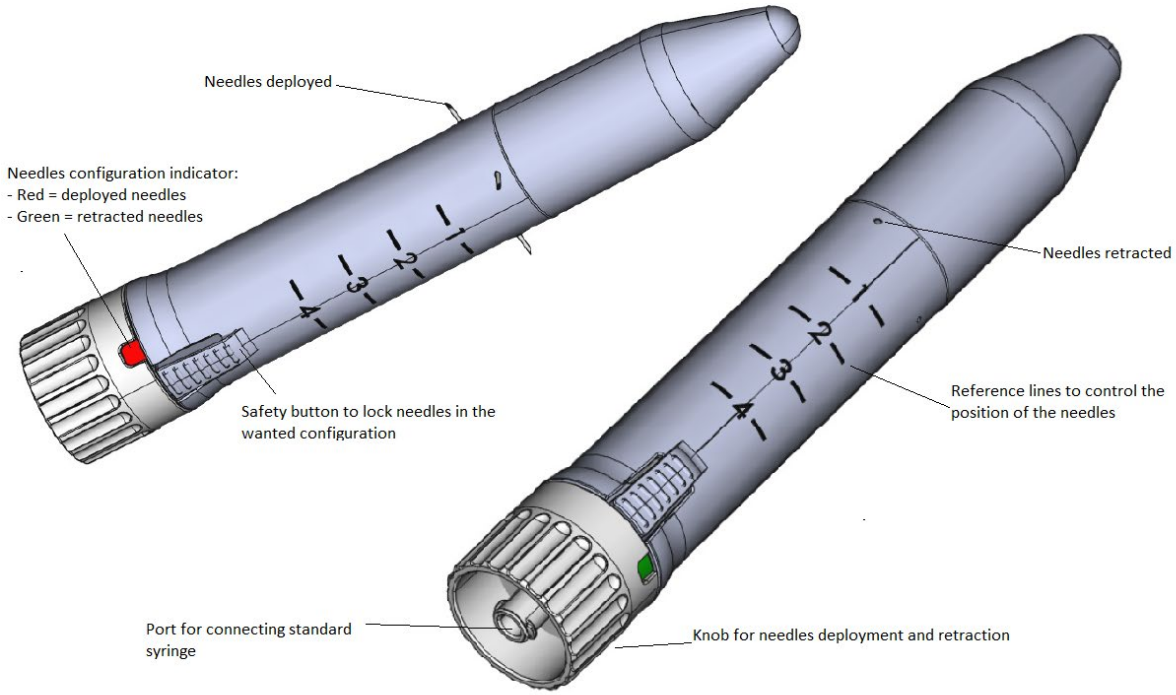
Company name: Doc-Invent SA
Address: Chemin Rian-Pré 40, 1010 – Lausanne (CH)
Product name: Fisscure®

Description of the FissCure device

Fisscure is a manually operated mechanical device consisting of a conical-pointed cylindrical tube, equipped with an internal action mechanism necessary for the release of 4 needles from the cylinder surface perpendicular to the longitudinal axis of the device, separated by an angular distance of 90°. The mechanism is operated by the doctor from the proximal part of the device, where there is a knob that can be turned around the axis of the device, which has a safety button for releasing or locking the mechanism enabling injection. In the anal sphincter, the physician refers the needle position to the reference lines.



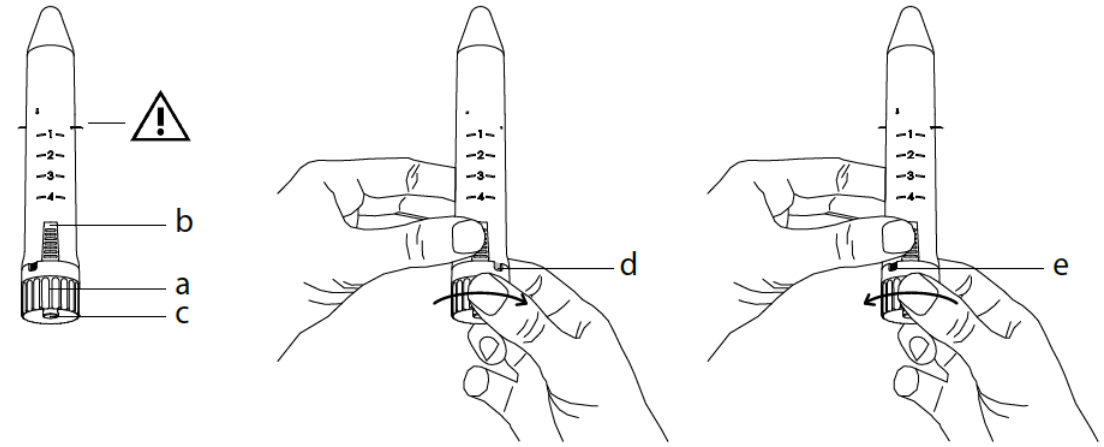
The outer cylinder is equipped with indication lines that allow the doctor to safely insert the device at the depth necessary to perform the treatment at the right point in the anal channel.
Before introducing the device, a syringe containing the botulinum toxin drug is connected to the connection port in the centre of the proximal end of the device. The drug conducting lines and needles in the device are primed and air is removed. Then the device is introduced into the anal channel. Once introduced to the correct position, the needles are deployed. To verify the needles have not penetrated an artery, a vein or a haemorrhoidal plexus, the practitioner shall aspire with the syringe and checks there is no blood, then the injection of the drug over the 4 needles connected to the single central port is performed. After injection, the needles are retracted and the device is removed from the anal canal. A double indicator is present on the device to prevent the operator from accidentally removing the device when the needles are still in working position.

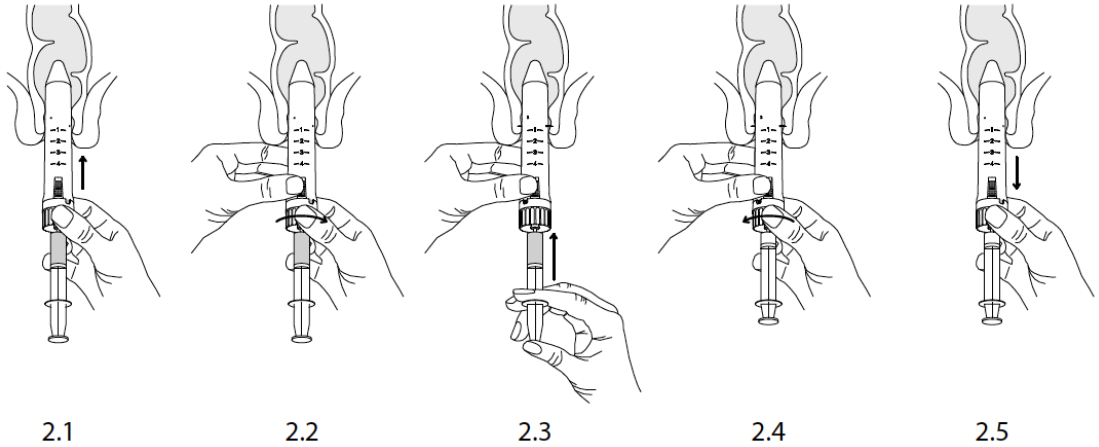
CONFIGURATIONS OF THE DEVICE

As shown in the figure above, the device has two possible configurations.
In the first configuration the needles are retracted inside the device. In this configuration the operator can slide the device along the anal sphincter, in order to place it at the height necessary to perform the treatment.
This configuration is always recognizable by the user thanks to the indicator present on the terminal handle, that in this case will have a green colour.
The second configuration present the needles deployed outside the device and allow the operator to administer the medicine to the patient. This configuration is always recognizable because the indicator present on the proximal handle will switch from the green colour of the previous configuration to the red colour.
The two configurations are interchangeable at any time through the rotation of the handle, holding down the safety button. When the button is not pressed, its mechanism ensures the locking of the device in the desired configuration.

MECHANISM OF ACTION:

The knob rotated by the operator rotates together with a toothed shaft inside the device that gives a transverse movement of some toothed components, called needle holders, that flow inside special guides for a path with a single degree of freedom of a length established during the design and development of the device.
This transverse movement allows the release and re-entry of the needles, which are mounted on the needle holders. Needle holders are part of the fluid-path through which the medicinal substance must pass. In order to operate the rotation of the knob, the operator must press the safety button, which ensures the locking of the mechanism both in the configuration of insertion of the device in the anal cavity, and in the configuration for the application of treatment.





Intended use

This device is used for the treatment of anal fissures in adults by injection of botulinum toxin in the internal anal sphincter.
The device intends to position the four injection needles precisely on the localized area of the anal sphincter to allow injection in a standardized manner to relax the internal anal sphincter in order to allow healing of anal fissures.

Intended user

The device will be used by a medical doctor specialised in proctology.

Target patient population

This device is used for treatment of anal fissures in adults with botulinum toxin also eligible for a treatment with botulinum toxin in single doses administered by a handheld syringe. The treatment that is intended to be applied to the patients throughout this device is not suitable for people that have one or more of the following clinical conditions:

- Known intolerance or allergy to botulinum toxin
- Age under 18
- Pregnancy or breastfeeding
- Non-compliant patients
- Immunosuppressed patients
- Complex fissures
- Severe haemorrhoidal disease
- Severe cardiopulmonary disease
- Neurologic disease
- Patient with a coagulopathy

Packaging system

The device is intended to be delivered in sterile package after Ethylene Oxide sterilization. The packaging is composed by the sterile barrier system made of a PET blister sealed with a Tyvek layer, a secondary cardboard packaging that will contain the IFU and a tertiary packaging with function of transport packaging.

Classification

The device is a medical device per definition provided in article 2.1 of European Regulation 2017/745 on medical devices.
The device is intended to be used for surgical purpose and is an invasive device per definition provided in article 2.6 of European Regulation 2017/745 on medical devices.
The device is intended for a transient use per definition provided in the annex VIII of European Regulation 2017/745 on medical devices.
The device is delivered sterile and is for single use only.
It is not active, and it does not provide any measuring function.
It falls in the definition of “surgically not active invasive device”, therefore the device is a **class IIa** medical device.

Medical device classification code:
MDA not applicable
MDN 1202
MDS 1005
MDT 2002, 2008, 2011

Product Specification

Attribute	Description
Length	≈ 155 mm
Diameter	≈ 26 mm
Weight	27,5 g
Syringe connectivity	Standard luerlock
Materials in contact with the patient	ABS/PC polymers blend, stainless steel
Materials in contact with the drug to be applied	TPE, stainless steel
Sterility status	The device is delivered in sterile condition after EtO sterilization treatment
Packaging	SBS: PET blister sealed with a Tivek layer. 2^{ndry} packaging: cardboard box