Always refer to product instructions for use for complete indications, contraindications, warnings, precautions and operating instructions.

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury including breakage of the product components. Reprocessing and/or resterilization of this device may create the risk of contamination, patient infection and/or device malfunction. Do not reuse, reprocess or resterilize this device.

CONTENTS

One AbGrab® abdominal wall lifting device

DESCRIPTION

AbGrab® is a sterile, single patient use device designed to lift abdominal tissue for laparoscopic surgery access. The device is intended to be connected to a hospital vacuum system via medical tubing (not included) and be operated between 60 kPa (450 mmHg) – 97 kPa (727 mmHg) of vacuum pressure. After the vacuum system has been turned on and connected to AbGrab® via medical tubing, the lip of the AbGrab® cup should be placed against the abdomen of a patient, creating a negative pressure between the device and the skin. When coupled with manual lifting, AbGrab® will raise the abdominal wall, allowing for surgeon directed trocar or Veress needle insertion. AbGrab® is compatible with both Veress needle and direct trocar insertion techniques. After trocar or Veress needle entry is complete, AbGrab® can be lowered, then detached from the abdomen by removing the medical tubing from AbGrab® or by removing the medical tubing from the vacuum system.

INDICATIONS FOR USE

AbGrab® is intended to lift the abdominal wall prior to primary port entry in a variety of gynecologic, general, colo-rectal, and urologic laparoscopic procedures.

CONTRAINDICATIONS

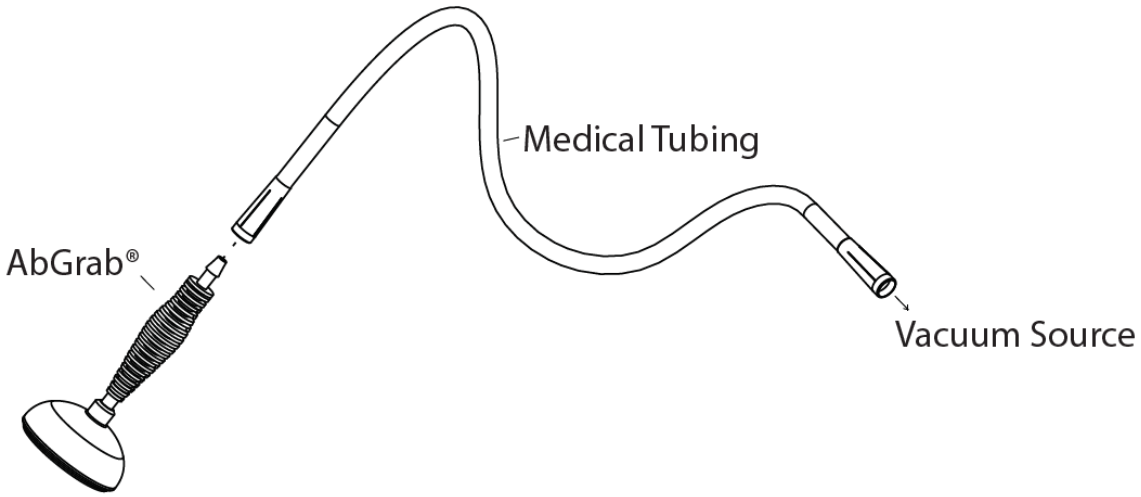
1. This device is not intended for use when laparoscopic techniques are contraindicated.
2. This device is not intended for use except as indicated.

WARNINGS & PRECAUTIONS

1. AbGrab® is intended for use only as indicated.
2. Laparoscopic procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. Medical literature relative to techniques, complications and hazards should be consulted prior to use.
3. AbGrab® is for EXTERNAL USE ONLY on intact skin tissue. NOT FOR INTERNAL USE.
4. AbGrab® is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD IF PACKAGING IS DAMAGED. DISCARD AFTER USE. DO NOT RESTERILIZE.

5. Abdominal wall lifting should only be performed or supervised by a trained and experienced operator.
6. The potential for abdominal adhesions or anatomical anomalies should be considered before using this device.
7. Do not use on patients with known allergy or hypersensitivity to AbGrab®.
8. Never apply AbGrab® to an area other than the abdomen, operate the device outside of recommended vacuum levels (60 kPa (450 mmHg) – 97 kPa (727 mmHg)), leave AbGrab® engaged on the skin for longer than 60 seconds, or use if AbGrab® is unable to hold the skin reliably.
9. AbGrab® is not appropriate for use on all tissues. AbGrab® may not be able to create adequate suction on skin with poor integrity or skin with very deep stretch marks (stria) or scars. If AbGrab® will not attach to an area of skin, attempt to attach AbGrab® in a slightly different location. If AbGrab® will not hold the skin reliably, discontinue use of AbGrab®.
10. Caution: U.S. federal law restricts this device to sale by or on order of a physician.

SCHEMATIC VIEW AND MATERIAL COMPOSITION



Material composition:
AbGrab®: TPC-ET (thermoplastic polyester elastomer)
Foam: Polyester
Adhesive: Double Sided Adhesive Transfer Tape

GUIDELINES

These directions are intended as general guidelines. Practitioners should refer to current institutional and recognized guidelines that address abdominal tissue lifting for laparoscopic surgery access.

1. Inspect AbGrab® packaging and AbGrab® itself for damage prior to use. Do not use if damaged.
2. Carefully examine skin to ensure adequate skin integrity of target location prior to positioning AbGrab® over the attachment area. The attachment area is typically located approximately 3 cm lateral of either side of the umbilicus when using two AbGrab® devices or 3 cm below the umbilicus when using one AbGrab®.

3. Using aseptic technique, wipe the tissue as clean and dry as possible.
4. Connect AbGrab® to the wall vacuum system or a portable vacuum system via medical tubing. Verify the proper connection. If using 2 AbGrab® devices, repeat with the 2nd AbGrab®.
5. Confirm there are no open connections or open auxiliary lines to the vacuum system. AbGrab® will not generate adequate negative pressure if a connection or line is left open.
6. Turn on vacuum system and verify the system is set to generate a vacuum pressure of 60 kPa (450 mmHg) – 97 kPa (727 mmHg).
7. To use AbGrab®, grasp the handle of the device with the palm of the hand and place the lip of the cup against the abdominal wall attachment area, creating a negative pressure between the device and the skin. If using 2 AbGrab® devices, repeat with the 2nd AbGrab®.
8. Once sufficient negative pressure has been generated, as indicated by a negative pressure reading of 60 kPa (450 mmHg) – 97 kPa (727 mmHg) on the wall or portable vacuum system pressure gauge, manually lift the AbGrab® handle(s) to lift the abdominal wall tissue.
9. Proceed with desired access technique for laparoscopic procedure (Veress needle or direct trocar).
10. Once the Veress needle or trocar has been inserted and the abdominal wall has been lowered, release AbGrab® from the skin by removing the medical tubing from AbGrab® or from the vacuum system. A twisting motion while pulling axially on the tubing may facilitate removal.
11. If lifting is misaligned or too forceful, AbGrab® may disengage (pop-off). In the event of pop-off, check the tissue for excessive trauma before reapplying AbGrab®.
12. If AbGrab® will not attach to an area of skin, attempt to attach AbGrab® in a slightly different location acceptable to the practioner. If AbGrab® will not hold the skin reliably on the 2nd attempt, discontinue use of AbGrab®.
13. Dispose of AbGrab® in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

CONTACT INFORMATION

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SYMBOL LEGEND

	Manufacturer
	Catalog or Reference number
	Batch or Lot code

	Use by date
	Do not re-use
	Do not re-sterilize
	Do not use if packaging is damaged
	Not made with Natural Latex Rubber
	Consult instructions for use
QTY	Quantity: Pouch – 1 Unit – 2 Shipper Case – 10
	Caution or Warning
	Sterilized using ethylene oxide
	Prescription: Rx Only