FISSCURE™

Single use device to inject botulinum toxin into the internal anal sphincter CE 0123

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SYMBOL

CE	CE Label
MD	Medical device
LOT	Lot number
	Legal manufacturer
	Date of fabrication
	Date of expiration
	For single use only
	Do not use if package is damaged
STERILE EO	Sterilised using ethylene oxide
	Refer to instructions
	Caution, consult accompanying documents
EC REP	EU Authorised Representative

INSTRUCTION MANUAL

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals for all equipment that will be used during the procedure and use the instruments as instructed.
If you have any question or comments about any information in this manual contact Doc-Invent.

WARNINGS

Content supplied sterile using an ethylene oxide process. Do not use if the package is damaged or after the expiration date. If damage is found, please notify Doc-Invent for return authorization.

Avoid touching the proximal part (i.e. close to the tip) of the instrument during manipulations in order to avoid prick accidents when the needles come out of the instrument.

The instrument does not need any specific preparation and should be used as explained in the section operational instructions section.

Do not disassemble the device.

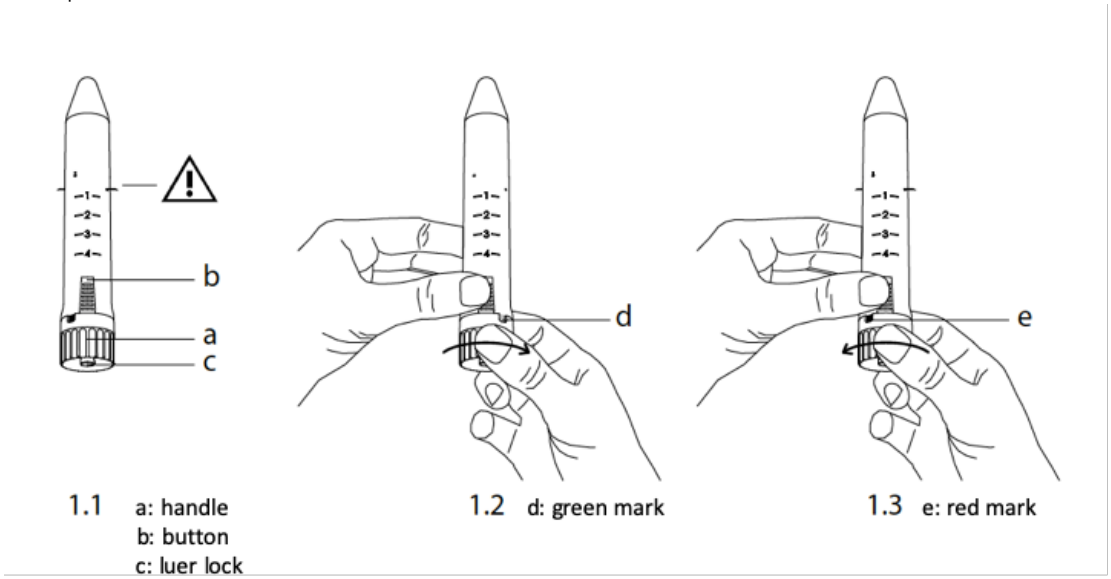
Do not use the instrument for any purpose other than the intended use.

This is a single use disposable instrument. Do not reuse, reprocess or resterilise the instrument. Attempts to reuse, reprocess or resterilise may lead to device failures and/or patient injury and/or transmission of disease.

Do not use the device with high injection volumes or high viscous fluid.

DEVICE DESCRIPTION

! WARNING: when manipulating the device, you have to avoid touching the proximal part of the device (i.e. close to the tip) in order to avoid a prick accident when the needles come out of the instrument.



1.1 a: handle
b: button
c: luer lock

1.2 d: green mark

1.3 e: red mark

As shown in figure 1.1, the device has a handle (a) that can be unlocked after pressing the button (b). A syringe (with or without a luer lock) containing botulinum toxin can be connected to the connector (c). This connector is in continuity with a fluid path that is connected to the four needles. Further, the device displays numbers 1 to 4. Those numbers indicate the distance in centimeters between the respective numbers and the site where the needles come outside the device.
The device has to be held in one hand. With the thumb of that hand the security button (b, figure 1.1) has to be pressed. This enables to unlock the handle and to move the handle in a clockwise direction. Once the handle is in movement the button should no longer be pressed. Once the handle movement comes at its end the handle will automatically be blocked in that position and pressure on the button will be necessary to unlock the handle again. The clockwise movement of the handle permits to release 4 needles out of the body of the instrument and the counter clockwise movement permits to retract the 4 needles.
When the needles are inside the instrument (figure 1.2) two green marks (d) can be seen on the handle. Those marks disappear when the needles are in outward position and two red marks (e) can then be seen on the handle as shown in figure 1.3.

INTENDED USE

The instrument is used to inject botulinum toxin in an easy and standardized manner into the internal anal sphincter.

INDICATIONS

The FISSCURE is intended to be used to inject botulinum toxin into the internal anal sphincter for the treatment of anal fissure.

INTENDED CLINICAL BENEFIT

Doc-Invent does not claim any direct clinical benefit associated with the intended use of the FISSCURE, in terms of treatment outcomes. The design of the FISSCURE provides enhanced usability advantages in terms of easier, more precise and safer injection of botulinum toxin into the internal anal sphincter when compared to a simple syringe and needle.

TARGET POPULATION
This device is used for the administration of botulinum toxin into the internal anal sphincter in adults. The use of the instrument is prohibited in the contraindicated patient population.

CONTRAINDICATIONS

The use of the instrument is prohibited in the following patient populations, or patients with the following conditions:

- Contraindications for the use of botulinum toxin or known allergy to it
- Individuals under the age of 18 years
- During pregnancy or breast feeding
- Immune deficiency or immunosuppressive medication
- Patients with coagulation disturbances (due to disease or medication)
- Severe cardiopulmonary disease
- Severe proctitis
- Severe hemorrhoidal disease

- Non-compliant patients (patients who are unable (i.e. mentally or physically impaired patients) to remain motionless during the time the FISSCURE is in the anal canal

INTENDED USER AND INTENDED USE ENVIRONMENT

The device is designed to be used by physicians specialized in proctology in office, ambulatory clinics or hospital settings.

OPERATIONAL INSTRUCTIONS

Inspection
Inspect the sterile packaging for tears, inadequate sealing, or water damage. Do not use the instrument, if the sterile packaging is damaged, wet, or improperly sealed.
Before using the device, check the correct functioning of the mechanism of unfolding the needles by operating the mechanism once, as explained in the section 'device description'.

- DO NOT USE DEVICES WHICH DURING THE CONTROL OF THE OPERATION OF THE NEEDLE UNFOLDING MECHANISM HAVE PRODUCED NOISES OF JAMMING GEARS OR DEVICES WHERE THE ROTATION OF THE KNOB IS NOT SMOOTH FROM THE MOMENT THE GREEN MARK IS VISIBLE TO THE TIME WHEN THE WHOLE RED MARK IS VISIBLE.
- DO NOT USE AN INSTRUMENT AFTER THE EXPIRATION DATE DISPLAYED ON THE STERILE PACKAGE.

Preparation of the instrument
Prepare the botulinum toxin according to the manufacturer's instructions and use a 2 to 3 ml syringe that contains the (diluted) botulinum toxin. Next attach a syringe that contains the botulinum toxin to the connecter (c, figure 1.1). Syringes with or without a luer lock can be used but syringes with a luer lock should be preferred since they avoid disconnection of the syringe from the instrument during manipulation and treatment. Once the syringe connected to the device, the needles have to be released outward as explained in the section "device description". Then the plunger of the syringe should be pressed in order to fill the empty space of the fluid path of the device with the botulinum toxin (about 0.4 ml). Once the first drop comes out of one or more of the needles this procedure should be interrupted and the needles again retracted into the device as explained in the section "device description".

Operation
Patient preparation
Make sure that the patient is in a comfortable position before starting the procedure. The lateral position lying on the left side is proposed but other positions are possible. If necessary, the patient can be sedated according to the operator's habits. This sedation can be necessary in case of a painful anal fissure or for anxious patients. **During the procedure the patient will feel a prick in the anal canal that in itself does not necessitate sedation.** It can be necessary to perform an anoscopy before the procedure and it is recommended to do a digital examination in order to estimate the length of the anal canal.

Procedure
I. Device positioning
The device, to which the syringe containing the botulinum toxin is connected, is inserted into the anal canal (figure 2.1) using some sterile medical lubricant as used to introduce anoscopes and endoscopes. The depth of insertion of the device depends on the desired placement of the needle that will penetrate into the internal anal sphincter. To have the needles come out in the anal canal at respectively 1, 2 or 3 cm from the anal verge, the numbers, respectively 1, 2 or 3 seen on the device has to be advanced up to the anal verge.
Once the device at the desired placement in the anal canal it should be kept with one hand in fixed position.

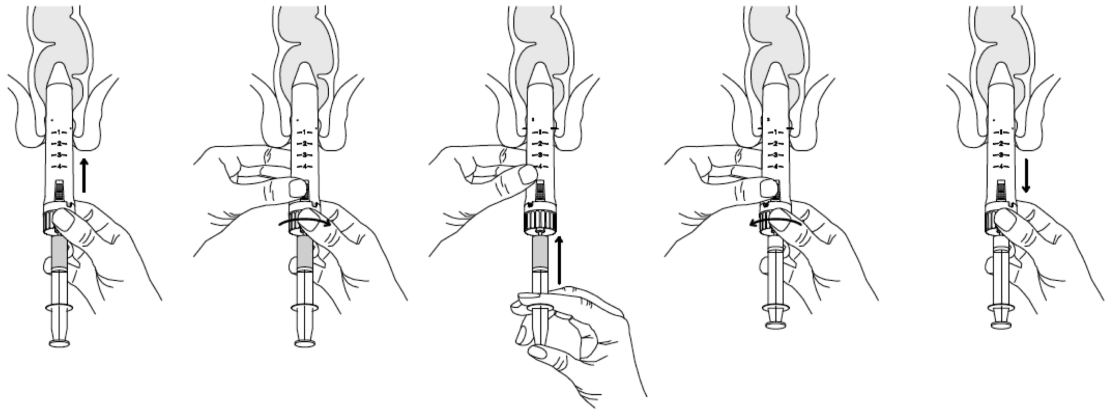
II. Needle release
With the thumb of the same hand the button is pressed and with the other hand the handle is turned in clockwise direction to deploy the needles (figure 2.2). During this manipulation the green marks on the handle disappear and the red marks are now visible. The button has only to be pressed to unlock the handle. Once the handle is in movement the pressure on the button has to be released.

III. Botulinum toxin injection
The hand that manipulated the handle is now used to pull on the plunger in order to be sure that none of the needles are in a blood vessel. Next, the plunger of the syringe is pressed in order to inject the botulinum toxin into the internal anal sphincter as shown in figure 2.3.

IV. Needle retraction
Next the same hand is used again to turn the handle in counter clockwise direction while with the other hand the button is pressed again with the thumb in order to enable this handle movement (figure 2.4). During this manipulation the red marks on the handle disappear and the green marks are now visible. The button has only to be pressed to unlock the handle. Once the handle is in movement the pressure on the button has to be released.

One single injection is enough to apply the full botulinum toxin treatment. There is no need to deploy multiple times the needles in order to complete the treatment if the depth of application chosen by the physician is correct.

V. Device withdrawal
The instrument can now be retracted from the anal canal as shown in figure 2.5 and disposed. Before disposing of the device, the user must check that all 4 needles are present in the device by unfolding the needles. Once the presence of the 4 needles has been verified, the user can retract the needles and discard the device.



2.1	2.2	2.3	2.4	2.5
° insert device at the desired depth	° keep device fixed with one hand ° press button to unlock handle ° move handle clockwise (do no longer press the button)	° keep device fixed with one hand ° inject with the other hand	° keep device fixed with one hand ° press button to unlock handle ° move handle counter clockwise (do not longer press the button)	° reassure that the green mark is visible ° withdrawal of the device

POTENTIAL COMPLICATIONS

- The injection of botulinum toxin into the internal anal sphincter may create an ecchymosis.
- The infection rate due to perforation of the anal canal by the four needles is estimated to be very low.
- Potential harm could be provoked to the patient if the device is retracted from the anal canal while the needles are not retracted into the device. For this reason, it is important to check that the needles are retracted, which is when the green marks are visible on the handle. In contrast to this, visualization of the red marks on the handle indicates that the needles are outside of the device.
- Other possible side-effects might be pain/discomfort with the injection.

RESCUE PROCEDURE IN CASE OF MECHANICAL FAILURE

Do not use the device if you observe any mechanical failure of the needle deployment/retraction mechanism.
Mechanical failure of the needle retraction during its use is very unlikely. However, in the case that this would happen we propose one of the following strategies:

1. **Use an anal speculum (+/- distending) with opturator**
   Use an anal speculum with an internal diameter of at least 30 mm (e.g. Chelsea Eaton anal speculum Large or Fansler operating speculum) or a distending anal speculum (e.g. anal distending speculum Auckland). The obturator has to be removed and the speculum has to be placed around the device and then inserted into the anal canal between the device and the anal wall. The speculum should be introduced into the anal canal to the depth where the needles are placed in the anal canal wall. This means that you have to look at the number on the mantle of the device visible at the anal verge and introduce the device as many centimeters inside as the indicated number (typically 1 to 3 cm). For the distending speculum, it has to be opened to at least 30 mm once in place. Thanks to the said speculum, a space will be created between the FISSCURE and the anal wall and the needles of the device will no longer be inside the anal wall, or be released from it by a gentle movement of the FISSCURE. This will allow you to remove the FISSCURE through the anal speculum without harm. Next the speculum can also to be retrieved from the anal canal, this after its closure for the distending speculum.

2. **Use of surgical probes**
   You can introduce gently multiple surgical probes (8 to 12 depending of the diameter of the probes) of at least 5mm diameter (e.g. Cooley vascular dilator malleable 5mm, Nabatoff probe Tip plastic material,…) along the longitudinal axis of the FISSCURE into the anal canal. The probes should be inserted about 4 cm into the anal canal. If you meet some resistance to introduce a probe it should be moved a bit since this can be due to contact with a needle. You can be helped to know the position of the needles compared to the button since needles come out i.e., at 30° and 120° left and 60° and 150° right compared to center of the button. Once enough probes are placed around the FISSCURE and a distention of at least 5mm obtained all around the device, the probes and device should be retracted together from the anal canal that will avoid any harm caused by the needles.
   If no or not enough surgical probes are available; you can use other blunt longitudinal tools to obtain the same effect, e.g. the use of 2 or more layers of plastic tongue depressors, bougies etc.

STORAGE

Store the device in sterile packages at room temperature in a clean and dry environment. Do not store them in direct sunlight.

Avoid a place where the packages can become damaged.

DEVICE DISPOSAL

The instrument is a single use, disposable item. Do not reuse or attempt to sterilize it. Reusing the instrument could pose an infection control risk, cause tissue irritation or malfunction.

After using the instrument, dispose of it in an appropriate manner.

MANUFACTURER RESPONSIBILITY

The manufacturers responsibility will not be involved if the recommendations for installation and preparation are not followed, if non-qualified persons do the intervention as mentioned in the user's qualifications or when the device is used for other purposes than the intended use mentioned in the manual for use. Moreover, the manufacturers responsibility cannot be claimed if the instructions described in the manual are not followed or any claim related to the botulinum toxin injected. Factors relating to the patient, diagnosis, treatment and other matters beyond Doc-Invent's control directly affect the instrument and the results obtained for its use. Doc-Invent's obligation is limited to the replacement of this instrument and Doc-Invent shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Doc-Invent neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Doc-Invent assumes no liability with respect to instruments that were reused, reprocessed or resterilised.

USER RESPONSIBILITY

It is the responsibility of the user to notify the manufacturer and the competent authority of the country where the device is used of any serious accident that may occur.


Do not use if package is damaged


This device is intended for single use only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