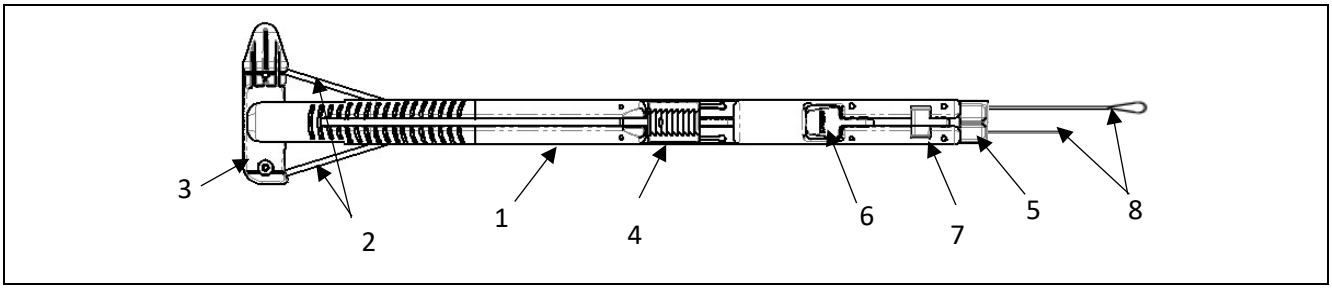
M-Close ™ Kit Instructions for Use



See Table 1 on page 2 for REF Numbers

ITEM	DESCRIPTION	ITEM	DESCRIPTION
1	M-Close Handle	5	Plunger
2	Needles	6	Latch Release
3	T-Bar	7	Limit Lever
4	T-Bar Activation Knob	8	Guidewire

CAUTION: Rx Only. Federal Law restricts this device to sale by or on the order of a licensed Physician or Surgeon.

M-Close Indications for Use: M-Close is a prescription only, single use, disposable, ligature passing, suturing apparatus and needle guide for the abdominal fascia and muscle following laparoscopic and general surgery.

Device Description: The device is a disposable, ligature passing, suturing apparatus and needle guide for the abdominal wall which is non-powered, hand-held, and hand-manipulated, intended to be used in various general surgical procedures. The device includes a ligature carrier pathway, needle guide, two needles, reference plane T-Bar, and a guidewire. The handle of the device provides two diametrically opposed enclosed guideways for the advancement and retraction of the needles under manual control of a plunger located at the proximal end of the device.

Required Accessories (not included)	• Trocar	• Suture

Warnings:

- This device is intended for single patient use. The ability of this device to be properly cleaned after use and re-sterilized has not been established. Re-use of the device may affect performance, safety, and/or the sterility of the device.
- Verify compatibility of the device to the planned trocar cannula before use to ensure proper function. M-Close can be inserted through 12-15mm trocars. If trocar inner diameter is <12mm, remove trocar first before inserting M-Close.
- Compatible sutures need to be at least 20 inches long and either be without a needle or have the needle cut off.
- This instrument should only be used by surgeons trained in surgical endoscopy according to established hospital protocol.
- Do not attempt to repair or modify the instrument in any way. If the user is unsure of the condition of the instrument, replace it with a new unit.
- To ensure proper positioning, the user should not let go of the device while in use.

Precautions:

- Read and become familiar with all instructions and directions before using this device.
- No modification of this device is allowed.

Storage: Store in a cool, dry environment.

Unpacking and initial setup.

- Aseptically open the sealed pouch, remove the components from the white board organizer, and place the device components on the sterile field.
- Verify that the orange Limit Lever is pivoted towards the plunger.
- Verify that the blue activation knob moves the T-Bar into a vertical orientation and that the T-Bar returns to the default horizontal position when the activation knob is released.
- Verify that the port trocar is a size that is compatible with the M-Close.

Volumes

	M-CLOSE	EXTENSION SET	TOTAL M-Close + 12 in. Extension Set
Length	8 in. (20.32 cm)	12 in. (30.48 cm)	20 in. (50.8 cm)
Volume	.4 ml	.4 ml	.8 ml

Device use:

- Begin port closure by moving the T-Bar activation knob upwards to orient the T-Bar vertically, then insert M-Close into the desired port.
- Pass M-Close through the trocar until the T-Bar returns to the extended position.
- Pull the trocar out, while leaving M-Close in the vacated port. **Caution: Do not withdraw M-Close back through the trocar valve as this could damage trocar or device.**
- Gently tug M-Close outwards to make sure the T-Bar is pressed snugly against the internal abdominal wall, so that the device is properly positioned during the remainder of its use. **Caution: Do not apply excessive force that could bend the M-Close shaft as this could damage the device.**
- Press the plunger down until it stops at the top of the Limit Lever and a "click" is felt. The needles should protrude from the M-Close handle beneath the skin. If the needles protrude above the skin, slightly advance M-Close until the needles are exiting beneath the skin, and then resume pressing the plunger down and tugging M-Close outwards. The needle guides are now in place for optional administration of physician selected fluid. **Caution: While piercing the peritoneum, cover the open ports on top of the plunger momentarily to prevent any sudden ejection of bodily fluids upwards through the device.**
- After completing any injections, flip the Limit Lever downwards. Press the plunger down again until it comes to a final stop. The needles are now positioned for passing the guidewire and suture.
- Insert the guidewire into either of the holes on the top of the plunger. Pass it through until the end exits from the other hole.
- Insert 2-3 inches of the desired suture through the loop at the end of the guidewire and feed the guidewire out until the looped end exits the device. The suture tails should be visible in each of the holes on the plunger.
- Keeping hands clear of the suture ends, press the white "RETRACT NEEDLES" button. The plunger will extend to its original position.
- Push M-Close slightly inwards so that the T-Bar is no longer pulled against the internal abdominal wall.

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- Push the blue activation knob upwards to turn the T-Bar vertically and remove the device from the body.
- The suture can now be tied.
- If the user desires to close another port, flip the Limit Lever back into its original position under the plunger and repeat the steps above.
- Discard the device after the last port is closed.

Disposal:

- After use, this product should be treated as a biohazard. Handle and dispose of it in accordance with hospital or facility medical practice following local state and federal laws.

Kit Contents*:

1

2

Items (1) and (2) are contained in the sterile M-Close pouch.

* All items in the kit are single use only. Do not re-sterilize. Do not use if any package is opened or damaged.

TABLE 1

Kit Contents	Qty	REF 27-101	REF 27-107
M-Close Suturing Device, Guidewire and Advancer	1	X	X
(1) 12 in. Extension Set	1	X	X
(2) Nerve Block Needle: 20G by 3.5" Quincke Style Tip	1	X	

Nerve Block Needle:

Indications for use: The Nerve Block Needle is intended for the administration of local anesthetic agents to provide regional and local anesthesia.
Suggested Instructions for use:

1- Perform aseptic preparation of the puncture site.
2- With the desired technique, insert needle through skin using stylet.
3- Remove stylet prior to injecting.
4- The M-Close (REF: 25-001) may be used as a needle guide without need for the stylet.
5- Perform the procedure.
6- Discard as biohazardous waste according to local and national laws and facility practices.

Symbol	Title of Symbol	Description of Symbol	Symbol Designation Number	Title of Symbol Standard Development Org. Standard
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-2012
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-2012
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-2012
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6	ISO 15223-2012
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-2012
	Do Not Re-sterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-2012
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-2012
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	ISO 15223-2012
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-2012
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	ISO 15223-2012
℞ Only	By Prescription Only	Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.	N/A	FDA 81 Federal Register pg. 38911-38931

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