LevaLap 1.0 TECHNICAL SHEET

CE 2797

About LevaLap™ 1.0

DEVICE FORM	· Clear optical and hollow hemisphere shape with suction port, septum and stability wings · Hemispheric design with dual holding points and vertical vacuum providing excellent ergonomics to facilitate handling during use · Atraumatic patient interface designed to adapt to various human anatomies
DEVICE DIMENSIONS	Diameter: 5.9 in or 15 cm Height: 3.9 in or 10 cm
PORT	Port securely attaches to standard operating room suction tubing (inner diameter range of 10 mm - 12 mm)
SEPTUM	· Patented injection septum compatible with currently available 14G (2.1 mm) Veress needles · 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
VACUUM BYPASS PLUG	A patented vacuum bypass plug within the suction port prevents suction blockage during the procedure.
MATERIALS OF CONSTRUCTION	· Vacuum bypass plug and device are made of K-Resin® KR03 · Septum is made of Polymax™ T01-017A-2Y · All materials are medical grade · Not made with natural rubber latex · 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
PACKAGING	Each LevaLap™ 1.0 is packaged in a Tyvek/PE pouch which maintains sterility. The devices are supplied in a shelf carton of 10 units.
MANUFACTURING	Fully injection-molded device enhances quality and durability: no adhesives used

PATIENT USE DESCRIPTION:

The LevaLap™ 1.0 Laparoscopic Access Device is for single patient use.

The LevaLap™ 1.0 provides for rapid creation of the temporary pneumoperitoneum during laparoscopic access.

The LevaLap™ 1.0 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.

The device aims to minimize procedural time and increase patient safety.

Standard Requirements for LevaLap™ 1.0

FUNCTIONAL USE		ACCESS CONDITIONS
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 </= 40 Kg/m² or no more than 100 lbs over ideal body weight
Minimum time to maintain vacuum	→	Physician applies suction until abdominal wall lifted into hemisphere
	→	Not to exceed 3 minutes of application time

GENERAL INQUIRY:

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