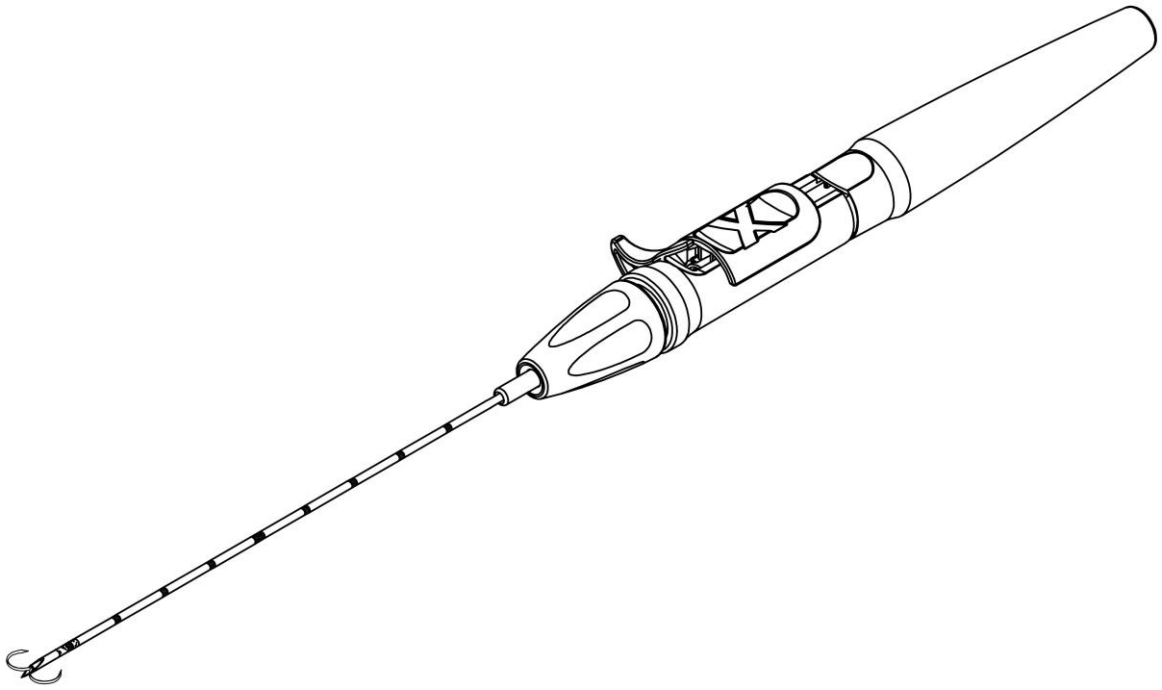
Tuflex Premium

REF 271650 271651

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA



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CONTENT

PICTURES

Figure 1

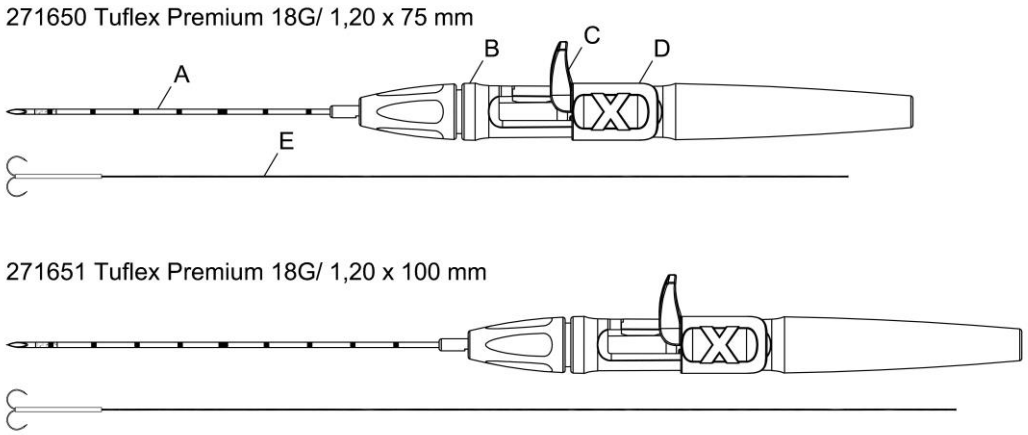


Figure 2

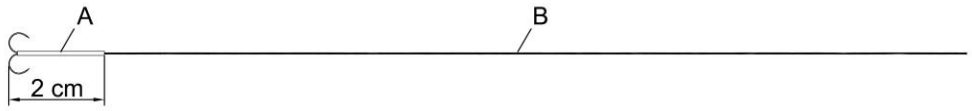
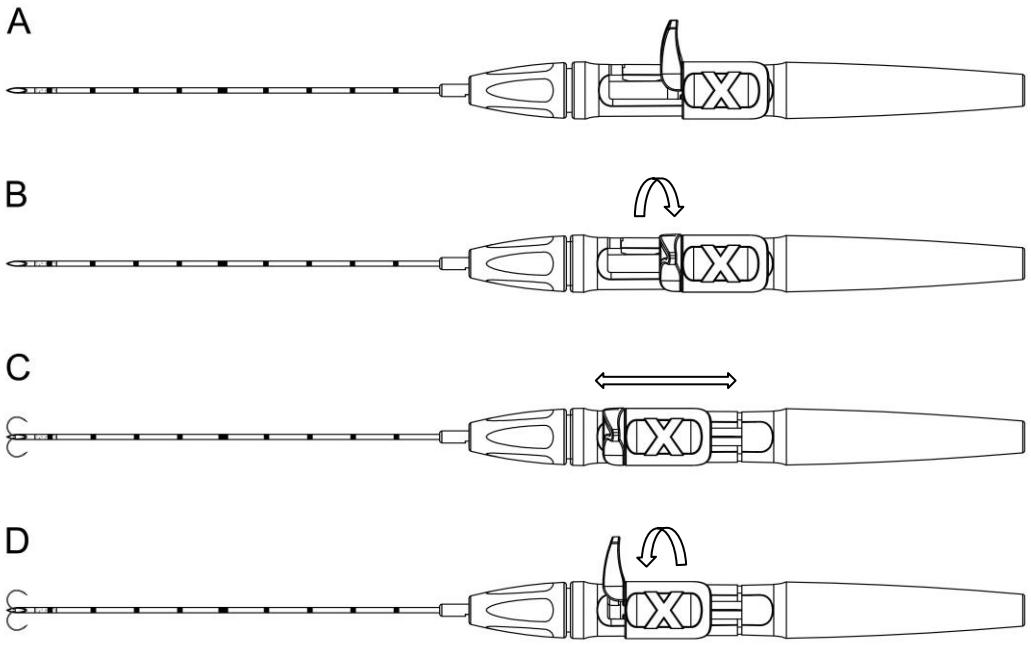


Figure 3



ENGLISH

Read instructions before use ***Keep for future reference***

Important Information:
Read this instruction manual thoroughly and be familiar with its contents prior to use. Failure to read the entire manual and familiarize yourself with all instructions before using the *Tuflex Premium* is unsafe and can result in life-threatening or severe injury to the patient or user and to damage or malfunction of the device.

Intended use and indications for use:
The *Tuflex Premium* is intended as a preoperative marker of non-palpable suspected breast lesions to facilitate the intraoperative localization of the findings by the surgeon.

Contraindications:
All contra-indications applicable to the relevant area of application, as known according to the rules of the art of medicine and anticipated for the use of cannulas and marker systems for preoperative marking of breast lesions, shall apply.

- The *Tuflex Premium* is not intended for use except as indicated above.
- The *Tuflex Premium* is not suitable for use with magnetic resonance imaging (MRI).
- The *Tuflex Premium* is contraindicated in patients with a nickel allergy.

Possible known complications:
Marker wire dislocating, accidental cutting of wire, breaking the wire, bleeding, infections, cosmetic complications.

Warnings:

- Only qualified physicians with the required knowledge, experience and training shall use the product.
- This manual does not include descriptions or instructions for surgical techniques. It is the responsibility of the physician performing any procedure to determine the appropriateness of the procedure to be performed and of the use of this device and to determine the specific technique for each patient.
- The product is only sterile, if used before the expiration date and if package is unopened and undamaged. DO NOT use after the expiration date or if package is open or damaged.
- When using the device near a breast implant, handle with care to avoid puncturing the breast implant.
- The product is NOT suitable for MRI use (magnetic resonance imaging)! Danger of injury!
- The product is NOT suitable in direct contact with electrosurgical instruments! Danger of spark discharging and injury!
- Care must be taken by using electrosurgical instruments: the product can be damaged in direct contact.
- DO NOT shorten the marking system wire after placing it!
- Single patient use only. DO NOT reuse or resterilize.
- It is important to apply the dressing in a way that when the dressing is removed later, the *Tuflex Premium* is not accidentally pulled out of the tissue if it is attached to an adhesive surface, for instance.
- If damage to the marking wire occurs, a follow-up check and, if necessary, removal of wire fragments remaining in the body is required.
- The *Tuflex Premium* is designed to remain in the body for a maximum of three days. If, after placement, the *Tuflex Premium* is worn overnight, a compression or sports bra with a front fastener must be worn to protect against dislocation of the wire.
- If, after placement of the *Tuflex Premium*, a patient is discharged home until the day of surgery, the doctor must inform the patient about the risk of a possible infection.
- If, after placement of the *Tuflex Premium*, a patient is discharged home until the day of surgery, the doctor must inform the patient that the dressing material may only be changed by medical specialists and that body cleaning must be carried out in such a way that the dressing area is protected from moisture.

Precautions:

- The *Tuflex Premium* distal double hook and flexible thread termination are made from a nickel-titanium alloy (Nitinol), which is why the product is contraindicated in patients with a nickel allergy.
- The marking wire is metallic, and thus, must not come in direct contact with electrosurgical instruments, because it will be damaged.
- The marker system distal double hook must be fully retracted into the cannula when the cannula is being positioned: Ensure that the distal double hook (Figure 3, A) is fully retracted into the cannula.
- There is risk of injury due to the sharp cannula tip. Use care especially when unpacking the cannula.
- The *Tuflex Premium* is not made from MRI compatible materials and is NOT suitable for the MR safety zone. There is a risk of injury in any MR procedure!
- **Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**

Information about the materials used in the marking system:
The distal double hook and wire termination are made from a nickel-titanium alloy (Nitinol). The tube is made of medical grade stainless steel.

MRI Safety Information:

MR unsafe

The *Tuflex Premium* is **not** suitable for use in an MRI scanner.

Product description:
The *Tuflex Premium* consists of the cannula (Figure 1, A) with handle (Figure 1, B), lever (Figure 1, C), plunger (Figure 1, D) and a preloaded marking system with distal double hook (Figure 1, E) and a flexible wire termination (Figure 2, B).
In addition to the distal double hook and flexible wire, the marking system comes with a stainless steel tube (Figure 2, A), which serves as a guide for the user during the surgical procedure.

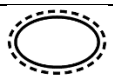
Directions for Use:
1. Before opening, make sure that the packaging is not already open or damaged and that it is within the expiration date.
2. Disinfect the area and administer local anesthetic in the zone around the puncture site. If appropriate, cover the area with sterile cloths.
3. Open the packaging and remove the product from packaging.
4. The marker system distal double hook must be fully retracted into the cannula when the cannula is being positioned: Ensure that the distal double hook (Figure 3, A) are fully retracted into the cannula.
5. Inserting the cannula: Insert the cannula into the breast using ultrasound/mammographic imaging, until the tip of the cannula is within the tumor itself or in the tumor zone. If necessary, make a puncture incision at the puncture site using a scalpel, to facilitate skin penetration. PLEASE NOTE: The *Tuflex Premium* is not suitable for use in the MR safety zone.
6. Once the target point is reached, the marking system with its distal double hook can now be placed in the tumor zone. To do this, move the lever on the handle to the left and then push it all the way forward (Figure 3, B and Figure 3, C).
7. Before removing the cannula, the distal double hook can be checked for correct placement. If the position is not right, the marking system can be retracted back into the cannula. To do this, pull the lever on the handle back again. Once the cannula is positioned correctly, the marking system can be released again for preoperative marking as described under 6 above.
8. Before removing the cannula, move the lever to the right until it locks (Figure 3, D). The marking system can no longer be retracted using the lever!
9. Carefully remove the cannula from the patient. PLEASE NOTE: DO NOT shorten the marking system wire once it has been placed.
10. Treat the wound site and stick the external part of the thread to the breast using sterile dressing material. It may be appropriate to stick the coiled-up thread down under a sterile plaster using a wound dressing and, if needed, to use additional sterile adhesive strips. The breast should not be compressed at the same time.
    It is important to apply the dressing in a way that when the dressing is removed later, the *Tuflex Premium* is not accidentally pulled out of the tissue if it is attached to an adhesive surface, for instance.
    If, after placement, the *Tuflex Premium* is worn overnight, a compression or sports bra with a front fastener must be worn to protect against dislocation of the wire. The patient shall further be informed about the risk of infection, how to protect the wound against moisture, and to contact a medical professional, when the dressing needs to be changed.
11. After use: dispose the application device properly, following internal guidelines if appropriate; however, at least one suitable container intended for contaminated cannulas should be provided to ensure safe disposal.
12. PLEASE NOTE for excision of the wire: The product it NOT suitable for contact with electrosurgical instruments! Damage of the product and injuries of the patient are endangered!

Warning:
The company SOMATEX does not assume any liability for the use of this product or its components in case of re-sterilization or reuse. This product may not be reused after a single application. The quality of the materials, coats and adhesive joints could degrade. Safe use is not guaranteed any longer. The product that is already used once is not designed for the required cleaning and sterilization processes. The sterility of the reprocessed disposable products is therefore not guaranteed. The risk of unwanted injuries and infections, especially cross-infections between patient and medical staff inappropriately increases.

Storage Instructions:
Protect from moisture. Keep dry.
Keep away from sunlight and heat (temperature 5 – 30 °C / 41 – 86 °F).

Any serious events that occur in relation to the product should be reported to SOMATEX Medical Technologies GmbH as well as the competent national authority.

SYMBOLS

SYMBOLS	EXPLANATION
	Consult instructions for use
	Catalogue number
	Lot / Batch code
	Date of manufacture
	Manufacturer
	Expiration date
	Sterilized by ethylene oxide
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
	Do not re-use
	Do not resterilize
	Do not use if the package is damaged
	Temperature limit
	Not made with natural rubber latex
	Keep away from sunlight and heat
	Keep dry
	MR unsafe
	Medical Device

INFO

Ordering:

REF	Name	Cannula Diameter	Cannula Length
271650	Tuflex Premium	18G/ 1,20 mm	75 mm
271651	Tuflex Premium	18G/ 1,20 mm	100 mm

Manufactured by:
SOMATEX Medical Technologies GmbH
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Germany

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