

Summary of Safety and Effectiveness

Valleylab Laparoscopic Handsets and Laparoscopic Electrodes

Intended Use

K964175

The Valleylab Laparoscopic Handsets (models E2750, E2750T, E2751 and E2751T) and the Electrodes (models E2770 series, E2780 series, E2780R series and E2780R-ASP) are intended for use in those laparoscopic or thoracoscopic surgical procedures where the delivery of electrosurgical current, irrigation and suction via a single handset is desirable.

The device is not intended to be used in endoscopic surgical procedures.

Product Description

The Valleylab Laparoscopic Handsets referenced above are sterile, disposable devices, capable of delivering either electrosurgical cutting or coagulation currents, as well as irrigation and suction. They are for single use only, and are not to be resterilized.

The Valleylab Laparoscopic Electrodes referenced above are sterile, disposable electrodes. The Electrodes are offered in two lengths, 28 cm and 36 cm., and are designed for use with a 5 mm trocar cannula, or larger trocar cannulas with appropriate 5 mm adapters. The Electrodes are for single use only, and are not to be resterilized.

Safety and Performance

Published studies indicate that laparoscopic and thoracoscopic electrosurgery is safe and effective in a variety of surgical procedures.

BIOCOMPATABILITY TESTING

The biological safety of the Valleylab Laparoscopic Handsets and Electrodes referenced above has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Patient contact components of the devices have been tested in accordance with USP Class V or ISO Standard 10993-1, Biological Evaluation of Medical Devices, Part 1.

ELECTRICAL TESTING

Electrical testing was performed on handsets and electrodes, with the following results:

- High voltage breakdown testing was conducted on handsets and electrodes at a minimum of 5200 volts RMS (60 Hz) for 60 seconds. All of the devices

passed this test. This testing exceeds AAMI HF18-1986 for dielectric withstand (hipot) which requires testing at 3000 volts RMS (60 Hz) for 60 seconds.

- High Frequency Leakage Current testing was conducted on the electrodes and confirmed to be well below the acceptable limit of 150mA (reference IEC Standard 601-2-2).
- The product has been designed to meet the requirements for High Frequency Breakdown testing according to IEC Standard 601-2-2, and this was confirmed during product qualification.