GUIDESTAR MEDICAL DEVICES

EpiZact Instructions for Use

REF	Catalog number
LOT	Batch code
	Use-by date
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged
	Single sterile barrier system with protective packaging inside
	Do not re-use
	Consult instructions for use
	Caution: Consult accompanying documents. Read instructions prior to use.
Rx Only	Prescription use only: Federal law restricts this device to sale by or on the order of a licensed practitioner.
MR	MR unsafe
	Non-pyrogenic
	Manufacturer

Product Description

EpiZact is a sterile, single use, syringe intended for use with an epidural needle for detecting a loss of resistance, which aids in verifying needle tip placement in the epidural space. EpiZact is used in conjunction with the following:

- Tuohy needle 16, 17, or 18 gauge, less than or equal to 6" in length
- Tuohy needle wing width less than or equal to 32 mm
- Sterile saline

Indications for Use

EpiZact is intended for use with an epidural needle for detecting a loss of resistance, which aids a clinician in verifying needle tip placement in the epidural space.

Contraindications

EpiZact should only be used to aid the implementation of the loss of resistance technique and can only be used on patients that are suitable for the technique. EpiZact must not be used unless the user has been adequately trained in the technique and is fully familiar with the IFU and intended purpose.

Absolute contraindications include patient refusal, severe uncorrected hypovolemia, increased intracranial pressure, infection at the site of injection and know hypersensitivity to local anesthetics. Relative contraindications include coagulation disorders, anticoagulant therapy, pre-existing neurological disease, fixed cardiac output states, uncooperative patients, spine abnormalities or surgeries, and sepsis.

Warnings

Read manufacturer's instructions prior to use.
Do not use if packaging is breached or damaged.
Do not use if device is damaged or broken.
Do not use after use-by-date.
Do not re-use, re-process, or resterilize.
Device is single use only.
Do not use if sterility is compromised after opening.
Use only for epidural needle placement using the loss of resistance technique.
Do not use for other functions or in other areas of the patient anatomy.
Do not use with Tuohy needle if wings on needle exceed 32 mm in width.

Re-Setting and Re-Filling

Caution: Device is single use and should only be re-set and refilled in the event of early triggering.

If the device runs out of saline during the procedure, it will trigger to prevent further advancement. The device can be refilled with saline through the female Luer connector, and the procedure can be continued. The device can be re-filled while attached to the Tuohy needle or first removed from the Tuohy needle then reattached.

Environment and Safety

The procedure should be carried out under sterile protocol, in an appropriate anesthetic environment.

Risks

There is risk with all epidurals performed by the loss of resistance (LOR) technique. The performance of the device can be influenced by patient specific factors, such as abnormal pressure in the epidural space. Note that a false trigger may occur if EpiZact's contents are emptied or if connections leak. EpiZact may also not trigger if the needle is obstructed by blood or tissue.

User must still use their clinical judgement to determine if loss of resistance detected is indicative of the correct positioning of the needle tip in the epidural space.

To be used only with Touhy needles 16, 17, or 18 gauge and length less than or equal to 6 inches. Use with other size needles may result in dural puncture.

Side Effects

Side effects are limited to discomfort from subcutaneous bleeding and bruising from the needle point entry.

GuideStar Medical Devices
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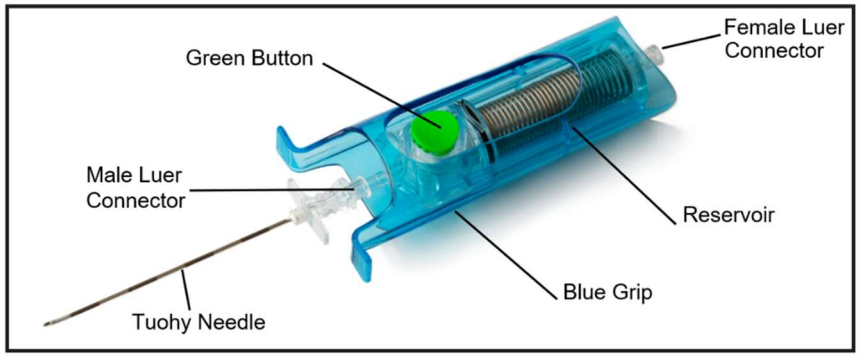
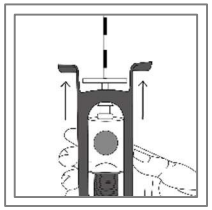
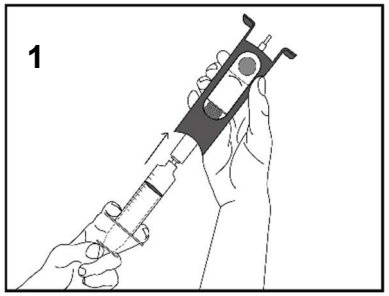


General

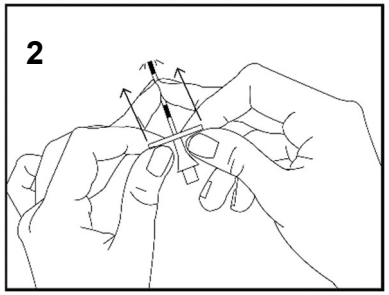
I. Users should familiarize themselves with instructions for use.
II. Open the package using aseptic technique.
III. Conduct a fit check of epidural needle wings with device prior to use:
   a. Attach needle to male Luer connector.
   b. Slide grip forward.
   c. Ensure grip slides freely past needle wings without contact. Do not use if contact occurs.



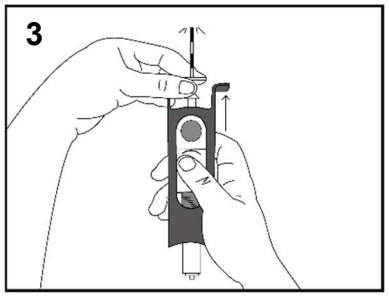
Use



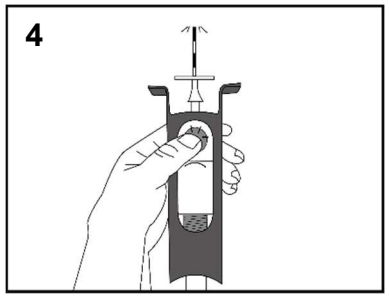
1. Fill the reservoir of EpiZact by attaching a saline-filled syringe to the female Luer at the back of the device. Fill until the reservoir no longer expands (approx. 8 mL). Once filled, remove the syringe from the device. (Fig. 1)



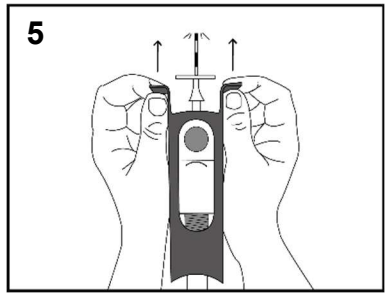
2. Position the tip of the Tuohy needle (16, 17, or 18 gauge) into the tissue as per conventional epidural procedure. Leave the stylet in place throughout needle positioning. (Fig. 2)



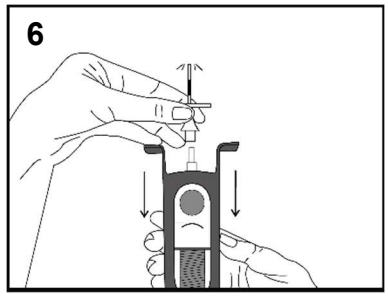
3. Remove stylet. While securely holding the Tuohy needle, attach the male Luer at the front of EpiZact. Ensure a tight connection before continuing. (Fig. 3)



4. Slide the blue grip away from the patient until it stops. Press and release the green button on the top of EpiZact. The green button should stay depressed when released. (Fig. 4) *Note: pressing the green button activates the saline to seek a loss of resistance*.



5. Advance the device, holding only the blue grip. Do not hold any other part of EpiZact or Tuohy needle. When a loss of resistance is detected, EpiZact will trigger and the blue grip will slide forward, which stops the needle. Once this occurs, stop advancing the blue grip. (Fig. 5)



6. Slide the blue grip back to expose needle hub and remove EpiZact from the Tuohy needle being careful not to disturb the needle position. (Fig. 6)

Disposal

Dispose of device as per institution protocol for hazardous waste.

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