

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1007600044280

Data înregistrării

30.07.2007

Data eliberării

30.07.2007

Bordeianu Tatiana, registrator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0067985





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS din Registrul de stat al persoanelor juridice

Nr. 531861 data 19.09.2023

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**

Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1007600044280**

Data înregistrării de stat: **30.07.2007**

Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 2. Comerțul cu ridicata al parfumurilor și produselor cosmetice**
- 3. Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă**
- 4. Intermedieri pentru vânzarea unui asortiment larg de mărfuri**
- 5. Alte tipuri de comerț cu amănuntul în magazine nespecializate**
- 6. Alte tipuri de comerț cu ridicata**
- 7. Închirierea altor mașini și echipamente**

Capitalul social: **5400 lei,**

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociații:

1. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%**

Beneficiar efectiv:

1.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **19.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461498

OXIVIT MED

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova

telefon: + 373 22 808002; fax: + 373 22 808003

web: www.oxivit-med.com; e-mail: info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

| Nr. | Numele, Prenumele | Codul Personal |
|-----|--------------------|----------------|
| 1 | Kojevnikov Dmitrii | 0972305012362 |

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 00500

Issued To:

**Covidien llc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices



First Issued: **1995-02-01**

Date: **2020-09-18**

Expiry Date: **2024-05-26**

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Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 00500

Certificate Scope:

The design, development and manufacture of electrosurgical generators and associated sterile and non-sterile accessories; sterile surgical smoke evacuation accessories; electrosurgical vessel sealing systems and associated sterile and non-sterile accessories; RF ablation generators and associated sterile and non-sterile accessories; microwave ablation generators and associated sterile and non-sterile accessories; sterile and non-sterile electromagnetic navigation accessories; ultrasonic surgical systems and associated sterile and non-sterile accessories.

Spanish:

Diseño, desarrollo y manufactura de generadores electroquirúrgicos y accesorios estériles y no estériles relacionados; accesorios estériles de evacuación de humo quirúrgico; sistemas electroquirúrgicos de sellado de vasos sanguíneos y accesorios estériles y no estériles relacionados; generadores de RF de ablación y accesorios estériles y no estériles relacionados; generadores de ablación por microondas y accesorios estériles y no estériles relacionados; accesorios de navegación electromagnética estériles y no estériles; sistemas quirúrgicos ultrasónicos y accesorios estériles y no estériles relacionados.

Portuguese:

Concepção, desenvolvimento e fabricação de geradores eletro-cirúrgicos e acessórios estéreis e não estéreis associados, acessórios estéreis de evacuação de fumaça cirúrgica, sistemas eletro-cirúrgicos de selagem de vasos e acessórios estéreis e não estéreis associados, geradores de ablação por RF e acessórios estéreis e não estéreis associados, geradores de ablação por microondas e acessórios estéreis e não estéreis associados, acessórios de navegação eletromagnética estéreis e não estéreis, sistemas cirúrgicos ultrassônicos e acessórios estéreis e não estéreis associados.



First Issued: **1995-02-01**

Date: **2020-09-18**

Expiry Date: **2024-05-26**

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Page 2 of 5

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 00500

Issued To:

Covidien Ilc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| NBOG code | Device description | Intended purpose per IFU |
|-------------------------------|--|--|
| Class IIb | | |
| MD 1104 | Electrosurgical electrodes | Intended to be used to remove tissue and control bleeding by use of high-frequency electrical current. |
| MD 1104 | Electrosurgical and vessel sealing RF generators | Intended for use with monopolar and bipolar accessories for cutting, coagulating, desiccating, and fulgurating tissue and sealing (fusing) vessels. |
| MD 1104 | Electrosurgical smoke evacuation system accessories and electrodes | Intended for use with standard monopolar electrosurgical generators, standard monopolar electrodes, and smoke evacuators |
| MD 1104 MD 1301 MD 0102 | RF ablation generators and accessories | Intended for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of tissue, including partial or complete ablation of non-resectable liver tumors and osteoid osteoma tumors within bone. |

First Issued: **1995-02-01**Date: **2020-09-18**Expiry Date: **2024-05-26**

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Page 3 of 5

Validity of this certificate is conditional on the quality system being maintained in accordance with the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products not manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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Supplementary Information to CE 00500

Issued To:

Covidien Ilc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| NBOG code | Device description | Intended purpose per IFU |
|-----------|--|---|
| MD 1402 | Microwave ablation generators and accessories. | Intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors. It is not for use in cardiac procedures. |
| MD 1104 | Cordless ultrasonic generator and accessories | Indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The device can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures. Can be used to coagulate isolated vessels up to 5 mm in diameter. |

First Issued: **1995-02-01**Date: **2020-09-18**Expiry Date: **2024-05-26**

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Covidien Ilc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| NBOG code | Device description | Intended purpose per IFU |
|------------------|---|--------------------------|
| Class IIa | | |
| MD 0102 | Smoke evacuation accessories | N/A |
| MD 1301 | Temperature probes for ablation systems | N/A |
| MD 1402 | Electromagnetic navigation accessories | N/A |

First Issued: **1995-02-01**Date: **2020-09-18**Expiry Date: **2024-05-26**

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Page 5 of 5

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00500**
 Date: **2020-09-18**
 Issued To: **Covidien Ilc**
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| Subcontractor: | Service(s) supplied |
|--|--|
| Bovie Medical Corporation 5115 Ulmerton Road Clearwater Florida 33760 USA | Design Finished Device Supplier Manufacture |
| Cadex Electronics, Inc. 22000 Fraserwood Way Richmond British Columbia V6W 1J6 Canada | Manufacture |
| ConMed Corporation 6455 S Yosemite Street Greenwood Village Colorado 80111 USA | Control of Manufacture Control of Sterilization Design Finished Device Supplier |



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15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| Subcontractor: | Service(s) supplied |
|--|---------------------------------------|
| Consolidated Medical Equipment Company Ave. Alejandro Dumas No. 11321 Complejo Industrial Chihuahua Chihuahua Chihuahua 31136 Mexico | Manufacture |
| Covidien Ireland Limited IDA Business and Technology Park Tullamore Ireland | EU Representative |
| Covidien Ilc 2824 Airwest Boulevard Plainfield IN 46168 USA | Labelling Manufacture Packaging |



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15 Hampshire Street
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USA

| Subcontractor: | Service(s) supplied |
|---|---|
| Covidien llc Boulevard Insurgentes 19030 Libramiento Tijuana B.C. 22225 Mexico | Control of Sterilization Manufacture |
| Covidien llc 5920 Longbow Drive Boulder Colorado 80301 USA | Design Finished Device Supplier Labelling Manufacture Packaging |
| Covidien llc 161 Cheshire Lane Suite 100 Plymouth Minnesota 55441-5433 USA | Control of Sterilization Manufacture |



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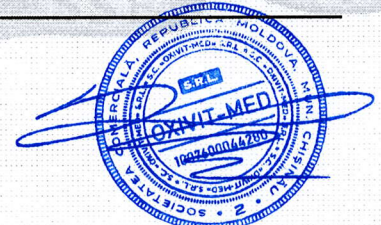
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| Subcontractor: | Service(s) supplied |
|--|--|
| Covidien Medical Products (Shanghai) Manufacturing, LLC Building #10 789 Puxing Road Shanghai 201114 People's Republic of China | Manufacture |
| Emblation Ltd. 3 Forrester Lodge Inglewood, Alloa Scotland FK10 2HU United Kingdom | Design Finished Device Supplier Manufacture |
| Greatbatch Medical S. de R.L. de C.V. Calle 5 Norte No. 511 Ciudad Industrial Tijuana BC CP 22444 Mexico | Manufacture |



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02048
USA

| Subcontractor: | Service(s) supplied |
|--|----------------------------------|
| International Sterilization Laboratory, LLC 217 Sampey Road Groveland Florida 34736 USA | ETO Sterilization |
| Isomedix Operations, Inc 2 Nucifora Boulevard Chester New York 10918 USA | Radiation (E Beam Sterilization) |
| Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA | Radiation (E Beam Sterilization) |



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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Subcontractor:

Service(s) supplied

Isomedix Operations, Inc.
 7685 Saint Andrews Avenue
 San Diego
 California
 92154
 USA

ETO Sterilization

Kirwan Surgical Products LLC
 180 Enterprise Drive
 Marshfield
 Massachusetts
 02050
 USA

**Control of Sterilization
 Manufacture**

Lake Region Medical
 Venusa de Mexico S.A. de C.V.
 1525-6 Hertz Street
 Cuidad Juarez
 Chihuahua
 32470
 Mexico

Manufacture



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15 Hampshire Street
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Massachusetts
02048
USA

| Subcontractor: | Service(s) supplied |
|--|---------------------|
| Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands | EU Representative |
| Medtronic Engineering and Innovation Center Private Ltd DLF Cyber City, Block No. 3 APHB Colony, Gachibowli, Telangana Ground Floor, Plot No. 129-132, APHB Hyderabad 500019 India | Design |
| Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA | ETO Sterilization |



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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Subcontractor:

Service(s) supplied

Modern Medical Equipment Manufacturing Ltd
 Flat A, 11/F
 Mai Wah Ind. Bldg.
 1- 7 Wah Sing Street
 Kwai Chung, New Territories
 Hong Kong

Manufacture

New Deantronics Taiwan Ltd.
 12F, No. 51, Sec. 4, ChongYang Rd.
 Tu Cheng Dist.
 New Taipei City
 23675
 Taiwan

Design
Finished Device Supplier
Manufacture

Sterigenics Radiation Technologies, LLC
 7695 Formula Place
 San Diego
 California
 92121
 USA

Radiation (E Beam Sterilization)



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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

Recognised as being involved in services relating to the product covered by:

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Subcontractor:

Service(s) supplied

Synergy Health AST, LLC
 9020 Activity Road, Suite D
 San Diego, California
 92126
 USA

Radiation (E Beam Sterilization)

Terumo BCT, Inc.
 10811 W. Collins Avenue
 Lakewood
 Colorado
 80215
 USA

ETO Sterilization

Trelleborg Sealing Solutions Tustin, Inc.
 222 Industrial Park Drive
 Elk Rapids
 MI 49629
 USA

Manufacture



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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No: **CE 00500**
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15 Hampshire Street
Mansfield
Massachusetts
02048
USA

Subcontractor:

Vanguard AG
 Landsberger Str. 266
 Berlin
 12623
 Germany

Service(s) supplied

Gas Plasma Sterilization
Manufacture



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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00500**
 Date: **2020-09-18**
 Issued To: **Covidien llc**
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| Date | Reference Number | Action |
|------------------|------------------|---|
| 01 February 1995 | | First Issued. |
| 13 December 1996 | | Addition of Sub-contractors. |
| 22 June 1998 | | Addition of Sub-contractors. |
| 25 January 1999 | | Addition of Sub-contractors. |
| 19 April 1999 | | Addition of Sub-contractors. |
| 28 February 2000 | | Addition of sterilisation Sub-Contractor. |
| 20 April 2000 | | Addition of Sub-Contractor. |
| 24 July 2000 | | Extension to the scope, bipolar monitoring devices added. |
| 12 July 2001 | | Addition of Sub-Contractors and Certificate renewal. |
| 03 April 2003 | 4356583 | Addition of Sub-Contractors and removal of Sub-Contractors. |
| 5 October 2003 | 4356583 | Extension of scope to include lesion generators and the addition of sub-contractor Ion Beam Applications in Queensbury New York for Ethylene Oxide Sterilisation. |
| 24 February 2005 | 4647875 | Certificate renewal and issue in new format. |



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Page 1 of 12

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| Date | Reference Number | Action |
|------------------|------------------|---|
| 21 March 2006 | 4799198 | Change of address format. Addition of sub-contractors: Gambro BCT (Lakewood), Sterigenics (Willowbrook), Sterigenics (Gurnee) and Linemaster (Woodstock). Change of sub-contractor address: Beam One (Lima). Removal of subcontractors: Steris Isomedix (Sandy), Delphi Medical Systems (Longmont) and Sterigenics (Santa Teresa). |
| 07 February 2008 | 7068083 | Extension to scope for Microwave generator. Addition of significant subcontractors 'Thermo Fisher Scientific', 'HEI Inc' in relation to the manufacture of microwave generators and accessories. Addition of 'Covidien Medical Products (Shanghai) Manufacturing' and 'Buffalo Filters, Buffalo' as a significant subcontractor for manufacturing activities Maintenance of addresses for other significant subcontractors. |



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Page 2 of 12

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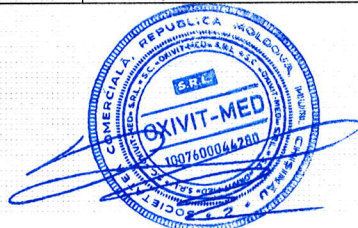
Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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| Date | Reference Number | Action |
|------------------|------------------|---|
| 18 February 2009 | 7316357 | Certificate re-issue due to: change of company name, removal of subcontractor 'Nelcor Puritan Bennett Mexico', change of subcontractor company name 'Aaron Medical Industries, Inc.' to 'Bovie Medical Corp', change of subcontractor company name 'Gambro BCT, Inc.' to 'Caridian BCT Sterilization Services, Inc.' and addition of "Covidien Ireland Limited" as EU Rep. |
| 27 January 2010 | 7464667 | Certificate renewal – scope amended "ultrasonic surgical aspirators and associated accessories" deleted "Lesion" amended to "ablation". Subcontractors removed: Kendall, a division of Tyco Healthcare Group LP, Norfolk UK– Gamma Sterilization, United States Surgical (USS) North Haven US – Manufacture & Design, HEI Inc, Boulder, US – Manufacture. Address amendment for Bovie Medical Corp and name correction for Cardian BCT. Address change for Design Standards Corporation from 182 Ceda Road to 957 Claremont Road. |
| 16 April 2010 | 7510978 | Change company name from Covidien LP (formerly known as Valleylab a division of Tyco Healthcare Group LP) to Valleylab, a division of Tyco Healthcare Group LP. |



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Page 3 of 12

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| Date | Reference Number | Action |
|------------------|------------------|---|
| 10 November 2010 | 7603788 | Company name change from Valleylab, a division of Tyco Healthcare Group LP to Covidien Energy-based Devices . The addition of Covidien Energy-based Devices as a significant sub contractor for Design and Manufacture. Changes to the format of the address on the certificate and to Covidien Energy-based Devices address. |
| 13 April 2012 | 7817940 | Extension of scope to include "ultrasonic surgical systems and associated accessories." |
| 12 June 2012 | 7841245 | Subcontractor name change from 'Caridian BCT Inc' to 'Terumo BCT'. The addition of Synergy Health (Suzhou) as a significant subcontractor for Sterilisation. Subcontractor name change from 'BeamOne, LLC' to Synergy Health Applied Sterilization Technologies, LLC' in 2 places. |
| 07 January 2013 | 7930922 | Addition of subcontractors Accellent Inc, El Paso, Texas and Venusa de Mexico S.A. de C.V., Chihuahua, Mexico both for manufacturing services. |



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Page 4 of 12

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USA

| Date | Reference Number | Action |
|-----------------|------------------|--|
| 26 January 2015 | 8258195 | Correction of subcontractor address for, 'Buffalo Filter and New Deantronics Taiwan Ltd.'. Addition of subcontractor, 'Buffalo Filter, CEA Medical Manufacturing, DeRoyal Industries, Inc., Modern Medical Equipment Manufacturing Ltd., SEI MEDICAL S.A. DE C.V. and Vanguard AG', for Sterile manufacture. Addition of subcontractor, 'Electrochem Solutions Inc, Contract Medical Manufacturing, LLC, New Deantronics Taiwan Ltd. for Design and manufacture. |
| 26 January 2015 | 8258496 | Certificate renewal. |
| 05 October 2015 | 8318433 | Addition of subcontractor, 'Covidien Ilc., 161 Cheshire Lane Suite 100, Plymouth, Minnesota, 55441-5433, USA', for manufacture and 'Emblation Microwave, Forrester Lodge, Inglewood, Alloa, FK10 2HU, Scotland, UK', for manufacture, design. Change of subcontractor name from Venusa de Mexico S.A. de C.V. an Accellent Company to Lake Region Medical. Amendment to scope. |



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Page 5 of 12

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Massachusetts
02048
USA

| Date | Reference Number | Action |
|---------------|------------------|---|
| 30 March 2016 | 8470731 | Removal of subcontractor, 'Electrochem Solutions Inc, 13955 SW Milikan Way, Beaverton, Oregon 97005, USA'. Change of subcontractor name from, 'Covidien Energy-based Devices (Formerly Valleylab, a division of Tyco Healthcare Group LP)', to 'Covidien', for manufacture, design. Addition of subcontractor, 'Greatbatch Medical S. de R.L. de C.V., Calle 5 Norte No. 511, Ciudad Industrial, Tijuana, Baja California, 22444, Mexico', for manufacture. Amendment to scope. |
| 06 May 2016 | 8524761 | Remove duplicate EU representative. |
| 01 March 2019 | 7794476 | Administrative Subcontractor Service wording update for 'Sterile Manufacture' to 'Gamma Sterilization, Manufacture' for Buffalo Filter, division of MEDTEK, 5900 Genesee Street, New York. 'Sterile Manufacture' to 'Gamma Sterilization, ETO Sterilization, Dry Heat Sterilization, Moist Heat Sterilization, Manufacture' for CEA Medical Manufacturing, 1735 Merchants Court, Colorado. |



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Page 6 of 12

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 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00500**
 Date: **2020-09-18**
 Issued To: **Covidien Ilc**
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

| Date | Reference Number | Action |
|------|------------------|--|
| | | <p>'Sterile Manufacture' to 'ETO Sterilization, Manufacture' for DeRoyal Industries, Inc, 200 DeBusk Lane, Tennessee</p> <p>'Sterile Manufacture' to 'Manufacture' for Modern Medical Equipment, Gold King Ind. Bldg., Hong Kong</p> <p>'Sterile Manufacture' to 'Manufacture' for SEI MEDICAL S.A. DE C.V., Roberto Fierro y Francisco Sarabia, Juarez</p> <p>'Sterilization' to 'ETO Sterilization' for Sterigenics US, LLC, 7775 South Quincy, Illinois</p> <p>'Sterilization' to 'ETO Sterilization' for Synergy Health (Suzhou), 26 Xinchang Road, Jiangsu</p> <p>'Sterilization' to 'Gamma Sterilization' for Synergy Health Americas, 500 West 4th Street, Ohio</p> <p>'Sterile Manufacture' to 'Gas Plasma Sterilization, Manufacture' for Vanguard AG, Landsberger Str. 266, Berlin</p> <p>Traceable to NB 0086.</p> |



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Massachusetts
02048
USA

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|-----------------|------------------|---|
| 17 October 2019 | 8747987 | <p>Addition of the subcontractors: Covidien (Plainfield); Medtronic Engineering and Innovation Center Private Ltd; NextPhase Medical Devices, LLC; Covidien (Tijuana); Royal Sterilization Systems; Cadex Electronics Inc.; Bovie Medical Corporation; New Deantronics Taiwan Ltd.; Sterigenics Shanghei ETO Ltd.; Sterigenics US, LLC.; Isomedix Operations, Inc.; Covidien llc, GI Solution; Sotera Health LLC; Trelleborg Sealing Solutions Tustin, Inc.</p> <p>Removal of the subcontractors: SEI MEDICAL S.S. DE C.V.; Accellent, Inc.; BOWA-Electronic GmbH & Co. KG; Linemaster Switch Corporation; United States Surgical (USS) A Div of Tyco Healthcare Group LP; CEA Medical Manufacturing; Synergy Health – Applied Sterilization Technologies, LLC (Denver, Co); Synergy Health Americas; Cole-Parmer Instrument Company; Design Standards Corporation; HEI, Inc.; Kendall, a division of Tyco, Nicolay GmbH; Sterigenics US, LLC (Gurnee, IL); Sterigenics (Queensbury, NY); Sutter Medizintechnik GmbH.</p> <p>Clarified scope wording adding to system granularity and an extension to scope to include surgical navigation.</p> |



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| Date | Reference Number | Action |
|-----------------|------------------|---|
| | | Corrected names or addresses of subcontractors to align with ISO certificates: Covidien LLC; Buffalo Filter, LLC.; DeRoyal Industries, Inc.; Emblation Ltd.; Vanguard AG. Maintenance of subcontractor activities to align with BSI subcontractor activities for: Buffalo Filter, division of MEDTEK; DeRoyal Industries, Inc.; Emblation Ltd; Sterigen cs US, LLC; Vanguard AG; Covidien LLC; "Finished device supplier" activity added to Emblation Ltd.; "ETO Sterilization" removed from DeRoyal Industries, Inc. activities. |
| 24 January 2020 | 3061488 | Certificate renewal. Amended scope to remove "procedure planning software", "software de planificacion de procedimientos" and "software de planeamento de processos". Removed subcontractors: Contract Medical Manufacturing, LLC, Oxford, USA; DeRoyal Industries, Inc., Powell, USA; Royal Sterilization Systems, New Tazewell, USA; Sterigenics US, LLC, Willowbrook, USA. Changed subcontractors: Covidien, LLC, Tijuana, Mexico to add Control of Sterilization and make a spelling correction to the name; Modern Medical Equipment Manufacturing Ltd to update address; |



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| Date | Reference Number | Action |
|------|------------------|--|
| | | <p>Buffalo Filter, LLC, Lancasters, USA to change "Control of Manufacture" to "Manufacture".</p> <p>Spelling corrections to the names of: Covidien llc, Mansfield, USA; Covidien llc, Plainfield, USA; Covidien llc, Plymouth, USA</p> <p>Added subcontractors: Isomedix Operations, Inc., San Diego, USA for ETO Sterilization; Medtronic B.V., Heerlen, The Netherlands as EU Representative; Midwest Sterilization Corporation, Jackson, USA for ETO Sterilization.</p> <p>Added Product Table.</p> |



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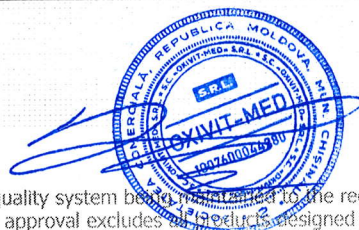
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| Date | Reference Number | Action |
|-------------------|------------------|---|
| 18 September 2020 | 3175231 | <p>Removed subcontractor Buffalo Filter, LLC.</p> <p>Added subcontractor ConMed Corporation for Design, Control of Manufacture, Finished Device Supplier and Control of Sterilization.</p> <p>Added subcontractor Consolidated Medical Equipment Company for Manufacture.</p> <p>Correction to subcontractor services supplied:</p> <ul style="list-style-type: none"> •"Finished Device Supplier" added to Bovie Medical Corporation, New Deantronics Taiwan Ltd. •"Finished Device Supplier" removed from Covidien llc, Plainfield, Covidien llc, Tijuana, Covidien llc, Plymouth, Covidien llc, GI Solutions. •"Assembly" changed to "Manufacture" for Trelleborg Sealing Solutions Tustin, Inc. •"Control of Sterilization" added to Covidien llc, Plymouth and Kirwan Surgical Products LLC <p>Correction to address of Emblation Ltd from FK10 2HU, Scotland to Scotland, FK10 2HU, UK.</p> <p>Correction to address of Medtronic Engineering and Innovation Center Private Ltd, correcting Hyderadad to Hyderabad</p> <p>Removed subcontractor NextPhase Medical Devices.</p> <p>Added subcontractor International Sterilization Laboratory, LLC for ETO Sterilization</p> <p>Added Isomedix Operations, Inc(Chester) for E Beam Sterilization</p> |



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|--|------------------|---|
| Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3 | | |
| 20 July 2021 | 3479846 | Addition of significant subcontractor Sterigenics Radiation Technologies, LLC |
| 22 October 2021 | 3559632 | Removal of subcontractor Covidien llc, GI Solutions, Sunnyvale Addition of Manufacture to Covidien llc, Plainfield |



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22 October 2021

Covidien llc
15 Hampshire Street
Mansfield
Massachusetts
02048
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

| Certificate | Directive and Annex | Reference Number | Changes approved |
|-------------|--|------------------|--|
| CE 00500 | 93/42/EEC Annex II excluding Section 4 | 3559632 | Removal of subcontractor Covidien llc, GI Solutions, Sunnyvale Addition of Manufacture activity to subcontractor Covidien llc, Plainfield |

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Gary Slack
Senior Vice President, Medical Devices



PRECISE ACCESS.^{1,†} **UNPARALLELED FREEDOM.¹**

Cordless ultrasonic vessel sealing and
dissection — now with a tapered, curved jaw
and streamlined cleaning and sterilization‡



Sonicision™ Curved Jaw
Cordless Ultrasonic
Dissection System

[†]30 out of 33 surgeons agreed

[‡]Compared to the first-generation Sonicision™ system.

Medtronic
Further, Together

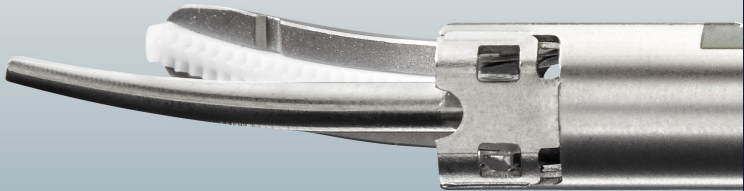


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39 cm Sonicision™ Curved Jaw Cordless
Ultrasonic Dissector



ADVANCING ULTRASONIC DISSECTION **TO HELP YOU ADVANCE CARE.**

Overcoming healthcare's biggest challenges. That's been the driving force behind the development of our energy products for more than 50 years.

It's why we invented our cordless ultrasonic dissector. So surgeons can have more freedom of movement within their procedures — and a safer OR.²

Now we've taken that idea to the next level.

Introducing the Sonicision™ curved jaw cordless ultrasonic dissection system — the next generation in cordless ultrasonic energy

This latest advancement to our energy portfolio is designed to enable:

- Access and visibility in tight spaces^{1,†}
- More procedural uses^{5–7,9,‡}
- A safer OR²
- Streamlined cleaning and sterilization[‡]



The Sonicision™ curved jaw device is the future of advanced ultrasonic dissection — ready for your procedures today.



[†]33 out of 33 surgeons surveyed after use agreed.

[‡]Compared to the first-generation Sonicision™ system.

ACCESS. MOBILITY. VERSATILITY.

A curved jaw ultrasonic dissector — without a cord

THE BENEFITS OF UNPLUGGING

Cordless vessel sealing and dissection in your procedures contributes to:

- Reduced tripping hazards
- Easier instrument exchanges^{1,†}
- Improved procedural focus^{1,8,†}
- More natural movement^{1,†}
- Improved freedom of movement and mobility^{1,‡}



"The innovative cordless design significantly enhances ease of use in the operating room with overall excellent effectiveness."

—Baker EH, et al. *Surgical Innovation*³

Freedom from cords^{1,§}:

- Improves movement, mobility,[†] and safety² in any OR
- Makes it easier to pass the device during procedures^{1,†}
- Supports more natural movement compared to devices with cords^{1,§}

Single button dual-mode energy activation^{1,Ω}:

- Is designed to improve focus on the procedure with intuitive, single button energy activation^{1,Ω}
- Allows access to minimum and maximum energy modes so the surgeon's eyes can stay on the surgical field^{1,††}
- Facilitates versatility within procedures by providing two distinct energy modes^{1,†}

The tapered, curved jaw¹:

- Facilitates precise access to tissue planes^{1,‡}
- Enables visualization of target structures^{1,Ω}
- Allows the surgeon to hug or follow curved anatomical structures^{1,††}
- Provides access in tight spaces^{1,Ω}

[†] 32 out of 33 surgeons surveyed after use agreed.

[‡] 29 out of 33 surgeons surveyed after use agreed.

[§] 30 out of 33 surgeons surveyed after use agreed.

^Ω 33 out of 33 surgeons surveyed after use agreed.

^{††} 31 out of 32 surgeons surveyed after use agreed.

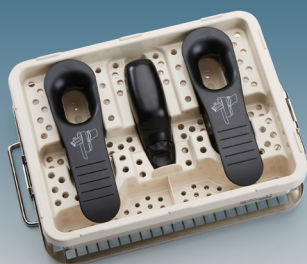
NEXT-GEN DESIGN. NEXT-GEN CONVENIENCE.



Sonicision™ Reusable Battery Pack (SCBA)



Sonicision™ Reusable Generator (SCGAA)



Sonicision™ Reusable Sterilization Tray (SCSTA)



An autowashable, autoclavable generator and nonsterile battery:

- Streamlines cleaning and sterilization[†]
- Reduces special handling of system components[†]
- Allows for use in more procedures before replacements are needed thanks to an increased overall useful life of the battery and generator^{6,9}
- Provides a wide variety of sterile barrier / steam sterilization cycle combinations to accommodate hospital needs⁵

An intuitive, easy to use[‡] battery charger:

- Makes it easy to interpret battery charge status[‡] and battery end of life indications^{§,5}
- Enables efficient battery usage management^{§,†}



[†]Compared to the first-generation Sonicision™ system.

[‡]28 out of 28 nurses surveyed after use agreed.

[§]27 out of 28 nurses surveyed after use agreed.

FREEDOM OF MOVEMENT. FOR LONGER THAN EVER.

More activations⁴ and improved efficiency⁴ compared to our first-generation Sonicision™ device

100%

of surgeons said the Sonicision™ curved jaw device is intuitive and comfortable to use throughout procedures^{1,†}

Our next-generation reusable battery pack (SCBA) delivers:



88%
greater capacity
for more interoperative
uses before a new
battery is needed^{4,6,‡}

+

2x more
procedural uses
in your hospital to
reduce the burden of
reordering^{5-7,‡}

Our enhanced reusable generator (SCGAA) delivers:



1.5x more procedural uses^{5,9}

Plus it's autowashable and autoclavable for streamlined[†] cleaning and sterilization.

† 33 out of 33 surgeons surveyed after use agreed.

‡ Compared to the first-generation Sonicision™ system.

A DESIGN FOR **THE WHOLE TEAM**

Nurses agree that the design of the Sonicision™ curved jaw device can bring improvements to the OR⁸

Cordless convenience

100%
of nurses agree

the cordless design of the Sonicision™ curved jaw device:

- Makes it easier to pass during procedures^{8,†}
- Enhances mobility^{8,†}
- Allows for use in any OR^{8,†}
- Improves the use of space in the OR^{8,†}

A focus on ease of use

100%
of nurses agree

that the Sonicision™ curved jaw system:

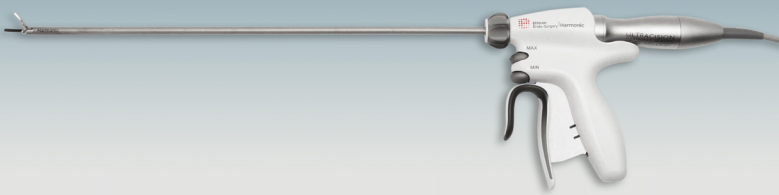
- Enables easy setup with an integrated torque wrench^{8,‡}
- Makes it easy to determine when the device is ready to use^{8,§}
- Communicates device status with easy-to-interpret colors and tones^{8,Ω}
- Features an easy-to-use battery charger with an intuitive user interface^{8,§}



A majority of nurses surveyed said that the Sonicision™ curved jaw device is easier to assemble than the Harmonic scalpel.^{8,††}

†29 out of 29 nurses surveyed after use agreed.
‡14 out of 14 nurses surveyed after use agreed.
§28 out of 28 nurses surveyed after use agreed.
Ω27 out of 27 nurses surveyed after use agreed.
††19 out of 29 nurses surveyed after use agreed.

COMPETITIVE COMPARISON



Sonicision™ curved jaw device vs. Harmonic ACE™* +

| | |
|---|---|
| Freedom of movement ^{1,8} | ■ |
| Ease of assembly ⁸ | ■ |
| Jaw design — access to target structures ¹ | ■ |
| Jaw design — visualization of target structures ¹ | ■ |
| Jaw design — ability to see tips ¹ | ■ |
| Blunt dissection ¹ | ■ |
| Surgical plume ¹ | ■ |
| Dissection speed ¹ | ■ |
| Ability to hold tissue in jaws during activation ¹ | ■ |

- Sonicision™ curved jaw device outperforms the Harmonic Ace™*+ device.
- No difference found between devices.

Jaw Comparison

| Device | Width at Tip of Active Blade | Width at Base of Active Blade | Length of Active Blade |
|-------------------------------|------------------------------|-------------------------------|------------------------|
| Sonicision™ Curved Jaw Device | 0.8 mm | 1.7 mm | 14.5 mm |
| Harmonic ACE™*+ | 1.1 mm | 2.2 mm | 14.4 mm |

The Sonicision™ curved jaw device features a thinner active blade than the Harmonic ACE™*+ device.^{10,†} The device’s jaw profile enables access in tight spaces while the jaw taper provides precise access to tissue planes and allows controlled dissection.¹

Sonicision™
curved jaw
device

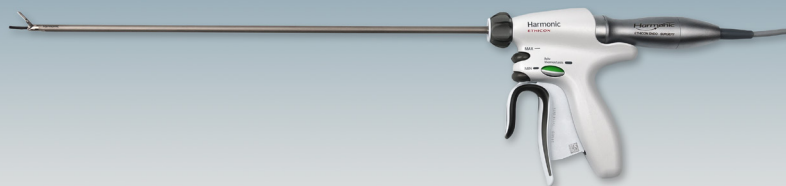


Harmonic
ACE™*+



†Active blade measured at the tip and the base.

COMPETITIVE COMPARISON



Sonicision™ curved jaw device vs. Harmonic ACE™+7

| | |
|---|--------------|
| Freedom of movement ^{1,8} | ■ |
| Ease of assembly ⁸ | ■ |
| Acute hemostasis ^{12,†} | ■ |
| 7 mm sealing indication | ■ |
| Thermal spread ¹² | ■ |
| Max jaw temperature ultrasonic jaw ^{13,‡} | ■ |
| Max jaw temperature nonactive, movable jaw ^{13,‡} | ■ |
| Max shaft temperature ¹³ | ■ |
| Jaw cool down time, ultrasonic jaw ^{13,‡} | ■ |
| Jaw cool down time nonactive, movable jaw ^{13,‡} | ■ |
| Dissection speed ^{13,‡} | ■ |
| Activation time using advanced hemostasis mode ^{13,§,††} | 17.7 seconds |

- Sonicision™ curved jaw device outperforms the Harmonic Ace™+7 device.
- No difference found between devices.
- The Sonicision™ curved jaw device is indicated differently, and coagulates isolated vasculature up to and including 5 mm in diameter.

† Testing performed across indicated vasculature in an acute porcine model.
 ‡ Measured across multiple activations on bench porcine mesentery.
 § Average of single activations.
 Ω Active blade measured at the tip and the base.
 †† Average of single activations on bench porcine mesentery.

Jaw Comparison

| Device | Width at Tip of Active Blade | Width at Base of Active Blade | Length of Active Blade |
|-------------------------------|------------------------------|-------------------------------|------------------------|
| Sonicision™ Curved Jaw Device | 0.8 mm | 1.7 mm | 14.5 mm |
| Harmonic ACE™+7 | 1.1 mm | 2.2 mm | 15.3 mm |

The Sonicision™ curved jaw device features a thinner active blade than the Harmonic ACE™+7 device.^{10,Ω} The device's jaw profile enables access in tight spaces while the jaw taper provides precise access to tissue planes and allows controlled dissection.¹

Sonicision™ curved jaw device



Harmonic ACE™+7



COMPETITIVE COMPARISON



Sonicision™ curved jaw device vs. Harmonic™* HD1000i

| | |
|---|--------------|
| Freedom of movement ^{1,8} | ■ |
| Jaw taper/jaw profile ¹⁰ | ■ |
| Acute hemostasis ^{12,†} | ■ |
| 7 mm sealing indication | ■ |
| Thermal spread ¹² | ■ |
| Max jaw temperature ultrasonic jaw ^{13,‡} | ■ |
| Max jaw temperature nonactive, movable jaw ^{13,‡} | ■ |
| Max shaft temperature ¹³ | ■ |
| Jaw cool down time, ultrasonic jaw ^{13,‡} | ■ |
| Jaw cool down time nonactive, movable jaw ^{13,‡} | ■ |
| Dissection speed ^{13,‡} | ■ |
| Activation time using advanced hemostasis mode ^{13,§,††} | 12.7 seconds |

- Sonicision™ curved jaw device outperforms the Harmonic HD1000i device.
- No difference found between devices.
- The Sonicision™ curved jaw device is indicated differently, and coagulates isolated vasculature up to and including 5 mm in diameter.

† Testing performed across indicated vasculature in an acute porcine model.
 ‡ Measured across multiple activations on bench porcine mesentery.
 § Average of single activations.
 Ω Active blade measured at the tip and the base.
 †† Average of single activations on bench porcine mesentery.

Jaw Comparison

| Device | Width at Tip of Active Blade | Width at Base of Active Blade | Length of Active Blade |
|-------------------------------|------------------------------|-------------------------------|------------------------|
| Sonicision™ Curved Jaw Device | 0.8 mm | 1.7 mm | 14.5 mm |
| Harmonic™* HD1000i | 1.1 mm | 2.2 mm | 19.0 mm |

The Sonicision™ curved jaw device features a thinner active blade than the Harmonic™* HD1000i device.^{10,Ω} The device's jaw profile enables access in tight spaces while the jaw taper provides precise access to tissue planes and allows controlled dissection.¹

Sonicision™ curved jaw device



Harmonic™* HD1000i



FIRST-GENERATION SONICISION™ DEVICE



First-generation Sonicision™ device vs. Sonicision™ curved jaw device

| | |
|-------------------------------------|---|
| Freedom of movement ¹ | ■ |
| Acute hemostasis ¹⁴ | ■ |
| Thermal spread ¹⁵ | ■ |
| Max jaw temperature ¹⁵ | ■ |
| Max shaft temperature ¹⁵ | ■ |
| Jaw cool down time ¹⁵ | ■ |
| Dissection speed ¹⁴ | ■ |

■ No difference found between devices.

Next-generation benefits

Compared to the first-generation Sonicision™ device, the Sonicision™ curved jaw device provides:

- A tapered, curved jaw design
- A more robust active blade^{16,17,†}
- A reusable battery pack that delivers:
 - 88% more battery capacity⁴
 - Twice the number of procedural uses — from 100 to 200^{5,7}
 - Easier post-procedure management due to battery's nonsterile nature^{5,‡}
- A reusable generator that enables:
 - Streamlined cleaning and sterilization because it's now autowashable and autoclavable[‡]
 - More procedural uses before reordering is needed — from 100 to 150^{5,9}
- A simplified battery charger that has an easy to interpret charge status and end of life indications to enable more efficient battery management^{8,§}

Sonicision™
curved jaw
device



First-generation
Sonicision™
device



†Based on comparison to the first-generation Sonicision™ device regarding survivability when contacting metal clips and stress induced by ultrasonic vibration.

‡Compared to the first-generation system.

§27 out of 28 nurses surveyed after use agreed.

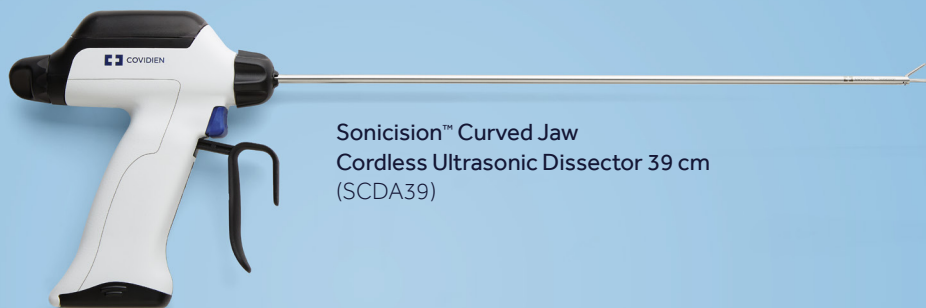
FOUR SIZES. ZERO CORDS. MANY APPLICATIONS.



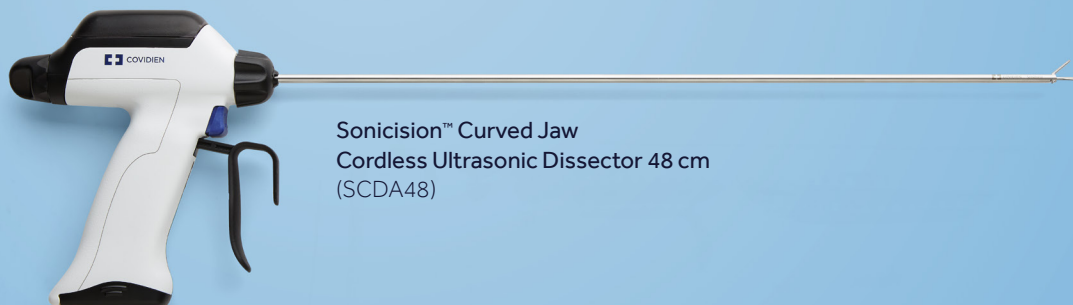
Sonicision™ Curved Jaw
Ultrasonic Dissector 13 cm
(SCDA13)



Sonicision™ Curved Jaw
Cordless Ultrasonic Dissector 26 cm
(SCDA26)



Sonicision™ Curved Jaw
Cordless Ultrasonic Dissector 39 cm
(SCDA39)



Sonicision™ Curved Jaw
Cordless Ultrasonic Dissector 48 cm
(SCDA48)

Our Sonicision™
curved jaw
cordless ultrasonic
portfolio can meet
most of your
procedural needs.



DEVICE REQUEST FORM

I'm requesting the following instruments be stocked in our facility so that I have consistent access to them for my cases:

- ☐ Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 13 cm (SCDA13)
- ☐ Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 26 cm (SCDA26)
- ☐ Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 39 cm (SCDA39)
- ☐ Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 48 cm (SCDA48)
- ☐ Sonicision™ Reusable Battery Pack (SCBA)
- ☐ Sonicision™ Reusable Generator (SCGAA)
- ☐ Sonicision™ Reusable Battery Insertion Guides (SCBIGA)
- ☐ Sonicision™ Battery Charger (CBCA)
- ☐ Sonicision™ Reusable Sterilization Tray (SCSTA)

The Sonicision™ curved jaw cordless ultrasonic dissector:

- Contributes to a safer OR[†]
- Allows for visualization and precise access to tissue planes[‡]
- Provides efficient dissection^{2,‡} and reliable vessel sealing³
- Comes in four lengths to accommodate your procedural needs

We believe that the Sonicision™ curved jaw device will add value for our patients and our hospital. Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,

Additional comments:

[†] 33 out of 33 surgeons surveyed after use agreed.

[‡] In a head-to-head comparison with the Harmonic ACE™+ device, 13 out of 14 surgeons surveyed after use said blunt dissection was similar; 1 said the Sonicision™ device was better.

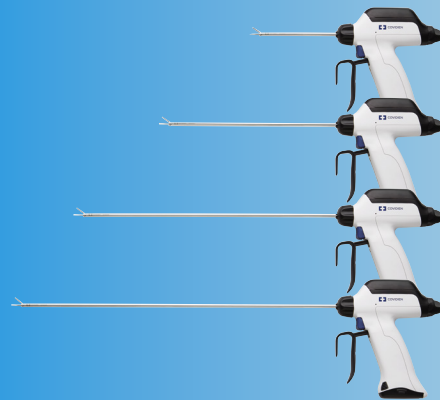
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| ORDERING INFORMATION | PRODUCT CODE | DESCRIPTION | QUANTITY |
|---|--------------|--|-----------|
|  | SCDA13 | Sonicision™ 13 cm Curved Jaw Cordless Ultrasonic Dissector | 6 per box |
|  | SCDA26 | Sonicision™ 26 cm Curved Jaw Cordless Ultrasonic Dissector | 6 per box |
|  | SCDA39 | Sonicision™ 39 cm Curved Jaw Cordless Ultrasonic Dissector | 6 per box |
|  | SCDA48 | Sonicision™ 48 cm Curved Jaw Cordless Ultrasonic Dissector | 6 per box |
|  | SCBA | Sonicision™ Reusable Battery Pack | 1 per box |
|  | SCGAA | Sonicision™ Reusable Generator | 1 per box |
|  | SCBIGA | Sonicision™ Reusable Battery Insertion Guide | 2 per box |
|  | CBCA | Sonicision™ Battery Charger | 1 per box |
|  | SCSTA | Sonicision™ Reusable Sterilization Tray | 1 per box |

PORTABLE PRECISION.

Introduce freedom
of movement to
your procedures

Contact your sales representative
for more information about the
Sonicision™ curved jaw dissector

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1. Based on internal test report #R0042752 rev A, Marketing evaluation of surgeon experience using the Sonicision™ curved jaw cordless ultrasonic dissector. Feb. 13–17, Feb. 28, March 3, May 16, 2017.
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Medtronic



Sonicision™ System Product Manual





[Energy whenever
and wherever
you want it]



The **SONICISION™** System
The industry's first cordless
ultrasonic dissection system now
offers the widest portfolio and
ease of standardization



Table of Contents

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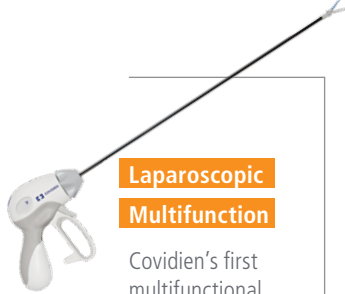
Why Ultrasonic?

Covidien has long been a pioneer in creating medical devices that use various forms of energy. Covidien Energy offers the largest energy-based, and now the most versatile cordless ultrasonic portfolio in the industry.



Monopolar

Hundreds of products you use every day with over 40 years of innovation



Laparoscopic Multifunction

Covidien's first multifunctional instrument for vessel sealing and monopolar dissection in minimally invasive surgery



Open Vessel Sealing

Instruments for hemostasis in open surgery



Efficient and Versatile

Multifunctional device offering one-step sealing, a Maryland dissector, grasper and cold scissors.

**MORE ENERGY
MORE PLACES**



Valleylab™ Devices

ForceTriad™ Energy Platform ▶



Bipolar

Energy and instruments for specialty procedures in gynecology, urology and neurosurgery

LigaSure™ Technology



Laparoscopic Vessel Sealing

Energy and instruments for hemostasis in minimally invasive surgery



Open Small Jaw Vessel Sealing

Instrument for hemostasis and fine dissection in open surgery



Ultrasonic Energy

With the Sonication™ device, Covidien has an expanded portfolio and is a single solution provider for energy devices.

The energy portfolio available allows complete standardization to reduce costs.

Product Overview

The **Sonicision™** cordless ultrasonic dissection device is an unparalleled advancement in ultrasonic energy. The device delivers comparable clinical effectiveness associated with leading ultrasonic technologies and unique benefits from **the industry's first cordless design**.

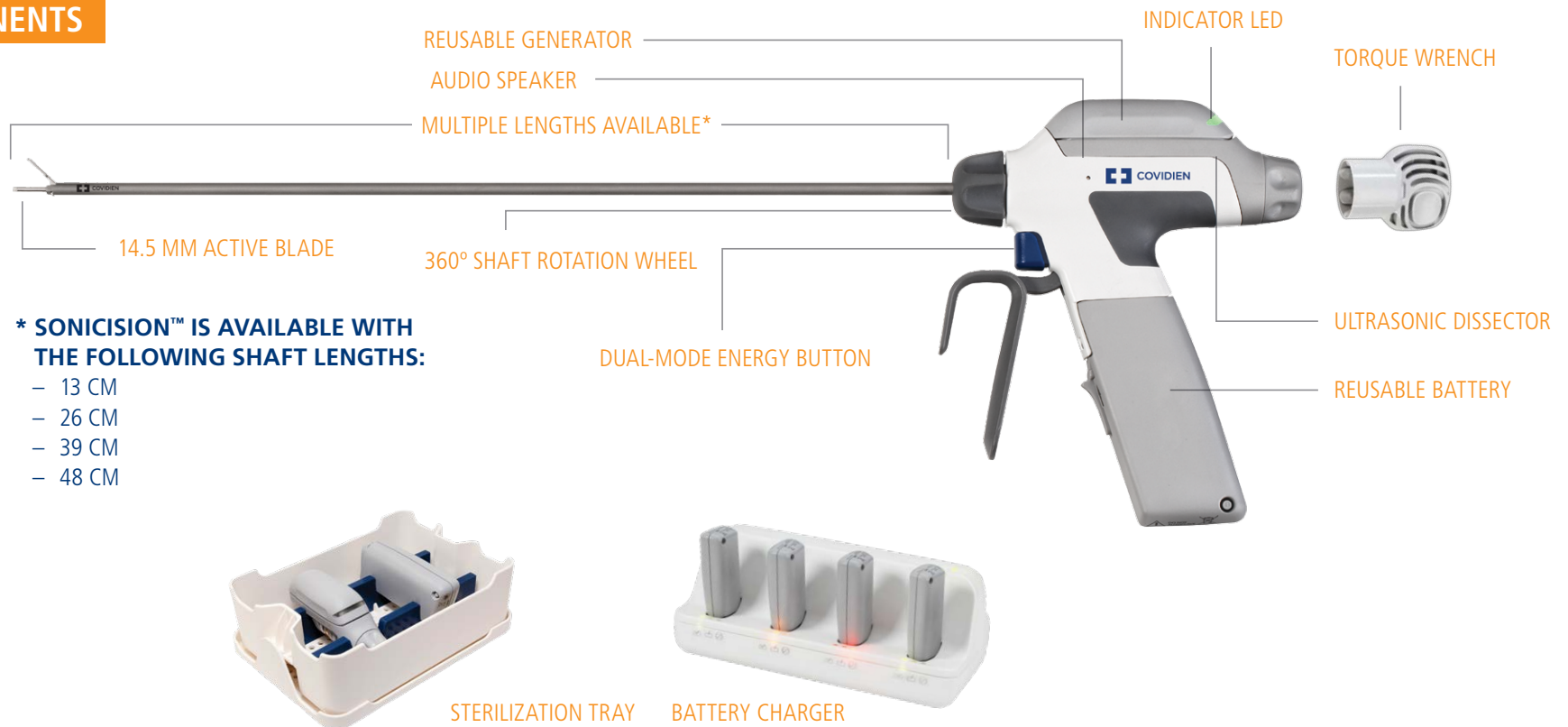
The Sonicision™ device allows **improved freedom of movement** in the operating room through the innovation of cordless technology. The streamlined design features a **quick and simple set up** that increases O.R. efficiency.

The Sonicision™ device also utilizes a unique **dual-mode energy activation control** for seamless transition between two power modes within a single button. This intuitive design allows a surgeon's eyes to remain in the surgical field rather than on the instrument **for improved procedural focus**.

The Sonicision™ system is composed of **single-use and reusable components** for maximum efficiency and utilization in surgical specialties that include: general (including upper gastrointestinal), bariatric, colorectal, pediatrics, gynecological and urological procedures.

The Sonicision™ device reliably seals vessels up to 5 mm, provides faster dissection speed² and up to 5x less plume than the Harmonic ACE™*³, and is comparable to the Harmonic ACE™* and Harmonic ACE+™* in thermal spread⁸, burst pressure¹¹, sealing time⁹ and temperature.^{2,4,10}

COMPONENTS



Product Overview

AVAILABLE LENGTHS

ULTRASONIC DISSECTOR

- Single patient use
- 5 mm diameter
- 14.5 mm active blade
- Dual-mode energy button (minimum and maximum)

13 CM LENGTH



Ordering Code: SCD13
Order Quantity: 6 ultrasonic dissectors 13 cm (1 torque wrench included with each dissector)

26 CM LENGTH



Ordering Code: SCD26
Order Quantity: 6 ultrasonic dissectors 26 cm (1 torque wrench included with each dissector)

39 CM LENGTH



Ordering Code: SCD396
Order Quantity: 6 ultrasonic dissectors 39 cm (1 torque wrench included with each dissector)

SCD391
(select countries only)
1 ultrasonic dissector 39 cm
(1 torque wrench included)

48 CM LENGTH



Ordering Code: SCD48
Order Quantity: 6 ultrasonic dissectors 48 cm (1 torque wrench included with each dissector)

Product Overview

AVAILABLE LENGTHS

REUSABLE BATTERY

Ordering Code: SCG
Order Quantity: 1 battery pack

- Reusable for up to 100 uses
- Sterilizable via low temperature hydrogen peroxide
- Advanced lithium polymer battery chemistry



BATTERY CHARGER

Ordering Code: CBC
Order Quantity: 1 battery charger (batteries not included)

- Four charging bays
- Supports charging of 4 batteries simultaneously



REUSABLE GENERATOR

Ordering Code: SCG
Order Quantity: 1 generator

- Reusable for up to 100 uses
- Sterilizable via low temperature hydrogen peroxide
- Integrated LED provides device feedback



STERILIZATION TRAY

Ordering Code: SCST (U.S. customers only)
SCST1 (outside U.S. customers only)
Order Quantity: 1 sterilization tray

- Holds one generator and one battery



Award-Winning Device

MDEA GOLD

The Medical Design Excellence Awards (MDEA) competition is the MedTech Industry's Premier Award — given to the most significant advances in medical product design and engineering of a groundbreaking product in the surgical equipment.



RED DOT

An international design and business competition awarded by the Design Zentrum Nordrhein, Westfalen in Essen, Germany. An internationally recognized quality label and award for excellent design selected by expert juries in the areas of product design, communication design and design concepts.



reddot award 2014
winner

ESP AWARD

At the 2013 Excellence in Surgical Products Award, the Sonicision™ System won in the Best in Show category (2nd place). Based on products that have contributed to surgical performance, efficiency and safety.



BOULDER IQ

The Innovation Quotient, or IQ, program honors the most innovative new products and services in Colorado. The Sonicision™ System won both the Innovation of the Year Award from the audience and the Business Products and Services category from a panel of judges.



2013 WINNER



Thermal spread, vessel burst pressure, hemostasis, seal time and blade temperature are comparable to the Harmonic ACE™* and Harmonic ACE+™*2, 4, 8-11

Clinical Performance

Performance of the Sonicision™ Cordless Ultrasonic Dissection Device compared to the Harmonic ACE™* and Harmonic ACE+™*.

OVERVIEW

- The Sonicision™ device mean thermal spread, mean vessel burst pressure, hemostasis, mean seal time and mean peak active blade temperature are comparable to the Harmonic ACE™* and Harmonic ACE+™*2,4,8-11
- The Sonicision™ device provides faster dissection speed than the Harmonic ACE™*2
- The Sonicision™ device produces up to 5x less plume than the Harmonic ACE™*3
- The Sonicision™ device provides faster active blade cool down time to 60°C than the Harmonic ACE™*1
- The Sonicision™ device reliably seals vessels up to 5 mm in diameter2

BACKGROUND

Energy-based hemostatic devices have evolved over the past century to become an essential tool in surgery. The latest innovation from Covidien into this arena is the completion of the Sonicision™ cordless ultrasonic portfolio. Now with four available shaft lengths, inclusive of the the longest and shortest pistol grip ultrasonic device on the market with optimized ergonomic design. In turn, this portfolio utilizes advanced ultrasonic technology to provide rapid dissection and hemostasis without the need for a stand-alone generator or cord, therefore increasing the ease of operation and freedom of movement. A variety of tests have been performed to date by Covidien to evaluate the performance of the Sonicision™ device compared to the Harmonic ACE™* and Harmonic ACE+™*.

The following table summarizes the pre-clinical comparative testing between the Sonicision™ device and the Harmonic ACE™*:

SUMMARY

Differences between the Sonicision™ cordless ultrasonic dissection device and the Harmonic ACE™* were found to be non-significant in regard to mean vessel burst pressure, mean thermal spread, mean peak active blade temperature and mean seal time. The Sonicision™ device was **statistically faster in mean dissection speed and mean active blade cool down time to 60 degrees C in these tests.**^{1,2,4}

| | Mean Vessel Burst Pressure (mmHg ± SD) ² | Mean Dissection Speed (sec ± SD) ² | Mean Peak Active Blade Temperature (°C ± SD) ⁴ | Mean Active Blade Cool Down Time to 60°C (sec ± SD) ¹ | Mean Thermal Spread (mm ± SD) ² | Mean Seal Time (sec ± SD) ² |
|-----------------------|---|---|---|--|--|--|
| Sonicision™ | 578 ± 284 | 24.8 ± 4.9 | 249.7 ± 24.3 | 41.2 ± 1.3 | 1.06 ± 0.05 | 5.2 ± 1.7 |
| ACE™* | 605 ± 288 | 33.8 ± 5.4 | 239.3 ± 28.4 | 50.4 ± 7.5 | 1.08 ± 0.5 | 4.9 ± 1.5 |
| P-Value | 0.48 | <0.001 | 0.173 | 0.006 | 0.82 | 0.20 |
| Statistical Relevance | NS | Statistically Significant | NS | Statistically Significant | NS | NS |

Sonicision™ provides faster dissection² and has a faster active blade cool down time⁴ than the Harmonic Ace™*.

| | Average Coagulation Obstruction | Average Cutting Obstruction |
|-----------------------|--------------------------------------|--------------------------------------|
| | Maximum Obstruction (%) ³ | Maximum Obstruction (%) ³ |
| Sonicision™ | 4.80 ± 0.86 | 8.76 ± 1.49 |
| ACE™* | 26.63 ± 3.70 | 12.65 ± 0.97 |
| P-Value | <0.001 | 0.026 |
| Statistical Relevance | Statistically Significant | NS |

Sonicision™ produces up to 5x less plume than the Harmonic Ace™*³



The following table summarizes benchtop testing between the Sonicision™ device and the Harmonic ACE+™*:

| | Mean Vessel Burst Pressure (mmHg ± SD) ¹¹ | Mean Dissection Speed (sec ± SD) ¹⁰ | Mean Peak Active Blade Temperature (°C ± SD) ¹⁰ | Mean Active Blade Cool Down Time to 60°C (sec ± SD) ¹⁰ | Mean Thermal Spread (mm ± SD) ⁸ | Mean Seal Time (sec ± SD) ⁹ |
|-----------------------|--|--|--|---|--|--|
| Sonicision™ | 868.4 ± 419.9 | 43.4 ± 7.0 | 263.1 ± 18.8 | 37.6 ± 4.4 | 1.44 ± 0.5 | 8.40 ± 3.60 |
| ACE+™* | 1030.1 ± 405.1 | 44.6 ± 4.3 | 266.3 ± 20.2 | 37.4 ± 5.8 | 1.25 ± 0.2 | 8.12 ± 3.74 |
| P-Value | P = 0.18 | P = 0.777 | P = 0.771 | P = 0.704 | P = 0.100 | P = 0.62 |
| Statistical Relevance | NS | NS | NS | NS | NS | NS |

The Harmonic Ace+™* showed no statistical improvements compared to the Sonicision™ ultrasonic dissector.





Procedural Applications

OPEN PROCEDURES

Colorectal

- Abdominoperineal Resection
- Low Anterior Resection

General

- Axillary Node Dissection
- Liver Resection
- Mastectomy
- Ventral Hernia

Gynecology

- Myomectomy
- Total Abdominal Hysterectomy

Pediatrics

- Appendectomy
- Colectomy
- Splenectomy

Thoracic

- Pneumonectomy
- Pulmonary Lymph Node Dissection

Urology

- Prostatotomy

LAPAROSCOPIC PROCEDURES

Bariatric

- Gastric Band
- Roux-en-Y
- Sleeve Gastrectomy

Colorectal

- Colectomy

General

- Adrenalectomy
- Appendectomy
- Cholecystectomy
- Nissen Fundoplication
- Splenectomy

Gynecology

- Hysterectomy
- Lysis Pelvic Adhesions
- Salpingo-Oophorectomy
- Supracervical Hysterectomy

Thoracic

- Lobectomy
- Minimally Invasive Esophagectomy

Urology

- Cystectomy
- Nephrectomy

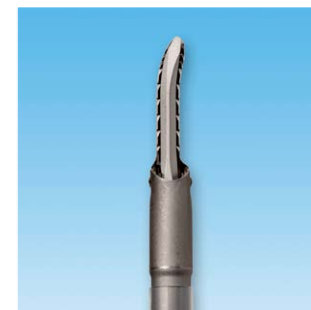
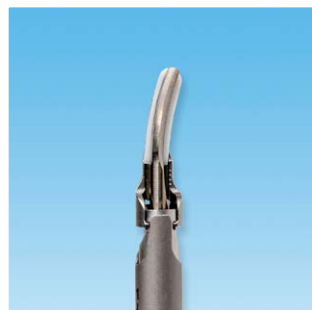
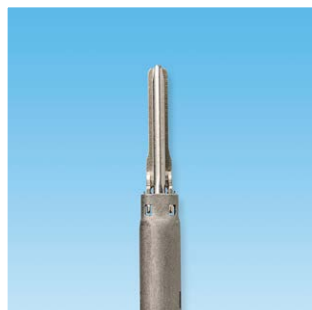
Complete Product Portfolio

The right energy solution for procedural need and surgeon preference — from a single manufacturer

| Dissection | Multi-Function | | Vessel Sealing |
|---|---|---|--|
| <ul style="list-style-type: none">• Smaller vessels | <ul style="list-style-type: none">• Primarily dissection with some vessel sealing | <ul style="list-style-type: none">• Primarily vessel sealing with some dissection | <ul style="list-style-type: none">• Up to 7 mm vessels |
| Electrosurgery | Ultrasonic | RF and ES | RF |
| Force TriVerse™ | Sonicision™ | LigaSure Advance™ II | LigaSure™ 5 mm |
| <ul style="list-style-type: none">• Sterile field power control• Access to Valleylab™ mode | <ul style="list-style-type: none">• Freedom (cordless)• Standardization• Faster set up and dissection² | <ul style="list-style-type: none">• Multi-functionality• Bariatric length (44 cm)• Valleylab™ mode dissection | <ul style="list-style-type: none">• Proven LS performance• Independent cutting and sealing• Cooler temperature profile |

Competitive Comparison

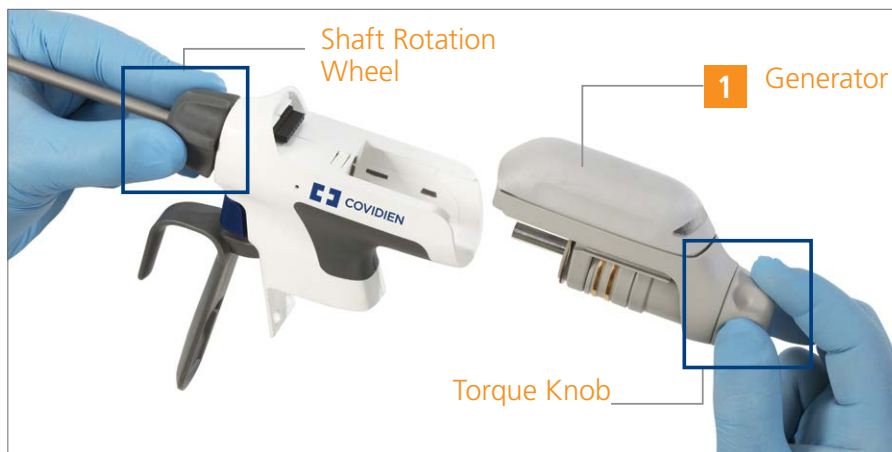
ULTRASONIC DISSECTOR COMPARISON



| Measure: | Sonicision™ | J&J Harmonic™ ACE | J&J Harmonic ACE+™* | Olympus Thunderbeat™* |
|---|--|--|------------------------|--|
| Shaft Length | - 13 cm - 26 cm - 39 cm - 48 cm | - 14 cm - 23 cm - 36 cm - 45 cm | - 23 cm - 36 cm | - 10 cm - 20 cm - 35 cm - 45 cm |
| Method of Activation | Hand 1 button, 2 stage | Hand 2 buttons | Hand 2 buttons | Hand 2 buttons |
| Frequency | 55.5 khz | 55.5 khz | 55.5 khz | 47.7 khz |
| Jaw Length ¹² | 14.5 mm | 11.1 mm | 10.7 mm | 16.5 mm |
| Total Weight of Device Assembled ¹³ (with cords and transducer) | 394.25 grams | 337.47 grams | 341.86 grams | 386.86 grams |

Assembly and Disassembly

STEP 1 – ATTACH AND TORQUE GENERATOR



1. Slide the generator into the opening of the ultrasonic dissector and hand tighten clockwise while holding the shaft rotation wheel.



2. Place torque wrench over the generator torque knob.
3. Rotate clockwise while holding rotation wheel in place until two clicks are felt or heard.

Remove torque wrench and keep in sterile field.

Assembly and Disassembly

STEP 2 – ATTACH BATTERY



1. Orient battery pack as shown.
2. Swing the battery forward and snap into place.

When properly assembled, a series of tones sound and the LED on the generator illuminates green.

STEP 3 – TEST



1. With jaws open, activate the dual-mode energy button in minimum (half squeeze) and maximum (full squeeze) power modes.

Device is ready for use if minimum and maximum power pulsating tones are heard.

Assembly and Disassembly

REPLACING BATTERY



1. Remove battery by pushing up on the battery pack release latch.
2. Swing the battery toward the rear of the ultrasonic dissector to disconnect.
3. Attach new battery as shown in Step 2 above.

When the device is fully assembled repeat STEP 3 - TEST.

INTRAOPERATIVE TROUBLESHOOTING



RED INDICATOR LIGHT
Device is non-functional

1. Clean jaw and blade (wipe with wet gauze and/or immerse in saline and activate energy with jaws open).
2. Disconnect and reconnect battery.
3. Replace battery.
4. Replace ultrasonic dissector.

Assembly and Disassembly

GENERATOR INDICATOR LIGHTS



GREEN

System is ready (minimum or maximum power).



RED

Device is non-functional (see intraoperative troubleshooting section or IFU).



FLASHING YELLOW

Battery charge is less than 20% capacity (approximately 10-20 activations remaining upon initial notice).



FLASHING PURPLE

Generator has reached end of life (replace generator).

Cleaning and Sterilization

CLEANING

1. Preparation for Cleaning

- Visually inspect the generator, battery, and sterilization tray for damage. Replace if damaged.
- Prepare a solution of pH neutral, pH neutral enzymatic or alkaline detergent in accordance with the manufacturer's instructions.

2. Soaking

- Soak the generator, battery and sterilization tray in the detergent mix for 5 to 10 minutes.

3. Manual Cleaning

- Manually clean the battery, generator and sterilization tray using a stiff, nylon bristle brush and the detergent solution.
- Thoroughly clean the generator retention ring, generator seam, battery seam, battery pack release latch and battery contact points. Do not use abrasive cleaning agents or metal cleaning tools, such as stainless steel brushes.
- Thoroughly rinse components with clean water.

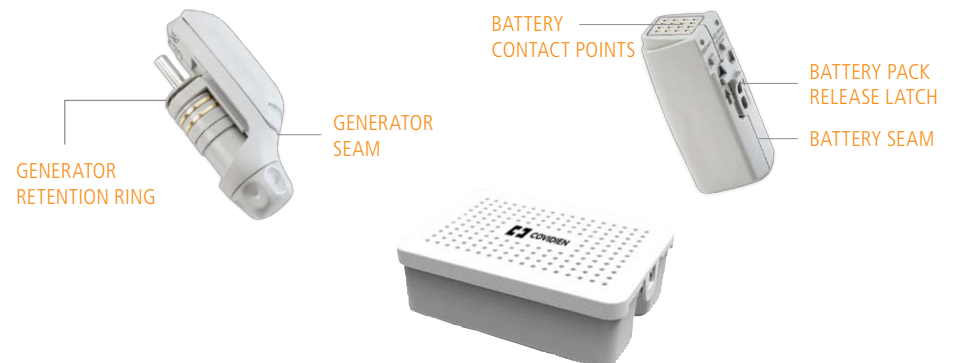
CAUTION: DO NOT wash components in automatic instrument washer or ultrasonic washer.

4. Drying

- Dry generator, battery and sterilization tray with a clean, lint-free cloth. With cool, clean oil-free air, blow dry all components until completely dry.

5. Disinfecting (optional)

- If facility processes require disinfection prior to sterilization, wipe the surfaces of the generator, battery and sterilization tray with an isopropyl-alcohol (up to 100%) surface disinfectant.



Cleaning and Sterilization

STERILIZING

1. Ensure generator, battery and sterilization tray are clean and dry before sterilization.
2. Place the generator and battery in the tray.
3. Cover sterilization tray base with lid and latch.
4. Utilize one of the following sterilization configurations:

| Sterilizer | Sterile Barrier | | |
|----------------------|--------------------|----------------------|----------------------|
| | Polypropylene Wrap | Tyvek Pouch (Single) | Tyvek Pouch (Double) |
| STERRAD™ 100S | ✓ | | |
| STERRAD™ NX™ | ✓ | ✓ | |
| STERRAD™ 100NX™ | ✓ | ✓ | ✓ |
| STERIS V-PRO™ 1 | ✓ | ✓ | ✓ |
| STERIS V-PRO™ 1 PLUS | ✓ | ✓ | ✓ |
| STERIS V-PRO™ maX | ✓ | ✓ | ✓ |

CAUTION: DO NOT STEAM AUTOCLAVE, FLASH or use EtO to sterilize any part of the device or accessories. Use low-temperature hydrogen peroxide sterilization only.

5. Follow these steps according to the sterile barrier selected:
 - **Polypropylene Wrap** – Wrap the sterilization tray in a compatible polypropylene sterilization wrap according to the manufacturer's instructions.
 - **Single Tyvek Pouch** – Place the sterilization tray in a single compatible Tyvek pouch, and seal according to the manufacturer's instructions.
 - **Double Tyvek Pouch** – Place the sterilization tray within two compatible Tyvek pouches, and seal according to the manufacturer's instructions. The Tyvek side of the inside pouch must be aligned with the Tyvek side of the outside pouch.
6. Sterilize the generator and battery within the enclosed sterilization tray using the following STERRAD™ or STERIS V-PRO™ models/cycles in accordance with manufacturer's instructions:

| Model | Cycle |
|-----------------------------|--------------------------|
| STERRAD™ 100S | Standard, Short or Long* |
| STERRAD™ NX™ | Standard |
| STERRAD™ 100NX™ | Standard |
| STERIS AMSCO™ V-PRO™ 1 | Lumen |
| STERIS AMSCO™ V-PRO™ 1 Plus | Lumen |
| STERIS AMSCO™ V-PRO™ maX | Lumen |

*Short and Long cycles are not available on 100S models sold in the United States

Cleaning and Sterilization

STORAGE

Storing System

- Store system components at 64° F to 77° F (or 18° C to 25° C). Elevated temperatures can result in reduced battery-service life.
- Recharge and re-sterilize battery packs after one month of continuous storage to ensure adequate charge when needed.



CENTRAL PROCESSING

Used battery and generator exit O.R.

Cleaning and Decontamination

Manual Cleaning

Battery, Generator and Sterilization Tray
soak five to ten minutes in pH-neutral enzymatic, scrub with a stiff, nylon bristle brush



Stage Generator until battery charge is complete

Charge Battery

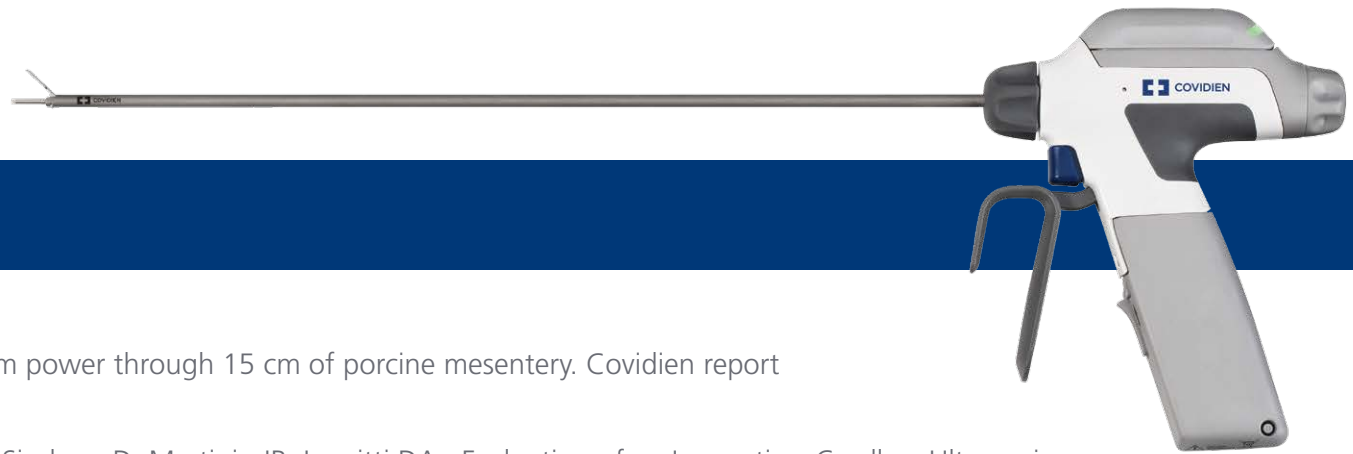


Place components in sterilization tray and wrap

Sterilize using low temperature sterilization (i.e. STERRAD™)

Store components. Recharge and sterilize batteries after one month of storage

CAUTION: Do not steam Autoclave, flash, or use EtO to sterilize any part of the device or accessories. Use low-temperature hydrogen peroxide gas plasma sterilization (i.e., STERRAD™) only.



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The Sonicision™ System


The Science of Performance, The Ease of a Full Portfolio

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5920 LONGBOW DRIVE
BOULDER, CO
80301
UNITED STATES

800-722-8772

WWW.COVIDIEN.COM/SONICISION



ULTRASONIC DISSECTION PRODUCTS

Sonicision™ 7 curved jaw cordless ultrasonic dissection device

The Sonicision™ 7 curved jaw ultrasonic dissector is a cordless device capable of coagulating and dissecting vessels.

Ordering information

Contact a representative

Description

Experience cordless freedom with the Sonicision™ 7 curved jaw ultrasonic device.

Effortless efficiency

- Dual-mode energy activation button provides more efficiency in surgical procedures than multi-button activation^{1,1}
- 7 mm vessel coagulation capability improves surgical efficiency over devices that coagulate vessels up to 5 mm^{1,1}
- Easy assembly enables procedural efficiency, allowing nurses to have the device ready before the surgeon and patient are in the operating room^{5,9,2,3}

The essence of ease

- Dual-mode energy control in one button improves procedural focus^{8,1}
- Design facilitates comfortable use throughout a variety of procedures^{8,2}
- Integrated torque wrench simplifies setup^{3,3}

The power of portability

- Enables more natural movement^{6,2}
- Makes instrument exchanges easier^{7,1,2}
- Saves space in the OR with a smaller footprint^{8,3}

Features

The tapered jaw design of the Sonicision™ 7 curved jaw device – designed for access and visibility

The tapered jaw design of the Sonicision™ 7 curved jaw device provides the access and visibility you need to advance care. Get precise access to tissue planes^{1,3} and access in tight spaces.^{4,3} Visualize target structures^{5,3} and the tips of the device throughout your procedures.^{4,3} Discover its ability to follow curved anatomical structures.^{3,3}



Next-generation design meets everyday convenience

With the Sonicision™ 7 curved jaw device, you'll get a generator and battery that are reliable and efficient before, during, and after your procedures.



- A reusable generator enables:

 - Use for 150 procedures before replacement⁴
 - Streamlined cleaning and sterilization because it's autowashable and autoclavable
- A reusable nonsterile battery pack provides:

 - 88% greater capacity^{11,5} to instill confidence of consistent power throughout long procedures
 - 200 procedural uses^{6,7} – twice the number of earlier devices¹¹
- An intuitive, easy-to-use^{4,3} battery charger that:

 - Makes it easy to interpret battery charge status^{4,3} and battery end-of-life indications^{8,3}
 - Enables efficient battery usage management^{4,3}

The culmination of innovation

Every step matters on the journey toward clinical innovation. That's why we gauge each piece of our cordless ultrasonic dissection system through that lens – and design meaningful solutions to your most pressing needs.

100%

100% of surgeons surveyed agree the Sonicision™ 7 curved jaw device is comfortable to use throughout procedures.^{8,2}

100%

100% of nurses surveyed agree the Sonicision™ 7 curved jaw device's troubleshooting steps are clear and easy to follow.^{4,3}

Majority

The majority of surgeons surveyed agree the Sonicision™ 7 device's dual-mode activation button is more intuitive than the activation buttons on the Harmonic Ace™ +7 device.^{90,1}

Ordering information

| Item number | Description | Units per case |
|-------------|--|----------------|
| SCD7A13 | Sonicision™ 7 13 cm curved jaw cordless ultrasonic dissector | 6 |
| SCD7A26 | Sonicision™ 7 26 cm curved jaw cordless ultrasonic dissector | 6 |
| SCD7A39 | Sonicision™ 7 39 cm curved jaw cordless ultrasonic dissector | 6 |
| SCD7A48 | Sonicision™ 7 48 cm curved jaw cordless ultrasonic dissector | 6 |
| BCBA | Sonicision™ battery charger | 1 |
| SCSTA | Sonicision™ sterilization tray | 1 |
| SCBA | Sonicision™ battery, reusable 200x | 1 |
| SCBIGA | Sonicision™ battery insertion guide | 2 |
| SCG7AA/AB | Sonicision™ 7 generator reusable 150x | 1 |

Resources

Sonicision™ 7 Curved Jaw Device Information Sheet
Get an overview of the features of the Sonicision™ 7 curved jaw cordless ultrasonic dissector.
PRODUCT • PDF • 6 MB

Sonicision™ 7 Curved Jaw Value Added Brochure
Review an in-depth value analysis of the Sonicision™ 7 curved jaw cordless ultrasonic device.
ECONOMICS AND REIMBURSEMENT • PDF • 11 MB

Sonicision™ 7 Curved Jaw Device Sustainability Information Sheet
Access general sustainability information and claims for the Sonicision™ 7 curved jaw cordless ultrasonic dissector.
PRODUCT • PDF • 4 MB

Videos

Sonicision™ 7 Curved Jaw Ultrasonic Dissector – Competitive Advantages (01:27)

Dr. Billy Discusses Design Features of the Sonicision™ 7 Curved Jaw Ultrasonic Dissector (04:09)

Dr. Billy Discusses the Benefits of Using the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Device (06:38)

Dr. Billy Discusses Using the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Device in Bariatric Procedures (04:14)

Dr. Temmermand Discusses Using Sonicision™ 7 Curved Jaw Cordless Ultrasonic Device in Thyroidectomy Procedures (04:22)

Related products

LigaSure™ XP Maryland jaw sealer-divider with nano-coating
The LigaSure™ XP Maryland jaw device offers next-level vessel sealing technology – including latching handles and one-step sealing.

LigaSure™ retractable L-hook laparoscopic sealer-divider
The LigaSure™ retractable L-hook laparoscopic sealer-divider combines the functionality of five laparoscopic devices into one versatile instrument.

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1 23 out of 27 surgeons surveyed after use agreed.

1 25 out of 27 surgeons surveyed after use agreed.

5 29 out of 33 surgeons surveyed after use agreed.

9 24 out of 29 (82%) nurses surveyed after use answered extremely easy (59%) or easy (24%).

1 21 out of 27 surgeons surveyed after use agreed.

8 33 out of 33 surgeons surveyed after use agreed.

14 14 out of 14 (100%) nurses surveyed after use agreed.

30 30 out of 33 surgeons surveyed after use agreed.

1 1 Compared to the first-generation Sonicision™ system.

1 28 out of 28 (100%) nurses surveyed after use agreed.

5 27 out of 28 (96%) nurses surveyed after use agreed.

90 In a head-to-head comparison with the Harmonic Ace™ +7 device, seven of eight surgeons surveyed after use said the dual mode activation button of the Sonicision™ 7 device was more intuitive to use than the activation buttons for the Harmonic Ace™ +7 device.

1. Based on internal test report RE00329878 rev A, Marketing evaluation of surgeon experience using the Sonicision™ 7 curved jaw cordless ultrasonic dissector. April 14-15 and 20-22, 2021.

2. Based on internal test report R0042752 rev A, Marketing evaluation of surgeon experience using the Sonicision™ curved jaw cordless ultrasonic dissector. February 13-17, February 28, March 3, May 16, 2017.

3. Based on internal test report R0049393 rev A, Operating room staff marketing evaluation of the Sonicision™ curved jaw cordless ultrasonic dissector. December 1, 6-7, 2016.

4. Based on internal test report RE00153542, rev B, Reusable life test verification report (SCGAA-TA9) August 24, 2017.

5. Based on internal test memo RE00153542, rev B, Battery capacity comparison between SCBA and SCBA. May 17, 2018.

6. Based on internal test report R0042707, rev A, Reusable life test verification report for the SCBA reusable battery pack. April 26, 2017.

7. Based on internal test report RE00113195, rev A, Reusable life test verification report for the SCBA reusable battery pack – Oxivir, September 13, 2017.