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Instructions for use

en

ETHILON™

POLYAMIDE 6 OR POLYAMIDE 6,6
STERILE SYNTHETIC NON-ABSORBABLE SURGICAL SUTURE, USP / Ph. Eur.

DESCRIPTION
ETHILON™ Suture is a sterile, monofilament, synthetic, non-absorbable, surgical suture composed of polyamide 6 $[NH\text{-}CO\text{-}(CH_2)_5]_n$ or polyamide 6,6 $[NH\text{-}(CH_2)_6\text{-}NH\text{-}CO\text{-}(CH_2)_4\text{-}CO]_n$.

ETHILON™ Suture is available undyed and dyed black with Hematine HCK (Color Index 75290), and dyed green with D&C Green No.5 (Color Index 61570) to enhance visibility in the surgical field.

ETHILON™ Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of various types and sizes, and in presentations as described in the HOW SUPPLIED section.

ETHILON™ Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Polyamide 6 or Polyamide 6,6 Suture and United States Pharmacopeia (USP) for Non-Absorbable Surgical Sutures. The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. sizes as equivalent which is reflected on the labeling.

INDICATIONS
ETHILON™ Suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, ophthalmic and neurosurgical procedures.

APPLICATION
Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

PERFORMANCE / ACTIONS
ETHILON™ Suture elicits an initial, minimal inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While polyamide is not absorbed, progressive hydrolysis of the polyamide ***in vivo*** may result in gradual loss of tensile strength over time.

CONTRAINDICATIONS
Due to the gradual loss of tensile strength which may occur over prolonged periods ***in vivo***, ETHILON™ Suture should not be used where permanent retention of tensile strength is required.

WARNINGS
Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing ETHILON™ Suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users. Like all foreign bodies, this product may potentiate infection.

PRECAUTIONS
In handling this or any other suture material, care should be taken to avoid damage. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the standard surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilament sutures.

Care should be taken to avoid damage when handling surgical needles. Grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the attachment end to the point. Grasping in the point area could impair the penetration performance and cause fracture of the needle. Grasping at the attachment end could cause bending or breakage. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking.

Users should exercise caution when handling surgical needles to avoid inadvertent needle stick injury. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood-borne pathogens. Discard used needles in "sharps" containers.

ADVERSE REACTIONS
Adverse reactions associated with the use of this device include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary or biliary tracts when prolonged contact with salt solutions such as urine or bile occurs, minimal inflammatory tissue reaction, and transient local irritation at the wound site.

STERILITY
ETHILON™ Suture is sterilized by irradiation. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

STORAGE
No special storage conditions required. Do not use after expiry date.

HOW SUPPLIED
Please note that not all sizes are available in all markets. Please contact your local sales representative for size availability.

ETHILON™ Suture is available as sterile monofilament strands in USP sizes 11-0 through 2 (metric sizes 0.1 – 5.0) in a variety of lengths, with and without permanently attached needles.

The sutures are also available in presentations containing the following:

1. Lead Seal and Surgical Bolster in which the lead seal is used to maintain the position of the bolster relevant to the suture knot to maintain proper tension.
2. Retention tubing (elastomer tubing), which is used to spread the load of the suture at the surface of the skin.

ETHILON™ Suture is available in one, two or three dozen units per box.

ETHICON, LLC
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EC REP Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

ETHILON™

ar خيط جراحي · cs ŠICÍ MATERIÁL · da SUTUR · de NAHTMATERIAL · el ΡΑΜΜΑ · en SUTURE · es SUTURA · fi OMMELAINE · fr FIL DE SUTURE · hu VARRÓANYAG · it SUTURA · kk ТІГУ МАТЕРИАЛЫ · ko 봉합사 · nl HECHTMATERIAAL · no SUTUR · pl NICI CHIRURGICZNE · pt FIO DE SUTURA · ro FIR DE SUTURĂ · ru ШОВНЫЙ МАТЕРИАЛ · sk CHIRURGICKÁ NIŤ · sv SUTUR · tr SÜTÜR · zh-cn 缝线 · zh-tw 縫合線

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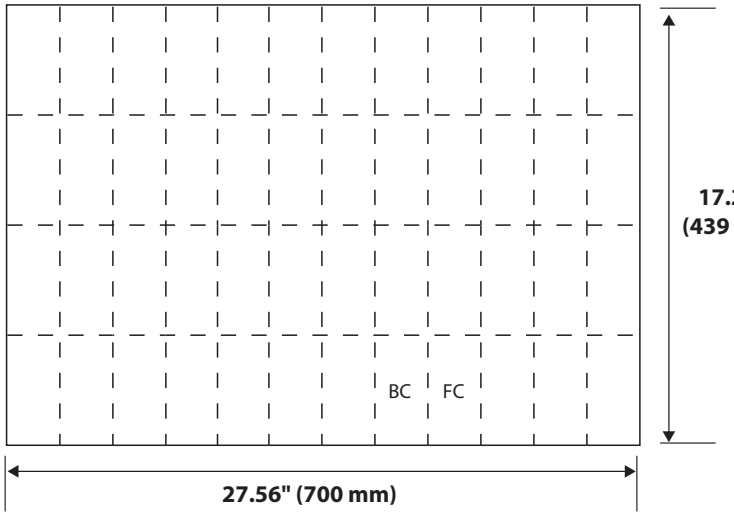
	ar يُستعمل مرة واحدة فقط / **cs**-Nepoužívat znovu / **da**-Må ikke genbruges / **de**-Nicht zur Wiederverwendung / **el**-Μην επαναχρησιμοποιείτε / **en**-Do not re-use / **es**-No reutilizar / **fi**-Ei saa käyttää uudelleen / **fr**-Ne pas réutiliser / **hu**-Ne használja újra / **it**-Non riutilizzare / **kk**-Қайта пайдаланбаңыз / **ko**-재사용하지 마십시오 / **nl**-Niet opnieuw gebruiken / **no**-Skal ikke brukes flere ganger / **pl**-Nie używać powtórnie / **pt**-Não reutilizar / **ro**-Nu reutilizați / **ru**-Не использовать повторно / **sk**-Nepoužívajte opakovane / **sv**-Får ej återanvändas / **tr**-Tekrar kullanmayın / **zh-cn**-不得重复使用 / **zh-tw**-不得重複使用
	ar-صالح للاستخدام خلال / **cs**-Použít do data / **da**-Anvendes inden / **de**-Verwendbar bis (Datum) / **el**-Ημερομηνία λήξης / **en**-Use-by date / **es**-Usar antes de fecha / **fi**-Viimeinen käyttöpäivä / **fr**-À utiliser avant / **hu**-Lejárati idő / **it**-Utilizzare entro il / **kk**-Жарамдылық мерзімі / **ko**-사용기한일 / **nl**-Uiterste gebruiksdatum / **no**-Utløpsdato / **pl**-Wykorzystać do dnia / **pt**-Data de validade / **ro**-A se utiliza până la data de / **ru**-Использовать до (дата) / **sk**-Dátum spotreby / **sv**-Används före-datum / **tr**-Son kullanma tarihi / **zh-cn**-使用有效期 / **zh-tw**-使用有效日期
LOT	**ar**-رمز الشغيلة / **cs**-Kód šarže / **da**-Batch kode / **de**-Chargenbezeichnung / **el**-Κωδικός παρτίδας / **en**-Batch code / **es**-Código de lote / **fi**-Eräkoodi / **fr**-Code de lot / **hu**-Tételkód / **it**-Codice di lotto / **kk**-Бума коды / **ko**-배치 코드 / **nl**-Batchcode / **no**-Batchkode / **pl**-Kod partii / **pt**-Código do lote / **ro**-Codul lotului / **ru**-Код партии / **sk**-Kód šarže / **sv**-Satskod / **tr**- Parti kodu / **zh-cn**-批号 / **zh-tw**-批號
STERILE R	**ar**-معقّم بالإشعاع / **cs**-Sterilizováno radiací / **da**-Steriliseret ved stråling / **de**-Sterilisiert durch Bestrahlung / **el**-Αποστειρωμένο με χρήση ακτινοβολίας / **en**-Sterilized using irradiation / **es**-Esterilizado mediante irradiación / **fi**-Steriloitu säteettämällä / **fr**-Stérilisé par irradiation / **hu**-Besugárzással sterilizálva / **it**-Sterilizzato con radiazioni ionizzanti / **kk**-Сәулелену арқылы зарарсыздандырылған / **ko**-방사선조사를 사용하여 멸균되었음 / **nl**-Gesteriliseerd door bestraling / **no**-Sterilisert med stråling / **pl**-Wysterylizowano promieniowaniem / **pt**-Esterilizado por irradiação / **ro**-Sterilizat prin iradiere / **ru**-Стерилизовано облучением / **sk**-Sterilizované žiarením / **sv**-Steriliserad med strålning / **tr**-Işıma ile sterilize edilmiştir / **zh-cn**-使用辐照灭菌 / **zh-tw**-經放射線滅菌
REF	**ar**-رقم الكتالوج / **cs**-Katalogové číslo / **da**-Varenummer / **de**-Katalognummer / **el**-Αριθμός καταλόγου / **en**-Catalogue Number / **es**-Número de catálogo / **fi**-Tuotenumero / **fr**-Numéro de référence au catalogue / **hu**-Katalógusszám / **it**-Numero di catalogo / **kk**-Каталог бойынша нөмері / **ko**-카탈로그 번호 / **nl**-Catalogusnummer / **no**-Katalognummer / **pl**-Numer katalogowy / **pt**-Número de catálogo / **ro**-Număr de catalog / **ru**-Номер по каталогу / **sk**-Katalógové číslo / **sv**-Katalognummer / **tr**-Katalog numarası / **zh-cn**-目录编号 / **zh-tw**-目錄型號
	ar-تحذير / **cs**-Upozornění / **da**-Bemærk / **de**-Achtung / **el**-Προσοχή / **en**-Caution / **es**-Atención / **fi**-Huomio / **fr**-Attention / **hu**-Vigyázat / **it**-Attenzione / **kk**-Назар аударыңыз / **ko**-주의 / **nl**-Let op / **no**-Forsiktig / **pl**-Przestroga / **pt**-Atenção / **ro**-Atenție / **ru**-Внимание / **sk**-Upozornenie / **sv**-OBS / **tr**-Dikkat / **zh-cn**-注意 / **zh-tw**-注意
	ar-مُنْتِج / **cs**-Výrobce / **da**-Producent / **de**-Hersteller / **el**-Κατασκευαστής / **en**-Manufacturer / **es**-Fabricante / **fi**-Valmistaja / **fr**-Fabricant / **hu**-Gyártó / **it**-Fabbricante / **kk**-Дайындаушы / **ko**-제조자 / **nl**-Fabrikant / **no**-Produsent / **pl**-Producent / **pt**-Fabricante / **ro**-Producător / **ru**-Производитель / **sk**-Výrobca / **sv**-Tillverkare / **tr**-İmalatçı / **zh-cn**-制造商 / **zh-tw**-製造廠
	ar-لا تعد تعقيم هذا المنتج / **cs**-Neprovádět opětovnou sterilizaci / **da**-Må ikke resteriliseres / **de**-Nicht erneut sterilisieren / **el**-Μην επαναποστειρώνετε / **en**-Do not resterilize / **es**-No reesterilizar / **fi**-Ei saa steriloida uudelleen / **fr**-Ne pas restériliser / **hu**-Ne sterilizálja újra / **it**-Non risterilizzare / **kk**-Қайта зарарсыздандырмаңыз / **ko**-재멸균하지 마십시오 / **nl**-Niet opnieuw steriliseren / **no**-Skal ikke resteriliseres / **pl**-Nie wyjaławiać powtórnie / **pt**-Não reesterilizar / **ro**-Nu reesterilizați / **ru**-Не стерилизовать повторно / **sk**-Nesterilizujte opakovane / **sv**-Får ej omsteriliseras / **tr**-Tekrar sterilize etmeyin / **zh-cn**-不得重复灭菌 / **zh-tw**-不得重複滅菌
EC REP	**ar**-ممثل مُعتمد لدى الاتحاد الأوروبي / **cs**-Zplnomocněný zástupce v Evropském společenství / **da**-Autoriseret repræsentant i EU / **de**-Bevollmächtigter in der Europäischen Gemeinschaft / **el**-Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / **en**-Authorized Representative in the European Community / **es**-Representante autorizado en la Comunidad Europea / **fi**-Valtuutettu edustaja Euroopan yhteisössä / **fr**-Mandataire agréé dans la Communauté européenne / **hu**-Engedéllyel rendelkező képviselet az Európai Közösségben / **it**-Rappresentante autorizzato nella Comunità Europea / **kk**-ЕО Ресми өкіл / **ko**-유럽연합 공식 대리인 / **nl**-Gemachtigd vertegenwoordiger in de Europese Unie / **no**-Autorisert representant i EU / **pl**-Autoryzowany przedstawiciel we Wspólnocie Europejskiej / **pt**-Representante autorizado na Comunidade Europeia / **ro**-Reprezentant autorizat în Uniunea Europeană / **ru**-Официальный представитель в ЕС / **sk**-Autorizovaný zástupca v Európskom spoločenstve / **sv**-Auktoriserad representant i Europeiska gemenskaperna / **tr**-Avrupa Topluluğu Yetkili Temsilcisi / **zh-cn**-欧洲共同体授权代理 / **zh-tw**-歐洲共同體授權代表
	ar-لا يُستخدم هذا المنتج إذا وُجدت العبوة تالفة / **cs**-Nepoužívat, jestliže je balení poškozeno / **da**-Må ikke anvendes, hvis pakningen er beskadiget / **de**-Bei beschädigter Verpackung nicht verwenden / **el**-Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά / **en**-Do not use if package is damaged / **es**-No usar si el envase está dañado / **fi**-Ei saa käyttää, jos pakkaus on vaurioitunut / **fr**-Ne pas utiliser si l'emballage est endommagé / **hu**-Ne használja, ha a csomagolás megsérült / **it**-Non utilizzare se l'imballaggio non è integro / **kk**-Егер қаптама зақымданған болса пайдаланбаңыз / **ko**-포장이 파손되어 있는 경우에는 사용하지 마십시오 / **nl**-Niet gebruiken als de verpakking beschadigd is / **no**-Skal ikke brukes hvis pakningen er skadet / **pl**-Nie używać, jeśli opakowanie jest uszkodzone / **pt**-Não utilizar se a embalagem estiver danificada / **ro**-Nu se utilizează dacă ambalajul este deteriorat / **ru**-Не использовать, если упаковка повреждена / **sk**- Nepoužívajte, ak je obal poškodený / **sv**-Får inte användas om förpackningen är skadad / **tr**-Ambalajı hasarlıysa kullanmayın / **zh-cn**-如果包装有损坏，不得使用 / **zh-tw**-如果包裝有破損，不得使用
	ar-عدد الوحدات / **cs**-Počet kusů / **da**-Antal enheder / **de**-Stückzahl / **el**-Αριθμός μονάδων / **en**-Number of Units / **es**-Número de unidades / **fi**-Yksikköjen lukumäärä / **fr**-Nombre d'unités / **hu**-Az egységek száma / **it**-Numero di unità / **kk**-Бірліктер саны / **ko**-제품 개수 / **nl**-Aantal eenheden / **no**-Antall enheter / **pl**-Liczba jednostek / **pt**-Número de unidades / **ro**-Număr de unități / **ru**-Число единиц / **sk**-Počet kusov / **sv**-Antal enheter / **tr**-Ünite sayısı / **zh-cn**-件数 / **zh-tw**-數量
MS/X	**ar**-متعدد الخيوط / **cs**-Multi-strand / **da**-Flertrådet / **de**-Mehrfachstrang / **el**-Πολλαπλών νημάτων / **en**-Multi-strand / **es**-Multihebra / **fi**-Monilankainen / **fr**-Multibrins / **hu**-Többszálú / **it**-Multifilo / **kk**-Көптүйін / **ko**-다중 가닥 / **nl**-Meerdere draden / **no**-Flertrådet / **pl**-Wielopasmowy / **pt**-Multifios / **ro**-Multifilament / **ru**-Многониточный / **sk**-Viacvláknová / **sv**-Multi-strand / **tr**-Çok iplikli / **zh-cn**-多股 / **zh-tw**-多股
	ar-انزل الغلاف/انزع/افتح هنا / **cs**-ZDE ODLOUPNĚTE/ ZDVIHNĚTE/OTEVŘETE / **da**-TRÆK AF/LØFT/ÅBEN HER / **de**-HIER ABZIEHEN/ANHEBEN/ÖFFNEN / **el**-ΑΠΟΚΟΛΛΗΣΤΕ/ ΑΝΑΣΗΚΩΣΤΕ/ΑΝΟΙΞΤΕ ΕΔΩ / **en**-PEEL/LIFT/OPEN HERE / **es**-DESPRENDER/LEVANTAR/ABRIR AQUÍ / **fi**-KUORI/ NOSTA/AVAA TÄSTÄ / **fr**-DÉTACHER/SOULEVER/OUVRIR ICI / **hu**-ITT HÚZZA LE/EMELJE FEL/NYISSA FEL / **it**-STRAPPARE/ SOLLEVARE/APRIRE QUI / **kk**-ОСЫ ЖЕРДЕН СЫДЫРЫҢЫЗ/КӨТЕРІҢІЗ/АШЫҢЫЗ / **ko**-여기를 떼어 내십시오/올리십시오/개봉하십시오 / **nl**-HIER OPENTREKKEN/ OMHOOGTREKKEN/OPENEN / **no**-RIV/LØFT/ÅPNE HER / **pl**-ODERWAĆ/UNIEŚĆ/OTWIERAĆ TUTAJ / **pt**-PUXAR/ LEVANTAR/ABRIR AQUI / **ro**-DEZLIPIȚI/RIDICAȚI/DESCHIDEȚI AICI / **ru**-СНЯТЬ/ПРИПОДНЯТЬ/ОТКРЫТЬ ЗДЕСЬ / **sk**-TU ODLÚPNUŤ/NADVIHNÚŤ/OTVORIŤ / **sv**-DRA AV/LYFT/ÖPPNA HÄR / **tr**-BURADAN SOYUN/ KALDIRIN/AÇIN / **zh-cn**-剥开/提起/此处开启 / **zh-tw**-剝開/提起/此處開啟
	ar-اقطع هنا / **cs**-ZDE ODTRHNĚTE / **da**-RIV HER / **de**-HIER AUFREISSEN / **el**-ΣΚΙΣΤΕ ΕΔΩ / **en**-TEAR HERE / **es**-RASGAR AQUÍ / **fi**-REVI TÄSTÄ / **fr**-DÉCHIRER ICI / **hu**-ITT SZAKÍTSA LE / **it**-ROMPERE QUI / **kk**-ОСЫ ЖЕРДЕН ЖЫРТЫҢЫЗ / **ko**-여기를 찢으십시오 / **nl**-HIER AFSCHEUREN / **no**-RIV HER / **pl**-ROZERWAĆ W TYM MIEJSCU / **pt**-RASGAR AQUI / **ro**-RUPEȚI AICI / **ru**-ОТОРВАТЬ ЗДЕСЬ / **sk**-TU ODTRHNÚŤ / **sv**-RIV HÄR / **tr**-BURADAN YIRTIN / **zh-cn**-由此撕开 / **zh-tw**-在此撕開

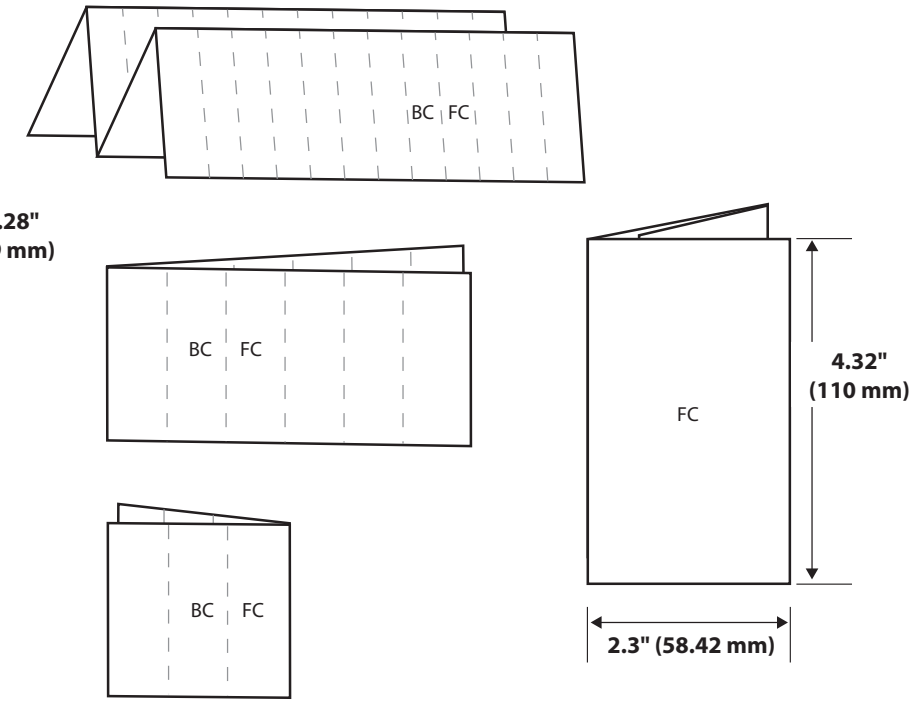
IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



Flat Size

FOLD PATTERN



Folded Size

TITLE	DESCRIPTION	LAB NUMBER	SPECIAL INSTRUCTIONS/COMMENTS	BINDING	COLORS
ETHILON™	**Map IFU**	**LAB100601593v2**	**n/a**	**n/a**	**Black**

FLAT SIZE	FOLDED SIZE	RMC NUMBER	PAGE COUNT	LANGUAGES	SELF COVER	PLUS COVER	SEALING METHOD	WAFER SEAL
27.56" x 17.28" 700 mm x 439 mm	**2.3" x 4.32" 58.42 mm x 110 mm**	**390323R02**	**2**	**ar, cs, da, de, el, en, es, fi, fr, hu, it, kk, ko, nl, no, pl, pt, ro, ru, sk, sv, tr, zh-cn, zh-tw**	[X]	[ ]		[X]

BLEED SIZE .5" (12.7 mm)	.125" (3.175 mm)	NONE	BLEED ALL SIDES	BLEED TOP	BLEED RIGHT	BLEED LEFT	BLEED BOTTOM
[ ]	[ ]	[X]	[ ]	[ ]	[ ]	[ ]	[ ]

DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

STOCK
Refer to MS159-007

ETHICON