Johnson & Johnson
MEDICAL COMPANIES

รายการที่ ๕ กรรไกรปลายโค้ง

วัตถุประสงค์ เป็นกรรไกรปลายโค้งใช้ตัดเนื้อเยื่อ สามารถต่อกับเครื่องมือและตัดแบบ แบบโมโนโพล่าร์ เพื่อห้ามเลือดขณะผ่าตัด

คุณลักษณะเฉพาะ

๑. เป็นกรรไกรปลายโค้งตัดเนื้อเยื่อสามารถต่อกับ เครื่องจี้ และตัดแบบโมโนโพล่าร์ได้
๒. ความยาวของก้านเครื่องมือไม่น้อยกว่า ๓๓ ซม.
๓. ก้านของเครื่องมือมีเส้นผ่าศูนย์กลางไม่มากกว่า ๕ มม.
๔. ก้านของเครื่องมือสามารถหมุนได้ไม่น้อยกว่า ๓๖๐ องศา มีความสะดวกในการปรับตำแหน่งขณะผ่าตัด
๕. ด้ามจับมีปุ่มล็อค (Ratchet Button) สามารถล็อคปากเครื่องมือให้อยู่ในตำแหน่งที่ต้องการ
๖. ผ่านการฆ่าเชื้อโรค (Sterilization) และสามารถใช้งานได้ทันที
๗. ผู้ยื่นเสนอราคาต้องมีสินค้าตามรายการพัสดุครบทุกรายการ

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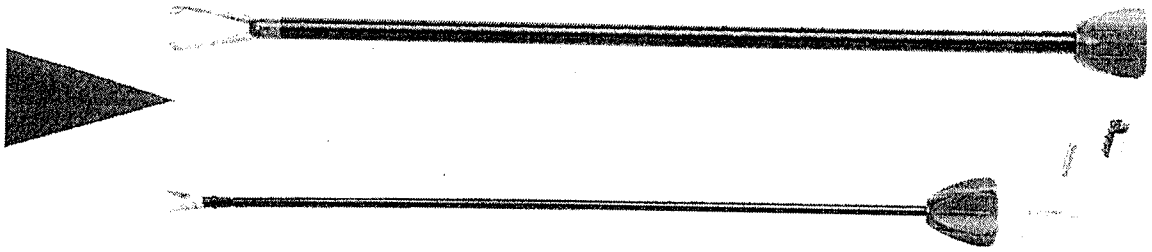
A division of Johnson and Johnson (Thailand) Ltd.
106 Moo 4 Lardkrabang Industrial Estate, Chalongkrung Road, Lamplatew, Lardkrabang, Bangkok 10520, Thailand Tel : +66 2792 7300 Fax : +66 2792 7304

ENDOPATH® Endoscopic Hand Instruments

Versatile and easy to use

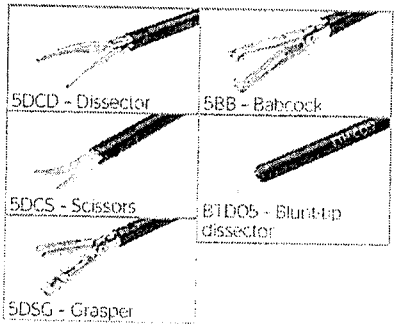
ENDOPATH® Endoscopic Hand Instruments are sterile, single-patient use endoscopic instruments designed for application in a variety of minimally invasive procedures. ENDOPATH® Endoscopic Hand Instruments facilitate grasping, mobilization, dissection and transection of tissue.



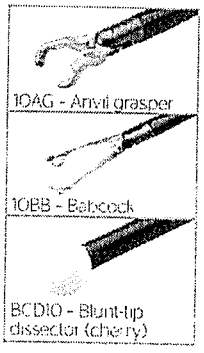
ENDOPATH® Endoscopic Hand Instruments features

- Available in dissector, scissors, grasper, babcock and blunt-tip dissector
- 5mm and 10mm diameter insulated shaft
- Shaft rotates 360°
- Disposable, single-patient use

5mm



10mm



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ENDOPATH® Endoscopic Hand Instruments

5mm

Product Code	Description	Qty/box
5DCD	Dissector, curved, with monopolar cautery	6
5DCS	Scissors, curved, with monopolar cautery	6
5DSG	Grasper	6
5BB	Babcock	6
BTD05	Dissector, blunt tip, 3 per pouch, 12 pouches per sales unit	36

10mm

Product Code	Description	Qty/box
10AG	Anvil grasper	6
10BB	Babcock	6
BCD10	Dissector, blunt tip (cherry), 3 per pouch, 12 pouches per sales unit	36

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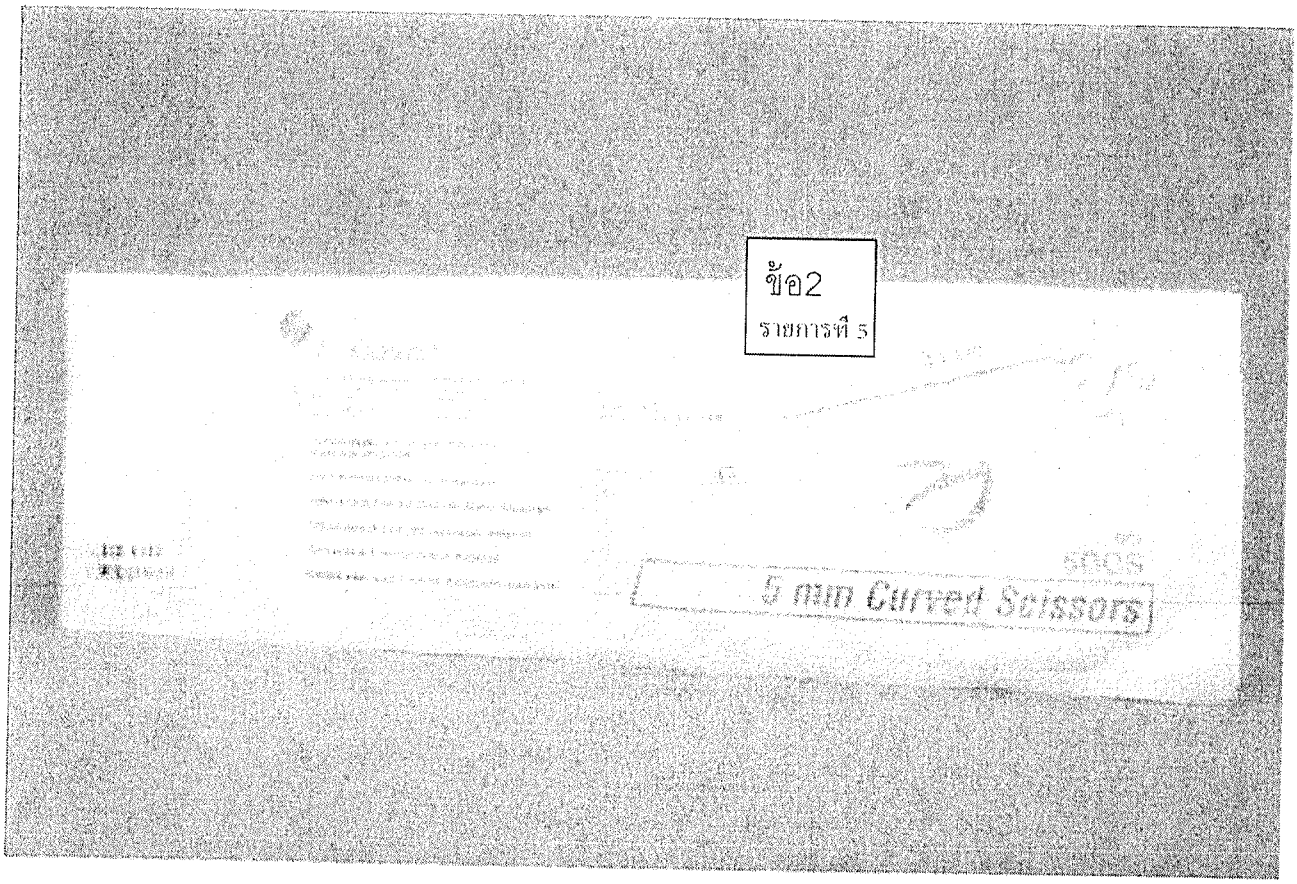
For complete product information, including full steps for use, indications, contraindications, warnings and precautions, please see the Instructions for Use.

กรรไกรปลายโค้ง

(Endopath Curved Scissors 5 mm. – 5DCS



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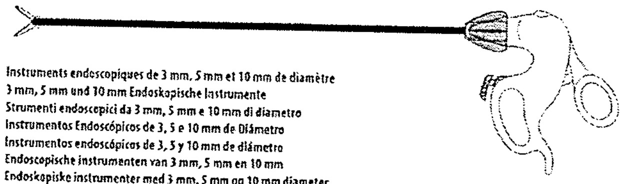
ENDOPATH®

3 mm, 5 mm and 10 mm Diameter Endoscopic Instruments



Instruments endoscopiques de 3 mm, 5 mm et 10 mm de diamètre
3 mm, 5 mm und 10 mm Endoskopische Instrumente
Strumenti endoscopici da 3 mm, 5 mm e 10 mm di diametro
Instrumentos Endoscópicos de 3, 5 e 10 mm de Diâmetro
Instrumentos endoscópicos de 3, 5 y 10 mm de diámetro
Endoscopische instrumenten van 3 mm, 5 mm en 10 mm
Endoskopiske instrumenter med 3 mm, 5 mm og 10 mm diameter
3, 5 ja 10 mm:n läpimittaiset endoskooppiset instrumentit
Ενδοσκοπικά Εργαλεία Διαμέτρου 3 χιλ., 5 χιλ. και 10 χιλ.
Endoskopiska instrument med 3, 5 och 10 mm diameter
Urządzenia endoskopowe o średnicy 3 mm, 5 mm i 10 mm
3 mm, 5 mm és 10 mm átmérőjű endoszkópos eszközök
Endoskopické nástroje o průměru 3, 5 a 10 mm
Endoskopické nástroje s priemerom 3 mm, 5 mm a 10 mm
Endoskopiske Instrumenter med diameter på 3 mm, 5 mm og 10 mm
3 mm, 5 mm ve 10 mm Çapında Endoskopik Aletler
Эндоскопические инструменты диаметром 3 мм, 5 мм и 10 мм
Instrumente endoscopice cu diametrul de 3 mm, 5 mm şi 10 mm
Instrumen Endoskopik Diameter 3 mm, 5 mm, dan 10 mm
Dụng cụ nội soi đường kính 3 mm, 5 mm và 10 mm
3-millimeetrise, 5-millimeetrise ja 10-millimeetrise diameetriga endoskoopilised instrumendid
3 mm, 5 mm un 10 mm diametra endoskopiskie instrumenti
3 mm, 5 mm ir 10 mm skersmens endoskopiniai instrumentai
Ендоскопски инструменти с диаметър 3 mm, 5 mm и 10 mm
Endoskopski instrumenti promjera 3 mm, 5 mm i 10 mm
Endoskopski instrumenti premera 3, 5 in 10 mm
Ендоскопски инструменти со дијаметар од 3 mm, 5 mm и 10 mm
Ендоскопски инструменти пречника 3 mm, 5 mm и 10 mm
Ендоскопски инструменти пречника од 3 мм, 5 мм и 10 мм
直径 3 mm、5 mm 和 10 mm 的内窥镜器械

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® 3 mm, 5 mm and 10 mm Diameter Endoscopic Instruments. It is not a reference to minimally invasive techniques

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

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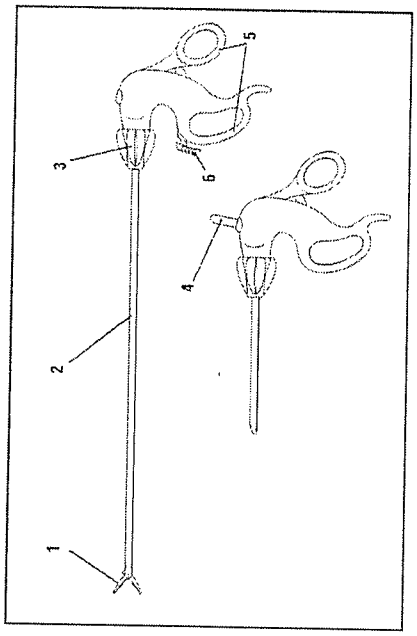

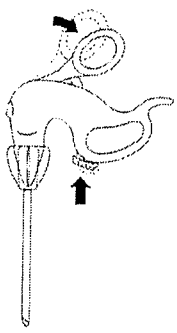

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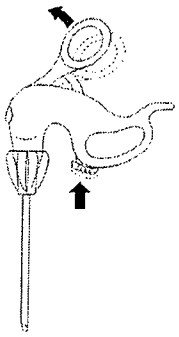

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Indications

The Endopath Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

Contraindications

- The instruments are not intended for contraceptive coagulation of fallopian tissue
- The instruments are not intended for use when minimally invasive techniques are contraindicated.

Device Description

The Endopath Endoscopic Instruments are sterile, single patient use instruments that have a rotating 3 mm, 5 mm or 10 mm diameter insulated shaft and are designed for use through appropriate Endopath Surgical Trocars and FLEXIPATH® Flexible Surgical Trocars. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. Some instruments have a monopolar cautery connector extending from the top of the handle and can be used for electrosurgery when properly attached to standard cautery cables and appropriate generators. Other instruments have ratchet handles, which allow the instrument jaws to be locked in place. The instrument jaws or scissor blades are activated by compression and release of the ring handles.

Illustration and Nomendature (Illustration 1)

1. Blades/Jaws
2. Insulated Shaft
3. Rotation Knob
4. Cautery Connector
5. Ring Handles
6. Ratchet Button

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.
Note: Instruments dropped outside the sterile field should be replaced.
Note: Remove black tip protector from end effector and red tip protector from cautery pin before use.
Note: Instruments with ratchet mechanisms are shipped in the locked position. Disengage the ratchet by depressing the gray ratchet button.

2 To rotate the shaft, turn the knob to the desired position.

3 For instruments with ratchet mechanisms: Position the jaws so that the tissue is between them. Close the ring handles to the desired position thereby clamping onto the tissue. Press the gray ratchet button (located on the front of the ring handle) to activate the ratchet mechanism and lock the instrument jaws onto the tissue. (Illustration 2)

4 To release tissue from the instrument jaws, press the ratchet button again and open the handles. (Illustration 3)

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.
- Refer to appropriate electrosurgical system user manual for indications and instructions to ensure that all safety precautions are followed.
- When using electrocautery, ensure the blades/jaws are fully visible to avoid inadvertent tissue damage.
- Do not use instruments with monopolar cautery as bipolar cautery instruments.

- Do not apply electrosurgical current directly to staples or clips.
- Damage to the instrument may occur if cutting of staples or clips is attempted.
- Do not introduce or withdraw the instrument with the blades/jaws open through a trocar sleeve.
- After removing the instrument, inspect the site for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
- The instrument will operate with electrosurgical generators having a high frequency **maximum** voltage of 3000 Volts peak. Refer to the electrosurgical generator's specification to verify compatibility and for indications and instructions, and ensure that all safety precautions are followed.
- 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. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that 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.

Environmental Conditions for Transport and Storage

Temperature, -22°C to 60°C
Relative Humidity 0% to 80%

How Supplied

The Endopath Endoscopic Instruments are 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. Sterilizuota spinduliuote. Sterilumas garantuojamas tik jei pakuotė nėra atidaryta ar pažeista. Pakartotinai nesterilizuoti.

STERILE R	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 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 instrukciją 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 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 Egy elleo 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 [illegible]

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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 партије 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 Χρησιμοποιείστε 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 „Uporabni 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.

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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. 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 šį prietaisą leidžiama parduoti tik gydytojui arba jo užsakymu. Внимание: федералният закон на САЩ ограничава продажбата на този уред до or или по предписание на лекар. Oprez: savezni zakon SAD-a ograničava prodaju ovog uređaja jedino liječnicima ili po njihovu nalogu. Pozor: v skladu z zveznim zakonom ZDA je prodaja te naprave omejena samo na zdravnike oziroma po zdravnikovem naročilu. Внимание: Сојузните закони (САД) постојано ограничуваат овој уред да се продава само од или по налог од лекар. Опрез: Савезни (САД) закон ограничава продају овог уређаја тако да се врши од стране или по налогу лекара. Опрез: Федерални закон у САД-у ограничава продају овог уређаја само од стране или по налогу лекара. [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
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 Befuldmægtiget 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-у 美国授权代表人

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%	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 воздуха Релативна влажност [illegible]

P40304P09

REF
1045 SBB, EDCb, 50CS, 505G, 1008

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22851 Norderstedt
GERMANY

Johnson & Johnson AG
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1-800-USE-ENDO

ETHICON ENDO-SURGERY, LLC
a Johnson&Johnson company

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ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0018632

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่

บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

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

ENDOPATH

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

ชื่อและที่ตั้งของเจ้าของผลิตภัณฑ์

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

ใบรับแจ้งรายการละเอียดฉบับนี้ใช้ได้จนถึงวันที่ 31 ธันวาคม พ.ศ. 2569 และให้ใช้เฉพาะสถานที่ที่ระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

ออกให้ ณ วันที่ 20 เดือน ธันวาคม พ.ศ. 2565

(ลายมือชื่อ) สำนักงานคณะกรรมการอาหารและยา

(ตำแหน่ง) กระทรวงสาธารณสุข

ผู้อนุญาต

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รับรองสำเนาถูกต้อง

เอกสารแนบท้าย

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0018632

รายละเอียดเครื่องมือแพทย์

The ENDOPATH Endoscopic instruments have a rotating 3 mm, 5 mm or 10 mm diameter insulated shaft and are designed for use through appropriate ENDOPATH Surgical Trocars and FLEXIPATH Flexible Surgical Trocars. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. Some instruments have a monopolar cautery connector extending from the top of the handle and can be used for electrosurgery when properly attached to standard cautery cables and appropriate generators. Other instruments have ratchet handles, which allow the instrument jaws to be locked in place. The instrument jaws or scissor blades are activated by compression and release of the ring handles.

มีรายละเอียดตามรายการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	Identifier	บริษัทผู้ผลิต	อื่นๆ
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	ETHICON ENDO SURGERY S.A. DE C.V. PLANTA II [illegible]	[illegible]
[illegible]	[illegible]	[illegible]	ETHICON ENDO SURGERY S.A. DE C.V. PLANTA II (MEXICO) CALLE DURANGO NO. 3751 COLONIA LOTE BRAVO CIUDAD JUAREZ CHIHUAHUA MEX 32575	[illegible]
[illegible]	[illegible]	[illegible]	ETHICON ENDO SURGERY S.A. DE C.V. PLANTA II (MEXICO) CALLE DURANGO NO. 3751 COLONIA LOTE BRAVO CIUDAD JUAREZ CHIHUAHUA MEX 32575	[illegible]
[illegible]	ENDOPATH	[illegible]	ETHICON ENDO SURGERY S.A. DE C.V. PLANTA II (MEXICO) CALLE DURANGO NO. 3751 COLONIA LOTE BRAVO CIUDAD JUAREZ CHIHUAHUA MEX 32575	[illegible]
6502620500036	ENDOPATH	5DCS	ETHICON ENDO SURGERY S.A. DE C.V. PLANTA II (MEXICO) CALLE DURANGO NO. 3751 COLONIA LOTE BRAVO CIUDAD JUAREZ CHIHUAHUA MEX 32575	Shape (Curved scissors), Size (5mm)
[illegible]	ENDOPATH	[illegible]	ETHICON ENDO SURGERY S.A. DE C.V. PLANTA II (MEXICO) CALLE DURANGO NO. 3751 COLONIA LOTE BRAVO CIUDAD JUAREZ CHIHUAHUA MEX 32575	[illegible]

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MEDICAL COMPANIES

รายการที่ ๖ คลิพหนีบเส้นเลือดและท่อขนาด ๕ มม.

วัตถุประสงค์ เป็นอุปกรณ์ที่ประกอบด้วยส่วนด้ามหนีบคลิพและส่วนที่เป็นตัวคลิพ (ligaclip) ซึ่งอยู่ที่ปลายของส่วนที่เป็นด้าม เพื่อใช้หนีบเส้นเลือด (vessel) หรือท่อ (duct) ได้แน่น (secured) เมื่อต้องการหยุด และป้องกันการไหลของของเหลวหรือเลือด

คุณลักษณะ

๑. ด้ามหนีบบรรจุคลิพทำด้วยไทเทเนียมไม่น้อยกว่า ๑๕ ตัว และพร้อมสำหรับยิงคลิพออกไปได้โดยทุกครั้งที่ยิง ไม่จำเป็นต้อง load คลิพออกมาเตรียมไว้ล่วงหน้า

๒. ก้านของด้ามหนีบ (shaft) ยาวไม่น้อยกว่า ๓๓ ซม.

๓. คลิพหนีบเส้นเลือดเหมาะสมและสามารถใช้ ในกรณีที่ต้องการทำ Cholangiography เพื่อยึดเหนี่ยว catheter ในท่อน้ำดี

๔. สามารถทำ MRI scan ได้อย่างปลอดภัย สำหรับคนไข้ที่มีคลิพอยู่ในร่างกาย

๕. เมื่อยิงคลิพไปแล้ว ๑๓ ตัว ที่ช่องหน้าต่างแสดงผล จะมีแถบสีส้ม ปรากฏขึ้น และ หลังจากยิงคลิพตัวที่ ๑๕ (ตัวสุดท้าย) แถบสีส้มจะปรากฏเต็มช่อง จะมีกลไกล็อคเพื่อป้องกันไม่ให้เผลอยิงและอาจเป็นอันตรายต่อ ท่อหรือเส้นเลือด

๖. ข้อต่อระหว่างก้านและด้ามจับ จะมีที่จับเพื่อทำให้ก้านหมุนได้ ๓๖๐ องศา ส่งผลให้สามารถ ยิงคลิพในตำหน่งและมุมต่าง ๆ ได้ตามที่ต้องการโดยง่าย

๗. คลิพมีขนาดกลาง/ใหญ่ กว้างไม่เกิน ๓.๖ มม. เมื่อยิงปิดแล้วขาของคลิพยาวไม่เกิน ๘.๘ มม

๘. ผิวด้านในของคลิพออกแบบให้มีร่องตามยาวและขวาง เพื่อส่งเสริมให้หนีบ ท่อหรือเส้นเลือดได้แน่นไม่หลุด (Secured)

๙. ใช้กับหรือผ่าน trocar ได้ตั้งแต่ ๕ มม.ขึ้นไป

๑๐. ผู้ยื่นเสนอราคาต้องมีสินค้าตามรายการพัสดุครบทุกรายการ

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106 Moo 4 Lardkrabang Industrial Estate, Chalongkrung Road, Lamplatew, Lardkrabang, Bangkok 10520, Thailand Tel : +66 2792 7300 Fax : +66 2792 7304

The **one source** for open and endoscopic ligation

Choose from a full portfolio of market leading solutions[1]

Efficiency

- Ethicon is the only company with a complete portfolio of multiple clip and single clip devices for all of your open and endoscopic surgery needs
- Supports standardization & SKU reduction goals

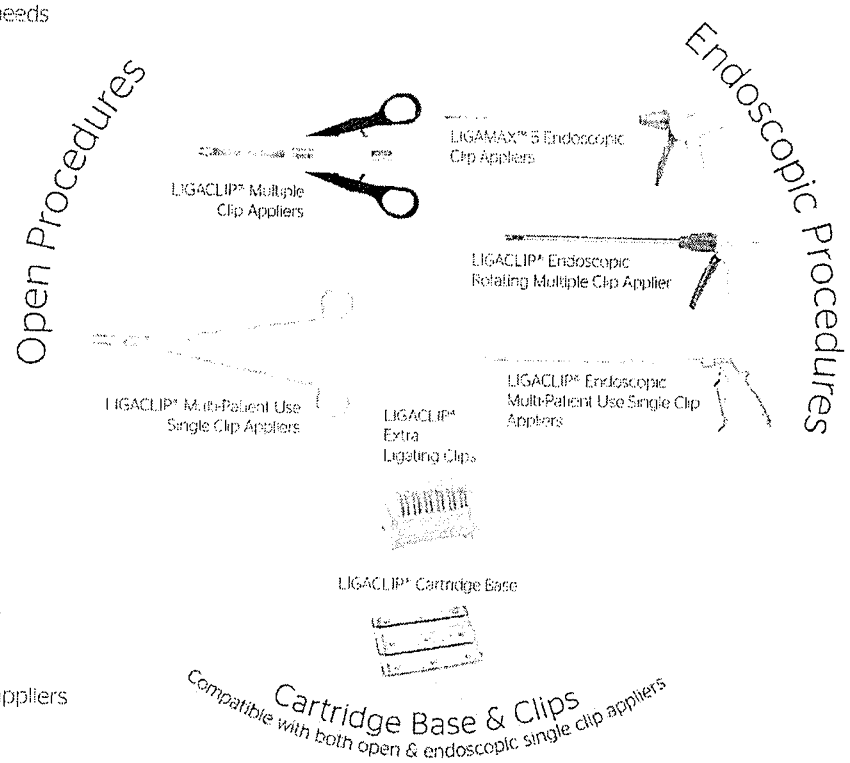
Performance

- Ethicon's clip appliers and clips are designed to deliver superior retention, efficient ligation and minimal vessel damage[2]
- All clips feature proprietary lateral and transverse grooves designed for secure fixation on the structure and increased resistance to dislodgement of a formed clip

รายการที่ 6 ข้อที่ 8

Value

- Flexibility to choose the optimal instrument for each procedure
- Economic segment provides reusable clip appliers for open and endoscopic procedures
- Lifetime warranty on reusable instruments



Product Offerings	Ethicon	Medtronic	Weck	Aesculap	ConMed	Applied
Endoscopic Multiple Clip Appliers for Single-Patient Use (MCA)	✔	✔	✔		✔	✔
Endoscopic Single Clip Appliers for Multi-Patient Use (SCA)	✔	✔	✔			
Open Multiple Clip Appliers for Single-Patient Use (MCA)	✔	✔				
Open Single Clip Appliers for Multi-Patient Use (SCA)	✔		✔	✔		

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Shaping the future of surgery

1. Per IMS sales data including all Ethicon open and endoscopic ligation device codes from 2010 - December 2014.
2. Benchtop testing comparing mean retention force of MCS20 to Covidien Premium Surgiclip™ S-9.0: 43% greater axial clip retention force (1.2373 lbs. vs 0.8650 lbs.) and 45% greater transverse clip retention force (0.50920 lbs. vs 0.35177 lbs.) using elastomeric tubing, p < 0.05.

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Endoscopic Multiple Clip Appliers

LIGAMAX™ 5 Endoscopic Multiple Clip Applier

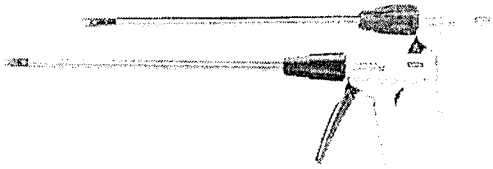
Superior clip, superior clip security[3,4]

LIGAMAX 5 Clip Appliers provide clips that are firmly maintained in the jaws of the device during surgical maneuvering to prevent dislodgement. No other leading clip applier provides greater in-jaw clip retention to reduce clip dislodgement.[4] A direct drive feeding mechanism allows for smooth, controlled clip advancement during feeding with minimal tip movement during clip placement. Unique lateral and transverse grooves on the clips enable secure fixation on structures.

รายการที่ 6 ข้อที่ 7

Product code	Diameter	Clip size	# of clips	Clip aperture	Closed clip length	Qty/box
EL5ML	5mm	Medium/Large	15	3.6mm	8.8mm	3

LIGACLIP® Endoscopic Rotating Multiple Clip Appliers



Fast, efficient ligation and minimal vessel damage

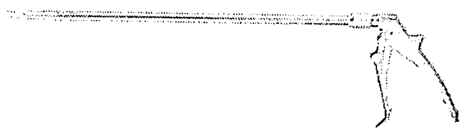
LIGACLIP® Endoscopic Clip Appliers are sterile, disposable, and automatic while delivering titanium ligating clips. Devices are preloaded with 20 clips that individually advance after each clip application.

Product code	Diameter	Clip size	# of clips	Clip aperture	Closed clip length	Qty/box
ER320	10mm	Medium/Large	20	4.2mm	8.8mm	3
ER420	12mm	Large	20	5.2mm	11mm	3

Endoscopic Single Clip Appliers

LIGACLIP® Multi-Patient Use Single Clip Appliers

Versatility and superior value



LIGACLIP® Endoscopic Multi-Patient Clip Appliers are reusable instruments that deliver and close metallic ligating clips.

Product code	Diameter	Qty/box	Clip code	# of clips	Clip aperture	Closed clip length	Qty/box
EL214	Medium	1	LT200 □	6	4mm	5.33mm	36
			LT202 □	20		•	15
EL314	Medium/Large	1	LT300 ■	6	6.4mm	8.99mm	18
EL414	Large	1	LT400 □	6	7.5mm	12.26mm	18

3. Benchtop testing on an elastomeric vessel model comparing the median axial force required to displace a properly formed LIGAMAX™ 5 clip vs leading 5mm competitor Covidien Endo Clip™ III. (1.481 lbs vs 1.136, p<0.0001)

4. Benchtop testing comparing the median force required to dislodge a partially formed clip from the jaws of the LIGAMAX 5 vs. leading competitive devices with anti-backup mechanism (Covidien ENDO CLIP III). Clip closed to 1st ratchet point after distal clip tips touch. (Axial: 3.948lbs vs 0.137, p<0.0001; Transverse: 3.629lbs vs. 2.033, p<0.0001)

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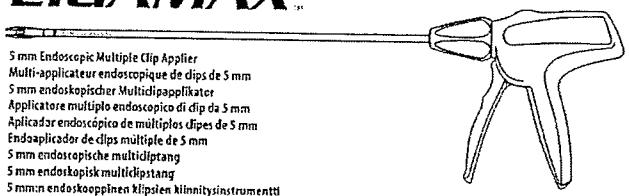
Ethicon
Endo-Surgery

LIGAMAX 5



5 mm Endoscopic Multiple Clip Applier
Multi-applicateur endoscopique de clips de 5 mm
5 mm endoskopischer Multiclipapplikator
Applicatore multiplo endoscopico di clip da 5 mm
Aplicador endoscópico de múltiplos clipes de 5 mm
Endoaplicador de clips múltiple de 5 mm
5 mm endoskopische multicliptang
5 mm endoskopisk multiclipstang
5 mm:n endoskooppinen klipsien kiinnitysinstrumentti
Ενδοσκοπική λαβίδα απόληψης πολλαπλών κλιπ 5 mm
5 mm endoskopisk multiclipsapplikator
Endoskopowa klipsownica o średnicy 5 mm do wielokrotnego zakładania klipsów
5 mm-es endoszkópos többszörös kapocsbehelyező
Endoskopický vícenásobný aplikátor sponek o průměru 5 mm
Endoskopický aplikátor viacerých svoriek priemeru 5 mm
5 mm endoskopisk multiklipsapplikater
5 mm Endoskopik Çoklu Klips Uygulayıcı
5 мм эндоскопический многозарядный клипсонакладыватель
Dispozitiv endoscopic pentru aplicarea de cleme multiple de 5 mm
Pengaplikasi Klip Multipel Endoskopik 5 mm
Kìm kẹp đa clip nội soi 5 mm
5-millimeetrine endoskoopiline klipside paigaldaja
5 mm endoskopiskais daudzskaviņu uzlicējs
5 mm endoskopinis užtaisytas klipų uždėjimo instrumentas
5 mm ендоскопски многозарядец кляп апликатор
Endoskopski višestruki aplikator kvačica 5 mm
5 mm endoskopski aplikator z večzaponkami
5 mm ендоскопски апликатор на повеќе штипки
Ендоскопски вишеструки апликатор копчи од 5 mm
Ендоскопски 5-милиметарски апликатор за више кварица
5 mm内镜式连发结夹器

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 LIGAMAX^{5} – 5 mm Endoscopic Multiple Clip Applier. It is not a reference to ligation techniques

LIGAMAX is a trademark of Ethicon Endo-Surgery

Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones, Instructies, Brugervejledning, Ohjeet, Οδηγίες, Anvisningar, Instrukcje, Utasítások, Návod k použití, Návod na použitie, Instrukcjoner, Talimatlar, Инструкции, Instrucțiuni, Instruksi, Hướng dẫn, Kasutusjuhend, Instrukcijas, Instrukcija, Инструкции, Uputе, Navodila, Упатства, Упутства, Упутства, 使用说明

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Indications

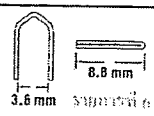
The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

Contraindications

- DO NOT use the instrument for contraceptive tubal occlusion
- DO NOT use the instrument on tissue structures or vessels upon which metal ligating clips would not normally be used.

Device Description

The 5 mm Endoscopic Multiple Clip Applier is a sterile, single patient use instrument designed to provide a means of ligation through an appropriately-sized trocar. The instrument contains 15 titanium clips and the shaft can be rotated 360 degrees in either direction.

Product Code	Shaft Diameter	Clip Size/ No. of Clips	Clip Dimensions	Overall Shaft Length (approx.)
ELSML	5.5 mm	Medium/Large 15		33 cm

MR Conditional

Non-clinical testing has demonstrated the implantable clips made of titanium in this device are MR Conditional. A patient with the implanted clips can be scanned safely immediately after placement of the clips, under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Highest spatial magnetic gradient field of 6.5 Tesla/m
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 20 minutes of scanning (per pulse sequence)

MRI Related Heating

In non-clinical testing, a clip produced a temperature rise of less than 2°C using the following conditions:

- At 3-Tesla (Magnetom Trio Siemens Medical Solutions MR scanner, software version Numaris/4 syngo MRA30), a maximum MR system-reported whole body averaged SAR of 1.2 W/kg
- 20 minutes of continuous MR scanning (per pulse sequence) using transmit/receive RF body coil.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the clips. Therefore, optimization of MR imaging parameters to compensate for the presence of the clips may be necessary.

The worst case signal void size for a clip was:

Pulse Sequence	SE	SE	GRE	GRE
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal Void Size (mm²)	192	336	378	348

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Illustration and Nomenclature (Illustration 1)

1. Jaws
2. Line of Demarcation
3. Shaft
4. Rotation Knob
5. Indicator Window
6. Handle
7. Trigger

English

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 protective cap from the jaws of the instrument.
3. Insert the clip applier through an appropriately-sized trocar. The empty jaws will passively collapse as they are inserted through a 5 mm trocar (Illustration 2) and reopen when completely through the trocar (Illustration 3).
   Caution: Do not insert the clip applier through a trocar if a clip is present in the jaws. This may result in clip malformation, dislodged clips, or damage to the instrument. If a clip is present in the jaws, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws before inserting the device through the trocar.
4. Prior to loading a clip in the jaws and firing the instrument, ensure that the jaws are fully open by verifying that the line of demarcation between the jaws and the instrument shaft is past the distal end of the trocar cannula. (Illustration 3)
5. Prior to positioning the jaws around the tubular structure or vessel, load a clip into the jaws by partially squeezing the trigger in a smooth continuous motion for approximately one-third of the total firing stroke. (Illustration 4)
   Caution: Inspect the jaw tips to ensure the clip is fully advanced in the jaws. (Illustration 4)
6. Position the jaws with the preloaded clip completely around the tubular structure or vessel to be ligated. The structure to be ligated should be positioned against the apex of the clip. (Illustration 5)
   Note: The shaft can be rotated 360 degrees to facilitate visualization and accurate placement.
   Caution: Ensure that the clip is the correct size for the vessel or tubular structure being ligated. If the vessel or tubular structure is too large for the clip, remove the device and use an appropriately sized ligation device.
   Caution: Do not excessively twist or torque the instrument jaws when positioning or firing the instrument on a tubular structure or vessel. Excessive twisting or torquing may result in clip malformation. (Illustration 6)
7. Complete the firing cycle by squeezing the trigger until it stops against the handle to completely form the clip on the targeted structure or vessel. (Illustration 7)
   Caution: The trigger must be fully squeezed against the handle to ensure complete clip formation.
8. After firing, fully release the trigger.
   Note: A clip will not be loaded in the jaws until the trigger is squeezed again.
9. Check to ensure that each clip has been securely placed around the tissue being ligated.
   Note: If a clip is dislodged prematurely from the jaw tips or a clip fails to advance, remove the jaws from the targeted structure and fully squeeze and release the trigger to reset the device. Continue to use the instrument as noted in step 5.
10. The 5 mm Endoscopic Multiple Clip Applier can be used to secure a catheter for cholangiography. During closure on the cystic duct and catheter, release the trigger after hearing the final audible click, prior to the trigger stopping against the handle.
11. When the 13th clip is fired, an orange bar will begin to appear in the indicator window on top of the device handle. (Illustration 8) The orange bar fills the indicator window when the final clip is fired.
    Note: The instrument contains a last clip lockout feature designed to increase the force required to close the trigger, thereby reducing the possibility that the empty jaws will be closed on a structure or vessel. Do not attempt to fire through the lockout. If force applied to trigger exceeds the last clip lockout, the jaws may remain closed. If the jaws do not open when the trigger is released, pull the trigger outward to re-open the jaws. Do not refire the instrument.

12 To remove the instrument, ensure there is no clip remaining in the jaws and withdraw the instrument from the trocar.
Note: If a clip is present in the jaws and the clip applier needs to be removed from the patient, fully squeeze and hold the trigger against the handle while removing the clip applier through the trocar with the jaws in the closed position. Once the clip applier is removed, fully release the trigger to release the clip from the jaws. The clip applier is then ready for the next clip application.

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.
- Ensure that the clip is the correct size for the vessel or tubular structure being ligated.
- Do not insert the clip applier through a trocar if a clip is present in the jaws. This may result in clip malformation, dislodged clips, or damage to the instrument. If a clip is present in the jaws, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws before inserting the device through the trocar.
- Inspect the jaw tips to ensure the clip is fully advanced in the jaws of the instrument.
- Ensure that each clip is securely and completely positioned around the tissue being ligated before completion of firing cycle.
- Do not excessively twist or torque the instrument jaws when positioning or firing the instrument on a tubular structure or vessel. Excessive twisting or torquing may result in clip malformation.
- Do not excessively apply a side load to the jaws that would cause them to partially collapse and potentially result in a clip malformation. The device jaws should be fully open and parallel upon initiating the firing of the instrument.
- Do not push with excessive force on the proximal end of the instrument. Excessive force may result in clip malformation.
- The trigger must be fully squeezed against the handle to ensure complete clip formation.
- Ensure full release of the trigger after firing. A partial release of the trigger may disrupt clip feeding sequence and may result in clip malformation.
- Do not attempt to fire through the last clip lockout. Closing the instrument's jaws over a vessel or structure without a clip could result in damage to the vessel or structure.
- Do not attempt to remove closed jaws from the structure or vessel. This could result in damage to the structure or vessel. Pull the trigger outward to re-open the jaws.
- Avoid firing the instrument over another clip or instrument. Firing the instrument in this manner may distort or yield the instrument jaws, which can cause the instrument to release the clip prematurely. Firing the instrument over another clip or instrument can also damage a properly deployed clip, disrupt related vessels and structures, and damage the instrument.
- Excessive tissue manipulation with clip in jaws may result in clip dislodgement.
- 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 LIGAMAX^5 – 5 mm Endoscopic Multiple Clip Applier is supplied sterile for single patient use. Discard after use.

MR	MR (Magnetic Resonance) Conditional Compatible dans certains environnements de résonance magnétique Bedingt MR-(Magnetresonanz)-sicher A compatibilità condizionata con la risonanza magnetica Uso condicionado no ambiente de RM (Ressonância magnética) Condicionado para RMN (resonancia magnética nuclear) MR-conditioneel (MR = magnetische resonantie) MR-betinget (magnetisk resonans) MR (magneettiresonanssi) -ehdollinen Ασφαλές για MR (απεικόνιση μαγνητικού συντονισμού), υπό όρους MR (magnetisk resonans)-säker under vissa förutsättningar Warunkowo bezpieczny w obszarze oddziaływania rezonansu magnetycznego MR (mágneses rezonancia-) vizsgálatra feltételesen alkalmas Podmíněně bezpečné pro MR (MR Conditional) Podmienečne vhodné pre použitie magnetickej rezonancie MR-sikker (magnetresonans) under visse forutsetninger (MR Conditional) MR (Manyetik Rezonans) Koşullu Güvenceli Условно безопасно при МР (магнитно-резонансном исследовании) Compatibilitate MR (rezonanță magnetică) condiționată MR (Resonasi Magnetik) Bersyarat Tương thích với cộng hưởng từ có điều kiện Tingimuslik sobivus magnetresonantskeskkonda Drošs MR (magnētiskās rezonanses) vidē Salyginis suderinamumas su MR (magnetinių rezonansu) MP (магнитно-резонансна) съвместимост Uvjetna uporaba MR-a (magnetske rezonancije) Pogojno združljiv z MR (magnetno resonanco) Условно компатибилен при МР (Магнетна резонанца) Условно дозвољено за коришћење с магнетном резонанцом (МР) Коришћење магнетне резонанце (МР) само под одређеним условима MR [illegible]
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 Atencion: la ley federal de EE.UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripción medica. 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 ιατρούς ή κατόπιν εντολής ιατρού. Försiktighet Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan.

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 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 Perspėjimas. Pagal federalinius (JAV) įstatymus ši prietaisą leidžiama parduoti tik gydytojui arba jo užsakymu Внимание: федералният закон на САЩ ограничава продажбата на този уред до или по предписание на лекар. Oprez: savezni zakon SAD-a ograničava predaju 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]

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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 integro. No reesterilizar Gesteriliseerd met straling. Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren. Steriliseret ved straling. 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 Αποστειρωμένοι 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. Nesterilizujte. 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.

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STERILE R	Sterilizēts ar starojumu Sterilitāte tiek garantēta, ja vien iepakojums nav atvērts vai bojāts Nesterilizējiet atkārtoti. 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 辐射灭菌。 如果产品包装已打开或者有破损，请勿使用。不得再次灭菌
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	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 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
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	Representante autorizado na Comunidade Europeia
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REF

ELSML

EC REP	Ethicon Endo-Surgery (Europe) GmbH Hummelsbuetteler Steindamm 71 22851 Norderstedt Germany
USA REP	ETHICON ENDO-SURGERY, INC. 4545 Creek Road Cincinnati, OH 45242-2839 USA 1-877-ETHICON

Ethicon Endo-Surgery

CE 0123

ETHICON ENDO-SURGERY, LLC
475 Calle C
Guaynabo, PR 00969 USA

Rev. 2013-09

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ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดเลขที่ 65-2-2-2-0008875

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่

บริษัท จอห์นสัน แอนด์ จอห์นสัน (ไทย) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนเลขที่ สน 515/2554 เพื่อแสดงว่าเป็นผู้แจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๗ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

LIGAMAX 5 Endoscopic Multiple Clip Applier

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 และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

ออกให้ ณ วันที่ 10 เดือน มิถุนายน พ.ศ. 2565

(ลายมือชื่อ) สำนักงานคณะกรรมการอาหารและยา
(ตำแหน่ง) กระทรวงสาธารณสุข
ผู้อนุญาต

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รับรองสำเนาถูกต้อง

เอกสารแนบท้าย

ใบรับแจ้งรายการละเอียดเลขที่ 65-2-2-2-0008875

รายละเอียดเครื่องมือแพทย์

The 5 mm Endoscopic Multiple Clip Applier is a sterile, single patient use instrument designed to provide a means of ligation through an appropriately-sized trocar. The instrument contains 15 titanium clips and the shaft can be rotated 360 degrees in either direction.

ชื่อและที่อยู่ของผู้ผลิต

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

มีรายละเอียดความการเครื่องมือแพทย์ หรืออุปกรณ์เสริม ดังนี้

NEWCODE	ชื่อผลิตภัณฑ์	[illegible]	บริษัทผู้ผลิต	อื่นๆ
65404405300307	LIGAMAX 5 Endoscopic Multiple Clip Applier	PCS/BL	[illegible]	
65470485000008	LIGAMAX 5 Endoscopic Multiple Clip Applier	PCS/BL	ETHICON ENDO-SURGERY S.A. DE C.V. PLANTA [illegible] CALLE DURANGO No.2751 CD JUAREZ Chihuahua MEX 32695	

ภาคผนวกที่ 6 ใบที่ 10

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Johnson & Johnson
MEDICAL COMPANIES

รายการที่ ๗ ตัวเจาะหน้าท้องปลายใสขนาด ๑๒ 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) ส่วนด้านบนเป็นพลาสติกสีขาวขุ่นมีความลาดเอียงเพื่อสอดใส่เครื่องมือผ่านเข้าไปในตัวเจาะได้ง่าย โดยไม่ต้องใช้มือช่วยจับ
๕. ท่อชั้นนอกของตัวเจาะส่วนด้านล่างมีลักษณะใส เพื่อให้สามารถมองเห็นเครื่องมือ ขณะผ่านเข้าออก หรือขณะที่นำชิ้นส่วนของเนื้อเยื่อออกมา
๖. ด้านในของท่อชั้นนอกของตัวเจาะประกอบด้วยแผ่นยางสีดำมีรูตรงกลาง มีความยืดหยุ่นพอดีที่จะแนบกับเครื่องมือที่ผ่านเข้าออกขนาด ๑๒ มม.
๗. ก้านของท่อยาว ๑๐๐ มม. บริเวณส่วนกลางของก้านท่อชั้นนอกนี้จะมีเกลียวเล็กๆ เพื่อยึดผนังหน้าท้องไม่ให้เลื่อนหลุดขณะใช้งาน
๘. บรรจุแบบปลอดเชื้อ (Sterile Package) และสามารถใช้งานได้ทันที
๙. ผู้ยื่นเสนอราคาต้องมีสินค้าตามรายการพัสดุครบทุกรายการ

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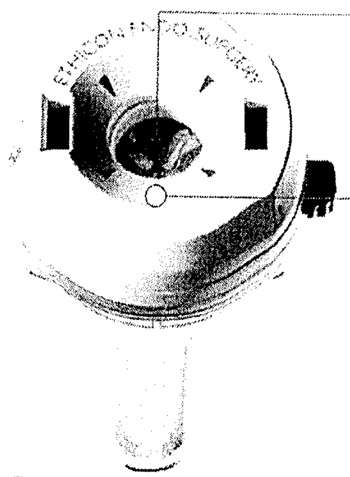
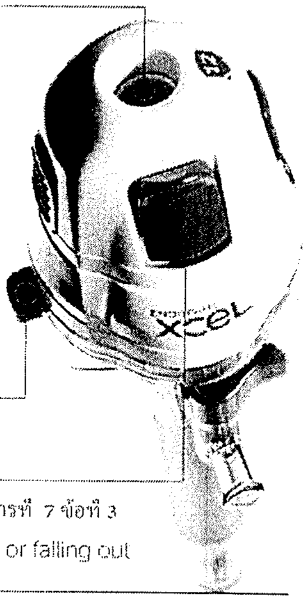
106 Moo 4 Lardkrabang Industrial Estate, Chalongkrung Road, Lamplatew, Lardkrabang, Bangkok 10520, Thailand Tel : +66 2792 7300 Fax : +66 2792 7304

ENDOPATH XCEL® Bladeless Trocars





Optical Entry
รายการที่ 7 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 7 ข้อที่ 6
- Maintains insufflation
- Accommodates a wide range of instrument sizes (4.7mm to 12.9mm)

Funnel Lead-In
รายการที่7 ข้อที่ 4

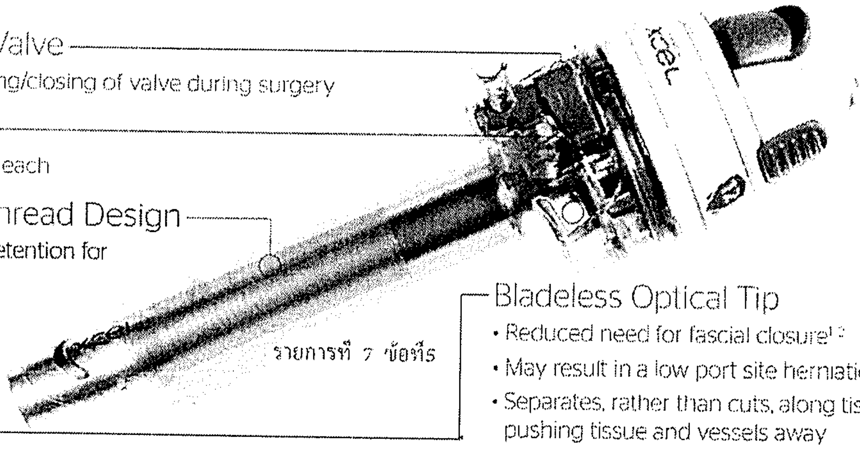
- Enables smooth, one-handed instrument exchange

Release Lever

- Unlocks housing to facilitate large specimen removal

Camera Scope-Locking Tab

- Holds camera locked in place during visually guided entry รายการที่ 7 ข้อที่ 3
- Helps provide visual clarity and protects camera from scratching or falling out



Recessed Stopcock Valve

- Mitigates inadvertent opening/closing of valve during surgery

Low-Profile Housing

- Enables further instrument reach

Integrated Stability Thread Design

- Maximizes abdominal wall retention for minimal trocar slip-outs

รายการที่ 7 ข้อที่ 7

รายการที่ 7 ข้อที่5

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; 15:122-6.
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 13 of 417 patients (3%) of the blunt trocar group and in 29 of 421 patients (6.9%) of the bladed trocar group (p<0.020). Antoniou SA, Antoniou GA, Koch OO 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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Johnson & Johnson

Shaping the future of surgery

FOR JOHNSON & JOHNSON (THAILAND) LTD.

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 รายการที่ 7 ข้อที่7	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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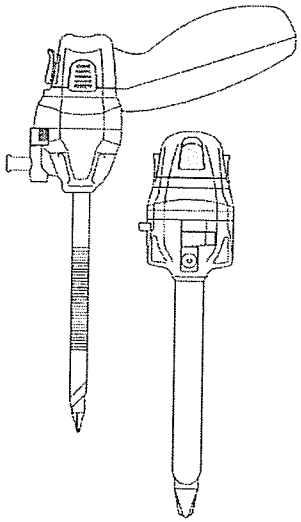
ENDOPATH® XCEL™

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, Ohjeet, Οδηγίες, Anvisningar, Instrukcje, Utasítások, Návod k použití, Návod na použitie, Instrukcjoner, Talimatlar, Инструкции, Instrucțiuni, Inštrukcie, Hướng dẫn, Kasutusjuhend, Instrukcijas, Instrukcija, Инструкции, Upute, Navodila, Упатства, Упутства, Упутства, 使用说明

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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.

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.

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 Nomenclature (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.

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.

รายการที่ 7 ข้อที่ 8

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. Nerestelizujte 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 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 ги Упатствата за употреба Погледајте Упутства за коришћење Погледајте упутства за употребу [illegible]
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	Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato Käytettävä viimeistään Χρησιμοποιείται 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
	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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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 solo 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: Ifølge 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. Försiktighet: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares ordination

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Symbol	Description
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 лекара или по његовом налогу. 警告：美国联邦法律规定本器械仅限由医生或凭医生处方销售

Symbol	Description	
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 单位数量
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 Befuldmægtiget 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 美国授权代理人	

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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
a Johnson & Johnson company

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ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดที่ 65-2-2-2-0015023

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 และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

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]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	ENDOPATH XCEL Bladeless Trocar with Stability Sleeves	B12LT	NPA DE MEXICO S. DE R.L. DE C.V. (MEXICO) Blvd. Hector Teran Teran #20662-C MEX 22465	Shape (Bladeless Trocar), Size (12 mm x 100 mm)
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

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