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SUMMARY OF SAFETY AND EFFECTIVENESS FOR

CUSA System 200 with Soft Start, and CUSA Lap™ Accessory

Intended Use

The CUSA System 200 with Soft Start, and the CUSA Lap™ Accessory are to be used during laparoscopic and thoracoscopic surgery where the fragmentation, emulsification and aspiration of soft tissue is desirable.

Product Description

The CUSA System 200 is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. The CUSA Lap™ Accessory can be used only with CUSA 200 Systems equipped with Soft Start circuitry and currently available CUSA handpieces. The Accessory consists of a Laparoscopic Extended Life Tip, Laparoscopic Flue, Laparoscopic Sterilizer Case and Tray, Laparoscopic Extended Life Tip Torquing Socket wrench, and Soft Start Circuit Board with External Activation Switch. The CUSA System 200 with soft start and the CUSA Lap™ Accessory may be used with the CUSA Electrosurgical Module (CEM), which will provide electrosurgical capability. This provides the surgeon with the option of delivering cutting or coagulating current through the CUSA tip to the surgical site.

Safety and Performance

The CUSA System 200 with soft start and the CUSA Lap™ Accessory have been tested and shown to meet the following requirements:

Reliability Testing:

- * Dielectric withstand (60 Hz) of the flue
- * Trocar insertion/extraction capability

Biocompatibility Testing:

Patient contact materials of the CUSA handpiece and CUSA Lap™ Accessory have been shown to be biocompatible and remain the same as those of legally marketed products.