



INSTRUCTIONS FOR USE

SET FOR VENOUS INSUFFICIENCY TREATMENT, FLEBOGRIF

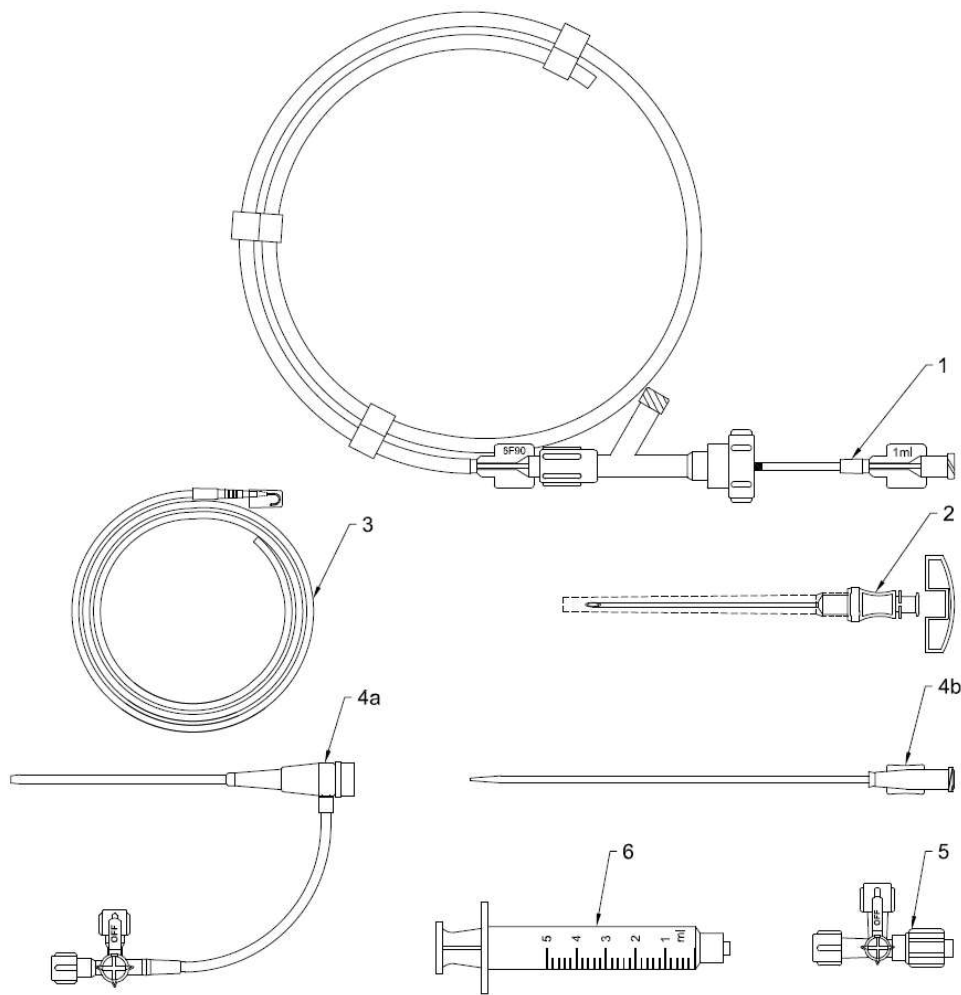
FLEBOGRIF™



READ THESE INSTRUCTIONS BEFORE USE

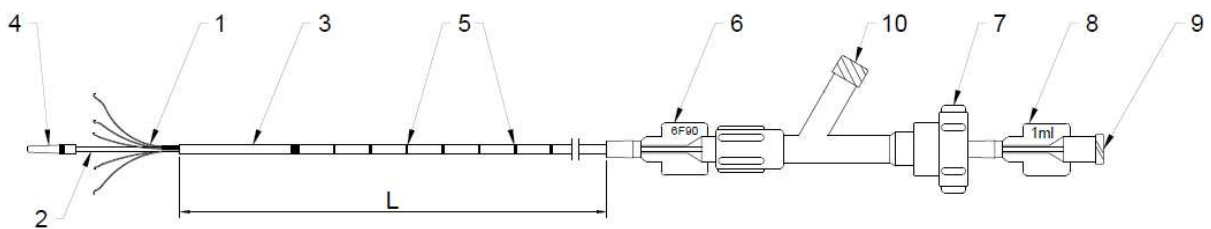
1. DEVICE DESCRIPTION

The set for venous insufficiency treatment Flebogrif consists of several components: catheter, needle, guidewire, introducer sheath, dilator, three-way stopcock and syringes (Fig. 1.). The catheter is equipped with a cutting elements consisting of five retractable, branching arms arranged circumferentially designed to scratch the inner wall of the vein.



- 1. Flebogrif catheter 6 F
- 2. Needle 18 G
- 3. J-type guidewire 0.034''
- 4a. Introducer sheath 6 F
- 4b. Dilator
- 5. Three-way stopcock
- 6. Luer-lock syringe 5 ml 2 pcs

Fig. 1. Components of the Set for venous insufficiency treatment Flebogrif



- 1. Cutting elements
- 2. Inner shaft
- 3. Outer sheath
- 4. Soft tip
- 5. Length markers
- 6. Size information
- 7. Clamping knob (Y connector)
- 8. Inner shaft hub with the dead space information
- 9. Sclerosant injection port (female luer-lock connector)
- 10. Flushing port (female luer-lock connector)
- L - Effective (usable) length

Fig. 2. Flebogrif catheter



The catheter consists of two coaxially cooperating parts:

- internal - designed to be a lumen for the guidewire and to deliver the foamed sclerosant. The distal part includes of a cutting elements and atraumatic tip. The proximal part consists of a female luer-lock hub informing about the dead space volume of the catheter and a marker indicating the opening / closing of the cutting elements;
- external - with length markers every 1 cm (starting at 10 cm from the distal end).

The cutting elements are retracted by sliding the outer part over the inner part. Turning the n on the Y connector allows the cutting elements to be locked in the open position.

Table 1. Device parameters

Catheter diameter	6 F (2.08 mm)
Catheter length	60 cm or 90 cm
Catheter dead space volume	0.8 ml for 60 cm catheter; 1 ml for 90 cm catheter
Needle size	18 G
Needle length	7 cm
Guidewire diameter	0.034" (0,86 mm)
Guidewire length	150 cm for 60 cm catheter; 180 cm for 90 cm catheter
Guidewire coating	PTFE (polutetrafluoroethylene)
Introducer sheath with dilator diameter	6 F (minimum ID 2.18 mm)
Syringe volume	5 ml
Syringe connector type	luer-lock

2. PRODUCT RANGE

The Flebogrif is available in 60 cm and 90 cm length versions.

3. INTENDED PURPOSE / INDICATIONS

The Set for Venous Insufficiency treatment, Flebogrif is intended for mechanochemical ablation of lower extremity superficial truncal veins.

3.1 CONTRAINDICATIONS

The use of the Flebogrif is usually contraindicated in the following cases:

- active thrombosis of deep veins and their occlusion;
- pregnant women;
- significant lower limb ischemia;
- severe lymphedema (grade 2 or 3);
- coagulation disorders;
- allergy or hypersensitivity to a sclerosing agent and/or device materials (polyamide, polyethylene, stainless steel);



- contraindications to intravascular use of sclerosing agent foam due to other conditions.

3.2 POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with the use of this device include (in alphabetical order), but are not limited to:

- allergy or hypersensitivity to device materials or a sclerosing agent;
- bleeding;
- complications resulting from the use of sclerosing agent;
- deep venous thrombosis;
- embolism;
- hematoma;
- hyperpigmentation;
- induration along the course of the treated vein;
- pain;
- perforation of the vessel;
- prolonged pain;
- saphenous nerve neuralgia;
- skin necrosis;
- superficial phlebitis;
- wound infection.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer at reklamacje@balton.pl and the competent authority of the country in which the user and/or patient is established.

3.3 INTENDED USER PROFILE

Intended users of the device are only physicians adequately trained in endovenous procedures.

3.4 USE ENVIRONMENT

The use of Flebogrif is permitted in operating / procedure rooms adapted for endovenous procedures. An essential requirement is the availability of an ultrasound Duplex Doppler scanner.

3.5 PATIENT TARGET GROUP

The target group are patients requiring ablation of trunks of superficial veins in the lower extremity (great saphenous vein and small saphenous vein). No known data restrict the use of this device in patients of particular gender or race.

Before deciding on the use of the device, potential benefits and risks should be considered individually for every patient.



4. WARNINGS



- This device is designed for single use in a single patient only. Do not resterilize or reuse. Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or resterilization may also create a risk of contamination of the product and cause patient infection, including the transmission of infectious disease(s). Contamination of the product may lead to injury, illness or death of the patient.
- Do not use if the package is opened or damaged.
- Do not use after the expiration date given on the package label.
- Do not use if labeling is incomplete or illegible.
- Do not withdraw the guidewire against the needle bevel - it may damage or shear off the tip of the guidewire.
- Do not inject the sclerosing agent through the flushing port (Fig. 2. point 10. - Flushing port (female luer-lock connector))

5. PRECAUTIONS

- Perform ultrasound examination prior to the procedure.
- Any movements of the Flebogrif should take place over the guidewire.
- Always confirm the correct positioning of Flebogrif catheter under ultrasound guidance.
- Close the cutting elements prior to removing the Flebogrif catheter from the patient.
- This device is intended to be used in the great saphena vein and small saphena vein.
- Confirm the right position of the Flebogrif catheter distal section in the superficial vein and deep vein junction (2 cm before the junction) under ultrasound.
- In case of veins of a diameter larger than 10÷12 mm, consider double scratching of the inner vein wall (first pass over the guidewire - scratching only; the foam injecting during the second scratch).
- Evaluate the patient according to The Venous Thromboembolism Scale.
- Do not use excessive force while introducing, manipulating and removing the device. If resistance is felt, check the possible cause of resistance before deciding to continue the procedure.
- The patient should be given all information about the procedure and the correct conduct during and after the procedure.

6. HOW SUPPLIED



6.1. CONTENT OF THE PACKAGING

One (1) set, on a container in the pouch, packed with Instructions for Use in a unit box.

6.2. STERILITY

This device is supplied sterilized with ethylene oxide gas on a container in a pouch. Only the content of the pouch should be considered sterile. The device is only sterile if this packaging is not opened or damaged.

7. HANDLING AND STORAGE

Store at room temperature in a dry place, in a unit box, as supplied.

Do not expose to temperatures outside the range: 10 °C ÷ 30 °C.

8. DISPOSAL INSTRUCTIONS

The used device shall be treated as medical waste. After use, dispose the device and packaging in accordance with healthcare facilities, administrative and/or local government policy.

9. WARRANTY

If a delivered device is damaged or has any other defects, please inform the manufacturer and keep the device in its original packaging.

10. OPERATIONAL INSTRUCTIONS

Balton sp. z o.o. shall not be liable for any direct, incidental or consequential damages resulting from the misuse of this product.

10.1 REQUIRED DEVICES AND SUBSTANCES

Table 2. Required devices and substances

AMOUNT	DEVICE / SUBSTANCE
as needed	Sterile, normal saline
as needed	Sclerosing agent
as needed	Scalpel

10.2 PREPARATION

1. Check the primary packaging (pouch) for possible damage and expiry date.



If there is a suspicion that sterility may be compromised and/or the expiry date has been exceeded, it must not be used.

2. Open the pouch and open the container.
3. Check if the set components are not bent, kinked or damaged.





If there is a suspicion that the device is damaged, it must not be used.

4. Check the patency and track the path of the superficial vein selected for ablation, using the Duplex Doppler ultrasound probe, with a particular focus on superficial vein and deep vein junction.
5. Determine the lowest point of incompetent vein in which the Flebogrif catheter will be introduced.
6. Determine the site in which the Flebogrif catheter will be introduced to the vein, distally from the segment with identified insufficiency of venous valves, and in the case of whole vein insufficiency, maximally peripherally, keeping in mind the necessity of sufficient vein visibility in ultrasound at the determined puncture site.



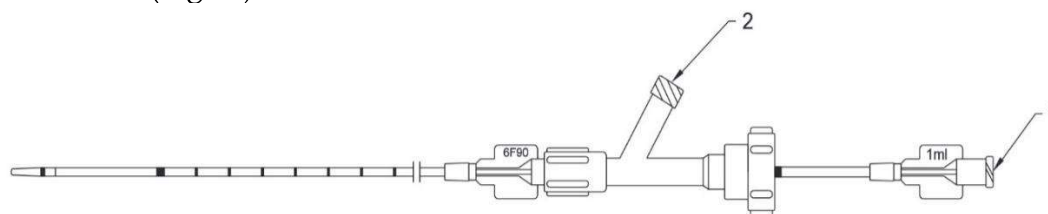
Additionally, it is helpful to identify the level of great side branches and direct perforators' origin.

7. Lay the patient in the supine position for ablation of the saphenous vein or in the prone position for ablation of the peroneal vein.
8. Disinfect the patient's skin and cover with a sterile drape.
9. Remove elements of the set from the plastic container.
10. Flush the needle with normal saline solution and remove the needle's protector.
11. Flush the guidewire in the hoop with normal saline solution.
12. Remove the protective cap from the distal tip of the guidewire.
13. Slightly, slide the guidewire out of the hoop.
14. Flush the dilator and the introducer's sheath with normal saline solution.
15. Insert the dilator into the introducer sheath through hemostatic valve and snap into place.



The dilator must be snapped into place in the hemostatic valve to avoid damaging of the vessel.

16. Remove the catheter from the hoop and flush both its ports with normal saline solution (Fig. 4.).



1. Sclerosant injecting port (female luer-lock connector)
2. Flushing port (female luer-lock connector)

Fig. 4. Ports to be flushed

10.3 PROCEDURE





Perform ultrasound examination prior to the procedure.

1. Anesthetize the skin in the selected site of puncture.
2. Puncture the vein with an 18 G needle under ultrasound guidance.



Puncture with an 18 G needle should always be performed under ultrasound guidance.

3. Straighten the guidewire tip and insert the guidewire to the needle.
4. Remove the needle.
5. Insert the guidewire to the superficial and deep vein junction (Fig. 5).



Do not insert the guidewire into the deep vein to minimize the possible risk of thrombotic complications.

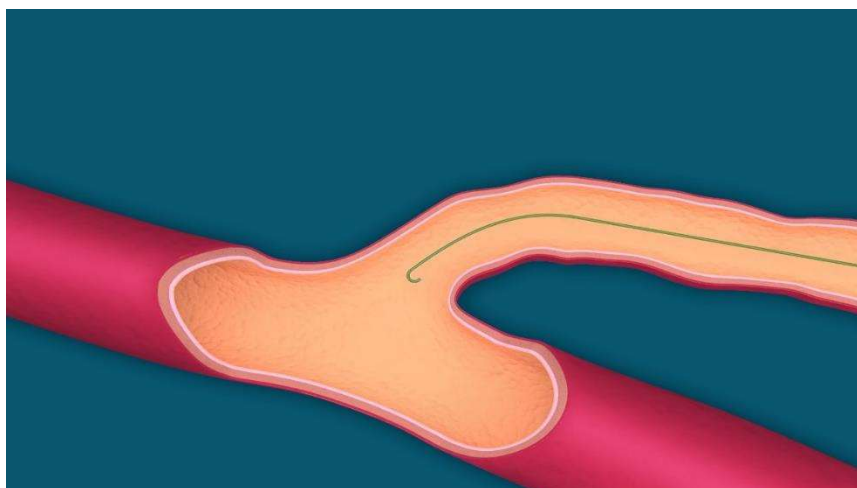


Fig. 5. Guidewire introducing

6. Put the sheath with a dilator on the guidewire.
7. Introduce the sheath and dilator assembly over the guidewire to the punctured vein.



Before introducing the sheath with dilator, you can make a small skin incision with a scalpel, which makes the sheath introduction easier.

8. Withdraw the dilator from the sheath.
9. Introduce Flebogrif catheter through the sheath, over the guidewire across the entire length of the ablated vein, placing the tip 2 cm below the superficial and deep vein junction (Fig. 6).



Always insert the Flebogrif catheter over the guidewire.

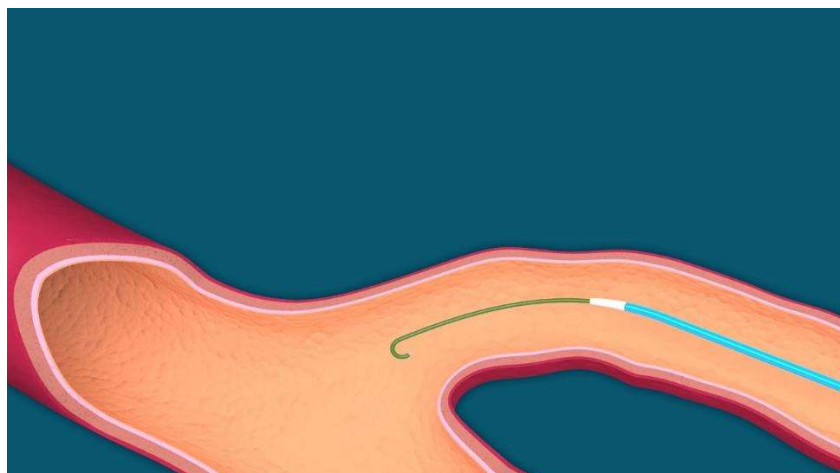


Fig. 6. Introducing the catheter over the guidewire

10. Confirm the correct position of the Flebogrif catheter (2 cm below the junction of the superficial vein and the deep vein) under ultrasound guidance.



In case the position of Flebogrif catheter is to be changed, make sure the cutting elements are closed.

Always change the position using the guidewire.

11. Remove the guidewire.
12. Open the clamping knob of the Y connector (counterclockwise) (Fig. 7.).



Fig. 7. Opening of the hemostatic valve

13. Immobilize the hub (Fig. 2. point 8. - Inner shaft hub with the dead space information).
14. Using your other hand, move the outer sheath with Y connector over the inner shaft all the way towards the inner shaft hub (Fig. 8a.). Cutting elements are open (Fig. 8b.).



Fig. 8a. Moving the Y connector



Fig. 8b. Opening of the cutting elements



At this point, the cutting elements are open and pressed against the vein wall.

15. Tighten the clamping knob of the Y connector (clockwise) (Fig. 9).



Fig. 9. Tightening the clamping knob of the Y connector

16. Read the Instructions for the use of the sclerosing agent.



The dose of a sclerosing agent should be determined in accordance with the recommendations of its manufacturer.

Prepare the foam immediately before injecting. Pay attention to the foam stability time according to the sclerosant's Instructions for use.

The ratio of air or CO₂ to sclerosing agent should be 4:1 (4 units of air or CO₂ to 1 unit of sclerosing agent).

17. Prepare the foam:

- a. Aspirate 1 ml of sclerosing agent to one syringe and 4 ml of air or CO₂ to another.
- b. Connect two syringes with a three-way stopcock (Fig. 10.).



- c. Move the mixture of gas and sclerosing agent back and forth between both syringes, alternatively depressing their pistons, until foam forms.



Fig. 10. Syringes connected with a three-way stopcock

18. Connect the syringe with a prepared dose of foamed sclerosing agent to the Flebogrif hub (Fig. 2. point 9. - Sclerosant injection port (female luer-lock connector)).



Do not inject the sclerosing agent through the flushing port (Fig. 2 point 10. - Flushing port (female luer-lock connector)).

19. Fill the lumen of the Flebogrif catheter with the sclerosing agent.



The dead space volume is marked on the catheter hub - 0.8 ml for 60 cm long version and 1.0 ml for 90 cm one (Fig. 11.).



Fig. 11. Dead space volume of the catheter

20. Confirm the position of the cutting elements under ultrasound.



While injecting the foam, press the junction of superficial and deep vein with the ultrasound head.

21. Pull the Flebogrif catheter in a steady motion, scratching the vein inner wall with the open cutting elements, simultaneously injecting the sclerosing agent (not less than 1 ml for every 5 cm of the vein).



This process should be continued along the entire length of the ablated vein, until the last 10 cm of the Flebogrif catheter remains in the vein.



If the ablated segment is relatively short, you can pull out the introducer sheath and continue pulling the Flebogrif catheter with open cutting elements out for approximately another 5 cm.

22. Unscrew the clamping knob of the Y connector (counterclockwise).
23. Fold the cutting elements by pulling the inner shaft out of the outer sheath until a black marker is visible outside the Y connector (Fig. 12.).



Do not pull the inner shaft once the black marker appears outside the Y connector.



Fig. 12. Cutting elements position marker (folded elements)

24. Tighten the clamping knob of the Y connector (clockwise).
25. Before removing the Flebogrif catheter make sure cutting elements are fully folded and sclerosing agent injection is over.







The black marker should be visible outside the Y connector.

26. Remove the Flebogrif catheter and the introducer sheath from the vein.
27. After completing the procedure, apply the compression therapy with an elastic compression stocking / bandage (at 30 - 40 mmHg), for at least 2 weeks (recommended).




















11. CLINICAL STUDIES

Clinical studies for this device are available on the manufacturer's website.

SYMBOLS GLOSSARY

	CE mark		Medical device
	Unique device identifier		Manufacturer



	Date of manufacture		Use-by date
REF	Catalogue number	LOT	Batch code
	Consult instructions for use or consult electronic instructions for use		Do not use if package is damaged and consult instructions for use
	Caution	STERILEEO	Sterilized using ethylene oxide
	Do not re-sterilize		Do not re-use
	Single sterile barrier system		Single sterile barrier system with protective packaging outside
	Non-pyrogenic		Keep away from sunlight
	Fragile, handle with care		Temperature limit
Not made with natural rubber latex	Not made with natural rubber latex		Additional information facilitating proper use
	n units per package		Keep dry
	Recyclable packaging material		Outer catheter diameter
	Catheter length	INT	Introducer size
GW USE	Guidewire compatibility	NEEDLE	Needle size
SYRINGE	Syringe volume	CH REP	Swiss Authorised Representative