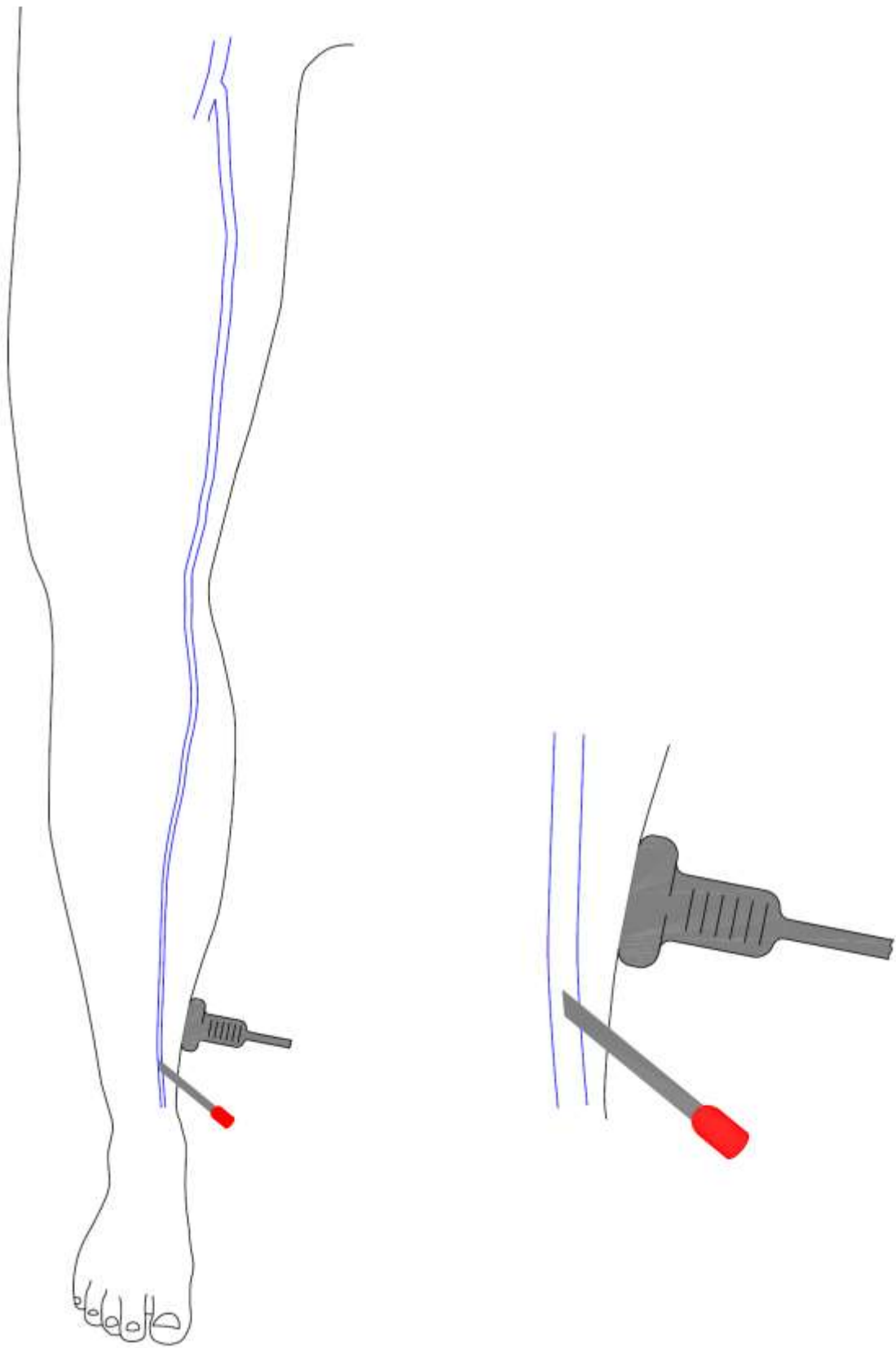


An option to treat a saphenous vein by chemo-mechanical ablation

On the following pages you will find a theoretical model. If there is a medical enterprise that is interested in realizing this concept they can contact me.

The following pages will illustrate one option for ablatively treating a saphenous vein. This method is mechanical and chemical. The administration of Aethoxysklerol® leads to a chemical destruction of the vein wall. The vein wall is then additionally destroyed with a balloon with cutting elements. On the following pages, this procedure will be explained in detail.

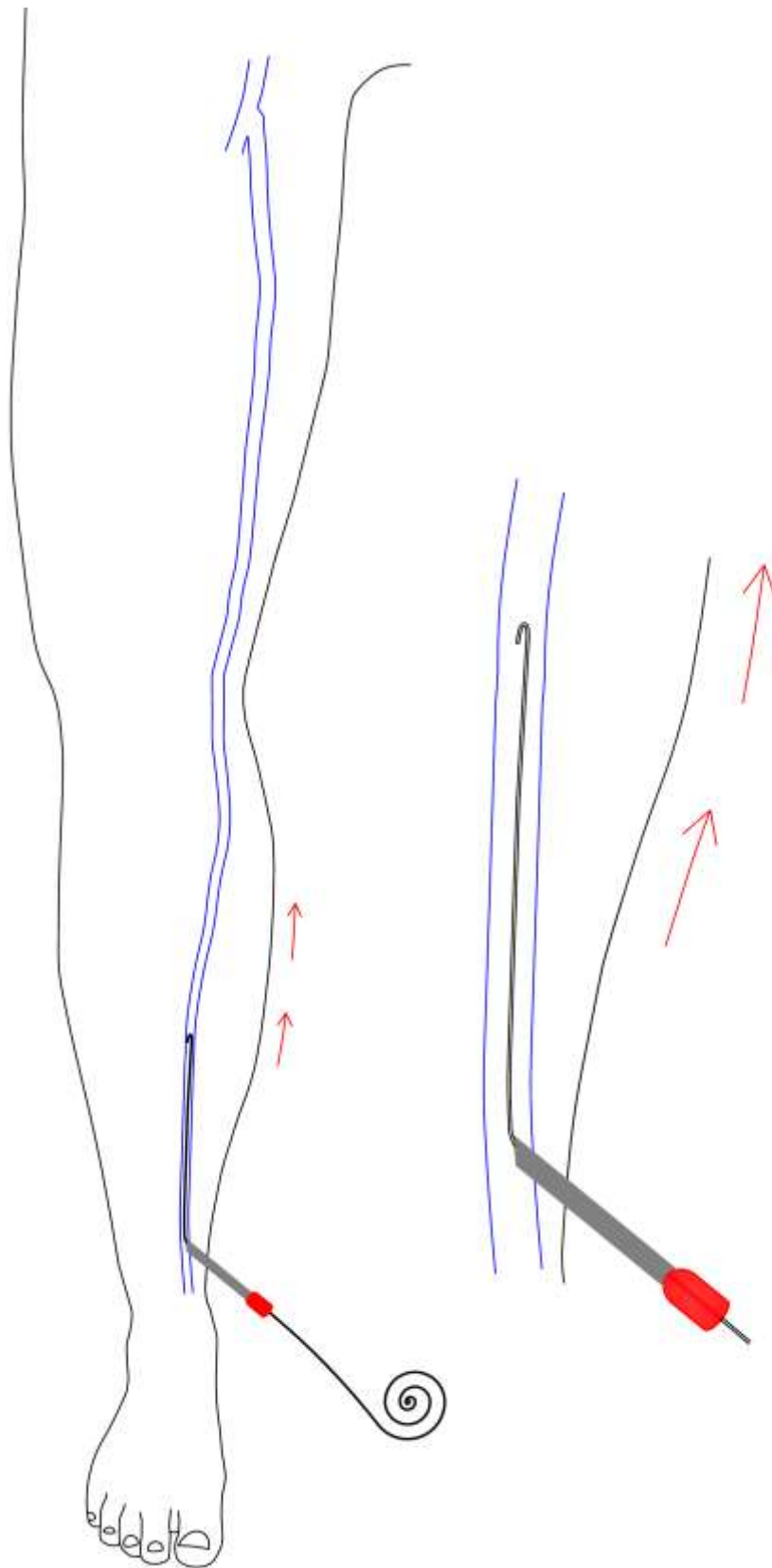
Puncturing the great saphenous vein



Puncturing the great saphenous vein

By means of ultrasound, the great saphenous vein is punctured at the distal point of insufficiency.

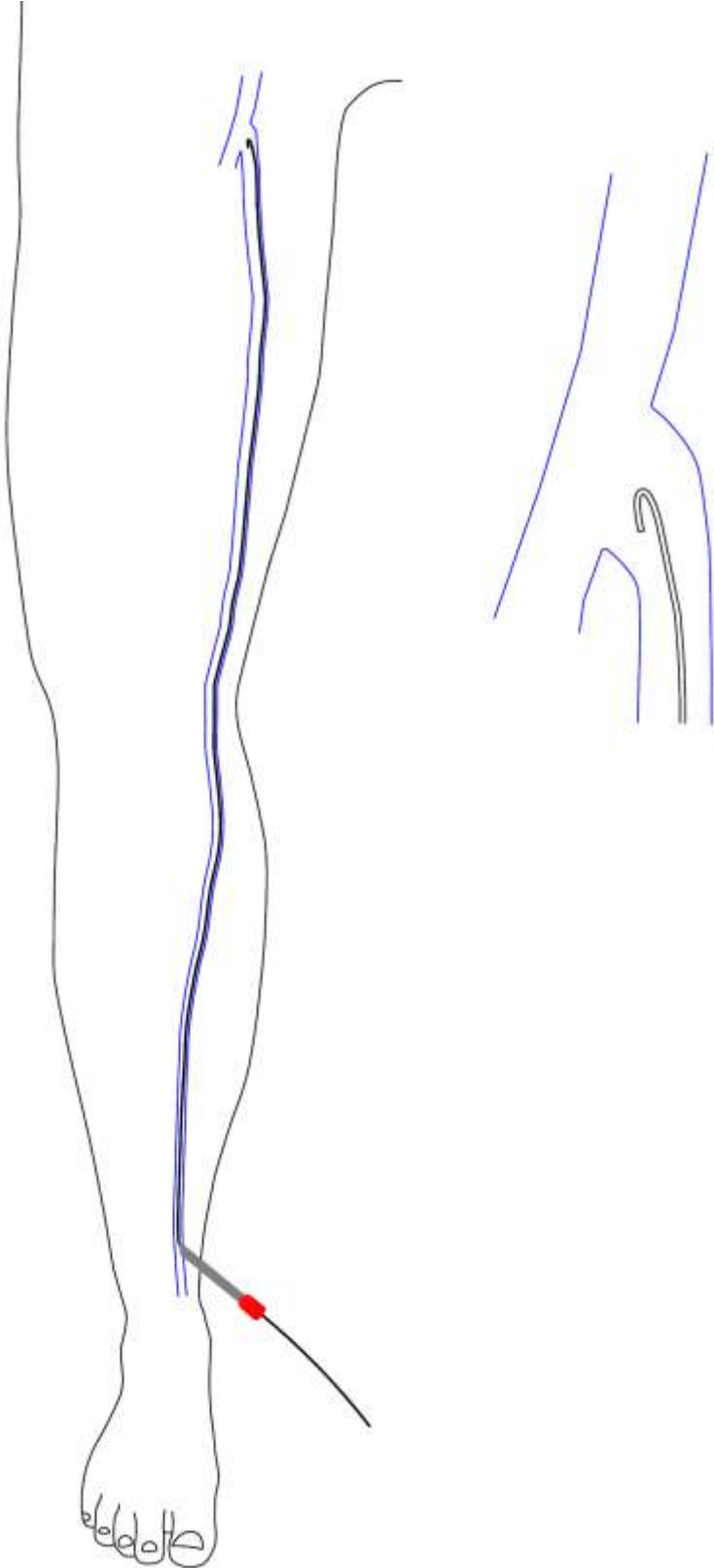
Pushing the wire up into the great saphenous vein



Pushing the wire up into the great saphenous vein

Under ultrasound control, a guide wire is pushed up the great saphenous vein to the sapheno-femoral junction (SFJ) via the needle.

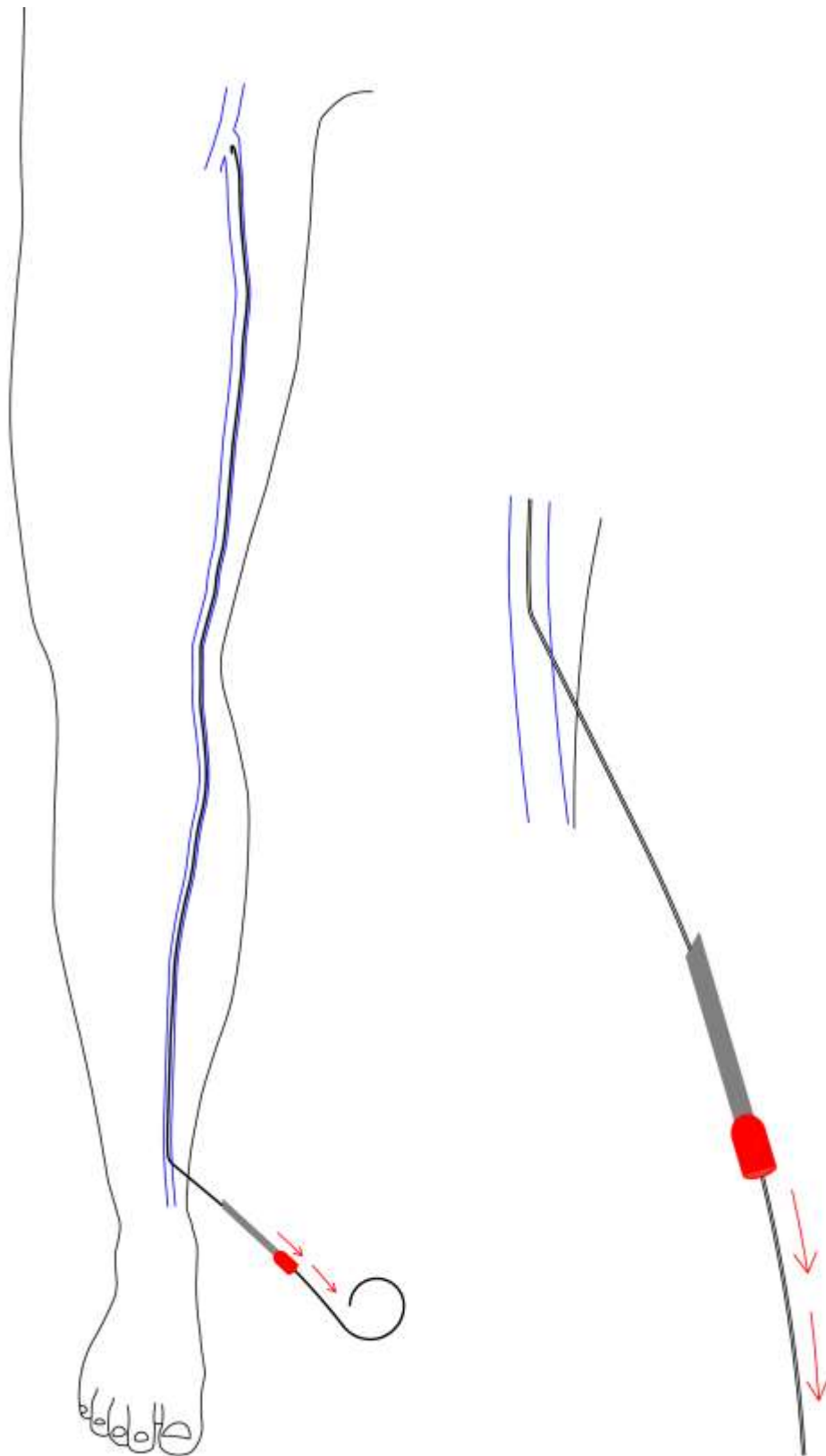
Placing the wire in front of the sapheno-femoral junction (SFJ)



Placing the wire in front of the sapheno-femoral junction (SFJ)

The wire is pushed in front of the sapheno-femoral or the sapheno-popliteal junction. This is done by means of ultrasound.

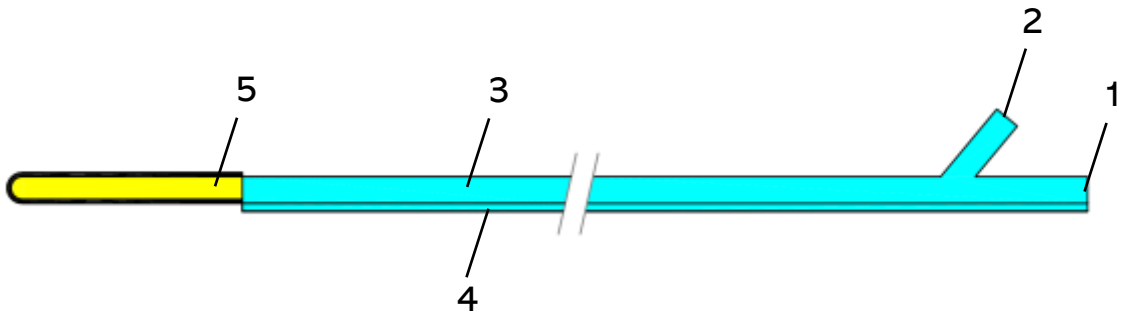
Removing the puncture needle



Removing the puncture needle

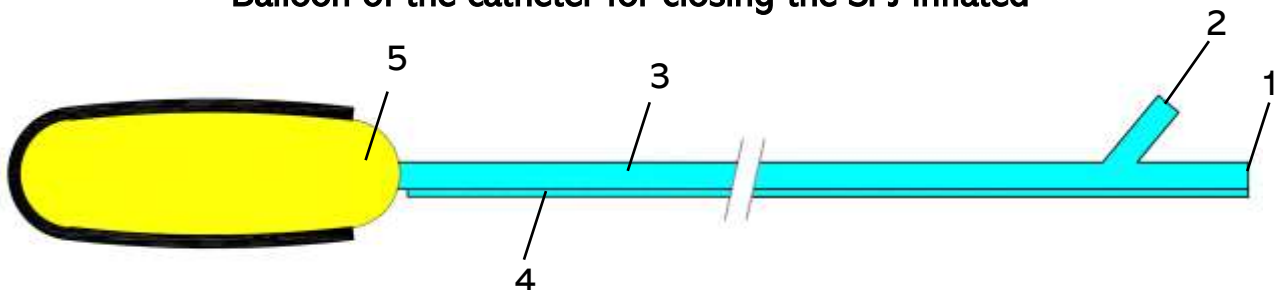
After the wire end has been placed in the region of the sapheno-femoral junction (SFJ), the puncture needle is removed. The wire is now in the great saphenous vein.

Balloon of the catheter for closing the SFJ not inflated



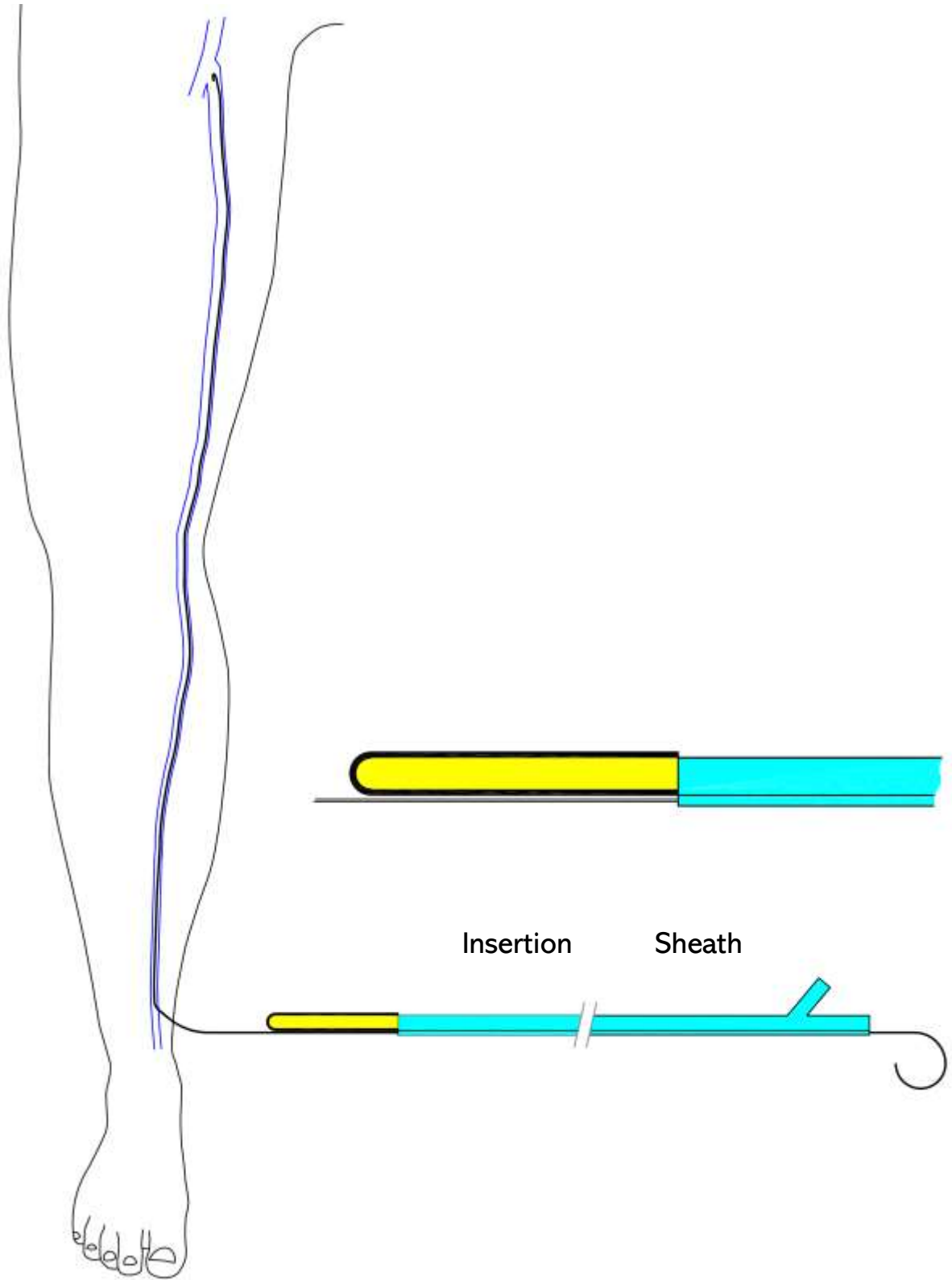
- 1: Opening for inserting the wire
- 2: Opening for the syringe for inflating the balloon
- 3: Channel for inflating the balloon
- 4: Channel for the guide wire
- 5: Balloon with membrane for closing the SFJ

Balloon of the catheter for closing the SFJ inflated



These drawings show a catheter, by means of which the sapheno-femoral junction (SFJ) can be closed. The front of the catheter contains a balloon on which a membrane sits. The idea is to move said balloon into the region of the sapheno-femoral or the sapheno-popliteal junction. The balloon can subsequently be inflated, whereby the membrane is pressed against the vein wall in the sapheno-femoral junction (SFJ). There are various options of attaching said membrane. The options for attaching said membrane are shown below.

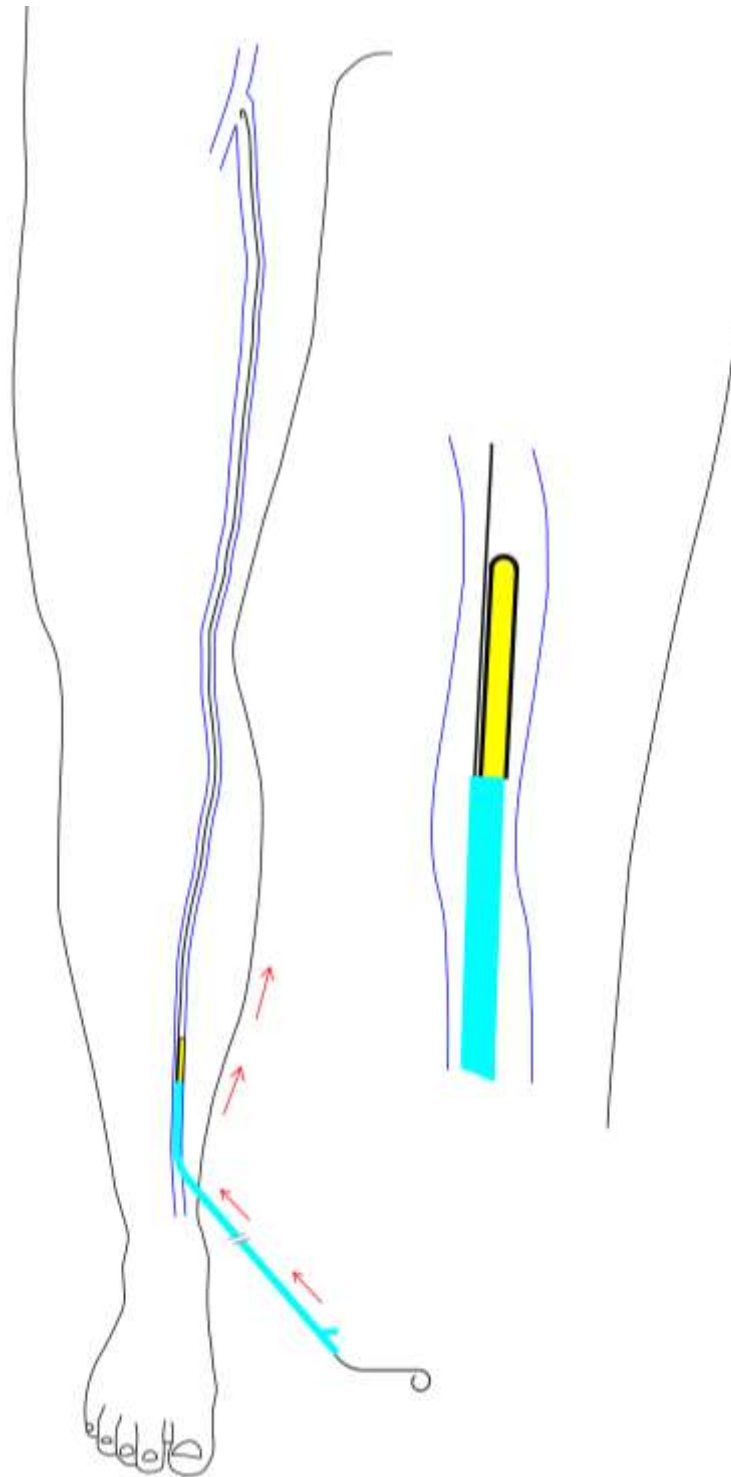
Inserting the wire into the catheter to close the sapheno-femoral junction (SFJ)



Inserting the wire into the catheter to close the sapheno-femoral junction (SFJ)

For closing the sapheno-femoral junction (SFJ), the catheter is inserted via the guide wire. For the sake of simplicity, this drawing does not show a sheath. The catheter must naturally be inserted into the vein via a sheath and then moved to the sapheno-femoral or the sapheno-popliteal junction via the guide wire.

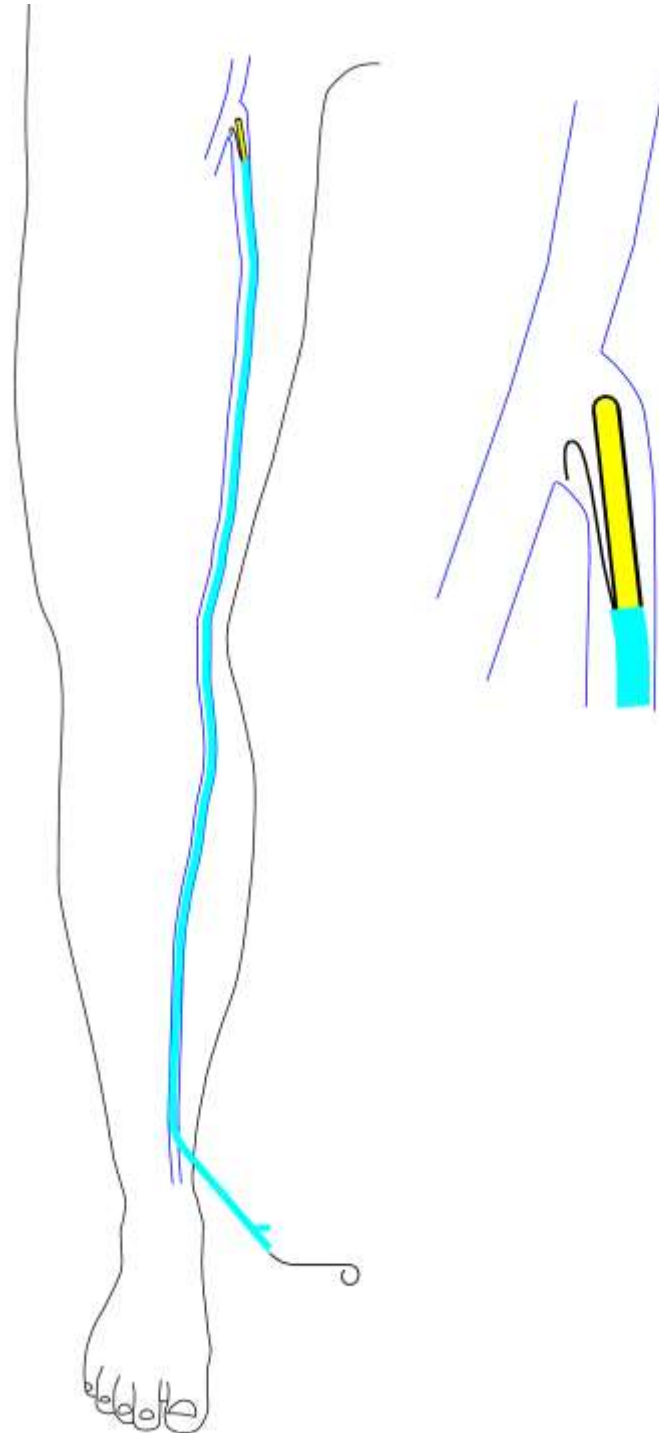
Pushing up the catheter to close the sapheno-femoral junction (SFJ)



Pushing up the catheter to close the sapheno-femoral junction (SFJ)

For closing the the sapheno-femoral junction (SFJ), the catheter is pushed up in the great saphenous vein.

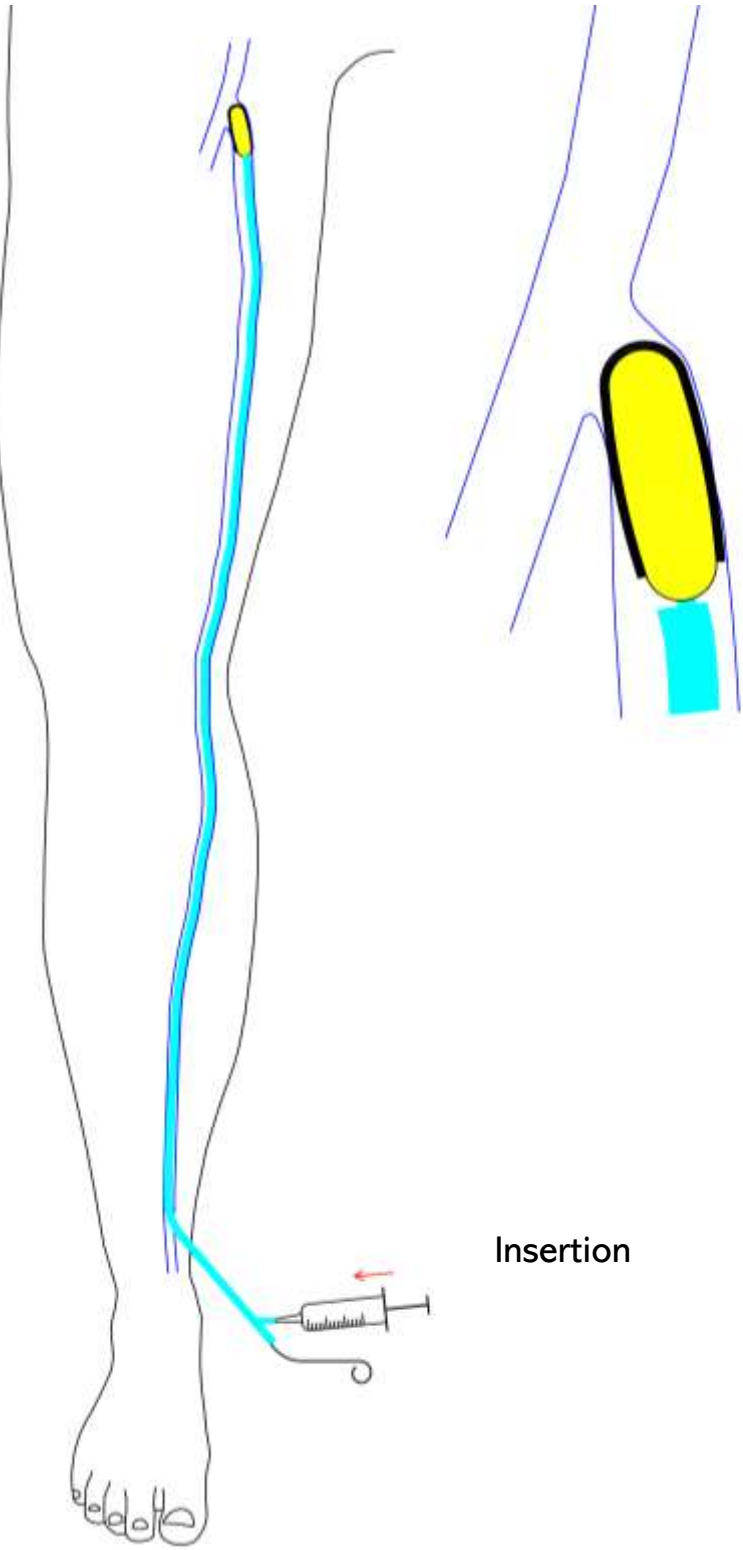
Placing the catheter to close the sapheno-femoral junction (SFJ)



Placing the catheter to close the sapheno-femoral junction (SFJ)

The catheter for closing the sapheno-femoral junction (SFJ) is now pushed up into and placed in the region of the sapheno-femoral junction (SFJ).

Inflating the balloon to place the membrane to close the sapheno-femoral junction (SFJ)

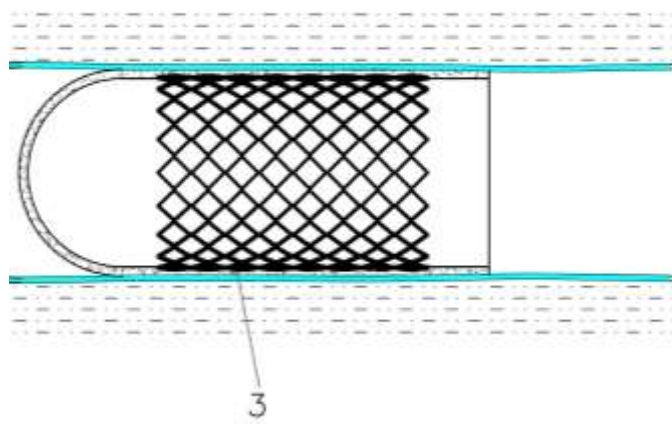
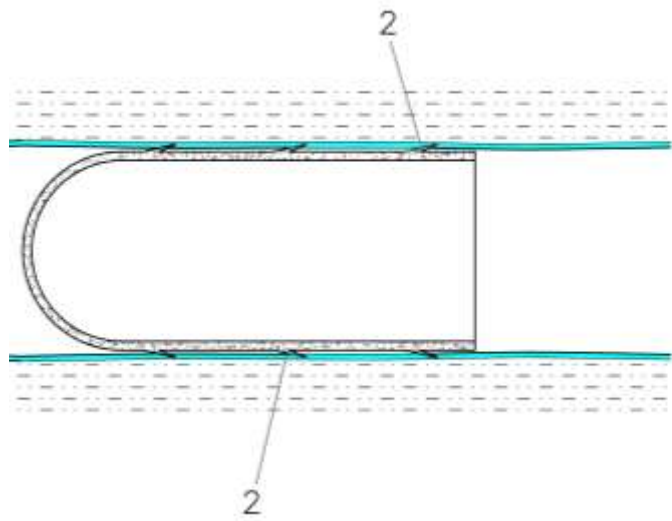
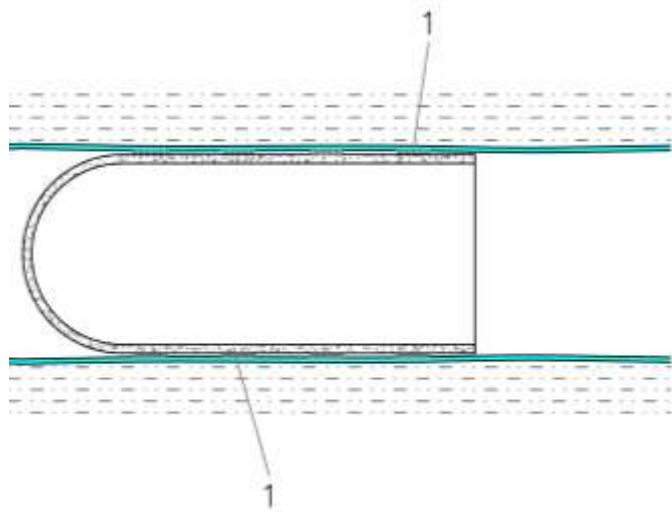


Insertion

Attaching the balloon

Inflating the balloon to place the membrane to close the sapheno-femoral junction (SFJ)

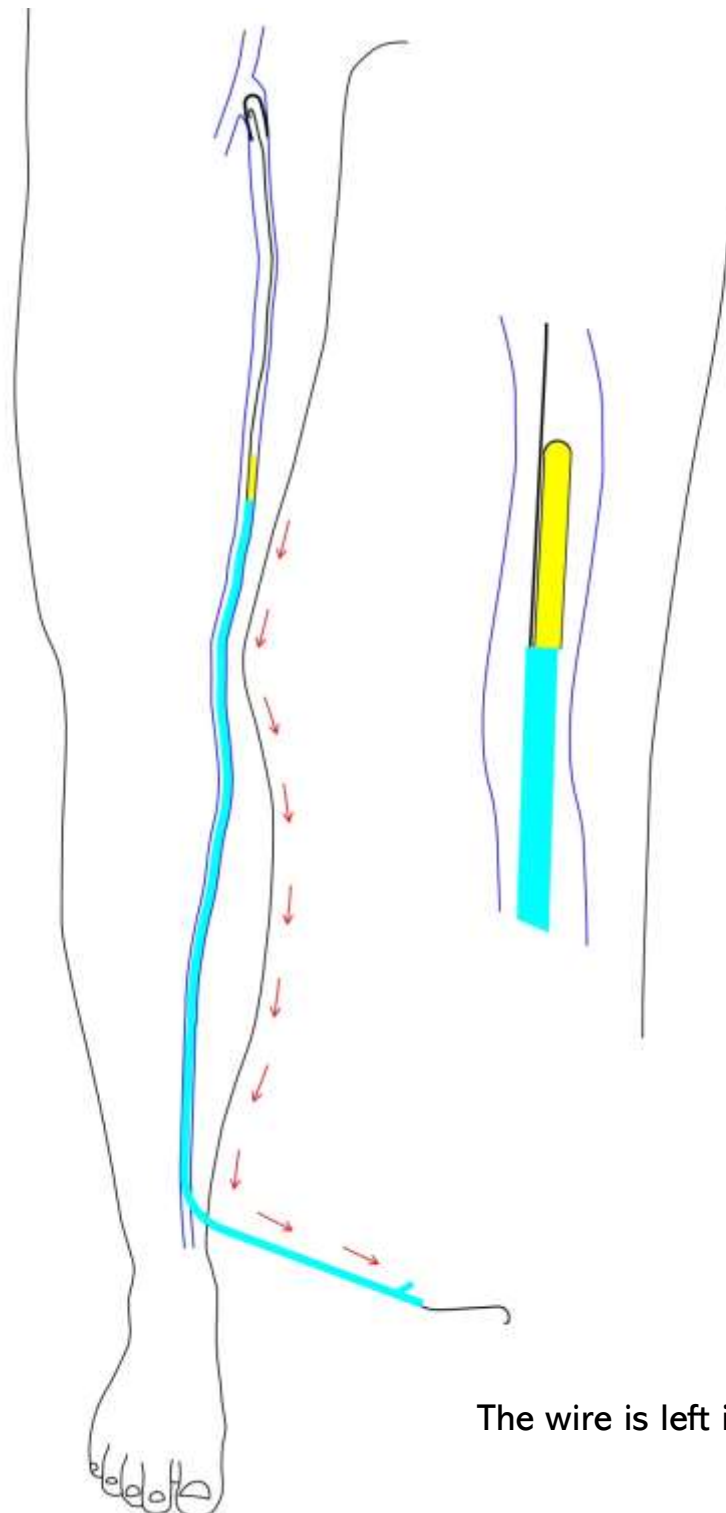
The balloon is now inflated. As a result, the membrane sitting on the balloon is pressed against the vein wall. The membrane for closing the sapheno-femoral junction (SFJ) is closed at the front, i.e., it is a type of sack. The sapheno-femoral junction (SFJ) is now sealed by inflating the balloon and attaching the membrane to the vein wall. The idea behind this seal is to avoid an early relapse and to also prevent a thrombosis in the vena femoralis communis or, even worse, a pulmonary embolism.



Attaching the balloon

This sheet shows several options for attaching the membrane to close the sapheno-femoral junction (SFJ). On the one hand, it would be possible for the membrane to be glued to the vein wall using an adhesive 1. This is shown in the top drawing. On the other hand, it would also be possible to anchor the membrane in the vein wall using barbs 2. Finally, there would be the option of fastening the entire thing similar to a stent graft 3. However, the sapheno-femoral junction (SFJ) is located in the motion segment of the hip joint. Therefore, the stent would have to be very flexible, extend only over a short stretch and preferably be resorbable.

Retracting the catheter after depositing the membrane to close the sapheno-femoral junction (SFJ)

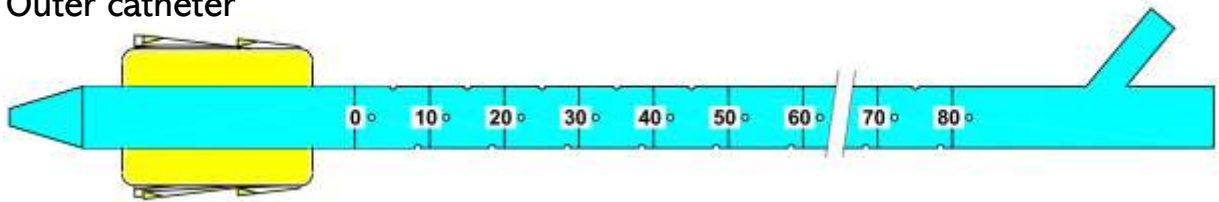


The wire is left inside.

Retracting the catheter after depositing the membrane to
close the sapheno-femoral junction (SFJ)

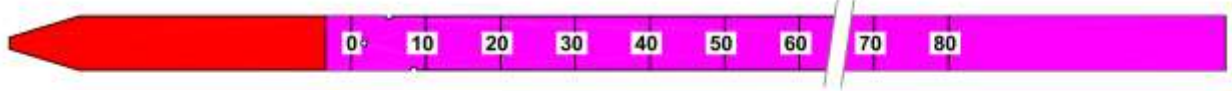
The balloon is deflated and retracted.

Outer catheter

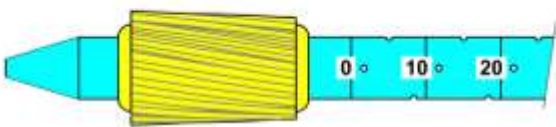
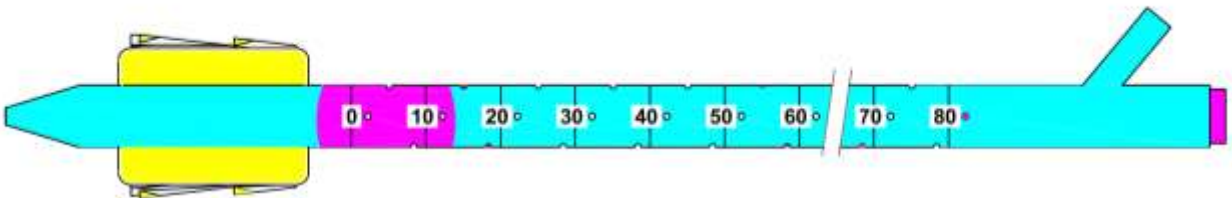
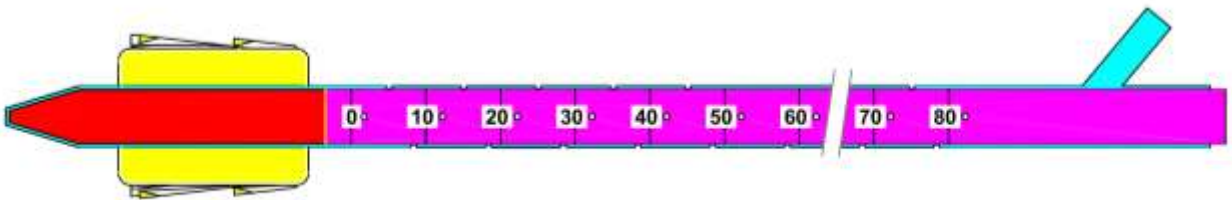


Inner catheter

Lumen closed

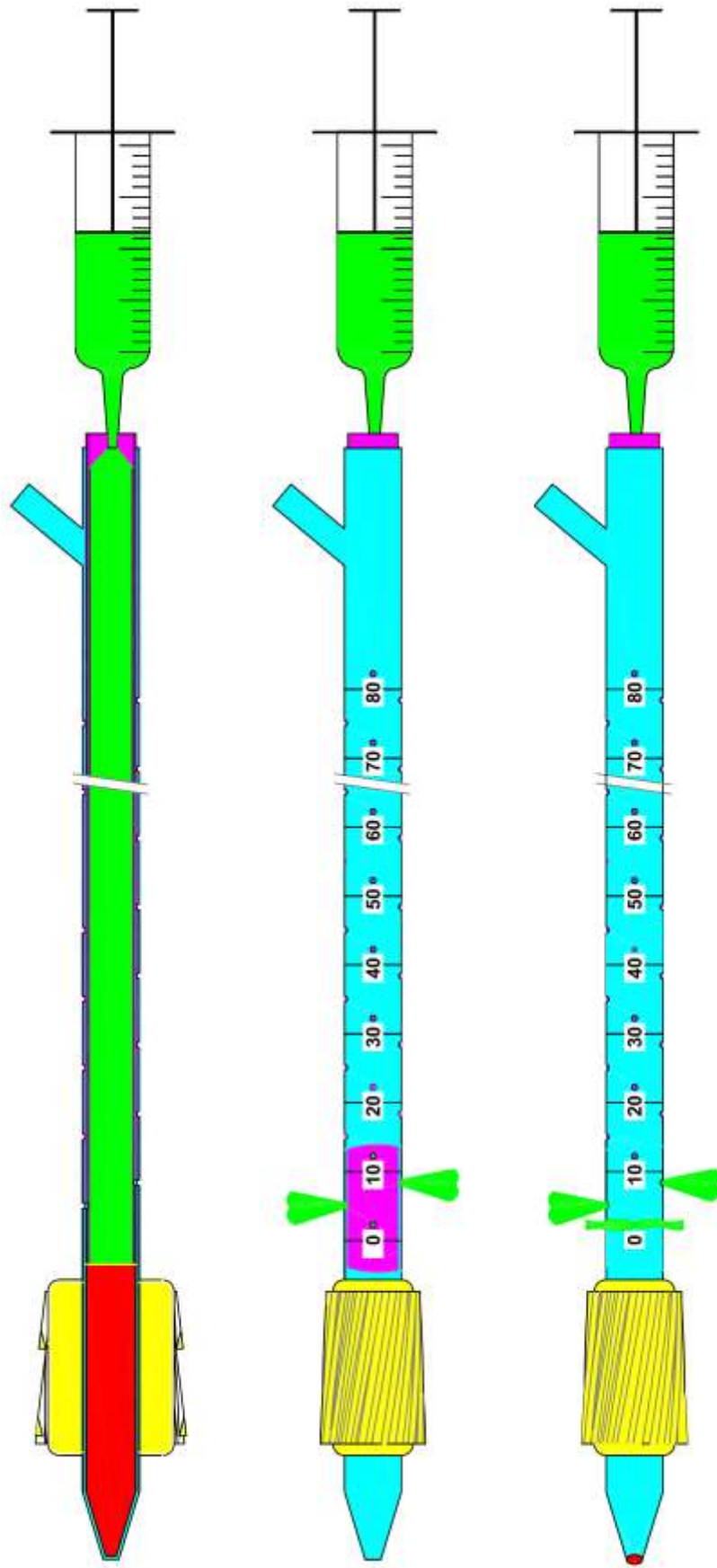


Inner in outer catheter

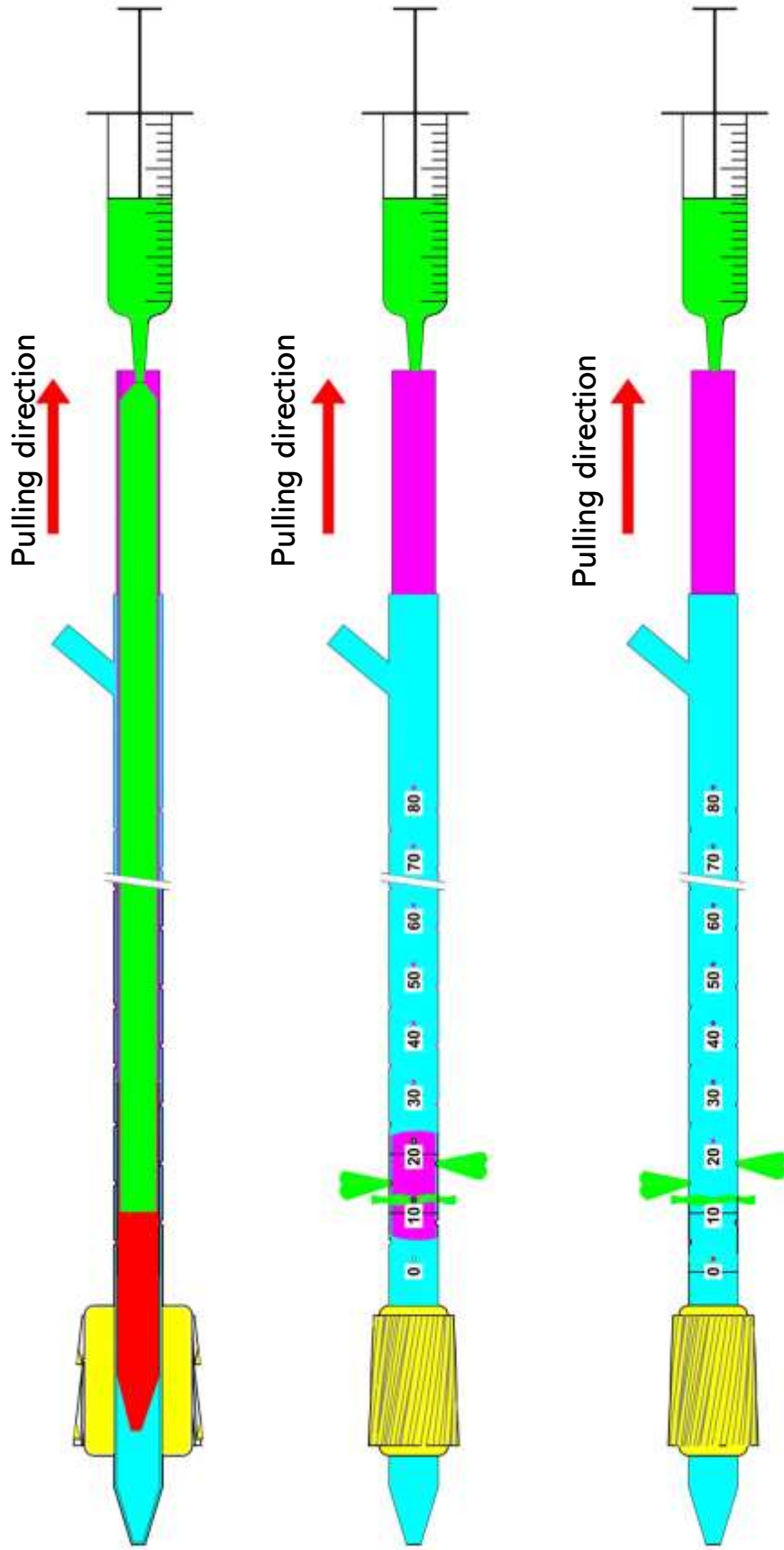


For didactic reasons, the balloon with the cutting elements is shown above in longitudinal section. Here, it is now shown three-dimensionally

The adjacent drawing shows a catheter that is used to chemically and mechanically destroy the great saphenous vein. The catheter consists of an outer and an inner catheter. At the front, the outer catheter is provided with a balloon with cutting elements. The idea is to subsequently inflate said balloon and use the cutting elements to destroy the vein wall of the insufficient vein. The outer catheter also has holes on its sides. A means for chemically destroying the vein wall is supposed to emerge through these holes before the vein wall is destroyed with the cutting elements. An inner catheter is located in the outer catheter. The lumen of this inner catheter is closed at the front. After the injection, Aethoxysklerol® emerges through openings that are congruent with the openings of the outer catheter and destroys the vein wall. The page also shows how the inner catheter lies in the outer catheter. At the bottom of the page, the arrangement of the cutting elements on the balloon can be seen. These are depicted similar to the spin in a rifle. The cutting elements are higher proximally than distally. This is intended to achieve maximum destruction of the vein wall.

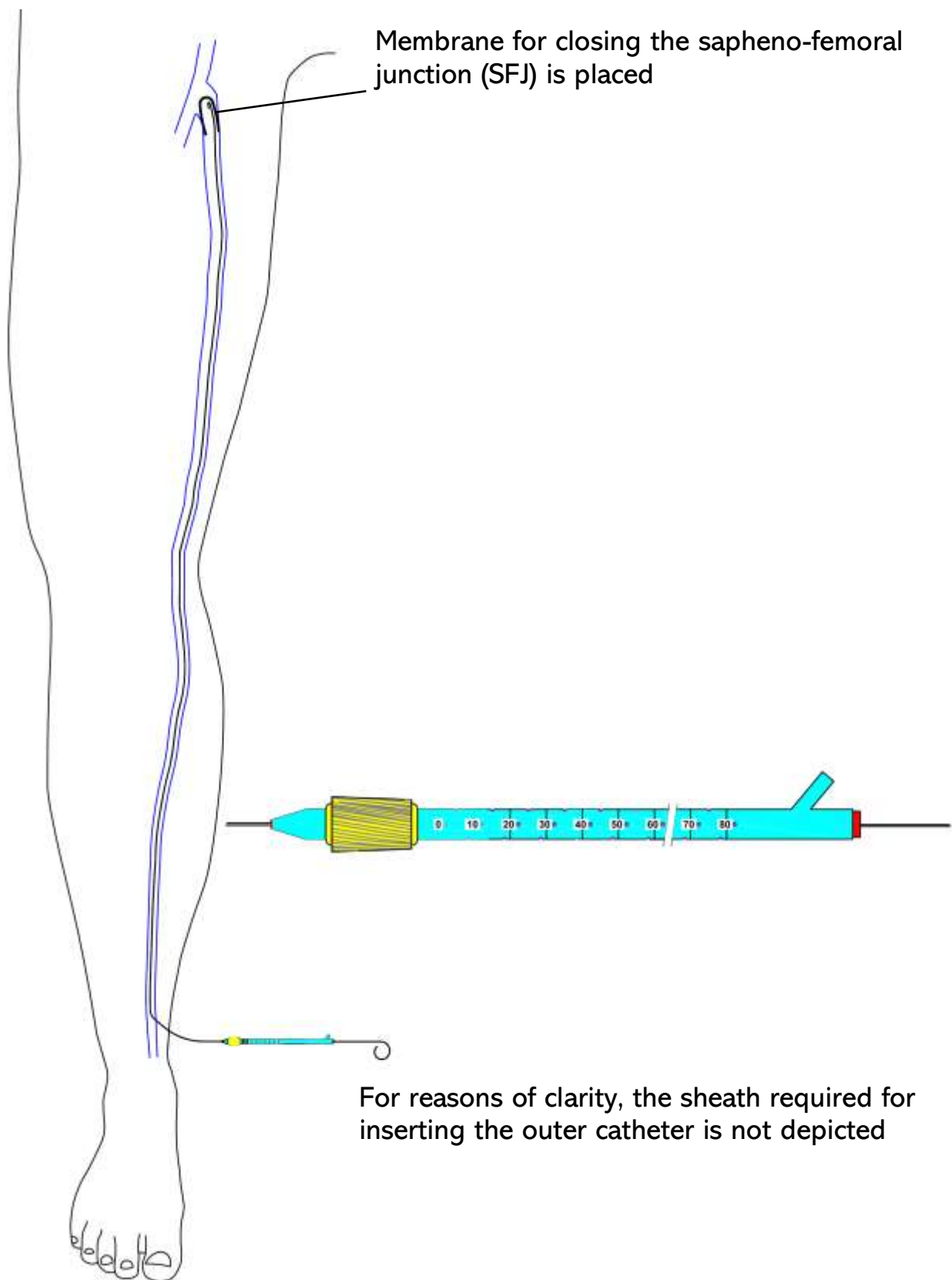


The inner and outer catheters are shown here. It is shown how the sclerosant emerges through the openings of the catheter and leads to the destruction of the vein wall.



In this case, the inner catheter has already been somewhat retracted. The sclerosant now emerges through openings further distally, shown here at 20 cm. The idea is that the inner catheter is pulled further and further distally. As a result, the insufficient vein portions can be efficiently sclerosed every 10 cm.

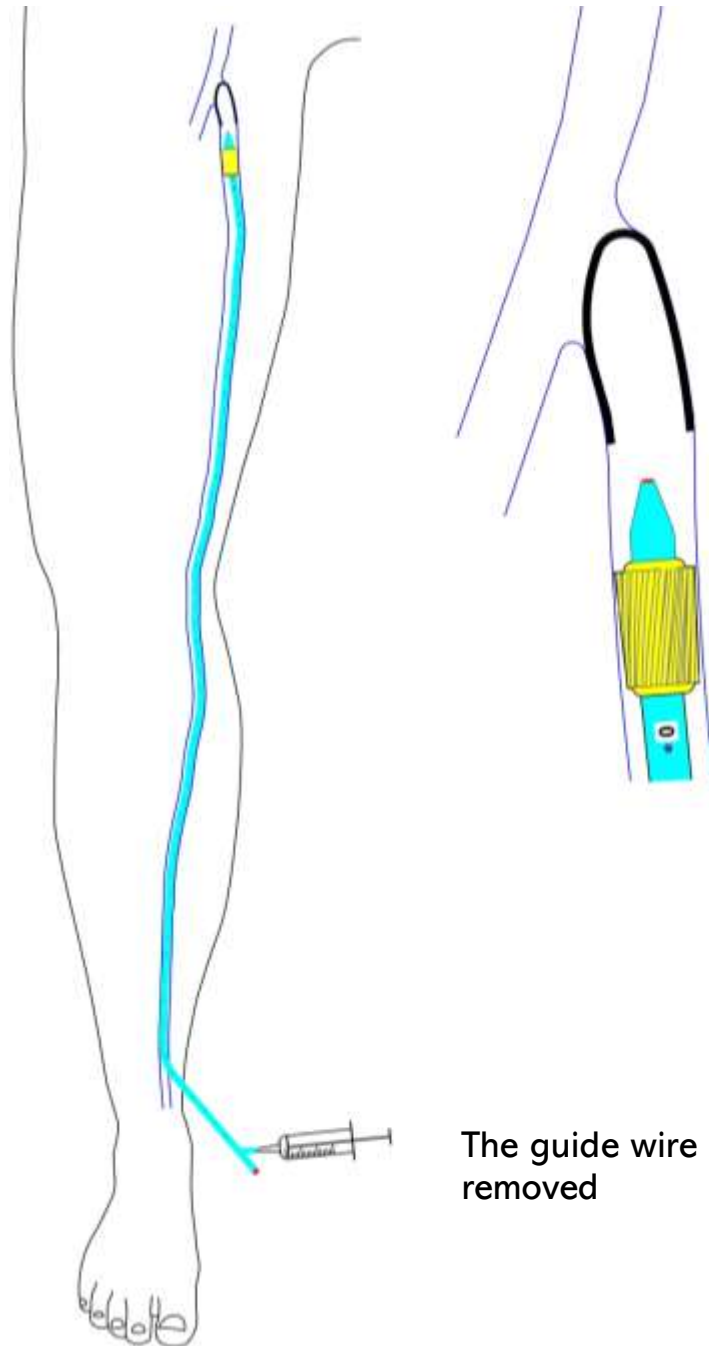
Inserting the outer catheter with an introducer



Inserting the outer catheter with an introducer

By means of an introducer, the outer catheter is inserted via the lying wire.

Placing the outer catheter in front of the membrane, with which the sapheno-femoral junction (SFJ) was closed. Balloon with cutting elements is inflated

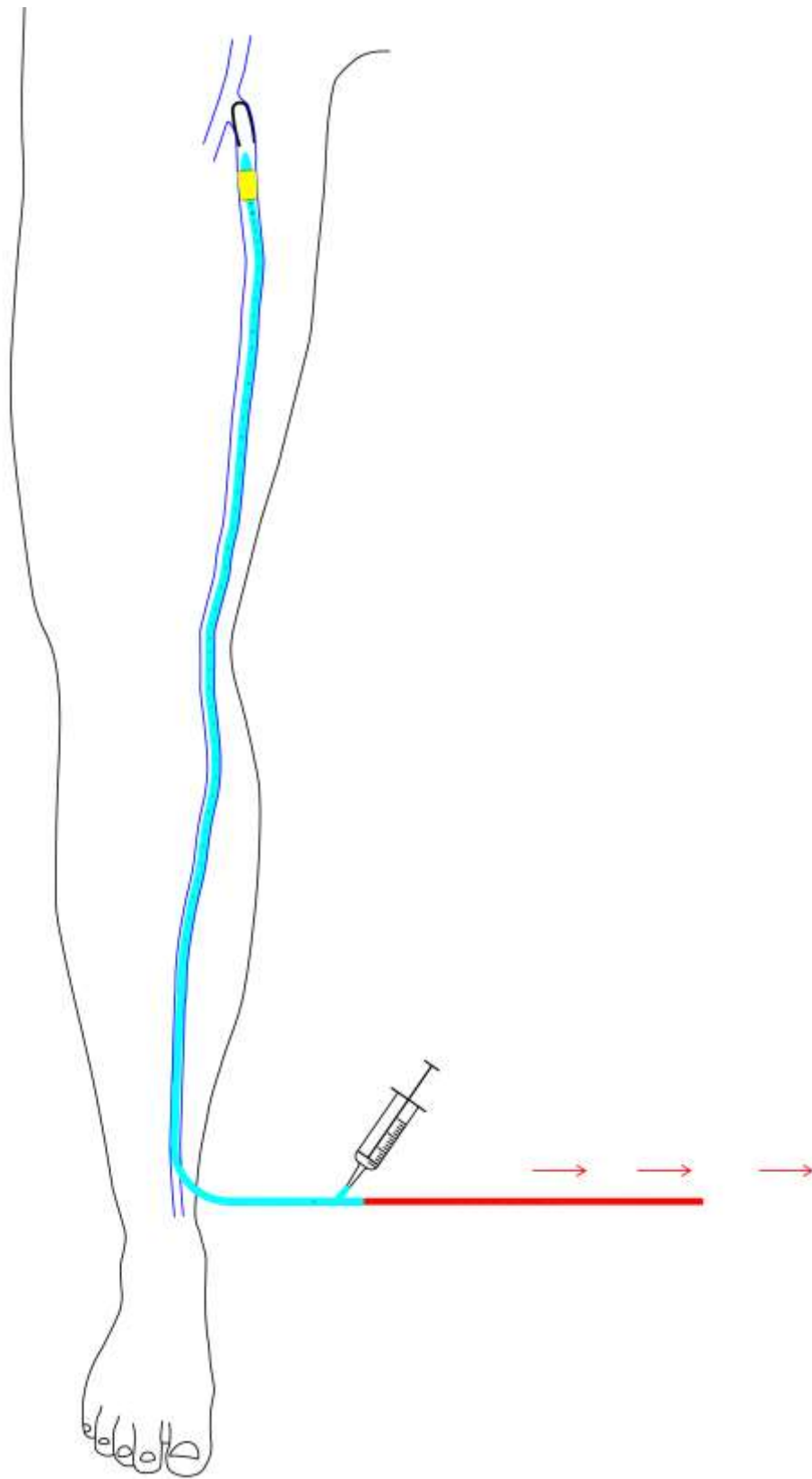


The guide wire has already been removed

Placing the outer catheter in front of the membrane

The outer catheter is now advanced via the guide wire to the sapheno-femoral junction (SFJ), which has already been closed with the membrane. The outer catheter is now placed and inflated.

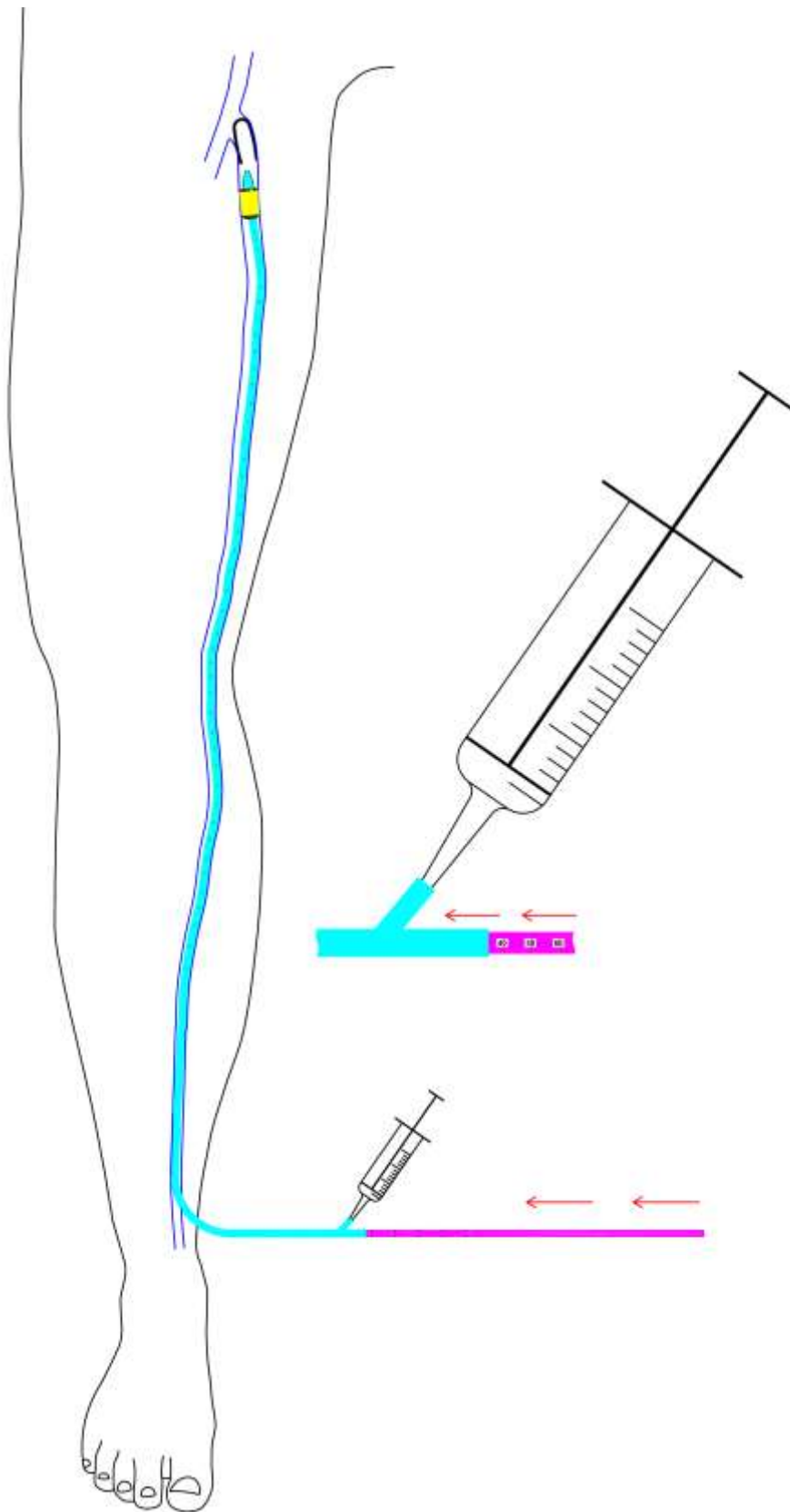
Removing the introducer



Removing the introducer

The introducer is removed from the lying outer catheter.

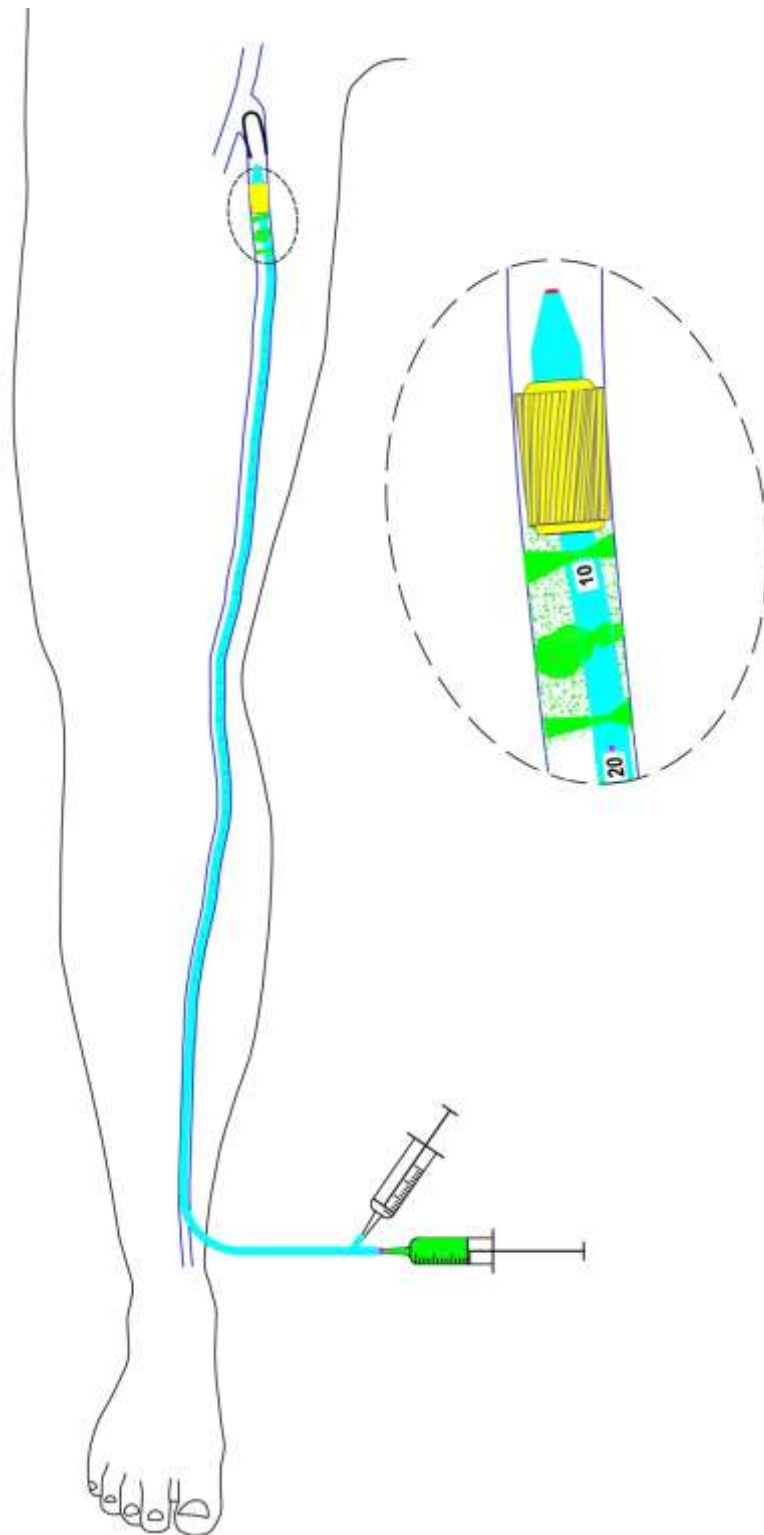
Inserting the inner catheter



Inserting the inner catheter

The inner catheter is now inserted into the outer catheter and fastened.

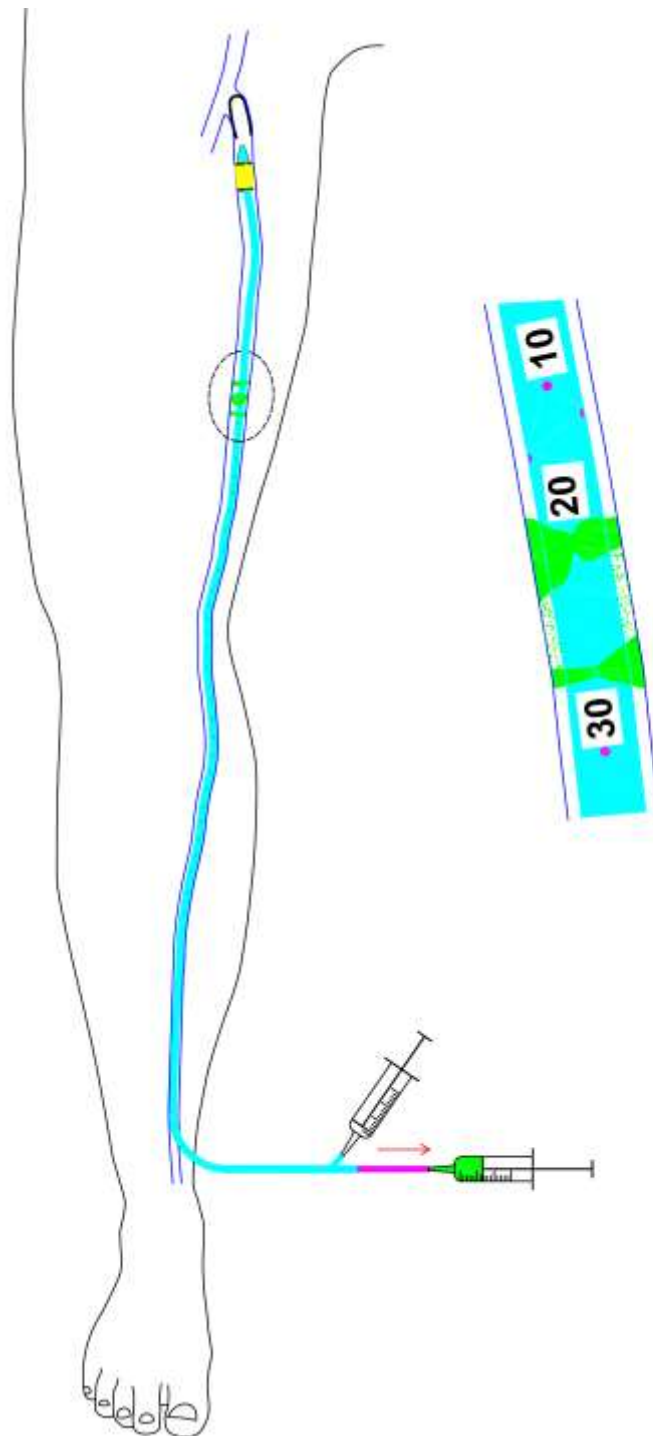
Releasing the sclerosant through the opening of the outer/inner catheter for the first 10 cm



Releasing the sclerosant through the opening of the outer/inner catheter for the first 10 cm

After the inner catheter has been placed, the sclerosant is released in the great saphenous vein via the inner catheter. It emerges through the openings for the first 10 cm and thus causes the great saphenous vein to be atrophied.

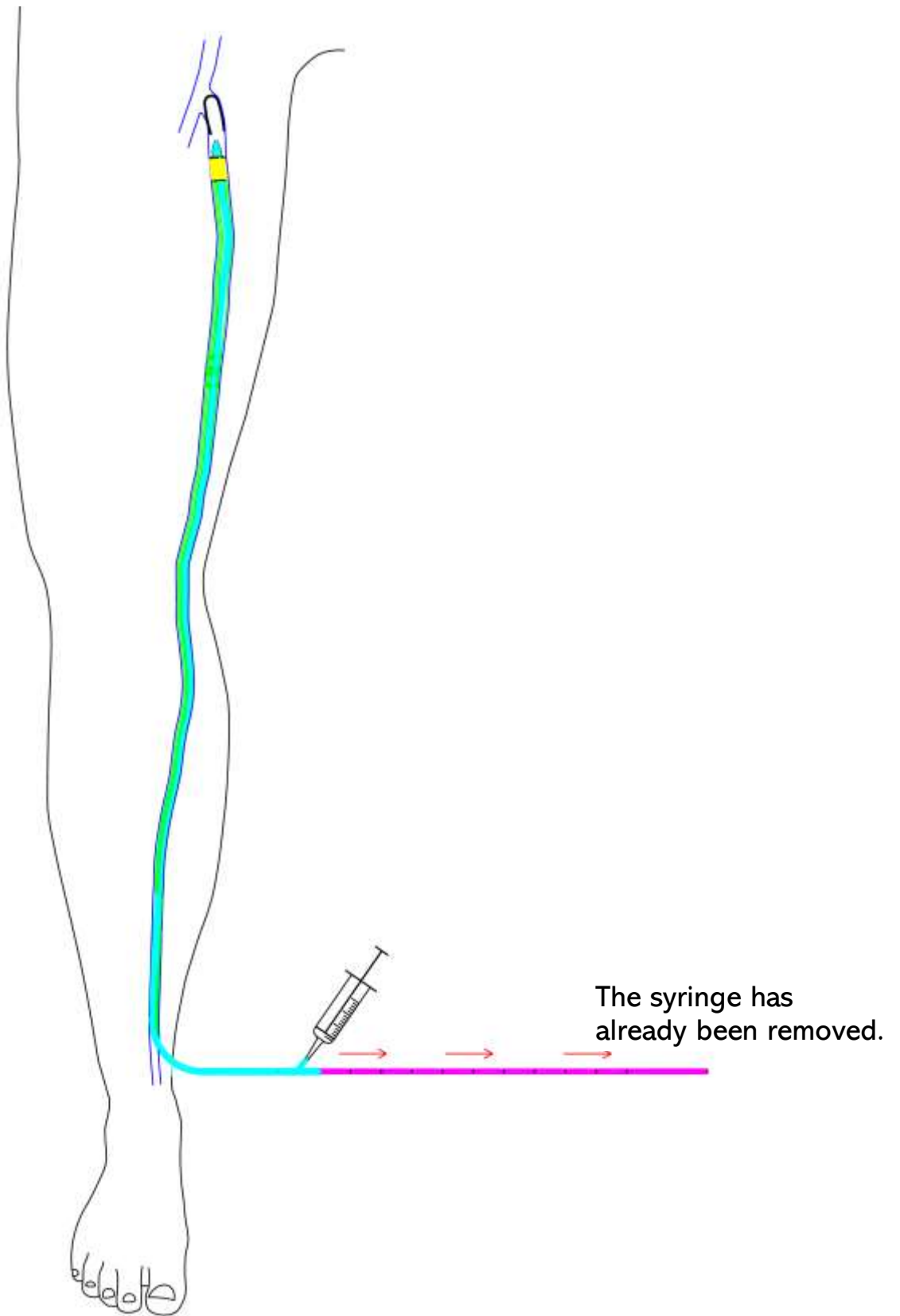
Retracting the inner catheter. Releasing the sclerosant via the openings of the outer/inner catheter for the next 10 cm



Retracting the inner catheter and releasing of the sclerosant

The inner catheter is now retracted in 10 cm steps. The sclerosant is dispensed through the openings every 10 cm. As a result, complete sclerotherapy of the great saphenous vein is achieved in segments.

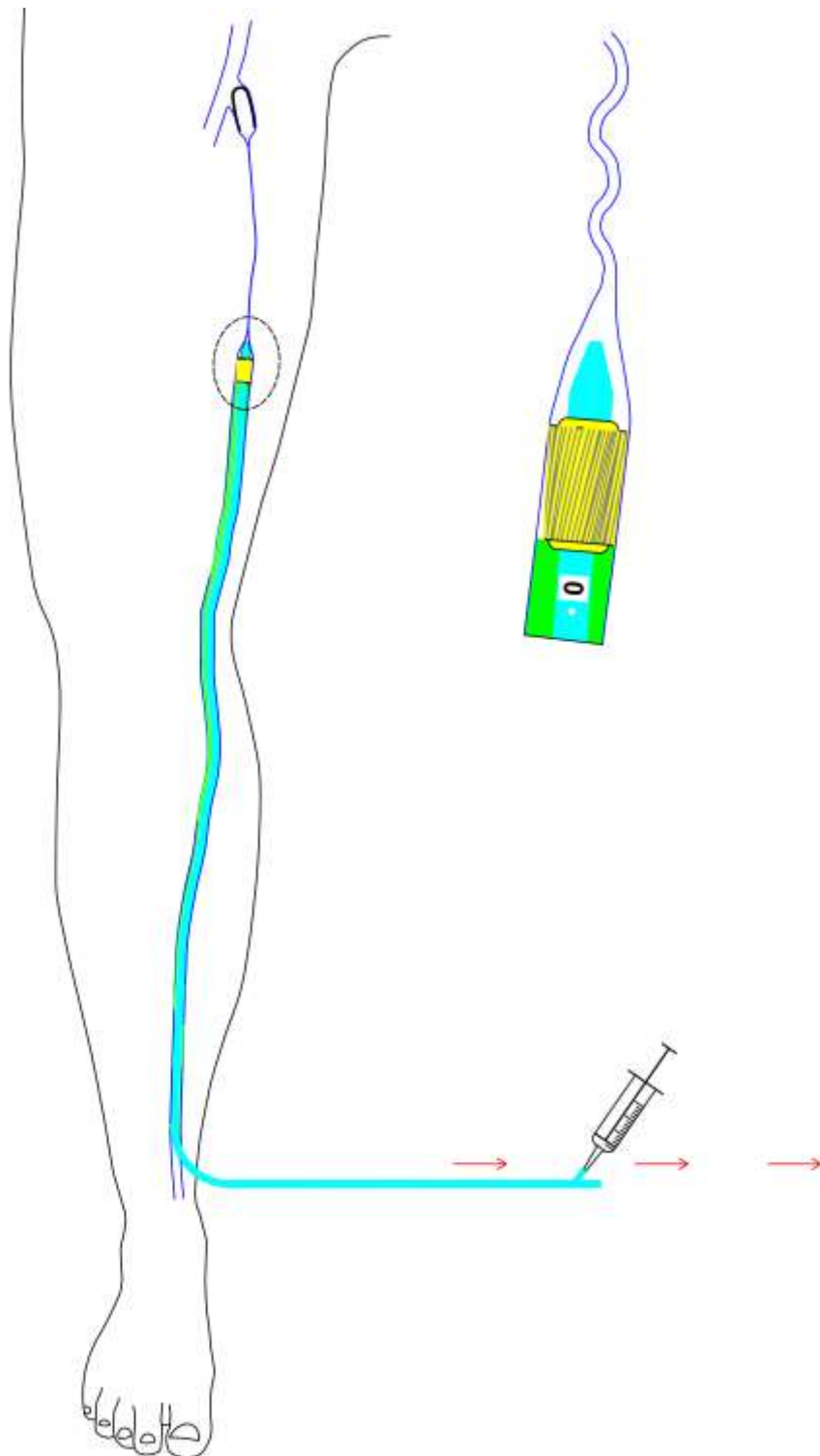
Complete removal of the inner catheter



Complete removal of the inner catheter

The inner catheter is completely removed.

Retracting the outer catheter, whereby the balloon with the cutting elements remains inflated (1)



Retracting the outer catheter

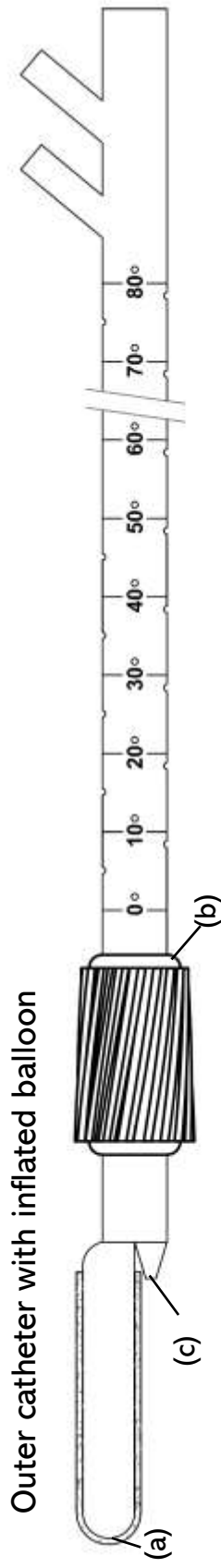
After the sclerotherapy of the great saphenous vein has been completed, the outer catheter with the inflated balloon with the cutting elements is retracted. This additionally destroys the vein wall.

Retracting the outer catheter, whereby the balloon with the cutting elements remains inflated (2)



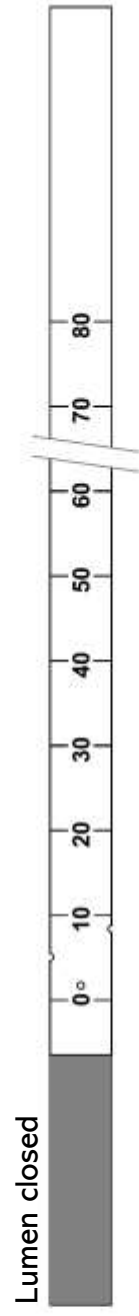
Retracting the outer catheter 2

The outer catheter with balloon and cutting elements is now completely retracted from the vein.

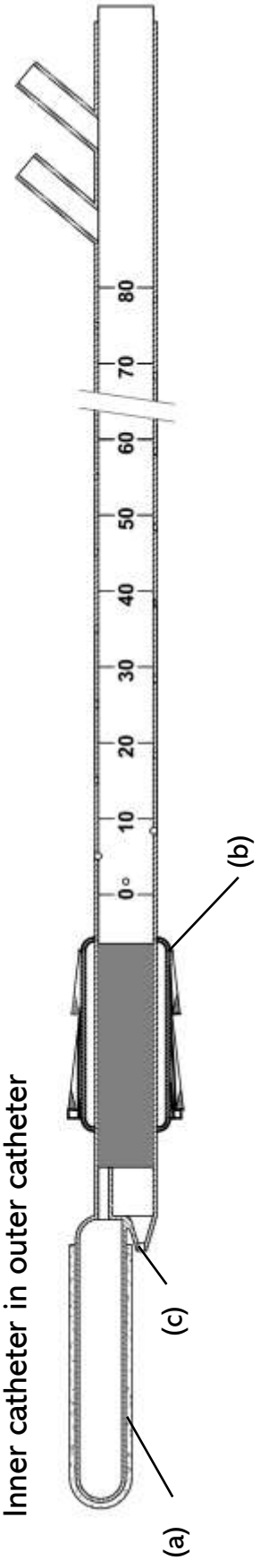


Inner catheter

- a) Balloon with the membrane for closing the SFJ
- b) Balloon with cutting elements
- c) Opening for guide wire



Inner catheter in outer catheter



Here, a catheter is shown in which the balloon with the membrane for closing the sapheno-femoral or the sapheno-popliteal junction is also attached to the outer catheter. As a result, we have all three devices for the treatment of an insufficient saphenous vein on one catheter, namely:

- i. a balloon with the membrane for closing the sapheno-femoral or the sapheno-popliteal junction
- ii. the balloon with the cutting elements
- iii. the outer and inner catheter with the side openings for sclerotherapy of the saphenous vein.