Johnson&Johnson

MEDICAL COMPANIES

รายการที่ ๘ ตัวเจาะหน้าท้องปลายใสขนาด ๕ มม. ความยาว ๑๐๐ มม. ปลายใสแบบเดี่ยว

วัตถุประสงค์ เป็นอุปกรณ์ที่ใช้เจาะผนังหน้าท้อง เพื่อใช้เป็นทางหรือช่อง สำหรับใส่เครื่องมือในการผ่าตัดภายใต้กล้อง

คุณลักษณะ

๑. เป็นอุปกรณ์ที่ใช้เจาะผนังหน้าท้อง เพื่อใช้เป็นทางหรือช่อง สำหรับใส่เครื่องมือในการผ่าตัดภายใต้กล้อง

๒. อุปกรณ์ส่วนที่ใช้เจาะมีปลายเป็นพลาสติกใสปลายแหลมแต่ไม่คม ที่ด้านข้างทั้ง ๒ ข้าง มีปีกเล็กๆ สำหรับแยกเนื้อเยื่อ

๓. ก้านเจาะจะมีช่องใส่กล้อง (Scope) อยู่บริเวณด้านบนพร้อมกับมีที่ล็อคด้านหน้า

๔. ท่อชั้นนอกของตัวเจาะหน้าท้อง (Trocar sleeve) ส่วนด้านบนเป็นพลาสติกสีขาวขุ่นมีความลาดเอียง เพื่อสอดใส่เครื่องมือผ่านเข้าไปในตัวเจาะได้ง่าย โดยไม่ต้องใช้มือช่วยจับ

๕. ท่อชั้นนอกของตัวเจาะส่วนด้านล่างมีลักษณะใส เพื่อให้สามารถมองเห็นเครื่องมือ ขณะผ่านเข้าออก หรือขณะที่นำชิ้นส่วนของเนื้อเยื่อออกมา

๖. ด้านในของท่อชั้นนอกของตัวเจาะประกอบด้วยแผ่นยางสีดำมีรูตรงกลาง มีความยืดหยุ่นพอดีที่จะแนบกับเครื่องมือที่ผ่านเข้าออกขนาด ๕ มม.

๗. ก้านของท่อยาว ๑๐๐ มม. บริเวณส่วนกลางของก้านท่อชั้นนอกนี้จะมีเกลียวเล็กๆ เพื่อยึดผนังหน้าท้องไม่ให้เลื่อนหลุดขณะใช้งาน

๘. บรรจุแบบปลอดเชื้อ (Sterile Package) และสามารถใช้งานได้ทันที

๙. ผู้ยื่นเสนอราคาต้องมีสินค้าตามรายการพัสดุครบทุกรายการ

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A division of Johnson and Johnson (Thailand) Ltd.

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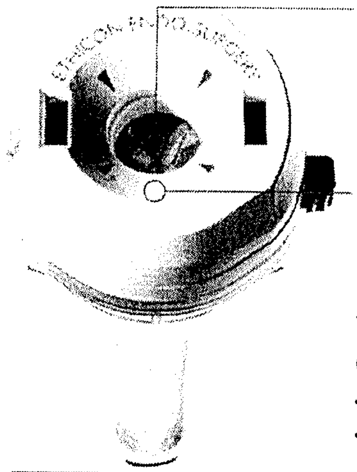
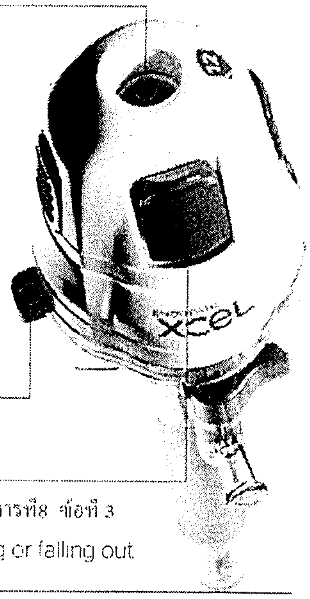
ENDOPATH XCEL® Bladeless Trocars





Optical Entry
รายการที่ 8 ข้อที่ 3
- Visualization is optically guided by a 0° endoscope
- Enables visualization of tissue layers during insertion

Durable Universal Seal
- No reducer caps needed รายการที่ 8 ข้อที่ 6
- Maintains insufflation
- Accommodates a wide range of instrument sizes (4.7mm to 12.9mm)

Funnel Lead-In
รายการที่ 8 ข้อที่ 4
- Enables smooth, one-handed instrument exchange

Release Lever
- Unlocks housing to facilitate large specimen removal

Camera Scope-Locking Tab
- Holds camera locked in place during visually guided entry รายการที่ 8 ข้อที่ 3
- Helps provide visual clarity and protects camera from scratching or falling out

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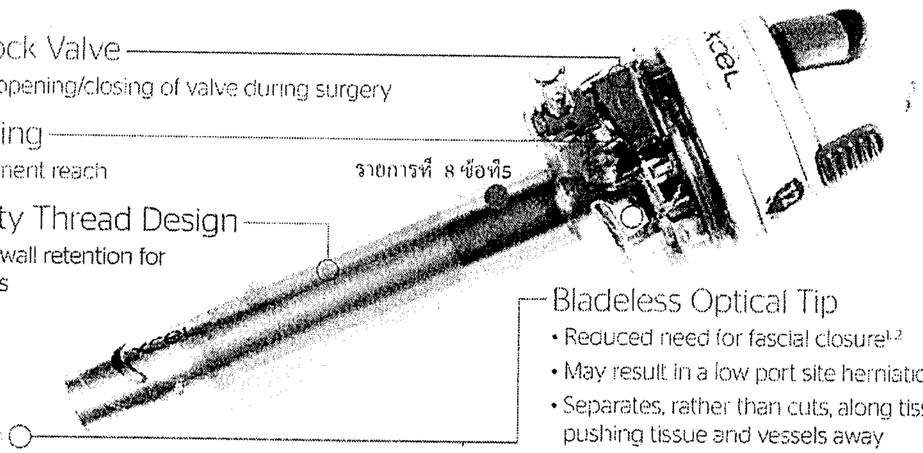

Recessed Stopcock Valve
- Mitigates inadvertent opening/closing of valve during surgery

Low-Profile Housing
- Enables further instrument reach

รายการที่ 8 ข้อที่ 5

Integrated Stability Thread Design
- Maximizes abdominal wall retention for minimal trocar slip-outs

รายการที่ 8 ข้อที่ 7

Bladeless Optical Tip
- Reduced need for fascial closure[1,2]
- May result in a low port site herniation rate[2]
- Separates, rather than cuts, along tissue fibers, pushing tissue and vessels away
- Reduced risk of abdominal wall vasculature injuries with bleeding complications[3]

More Options – More Value

At Ethicon, we recognize that not all ports require the same level of trocar functionality. We offer the flexibility to choose the trocar for the right level of performance, when and where it's needed.

- ENDOPATH XCEL Trocars with OPTIVIEW® Technology for camera ports
- ENDOPATH XCEL Trocars for working ports
- ENDOPATH BASX® Trocars for retraction ports

References

1. A review published in 2011 evaluated prospective and retrospective case series, randomized trials, literature reviews and randomized animal studies of trocar hernias on abdominal wall defects from gynecologic, urologic, and general surgery literature and concluded that the evidence did not support routine closure of paramedian defects when a blunt tip trocar is used.

2. Yamamoto M, Minikel L, Zaritsky E. Laparoscopic 5-mm Trocar Site Herniation and Literature Review. JSLS 2011; 15:122-126.

3. In a systematic review and meta-analysis of RCTs that compared the clinical use of blunt tip and bladed trocars, significant injury of the abdominal wall vasculature with bleeding complication was reported in 12 of 417 patients (3%) of the blunt trocar group and in 38 of 431 patients (9%) of the bladed trocar group (p=0.0020). Antoniou S, Antoniou G, Koch O, et al. Blunt vs Bladed Trocars in Laparoscopic Surgery: A Systematic Review and Meta-Analysis of Randomized Trials. Surg Endosc 2013; 27(7): 2312-2320.

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Bladeless Trocars

Code	Description	Length
B5ST	Stability sleeve, 5mm diameter	75mm
B5LT	Stability sleeve, 5mm diameter	100mm
B5XT	Stability sleeve, 5mm diameter	150mm
B8LT	Stability sleeve, 8mm diameter	100mm
B11LT	Stability sleeve, 11mm diameter	100mm
B11LP	Smooth sleeve, 11mm diameter	100mm
B11LTH	Stability sleeve with handle, 11mm diameter	100mm
B11LPH	Stability sleeve with handle, 11mm diameter	100mm

Code	Description	Length
B12SRT	Stability sleeve, 12mm diameter	75mm
B12LT	Stability sleeve, 12mm diameter	100mm
B12LP	Smooth sleeve, 12mm diameter	100mm
B12LTH	Stability sleeve with handle, 12mm diameter	100mm
B12LPH	Stability sleeve with handle, 12mm diameter	100mm
B12XT	Stability sleeve, 12mm diameter	150mm
B15LT	Stability sleeve, 15mm diameter	100mm

Instruments per Sales Unit: 6

Universal Sleeves

Code	Description	Length
CB5ST	Stability sleeve, 5mm diameter	75mm
CB5LT	Stability sleeve, 5mm diameter	100mm
CB11LT	Stability sleeve, 11mm diameter	100mm
CB12LT	Stability sleeve, 12mm diameter	100mm

Instruments per Sales Unit: 6

How to Order

All purchase orders are made to Johnson & Johnson Health Care Systems, Inc. (JJHCS) or your authorized distributor.

Electronic Ordering Options

(Note: Placing orders electronically avoids minimum order fees for your hospital.)

Johnson & Johnson Gateway: www.jnjgateway.com/commerce
For questions about your order, visit the website or call 1-866-JNJ-GATE (565-4283).

Global Healthcare Exchange (GHX): www.ghx.com
For questions about your order, visit the website or call 1-800-YOUR-GHX (968-7449).

Electronic Data Interchange (EDI): JJHCS EDI Help Line: 1-800-262-2888

Nonelectronic/Manual Ordering Options

Call JJHCS at 1-800-255-2500 between 8:30 a.m. and 9:00 p.m. Eastern Standard Time or fax your order to 1-732-562-2212.

Customer Support

For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of a 510(k) clearance letter or complaints, please contact our Customer Support Center at **customersupport@eesus.jnj.com** or by calling **1-877-ETHICON** (384-4266). Our Support Center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions.

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For complete product information, including full steps for use, indications, contraindications, warnings and precautions, please see the Instructions for Use.

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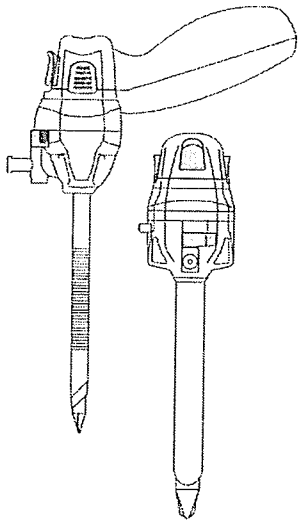
ENDOPATH® XCEL™

Bladeless Trocar
Trocart sans lame
Bladeless Trokar ohne Klinge
Trocar senza lama
Trocarte sem Lâmina
Trócar sin hoja
Lemmetloze trocar
Trokar uden blad
Terätön troakaari
Τροκάρ χωρίς λεπίδες
Trubbig troakar
Trokar bezostrzowy
Él nélküli szúrócsap
Trokar bez ostří
Bezčepielkový trokár
Trokar uten blad
Bıçaksız Trokar
Троакар без лезвия
Trocar fără lamă
Trocar Tanpa Pisau
Trocar không Lưỡi
Terata trokaar
Bezasmens troakārs
Beašmenis troakaras
Троакар без острие
Troakar bez oštrice
Trokar brez rezila
Трокар без сечило
Трокар без ножа
Троакар без сјечива
微创穿刺器



Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide instructions for use of the ENDOPATH® XCEL™ Bladeless Trocar. It is not a reference to trocar insertion techniques.

ETHICON ENDO-SURGERY, LLC
a Johnson & Johnson company

Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones, Instructies, Brugervejledning, Οδηγίες, Anvisningar, Instrukcje, Utasítások, Návod k použití, Návod na použitie, Instruksjoner, Talimatlar, Инструкция, Instrucțiuni, Inštrukcie, Hướng dẫn, Kasutusjuhend, Instrukcijas, Instrukcija, Инструкции, Upute, Navodila, Упатства, Упутства, Упутства, 使用说明

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วัตถุประสงค์ รายการที่ 8

Indications

The ENDOPATH® XCEL™ Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions

รายการที่ 8 ข้อที่ 1

Contraindications

This device is not intended for use when minimally invasive techniques are contraindicated.

Device Description

The Bladeless Trocar, with or without integrated pistol handle, is a sterile single patient use instrument consisting of a radiolucent sleeve and obturator in sizes 5 mm, 8 mm, 11 mm, 12 mm and 15 mm diameter. The obturator contains a clear, tapered optical element. The 5 mm, 11 mm, and 12 mm diameter obturators accommodate an appropriately sized 0° endoscope and provide visibility of individual tissue layers during insertion. The 8 mm and 15 mm devices do not provide optical entry capabilities. The trocar sleeves for the 8 mm, 11 mm, 12 mm and 15 mm devices contain two seals, an outer integrated removable self-adjusting seal that accommodates instruments ranging from 5 mm to 15 mm in diameter where indicated and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. The 5 mm trocar sleeve does not contain an integrated removable outer seal and accommodates only 5 mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

รายการที่ 8 ข้อที่ 2

Clinical Section

Examples of procedures in which trocars may be used include:

Abdominal	Thoracic	Gynecological
Cholecystectomy Appendectomy Jejunectomy Gastric Banding	Wedge resection	Hysterectomy Tubal Ligation

Illustration and Nomendature (Illustration 1)

1. Obturator
2. Obturator Handle
3. Pistol Handle
4. Scope Locking Cam (housed in obturator handle)
5. Obturator Locking Button (housed in obturator handle)
6. Outer Seal
7. Outer Seal Release Lever
8. Stopcock
9. Trocar Smooth Sleeve
10. Trocar Stability Sleeve
11. Optical Element
12. Bladeless Tip
13. Bladeless Tip Symbol

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

Prepare the patient in accordance with proper surgical techniques prior to insertion of the trocar.

IMPORTANT: The following instructions are recommended to ensure a thorough understanding of proper insertion technique for the Bladeless Trocar.

- Success with the Bladeless Trocar depends upon recognizing and differentiating between tissue layers. Therefore, utilize the Bladeless Trocar as a secondary port following insufflation to gain experience visualizing the tissue layers.
- After achieving experience with the above technique, the Bladeless Trocar may be inserted as a primary port after insufflation.
- When proficiency with the device has been achieved, the Bladeless Trocar may be inserted without pneumoperitoneum.

รายการที่ 8 ข้อที่ 8

English

Follow the steps below for 5 mm, 11 mm, and 12 mm Bladeless Trocar insertion with the use of an endoscope.

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. The trocar obturator and sleeve are packaged unassembled. To assemble, remove the protective tip covering from the obturator and trocar sleeve and discard. Assemble the trocar by inserting the obturator into the trocar sleeve until they lock securely together.
   Note: The trocar is packaged with the stopcock in the open position. Close the stopcock before use. The stopcock is in the closed position when the stopcock lever is parallel to the sleeve.
3. Connect the appropriately sized 0° endoscope to the light supply and monitor as directed in the manufacturer's instructions. Verify proper connection of the endoscope and ensure the clarity of the picture on the monitor.
4. Insert the endoscope into the opening at the proximal end of the obturator until it reaches the distal tip of the obturator (Illustration 2).
5. Rotate the endoscope as desired. Secure the endoscope in the obturator using the scope locking cam (Illustration 3).
6. To provide a clear image on the monitor, insert the endoscope into the obturator, touch the tip of the optical element to a convenient soft surface, and focus the camera.
7. Create an incision using standard surgical procedure which allows the trocar to be introduced.
   Note: An inadequate incision may cause increased resistance to insertion, increasing the required penetration force, and possibly resulting in a loss of control during entry.
8. Introduce the obturator through the skin incision using a 30° to 90° rotating motion. Apply light and continuous but controlled downward pressure on the obturator (Illustration 4).
   View the penetration of the obturator tip through the individual tissue planes by using the endoscope and video camera. The individual tissue planes may be seen as the obturator tip advances.
9. When the trocar is in the abdominal or thoracic cavity, press the locking buttons to remove the obturator and endoscope, leaving the sleeve in place. Release the scope locking cam and remove the endoscope from the obturator. The internal seal in the sleeve automatically closes as the obturator is withdrawn. The seal system maintains insufflation in the absence of an instrument in the sleeve (Illustrations 5 and 6).
10. To insufflate, attach a gas line to the stopcock on the trocar sleeve and open the stopcock. The seal system maintains insufflation in the absence of an instrument in the sleeve.
11. For specimen removal during the procedure, with the exception of the 5 mm trocar sleeve, the outer seal can be removed by pushing the outer seal release lever in a counterclockwise direction and lifting off the outer seal. After removal of the specimen, replace the outer seal on the trocar. Orient the reducer cap so it is aligned correctly with the top of the trocar. Position the seal latches over the corresponding holes in the top of the trocar and press down to snap cap in place (Illustration 7).
    Note: The 5 mm trocar sleeve does not contain a removable outer seal.
12. Upon completion of the procedure, remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.

Follow the steps below for Bladeless Trocar insertion without the use of an endoscope.

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. The trocar obturator and sleeve are packaged unassembled. To assemble, remove the protective tip covering from the obturator and trocar sleeve and discard. Assemble the trocar by inserting the obturator into the trocar sleeve until they lock securely together.
   Note: The trocar is packaged with the stopcock in the open position. Close the stopcock before use. The stopcock is closed when the stopcock lever is parallel to the sleeve.
3. Create an incision using standard surgical procedure which allows the trocar to be introduced.
   Note: An inadequate incision may cause increased resistance to insertion, increasing the required penetration force, and possibly resulting in a loss of control during entry.
4. Introduce the obturator through the skin incision using a 30° to 90° rotating motion. Apply light and continuous but controlled downward pressure on the obturator (Illustration 4).
5. When the trocar is in the abdominal or thoracic cavity, press the locking buttons to remove the obturator, leaving the sleeve in place. The internal seal in the sleeve automatically closes as the obturator is withdrawn. The seal system maintains insufflation in the absence of an instrument in the sleeve (Illustration 5).

6 To insufflate, attach a gas line to the stopcock on the trocar sleeve and open the stopcock. The seal system maintains insufflation in the absence of an instrument in the sleeve.

7 For specimen removal during the procedure, with the exception of the 5 mm trocar sleeve, the outer seal can be removed by pushing the outer seal release lever in a counterclockwise direction and lifting off the outer seal. After removal of the specimen, replace the outer seal on the trocar. Orient the reducer cap so it is aligned correctly with the top of the trocar. Position the seal latches over the corresponding holes in the top of the trocar and press down to snap cap in place (Illustration 7). Note: The 5 mm trocar sleeve does not contain a removable outer seal.

8 Upon completion of the procedure, remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.

Bladeless Trocar Additional Sleeve Information

If using a Bladeless Trocar with additional sleeves, follow Instructions for Use with or without the use of an endoscope for additional port insertions.

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Using minimally invasive instruments with a diameter smaller than specified for the Bladeless Trocar may result in desufflation of the abdominal cavity.
- The optical features in the obturator design are intended to minimize the likelihood of penetrating injury to intra-abdominal and intra-thoracic structures. However, the standard precautionary measures employed in all obturator insertions must be observed.
- Although the Bladeless Trocar has a blunt tip, care must still be taken, as with all trocars, to avoid damage to major vessels and other anatomic structures (such as bowel or mesentery). To minimize the risk of such injury, be sure to:
  - Establish adequate pneumoperitoneum;
  - Properly position the patient to help displace organs out of the area of penetration.
  - Note important anatomical landmarks.
  - Direct the trocar tip away from major vessels and structures.
  - Do not use excessive force.
- Once complete entry has been made into the abdominal or thoracic cavity, the Bladeless Trocar should not be advanced for additional penetration. Continued entry of the obturator device at this point could cause injury to intra-abdominal or intra-thoracic structures.
- Once partial entry has been accomplished, very little pressure may be required to complete entry. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.
- Use caution when introducing or removing instruments through the trocar sleeve in order to prevent inadvertent damage to the seals which could result in loss of pneumoperitoneum. Special care should be used when inserting sharp or angled edged endoscopic instruments to prevent tearing the seal.
- When using a sleeve with integrated stability threads, additional stability devices should not be used.
- After removing the Bladeless Trocar from the cavity, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

- This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

How Supplied

The ENDOPATH® XCEL™ Bladeless Trocar is supplied sterile for single patient use. Discard after use.

STERILE R	Sterilized by Irradiation. Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize Stérilisé par irradiation. Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser Strahlensterilisiert Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist. Nicht resterilisieren. Sterilizzato con radiazioni. Sterilità garantita, a meno che la confezione non venga aperta o danneggiata. Non risterilizzare. Esterilizado por irradiação. Esterilização garantida, excepto se a embalagem estiver aberta ou danificada. Não reesterilizar Estéril por radiación. Esterilización garantizada mientras el envase esté íntegro. No reesterilizar. Gesteriliseerd met straling. Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren. Steriliseret ved stråling. Garanteret sterilt, med mindre pakken er åbnet eller beskadiget. Må ikke gensteriliseres Steriloitu säteilyttämällä. Tuote on steriili, kun pakkaus on avaamaton ja ehjä. Ei saa steriloida uudestaan Αποστειρωμένο με ακτινοβολία. Η στειρότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε. Steriliserad med bestrålning Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras. Urządzenie/sprzęt sterylizowane promieniowaniem. Jałowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone. Nie sterylizować ponownie. Besugárzással sterilizálva. A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás. Tilos újra sterilizálni! Sterilizace se provádí ozářením. Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte. Sterilizované ožarovaním. Sterilita je zaručená, ak nie je otvorený alebo poškodený obal. Neresterilizujte Sterilisert ved stråling. Garantert steril hvis ikke pakningen er åpnet eller skadet. Skal ikke resteriliseres. Radyasyonla Sterilize Edilmiştir Ambalaj Açılmadığı ve Hasar Görmediği Sürece Sterilite Garanti Edilir. Tekrar Sterilize Etmeyin. Стерилизовано радиацией Стерильность гарантируется до момента вскрытия или повреждения упаковки Повторная стерилизация запрещена Sterilizate prin iradiere. Sterilitatea este garantată, cu excepția cazurilor în care ambalajul este deschis sau deteriorat. A nu se resteriliza Disterilkan dengan cara Iradiasi. Kesterilan Terjamin Kecuali Kemasan Dibuka atau Rusak. Jangan Sterilisasi Ulang. Tiệt trùng bằng chiếu xạ. Sản phẩm được đảm bảo vô trùng trừ khi bao bì đã được mở hoặc bị hỏng. Không được tiệt trùng lại Steriliseeritud kiirgusega Steriilsus on tagatud vaid siis, kui pakend on avamata ja kahjustusteta. Mitte resteriliseerida Sterilizēts ar starojumu. Sterilitāte tiek garantēta, ja vien iepakojums nav atvērts vai bojāts Nesterilizējiet atkārtoti.

STERILE R	Sterilizuota spinduliuote. Sterilumas garantuojamas tik jei pakuotė nėra atidaryta ar pažeista. Pakartotinai nesterilizuoti Стерилизира се с радиация. Стерилността е гарантирана, освен при отворена или повредена опаковка. Да не се стерилизира повторно Sterilizirano zračenjem. Sterilnost zajamčena, osim ako je pakiranje otvoreno ili oštećeno. Nemojte ponovo sterilizirati. Sterilizirano z uporabo sevanja Sterilnost je zagotovljena, če ovojnina ni odprta ali poškodovana. Ne sterilizirajte znova Стерилизирано со зрачење Стерилноста е гарантирана доколку пакувањето не е отворено или оштетено. Да не се стерилизира повторно. Стерилисано зрачењем. Стерилност је гарантована осим ако паковање није отворено или оштећено. Немојте поново да стерилишете Стерилизовано зрачењем. Стерилизованост је загарантована, осим у случају да је пакет отворен или оштећен. Немојте поново да стерилишете. [illegible] [illegible]	
⚠	See Instructions For Use Voir notice d'utilisation Bitte Gebrauchsanweisung beachten Vedere le istruzioni per l'uso Ver Instruções de Uso Ver instrucciones de uso Zie gebruiksaanwijzing Se brugsvejledningen Katso käyttöohjeet Διαβάστε τις Οδηγίες Χρήσεως Se bruksanvisning Zobacz Instrukcja użytkowania Lásd a használati útmutatót Prostudujte návod k použití Prečítajte si návod na použitie Se bruksanvisningen	Kullanma Talimatına Bakınız Смотри инструкцию по применению Consultaţi instrucţiunile de utilizare Lihat Petunjuk Penggunaan Xem Hướng dẫn sử dụng Vaadake kasutusjuhendit Skatiet lietošanas instrukciju Žr. naudojimo instrukcija Виж "Инструкциите за употреба" Vidi upute za uporabu Glejte Navodila za uporabo Видете во Упатството за употреба Погледајте Упутства за коришћење Погледајте упутства за употребу [illegible]
(2)	Single Patient Use A utiliser sur un seul patient lors d'une seule et même intervention Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één patiënt Til anvendelse på én patient Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta	Kun til bruk på én pasient Tek Hastada Kullanılabilir Для применения у одного пациента De unică utilizare Penggunaan Sekali Pakai Sử dụng cho một bệnh nhân duy nhất Kasutamiseks ühel patsiendil Lietošanai vienam pacientam Skirta naudoti vieną kartą vienam pacientui За употреба само при един пациент Uporaba na jednome pacijentu Za uporabo pri enem bolniku За употреба само на еден пациент За употребу на једном пацијенту Само за једнократну употребу [illegible]

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LOT	Lot	Lot
	N° de lot	Серия
	Ch -B	Lot
	Lotto	Lot
	N° de lote	Lô sản xuất
	N° de lote	Partii
	Lotar	Partija
	Parti	Partija
	Eràn koodi	Партија
	Αρ. παρτίδος	Serija
	Batchnummer	Serija
	Numer partii produkcyjnej	Серија
	Tétel	Партија
	Šarže	Број серије
	Šarža	批号
	Lot	
	Use Until Date	Son Kullanma Tarihi
	A utiliser avant	Срок годности
	Verw. bis	A se utiliza înainte de data
	Utilizzare entro	Digunakan Hingga Tanggal
	Validade	Sử dụng đến ngày
	A utilizar antes de	Kasutamise lõpptähtaeg
	Gebruik vóór	Derīguma termiņš
	Holdbar til angivne dato	Tinka naudoti iki
	Käytettävä viimeistään	Използвай до дата
	Χρησιμοποιείτε *μέχρι την*	Datum „Upotrebiti do"
	Använd före	Rok uporabe
	Konec okresu przydatności do użytku	Да се употребя до
	A felhasználható dátum	Датум истека рока трајања
	Použít do data	Користити до датума
	Použitelné do	有效期
	Brukes før-dato	
	Manufacturer	Üretici
	Fabricant	Производитель
	Hersteller	Producător
	Fabbricante	Producent
	Fabricante	Nhà sản xuất
	Fabricante	Tootja
	Fabrikant	Ražotājs
	Producent	Gamintojas
	Valmistaja	Произвођач
	Κατασκευαστής	Proizvođač
	Tillverkare	Proizvajalec
	Producent	Производител
	Gyarto	Произвођач
	Výrobce	Производач
	Výrobca	制造商
	Produsent	

EC REP	Authorized Representative in the European Community
	Représentant autorisé dans la Communauté européenne
	Bevollmächtigter in der Europäischen Gemeinschaft
	Rappresentante autorizzato per la Comunità Europea
	Representante autorizado na Comunidade Europeia
	Representante autorizado en la Comunidad Europea
	Bevoegd vertegenwoordiger bij de Europese Gemeenschap
	Autoriseret repræsentant i det europæiske fællesskab
	Valtuutettu edustaja Euroopan yhteisön alueella
	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα
	Auktoriserad representant i Europeiska gemenskapen
	Autoryzowany przedstawiciel w Unii Europejskiej
	Az Európai Közösség meghatalmazott képviselője
	Autorizovaný zástupce v Evropském společenství
	Autorizovaný zástupca EÚ
	Autoriseret repræsentant i Det europæiske fællesskab
	Avrupa Topluluğunda Yetkili Temsilci
	Уполномоченный представитель в Европейском Сообществе
	Reprezentant autorizat în Comunitatea Europeană
	Perwakilan Resmi di Komunitas Eropa
	Đại diện uỷ quyền tại Cộng đồng Châu Âu
	Volitatud esindaja Euroopa Ühenduses
	Pilnvarotais pārstāvis Eiropas Kopienā
	Įgaliotasis atstovas Europos Bendrijoje
	Упълномощен представител в Европейската общност
	Ovlašteni predstavnik u Europskoj zajednici
	Pooblaščeni zastopnik za Evropsko skupnost
	Овластен претставник во Европската заедница
	Овлашћени представник у Европској унији
	Овлашћени представник у Европи
	欧洲授代表
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Mise en garde : La Loi Fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un medecin ou sur sa prescription.
	Achtung: Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden.
	Attenzione: la legge federale americana consente la vendita di questo dispositivo solo a medici oppure dietro richiesta medica.
	Atenção: A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes.
	Atención: la ley federal de EE.UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripción médica.
	Let op: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht.
	Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge.
	Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.
	Προσοχή: Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του εργαλείου αυτού μόνον από γιατρούς ή κατόπιν εντολής γιατρού
	Forsiktighet: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan.

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Rx Only	Przestroga. Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie lekarzowi lub na jego zamówienie. Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető Upozornění. Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis. Pozor. Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis. Forsiktig: Ifølge amerikansk lovgivning kan dette utstyret kun selges av eller etter forordning av en lege. Dikkat: A.B.D. federal kanunlarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir. Внимание! Федеральный закон США разрешает продажу этого устройства только врачам или по заказу врачей Atenţie: Legea federală S.U.A. restricţionează vânzarea acestui dispozitiv doar la medici sau pe baza comenzii unui medic Perhatian: Hukum Federal (USA) membatasi penjualan alat ini oleh atau atas perintah dokter Thận trọng: Đạo luật Liên bang (Hoa Kỳ) hạn chế thiết bị này chỉ được bán bởi hoặc theo yêu cầu của bác sĩ. Ettevaatust! Ameerika Ühendriikide föderaalseadus lubab seda seadet müüa arstil või arsti tellimusel. Uzmanību! Saskaņā ar federālo (ASV) likumdošanu šo ierīci drīkst pārdot tikai ārstam vai pēc ārsta rīkojuma. Perspėjimas. Pagal federalinius (JAV) įstatymus šį prietaisą leidžiama parduoti tik gydytojui arba jo užsakymu Внимание: федералният закон на САЩ ограничава продажбата на този уред до от или по предписание на лекар. Oprez: savezni zakon SAD-a ograničava prodaju ovog uređaja jedino liječnicima ili po njihovu nalogu. Pozor: v skladu z zveznimi zakoni ZDA je prodaja te naprave omejena samo na zdravnike oziroma po zdravnikovem naročilu. Внимание: Сојузните закони (САД) поставуваат ограничување овој уред да се продава само по налог на лекар. Опрез: Савезни (САД) закон ограничава продају овог уређаја тако да се врши од стране или по налогу лекара. Опрез: Федерални закон у САД ограничава продају овог уређаја само од стране љекара или по његовом налогу 警告：[illegible]

1	Unit Quantity Quantité par unité Stück pro Verpackungseinheit Quantità Quantidade de unidades Cantidad unitaria Dosering Enhedsmængde Yksikkömäärä Ποσότητα μονάδας Antal enheter Ilość sztuk w opakowaniu Egységek száma csomagonként Počet jednotek v balení Počet jednotiek v balení Enhetsmengde	Birim Miktarı Количество элементов Cantitate unitară Jumlah Unit Đơn vị đóng gói Komplekti kuuluvate seadmete arv Vienību skaits Vienetų skaičius pakuotėje Брой изделия в опаковката Količina Količina enot Количина Количина Количина [illegible]
USA REP	Authorized Representative in the USA Représentant autorisé aux États-Unis d'Amérique Bevollmächtigter in den USA Rappresentante autorizzato per gli Stati Uniti Representante autorizado nos EUA Representante autorizado en EE.UU. Bevoegd vertegenwoordiger in de VS Bemyndiget repræsentant i USA Valtuutettu edustaja Yhdysvalloissa Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ Auktoriserad representant i USA Autoryzowany przedstawiciel w Stanach Zjednoczonych Ameryki Meghatalmazott képviselő az Egyesült Államokban Autorizovaný zástupce v USA Autorizovaný zástupca v USA Autorisert representant i USA A.B.D.'de Yetkili Temsilci Уполномоченный представитель в США Reprezentant autorizat în S.U.A. Perwakilan Resmi di AS Đại diện ủy quyền tại Hoa Kỳ Volitatud esindaja Ameerika Ühendriikides Pilnvarotais pārstāvis ASV Įgaliotasis atstovas JAV Упълномощен представител в САЩ Ovlašteni predstavnik u SAD-u Pooblaščeni zastopnik za ZDA Овластен претставник во САД Овлашћени представник у САД Овлашћени представник у САД [illegible]	

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REF
B5LP, B5LT, B5SP, B5ST, B5LPH, B5XT, B8LT, B11LT, B11LP, B11LPH, B11LTH, B12LT, B12LP, B12LPH, B12LTH, B12SRT, B12XT, B15LT

EC REP Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuetteler Steindamm 71
22851 Norderstedt
GERMANY

Johnson & Johnson AG
CH-8957 Spreitenbach
SWITZERLAND

USA REP ETHICON ENDO-SURGERY, INC.
Cincinnati, OH 45242-2839 USA
1-800-USE-ENDO

ETHICON ENDO-SURGERY, LLC
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ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0015025

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่

บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สน. 515/2554 เพื่อแสดงว่าเป็นผู้แจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๙ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

ENDOPATH Trocars

รายละเอียดเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ณ สถานที่นำเข้าเครื่องมือแพทย์ชื่อ บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ตั้งอยู่เลขที่ 106

ตรอก/ซอย นิคมอุตสาหกรรมลาดกระบัง ถนน ฉลองกรุง หมู่ที่ 4

ตำบล/แขวง ลำปลาทิว อำเภอ/เขต ลาดกระบัง

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10520 โทรศัพท์ 02-792 7300 โทรสาร 02-792 7304

ใบรับแจ้งรายการละเอียดฉบับนี้ใช้ได้จนถึงวันที่ 31 ธันวาคม พ.ศ. 2569 และให้ใช้เฉพาะสถานที่ที่ระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

ออกให้ ณ วันที่ 3 เดือน ตุลาคม พ.ศ. 2565

(ลายมือชื่อ) สำนักงานคณะกรรมการอาหารและยา

(ตำแหน่ง) กระทรวงสาธารณสุข

ผู้อนุญาต

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เอกสารแนบท้าย

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0015023

รายละเอียดเครื่องมือแพทย์

The ENDOPATH XCEL Bladeless Trocar with OPTIVIEW Technology is a sterile single patient use instrument consisting of a radiolucent sleeve and obturator in sizes 5 mm and 12 mm diameter. The obturator contains a clear, tapered optical element. The 5 mm and 12 mm diameter obturators accommodate an appropriately sized 0 endoscope and provide visibility of individual tissue layers during insertion. OPTIVIEW Technology reduces the incidence of trocar-induced smudging during camera reinsertion. The trocar sleeves for the 12 mm devices contain two seals: an outer integrated removable self-adjusting seal that accommodates instruments ranging from 5 mm to 12 mm in diameter where indicated and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. The 5 mm trocar sleeve does not contain an integrated removable outer seal and accommodates only 5 mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

ชื่อและที่ตั้งของผู้ผลิตผลิตภัณฑ์

ETHICON ENDO-SURGERY, LLC. 475 CALLE C, GUAYNABO, PR 00969, USA

มีรายละเอียดรายการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	identifier	บริษัทผู้ผลิต	อื่นๆ
[illegible]	[illegible]	2DS1	[illegible]	[illegible] 100 mm
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
6546840500070	ENDOPATH XCEL Bladeless Trocar with Stability Sleeves	D5LT	NPA DE MEXICO S. DE R.L. DE C.V. (MEXICO) Blvd Hector Teran Teran #20852-C MEX 22465	Shape (Bladeless Trocar), Size (5 mm x 100 mm)
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Johnson & Johnson
MEDICAL COMPANIES

รายการที่ ๙ ไส้ตัวตัดเย็บเนื้อเยื่อ แบบโค้ง

วัตถุประสงค์ เป็นไส้ตัวตัดเย็บเนื้อเยื่อแบบโค้ง ในการใช้งานต้องบรรจุไส้นี้ลงไปในช่องบริเวณปากเครื่องมือของตัวตัดเย็บเนื้อเยื่อ

คุณลักษณะ

๑. ไส้ตัวตัดเย็บเนื้อเยื่อมีลักษณะโค้ง มีร่องบรรจุตัวเย็บจำนวน ๔๖ ร่อง โดยร่องจะเรียงสับหว่างกัน ๔ แถว มีแนวเย็บยาว ๔๐ มม.

๒. ตัวเย็บซึ่งบรรจุในร่องทำด้วยไทเทเนียมอัลลอย์ (Titanium Alloy)

๓. ภายในตัวตัดเย็บมีไส้ตัวตัวตัดเย็บเนื้อเยื่อมีลักษณะโค้งประกอบด้วยใบมีดที่คั่นระหว่างตัวเย็บด้านละสองแถวเรียงกัน

๔. ไส้ตัวตัดเย็บไส้ตัวตัดเย็บเนื้อเยื่อมีลักษณะโค้ง Green Cartridg แบบหนา สำหรับเนื้อเยื่อที่มีความหนาไม่เกิน ๒.๐ มม.

๕. ผู้ยื่นเสนอราคาต้องมีสินค้าตามรายการพัสดุครบทุกรายการ

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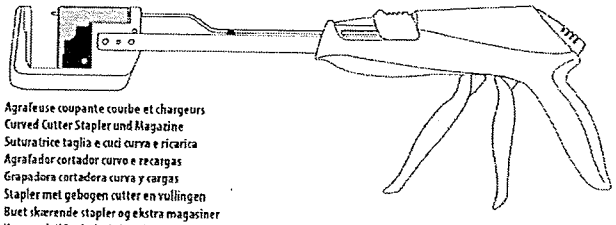
CONTOUR
Curved Cutter Stapler and Reloads



Agrafeuse coupante courbe et chargeurs
Curved Cutter Stapler und Magazine
Suturatrice taglia e cuci curva e ricarica
Agrafador cortador curvo e recargas
Grapadora cortadora curva y cargas
Stapler met gebogen cutter en vullingen
Buet skærende stapler og ekstra magasiner
Kaareva leikkuri-niitoja ja vaihto-osat
Κυρτός κοπτοράπτης και ανταλλακτικά φυσίγγια
Böjd kniv/suturmaskin och omladdningar
Zakrzywiony stapler tnący i magazynki
Hajlított vágó/tűzőgép és utántöltők
Zakřivený řezací stapler s náhradními náplněmi
Zakrivená rezačka zošívačka a náboje
Buet kniv/stiftemaskin og ladepatroner
Eğri Kesici Zımbalayıcı ve Yedekler
Изогнутый шивающе-режущий аппарат и запасные кассеты к нему
Cutter Stapler cu cap curb si cartuse
Stapler Pemotong Lengkung dan Pengisi Ulang
Dụng cụ khâu cắt cong và băng ghim
Kumer lõikur-stapler ja täitekassetid
Liektais griezējšuvējs-skavotājs un magazīnas
Lenktas siuvimo ir pjovimo instrumentas ir keičiamosios kasetės
Извит режещ сшивател и пълнители
Zakrivljeni rezač i spajač s punjenjima
Ukrivljen rezalni spenjalnik in polnila
Закривен секач со спојница и влошки
Стаплер са закривљеним секачем и пуњења
Закривљени резач спајач и пуњења
弧形切割吻合器和钉仓

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or disruption

Important: This package insert is designed to provide instructions for use of the CONTOUR® Curved Cutter Stapler and Reloads. It is not a reference to surgical stapling techniques.

CONTOUR is a trademark of Ethicon Endo-Surgery

ETHICON ENDO-SURGERY, LLC
a Johnson & Johnson company

Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instrucões, Instrucciones, Instructies, Brugervejledning, Ohjeet, Οδηγίες, Anvisningar, Instrukcje, Utasítások, Návod k použití, Návod na použitie, Instruksjoner, Talimatlar, Инструкции, Instrucțiuni, Instrukci, Hướng dẫn, Kasutusjuhend, Instrukcijas, Instrukcija, Инструкции, Upute, Navodila, Упатства, Упутства, Упутства, 使用说明

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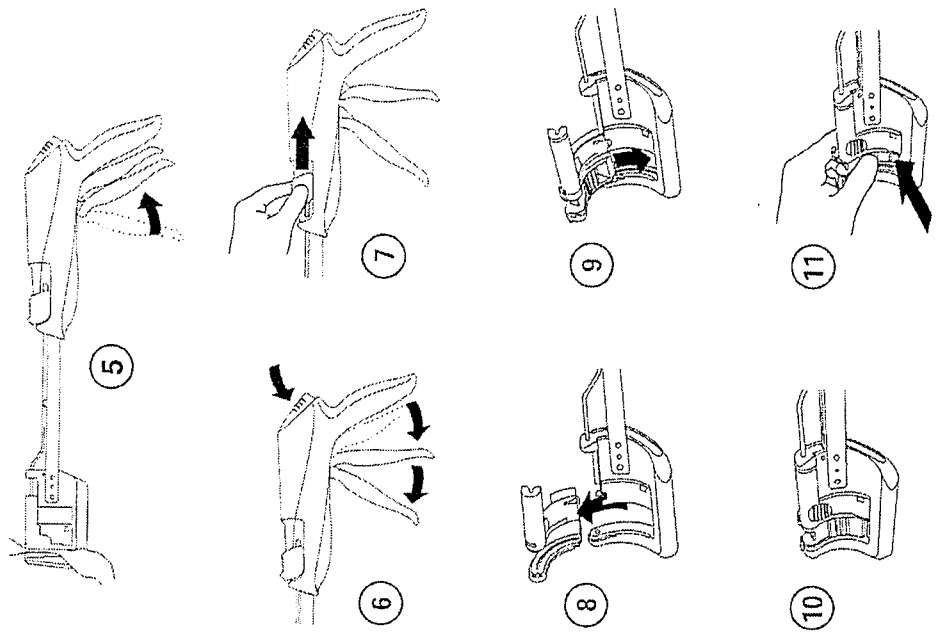

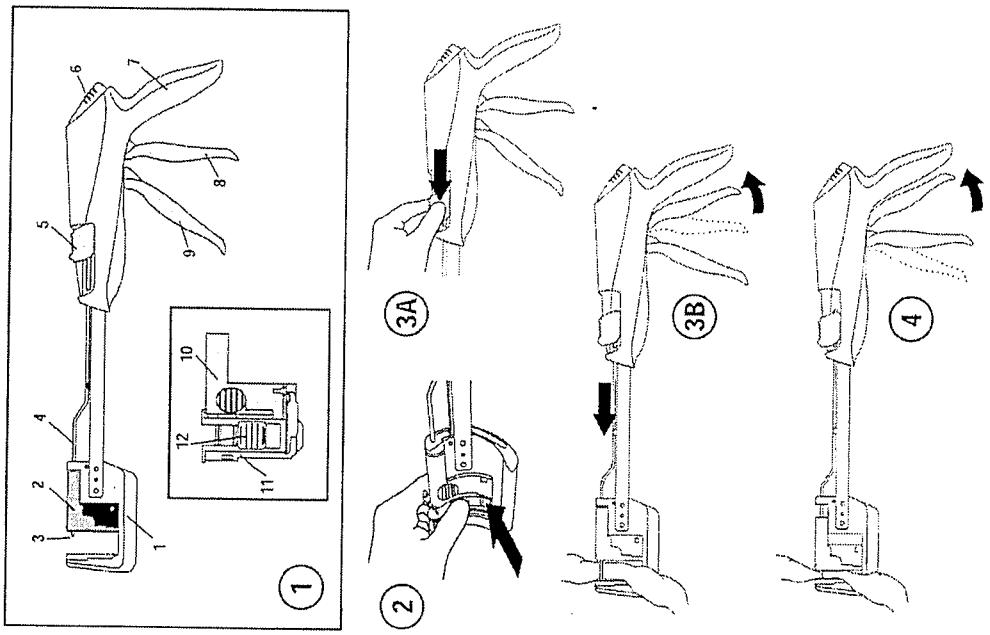

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Indications
The CONTOUR Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic,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

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.

Device Description
The CONTOUR Curved Cutter Stapler is a multifire, single patient use device with a curved head that cuts and staples. The device delivers four staggered rows of titanium staples, with a knife between the second and third row of staples, and creates a 40 mm curved transection. The device is designed with a feature which prevents closing if a used reload or no reload is in the instrument. Another feature is provided to prevent firing unless the closure trigger is latched in the closed position. A retaining pin holds tissue in place and can be positioned either manually or by squeezing the closure trigger.

The instrument may be reloaded five times, for a maximum of six firings per instrument during a single procedure. Each reload cartridge module includes a knife blade with two staggered rows of staples on each side, an anvil, a cutting washer, a retaining pin, and a staple retainer. Reload cartridges are available in two sizes. Refer to the table below.

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.

MR Conditional
Non-clinical testing has demonstrated the implantable staple made of titanium (Ti3Al2.5V) alloy in these devices is MR Conditional. A patient with the implanted staples can be scanned safely immediately after placement of these staples, under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 720 Gauss/cm
- Maximum whole body averaged specific absorption rate (SAR) of 2.7 W/kg for 15 minutes of scanning

MRI Related Heating
In non-clinical testing, the implantable staple made of titanium (Ti3Al2.5V) alloy in the CONTOUR® Curved Cutter Staplers produced a temperature rise of less than 2°C at a maximum whole body averaged specific absorption rate (SAR) of 2.7 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3-Tesla/128-MHz, Excite, Software HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR scanner.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the CONTOUR® Curved Cutter Staplers implantable staple. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) per staple extends approximately 3-mm relative to the size and shape of the implantable staple.

Pulse Sequence	TI-SE	TI-SE	GRE	GRE
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal Void Size (mm^2)	17	5	42	24

Illustration and Nomendature (Illustration 1)

1.	Curved Head	7.	Handle
2.	Cartridge Module	8.	Closure Trigger
3.	Retaining Pin	9.	Firing Trigger
4.	Push Rod	10.	Cartridge Module
5.	Retaining Pin Actuator	11.	Cartridge Anvil
6.	Release Button	12.	Staple Retainer

General Instructions for Use
Verify compatibility of all instruments and accessories prior to using the instrument.
(Refer to **Warnings and Precautions**.)

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. Remove the staple retainer from the instrument by pushing on the pad labeled "Push to Remove" (Illustration 2). Hold the cartridge when removing the retainer. Check that the cartridge is fully loaded into the instrument (press down) after the retainer has been removed. Discard the staple retainer.
3. Grasp the instrument handle in the palm of the hand with the fingers around the closure trigger. Position tissue to be cut and stapled between the anvil and the cartridge.
   NOTE: Any tissue covering the hole in the anvil will be pierced by the retaining pin. Reposition the tissue if necessary.
4. Either manually advance the retaining pin using the actuator button on top of the handle to capture the tissue within the jaw opening (Illustration 3A) or automatically advance the retaining pin by squeezing the closure trigger (Illustration 3B). Note that there is an audible click halfway through the closure stroke indicating that the device is in the intermediate position. In the intermediate position, the pin is fully seated in the anvil capturing the tissue, and the jaws are partially open. Reposition tissue within the instrument if desired. The closure trigger can be released at this point, and the instrument will maintain its jaw opening to allow for final positioning of the tissue to be cut and stapled. The retaining pin is fully engaged.
   Caution: Make sure tissue to be stapled is properly positioned in the jaws before stapling. Bunching, stretching or uneven loading of tissue could result in leakage, lack of hemostasis, or disruption of staple line.
   NOTE: If using the automatic advancement of the retaining pin, ensure that the tissue is correctly placed to avoid accidental piercing of tissue.
   NOTE: Do not grasp the firing trigger before the instrument is to be fired.
   NOTE: Recommended operation is to manually advance the Retaining Pin.
5. Squeeze the closure trigger and handle together until the closure trigger is latched. Listen for an audible click. When the closure trigger is latched, the firing trigger moves to the ready-to-fire position (Illustration 4). The cartridge has clamped onto the tissue which is ready to be cut and stapled. Ensure that the closing stroke is completed. All fingers should be completely removed from the closing trigger to ensure that the closing system holds.
   NOTE: If the tissue needs to be repositioned within the instrument before stapling, open the jaws by squeezing the handle and closure trigger together slightly, push the release button, and slowly release

English

grasp of the closure trigger. The closure trigger will return to the fully open position and the jaws will release the tissue but the retaining pin will remain extended. Tissue can now be repositioned.
NOTE: The CONTOUR Curved Cutter Stapler is designed with a feature which allows partial closing if a used reload, no reload, or an incorrectly inserted reload is in the instrument. In these cases, the device will close approximately one-third of the stroke and stop, but will return to the full open position when the closure trigger is released. The used or unloaded cartridge module should then be replaced with a new reload or, if no cartridge was present, a cartridge should be loaded in the instrument. After following the above steps, any device which does not close either partially or completely should not be used.
NOTE: After closing, pausing for 15 seconds prior to firing may result in better tissue compression and better staple form.
NOTE: If closure trigger (1) is difficult to lock, reposition the instrument and take a smaller amount of tissue. (See Contraindications for appropriate reload selection.)

6 With the handle and closure trigger grasped in the palm of the hand, place all fingers around the firing trigger. Before firing, check to ensure the retaining pin is seated in the anvil.
Caution: Always ensure complete closing prior to firing.
Caution: Before firing, verify that the intended tissue is in the closed jaws of the instrument. If the pin is not properly positioned, staples may not form properly, which may result in leakage or disruption of the staple line.
Caution: When positioning the stapler on the application site, ensure that no obstructions such as clips, stents, guide wires, etc., are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.
Caution: Care should be taken not to fire this instrument when the resulting staple line will be in tension.

7 Completely fire the instrument by squeezing the firing trigger until it touches the closure trigger (plastic to plastic), signifying that the instrument has fired the staples and knife blade, and the tissue has been transected. (Illustration 5) The firing trigger automatically returns to the intermediate position as soon as the hand releases it, leaving the closure trigger in the fully closed position. Make sure that the release button is not pressed during firing as proper formation of staples and cut line may be compromised.
Caution: Attempting to force the trigger to complete the closing stroke with too much tissue or thickened tissue may result in poor staple line integrity with possible leakage or disruption. In addition, instrument damage or failure may result.
Caution: The firing stroke must be completed. Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.

8 After firing the instrument, open the jaws of the instrument by squeezing the closure trigger and pushing the release button with the thumb. For controlled release, while holding the release button down, open your hand to release the closure trigger. (Illustration 6) The cartridge drivers are exposed as a spent cartridge indicator. If the instrument becomes locked onto tissue and will not open by pressing the release button, the device can be opened by depressing the release button and pulling the closure trigger simultaneously.
Caution: Examine the staple line for hemostasis and proper staple formation. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
Caution: Following a division of the rectum, it is recommended that a leak test is performed prior to the creation of the anastomosis.

9 Retract the retaining pin manually. Ensure that the staple line and the cut line are complete. Remove the instrument. (Illustration 7)

Muscle Stapling Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument.
(Refer to **Warnings and Precautions.**)

1 Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.

2 Remove the staple retainer from the instrument by pushing on the pad labeled "Push to Remove" (Illustration 2). Hold the cartridge when removing the retainer. Check that the cartridge is fully loaded into the instrument (press down) after the retainer has been removed. Discard the staple retainer.

3 Grasp the instrument handle in the palm of the hand with the fingers around the closure trigger. Position tissue to be cut and stapled between the anvil and the cartridge.

NOTE: Any tissue covering the hole in the anvil will be pierced by the retaining pin. Reposition the tissue if necessary.

4 Recommended operation, in skeletal muscle, is to manually advance the Push Rod using the Retaining Pin Actuator. Squeeze the closure trigger (Illustration 3B). Note that there is an audible click halfway through the closure stroke indicating that the device is in the intermediate position. In the intermediate position, the pin is fully seated in the anvil capturing the tissue, and the jaws are partially open. Reposition tissue within the instrument if desired. The closure trigger can be released at this point, and the instrument will maintain its jaw opening to allow for final positioning of the tissue to be cut and stapled. The retaining pin is fully engaged.
Caution: Make sure tissue to be stapled is properly positioned in the jaws before closing the jaws or stapling. Bunching, tension, stretching or uneven loading of tissue could result in leakage, lack of hemostasis, or disruption of staple line.
NOTE: In thick skeletal muscle tissue, two approaches are recommended for device closure:
- A single slow, controlled and continuous squeeze of the Closure Trigger
- Progressively squeezing and relaxing (pumping) the Closure Trigger

NOTE: Do not grasp the firing trigger before the instrument is to be fired.

5 Squeeze the closure trigger and handle together until the closure trigger is latched. Listen for an audible click. When the closure trigger is latched, the firing trigger moves to the ready-to-fire position (Illustration 4). The cartridge is clamped onto the tissue, which is ready to be stapled and cut. Ensure that the closing stroke is completed. All fingers should be completely removed from the closing trigger to ensure that the closing system holds.
NOTE: If the closure trigger is difficult to lock, reposition the instrument and take a smaller amount of tissue.
NOTE: Do not use excessive force to close the instrument. Forcing the instrument to fully close, with excess tissue, may result in the closure trigger breaking.
NOTE: If the tissue needs to be repositioned within the instrument before stapling, open the jaws by squeezing the handle and closure trigger together slightly, push the release button, and slowly release grasp of the closure trigger. The closure trigger will return to the fully open position and the jaws will release the tissue but the retaining pin will remain extended. Tissue can now be repositioned.
NOTE: The muscle stapling CONTOUR Curved Cutter Stapler is designed with a feature that allows partial closing if a used cartridge reload, no cartridge reload, or an incorrectly inserted cartridge reload is in the instrument. In these cases, the device will close approximately one-third of the stroke and stop, but will return to the full open position when the closure trigger is released. The used or unloaded cartridge module should then be replaced with a new cartridge reload or, if no cartridge was present, a cartridge should be loaded in the instrument. After following the above steps, any device that does not close either partially or completely should not be used.
NOTE: After closing, pausing for 15 seconds prior to firing may result in better tissue compression and better staple form.

6 With the handle and closure trigger grasped in the palm of the hand, place all fingers around the firing trigger. Before firing, check to ensure the retaining pin is seated in the anvil.
Caution: Always ensure complete jaw closure prior to firing.
Caution: Before firing, verify that the intended tissue is in the closed jaws of the instrument. If the pin is not properly positioned, staples may not form properly, which may result in leakage or disruption of the staple line.
Caution: When positioning the stapler on the application site, ensure that no obstructions such as clips, stents, guide wires, etc., are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.

7 Completely fire the instrument by squeezing the firing trigger until it touches the closure trigger (plastic to plastic), signifying that the instrument has fired the staples and knife blade, and the tissue has been transected. (Illustration 5) The firing trigger automatically returns to the intermediate position as soon as the hand releases it, leaving the closure trigger in the fully closed position. Make sure that the release button is not pressed during firing as proper formation of staples and cut line may be compromised.
Caution: Attempting to force the trigger to complete the closing stroke with too much tissue or thickened tissue may result in poor staple line integrity with possible leakage or disruption. In addition, instrument damage or failure may result.

Caution: The firing stroke must be completed. Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.

8 After firing the instrument, open the jaws of the instrument by squeezing the closure trigger and pushing the release button with the thumb. For controlled release, while holding the release button down, open your hand to release the closure trigger. (Illustration 6) The cartridge drivers are exposed as a spent cartridge indicator. If the instrument becomes locked onto tissue and will not open by pressing the release button, the device can be opened by depressing the release button and pulling the closure trigger simultaneously.

Caution: Examine the staple line for hemostasis and proper staple formation. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.

9 Retract the retaining pin manually. Ensure that the staple line and the cut line are complete. Remove the instrument. (Illustration 7)

Reloading the CONTOUR Curved Cutter Stapler

1 Using sterile technique, remove the reload from the package. To avoid damage, do not flip the reload into the sterile field.

2 Depress the release button to ensure the instrument is in the open position. Ensure that the retaining pin has been retracted.

3 Remove the used reload from the instrument. Grasp the top of the reload and lift upward, unsnapping the reload from the jaws. (Illustration 8) Properly discard the used reload. Thoroughly clean the instrument by vertically submerging completely the anvil and cartridge channel in a sterile solution and swish vigorously. After swishing, visually inspect the anvil and cartridge channel and remove all residual staples and/or foreign matter from instrument prior to reloading.

Caution: Failure to properly clean the instrument prior to reloading could damage the instrument, compromise cut line and staple formation of subsequent firings.

4 Examine the new reload for the presence of a staple retainer. If the retainer is not in place, discard the reload. Do not remove the staple retainer until the reload cartridge is inserted into the device.

NOTE: The staple retainer cannot be removed until the cartridge is correctly loaded into the device. The loaded device cannot be used until the staple retainer is removed.

5 Insert the new reload into the metal housing and snap into position. (Illustration 9) The tracks on each side of the reload should be used as guides to align the reload within the jaws of the instrument. When the reload is properly aligned, push the reload into the instrument until it is fully seated. (Illustration 10) Remove the staple retainer. (Illustration 11) Check that the reload is held firmly within the jaws.

NOTE: If the cartridge is removed from the device, whether the cartridge is spent or not, and if the staple retainer has already been removed from the cartridge, the cartridge cannot be reloaded into the device.

6 After reloading and after removing the staple retainer, observe the surface of the new reload. If drivers protrude out of the reload, replace with another reload.

7 The stapler is now reloaded and ready for use.

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together during a procedure, verify compatibility prior to initiation of procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Pre-operative radiotherapy may result in changes to tissue characteristics. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected staple. Careful consideration should be given to any pre-surgical treatment the patient may have undergone, which may require alterations to surgical technique or alternative surgical procedures.
- Do not fire device without a loaded cartridge.

- Be sure to remove the staple retainer prior to inserting tissue and closing the device.
- If the staple retainer is not in place in a cartridge module, discard the cartridge module and replace with a new one. Do not remove the staple retainer from the cartridge until the reload cartridge has been inserted into the instrument.
- Before closing the instrument on tissue, observe the surface of the new reload where the staples will emerge. If colored drivers protrude out of the reload, replace with another reload.
- Make sure tissue to be stapled is properly positioned in the jaws before stapling. Bunching, stretching or uneven loading of tissue could result in leakage, lack of hemostasis, or disruption of staple line.
- Ensure that unintentional tissue is not cut.
- Always ensure complete closing prior to firing.
- Before firing, verify that the intended tissue is in the closed jaws of the instrument. If the pin is not properly positioned, staples may not form properly, which may result in leakage or disruption of the staple line.
- When positioning the stapler on the application site, ensure that no obstructions such as clips, stents, guide wires, etc., are incorporated into the instrument jaws. Firing over an obstruction may result in incomplete cutting action and/or improperly formed staples.
- Make sure that the release button is not pressed during firing as proper formation of staples and cut line may be compromised.
- Care should be taken not to fire this instrument when the resulting staple line will be in tension.
- Before firing, check to ensure the retaining pin is seated in the anvil. If the pin is not properly positioned, staples may not form properly, which may result in leakage or disruption of the staple line.
- Do not fire the instrument unless the closure trigger is properly latched against the handle.
- The firing trigger must be pulled back completely against the closure trigger to properly fire the instrument. Do not partially fire the instrument.
- Attempting to force the trigger to complete the closing stroke with too much tissue or thickened tissue may result in poor staple line integrity with possible leakage or disruption. In addition, instrument damage or failure may result.
- The firing stroke must be completed. Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.
- After firing and release and before removing the instrument, check that the cut is complete.
- Retract the retaining pin manually prior to removing the device.
- Examine the staple lines for hemostasis and complete closure. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Following a division of the rectum, it is recommended that a leak test is performed prior to the creation of the anastomosis.
- The CONTOUR Curved Cutter Stapler may be reloaded during a single procedure. Do not reload the instrument more than five times for a total of six firings per instrument.
- Failure to properly clean the instrument prior to reloading could damage the instrument, compromise cut line and staple formation of subsequent firings.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.

How Supplied

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

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STERILE R	Sterilized by Irradiation Sterility Guaranteed Unless Package Opened or Damaged Do Not Resterilize Stérilisé par irradiation Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser Strahlensterilisiert Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist Nicht resterilisieren Sterilizzato con radiazioni. Sterilità garantita, a meno che la confezione non venga aperta o danneggiata Non risterilizzare. Esterilizado por irradiação Esterilização garantida excepto se a embalagem estiver aberta ou danificada Não reesterilizar Estéril por radiación Esterilización garantizada mientras el envase esté íntegro. No reesterilizar Gesteriliseerd met straling Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd Niet opnieuw steriliseren Steriliseret ved stråling Garanteret sterilt, med mindre pakken er åbnet eller beskadiget Må ikke gensteriliseres. Steriloitu säteilyttämällä Tuote on steriili, kun pakkaus on avaamaton ja ehjä Ei saa steriloida uudestaan Αποστειρωμένο με ακτινοβολία. Η στειρότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε. Steriliserad med bestrålning Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras Urządzenie/sprzęt sterylizowane promieniowaniem. Jałowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone Nie sterylizować ponownie Besugárzással sterilizálva. A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás Tilos újra sterilizálni! Sterilizace se provádí ozářením. Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte Sterilizované ožarovaním. Sterilita je zaručená, ak nie je otvorený alebo poškodený obal Nerestertlizujte Sterilisert ved stråling Garantert steril hvis ikke pakningen er åpnet eller skadet Skal ikke resteriliseres Radyasyonla Sterilize Edilmiştir Ambalaj Açılmadığı ve Hasar Görmediği Sürece Sterilite Garanti Edilir Tekrar Sterilize Etmeyin. Стерилизовано радиацией. Стерильность гарантируется до момента вскрытия или повреждения упаковки. Повторная стерилизация запрещена. Sterilizate prin iradiere Sterilitatea este garantată, cu excepţia cazurilor în care ambalajul este deschis sau deteriorat. A nu se resteriliza Disterilkan dengan cara Iradiasi. Kesterilan Terjamin Kecuali Kemasan Dibuka atau Rusak. Jangan Sterilisasi Ulang. Tiệt trùng bằng chiếu xạ. Sản phẩm được đảm bảo vô trùng trừ khi bao bì đã được mở hoặc bị hỏng. Không được tiệt trùng lại Steriliseeritud kiirgusega Steriilsus on tagatud vaid siis, kui pakend on avamata ja kahjustusteta. Mitte resteriliseerida Sterilizēts ar starojumu Sterilitāte tiek garantēta, ja vien iepakojums nav atvērts vai bojāts. Nesterilizēt atkārtoti

STERILE R	Sterilizuota spinduliuote Sterilumas garantuojamas tik jei pakuotė nera atidaryta ar pažeista. Pakartotinai nesterilizuoti Стерилизира се с радиация Стерилността е гарантирана, освен при отворена или повредена опаковка. Да не се стерилизира повторно. Sterilizirano zračenjem Sterilnost zajamčena, osim ako je pakiranje otvoreno ili oštećeno. Nemojte ponovo sterilizirati Sterilizirano z uporabo sevanja. Sterilnost je zagotovljena, če ovojnina ni odprta ali poškodovana. Ne sterilizirajte znova Стерилизирано со зрачење Стерилноста е гарантирана доколку пакувањето не е отворено или оштетено. Да не се стерилизира повторно Стерилисано зрачењем. Стерилност је гарантована осим ако паковање није отворено или оштећено. Немојте поново да стерилишете Стерилизовано зрачењем Стерилизованост је загарантована, осим у случају да је пакет отворен или оштећен. Немојте поново да стерилишете 辐射灭菌。 如果产品包装未打开或未被破损，保证无菌。不得再次灭菌。	
⚠	See Instructions For Use Voir notice d'utilisation Bitte Gebrauchsanweisung beachten Vedere le istruzioni per l'uso Ver Instruções de Uso Ver instrucciones de uso Zie gebruiksaanwijzing Se brugsvejledningen Katso käyttöohjeet Ανατρέξτε τις Οδηγίες Χρήσεως Se bruksanvisning Zobacz Instrukcja użytkowania Lásd a használati útmutatót Prostudujte návod k použití Prečítajte si návod na použitie Se bruksanvisningen	Kullanma Talimatına Bakınız Смотри инструкцию по применению Consultaţi instrucţiunile de utilizare Lihat Petunjuk Penggunaan Xem Hướng dẫn sử dụng Vaadake kasutusjuhendit Skatiet lietošanas instrukciju Žr. naudojimo instrukcija Виж "Инструкциите за употреба" Vidi upute za uporabu Glejte Navodila za uporabo Видете во Упатството за употреба Погледајте Упутства за коришћење Погледајте упутства за употребу 参见使用说明
LOT	Lot N° de lot Ch.-B Lotto N° do lote N° de lote Lotnr. Parti Erän koodi Αρ. παρτίδας Batchnummer Numer partii produkcyjnej Tétel Šarže Šarža Parti	Parti Серия Lot Lot Lô sản xuất Partii Partija Partija Партида Serija Serija Серија Партија Број серије 批号

	Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato Käytettävä viimeistään Χρησιμοποιείτε μέχρι την Använd före Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použít do data Použiteľné do Brukes før-dato	Son Kullanma Tarihi Срок годности A se utiliza înainte de data Digunakan Hingga Tanggal Sử dụng đến ngày Kasutamise lõpptähtaeg Derīguma termiņš Tinka naudoti iki Използвай до дата Datum „Uporabiti do" Rok uporabe Да се употреби до Датум истека рока трајања Користити до датума 有效期
Rx Only	Caution. Federal (USA) law restricts this device to sale by or on the order of a physician. Mise en garde : La Loi Fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription. Achtung: Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden. Attenzione: la legge federale americana consente la vendita di questo dispositivo solo a medici oppure dietro richiesta medica Atenção. A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes Atención: la ley federal de EE UU impone que este producto sólo puede ser vendido por un médico o bajo prescripción médica Waarschuwing: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht. Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge. Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä Προσοχή. Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του εργαλείου αυτού μόνον από ιατρούς ή κατόπιν εντολής ιατρού Varning: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan. Przestroga: Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie lekarzowi lub na jego zamówienie. Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető Upozornění: Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis Pozor: Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis Forsiktig: Ifølge amerikansk lovgivning kan dette utstyret kun selges av eller etter forordning av en lege Dikkat: A.B.D. federal kanunlarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir. Внимание! Федеральный закон США разрешает продажу этого устройства только врачам или по заказу врачей	

Rx Only	Atenție: Legea federală S.U.A. restricționează vânzarea acestui dispozitiv doar la medici sau pe baza comenzii unui medic Perhatian: Hukum Federal (USA) membatasi penjualan alat ini oleh atau atas perintah dokter Thông báo thận trọng: Đạo luật Liên bang (Hoa Kỳ) hạn chế thiết bị này chỉ được bán bởi hoặc theo yêu cầu của bác sĩ Ettevaatust! Ameerika Ühendriikide föderaalseadus lubab seda seadet müüa arstil või arsti tellimusel Uzmanību! Saskaņā ar federālo (ASV) likumdošanu šo ierīci drīkst pārdot tikai ārstam vai pēc ārsta rīkojuma Perspėjimas: Pagal federalinius (JAV) įstatymus ši priemonė leidžiama parduoti tik gydytojui arba jo užsakymu. Внимание: федералният закон на САЩ ограничава продажбата на този уред до от или по предписание на лекар Oprez: savezni zakon SAD-a ograničava prodaju ovog uređaja jedino liječnicima ili po njihovu nalogu. Pozor: v skladu z zveznimi zakoni ZDA je prodaja te naprave omejena samo na zdravnike oziroma po zdravnikovem naročilu Внимание: Сојузните закони (САД) поставуваат ограничување овој уред да се продава само по налог на лекар Опрез: Савезни (САД) закон ограничава продају овог уређаја тако да се врши од стране или по налогу лекара Опрез: Федерални закон у САД ограничава продају овог уређаја само од стране лекара или по његовом налогу. 警告：[illegible]
	Manufacturer Fabricant Hersteller Fabbricante Fabricante Fabricante Fabrikant Producent Valmistaja Κατασκευαστής Tillverkare Producent Gyártó Výrobce Výrobca Produsent Üretici Производитель Producător Produsen Nhà sản xuất Tootja Ražotājs Gamintojas Производител Proizvođač Proizvajalec Производител Произвођач Произвођач 制造商

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USA REP	Įgaliotasis atstovas JAV Упълномощен представител в САЩ Ovlašteni predstavnik u SAD-u Pooblaščeni zastopnik za ZDA Овластен претставник во САД Овлашћени представник у САД Овлашћени представник у САД 美国授权代表人	
②	Single Patient Use À utiliser sur un seul patient lors d'une seule et même intervention Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één patiënt Til anvendelse på én patient Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta	Kun til bruk på én pasient Tek Hastada Kullanılabilir Для применения у одного пациента De unică utilizare Penggunaan Sekali Pakai Sử dụng cho một bệnh nhân duy nhất Kasutamiseks ühel patsiendil Lietošanai vienam pacientam Skirta naudoti viena karta vienam pacientui За употреба само при един пациент Uporaba na jednome pacijentu Za uporabo pri enem bolniku За употреба само на еден пациент За употребу на једном пацијенту Само за једнократну употребу 单个患者使用
1	Unit Quantity Quantité par unité Stück pro Verpackungseinheit Quantità Quantidade de unidades Cantidad unitaria Dosering Enhedsmængde Yksikkömäärä Ποσότητα μονάδας Antal enheter Ilość sztuk w opakowaniu Egységek száma csomagonként Počet jednotek v balení Počet jednotiek v balení Enhetsmengde	Birim Miktarı Количество элементов Cantitate unitară Jumlah Unit Đơn vị đóng gói Komplektis kuuluvate seadmete arv Vienību skaits Vienetų skaičius pakuotėje Брой изделия в опаковката Količina Količina enot Количина Количина Количина 单位数量

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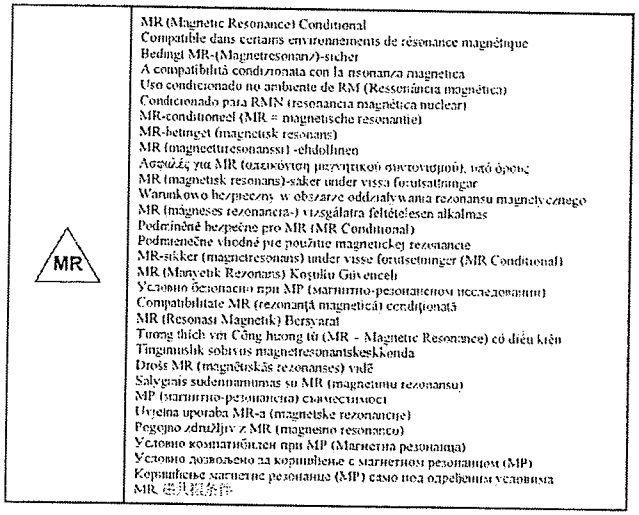

REF
CS40B, CS40G, CR40B, CR40G

EC REP
Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuttler Steindamm 71
22851 Norderstedt
GERMANY

USA REP
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242-2839 USA
1-800-USE-ENDO

ETHICON ENDO-SURGERY, LLC
a Johnson & Johnson company

CE 0123

Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969 USA

Rev. 2013-04

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ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0009890

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่

บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สม 515/2554

เพื่อแสดงว่าเป็นผู้แจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์ตามมาตรา ๓๙ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

CONTOUR Curved Cutter Stapler

รายละเอียดเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ณ สถานที่นำเข้าเครื่องมือแพทย์ชื่อ บริษัท จะห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ตั้งอยู่เลขที่ 195

ตึก/อาคาร อิตัลไทย ทาวเวอร์ ถนน รัชดาภิเษก หมู่ที่ 4

ตำบล/แขวง ห้วยขวาง อำเภอ/เขต ห้วยขวาง

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10320 โทรศัพท์ 02-792 7300 โทรสาร 02-792 7304

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้จนถึงวันที่ 31 ธันวาคม พ.ศ. 2569 และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

ออกให้ ณ วันที่ 29 เดือน มิถุนายน พ.ศ. 2565

(ลายมือชื่อ) สำนักงานคณะกรรมการอาหารและยา
(ตำแหน่ง) กระทรวงสาธารณสุข
ผู้อนุญาต

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เอกสารแนบท้าย

ใบสำคัญการขึ้นทะเบียนที่ 65-2-2-2-000999

รายละเอียดเครื่องมือแพทย์

The CONTOUR Curved Cutter Stapler is a multifire, single patient use device with a curved head that cuts and staples. The device delivers four staggered rows of titanium staples, with a knife between the second and third rows of staples, and creates a 90 mm curved transection. The device is designed with a feature which prevents closing if a used reload or no reload is in the instrument. Another feature is provided to prevent firing unless the closure trigger is latched in the closed position. A retaining pin holds tissue in place and can be positioned either manually or by squeezing the closure trigger. The instrument may be reloaded five times, for a maximum of six firings per instrument during a single procedure. Each reload cartridge module includes a knife blade with two staggered rows of staples on each side, an anvil, a cutting washer, a retaining pin, and a staple retainer. Reload cartridges are available in two sizes.

ชื่อและที่อยู่ของผู้ผลิตเครื่องมือแพทย์

ETHICON ENDO-SURGERY, LLC, 475 CALLE C, GUAYNABO, PR 00969, USA

รายละเอียดเครื่องมือแพทย์ที่ขึ้นทะเบียน ดังนี้

NEVCODE	ชื่อเครื่องมือ	Identifier	หน่วยบรรจุ	ชื่อรุ่น
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

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[illegible]

Johnson&Johnson
MEDICAL COMPANIES

รายการที่ ๑๐ หัวจี้ตัดแบบกรรไกรโค้งแบบโฟกัสพลัส ขนาด ๑๗ ซม.

วัตถุประสงค์ หัวจี้ตัดแบบกรรไกรโค้ง "แบบโฟกัสพลัส" (FOCUS Long shear + Adaptive Tissue Technology) เป็นเครื่องมือสำหรับผ่าตัดที่บริเวณเนื้อเยื่ออ่อน เมื่อต้องควบคุมการ Bleeding และการบาดเจ็บจากความร้อนน้อยที่สุด โดยเครื่องมือนี้สามารถใช้เป็นอุปกรณ์เสริมได้หรือใช้ทดแทนการผ่าตัดด้วยมีด (scalpels) , ไฟฟ้า (electrosurgery) หรือ เลเซอร์ (laser)

คุณลักษณะ

๑. หัวจี้ตัดกรรไกรโค้ง มีความยาวตั้งแต่ก้านจนถึงปลายอุปกรณ์ยาวไม่เกิน ๑๗ ซม. พร้อมปุ่มควบคุมการทำงานด้วยมือ ๒ ปุ่ม ด้ามจับลักษณะคล้ายกรรไกร

๒. ใบมีดด้านที่ใช้จี้ตัด มีลักษณะโค้งเรียว มีความยาวไม่เกิน ๑๖ มม. สะดวกในการปรับมุมและตำแหน่งการจับในขณะผ่าตัด ทำให้เกิดความแม่นยำในการเสาะจับและจี้ตัดเนื้อเยื่อ และสามารถจี้ตัดเส้นเลือด (Cut and Coagulation) ที่มีขนาดเส้นผ่าศูนย์กลางได้ถึง ๕ มม.

๓. เครื่องมือนี้มีปลายแบบโค้งและแขนหนีบพร้อมแผ่นเทฟลอน

๔. ในกล่องเครื่องมือบรรจุมาพร้อมกับประแจวัดแรงบิดสีม่วง (Purple Torque Wrench)

๕. ขีดสองขีดบนเครื่องมือนี้มีวัตถุประสงค์เพื่อแสดงขนาดของเส้นเลือด โดยปุ่ม MAX คือจะใช้กับเส้นเลือดขนาดเล็กและการตัดเร็วที่สุด ปุ่ม MIN จะใช้ในเส้นเลือดขนาดใหญ่ขึ้นเล็กน้อยความเร็วในการตัดจะลดลง ระบุไว้สำหรับเส้นเลือดที่มีขนาดไม่เกิน ๕ มม. ปรับตัวได้

๖. Adaptive Tissue Technology ช่วยให้เครื่องกำเนิดไฟฟ้ามีความสามารถในการระบุและตรวจสอบหัวจี้ระหว่างการใช้งาน ซึ่งทำให้ generator สามารถปรับและลดพลังงานพร้อมเสียง feedback ให้กับผู้ใช้งาน

๗. ใช้กับด้ามจี้แบบบลูเป็นด้ามจี้สำหรับเครื่องมือจี้ตัด "แบบโฟกัส" และสามารถทำงานคู่กับเครื่องรุ่น Harmonic Generator 11 (GEN11)

๘. ผู้ยื่นเสนอราคาต้องมีสินค้าตามรายการพัสดุครบทุกรายการ

FOR JOHNSON & JOHNSON (THAILAND) LTD.

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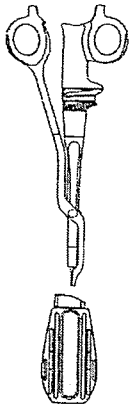
HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology
Ciseaux longs HARMONIC FOCUS® + technologie tissulaire adaptative
HARMONIC FOCUS® Lange Koagulationsschere + Adaptive Gewebetechnologie
Forbici lunghe HARMONIC FOCUS® + tecnologia adattativa al tessuto
Tesoura Comprida + Tecnologia Adaptativa aos Tecidos HARMONIC FOCUS®
Tijeras largas + Tecnología de adaptación tisular HARMONIC FOCUS®
HARMONIC FOCUS® lange schaar + adaptieve weefseltechnologie
HARMONIC FOCUS® lang saks + adaptiv vævsteknologi
HARMONIC FOCUS® pitkä leikkausinstrumentti + mukautuva kudosteknologia
Μακρύ ψαλίδι HARMONIC FOCUS® + με Προσαρμοζόμενη τεχνολογία ιστού
HARMONIC FOCUS® lång sax + adaptiv vävnadsteknik
Długie nożyce HARMONIC FOCUS® + Adaptacyjna technologia tkankowa
HARMONIC FOCUS® hosszú ollló + intelligens szövet-technológia
Dlouhé nůžky HARMONIC FOCUS® s adaptivní tkáňovou technologií
Dlhé nožnice HARMONIC FOCUS® s adaptívnou tkanivovou technológiou
HARMONIC FOCUS® Lange skjærere + Adaptiv vevsteknologi
HARMONIC FOCUS® Uzun Makas + Adaptif Doku Teknolojisi
Длинные ножницы с технологией адаптации к тканям HARMONIC FOCUS® +
Pensă foarfecă lungă HARMONIC FOCUS® + cu tehnologie de adaptare la țesut
Teknologi Jaringan Adaptif + Gunting Besar Panjang HARMONIC FOCUS®
Dao cắt HARMONIC FOCUS® Long Shears + Công nghệ Mô thích ứng
HARMONIC FOCUS® pikad käärid + adaptiivne koetehnoloogia
HARMONIC FOCUS® garās šķēres + adaptīva audu tehnoloģija
HARMONIC FOCUS® ilgos žirklės su audinių pritaikymo technologija
Дълги ножици HARMONIC FOCUS® + адаптивна технология за тъкани
HARMONIC FOCUS® duge škare + tehnologija adaptivnog tkiva
Dolge škarje HARMONIC FOCUS® + prilagodljiva tkivna tehnologija
HARMONIC FOCUS® долги ножици + технологија за приспособување на ткивото
HARMONIC FOCUS® дуге маказе + адаптивна технологија за ткиво
HARMONIC FOCUS® дугачке маказе са адаптивном технологијом ткива
HARMONIC FOCUS® 长手术剪+自适应组织技术



Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences, such as failure to ligate.

Important: This package insert is designed to provide instructions for use of the HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology. It is not a reference to ligature techniques.

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วัตถุประสงค์ รายการที่ 10

Indications

The 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.

Contraindications

- The instrument is not indicated for incising bone.
- The instrument is not intended for contraceptive tubal occlusion.

Warnings and Precautions

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.
- Verify compatibility with generators. HARMONIC FOCUS+ Long Shears are compatible only with Ethicon Endo-Surgery Generator G11 (GEN11) software version 2013_1 or later. Software revision can be found under "System Information" in the Generator G11 (GEN11) "Settings" Menu. Refer to the Generator G11 (GEN11) Operator's Manual for more information.
- Audible high-pitched ringing, resonating from the blade or Hand Piece, are an abnormal condition and an indicator that the blade or hand piece is not operating properly. The ringing may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high shaft temperatures and user or patient injury.
- In case of system failure, ensure the availability of the appropriate back-up equipment relevant to the specific procedure.
- Blood and tissue buildup between the blade and shaft may result in abnormally high temperatures at the distal end of the shaft. To prevent burn injury, remove any visible tissue buildup at the distal end of the shaft.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blade, clamp arm, and distal end of the shaft should not be in contact with the patient, drapes, or flammable materials while not in use.
- During and following activation in tissue, the instrument blade, clamp arm, and distal portion of the shaft may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- Incidental and prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.

- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades, which may be identified by generator solid tone or instrument error.
- Avoid accidental contact with other instruments during use. Scratches on the blade may lead to premature blade failure.
- Care should be taken not to apply pressure between the instrument blade and tissue pad without having tissue between them. Clamping the tissue pad against the active blade without tissue on the full length of the blade will result in higher blade, clamp arm and distal shaft temperatures and can result in possible damage to the instrument. If this happens, there may be a system failure signaled by a continuous tone or alert screen when either of the foot pedals or hand control buttons is depressed.
- Keep the jaws of the device open when backcutting or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad and increased blade, clamp arm, and distal shaft temperatures.
- To avoid user or patient injury, do not activate an electrosurgical device in close proximity to the HARMONIC® instruments. The aerosols created by the activation of the HARMONIC instruments in fatty tissue are potentially flammable.
- The entire exposed blade tip and any exposed blade shaft is active and will cut/coagulate tissue when the HARMONIC FOCUS+ Long Shears blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the HARMONIC FOCUS+ Long instrument.
- Use only the HARMONIC® Foot Switch, and the Blue Hand Piece, with the HARMONIC FOCUS+ Long Shears instrument to ensure compatibility with the Generator.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- The sealing performance of this instrument has not been assessed on atherosclerotic vessels. Exercise caution when transecting these vessels as they may not seal properly.
- Minimum starting power level defaults to power level 3.
- Successful hemostasis may require adjunct measures when HARMONIC FOCUS+ Long Shears instruments are used on solid organs. Due to the difficulty of visualizing internal structures, proceed slowly and do not attempt to transect large masses of tissue in one activation. Avoid the division of large vascular/biliary bundles when using the HARMONIC FOCUS+ Long Shears instrument under these conditions.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery may not be compatible with the HARMONIC FOCUS+ Long Shears instrument. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- Do not torque the instrument by hand or damage may occur to the hand piece. Do not use any means other than the torque wrench to attach or detach the instrument from the hand piece.
- Take care to avoid damage to the shears when removing the torque wrench from the instrument.
- Take care to avoid injury from the blade tip while removing the torque wrench from the instrument.
- Do not clean the instrument with abrasives.
- Instruments or devices, which come into contact with bodily fluids, may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.

Device Description

The HARMONIC FOCUS+ Long Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 17 cm in length with a 16 mm active

รายการที่ 10 ข้อที่ 1, 2, 3

blade length. The HARMONIC FOCUS+ Long Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Each HARMONIC FOCUS+ Long Shears instrument is packaged with one sterile, single patient use, disposable purple torque wrench. Use only the purple torque wrench with the HARMONIC FOCUS+ Long Shears instrument. The torque wrench should not be discarded until the completion of the surgical case. Do not attempt to sterilize the disposable torque wrench.

The two dashes on the instrument are intended to represent relative vessel size. The MAX ▭ button is typically used for smaller vessels where cutting speed is fastest. The MIN ▭ button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. Adaptive Tissue Technology provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and decrease its power output as well as provide audible feedback to the user as appropriate.

The HARMONIC FOCUS+ Shears is designed for use exclusively with the Generator G11 (GEN11) software version 2013_1 or later and HARMONIC Blue Hand Piece, packaged separately. Software revision can be found under "System Information" in the Generator G11 (GEN11) "Settings" Menu. Refer to the Generator G11 (GEN11) Operator's Manual for more information.

Refer to the Instructions for Use of the HARMONIC Blue Hand Piece and Test Tip (TTBLUE) for instructions regarding the hand piece.

Illustration and Nomenclature (Illustration 1)

1. Torque Wrench
2. Blade
3. Clamp Arm and Tissue Pad
4. Handle Housing
5. Finger Rings
6. Finger Ring Rests
7. MIN Hand Control (proximal)
8. MAX Hand Control (distal)
9. Hand Piece (not included)

Transport and Storage Conditions

Temperature -22°C to +60°C
Relative Humidity 10–80%

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).
The hand piece and test tip, packaged separately, are shipped non-sterile and must be sterilized per the insert instructions prior to each use.

Assembly

1. Using aseptic technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. While holding the hand piece, attach the instrument by rotating it onto the hand piece in a clockwise rotation as viewed from the distal end of the instrument (finger tight only) (Illustration 2).
3. Use the purple torque wrench to tighten the instrument onto the hand piece. Turn the wrench clockwise while holding the hand piece until it clicks twice, indicating that sufficient torque has been applied to secure the instrument (Illustration 3). In the event that the torque wrench must be re-positioned on

the instrument, ensure that the torque wrench is re-positioned correctly, as shown in Illustration 3. When properly aligned, the short side of the torque wrench should be aligned with the instrument hand controls, handle housing, and the Hand Piece, and the "Dispose of Properly" icon on the torque wrench should be on top. To ensure properly assembly, do not grip the instrument handle while applying torque with the Torque Wrench.
Caution: Do not torque the instrument by hand or damage may occur to the hand piece. Do not use any means other than the torque wrench to attach or detach the instrument from the hand piece.
4. Remove the torque wrench from the instrument. Do not discard the disposable torque wrench until the completion of the surgical case. The torque wrench is used for removal of the instrument from the hand piece following the procedure (Illustration 4). In the event the torque wrench falls out of the sterile field, replace with a sterile, purple torque wrench. Do not re-sterilize the disposable torque wrench. **Caution**: Take care to avoid damage to the shears when removing the torque wrench from the instrument.
5. The second activation tone can be turned off under the "Settings" Menu on the G11 generator. See Generator G11 (GEN11) Operator's Manual for more information.
   - This will deactivate the second activation tone only; this will not affect the Adaptive Tissue Technology's modulation and decrease of power output.

Operation

Refer to a compatible HARMONIC Generator User Manual for hand piece attachment and system operation instructions.

1. Connect the assembled hand piece and instrument to the generator and turn the generator power on. Do not turn the generator power on before the hand piece and instrument are connected to the generator.
2. Select the desired variable or maximum power level using the INCREASE and DECREASE buttons on the generator.
   - Minimum starting power level defaults to power level 3 (Illustration 5). For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.
   - MAX power is set at power level 5 and cannot be adjusted.
3. The HARMONIC FOCUS+ Long Shears instrument may be operated with either the foot switch or hand control. For foot switch or hand control function, refer to a compatible HARMONIC Generator User Manual for further detail and setup and operation instructions.
4. For optimal performance, clean the instrument blade and clamp arm throughout the procedure by activating the instrument tip in sterile saline (Illustration 6). The instrument can be wiped with a sterile moist gauze sponge to remove tissue, if necessary.
WARNING: Do not touch the instrument to metal while activated (Illustration 7). See **Warnings and Precautions.**
5. If tissue is still visible in the clamp arm, use hemostats to remove residue (Illustration 8).
6. The blade is ultrasonically energized when either the foot switch pedal is depressed or one of the hand controls is depressed.
   - Pressing either the left foot pedal of the foot switch or the proximal hand control (MIN) on the instrument activates the selected minimum power level.
   - Pressing either the right foot pedal of the foot switch or distal hand control (MAX) on the instrument activates the maximum power level.
   - The generator provides an audible tone to indicate when the instrument blade is active.
   - The generator changes to a second activation tone as Adaptive Tissue Technology regulates the delivery of energy.

- Thermal influences such as fluids or minimal to no tissue in the jaws may affect the presence or timing of the tone change.
- The tone change does not provide confirmation of tissue effect. When the second tone is heard, the situation should be assessed and the intended surgical action completed, such as gradual application of tension to facilitate transection.
- The secondary activation tone change is not a substitute for surgical experience.

WARNING: Avoid accidental contact with other instruments during use. Scratches on the blade may lead to premature blade failure.

7 Close the clamp arm and insert the instrument through the incision. Use the HARMONIC FOCUS+ Long Shears for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the top of the blade with the jaws open if using for backcutting.

Caution: Do not use finger ring rests to extend reach during procedure, as this could result in poor vessel sealing and unstable positioning of the instrument (Illustration 9).

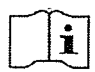
WARNING: Keep the jaws of the device open when backcutting or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad, and increased blade, clamp arm, and distal shaft temperatures.

Disassembly

1 Turn the generator **OFF** at the power switch.
2 Close the clamp arm and place the purple torque wrench over the distal end of the instrument.
3 While holding the hand piece, loosen the instrument by turning the torque wrench counterclockwise. Continue to loosen by turning the instrument manually to completely unscrew it from the hand piece.
4 Remove the torque wrench from the instrument. Dispose of the instrument and the torque wrench in an appropriate container.

How Supplied

The HARMONIC FOCUS+ Long Shears and purple torque wrench are supplied sterile for single patient use. Discard after use.

	Relative Humidity Humidité relative Relative Feuchte Umidità relativa Humidade relativa Humedad relativa Relatieve luchtvochtigheid Relativ fugtighed Suhteellinen kosteus Σχετική υγρασία Relativ luftfuktighet Wilgotność względna Relatív páratartalom Relativní vlhkost Relatívna vlhkosť Relativ luftfuktighet	Bağıl Nem Относительная влажность Umiditate relativă Kelembaban Relatif Độ ẩm tương đối Suhteline õhuniiskus Relatīvais mitrums Santykinė drėgmė Относителна влажност Relativna vlažnost Relativna vlažnost Релативна влажност Релативна влажност Релативна влажност 相对湿度
	Temperature Température Temperatur Temperatura Temperatura Temperatura Temperatuur Temperatur Lämpötila Θερμοκρασία Temperatur Temperatura Hőmérséklet Teplota Teplota Temperatur	Sıcaklık Температура Temperatură Temperatur Nhiệt độ Temperatuur Temperatūra Temperatūra Температура Temperatura Temperatura Температура Температура Температура 温度
	See Instructions For Use Voir notice d'utilisation Bitte Gebrauchsanweisung beachten Vedere le istruzioni per l'uso Ver Instruções de Uso Ver instrucciones de uso Zie gebruiksaanwijzing Se brugsvejledningen Katso käyttöohjeet Ανατρέξτε τις Οδηγίες Χρήσεως Se bruksanvisning Zobacz Instrukcja użytkowania Lásd a használati útmutatót Prostudujte návod k použití Prečítajte si návod na použitie Se bruksanvisningen	Kullanma Talimatına Bakınız Смотри инструкцию по применению Consultați instrucțiunile de utilizare Lihat Petunjuk Penggunaan Xem Hướng dẫn sử dụng Vaadake kasutusjuhendit Skatiet lietošanas instrukciju Žr. naudojimo instrukcija Виж "Инструкциите за употреба" Vidi upute za uporabu Glejte Navodila za uporabo Видете во Упатството за употреба Погледајте Упутства за коришћење Погледајте упутства за употребу 参见使用说明

	Do not use the HARMONIC FOCUS Long Shears with ULTRACISION* Generator (GEN01/GEN32/GEN04) Ne pas utiliser les ciseaux longs HARMONIC FOCUS avec le générateur ULTRACISION* (GEN01/GEN32/GEN04) Verwenden Sie die HARMONIC FOCUS Lange Koagulationsschere nicht mit dem ULTRACISION* Generator (GEN01/GEN32/GEN04) Non usare le forbici lunghe HARMONIC FOCUS con il generatore ULTRACISION* (GEN01/GEN32/GEN04) Não utilize a Tesoura Comprida HARMONIC FOCUS com o Gerador ULTRACISION* (GEN01/GEN32/GEN04). No utilizar las tijeras largas HARMONIC FOCUS con el generador ULTRACISION* (GEN01/GEN32/GEN04). Gebruik de HARMONIC FOCUS lange schaar niet met een ULTRACISION*-generator (GEN01/GEN32/GEN04). Brug ikke HARMONIC FOCUS lang saks sammen med ULTRACISION*-generator (GEN01/GEN32/GEN04). HARMONIC FOCUS pitkä leikkausinstrumentti -instrumenttia ei saa käyttää ULTRACISION*-generaattorin kanssa (GEN01/GEN32/GEN04). Μη χρησιμοποιείτε το Μακρύ ψαλίδι HARMONIC FOCUS με Γεννήτρια ULTRACISION* (GEN01/GEN32/GEN04) Använd inte HARMONIC FOCUS lång sax med ULTRACISION*-generator (GEN01/GEN32/GEN04) Nie wolno używać długich nożyc HARMONIC FOCUS z generatorem ULTRACISION* (GEN01/GEN32/GEN04). A HARMONIC FOCUS hosszú ollót tilos az ULTRACISION* generátorral használni! (GEN01/GEN32/GEN04). Nepoužívejte dlouhé nůžky HARMONIC FOCUS s generátorem ULTRACISION* (GEN01/GEN32/GEN04). Nepoužívajte dlhé nožnice HARMONIC FOCUS s generátorom ULTRACISION* (GEN01/GEN32/GEN04). Ikke bruk HARMONIC FOCUS lange skjærere med ULTRACISION*-generator (GEN01/GEN32/GEN04). HARMONIC FOCUS Uzun Makası ULTRACISION* Jeneratör (GEN01/GEN32/GEN04) ile birlikte kullanmayın. Запрещается использовать длинные ножницы HARMONIC FOCUS с генератором ULTRACISION* (GEN01/GEN32/GEN04) Nu utilizați pensa foarfecă lungă HARMONIC FOCUS cu generatorul ULTRACISION* (GEN01/GEN32/GEN04). Jangan gunakan Gunting Besar Panjang HARMONIC FOCUS bersama Generator ULTRACISION* (GEN01/GEN32/GEN04) Không được sử dụng Dao cắt HARMONIC FOCUS Long Shears với Máy phát ULTRACISION* (GEN01/GEN32/GEN04) Ärge kasutage HARMONIC FOCUS pikki kääre koos ULTRACISION* generaatoriga (GEN01/GEN32/GEN04). Neizmantojiet HARMONIC FOCUS garās šķēres kopā ar ULTRACISION* generatoru (GEN01/GEN32/GEN04). Nenaudokite HARMONIC FOCUS ilgų žirklių su ULTRACISION* generatoriumi (GEN01/GEN32/GEN04) Не използвайте дългите ножици HARMONIC FOCUS с генератор ULTRACISION* (GEN01/GEN32/GEN04) Ne koristiti HARMONIC FOCUS duge škare s ULTRACISION* generatorom (GEN01/GEN32/GEN04) Dolgih škarij HARMONIC FOCUS ne uporabljajte skupaj z generatorjem ULTRACISION* (GEN01/GEN32/GEN04).

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STERILE | EO	Sterilized by Ethylene Oxide Stérilisé à l'oxyde d'éthylène Sterilisiert mit Ethylenoxid Sterilizzato a ossido di etilene Esterilização por óxido de etileno Esterilizado por óxido de etileno Gesteriliseerd met ethyleenoxide Steriliserede med ethylenoxid Steriloitu etyleenioksidilla Αποστειρωμένα με αιθυλενοξείδιο Steriliserade med etylenoxid Produkt sterylizowany tlenkiem etylenu Etilén-oxiddal sterilizálva Sterilizováno etylenoxidem Sterilizované etylén oxidom Sterilisert med etylenoksid	EO ile Sterilize Edilmiştir Стерилизовано этиленоксидом Sterilizat cu oxid de etilenă Disterilisasi menggunakan Etilen Oksida Tiệt trùng bằng ethylen oxyd Steriliseeritud etüleenoksiidiga Sterilizēts ar etilēnoksīdu Sterilizuota etileno oksidu Стерилизирана се с етилен оксид Sterilizirana etilen-oksidom Sterilizirano z etilenoksidom Стерилизирано со етилен оксид Стерилисано етилен оксидом Стерилизовано етилен-оксидом 环氧乙烷灭菌
	Single Patient Use A utiliser sur un seul patient lors d'une seule et même intervention Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één patient Til anvendelse på én patient Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egy etlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta	Kun til bruk på én pasient Tek Hastada Kullanılabilir Для применения у одного пациента De unică utilizare Penggunaan Sekali Pakai Sử dụng cho một bệnh nhân duy nhất Kasutamiseks ühel patsiendil Lietošanai vienam pacientam Skirta naudoti vieną kartą vienam pacientui За употреба само при един пациент Uporaba na jednome pacijentu Za uporabo pri enem bolniku За употреба само на еден пациент За употребу на једном пацијенту Само за једнократну употребу 单一患者使用

LOT	Lot N° de lot Ch.-B. Lotto N° do lote N° de lote Lotnr. Parti Erän koodi Αρ. παρτίδας Batchnummer Numer partii produkcyjnej Tétel Šarže Šarža Lot	Lot Серия Lot Lot Lô sản xuất Partii Partija Partija Партида Serija Serija Серија Партија Број серије 批号
	Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato Käytettävä viimeistään Χρησιμοποιείτε μέχρι την Använd före Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použít do data Použiteľné do Brukes før-dato	Son Kullanma Tarihi Срок годности A se utiliza înainte de data Digunakan Hingga Tanggal Sử dụng đến ngày Kasutamise lõpptähtaeg Derīguma termiņš Tinka naudoti iki Използвай до дата Datum „Uporabiti do" Rok uporabe Да се употреби до Датум истека рока трајања Користити до датума 有效期

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	Manufacturer/Date of Manufacture Fabricant/Date de fabrication Hersteller/Herstellungsdatum Fabbricante/Data di fabbricazione Fabricante/Data de Fabrico Fabricante/Fecha de fabricación Fabrikant/Fabricagedatum Producent/Produktionsdate Valmistaja/Valmistuspäivämäärä Κατασκευαστής/Ημερομηνία κατασκευής Tillverkare/Tillverkningsdatum Producent/Data produkcji Gyártó/Gyártás ideje Výrobce/Datum výroby Výrobca/Dátum výroby	Produsent/Produksjonsdato Üretici/Üretim Tarihi Производитель/Дата изготовления Producător/Data fabricaţiei Produsen/Tanggal Produksi Nhà sản xuất/Ngày sản xuất Tootja/tootmiskuupäev Ražotājs/Ražošanas datums Gamintojas/pagaminimo data Производител/Дата на производство Proizvođač/datum proizvodnje Proizvajalec/Datum proizvodnje Производител/Датум на производство Произвођач/Датум производње Произвођач/датум производње 制造商/制造日期
	Do Not Resterilize Ne pas restériliser Nicht resterilisieren Non risterilizzare Não reesterilizar No reesterilizar Niet opnieuw steriliseren Må ikke gensteriliseres Ei saa steriloida uudestaan Μην επαναποστειρώνετε Får ej omsteriliseras Nie sterylizować ponownie Tilos újra sterilizálni! Nastrojí znovu nesterilizujte Neresterilizujte Skal ikke resteriliseres	Tekrar Steril Etmeyin Повторная стерилизация запрещена A nu se resteriliza Jangan Sterilisasi Ulang Không được tiệt trùng lại Mitte resteriliseerida Nesterilizējiet atkārtoti Pakartotinai nesterilizuoti Да не се стерилизира повторно Nemojte ponovo sterilizirati Ne sterilizirajte znova Да не се стерилизира повторно Немојте повторно да стерилизирате Немојте поново да стерилишете 不可再次灭菌

	Do Not Use if Package is Damaged Ne pas utiliser si l'emballage est endommagé Nicht verwenden, falls die Verpackung beschädigt ist. Non usare se la confezione è danneggiata Não utilizar se a embalagem estiver danificada No utilizar si el envase está dañado Niet gebruiken als de verpakking beschadigd is Må ikke anvendes, hvis pakken er beskadiget. Ei saa käyttää, jos pakkaus on vahingoittunut Μη χρησιμοποιείτε εάν η συσκευασία εμφανίζει φθορά Får ej användas om förpackningen är skadad. Nie używać, jeśli opakowanie jest uszkodzone. Ne használja, ha a csomagolás fel van bontva vagy sérült. Nepoužívejte, pokud je balení poškozené. Nepoužívajte, ak je balenie poškodené Må ikke brukes hvis emballasjen er skadet. Ambalaj Hasarlıysa Kullanmayın. Запрещается использовать, если упаковка повреждена A nu se utiliza dacă ambalajul este deteriorat. Jangan Gunakan Jika Kemasannya Rusak. Không sử dụng nếu gói sản phẩm bị hư hỏng. Mitte kasutada, kui pakend on kahjustatud Ja iepakojums ir bojāts, nelietot. Nenaudokite, jei pakuotė pažeista Не използвайте, ако опаковката е увредена. Nemojte rabiti ako je pakiranje oštećeno Ne uporabljajte, če je ovojnina poškodovana Да не се користи ако е оштетено пакувањето. Немојте да користите ако је паковање оштећено Не користите уколико је паковање оштећено. 如包装损坏，切勿使用

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Rx Only	Caution Federal (USA) law restricts this device to sale by or on the order of a physician Mise en garde La Loi Fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription Achtung. Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden Attenzione. la legge federale americana consente la vendita di questo dispositivo solo a medici oppure dietro richiesta medica. Atenção. A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes Atención: la ley federal de EE.UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripcion médica Let op: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht. Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge. Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä. Προσοχή: Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του οργάνου αυτού μόνον από ιατρούς ή κατόπιν εντολής ιατρού Försiktighet: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan. Przestroga. Prawo federalne (USA) zezwala na sprzedaz tego urzadzenia wylacznie lekarzowi lub na jego zamówienie Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető. Upozornění: Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis Pozor: Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis Forsiktig: Ifølge amerikansk lovgivning kan dette utstyret kun selges av eller etter forordning av en lege. Dikkat: A B D. federal kanunlarına göre bu cihaz sadece bir doktor tarafından veya emriyle satılabilir. Внимание! Федеральный закон США разрешает продажу этого устройства только врачам или по заказу врачей. Atenție Legea federală S U.A. restricționează vânzarea acestui dispozitiv doar la medici sau pe baza comenzii unui medic Perhatian Hukum Federal (USA) membatasi penjualan alat ini oleh atau atas perintah dokter. Thận trọng: Đạo luật Liên bang (Hoa Kỳ) hạn chế thiết bị này chỉ được bán bởi hoặc theo yêu cầu của bác sĩ. Ettevaatust! Ameerika Ühendriikide föderaalseadus lubab seda seadet müüa arstil või arsti tellimusel Uzmanību! Saskaņā ar federālo (ASV) likumdošanu šo ierīci drīkst pārdot tikai ārstam vai pēc ārsta rīkojuma.

Rx Only	Perspėjimas Pagal federalinius (JAV) įstatymus šį prietaisą leidžiama parduoti tik gydytoju arba jo užsakymu Внимание: федералният закон на САЩ ограничава продажбата на този уред до от или по предписание на лекар Oprez: savezni zakon SAD-a ograničava prodaju ovog uređaja jedino liječnicima ili po njihovu nalogu. Pozor: v skladu z zveznimi zakoni ZDA je prodaja te naprave omejena samo na zdravnike oziroma po zdravnikovem naročilu Внимание: Сојузните закони (САД) поставуваат ограничување овој уред да се продава само по налог на лекар Опрез: Савезни (САД) закон ограничава продају овог уређаја тако да се врши од стране или по налогу лекара. Опрез: Федерални закон у САД ограничава продају овог уређаја само од стране лекара или по његовом налогу [illegible]
USA REP	Authorized Representative in the USA Représentant autorisé aux États-Unis d'Amérique Bevollmächtigter in den USA Rappresentante autorizzato per gli Stati Uniti Representante autorizado nos EUA Representante autorizado en EE.UU. Bevoegd vertegenwoordiger in de VS Bemyndiget repræsentant i USA Valtuutettu edustaja Yhdysvalloissa Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ Auktoriserad representant i USA Autoryzowany przedstawiciel w Stanach Zjednoczonych Ameryki Meghatalmazott képviselő az Egyesült Államokban Autorizovaný zástupce v USA Autorizovaný zástupca v USA Autorisert representant i USA A.B.D.'de Yetkili Temsilci Уполномоченный представитель в США Reprezentant autorizat în S.U.A. Perwakilan Resmi di AS Đại diện ủy quyền tại Hoa Kỳ Volitatud esindaja Ameerika Ühendriikides Pilnvarotais pārstāvis ASV Įgaliotasis atstovas JAV Упълномощен представител в САЩ Ovlašteni predstavnik u SAD-a Pooblaščeni zastopnik za ZDA Овластен претставник во САД Овлашћени представник у САД Овлашћени представник у САД [illegible]

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1	Unit Quantity Quantité par unité Stück pro Verpackungseinheit Quantità Quantidade de unidades Cantidad unitaria Dosering Enhedsmængde Yksikkömäärä Ποσότητα μονάδας Antal enheter Ilość sztuk w opakowaniu Egységek száma csomagonként Počet jednotek v balení Počet jednotiek v balení Enhetsmengde	Bırım Miktarı Количество элементов Cantitate unitară Jumlah Unit Đơn vị đóng gói Komplekti kuuluvate seadmete arv Vienību skaits Vienetų skaičius pakuotėje Брой изделия в опаковката Količina Količina enot Количина Количина Количина [illegible]

P000099P01

REF
HAR17F

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Rev. 2015-04-30

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ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดที่ 68-2-2-2-0011277

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่

บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ผู้ได้รับอนุญาตให้ประกอบการนำเข้าเครื่องมือแพทย์ ใบอนุญาตที่ นข. 515/2554

เพื่อแสดงว่าได้ยื่นแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์ตามมาตรา 35 แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2551 และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

Generator G11

ชื่อการค้าเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ ตามเอกสารแนบท้าย

ชื่อสถานที่นำเข้าเครื่องมือแพทย์ที่ซื้อ บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ตั้งอยู่เลขที่ 106

ตรอก/ซอย นิคมอุตสาหกรรมลาดกระบัง ถนน ถนนกรุง หมู่ที่ 4

ตำบล/แขวง ลำปลาทิว อำเภอ/เขต ลาดกระบัง

จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10520 โทรศัพท์ 02-792 7300 โทรสาร 02-792 7304

ใบรับแจ้งรายการละเอียดฉบับนี้ใช้ได้จนถึงวันที่ 31 ธันวาคม พ.ศ. 2569 และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

ออกให้ ณ วันที่ 26 เดือน กรกฎาคม พ.ศ. 2565

(ลายมือชื่อ) สำนักงานคณะกรรมการอาหารและยา
(ตำแหน่ง) กระทรวงสาธารณสุข
ผู้อนุญาต

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เอกสารแนบท้าย

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0011377

รายละเอียดเครื่องมือแพทย์

The Generator G11 supplies energy to the HARMONIC and ENSEAL surgical instruments. The generator uses a touchscreen display interface and has a unique receptacle port that accepts either a HARMONIC or an ENSEAL instrument. Connectors (HGA11 for HARMONIC and EGA11 for ENSEAL) are used to enable the generator to power legacy instruments. All ENSEAL and HARMONIC devices compatible with the generator and provided by Ethicon and authorized manufacturers undergo an extensive verification and validation process. The Ethicon Endo-Surgery Generator G11 System is not designed to operate unauthorized devices. Such use is not in accordance with the design & use parameters, instructions and guidelines for the product.

ชื่อและที่ตั้งของเจ้าของผลิตภัณฑ์

ETHICON ENDO-SURGERY, LLC, 475 CALLE C, GUAYNABO, PR 00969, USA

มีรายละเอียดรายการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
[illegible]	[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	[illegible]	
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65470887000011	HARMONIC FOCUS Long Shears	HAR17F	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	[illegible]	
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