STABILIT® Introducer

ENGLISH

# INSTRUCTIONS FOR USE

**IMPORTANT INFORMATION – PLEASE READ BEFORE USE**

## CAUTION

Federal (USA) Law restricts this device to sale by or on the order of a physician.

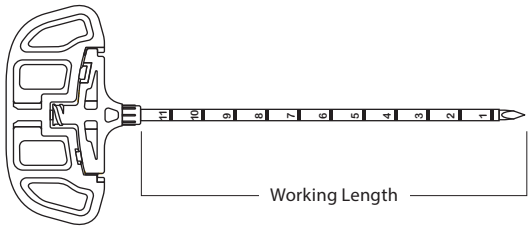
## INDICATION

The StabiliT® Introducer is indicated for percutaneous access to bone.

## DESCRIPTION

The StabiliT Introducer is indicated for percutaneous access to bone and consists of a cannula with either a trocar or bevel tip stylet. The Introducer cannula is 3.6mm in outer diameter. See the chart below for the device length.

| Device | Working Length |
|---|---|
| StabiliT Introducer (Short) | 10 cm |
| StabiliT Introducer (Long) | 12 cm |




## WARNINGS

1. This device should only be used by qualified physicians with training in the clinical procedure in which it is being used. Always use fluoroscopic guidance to avoid patient injury.
2. For safe use of the StabiliT Introducer, the physician should have specific training, experience, and thorough familiarity with the use and application of this product.
3. It is essential to maintain strict sterile technique during all phases of handling and use of this product. The product is sterilized by Ethylene Oxide. Do not use if package is opened or damaged.
4. Dispose of used product per Local, State and Federal Blood borne pathogen controls including Biohazard sharps container and disposal procedures.
5. Do NOT use this product in dense bone; device damage resulting in patient injury may occur. Breakage of the device may require intervention or retrieval.
6. The Introducer Stylet should be inserted and engaged with the Working Cannula during Introducer removal or manipulation.
7. For single patient 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.

## PRECAUTIONS

1. It is important to read the Instructions For Use and these precautions prior to device operation.
2. Use the StabiliT Introducer prior to Use By Date noted on the package to verify no damage has occurred.
3. Physicians using the StabiliT Introducer should be familiar with the physiology and pathology of the selected anatomy, and be trained in the performance of the chosen surgical technique.
4. The StabiliT Introducer should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images.

## ADVERSE EVENTS

Adverse events potentially associated with use of the device include:

- Nerve injury including puncture of the cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Embolism
- Hemorrhage
- Hemothorax or pneumothorax
- Hematoma
- Infection including deep or superficial wound infection
- Pain
- Unintended puncture wounds including vascular puncture and dural tear
- Fracture

## DIRECTIONS FOR USE

1. Make a skin incision over the selected area for access. Using fluoroscopic imaging guidance, manually advance the StabiliT Introducer to the selected bone surface checking AP/Lateral images to confirm proper placement. Do not advance the cannula without the stylet fully inserted into the cannula.

2. While holding the cannula in place, turn the stylet counter-clockwise to release and remove it from the cannula. The cannula is now ready to accept other instrumentation.

**NOTE:** Markings on the cannula may be used as reference markers only, they are not intended to replace the use of fluoroscopic observation.

**SYMBOL GLOSSARY**

| SYMBOL | DESIGNATION |
|---|---|
|  | Caution: Consult accompanying documents. Read instructions prior to use. |
|  | Use By: YYYY-MM-DD |
|  | Do not resterilize |
| STERILE EO | Sterilized using Ethylene Oxide |
|  | Keep away from sunlight |
|  | Keep dry |
| LOT | Lot Number |
| REF | Catalog Number |
|  | Single Use Device, DO NOT REUSE |
|  | Do not use if package is damaged |
|  | Bevel Tip |
|  | Trocar Tip |
| ℞ ONLY | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician |
|  | For electronic copy scan QR code or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U Customer Service. |

**HOW SUPPLIED**

The StabiliT Introducer is supplied sterile in a peel-open package. The device is sterilized using Ethylene Oxide and is intended for single use only. Do not resterilize. Do not use if the package is open or damaged. Notify manufacturer if damaged.

**STORAGE & HANDLING**

Handle with care. Store in original packaging in a clean, cool, and dry location. Avoid extreme humidity and temperature.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