Suturion

SutureTOOL System

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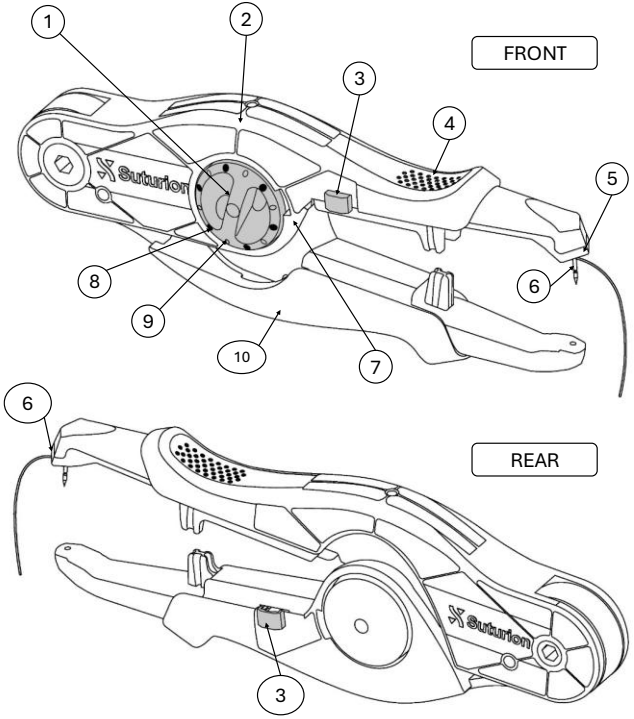
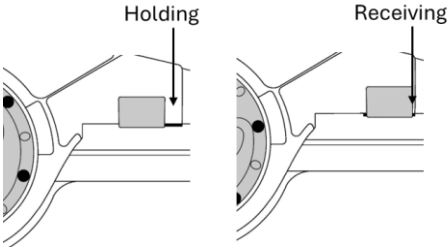


Figure 1



Positions of needle lock indicator

Figure 2

Securing SutureTOOL

Figure 3

Return to operational mode

Figure 4

Figure 5

Figure 6

INSTRUCTIONS FOR USE

DESCRIPTION

The SutureTOOL system consists of two components:

- *1018S SutureTOOL*™, which serves as a suture applicator.
- *The Sutures (1020S and 1055S),* consists of a double-pointed needle that has a PDO thread attached in the middle. The thread is a sterile synthetic absorbable monofilament suture made from the polyester poly(p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_n$. Polydioxanone polymer has been found to be non-antigenic and non-pyrogenic and elicits only a slight tissue reaction during absorption. The thread is dyed violet with Solvent Violet 13 (Color Index 60725).

  1020S and *1055S PDO suture* comply with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Synthetic Absorbable Monofilament Sutures and United States Pharmacopeia (USP) for Absorbable Surgical Suture, except for a slight oversize in diameter.

These components are single-use and sterile and intended to be used together for closing the abdominal wall after open surgery. The two components are packed separately.

When the arms are compressed, the needle passes through the tissue and is automatically picked up by the opposing arm. The device is then let open to release the

tissue, and the sequence is repeated on the other side of the incision, forming a complete stitch.

SYSTEM PARTS (Figure 1)

1. Adjustment wheel
2. Upper arm
3. Needle lock indicator (see Fig. 2)
4. Thumb grip
5. Small bites guide
6. Double-pointed needle
7. Marking notch
8. Indented mark
9. Raised mark
10. Lower arm

DEVICE SUPPLY

SutureTOOL system components are provided separately. 1018S Suture-TOOL™ is supplied in a box containing one (1) device, and the sutures (1020S Suture PDO USP 2-0, 1055S Suture PDO USP 0) are supplied as a package with 12 sutures.

INTENDED PURPOSE

The SutureTOOL system is intended for abdominal wall closure after laparotomy in patients 18 years old and older.

INDICATIONS AND CONTRAINDICATIONS

The indicated target group is patients 18 years old and older who are exposed to open abdominal surgery. The SutureTOOL is intended to be used by healthcare professionals familiar with abdominal fascia closure and absorbable sutures.

The suture in the SutureTOOL system, being absorbable, should not be used where prolonged (beyond 4 weeks) abdominal fascia approximation is required.

CLAIMS AND INTENDED CLINICAL BENEFITS

Performance claims

P1. The SutureTOOL system reduces the time required for abdominal fascia closure compared to standard techniques.

P2. The SutureTOOL system ensures a sufficient suture length to wound length ratio (SL/WL ≥ 4) during abdominal wall closure.

Safety claim

S1. The SutureTOOL system reduces the risk of glove puncture during abdominal wall closure.

Clinical benefit claim

B1. The SutureTOOL system supports wound healing by enabling effective approximation of the abdominal fascia during open surgery.

DIRECTIONS FOR USE

1. Open a sterile package of the SutureTOOL.
2. Ensure that the needle lock indicator on the upper arm is in the holding position and that the needle lock indicator on the lower arm is in the receiving position (see section *Controlling the SutureTOOL* before loading the device with the needle).
3. Load the SutureTOOL.
   a. Hold the instrument in the left hand.

b. Open the needle hole by moving the needle lock indicator on the upper arm forward with the thumb of the left hand.
c. Using your right hand, aim the needle at the hole in the upper arm. Use the envelope (or forceps) to handle the needle safely.
d. Release the needle lock indicator when the needle has been inserted into the hole. The needle will then be locked in the upper arm.
e. Compress the SutureTOOL completely several times to check that the needle transfer mechanism works.

4. Close the abdominal fascia.
   a. If not done during the incision: Separate the fascia and subcutaneous fat 1 cm on each side of the linea alba to expose the midline and facilitate correct closure.
   b. Before starting, make sure that the needle is in the upper arm. Be careful not to hold the forceps too close to the needle.
   c. Grasp the fascia on the far side of the incision. Place the first stitch just above the incision in the uncut fascia. Compress the SutureTOOL completely to push the needle through the fascia.
   d. Open the SutureTOOL fully by releasing the lower arm and, in the same single motion, pull the needle from the fascia. Release the forceps after the entire needle is pulled out.
   e. Grasp the fascia on the near side of the incision. Align the guide with the incision. Compress the

SutureTOOL fully to push the needle through the fascia, back to the upper arm.

f. Secure the SutureTOOL (see section *Controlling the SutureTOOL*) before placing it aside to avoid sharp injury. Make a self-locking start knot.
g. Open the SutureTOOL and place the rest of stitches until there is 3 cm of incision left. To achieve small bites, position the side of the guide parallel to the incision, with the top edge oriented toward the previous stitch (see section *How to use the small bites guide*). Apply moderate tension during suturing.
h. Avoid pulling the suture tight for the last 3 cm of the incision (see Figure 6). It can be difficult to remove the SutureTOOL if the sutures are too tight.
i. Complete the final stitch, ending with the needle in the upper arm to prevent tissue damage and to facilitate removal of the SutureTOOL from the incision.
j. Secure the SutureTOOL and cut the thread.
k. Tighten the final stitches. Finish with a self-locking stop knot. The SutureTOOL is not used in this step.
l. Remove the needle by pushing the needle lock indicator on the upper arm forward to open the needle hole and removing the needle.

CONTROLLING THE SUTURETOOL

Securing the SutureTOOL

1. Make sure that the needle is in the upper arm. Then, press the SutureTOOL and keep it closed. An indented mark on the adjustment wheel is visible in the marking notch.
2. Turn the adjustment wheel one mark counterclockwise (see Figure 3).
3. A raised mark is now visible in the marking notch. The SutureTOOL is now closed.

Return to operational mode

1. Hold the SutureTOOL closed. A raised mark on the adjustment wheel is visible in the marking notch.
2. Push the needle lock indicator forward. Hold in this position while turning the adjustment wheel one mark counterclockwise (see Figure 4).
3. An indented mark is visible in the marking notch. The SutureTOOL is now operational.

Note: The adjustment wheel shall only be turned counterclockwise.

HOW TO USE THE SMALL BITES GUIDE (Figure 5)

At the tip of the upper arm, there is a small bites guide. Position the side of the guide parallel to the incision, with the top edge of the guide toward the previous stitch.

PERFORMANCE
The progressive loss of a suture's tensile strength occurs as a consequence of the hydrolysis of poly(p-dioxanone), which allows absorption and subsequent metabolization in the body.
Studies on rats have shown that the absorption of the suture is complete within 180–210 days from implantation.

The retention ratio of the tensile strength is more than 65% of the initial strength after four weeks.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
A summary of Safety and Clinical Performance is available in the European database on medical devices (EUDAMED), where it is linked to the Basic UDI-DI.
URL: https://ec.europa.eu/tools/eudamed

PACKAGING
The devices are supplied in a sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package has been broken, the product is no longer sterile and should not be resterilized. Damaged packages or products should not be used and should be returned to Suturion AB.

SINGLE USE
Devices labeled for single use only should never be reused. Reuse of these devices may potentially result in

serious patient harm. Examples of hazards related to the reuse of these devices include but are not limited to significant degradation in device performance, cross-infection, and contamination.

DISPOSAL

Discard the devices according to hospital policy for biohazards and sharps. Use forceps to safely handle the needle.

PRODUCT COMPLAINTS

For product problems, contact Suturion AB at qa@suturion.com.

Any serious incident related to the device should be reported to Suturion AB and the competent authority.

WARNINGS AND PRECAUTIONS

General Use and Safety

•Single-use only: Do not reuse or resterilize the device. Reuse may result in infection (e.g., Hepatitis C).

•Only for intended use: Use the device only on indicated tissue. Off-label use (e.g., on bowel anastomosis) may cause tissue rupture.

•Do not use if packaging is damaged: This may compromise sterility.

Sharp Instruments

•Always use tweezers when handling the needle: Do not use hands to reload the needle to avoid risk of needle-stick injuries and infection transmission.

•Avoid placing hands in the working area: Keep hands outside the device's operation zone to prevent accidental pricks.
•Handle needles carefully: Needles are sharp and can cause tissue damage or injury during normal or improper use.
•Dispose of needles in a sharps container. Improper disposal can lead to needle-stick injuries to healthcare personnel.
•Dispose SutureTOOLs in biological risk container. Improper disposal can lead to infections of healthcare personnel.

Thread Handling
•Do not handle the thread with tweezers: This may weaken or break the thread, compromising wound closure.
•Ensure knots are properly tightened: Both overly loose and overly tight knots can lead to complications such as hernia, burst abdomen, or tissue necrosis.
•Loosen the last stitches: Failure to do so may hinder final closure or lead to increased procedure time.

Device Positioning and Use
•Ensure correct orientation of the device: Using the device upside-down can lead to poor stitch placement or failed suturing.
•Align the device parallel to the wound: Incorrect angling can compromise suture length-to-wound length ratio, risking wound healing.

•Place tweezers only in the designated area: Misplacement can block needle transfer and delay the procedure.

Loading and Operation

•Follow proper loading technique: Improper loading may break the needle or prevent docking, increasing operation time.

•Pull out the needle in a continuous motion while opening the ST: Pulling after opening can cause complications or extended operating time.

•End with the needle in the upper arm of the device: Incorrect ending may lead to internal tissue damage.

Labelling and Environmental Conditions

•Store the device according to environmental specifications: Exposure to high heat or humidity can compromise suture integrity, increasing infection risk.

•Understand and follow all symbols: Pay attention to harmonized symbols for single-use and environmental limits. Misinterpretation may lead to device misuse.

User Training

•Only trained personnel should use the device: Inadequate understanding of the device or IFU may lead to improper use and patient harm.

•Instructions are designed for right-handed use, but the SutureTOOL system remains fully usable for left-handed users.

ADVERSE REACTIONS

Adverse reactions associated with this device include: transient local irritation at the wound site, transient inflammatory foreign body response, and erythema. Like all foreign bodies, the suture may potentiate an existing infection.

MR SAFETY INFORMATION

The SutureTOOL system has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the SutureTOOL system in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

LEGAL MANUFACTURER

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Symbol	Title	Description
	Medical device	Indicates the item is a medical device
	Do not use if package is damaged, and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide

Symbol	Title	Description
	Unique device identifier	Indicates a carrier that contains unique device identifier information
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Do not re-use	Indicates a medical device that is intended for one single use only
	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use

PDO	Polydioxanone	Indicates a medical device that contains polydioxanone
	Date of manufacture	Indicates the date when the medical device was manufactured
	Manufacturer	Indicates the medical device manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used
CE	CE mark	The medical device complies with EU MDR 2017/745

	Dyed/ monofilament/ absorbable	Indicates that the suture is dyed, monofilament and absorbable
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed health care practitioner	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	Do not resterilize	Indicates a medical device that is not to be resterilized
	Double sterile barrier system	Indicates two sterile barrier systems
	Single sterile barrier system	Indicates a single sterile barrier system

	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information

	Straight, taper-point needle	Indicates that the needle is straight and taper-point