

HARMONIC® (Ultrasonic) – CIN-Energy

Product Information Re Transition from MDD to MDR

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Shaping
the future
of surgery

Agenda

- 1 Objective & Scope
- 2 Summary of Key Changes
- 3 Details of Key Changes
- 4 Product Information
- 5 Further Information



Objective & Scope

Objective | HARMONIC® (Ultrasonic)

Background

- The HARMONIC® instruments are sterile, single-patient use devices indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired
- All Labeling and Marketing assets must be updated to comply to the new Medical Device Regulation (MDR).



Objective

- After reading this document, you will be able to:
- Provide references to product information and IFU document link.
 - Understand indication and contraindication changes
 - Understand the new warning and precautions (hazardous and / or restricted substances) as a result of the EU Medical Device Regulation



Summary of Key Changes

Summary of Changes for Products in Scope

Change	Applicable
IFU updated for clinical indication claims or intended use.	YES
IFU updated for clinical contraindication claims.	YES
Additional languages and symbols added to the EU labels.	YES*
IFU general updates and rewording.	YES*
eIFU Available.	YES*
Restricted substances symbols added to Labels and IFU.	YES
Well Established Technology (WET).	NO
Patient Implant Card to comply with Article 18.	NO
Patient Target Group changed.	NO
Warnings/Precautions.	YES*
Expected Clinical Benefits.	NO
Adverse Events/Side-Effects.	NO
IFU updates for reprocessing of reusable instruments.	YES*
IFU updates for processing of single-use implants.	NO

* The above changes apply to all the products impacted by MDD to MDR transition.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.



Details of Key Changes

Changes in Indications for Use

MDD vs MDR

MDD

Indications (Product Code: HAR9F, HAR17F)

The ~~Harmonic Focus® / Harmonic Focus® Long Shears + Adaptive Tissue Technology/~~ are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic ~~exposure to orthopedic structures (such as spine and joint space) and other open~~ procedures.

MDR

Indications

The HARMONIC® FOCUS SHEARS + ADAPTIVE TISSUE TECHNOLOGY are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, and urologic procedures.

➤ *Narrowing of Indication statement*

Changes in Indications for Use

MDD vs MDR

MDD

Indications (Product Code: HAR23, HAR36)

The HARMONIC® ACE® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrocautery, lasers and steel scalpels in general, ~~plastic~~, pediatric, gynecologic, urologic, thoracic, ~~exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic~~ procedures.

Indications (Product Code: HARH23, HARH36, HARH45)

The HARMONIC® ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrocautery, lasers and steel scalpels in general, ~~plastic~~, pediatric, gynecologic, urologic, thoracic, ~~exposure to orthopedic structures (such as spine and joint space)~~, sealing and transection of lymphatic vessels, ~~and other open and endoscopic~~ procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.

MDR

Indications

The HARMONIC® ACE Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrocautery, lasers and steel scalpels in general, pediatric, gynecologic, urologic, thoracic procedures.

The HARMONIC® ACE+7, 5 mm Diameter Shears with Advanced Hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrocautery, lasers and steel scalpels in general pediatric, gynecologic, urologic, thoracic ~~procedures~~, sealing and transection of lymphatic vessels. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the ~~Energy button with~~ Advanced Hemostasis hand control button



➤ *Narrowing of Indication statement*

Changes in Indications for Use

MDD vs MDR

MDD

Indications (Product Code: HARHD20, HARHD36)

The HARMONIC® HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, ~~plastic~~, pediatric, gynecologic, urologic, thoracic procedures, ~~exposure to orthopedic structures (such as spine and joint space)~~, sealing and transection of lymphatic vessels, ~~and other open and endoscopic procedures~~. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

Indications (Product Code: HDH05)

The HARMONIC® 5 mm Instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, ~~plastic~~, gynecologic, ~~exposure to orthopedic structures (such as spine and joint space)~~, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

MDR

Indications

The HARMONIC® HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, pediatric, gynecologic, urologic, thoracic procedures and sealing and transection of lymphatic vessels. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

The HARMONIC® 5 mm Instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, and gynecologic procedures.



➤ *Narrowing of Indication statement*

Changes in Indications for Use

MDD vs MDR

MDD

Indications (Product Code: SNGCB)

-The HARMONIC® SYNERGY Dissecting Hook instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures, and oropharyngeal airway, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Indications (Product Code: SNGHK)

-The HARMONIC® SYNERGY® Combination Hook Blade instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Indications (Product Code: SNGHK2)

-The HARMONIC® SYNERGY Curved Blade instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space) and thoracic surgery.

MDR

Indications

-The HARMONIC® SYNERGY Dissecting Hook instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures, and oropharyngeal airway, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

-The HARMONIC® SYNERGY® Combination Hook Blade instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, exposure to orthopedic structures (such as spine and joint space), ENT (Ears, Nose, Throat), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

-The HARMONIC® SYNERGY Curved Blade instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, exposure to orthopedic structures (such as spine and joint space) and thoracic surgery.





➤ **Narrowing of Indication statement**
“gynecologic” removed from the indications for the above products



HARMONIC® - Restricted Substances

One or more components of this device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:

 #	Material Present	Residual Risk
 1	Cobalt: CAS No. 7440-48-4 EC No. 231-158-0	<i>Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.</i>

Product Codes Impacted:

- HAR17F
- HAR23
- HAR36
- HAR9F
- HARH23
- HARH36
- HARH45
- HARHD20
- HARHD36



Product Information

Product Information | Reference Documents

- The HARMONIC® FOCUS+, ACE+, HD 1000i, SYNERGY are intended for soft tissue incisions when bleeding control and minimal thermal injury are desired.
- The HARMONIC® Hand Piece and Blue Hand Piece are designed to convert electrical energy from a compatible HARMONIC® Generator to mechanical motion for the instrument blades. This Hand Piece is intended for use with a compatible HARMONIC® Generator. The Hand Piece is a re-useable instrument with a limited service life.
- The HARMONIC® Disposable Hand Switching Adaptor is a sterile, single-patient-use instrument intended to add hand switching capability to the HARMONIC® System
- For the most up to date Surgical Technique Guides and Product Catalogues linked to these brands, please contact your local Customer Service Team or Johnson & Johnson MedTech Sales Representative.
- Should you have any medical, scientific or technical questions, please submit them to our Medical Affairs team via the Medical Information Requests (MIR) portal link:
 - [Medical Information Request \(MIR\)](#)
- The EU MDR Resource Centre retains other relevant MDR information can be found via the following link:
 - [EU MDR Resource Centre](#)
- For more information about products and information please refer to the e-IFU page of this document.

Product Information | Reference Documents (IFU)

Use portal link below, with this information the relevant IFU(s) can be found with the SKU:

MDR: <https://www.e-ifu.com/>

ePIL (Patient Information Leaflet) on www.ic.jnjmedicaldevices.com

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.



Home Favorites History Settings Help

Welcome to e-IFU

The e-IFU website provides you with Instructions For Use (IFU) from Johnson & Johnson Medical Devices Companies.

This website is intended for Healthcare Professionals only.



Search by product code, product name, etc. Search box requires a minimum of three characters. For exact search results, enclose the search term in quotations.

This search will output the latest approved version of the IFU within your selected location. If you have any additional questions, please contact your local Johnson & Johnson Company for support. Contact information can be found on the "Contact Us" tab.





Further Information

Restricted Substance (RS) Primer & Fact Sheet

Note:

Presence of Restricted Substance (RS) such as cobalt, Hazardous Substance (HS) symbols have been added to the IFU and labels.

Our Portfolio

What does this mean for our product portfolio?
An internal assessment process has been implemented to scrutinize for the presence of RS in our products (e.g., patient contact devices) as well as to prepare the justification for use and labeling information when required.

Cobalt, as used in Cobalt Chrome alloy and as an impurity within Stainless Steel, is the Restricted Substance that has the most impact within our portfolio.

What does this mean regarding the safety of our products?

All CE marked products have been screened for RS and assessed for patient safety by the manufacturer in accordance to MDR; in addition, when CE marked, these products have been independently reviewed and approved by notified bodies for safety and conformance.

Restricted Substances Primer

The Requirements

What does the regulation require?

The EU MDR requires special attention to substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMRs 1A/1B), in accordance with the CLP legislation, and as endocrine disrupting chemicals (EDCs), in accordance with EU REACH and BPR. Both groups of chemicals are commonly referred to as Restricted Substances (RS).

Use of these materials above 0.1% w/w – when used in devices that are invasive and come into direct contact with the body, or (re)administer, transport or store from the body, liquids or other substances, to and labeling to indicate the presence of RS above these concentrations.

What if RS are identified above allowed limits in patient contact devices?

Changes to product labeling and patient information (PI/AMI/PI) are the primary changes needed.

Specifically, the presence of Restricted Substances (RS) and Cobalt L-Labeling information must be included.

RS will be included as a line item within EUCAMED once EUCAMED is live.

Health Care Professionals (HCPs) and patients may have questions regarding EUCAMED site is available.

Will MDD products require label changes?

MDD approved products already on the market may still be available on the market.

Product labeling and patient information for those products will NOT have MDR compliance. These products remain conformant.

For other Restricted Substance related questions, please contact Tim Hsu at thsu@ethicon.com.

© Johnson & Johnson Medical Devices. All rights reserved. For internal use only.

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Shaping
the future
of surgery



Thank you.

© Johnson & Johnson Medical Pty Ltd.

1-5 Khartoum Road, North Ryde, NSW 2113

211827-220504 EMEA

If you have questions, please contact your local customer service team or Johnson & Johnson MedTech sales representative. Alternatively, if you have any medical, scientific or technical questions please submit these questions to our Medical Affairs team via the Medical Information Requests (MIR) portal: [Medical Information Request \(MIR\)](#).

Disclaimer: This summary is offered without warranty of any kind, and any affiliate within the Johnson & Johnson family of companies accept(s) no responsibility or liability for any loss or damage arising from the use of or reliance upon this information.

ETHICON
PART OF THE  FAMILY OF COMPANIES

Reimagining how we heal™
