SOLO-DEX®

FASCILE® CONTINUOUS PERIPHERAL NERVE BLOCK CATHETER MINI-KIT

QTY: 1 Each

Contains: One (1) Catheter/Needle Assembly, 100 mm; One (1) Extension Set; and One (1) 0.2 Micron Filter

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

DEVICE DESCRIPTION

The Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Mini-Kit is a needle comprised of an open tip catheter over a needle, and key components required to complete the Peripheral Nerve Block procedure.

MATERIALS

The Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Kit consists of 304 Stainless Steel (Needle Stylet), Marlex 9018 High Density Polyethylene (HDPE) (Catheter), poly(Acrylonitrile Butadiene Acrylate) (ABS), COPE, DEHP-Free Polyvinyl Chloride (PVC), Low Density Polyethylene (LDPE), High Density Polyethylene (HDPE), Polypropylene (PP) (Extension set), Acrylic, Non-woven Polyester, Polytetrafluoroethylene (PTFE), Polyethersulfone (PES) Filter.

INDICATIONS FOR USE

The Solo-Dex Fascile® Peripheral Nerve Block Needle Kit is intended for use in regional anesthesia and pain therapy to locate peripheral nerves by transferring electrical impulses from a nerve stimulator, or to be seen by ultrasound visualization of the device. The needle is used to inject and facilitate the continuous and/or intermittent administration of local anesthetics or analgesics to the targeted nerve bundle in surgical procedures.

In packaged set configurations, the Solo-Dex Fascile® Continuous Peripheral Nerve Block Catheter and Needle Mini-Kit, consisting of the peripheral nerve block needle, catheter, and related peripheral nerve block procedural accessories, is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management during pre-operative, peri-operative and post-operative periods associated with surgical procedures. The catheter may remain indwelling for up to 120 hours.

CONTRAINDICATIONS

- Pre-existing neurological diseases
- Infection or hematoma around the desired puncture or insertion site.
- Anticoagulated states (clotting disorders, anticoagulant therapy) as relative contraindication.
- Excess preoperative anxiety (not responsive to interventions) and inability to tolerate positioning.
- Pre-existing coagulopathies, either endogenous (e.g., thrombocytopenia) or iatrogenic (e.g., Warfarin therapy) due to increased risk of hematoma.
- Anatomic anomalies that make identification of physical landmarks difficult.
- Hepatic disease that may interfere with clearance.
- Failure to obtain patient's consent.
- Acute plexus neuritis.
- Known hypersensitivity to one or more materials employed.
- Fascile catheter system is not suitable for use with newborns, infants (birth to 2 years) and patients with weights below 3.0 kg.

RISK ASSOCIATED WITH PERIPHERAL NERVE BLOCK PROCEDURES

- Mechanical neural damage caused by needle tip or intraneural injection.
- Neural damage resulting from toxic reactions to local anesthetic.
- Inadvertent intravascular injection of local anesthetic.
- Inadvertent epidural or intrathecal injection of local anesthetic in case of peripheral blocks in the area of the spinal column.
- Increased risk of thrombosis and risk of thromboembolism.
- Nervous lesions
- Pneumothorax
- Incomplete block

WARNINGS

- Re-use of single-use devices creates a potential risk to the patient and/or the user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury of the patient.
- Use only if the packaging is intact.
- Use the properly stored product by the date stated on the packaging.
- Prior to use read all instructions, precautions, and warnings. Failure to do so may result in severe patient injury.
- For single use only.
- Do not re-sterilize or reuse.
- Do not alter the needle, catheter, or any other kit/set component during insertion, use, or removal.
- Components are not made with natural rubber latex.
- Components not made with plasticizer diethylhexylphthalate (DEHP).

PRECAUTIONS:

- The product should only be used by anesthesia providers that have been adequately trained in nerve block technique, and are well versed in the anatomical landmarks, safe techniques, and potential complications.
- Aseptic technique should be employed to avoid contamination of the needle and catheter portions that will be inserted through skin and into tissue including the tips and shaft.
- When local anesthetic is being injected, aspiration tests should be intermittently carried out to ensure that an incorrect intravascular placement has not accidently occurred.
- Do not re-insert the needle into the catheter in order to prevent catheter shearing.
- If muscle contractions occur when the current is < 0.2 mA, retract the stimulation cannula until slight contractions at a current of approximately 0.3 mA.
- If paresthesia is caused inadvertently as a result of direct contact with the nerve, the stimulation cannula must, under no circumstance, be inserted any further.

DIRECTIONS FOR USE:

The information contained in this package insert is necessary but not sufficient for the use of this device. This information is not intended as a substitute for the professional judgment, skill and experience of the clinician in careful patient selection; preoperative planning; device selection; knowledge of the anatomy and biomechanics of the tissue.

The Fascile Continuous Peripheral Nerve Block Catheter and Needle Mini-Kit should be used by physicians trained on the procedure for which the device is intended. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient. All available data, including the patient's signs and symptoms and other diagnostic test results, should be considered before determining a specific treatment plan.

Presurgical Procedure

- Position the patient appropriately. Scan patient with ultrasound for anatomical landmarks and to ascertain needle puncture site, angle and expected depth to reach the targeted nerve(s). NOTE: CONSULT INSTRUCTIONS FOR USE FROM ULTRASOUND IMAGING MACHINE MANUFACTURER.
- Procedure needs to be performed using aseptic technique to avoid contamination of needle tip and catheter tip and shaft. Disinfect the block site thoroughly.
- Inject a skin wheal of local anesthetic at the puncture site using a standard the 3cc syringe and an appropriate needle (e.g., a 25 gauge 1.5 inch needle).
- Carefully remove the catheter and needle assembly from the pouch; Assure the catheter and needle do not rotate and the notch in the needle hub and "4F" on the catheter hub stay aligned (Fig 1 [A]).
- Inspect needle and catheter for damage.
- While holding the catheter hub and Straightening Straw, advance Straightening Straw over tip of catheter to straighten the catheter tip (Fig 1 [B]), being careful not to touch catheter shaft or tip.
- Engage needle fully through catheter so that the needle tip is extended beyond the catheter tip (Fig 1 [C]).
- Remove Straightening Straw from the combined catheter and needle assembly, discard Straw (Fig 1 [D]). Re-inspect catheter to identify any damage to the catheter by the needle.

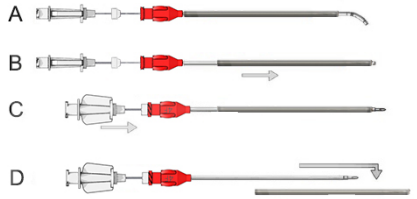

Fig 1

- If optional nerve stimulation is to be employed, connect the stimulation clip onto the needle shaft. By pressing the button on the proximal end of the stimulation clip, the clip will eject on the distal end.
- Connect the nerve stimulator's electrode cable to the stimulation connector and the skin electrode. Set initial nerve stimulator parameters.
- Prime the needle and catheter by attaching a 5cc syringe with local anesthetic to the hub of the Luer needle and catheter assembly. Inject solution to remove air from the needle.
- Orient the notch on the needle hub and the mark on the catheter hub to align the needle bevel and the curvature of the catheter tip in the preferred direction; the catheter will bend away from the notch on the catheter hub.

Catheter/Needle Insertion and Location

- By holding the attached syringe, insert needle and catheter assembly through puncture site on the skin and advance towards target nerve(s) under ultrasound guidance (Fig. 2).

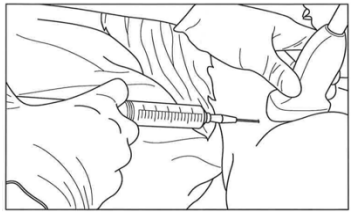

Fig 2

- Optional (optional if nerve stimulation feature is employed): Utilize optional nerve stimulation to identify neural structures. Reduce the current and optimize catheter/needle position when noticeable contractions occur. The tip of the needle has reached an optimal point when noticeable contractions occur at a current of approximately 0.2 - 0.5 mA.
- Hydro-dissect around nerve(s) by injecting solution in syringe, with intermittent aspiration, until optimal catheter position adjacent to target nerve(s) are achieved.
- Adjust the final catheter placement by placing the tip of the catheter directly adjacent the desired blocked nerve; make sure the curve of the catheter bends towards the nerve by having the side of the catheter hub with the “4F” label to be facing away from the nerve.
- Maintaining continuous ultrasound visualization, advance the catheter tip off of needle using index finger of the hand holding the syringe. Withdraw needle completely (Fig. 3).

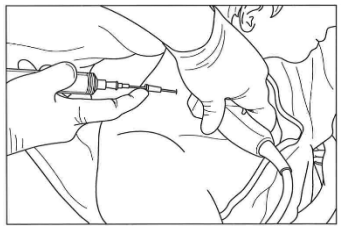

Fig 3

- Attach a 20 cc syringe to the hub of the catheter and inject test dose (up to 5ml) of local anesthetic while maintaining continued visualization with ultrasound (Fig. 4). Inject additional solution, with intermittent aspiration, to confirm appropriate spread of solution through catheter. Reposition catheter as needed to obtain appropriate spread of solution.
- CAUTION: IF NEEDLE IS NEEDED TO REPOSITON CATHETER, WITHDRAW CATHETER COMPLETELY AND START THE PROCEDURE WITH A NEW KIT.

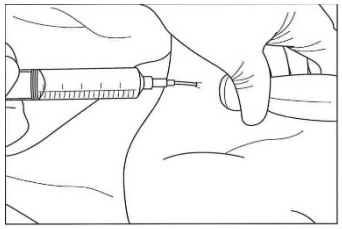

Fig 4

- Attach the extension tubing to the catheter; if the 0.2µ filter is desired it can be attached after the extension tubing
- Secure the catheter at the injection site using the securement device and adhesive strips, available in the pouch. See Tegaderm dressing application instructions for securement dressing.
- Properly dispose of sharp needles in sharps (needles) container in accordance with US OSHA or other governmental standards for bloodborne pathogens.

Securement

- Assure insertion site is dry before dressing. Avoid kinking when securing catheter in place. Secure catheter hub to skin using securement dressing.

Removal of the Catheter

- When therapy is complete, remove dressing, grasp catheter hub and remove slowly with a steady constant pull.
- Inspect catheter to ensure complete removal.
- Discard catheter per standard hospital protocol.

PACKAGING

Fascile® system is packaged as a single Tyvek pouch which has been sterilized with ethylene oxide. Handle with care.

HANDLING AND STORAGE

Fascile® system should be stored under general warehouse conditions. Protect the Fascile® system from direct exposure to light, heat, and humidity.

SYMBOL GLOSSARY DEFINITIONS

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
MD	MDR 2017/745	Medical Device	Indicates that the device is a medical device as defined in MDR 2017/745
	ISO 15223-1, Clause 5.1.1	Manufacturer	Indicates the medical device manufacturer.
EC REP	ISO 15223-1 Clause 5.1.2	Authorized European Representative	Indicates the Authorized Representative in the European Community
REF	ISO 15223-1, Clause 5.1.6	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	ISO 15223-1, Clause 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.4	Use by	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Clause 5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Clause 5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
STERILIZE	ISO 15223-1, Clause 5.2.6	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
STERILE EO	ISO 15223-1, Clause 5.2.3	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1, Clause 5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
Rx Only	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109	Prescription only	Requires prescription in the United States.
MR	ASTM F2503-20	MR Safe	An item that poses no known hazards resulting from exposure to any MR environment.

CUSTOMER COMPLAINTS

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/ or performance directly to Solo-Dex. Email: info@solo-dex.com Tel: For North America and the European Union, +1 (604) 235-9962.

When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, and patient case number. Notify Solo-Dex immediately of an incident resulting in patient death or serious injury.

FURTHER INFORMATION

If further directions for the use of this system are needed, contact Solo-Dex Customer Service, email: info@solo-dex.com | Tel: +1 (801) 631-7288

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