

Note: There are three recommended methods of fixing slides. Check with your cytopathologist as to which of the following methods they recommend.

1. Air dry slides.
2. Immerse in 95% ethyl or methyl alcohol.
3. Spray with fixative (95% ethyl or methyl alcohol). If aerosol spray fixative is used, avoid holding the can closer than 12 inches from the slide to prevent freezing the artifacts.*
*Frale Wm J.: Thin-Needle Aspiration Biopsy. Human Pathology. 1983; 14:20-73, pp. 13-14.
4. Dispose of in accordance with all applicable Federal, State, and local medical/Hazardous Waste Practices.

IMPORTANT

A benign fine-needle aspiration cannot be the sole basis for diagnosis of breast pathology. Benign cyologic diagnosis should be ignored if clinical and laboratory evidence suggest a malignancy.

If aspirate is bloody or cloudy—or if you can still palpate a swelling after the aspiration—the cystic contents should be analyzed. Adding a few drops of heparin to a hemorrhagic aspirate is recommended to prevent clotting*.

Bloody aspirate or cystic fluid must be spread on a glass slide with the aid of a thick cover slide or second slide as you would for a routine blood smear.

Tissue fragments that are collected at the end of the smear are gently squeezed by flat pressure with cover slip or slide used to spread smear.

* Franz S, Zajicek J.: Acta Radiologica. 1968; p. 244.

EXPLANATION OF SYMBOLS



Reorder Number



Batch Code



Use-by date



Do not re-use



Do not re-sterilize



Do not use if package is damaged



Consult instructions for use



Caution



Not made with natural rubber latex

R_x Only

Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner



Sterilized Using Ethylene Oxide



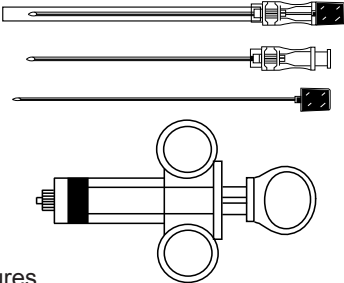
Manufacturer

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**Breast Aspiration
Biopsy Needle • 22 Gauge
MX41 • MX42**



Instructions for Use

DEVICE DESCRIPTION

The Breast Aspiration Biopsy Needle is a sterile, single-use device for use in office-based fine-needle aspiration procedures.

The Breast Aspiration Biopsy Needle is available in the following configurations:

- MX41** - 1.5” Dual Port Needle with 3-Finger Control, 12 cc Syringe
MX42 - 1.5” Dual Port Needle, no Syringe

INDICATIONS FOR USE

Any lesion of the breast that can be palpated where aspiration is thought to help:

- Establish a diagnosis
- Assist in determining extent of disease
- Evacuate a cyst
- Distinguish between diffuse suppurative mastitis and carcinoma with associated severe inflammation
- Confirm diagnosis of inoperable carcinoma of the breast prior to radiotherapy

Note: A benign cytologic diagnosis should be ignored if clinical and laboratory evidence suggests a malignancy.

CONTRAINDICATIONS

- This device is not intended for use except as indicated.
- This device is contraindicated for those patients where, in the physician’s judgment, there is an increased risk of complications associated with percutaneous removal of tissue samples.

CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- There may be occasional hematoma or focal mastitis and very rarely a pneumothorax has been reported.

WARNING

Complications are rare, but may include:

- Bleeding
- Infection
- Bruising

Factors that may increase the risk of complications include:

- Obesity
- Smoking
- Poor nutrition
- Chronic illness, like diabetes
- Bleeding disorder

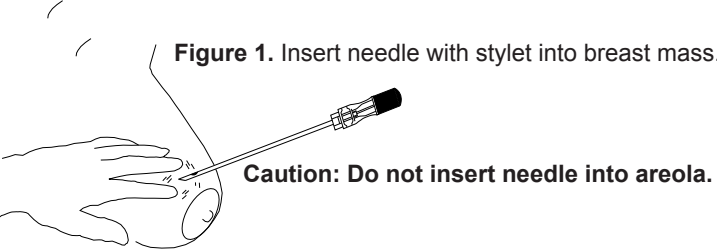
- Contents supplied sterile. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

PREPARATION OF PATIENT PRIOR TO FINE-NEEDLE ASPIRATION

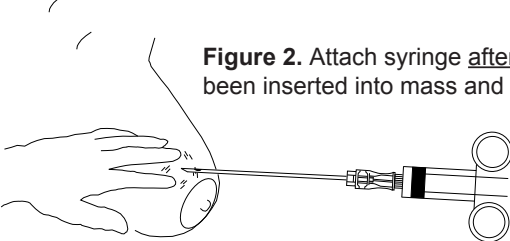
1. Most patients are very apprehensive—it is very important that you explain every step of the procedure to reassure and put your patient at ease.
2. Explain that the needle you will be using is smaller than the one used for venapuncture and, therefore, should be less painful than having blood drawn from a vein.
3. Though some doctors do not use any anesthetic, your patients may be more comfortable if you anesthetize the skin locally, as it is sometimes necessary to insert the biopsy needle three times to obtain sufficient cells for adequate diagnosis.

INSTRUCTIONS FOR USE

1. Determine in which position to put your patient so that the breast mass is most accessible to needling.
2. Disinfect the skin over area of the puncture site with a suitable antiseptic solution. Use local anesthesia as desired.
3. After mass is located, immobilize with your free hand.
4. With stylet in needle, touch needle to skin and determine needle direction before puncturing the skin. Keeping the mass immobilized, introduce needle into the mass in one quick thrust. **Figure 1**



5. Remove stylet. Attach syringe to needle. (Plunger of syringe should be at bottom of syringe barrel). **Figure 2**



6. Apply full vacuum by pulling back on the plunger while the needle is moved back and forth in short strokes. **Figure 3**

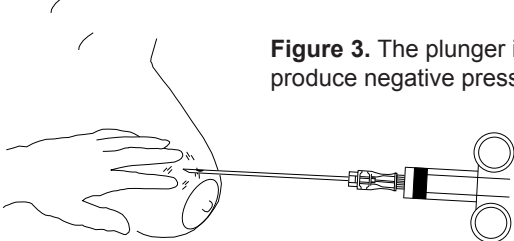


Figure 3. The plunger is retracted to produce negative pressure in the syringe.

7. Move the needle back and forth along the same plane or back and forth in different directions. **Figure 4**

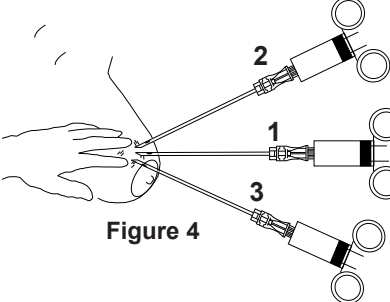


Figure 4

8. Before withdrawing the needle, release the plunger, allowing the pressure in the syringe to equalize so there is no negative pressure in the syringe as the needle is withdrawn. **Figure 5**

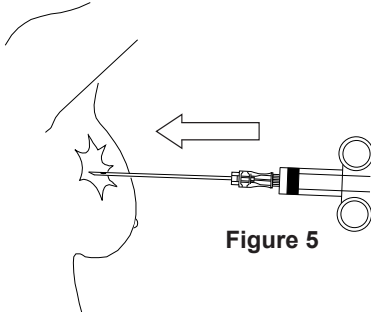


Figure 5

9. Apply pressure over the needle site with sterile cotton ball or gauze immediately for 10-20 minutes to prevent a hematoma. **Figure 6**



Figure 6

PREPARATION OF SLIDES

Aspirated material tends to clot rapidly, so there should be no delay in preparing smears.

1. Disconnect needle from syringe; fill syringe with air and reattach to needle. **Figure 7a**

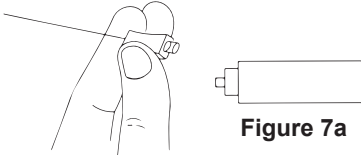


Figure 7a

2. Reattach needle to the syringe. **Figure 7b**

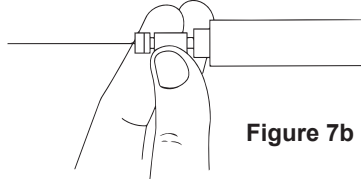


Figure 7b

3. Hold needle so that the tip and side port are placed over the center of the slide, ensuring a drop of specimen falls onto the center of the slide. The four or five drops obtained from an aspiration should be quickly placed onto separate slides. It is important to keep the needle touching the glass slide so there is no air gap between the needle and slide. **Figure 7c**

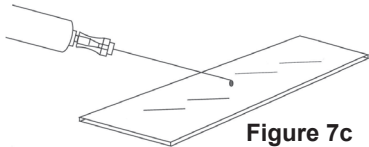


Figure 7c

4. Invert second cover slip or second slide over each of the above slides. As the drop spreads, slides are gently pulled apart, confining smear to a small area on the slide. **Figure 8a and 8b**



Figure 8a

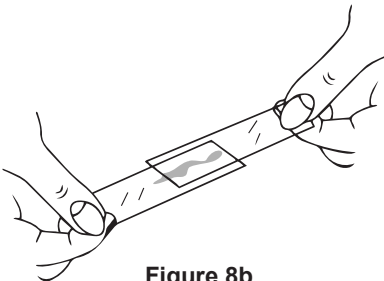


Figure 8b