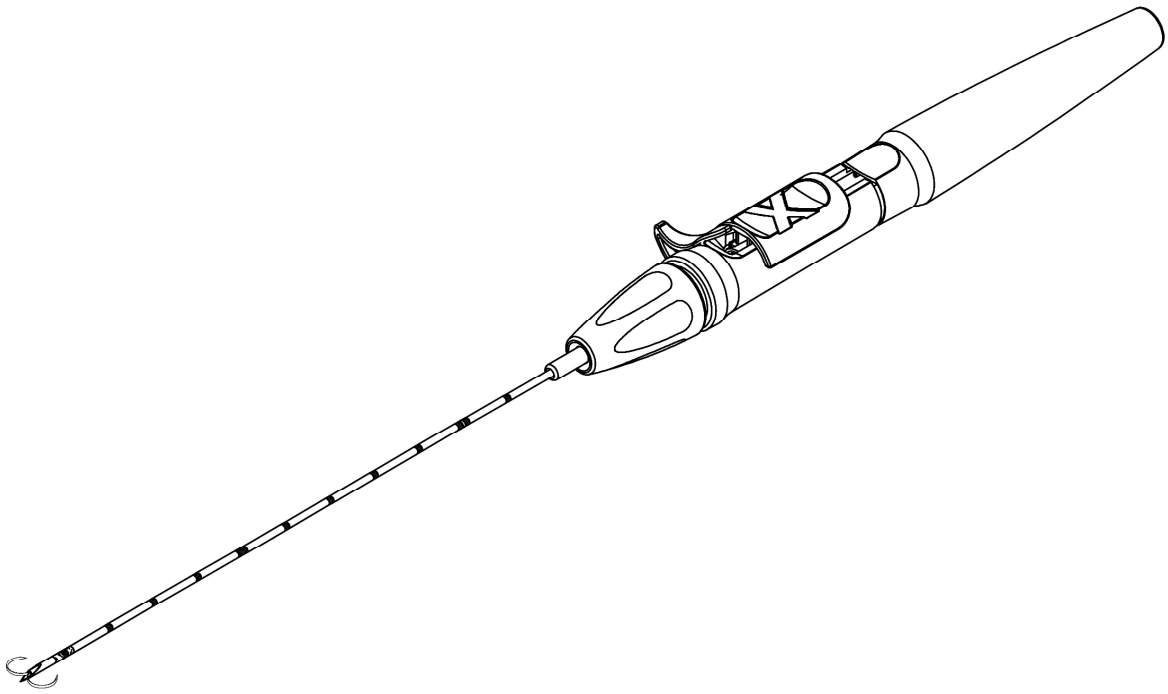
Tuflex Premium

REF 271650 271651 271652

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA



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MEDICAL TECHNOLOGIES GMBH

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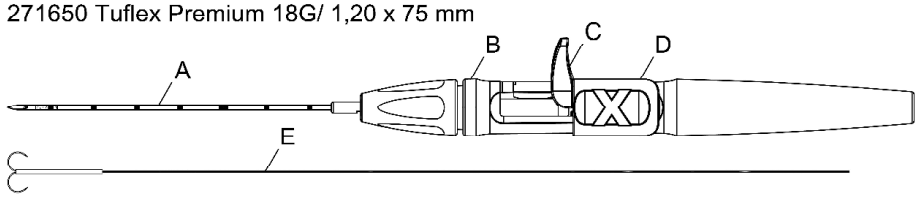
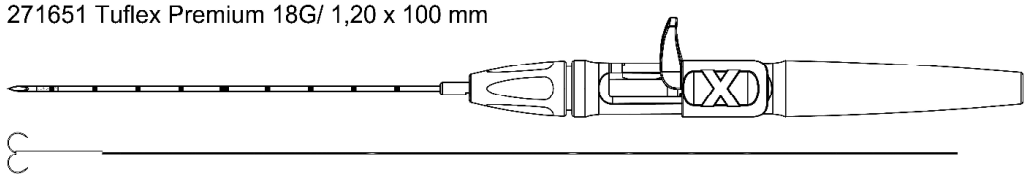
PICTURES

Figure 1

271650 Tuflex Premium 18G/ 1,20 x 75 mm



271651 Tuflex Premium 18G/ 1,20 x 100 mm



271652 Tuflex Premium 18G/ 1,20 x 120 mm

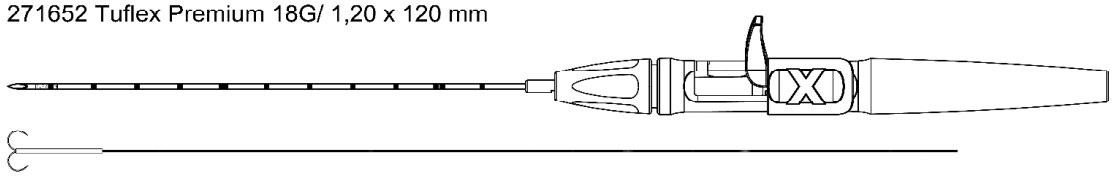


Figure 2

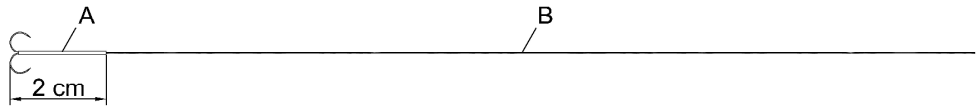
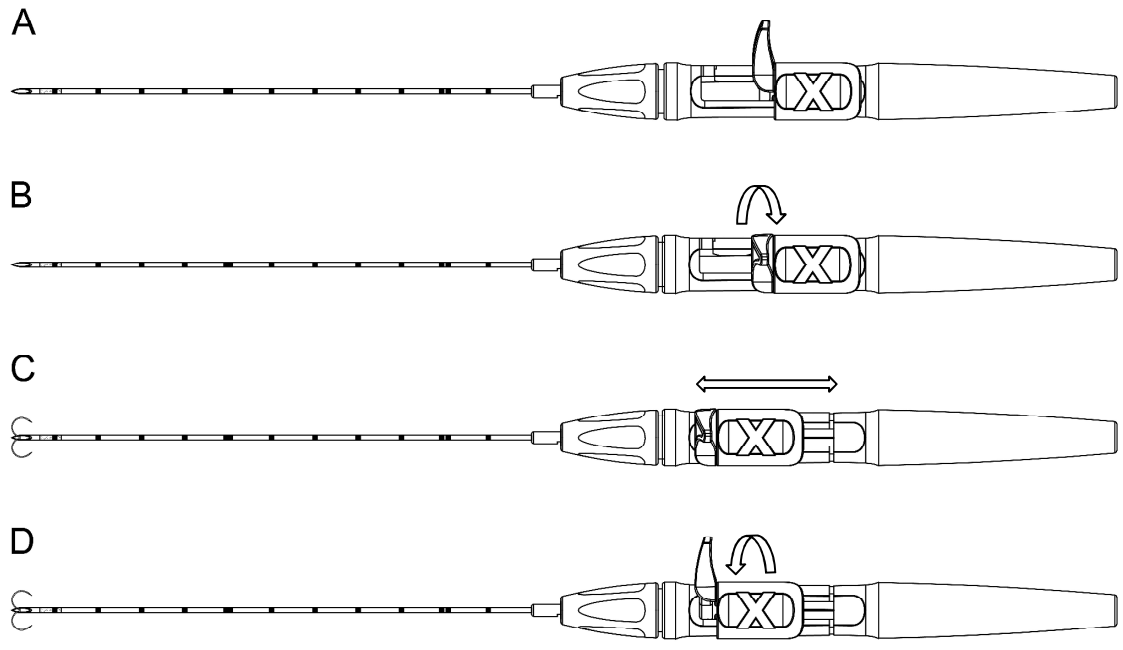


Figure 3



ENGLISH

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

Important Information:
Read this instruction manual thoroughly and be familiar with its contents prior to use of the *Tuflex Premium*. 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 severe nickel allergy.

Possible known complications:
Marker wire dislocating, accidentally cutting the 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.
- The product is NOT suitable for MRI use (magnetic resonance imaging)! Danger of injury!
- 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 there is a longer time period between placement and surgery, it may make sense to recommend the patient also wears a (sports) bra.

Precautions:

- The *Tuflex Premium* twin arches and flexible thread termination are made from a nickel-titanium alloy (Nitinol), which is why the product is contraindicated in patients with a severe nickel allergy.
- The marker system twin arches must be fully retracted into the cannula when the cannula is being positioned: Check that the twin arches (Figure 3, A) are 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 twin arches 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 twin arches (Figure 1, E) and a flexible wire termination (Figure 2, B).
In addition to the twin arches 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 twin arches must be fully retracted into the cannula when the cannula is being positioned: Check that the twin arches (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 twin arches 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 twin arches 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 there is a longer time period between placement and surgery, it may make sense to recommend the patient also wears a (sports) bra.
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.

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:

Keep away from sunlight and heat.
Store in a dry area at a temperature of 5 – 30 °C.

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
	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
	Green indicator: Product is sterilized

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
271652	Tuflex Premium	18G/ 1,20 mm	120 mm

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