LevaLap 1.0

TECHNICAL SHEET

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 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.

CE
744018
Notified Body BSI Group The Netherlands B.V., 2797

FDA
K212786

Summary of device characteristics:

DEVICE FORM	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
DEVICE DIMENSIONS	Diameter: 5.9 inches or 15 cm Height: 3.9 inches or 10 cm
PORT	Port securely attaches to standard operating room suction tubing (inner diameter range of 10 - 12 mm).
SEPTUM	**Patented injection septum** 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
VACUUM BYPASS PLUG	**A patented vacuum bypass plug** is integrated within the suction port prevents suction blockage during the procedure.
MATERIALS OF CONSTRUCTION	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
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.

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 </= 40 Kg/m² 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

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