











STANDARD BARIATRICS STANDARD CLAMP, DISPOSABLE

Standard Clamp, Disposable – SCD25

12mm diameter clamp with 270mm clamp length

	Federal law restricts the device to sale by or on the order of a physician.		Read instructions carefully.
	Manufacturer		Caution, consult accompanying documents
	Catalog number		Lot number
	Use By Date		Do not re-use
	Do not use if package is damaged		Do not re-sterilize

INDICATIONS FOR USE

The Standard Clamp, Disposable is indicated for use in laparoscopic procedures to grasp, clamp, and manipulate soft tissues.

INTENDED USE

The Standard Clamp, Disposable is intended to be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. The Standard Clamp, Disposable is intended to be inserted into the peritoneal cavity through a 12mm trocar and used in up to six cycles of opening and closure to grasp, clamp and manipulate long, 1.2 to 4.5mm thick, planes of soft tissues such as the stomach. The Standard Clamp, Disposable is not intended for direct contact with the cardiovascular system, lymphatic system or cerebrospinal fluid. The Standard Clamp, Disposable can be used while a surgeon uses devices such as a stapler adjacent to tissue that is clamped with the Standard Clamp, Disposable, e.g., to help guide endoscopic staplers during resection of tissue such as in sleeve gastrectomy.

DEVICE DESCRIPTION

The Standard Clamp, Disposable is a gamma sterilized, hand-held, non-energized laparoscopic device with a 12mm diameter, 270mm long aluminum clamp that has a stainless steel shaft. Pushing the red release button on the Standard Clamp, Disposable, opens the jaws (Figure 1, upper sketch). Pulling the black trigger on the Standard Clamp, Disposable closes the jaws (Figure 1, lower sketch).

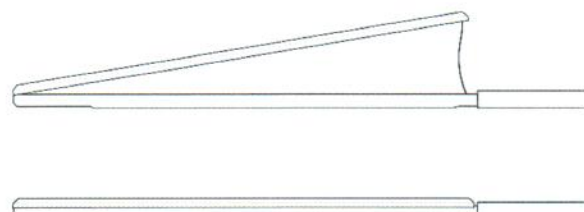


Figure 1: Standard Clamp, Disposable with jaws open (top) and closed (bottom).

CONTRAINDICATION

The Standard Clamp, Disposable is contraindicated used for anything other than its intended use.

WARNING

1. The Standard Clamp, Disposable has been assessed to clamp tissues between 1.2 and 4.5 mm thick. Do not use on tissue outside this range.
2. Do not use Standard Clamp, Disposable if damaged or if packaging is open or damaged.
3. Do not use Standard Clamp, Disposable for a patient with allergy or sensitivity to aluminum or steel.
4. Do not resterilize/reuse Standard Clamp, Disposable. Reuse risks Standard Clamp, Disposable degradation and cross-contamination, which can lead to infection or transmission of bloodborne pathogens to patients and users.
5. Use Standard Clamp, Disposable in accordance with these instructions for use. Improper use may cause serious injury.
6. Read all sections of this insert prior to use.

PRECAUTION

1. The Standard Clamp, Disposable is supplied sterile. Inspect packaging prior to use to ensure there is no damage.
2. During insertion into and removal from the peritoneal cavity, the Standard Clamp, Disposable jaws must be fully closed. Open jaws will cause difficult insertion or withdrawal of the instrument and may result in damage to the instrument or patient injury.
3. Use caution when closing the Standard Clamp, Disposable jaws on tissue.
4. If tissue is placed in between the jaws and the jaws do not open when the lever is released, check for any obstructions and attempt to re-open the Standard Clamp, Disposable.
5. Prior to closure, ensure there is no tissue inadvertently captured between the retracting bands at the proximal end of the Standard Clamp, Disposable.

DIRECTIONS FOR USE

1. Remove the Standard Clamp, Disposable from packaging and close the jaws of the device by pulling on the black trigger. The Standard Clamp, Disposable device is fully closed after five (5) clicks are heard.
2. Insert clamp into the peritoneal cavity through a 12 mm trocar.
3. Advance Standard Clamp, Disposable to the soft tissue target and open jaws by depressing the red release button located on the back of the handle. Ensure the jaws of the Standard Clamp, Disposable device are visible and unobstructed prior to opening.
4. Place the Standard Clamp, Disposable jaws in the desired location ensuring tissue is flat and evenly

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distributed between the jaws and that no folds of tissue are created prior to closing the device. If tissue is folded, reposition the tissue.

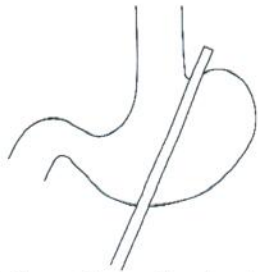


Figure 2: Standard Clamp, Disposable placed on flat, unfolded soft tissue. Note that the tissue is evenly distributed between the jaws.

5. Prior to closure, ensure no tissue is inadvertently captured between the retracting bands at the proximal end of the device. Close the Standard Clamp, Disposable jaws by pulling the black trigger. The device is fully closed after five (5) clicks are heard. The Standard Clamp, Disposable may be repositioned by opening the jaws, repositioning, and reclosing in the desired location. The Standard Clamp, Disposable may be opened and closed as necessary during the procedure. The Standard Clamp, Disposable performance has been tested for 6 cycles of opening/closing.

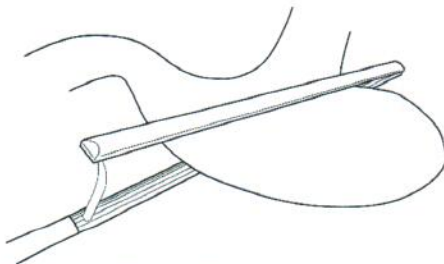


Figure 3: Standard Clamp, Disposable in the open position while placing on soft tissue. Tissue is placed to ensure there is no tissue between the retracting bands at the proximal end of the device.

6. To disengage the Standard Clamp, Disposable, open the jaws by pressing the red release button. With the jaws open, ensure all tissue is disengaged from the Clamp. Close the jaws fully to ensure that the device may be removed from the trocar.
7. Dispose of the Standard Clamp, Disposable per local ordinances.

INSPECTION AND HANDLING

Standard Clamp, Disposable devices are carefully inspected before shipment. Standard Clamp, Disposable and packaging should be inspected upon receipt as packaging may become damaged in transit. All Standard Clamp, Disposable must be inspected prior to use. Instruments should be handled and operated by personnel completely familiar with their use. Handle the Standard Clamp, Disposable with care at all times.

HOW SUPPLIED

The Standard Clamp, Disposable is provided sterile and intended for single patient use. Ensure sterile packaging is intact prior to use. Dispose of device per local ordinances. Do not resterilize, reprocess or reuse the Standard Clamp, Disposable.

PACKAGING AND STORAGE

The Standard Clamp, Disposable is provided in sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Standard Clamp, Disposable should always be handled with great care in transportation and storage.

QUESTIONS

For questions related to this product please contact Standard Bariatrics customer service: 513-620-7751



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