



## DEVICE DESCRIPTION:

The LevaLap™ 1.0 Laparoscopic Access Device is a **SINGLE USE ONLY, CE Marked (Class Is)** and **FDA approved (Class II)** device.

The LevaLap™ 1.0 is a **dome shaped optically clear device** which provides a means of access allowing for **rapid creation of the temporary pneumoperitoneum during laparoscopic procedures**. The LevaLap Laparoscopic Access Device is placed on a selected area of the abdomen and is attached to standard OR suction. Once suction is applied, it lifts the abdominal wall, creating additional safer space for Veress needle introduction.

A **patented vacuum bypass plug** integrated within the suction port prevents suction blockage during the procedure. The device is designed to be simple to use and aims to minimize procedural time and increase patient safety.



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## Summary of device characteristics:

<b>DEVICE FORM</b>	Clear optical and hollow dome shape with suction port, septum and stability wings. · Hemispheric design with dual holding points and vertical vacuum provides excellent ergonomics to facilitate handling during use · Patient interface is atraumatic and designed to adapt to the various human anatomies
<b>DEVICE DIMENSIONS</b>	Diameter: 5.9 inches or 15 cm Height: 3.9 inches or 10 cm
<b>PORT</b>	Port securely attaches to standard operating room suction tubing (inner diameter range of 10 - 12 mm).
<b>SEPTUM</b>	<b>Patented injection septum</b> is compatible with currently available 14G (2.1 mm) Veress needles regardless of length. · Facilitates Veress Needle puncture · No "pop through" of injection site during needle insertion · Absorbs and distributes Veress needle pressure · Snap ring of septum provides complete seal and security · Patented angulated septum allows 150 degree angulation of Veress needle
<b>VACUUM BYPASS PLUG</b>	A <b>patented vacuum bypass plug</b> is integrated within the suction port prevents suction blockage during the procedure.
<b>MATERIALS OF CONSTRUCTION</b>	LevaLap™ 1.0 and port are made of Kresin KR03. The septum is made of Polymax T01-017A-2Y. · All materials are medical grade. · Strong yet light · Fully disposable and recyclable · K-Resin biocompatible and thermoplastic copolymer provides greater transparency, visibility and radiation sterilization compatibility · The septum memory material allows vacuum retention upon puncture with a Veress needle · Material allows complete visualization of the area under the hemisphere during the procedure · Compatible with commonly used surgical preparation antiseptics
<b>PACKAGING</b>	Each LevaLap™ 1.0 is packaged in a Tyvek/PE pouch which maintains sterility. The devices are supplied in a shelf carton of 20 units.
<b>MANUFACTURING</b>	Fully injection-molded device enhances quality and durability: no adhesives used.

## Key performance specifications of LevaLap™ 1.0 device:

REQUIREMENT	TECHNICAL SPECIFICATION
Compatible with standard OR suction; can withstand intended negative pressure	→ Not to exceed 60 mmHg (80 mbar or 8 kpa)
Functional for most patients undergoing laparoscopic surgery	→ Body Mass Index $\leq$ 40 Kg/m <sup>2</sup> or no more than 100 pounds over ideal body weight
Minimum time to maintain vacuum	→ Physician instructed to apply suction until abdominal wall lift deemed appropriate in the physician's judgment, not exceeding a period of 3 minutes of total application time

