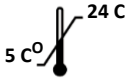
LABELING / MARKING REMARKS:

STERILE EO	Sterilized with Ethylene Oxide.
STERILE	Sterilized with dry heat.
	Pay attention to label warnings.
	Do not use if the product is damaged or package is already opened.
	Single use only. Cannot be used second time.
	Cannot be re-sterilized.
	Keep away from sunlight.
	Please read instructions for use before.
	May create potential Biologic Wast after use.
	Keep in dry places.
	Breakable.
	Keep in controlled environment between 5 to 24 °C.
	Expiration date
	Manufacturer
REF	Reference number
LOT	Lot number
Rx	Caution: Federal Law restricts this device to sale by or on the order of a physician

INVAMED

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