Health problem addressed

Devices intended to break up and remove cataractous lenses of the eye. Cataracts inhibit the transmission of light to the retina and cause a painless blurring of vision. Cataracts are caused by changes in the chemical composition of the lens associated with many factors including age, environment, drugs, systemic diseases, traumatic eye injuries, certain diseases of the eye, and genetic or birth defects.

Product description

These units consist of a hollow probe (i.e., a phaco probe) that includes an irrigation sleeve, an oscillating tip that converts electric energy into ultrasonic waves, and a channel for aspiration of lens fragments; the units also include a vacuum pump and controls for the output levels, irrigation rate, and mode of operation. CSUs (cryosurgical units) apply a refrigerant (cryogen) to withdraw heat from target tissue either through direct application or indirectly through contact with a cryogen-cooled probe.

Principles of operation

These devices are intended to remove cataractous lenses by the insertion of a probe that cuts and emulsifies the lenses using ultrasonic waves (phacoemulsification).

Operating steps

An incision is made to gain access to the eye’s anterior chamber. A viscoelastic material is then infused to deepen the anterior chamber. After removing the anterior lens capsule and hydrodissecting the lens to separate it from the cortex and capsule, the surgeon inserts a phacoemulsification probe tip. The probe tip oscillates rapidly creating ultrasonic waves that cut tissue. The cataractous lens is emulsified and the lens fragments are then aspirated from the eye through the hollow tip of the phacoemulsifier.

Reported problems

Thermal lesions to the sclera and cornea due to insufficient irrigation and aspiration flow; metal fragments being left in patients’ eyes following phacoemulsification and of phacoemulsification units failing to vacuum; torn posterior capsule due to high vacuum; postoperative endophthalmitis resulting from bacterial contamination; surgically induced astigmatism; corneal burns.

Use and maintenance

User(s): Surgeon
Maintenance: Medical staff; technician; biomedical or clinical engineer
Training: Initial training by manufacturer and manuals; supervised training with experienced surgeons

Environment of use

Settings of use: Operating room
Requirements: Stable power source

Product specifications

Approx. dimensions (mm): 245 x 220 x 154
Approx. weight (kg): 5.6
Consumables: NA
Price range (USD): 13,000 - 105,000
Typical product life time (years): 10
Shelf life (consumables): NA
Types and variations

Modular (in console); stand-alone; portable