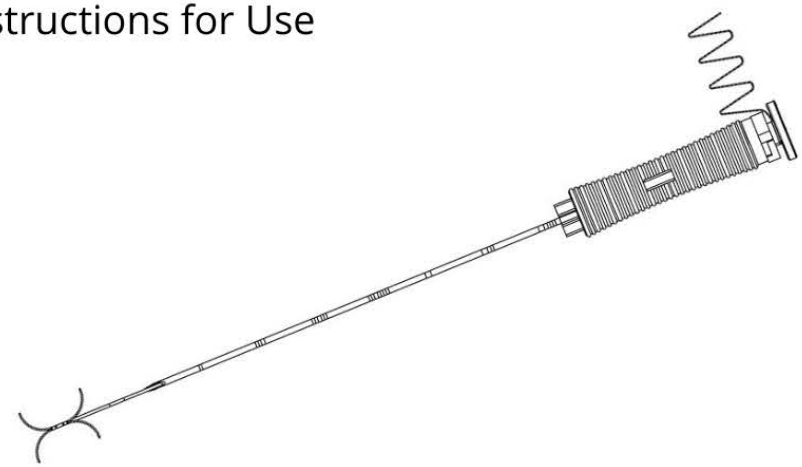
MAMMO FLEX

Quad-Flex Localization System

Instructions for Use

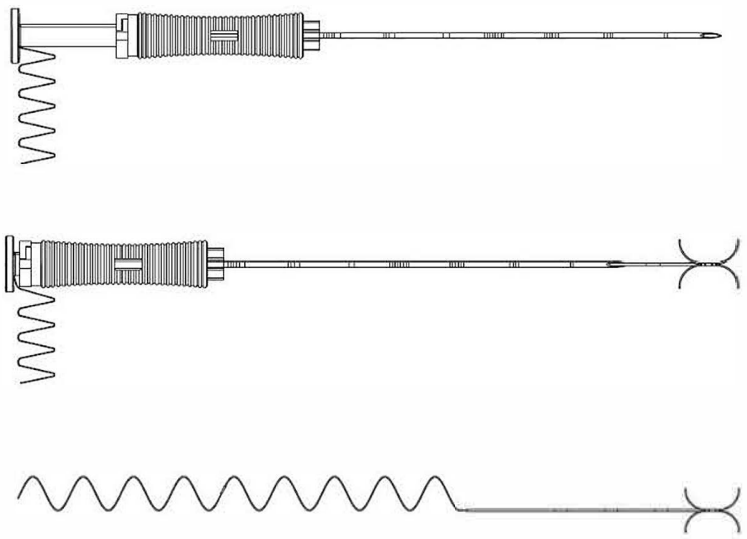


Manufacturer

DFC Medical, LLC
4100 S Shepherd Dr
Houston TX 77098

Device Description

The Mammo-Flex device consists of a handle with a plunger attached to a needle. The needle is preloaded with a marking system. The marking system consists of an implantable hook with two distal arms and two proximal arms. The hook is attached to a metallic thread that has three marker bands at the distal aspect that provide additional information as to the location of the localized lesion. The distal 5cm of the thread and the marker bands are covered by a heat shrink polymer that protects against incidental contact with electrosurgical instruments. The proximal 15cm of the metallic thread is coiled to aide in the management and securement of the thread. The device is provided sterile (sterilized with ethylene oxide).



Indications

The Mammo-Flex is intended as a preoperative lesion marker and as an operative guide for surgical excision.

Contraindications

The Mammo-Flex is only intended for use as indicated here. All contraindications relevant to the rules of the art of medicine apply relevant to preoperative localization.

Mammo-Flex is not intended for use in patients with a known nitinol allergy.

Mammo-Flex is not intended for use with MRI.

Warnings

Caution should be used when using this device on patients with breast implants to avoid puncture during placement.

Caution should be used when using this device in close proximity to muscles to avoid the possibility of tethering the thread.

This device should not be implanted for longer than 30 days. However, a more practical usage would suggest the implantation time not exceed 7 days.

This device is for single use only. Do not reuse or resterilize.

Precautions

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

This device should only be used by qualified physicians with the appropriate training and knowledge.

The 2 distal arms should be fully retracted before attempting to reposition.

Potential Complications

Inadvertent removal of the Mammo-Flex after localization, dislocation of the hook from the desired location, hematoma, and infection.

Directions for use

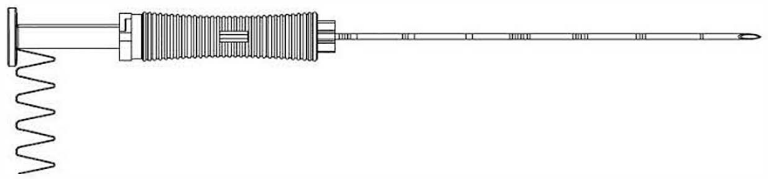
1. Inspect the package prior to use. Verify the sterile packaging is not damaged or opened and that the product is within the expiration date.

2. Remove the device from the packaging.

3. Clean and prep the patient in the normal fashion.

4. Under image guidance insert the needle into the tissue to the desired location.

5. With correct placement verified, unlock the device by turning the plunger counterclockwise.



6. Partially deploy the 2 distal arms by advancing the plunger to the line indicating partial deployment.

7. Again, verify correct placement with imaging. In the event repositioning is required, fully retract the 2 distal arms by fully retracting the plunger. Reposition under image guidance. Once the desired location is reached, re-deploy the 2 distal arms. Again, verify correct placement with imaging.

8. With correct placement verified, fully deploy the hook by fully depressing the plunger.

9. Remove the handle and needle.

10. Acquire appropriate post procedure imaging to verify correct placement and to communicate localization to surgeon.

11. Clean and dry the skin around the exiting thread.

12. Remove the provided tegaderm patch from its packaging.

13. Push the coiled thread to the skin. Any excess thread with heat shrink exiting the skin should be folded on itself to provide the smallest foot print possible.

14. Remove the backing of the provided tegaderm. Use the provided tegaderm patch to bandage the area of interest taking care to completely conceal the thread under the cotton portion of the provided tegaderm patch. The tissue should not be in compression while applying the patch.

15. Remove the remaining covering material from the periphery of the adhered tegaderm patch.

MRI Safety Information

The Mammo-Flex has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Quad-Flex in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Manufacturer

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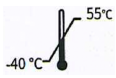
Houston TX 77098

Mammo-Flex Quad-Flex Localization System

Glossary of Symbols

This glossary provides the title and explanation of the symbols used on the packaging and labeling of the Mammo-Flex Quad-Flex Localization System.

Symbol	Symbol Title	Explanatory Text
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Size (Gauge and Length)	Indicates the size (gauge and length) of the medical device
	Batch Code (Lot Number)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Date of Manufacture	Indicates the date when the medical device was manufactured
	Use-By Date	Indicates the date after which the medical device is not to be used
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	Prescription Only	Indicates the following: Caution: Federal law restricts this device to sale by or on the order of a physician.
	Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Do not re-use	Indicates a medical device that is intended for one single use only
	Sterilized using ethylene oxide Single sterile barrier system	Indicates a medical device that has been sterilized using ethylene oxide and is packaged in a single sterile barrier system
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed (10% to 80% humidity)
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed (-40° C to 55° C)
	Contents	The quantity of medical devices within the package (one)
	Manufacturer	Indicates the medical device manufacturer