

REFERENCES

1. Data on file 510(K) Summary, K200774. Integra LifeSciences. Princeton, NJ, USA. 2. Single-use Integra products that come sterile.
3. CUSA Electrosurgery Module. 4. Includes footswitch and contamination guard (2 pack). 5. Precision (36 kHz) and Power (23 kHz) handpieces include one cleaning brush.

INDICATIONS

The CUSA Clarity 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.

The CUSA Clarity Ultrasonic Surgical Aspirator is indicated for use in: Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:

Neurosurgery – including removal of primary and secondary malignant and benign brain and spinal tumors, including but not limited to meningiomas and gliomas

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy

Urological surgery- including removal of renal 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 hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

CONTRAINDICATION

This ultrasonic aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids. Please refer to the CUSA Clarity Operator's Manual for full indications, contraindications, cautions, and warnings. For use in US only.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

For more information or to place an order, please contact:

United States

USA 800-654-2873 **=** 888-980-7742 fax International +1 609-936-5400 **=** +1 609-750-4259 fax



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CUSA® Clarity

GENERAL CATALOG

Ultrasonic Tissue Ablation System



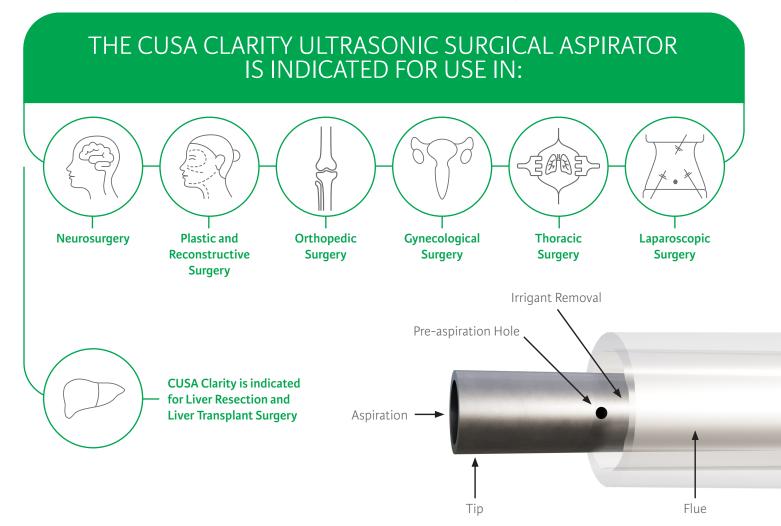


HOW DOES THE CUSA® CLARITY ULTRASONIC ASPIRATOR SYSTEM WORK?

The system performs three functions simultaneously:

- 1. Cavitation to fragment or rupture unwanted cells
- 2. Irrigation to cool the tip and provide a liquid medium to suspend tissue
- 3. Aspiration to clear the operative field and maintain tissue-tip coupling

The CUSA Clarity 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.







STREAMLINED SETUP, PRECISION, POWER AND SAFETY



STREAMLINED

One-step tubing setup with CUSA Quick Connect™ Cartridge and Tubing Set. Users can also control amplitude, irrigation and aspiration levels during surgery using the scales and buttons on the touchscreen display.



PRECISION & POWER

Choose the CUSA Clarity 36 kHz handpiece, which offers a lightweight and ergonomic design. Or choose the CUSA Clarity 23 kHz handpiece with an optional CEM[™] nosecone for cautery at the touch of a button.

The 36 kHz handpiece is designed for safety and control in neurosurgical procedures, using high-frequency vibration to localize effect. The benefits are enhanced tissue selectivity, preservation of healthy tissue, and more efficient debulking and resection.

36 kHz handpiece fully assembled



SAFETY

The unique and proprietary CUSA Clarity Tissue Select® Safety Setting enhances selectivity, enabling greater control when resecting near critical structures.

- Gives surgeon greater control and precision when resecting near critical structures
- Enhances tissue selectivity while maintaining fragmentation capability. The power to the site is limited while strength and efficacy in tissue removal are still provided.
- Provides maximum tissue selectivity
- Gives surgeon superior tactile feedback

23 kHz handpiece fully assembled w/ CEM nosecone

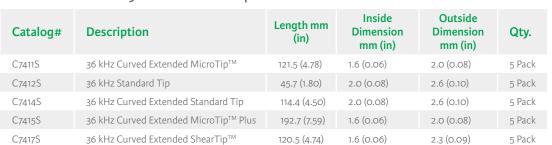
A sterile, disposable "CUSA Electrosurgey Module" (CEM™) nosecone with button activation fits on the ultrasonic handpiece, allowing the user to remove unwanted tissue and coagulate tissue all with one handpiece assembly. When used with the CUSA Clarity CEM nosecone, the 23 kHz handpiece can provide both ultrasonics and coagulation, simultaneously or individually.

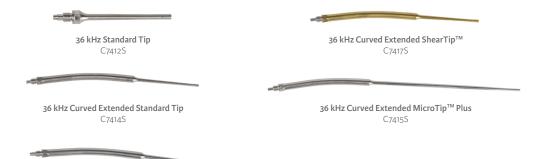




CLARITY TIPS*

CUSA® Clarity 36 kHz Tips





CUSA® Clarity 23 kHz Tips

36 kHz Curved Extended MicroTip™

Catalog#	Description	Length mm (in)	Inside Dimension mm (in)	Outside Dimension mm (in)	Qty.
C7401S	23 kHz Standard Tip	78.5 (3.09)	2.0 (0.08)	2.6 (0.10)	5 Pack
C7405S	23 kHz MacroTip™	77.2 (3.04)	2.6 (0.10)	3.2 (0.13)	5 Pack
C7418S	23 kHz Tough Tissue Tip	78.7 (3.10)	2.0 (0.08)	2.8 (0.11)	5 Pack
C7420S	23 kHz Bone Tip	167.1 (6.58)	1.1 (0.05)	3.7 (0.14)	5 Pack





SYSTEM AND ACCESSORIES

CUSA® Clarity Accessories

Catalog#	Description	Qty.
C7136	36 kHz Sterilization Tray	Each 1
C7636	36 kHz Sterilizable Torque Base	Each 1
C7602 ²	36 kHz Torque Wrench	5 Pack
C7300 ²	CUSA Quick Connect™ Cartridge & Tubing Set	5 Pack
C7500	Cleaning Brush	Each 1
C7005	Contamination Guard	2 Pack
C7550	Specimen Trap	12 Pack

Catalog#	Description	Qty.
C7123	23 kHz Sterilization Tray	Each 1
C7623	CUSA Clarity 23 kHz Sterilizable Torque Base	Each 1
C7601 ²	CUSA Clarity 23 kHz Torque Wrench	5 Pack
C7502	CUSA Clarity 23 kHz Handpiece Cleaning Brush	Each 1
C7523 ^{2, 3}	CUSA Clarity 23 kHz CEM [™] Sterile Nosecone	5 Pack



CUSA Clarity 36

36 kHz handpiece

fully assembled

23 kHz handpiece fully assembled

Cartridge & Tubing Set C7300



C7136 and C7123



C7623 and C7636



Torque Wrench C7601 and C7602



C7005



Cleaning Brush

C7500 and C7502



Specimen Trap



CFM Nosecone C7523

CUSA® Clarity System

Catalog#	Description	Qty.
C7000	Console ⁴	Each 1
C7001	Custom Cart	Each 1
C7036	36 kHz Handpiece⁵	Each 1
C7023	23 kHz Handpiece ⁵	Each 1
C7002	Replacement Footswitch	Each 1





^{*}Single-use, sterile tip pack includes a tip, nosecone, flue, and stylet