NON – STERILE. This product must be cleaned and sterilized prior to each use.

Consult EN554 or AAMI ST46-1993 standards for routine control of sterilization by moist heat.

The Ultrasonic tip has a limited lifetime. This lifetime depends on cataract rating (soft vs. hard), ultrasonic cleaning, autoclaving, and handling. Millennium Surgical Corp recommends that the tip be re-inspected after each ultrasonic cleaning and autoclaving. Observance of titanium particle breakdown (flaking) can be easily accomplished with a standard microscope.

To ensure safety and efficacy, Millennium Surgical Corp recommends that the tip not exceed twenty (20) cataract extraction procedures unless it shows signs of titanium flaking. If titanium flaking is observed, discard the tip immediately.

US Federal Law restricts this device for sale or on order of a physician.

Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!