

# STANDARD BARIATRICS STANDARD CLAMP, DISPOSABLE

Standard Clamp 25cm, Disposable – SCD25

Standard Clamp 22cm, Disposable – SCD22

12mm diameter clamp

<b>Rx ONLY</b>	Federal law restricts the device to sale by or on the order of a physician.		Read instructions carefully.
	Manufacturer		Caution, consult accompanying documents
<b>REF</b>	Catalog number	<b>LOT</b>	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 25cm, Disposable and Standard Clamp 22cm, Disposable are indicated for use in laparoscopic procedures to grasp, clamp, and manipulate soft tissues. The Clamps are indicated for use in bariatric procedures such as sleeve gastrectomy as a guide, to clamp and manipulate flat tissue and organs, such as the stomach.

## INTENDED USE

The clamp is intended to be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. The clamp 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 clamp is not intended for direct contact with the cardiovascular system, lymphatic system or cerebrospinal fluid. The clamp can be used while a surgeon uses devices, such as a stapler, adjacent to tissue that is clamped with the clamp, e.g., to help guide endoscopic staplers during resection of tissue such as in sleeve gastrectomy.

## DEVICE DESCRIPTION

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

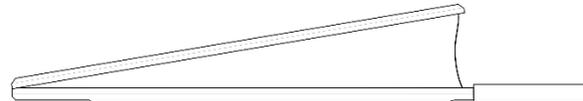


Figure 1: Clamp with jaws open (top) and closed (bottom).

## CONTRAINDICATION

The Standard Clamp 25cm, Disposable and Standard Clamp 22cm, Disposable are contraindicated when used for anything other than their intended use.

## WARNING

1. The clamp 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 the clamp if damaged or if packaging is open or damaged.
3. Do not use the clamp for a patient with allergy or sensitivity to aluminum or steel.
4. Do not resterilize/reuse the clamps. Reuse risks include: degradation and cross-contamination, which can lead to infection or transmission of bloodborne pathogens to patients and users.
5. Use the clamp 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 clamp is supplied sterile. Inspect packaging prior to use to ensure there is no damage.
2. Remove the clamp from package by grasping the handle. Do not grab the jaws of the clamp as this may cause damage.
3. During insertion into and removal from the peritoneal cavity, the clamp jaws must be fully closed. Open jaws will cause difficult insertion or withdrawal of the clamp and may result in damage to the clamp or patient injury.
4. Use caution when closing the clamp jaws on tissue.
5. 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 clamp jaws.
6. Prior to closure, ensure there is no tissue inadvertently captured between the retracting bands at the proximal end of the clamp.

## DIRECTIONS FOR USE

1. Remove the clamp from packaging and close the jaws by pulling on the black trigger. The jaws of the clamp are fully closed after five (5) clicks are heard.
2. Insert clamp into the peritoneal cavity through a 12 mm trocar.

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3. Advance the clamp 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 clamp are visible and unobstructed prior to opening.
4. Place the clamp jaws in the desired location ensuring tissue is flat and evenly distributed between the jaws and that no folds of tissue are created prior to closing the device (Figure 2). If tissue is folded, reposition the tissue.

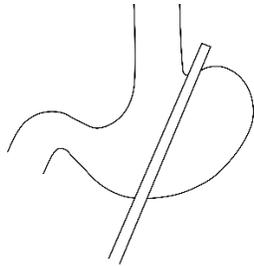


Figure 2: Clamp placed on flat, unfolded soft tissue. Note that the tissue is evenly distributed between the jaws.

5. Prior to closure, ensure no tissue is inadvertently captured between the retracting bands at the proximal end of the device (Figure 3). Close the clamp jaws by pulling the black trigger. The device is fully closed after five (5) clicks are heard. The clamp may be repositioned by opening the jaws, repositioning, and reclosing in the desired location. The clamp may be opened and closed as necessary during the procedure. The clamp performance has been tested for 6 cycles of opening/closing.

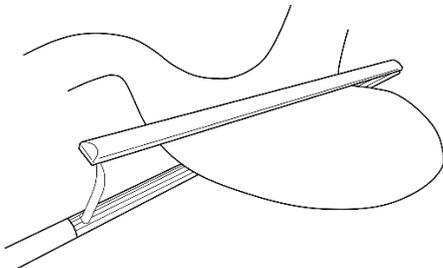


Figure 3: Clamp in the open position while placing on soft tissue. Tissue is placed to ensure there is no tissue between the retracting bands at the proximal end of the device.

6. To disengage the clamp, 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 clamp may be removed from the trocar.
7. Dispose of the clamp per local ordinances.

## INSPECTION AND HANDLING

The Standard Clamp 25cm, Disposable and Standard Clamp 22cm, Disposable devices are carefully inspected before shipment. The clamp and packaging should be inspected upon receipt as packaging may become damaged in transit. All clamps must be inspected prior to use.

Clamps should be handled and operated by personnel completely familiar with their use. Handle the clamp with care at all times.

## HOW SUPPLIED

The Standard Clamp 25cm, Disposable and Standard Clamp 22cm, Disposable devices are provided sterile and intended for single patient use. Ensure sterile packaging is intact prior to use. Dispose of clamp per local ordinances. Do not resterilize, reprocess or reuse the clamp.

## PACKAGING AND STORAGE

The Standard Clamp 25cm, Disposable and Standard Clamp 22cm, Disposable devices are provided in sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The clamp 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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