

SUMMARY OF SAFETY AND EFFECTIVENESS BALLOON CANNULA

The Summary of Safety and Effectiveness on Laparoscopic surgery and the instruments used reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Intended Use

The Family of Balloon Cannula are a single use, disposable sterile trocar and sleeve device intended for use during minimally invasive surgery to provide access for operative and diagnostic instrumentation.

Indications

The ability of the Family of Balloon Cannulas to meet its intended function includes the function and employment of the balloon and the control disc to assure an adequate anchor to allow for instrumentation access and removal during minimally invasive surgery. Furthermore, the balloon's tamponage effect, trap door and seals minimize the loss of CO₂ gas during minimally invasive operative procedures.

Caution

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Substantial Equivalency Information

The Family of Balloon Cannula are similar to the Hasson Stabilizing Access Cannula (SACtm).

	Hasson SAC tm	Balloon Cannula
Materials		
- Balloon	Silicone	Silicone
- Cannula/Body	Thermoplastic	Thermoplastic
- Trocar	Stainless Steel	Aluminum
Sizes	10/12 and 5mm	Range: 2-15mm
Functions		
- Anchor System	Balloon / Cone	Balloon Disc
Sterilization	Gamma SAL 10 ⁻⁶	Gamma SAL 10 ⁻⁶

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Family of Balloon Cannula are comparable to that of the Hasson Stabilizing Access Cannula (SACtm).