CONTOUR® Curved Cutter Stapler and Reloads

CIN-EndoMech

Product Information Re Transition from MDD to MDR

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Agenda

1. Objective and Scope
2. Details of Key Changes
3. Product Information

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Objective & Scope

Objective | CONTOUR® Curved Cutter Stapler and Reloads

Background

- The CONTOUR® Curved Cutter Stapler is intended for transection and resection in colorectal surgical procedures.
- All Labelling 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 additions and modifications to IFUs to comply with EU MDR
- Understand indication changes
- Understand the new warning and precautions (hazardous and / or restricted substances) as a result of the EU MDR regulations.

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Details of Key Changes

Indications | CONTOUR® Curved Cutter Stapler and Reloads

MDD vs MDR

MDD

INDICATIONS

The CONTOUR® Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses.
The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

MDR

Indications

The CONTOUR® Curved Cutter Stapler is intended for transection and resection in colorectal surgical procedures.

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Contraindications | CONTOUR® Curved Cutter Stapler and Reloads

MDD vs MDR

MDD

Contraindications

- This instrument is not intended for use when surgical stapling is contraindicated.
- Do not use the instrument with blue reload on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily to below 1.5 mm.
- Do not use the instrument with green reload on any tissue that requires excessive force to compress to 2.0 mm or on any tissue that compresses easily to below 2.0 mm.
- Do not use on ischemic or necrotic tissue.
- Do not use on major vessels without provision for proximal and distal control.
- Do not use the instruments on any portion of the aorta, the coronary, carotid, or pulmonary arteries or veins, the superior or inferior vena cava, common, internal or external iliac arteries and veins and the brachiocephalic trunk.
- Do not use the instrument on the vaginal cuff.

MDR

Contraindications

- This instrument is not intended for use when surgical stapling is contraindicated.
- Tissue thickness should be carefully evaluated before firing any stapler. Refer to the Product Codes Table* below for tissue compression requirement (closed staple height) for each staple size. If tissue cannot comfortably compress to the closed staple height listed in the table, or easily compresses to less than the closed staple height listed in the table, the tissue is contraindicated as it may be too thick or too thin for the selected staple size.
- Do not use on ischemic or necrotic tissue.
- Do not use on vessels.

* *(see Description section in the IFU or slide 8 for the table)*

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Product Codes Table | | CONTOUR® Curved Cutter Stapler and Reloads

MDD vs MDR

MDD

The product codes for the CONTOUR Curved Cutter Stapler and reloads are as follows:

Instrument	Reload	Description	Number of Staples	Reload Color	Tissue Thickness
CS40B	CR40B	Standard	46	Blue	1.5 mm
CS40G	CR40G	Thick	46	Green	2.0 mm

NOTE: The blue (standard) and green (thick) reloads can be used interchangeably with the instruments.

MDR

The product codes for the CONTOUR™ Curved Cutter Stapler and Reloads are as follows:

Instrument	Reload	Description	Number of Staples	Reload Color	Closed Staple Height
CS40B	CR40B	Standard	46	Blue	1.5 mm
CS40G	CR40G	Thick	46	Green	2.0 mm

NOTE: The blue (standard) and green (thick) reloads can be used interchangeably with the instruments.

This device is intended to be used by healthcare professionals trained and experienced in surgical procedures involving use of curved staplers for transection and resection.

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Restricted Substances | CONTOUR® Curved Cutter Stapler and Reloads

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	*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.*

The footnote adjacent to the above symbol on the packaging refers to the relevant Material Present

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Product Information

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Product Information | Reference Documents

- The CONTOUR® Curved Cutter Stapler is a multifire, single-patient-use device with a curved head that cuts and staples. The instrument may be reloaded five times, for a maximum of six firings per instrument during a single procedure. Reload cartridges are available in two sizes. The blue (standard) and green (thick) reloads can be used interchangeably with the instruments.

- The CONTOUR® Curved Cutter Stapler is supplied sterile and preloaded with one cartridge for single-patient use.

- 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.

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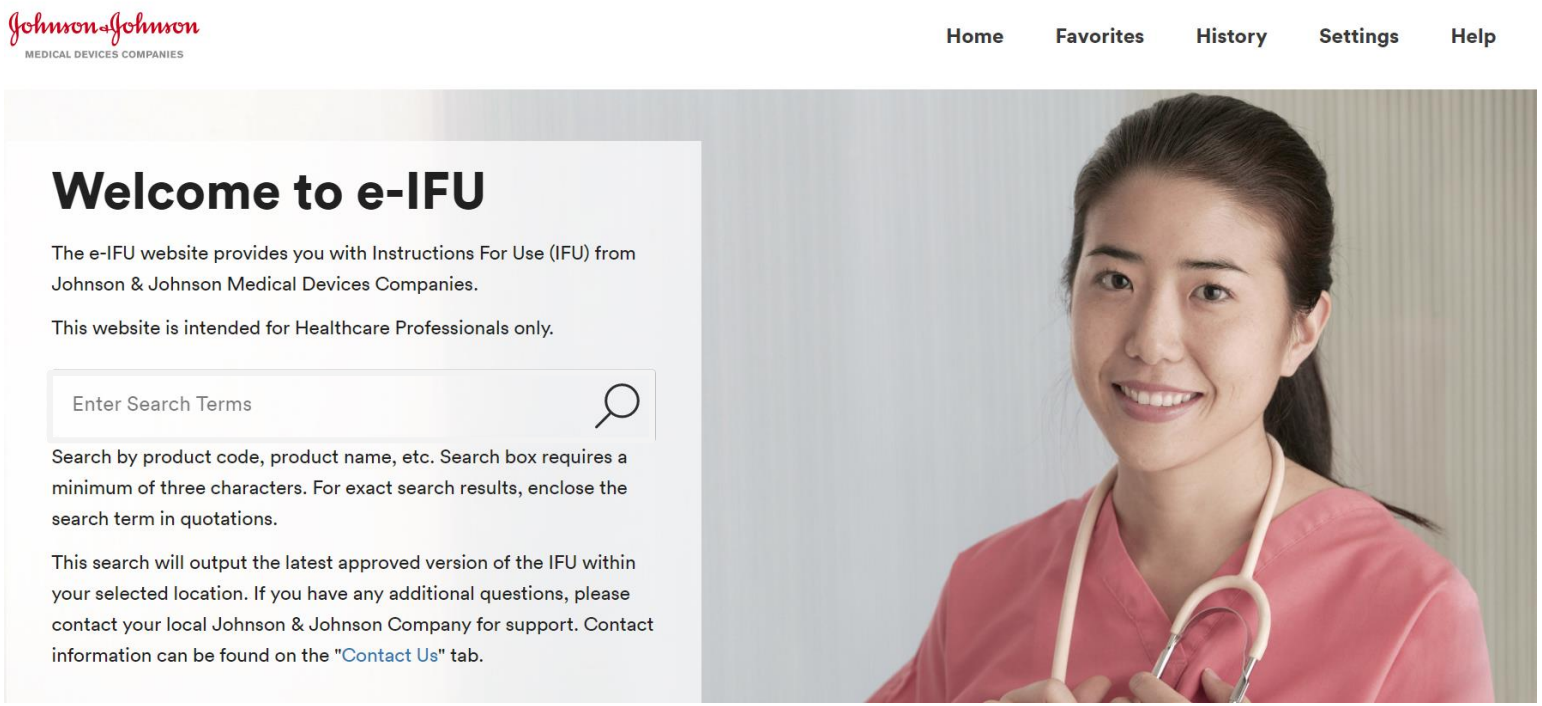
Product Information | Reference Documents (IFU)

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.



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Thank you.

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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).

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