June 20, 2018

To U.S. Integra® CUSA® Ultrasonic Surgical Aspirator System customers:


The Guidance Document requires that manufacturers of Ultrasonic Surgical Aspirator devices update the labeling of the devices to include a contraindication for use with uterine fibroids.

This contraindication applies to all Ultrasonic Surgical Aspirator devices that fit the FDA-defined criteria described in the Guidance Document and is not CUSA-specific.

This notification is being issued by Integra LifeSciences to inform you that the labeling of the CUSA® NXT Ultrasonic Surgical Aspirator System, CUSA® Excel Ultrasonic Surgical Aspirator System and CUSA® Clarity Ultrasonic Surgical Aspirator System are being updated to include the following contraindication:

This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification and aspiration of uterine fibroids.

Copies of the updated sections of labeling can be found attached to this notification document.

Timothy J. Connors
Manager, Regulatory Affairs

20 Jun 2018

Date
CHAPTER 1  PATIENT AND OPERATING ROOM SAFETY

System Overview

The CUSA® NXT Ultrasonic Surgical Aspirator System facilitates the removal of tissue. The system provides selective tissue disintegration with simultaneous irrigation and aspiration.

Intended Use

The CUSA NXT Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

Using this System in Ultrasonic Surgery

The basic operating principle of ultrasonic surgery involves the longitudinal vibration of the hollow handpiece tip at ultrasonic frequency against tissue. The mechanical action of the tip is similar to a tiny "surgical hammer" that breaks off cellular material. When the tip contacts the fluid filled tissue, the resulting slurry of emulsified material from the tissue is aspirated through the center of the handpiece. A slow flow of irrigant around the tip assists in the removal of waste tissue.

The selective action of the instrument arises from the disruption of fluid containing cellular material while fibrous and elastic tissue such as nerves and blood vessels remain relatively unaffected at the ultrasonic frequencies used.

Warning

No modification of this equipment is allowed.

Contraindications

This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.
Contraindication

- Urological Surgery - including removal of real parenchyma during nephrectomy or partial nephrectomy
- General Surgery - including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures
- Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor heptectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy.

Warning

The CUSA Excel/CUSA Excel+ System cannot be used in an MRI (Magnetic Resonance Imaging) environment.

Warning

No modification of this equipment is allowed.

Notice

When you receive the CUSA Excel/CUSA Excel+ System and accessories, if any component is damaged, contact your Integra service representative for assistance. If the packaging for a sterile accessory is damaged, do not use the sterile accessory.

Contraindication

This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Intended Users

The intended users of this guide and the equipment it describes are qualified medical professionals who are trained in the particular surgical technique and surgical procedure to be performed, and trained in the use of this equipment. The CUSA Excel/CUSA Excel+ System should only be used in a surgical environment by qualified medical professionals.

Warning

It is the responsibility of the Healthcare Facility to ensure that intended users of CUSA Excel/CUSA Excel+ System are appropriately trained in the use of this equipment.
Contraindications

Contraindication

This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Intended Users

You should use the CUSA Clarity system only in a surgical environment by qualified medical professionals trained in the use of this equipment.

This system must be set up/disassembled by operating room (OR) staff (for example, surgical nurse, neuro technician). The OR staff is also likely to operate the device controls. The handpiece and footswitch are controlled by the surgeon.

**WARNING**

It is the responsibility of the Healthcare Facility to ensure that intended users of the CUSA Clarity system are appropriately trained in the use of this equipment.

Safety Information

The safe and effective use of ultrasonic surgery depends to a large degree on factors solely under the control of the operator. Only medical professionals that are properly trained in the use of ultrasonic equipment should operate the CUSA Clarity system. It is important that medical professionals read, understand, and follow the operating instructions supplied with this equipment.

Before starting any surgical procedure, medical professionals should be familiar with the medical literature, complications, and hazards of using ultrasonic surgery in that procedure.