A DIVISION OF INTEGRA LIFESCIENCES

Codman®

SPECIALTY SURGICAL

Integra® Ultrasonics

CUSA® Clarity - Product catalogue

DOCUMENT FOR USE IN EUROPE, MIDDLE-EAST AND AFRICA ONLY.

INTEGRA Warranty for CUSA® Clarity Ultrasonic Surgical Aspirator

1. Warranty.

Integra Lifesciences Corporation and its wholly owned subsidiaries («Integra») warrant to Integra authorized distributors and the original purchaser only that each new Integra CUSA® Clarity Ultrasonic Surgical Aspirator (hereinafter the Equipment or the product) is free from manufacturing defects in material and workmanship under normal use and service for a period of one (1) year (except as otherwise expressly provided as to accessory items) from the date of invoice by Integra (or its authorized distributor) to the original purchaser, but in no event beyond the expiration date stated on any product labeling (hereinafter the Warranty Period). For purposes of products sold by Integra through an authorized distributor of Integra, «original purchaser» shall include the purchaser of Integra products to whom the distributor first sells the product. The original purchaser is hereinafter referred to as Customer.

1.1. *Coverage.* During the Warranty Period, Integra shall provide free-of-charge service and maintenance consistent with the provisions of Section 3 of this Warranty, so that the Equipment conforms to the specifications defined in the CUSA® Clarity Ultrasonic Surgical Aspirator Operator's Manual, as such Operator's Manual may be modified by Integra from time to time (the "Specifications").

1.2. *Exclusions.* The Warranty shall not apply in any manner to service or maintenance of the Equipment, or to replacement of its parts, with respect to:

- i. use of Equipment with any tips and flues other than those manufactured by Integra LifeSciences:
- ii. defects arising out of materials or parts provided, modified or designed by anyone other than an authorized Integra service agent (the Integra "Service Agent");
- iii. defects emanating from improper or negligent installation, storage or use of the Equipment or any component thereof, including but not limited to operating the Equipment not in accordance with instructions provided in the Operator's Manual;
- iv. defects arising from improper or negligent cleaning or sterilization methods or improper maintenance of the Equipment;
- v. defects resulting from repairs or service of the Equipment provided other than by Integra or its authorized representatives;
- vi. defects arising from accidental damage to the Equipment, acts of God, electrical power damage, equipment malfunction, unusual stress, unreasonable operating procedures or abnormal or extreme operating conditions; and and normal wear and tear.

2. Service, Repairs and Replacement.

2.1. Service and Repairs. All service and repairs covered by this Warranty may be referred to hereinafter as "in-warranty repairs," and all service and repairs not covered by this Warranty may be referred to as "out-of-warranty repairs." Integra's sole obligation for in-warranty repairs shall be to make all necessary adjustments and repairs in accordance with this Warranty. Integra shall charge Customer at Integra standard rates for any out-of-warranty repair performed by Integra.

2.2. Equipment Replacement. The defective Equipment or part thereof that is replaced in accordance with the Warranty shall be the property of Integra. Integra reserves the right to fill spare parts requests using refurbished sub-assemblies provided that such sub-assemblies are functionally equivalent to new sub-assemblies and carry the same warranty as the replaced sub-assemblies.

2.3. Notification. In order to avail itself of its rights under the Warranty, Customer or Integra authorized distributors, must immediately notify Integra of any defects and provide Integra every opportunity to inspect and remedy defects.

3. Repair Parts and Services.

3.1. Included under the Warranty are the following services :

3.1.1. *Consoles.* Integra shall, if possible, perform on-site repair of consoles or replace a console by a new or refurbished console (at the discretion of Integra), as the case may be, and where not possible Integra shall arrange and pay to ship the affected Equipment to the designated repair facility, and shall repair the affected Equipment.

3.1.2. *Handpieces.* Integra shall repair or replace any defective handpieces covered by the Warranty by a new or refurbished handpiece (at the discretion of Integra) that shall carry the same warranty as the original equipment (an "Exchange Handpiece").

3.2. *Modifications to Covered Equipment.* From time to time, at its sole discretion, Integra may propose modifications to the covered Equipment and to the Specifications for the Equipment. Subject to Customer's approval and at its sole expense, the Customer may request Integra to make such modifications to the covered Equipment and to the Specifications. Integra shall make such modifications for the Customer, which modifications may include the installation of new parts in the Equipment, at a price equal to the then-current list price for such modifications, as such list price is established by Integra in its sole discretion.

4. Quality Control.

4.1. Customer shall maintain reasonable standards of quality control, operations, procedures, safety testing and inspection of Equipment to ensure that unnecessary service or maintenance is not required hereunder.

4.2. Customer shall provide a technical counterpart to Integra's Service Agent for assistance in Integra's telephonic diagnosis of the malfunction with the Equipment. Customer shall reasonably accept Integra's determination whether a repair or service is an in-warranty repair or an out-of-warranty repair.

5. Limitation of Liability.

5.1. Integra's sole responsibility under the warranties described in Section 1 shall be repair or replacement, at Integra's sole discretion at Integra's expense, subject to the terms of this warranty and applicable agreements. THE WARRANTIES DESCRIBED IN SECTION 1 HEREOF ARE EXCLUSIVE AND ARE GIVEN AND ACCEPTED IN LIEU OF ALL OTHER WARRANTIES OF INTEGRA OR ITS SERVICE AGENTS WITH RESPECT TO THE QUALITY, PERFORMANCE AND OPERATION OF THE EQUIPMENT, WRITTEN OR ORAL, EXPRESS OR IMPLIED, AND WHETHER OR NOT ATTRIBUTABLE TO SERVICE PERFORMED PURSUANT TO THE WARRANTY. ALL OTHER REPRESENTATIONS OR WARRANTIES OF INTEGRA OR ITS REPRESENTATIVES, EXPRESS OR IMPLIED, WITH RESPECT TO THE EQUIPMENT OR THE SERVICES, DIAGNOSIS, ADVICE, ASSISTANCE OR PARTS TO BE TENDERED PURSUANT TO THE WARRANTY, INCLUDING, WITHOUT LIMITATION, THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXPRESSLY DISCLAIMED. IN NO EVENT SHALL INTEGRA, ITS ASSIGNEES OR SERVICE AGENTS BE LIABLE FOR LOSS OF USE, REVENUE OR PROFIT OR ANY OTHER INDIRECT, INCIDENTAL, EXEMPLARY, CONSEQUENTIAL, SPECIAL OR OTHER DAMAGES, WHETHER ARISING IN CONTRACT OR IN TORT, BY VIRTUE OF THE WARRANTY OR ANY PERFORMANCE OR BREACH BY INTEGRA, ITS ASSIGNEES OR SERVICE AGENTS HEREUNDER OR PURSUANT HERETO.

5.2. Customer agrees that, notwithstanding the technical assistance provided pursuant to the Warranty by Integra or its representatives, Customer shall be fully and solely responsible for all treatments performed or attempted with the Equipment. INTEGRA MAKES NO REPRESENTATION OR WARRANTY AS TO THE EFFICACY OF THE EQUIPMENT OR OF THE TECHNICAL ASSISTANCE TO BE RENDERED BY INTEGRA, ITS ASSIGNEES OR SERVICE AGENTS, FOR PURPOSES OF THE PARTICULAR TREATMENT THAT CUSTOMER INTENDS TO PERFORM FOR THIRD PARTIES. Moreover, Integra disclaims any liability with respect to the efficacy of the Equipment or of said technical assistance or with respect to any claims by third parties related to any treatment performed by Customer.

5.3. THIS INTEGRA LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON INTEGRA'S PART OR THE PART OF ITS DISTRIBUTORS, AND INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA'S PRODUCTS.

INTEGRA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. No warranty or guarantee may be created by any act or statement nor may this Standard

Codman SPECIALTY SURGICAL

Warranty be modified in any way, except as a result of a writing signed by an officer of Integra. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

5.4. IN NO EVENT SHALL INTEGRA AUTHORIZED DISTRIBUTORS BE LIABLE TOWARDS CUSTOMER FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and Integra authorized distributors shall not be responsible towards Customer for, any loss, arising in connection with the purchase or use of any Integra product that has been repaired by anyone other than an authorized Integra service representative or altered in any way so as to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by Integra. THIS INTEGRA DISTRIBUTOR LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES TOWARDS CUSTOMER, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES TOWARDS CUSTOMER ON INTEGRA AUTHORIZED DISTRIBUTOR'S PART. INTEGRA AUTHORISED DISTRIBUTORS DISCLAIM ALL OTHER WARRANTIES TOWARDS CUSTOMER, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS OR OTHER THIRD PARTIES.

5.5. Force Majeure. Notwithstanding anything to the contrary herein contained, if the performance of the Warranty by Integra, Integra authorized distributors, or Customer or any obligation of Integra, Integra authorized distributors, or Customer hereunder is prevented, restricted or interfered with by reason of fire, explosion, act of God, labor disputes or accidents affecting performance under the Warranty, or war, mobilization, civil commotions, blockade or embargo, or any future law, regulation, ordinance or requirement of any government or regulatory agency or any other act, whatsoever similar to those above enumerated, or any other circumstance being beyond the reasonable control of Integra, Integra authorized distributors, or Customer, then and in that event Integra, Integra authorized distributors, or Customer, as the case may be, shall promptly notify the other party hereto of the difficulties resulting therefrom, and any of the foregoing events shall excuse any performance required under the Warranty.

Customer Services:

International
+33 (0) 437 47 59 50
+33 (0) 437 47 59 25 (Fax)
csemea@Integralife.com

Ireland
+353 1800 901567 (tel)
+353 1822 5952 (fax)
custsvcire@integralife.com

France
+33 (0) 437 47 59 10
+33 (0) 437 47 59 29 (Fax)
custsvcfrance@Integralife.com

Austria
+43(0) 720 816 067
+43(0) 192 872 01
CustSvcAustria@integralife.com

Belgium & Luxembourg
+32 (0) 2 257 4130
+32 (0) 2 253 2466 (Fax)
custsvcbenelux@integralife.com

Germany
+49 (0) 2102 5535 6200
+49 (0) 2102 5536 636 (Fax)
custsvcgermany@integralife.com

Netherlands
+31(0) 852 083 167
+31(0) 207 093 627 (Fax)
custsvcnetherlands@integralife.com

Switzerland
+41 22 721 23 30
+41 22 721 23 99 (Fax)
custsvcsuisse@integralife.com

United Kingdom
+44 (0) 1264 345 780
+44 (0) 1264 363 782 (Fax)
custsvcs.uk@integralife.com

Italy
+39 (0)2 577 89 21
+39 (0)2 575 113 71 (Fax)
custsvcitaly@integralife.com

Recommended Starting Set*

*** For 10 Neuro surgery cases**

Item	Description	Quantity
C7000	CUSA® Clarity Console with Footswitch	1
C7001	CUSA® Clarity Cart	1
C7036	36 kHz Handpiece with Cleaning Brush	2
C7136	36 kHz Sterilization Tray	2
C7300	CUSA® Quick Connect™ Cartridge and Tubing Set	2 box 5
C7411S	36 kHz Curved Extended MicroTip™	1 box 5
C7414S	36 kHz Curved Extended Standard Tip	1 box 5
C7602	36 kHz Torque Wrench	2 box 5
C7005	Contamination Guards	1 box 2
C7636	36 kHz Reusable Torque Base	2

*** For 10 Liver surgery cases**

Item	Description	Quantity
C7000	CUSA® Clarity Console with Footswitch	1
C7001	CUSA® Clarity Cart	1
C7023	23 kHz Handpiece with Cleaning Brush	2
C7123	23 kHz Sterilization Tray	2
C7300	CUSA® Quick Connect™ Cartridge and Tubing Set	2 box 5
C7401S	23 kHz Standard Tip	1 box 5
C7418S	23 kHz Tough Tissue Tip	1 box 5
C7601	23 kHz Torque Wrench	2 box 5
C7005	Contamination Guards	1 box 2
C7623	23 kHz Reusable Torque Base	2

Document for use in Europe, Middle-East and Africa only

Capital Equipment

C7000/C7001

C7002

Catalog No.	Description	Quantity
C7000	CUSA® Clarity Console with footswitch	Each 1
C7001	Cart	Each 1
C7002	Footswitch	Each 1

Handpieces

C7036

C7023

Catalog No.	Description	Quantity
C7036	36 kHz Handpiece (including cleaning brush)	Each 1
C7023	23 kHz Handpiece (including cleaning brush)	Each 1

36 kHz Tips

Conventional Tips

C7411S/SEA/EUT

C7412S/SEA

C7414S/SEA/EUT

p02.10.4
p02.10.8
10.9
p02.10.3
p02.10.6
p02.10.7
p02.10.2

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
Single Use Tips (Each pack contains 1 tip, 1 nosecone with integrated O-rings, 1 stylet and 1 flue)					
C7411S	36 kHz Curved Extended MicroTip™	Yes	12,15 cm (4.78 in)	1,6 mm (0.062 in)	Box 5
C7411SEA					Each 1
C7412S	36 kHz Standard Tip Short	Yes	4,57 cm (1.80 in)	2,0 mm (0.078 in)	Box 5
C7412SEA					Each 1
C7414S	36 kHz Curved Extended Standard Tip	Yes	11,44 cm (4.50 in)	2,0 mm (0.078 in)	Box 5
C7414SEA					Each 1
Extended Use Tips (Each pack contains 1 tip, 5 nosecones with integrated O-rings, 5 stylets and 5 flues)					
C7411EUT	36 kHz Curved Extended MicroTip™	No	12,15 cm (4.78 in)	1,6 mm (0.062 in)	Each 1
C7414EUT	36 kHz Curved Extended Standard Tip	No	11,44 cm (4.50 in)	2,0 mm (0.078 in)	Each 1

Specialty Tips

p02.10.5

MicroTip™ Plus

C7415S/SEA

p02.10.10
p02.10.11

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
C7415S	36 kHz Curved Extended MicroTip™ Plus	Yes	19,27 cm (7.59 in)	1,6 mm (0.062 in)	Box 5
C7415SEA					Each 1

ShearTip™

C7417S/SEA

p02.10.12
p02.10.13

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
C7417S	36 kHz Curved Extended ShearTip™	Yes	12,05 cm (4.74 in)	1,6 mm (0.062 in)	Box 5
C7417SEA					Each 1

* Inner Diameter

Document for use in Europe, Middle-East and Africa only

23 kHz Tips

Conventional Tips

C7401S/SEA/EUT

poz. 10.15

poz. 10.16

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
Single Use Tips (each pack contains 1 tip, 1 nosecone with integrated O-rings, 1 stylet and 1 flue)					
C7401S	23kHz Standard Tip	Yes	7,85 cm (3.09 in)	2,0 mm (0.078 in)	Box 5
C7401SEA					Each 1
Extended Use Tips (each pack contains 1 tip, 5 nosecone with integrated O-rings, 5 stylets and 5 flues)					
C7401EUT	23kHz Standard Tip	No	7,85 cm (3.09 in)	2,0 mm (0.078 in)	Each 1

poz. 10.14

Specialty Tips

MacroTip™

C7405S/SEA

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
C7405S	23kHz MacroTip™	Yes	7,72 cm (3.04 in)	2,6 mm (0.104 in)	Box 5
C7405SEA					Each 1

Tough Tissue Tip

poz. 10.17

C7418S/SEA

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
C7418S	23kHz Tough Tissue Tip	Yes	7,87 cm (3.10 in)	2,0 mm (0.078 in)	Box 5
C7418SEA					Each 1

poz. 10. 18

Bone Tip

poz. 10.19

C7420S/SEA

Catalog No.	Description	Sterile	Tip length	Tip ID*	Quantity
C7420S	23kHz Bone Tip	Yes	16,71 cm (6.58 in)	1,1 mm (0.045 in)	Box 5
C7420SEA					Each 1

poz. 10.20

Electrosurgery module - CEM™ nosecone

C7523/EA

Catalog No.	Description	Sterile	Quantity
C7523	CUSA Clarity 23kHz CEM Nosecone	Yes	Box 5
C7523EA			Each 1

Compatible with Medtronic ForceFX® Electrosurgical Generator C.

Torquing Set

36kHz Torquing set

23kHz Torquing set

C7602/EA

C7636

C7601/EA

C7623

Catalog No.	Description	Sterile	Quantity
C7602	36 kHz Torque Wrench	Yes	Box 5
C7602EA			Each 1
C7636	36 kHz Reusable Torque Base	No	Each 1
C7601	23 kHz Torque Wrench	Yes	Box 5
C7601EA			Each 1
C7623	23 kHz Reusable Torque Base	No	Each 1

poz.10.1

poz. 10.21

Document for use in Europe, Middle-East and Africa only

Codman
SPECIALTY SURGICAL

CUSA Quick Connect™ Cartridge and Tubing Set
Compatible with both 36 kHz and 23 khz handpieces

C7300/EA

p02.10.22

Catalog No.	Description	Sterile	Quantity
C7300	CUSA Quick Connect™ Cartridge and Tubing Set	Yes	Box 5
C7300EA			Each 1

Accessories

C7136/C7123

C7500/C7502

C7005

C7550

Catalog No.	Description	Quantity
C7136	36 kHz Sterilization Tray	Each 1
C7123	23 kHz Sterilization Tray	Each 1
C7500	36 kHz Cleaning Brush	Each 1
C7502	23 kHz Cleaning Brush	Each 1
C7005	Contamination Guards	Box 2
C7550	Specimen trap	Box 12

p02.10.23

SPEED & SELECTIVITY

CUSA® Clarity

Indications: The CUSA Clarity Ultrasonic Surgical Aspirator system is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable: Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery.

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

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 indications, contraindications, hazards, warnings, precautions, and instructions for use.

Products mentioned in this document are CE class I, Is, IIa, IIb, III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".

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

Sales & Marketing EMEA
Integra LifeSciences Services (France) SAS
Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69800 Saint Priest ▪ FRANCE
Phone: +33 (0)4 37 47 59 00 ▪ Fax: +33 (0)4 37 47 59 99
integralife.eu

CE 0086 BSI

Manufacturer:
Integra LifeSciences (Ireland) Ltd
IDA Business and Technology Park
Sragh, Tullamore, County Offaly ▪ IRELAND

Integra Contact - Questions, Information & Product Ordering
International: +33 (0) 437 47 59 50 ▪ +33 (0) 437 47 59 25 (Fax) ▪ csemea@integralife.com
France: +33 (0) 437 47 59 10 ▪ +33 (0) 437 47 59 29 (Fax) ▪ custsvcfrance@integralife.com
United Kingdom: +44 (0) 1264 312 725 ▪ +44 (0) 1264 312 821 (Fax) ▪ custsvc.uk@integralife.com
Ireland: +353 1800 901567 (tel) ▪ +353 1822 5952 (fax) ▪ custsvcire@integralife.com
Germany: +49 (0) 2102 5535 6200 ▪ +49 (0) 2102 5536 636 (Fax) ▪ custsvcgermany@integralife.com
Austria: +43(0) 720 816 067 ▪ +43(0) 192 872 01 (Fax) ▪ CustSvcAustria@integralife.com
Italy: +39 (0)2 577 89 21 ▪ +39 (0)2 575 113 71 (Fax) ▪ custsvcitaly@integralife.com
Belgium & Luxembourg: +32 (0)2 257 4130 ▪ +32 (0)2 253 2466 (Fax) ▪ custsvcbenelux@integralife.com
Switzerland: +41 (0)2 27 21 23 00 ▪ +41 (0)2 27 21 23 99 (Fax) ▪ custsvcsuisse@integralife.com
Netherlands: +31(0)852083167 ▪ +31(0)207093627 (Fax) ▪ custsvcnetherlands@integralife.com

Integra and the Integra logo are registered trademarks of Integra LifeSciences Corporation in the United States and/or other countries. CUSA is a registered trademark of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries. ShearTip, MicroTip, MicroTip Plus and CUSA Quick Connect are trademarks of Integra LifeSciences Corporation or its subsidiaries. Document for use in Europe, Middle-East and Africa only. ©2019 Integra LifeSciences Corporation. All rights reserved. Last revision date: 10/2019. 0599077-3-EN