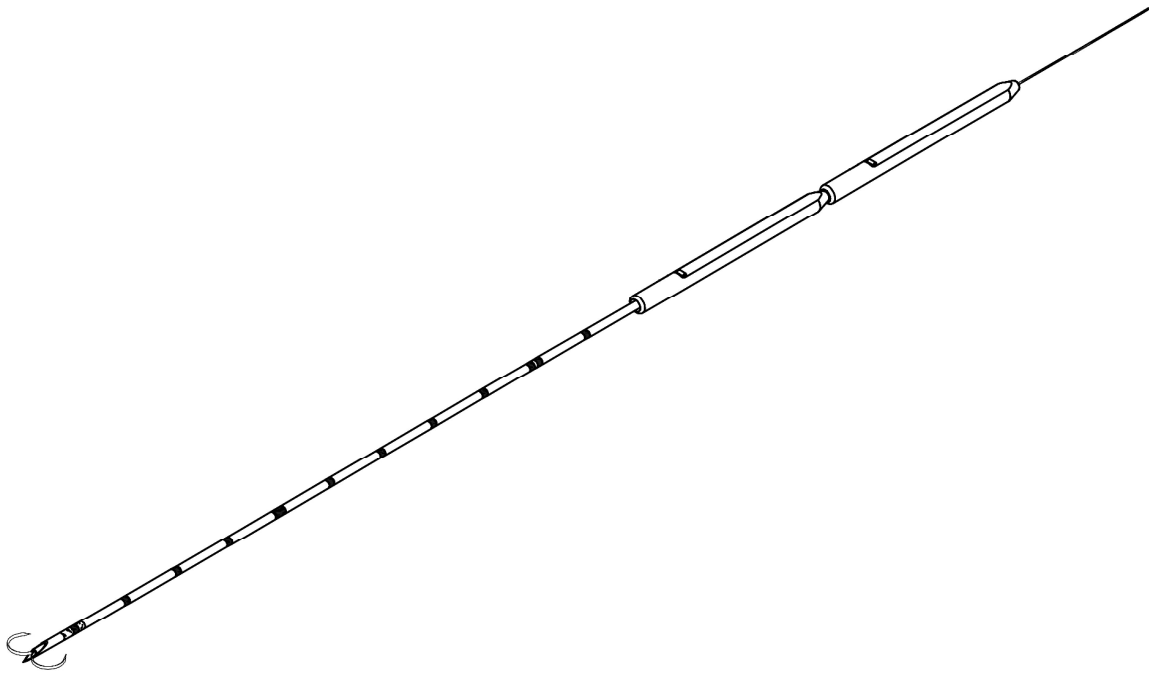


Tuflex

REF 271640 271641 271642 271643

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA



CONTENT

CONTENT 2

PICTURES..... 3

ENGLISH..... 4

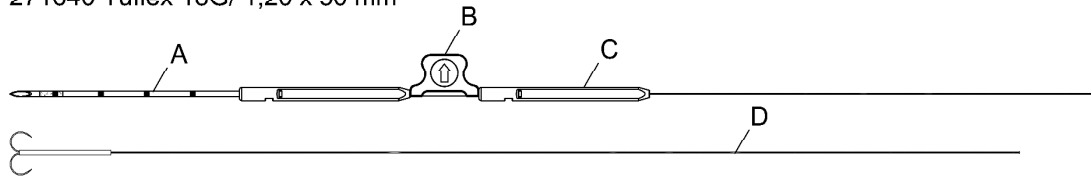
SYMBOLS..... 6

INFO 7

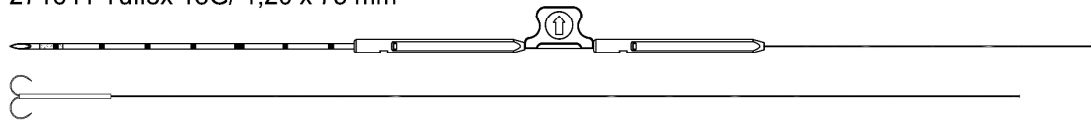
PICTURES

Figure 1:

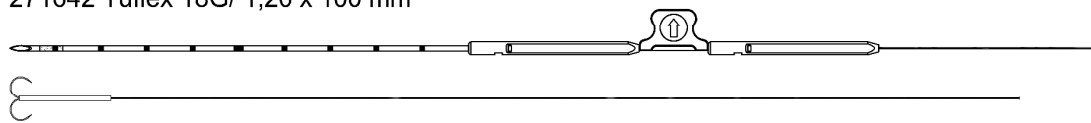
271640 Tuflex 18G/ 1,20 x 50 mm



271641 Tuflex 18G/ 1,20 x 75 mm



271642 Tuflex 18G/ 1,20 x 100 mm



271643 Tuflex 18G/ 1,20 x 120 mm

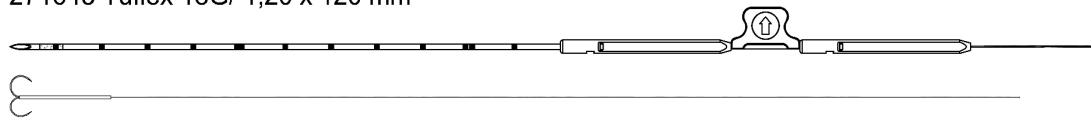


Figure 2:

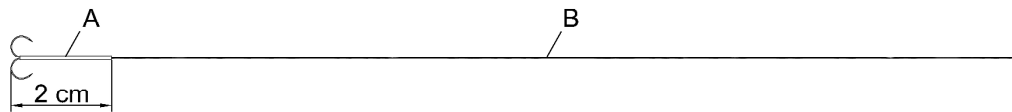
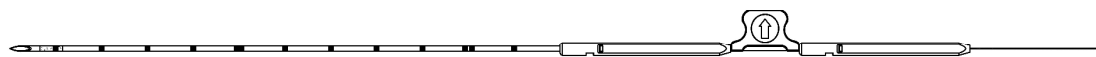


Figure 3:

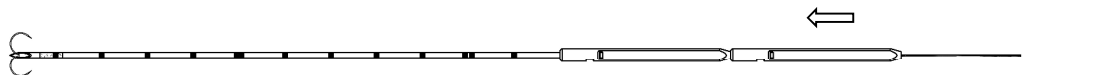
A



B



C



D



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*. Failure to read the entire manual and familiarize yourself with all instructions before using the *Tuflex* 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* 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* is not intended for use except as indicated above.
- The *Tuflex* is not suitable for use with magnetic resonance imaging (MRI).
- The *Tuflex* 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* 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* 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* 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* is **not** suitable for use in an MRI scanner.

Product description:

The *Tuflex* consists of the cannula with attachment (Figure 1, A), the safety clip (Figure 1, B), the ejector with attachment (Figure 1, C) and a preloaded marking system with distal twin arches (Figure 1, D) and a flexible thread termination (Figure 2, B). In addition to the twin arches and flexible thread, the marking system comes with a stainless steel tube (Figure 2, A), which serves as a guide for the user during the surgical procedure.

STERILE EO

MD


SOMATEX®
 MEDICAL TECHNOLOGIES GMBH

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* 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, hold the cannula attachment, remove the safety clip (Figure 3, B) and push the marking system fully out of the cannula using the plunger. The twin arches are fully deployed when the cannula attachments (Figure 3, C) touch each other.
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, hold the cannula attachment, retract the marking system back into the cannula until the black ring is visible on the plunger (Figure 3, D). Once the cannula is positioned correctly, the marking system can be released again for preoperative marking as described under 6 above.
8. Carefully remove the cannula from the patient. PLEASE NOTE: DO NOT shorten the marking system wire once it has been placed.
9. 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* 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.
10. 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:

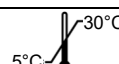
The company SOMATEX does not assume any liability for the use of this product or its components in case of re-sterilization or reuse. This product may not be reused after a single application. The quality of the materials, coats and adhesive joints could degrade. Safe use is not guaranteed any longer. 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.

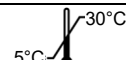
Store in a dry area at a temperature of 5 – 30 °C.

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 re-sterilize
	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

STERILEEO**MD****SOMATEX®**
MEDICAL TECHNOLOGIES GMBH

INFO

Ordering:

REF	Name	Cannula Diameter	Cannula Length
271640	Tuflex	18G/ 1,20 mm	50 mm
271641	Tuflex	18G/ 1,20 mm	75 mm
271642	Tuflex	18G/ 1,20 mm	100 mm
271643	Tuflex	18G/ 1,20 mm	120 mm

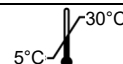


Manufactured by:
SOMATEX Medical Technologies GmbH
Hohenzollerndamm 150/151
14199 Berlin
Germany

Tel.: + 49 (0) 30 319 82 25-00
Fax: + 49 (0) 30 319 82 25-99
service@somatex.com
www.somatex.com

STERILE EO

MD

**SOMATEX**[®]
MEDICAL TECHNOLOGIES GMBH

SOMATEX[®]
MEDICAL TECHNOLOGIES GMBH