

For recognized legal manufacturer, refer to product label.



ETHICON, Inc.
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151
USA
1-877-ETHICON
+1-513-337-6928



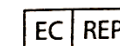
ETHICON, LLC
475 C Street
Los Frailes Industrial Park
Suite 401 Guaynabo, Puerto Rico 00969
USA
1-877-ETHICON
+1-513-337-6928



Ethicon LLC
Highway 183 Km 8.3
San Lorenzo 00754, Puerto Rico
USA
1-877-ETHICON
+1-513-337-6928



Johnson & Johnson INTERNATIONAL
c/o European Logistics Centre
Leonardo Da Vincilaan, 15
BE-1831 Diegem, Belgium
+1-513-337-6928



Johnson & Johnson Medical Ltd
Simpson Parkway
Kirkton Campus
Livingston
EH54 7AT
United Kingdom



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01/2016



SILK

ar خيط جراحي

cs ŠÍČÍ MATERIÁL

da SUTUR

de NAHTMATERIAL

el PAMMA

en SUTURE

es SUTURA

fi OMMELAINE

fr SUTURE

hu VARRÓANYAG

it SUTURA

ko 봉합사

nl HECHTDRAAD

no SUTUR

pl NICI CHIRURGICZNE

pt FIO DE SUTURA

ru ШОВНЫЙ МАТЕРИАЛ

sk CHIRURGICKÁ NIŤ

sv SUTUR

tr SÜTÜR

zh-cn 缝线

zh-tw 縫合線

Instructions for use

en

SILK

STERILE NON-ABSORBABLE SURGICAL SUTURE, USP / Ph. Eur.

DESCRIPTION

Silk Suture may be marketed as PERMA-HAND™ Silk or Virgin Silk Suture, and is a sterile, non-absorbable surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species *Bombyx mori* (*B. mori*) of the family Bombycidae. Silk for braided material is processed to remove the natural waxes and gums. Braided silk is coated with wax or silicone.

Silk Suture is available undyed and dyed black with Hematine HCK (Color Index Number 75290) to enhance visibility in the surgical field. For virgin silk, the sericin gum is not removed and holds the twisted filaments together. Virgin silk is available dyed blue with methylene blue (Color Index Number 52015).

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

Silk Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Braided Silk Suture and United States Pharmacopeia (USP) for Non-Absorbable Surgical Suture.

The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. sizes as equivalent which is reflected on the labeling.

INDICATIONS

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

APPLICATION

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

PERFORMANCE / ACTIONS

Silk Suture elicits an initial, minimal inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissues. While silk is not absorbed, progressive degradation of the proteinaceous silk fiber *in vivo* may result in a gradual loss of all of the suture's tensile strength over time.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to silk.

Due to the gradual loss of all of the suture's tensile strength which may occur over prolonged periods *in vivo*, silk 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 silk suture for wound closure, as risk of wound dehiscence may vary with the site of application and with the suture material used.

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

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 with the use of silk sutures include wound dehiscence, gradual loss of tensile strength over time, allergic response in patients who are known to be sensitive to silk, 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

Silk 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.

Silk Suture is available as sterile strands in sizes 9-0 through 5 (metric sizes 0.3 – 7.0) in a variety of lengths, with and without permanently attached needles and on LIGAPAK™ Dispensing Reels.

Silk Suture is also available as sterile strands attached to CONTROL RELEASE™ (CR) removable needles which enable the needles to be pulled off instead of being cut off.

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

	ar / cs-Pro jednorázové použití / da-Må ikke genbruges / de-Nicht zur Wiederverwendung / el-Μην επαναχρησιμοποιείτε / en-Do not reuse / es-No reutilizar / fi-Ei saa käyttää uudelleen / fr-Ne pas réutiliser / hu-Ne használja újra / it-Non riutilizzare / ko-재사용하지 마십시오 / nl-Niet opnieuw gebruiken / no-Ikke bruk flere ganger / pl-Nie używać powtórnie / pt-Não reutilizar / ru-Не использовать повторно / sk-Nepoužívať opakovane / sv-Får ej återanvändas / tr-Tekrar kullanmayın / zh-cn-请勿重复使用 / zh-tw-不得重複使用
	ar / cs-Datum použitelnosti / da-Anvendes inden / de-Verwendbar bis / el-Ημερομηνία λήξης / en-Use by / es-Usar antes de / fi-Viimeinen käyttöpäivä / fr-À utiliser avant / hu-Felhasználható / it-Utilizzare entro / ko-사용 기한 / nl-Uiterste gebruiksdatum / no-Brukes innen / pl-Wykorzystać do / pt-Usar até / ru-Использовать до / sk-Spotrebujte do / sv-Används före / tr-Son kullanma tarihi / zh-cn-有效期至 / zh-tw-有效期限
LOT	ar / cs-Číslo šarže / da-Batchkode / de-Chargennummer / el-Κωδικός παρτίδας / en-Batch code / es-Número de lote / fi-Eränumero / fr-Numéro de lot / hu-Tételkód / it-Numero di lotto / ko-배치 번호 / nl-Lotnummer (partij) / no-Partinummer / pl-Kod partii / pt-Código de lote / ru-Номер партии / sk-Sériové číslo / sv-Satskod / tr-Parti kodu / zh-cn-批号 / zh-tw-批號

STERILE R	ar / 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 sädetämällä / fr-Stérilisé par irradiation / hu-Besugárzással sterilizálva / it-Sterilizzato per irradiazione / ko-방사선조사를 사용하여 멸균되었음 / nl-Gesteriliseerd door bestraling / no-Sterilisert med stråling / pl-Wysterylizowano promieniowaniem / pt-Esterilizado por irradiação / ru-Стерилизовано облучением / sk-Sterilizované žiarením / sv-Steriliserad med strålning / tr-İşima ile sterilize edilmiştir / zh-cn-使用辐照灭菌 / zh-tw-經放射線滅菌
REF	ar / 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 / ko-카탈로그 번호 / nl-Catalogusnummer / no-Katalognummer / pl-Numer katalogowy / pt-Número de catálogo / 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 / cs-UPOZORNĚNÍ / da-BEMÆRK / de-ACHTUNG / el-ΠΡΟΣΟΧΗ / en-CAUTION / es-ATENCIÓN / fi-HUOMIO / fr-ATTENTION / hu-VIGYÁZAT / it-ATTENZIONE / ko-주의 / nl-LET OP / no-FORSIKTIG / pl-PRZESTROGA / pt-ATENÇÃO / ru-ВНИМАНИЕ / sk-UPOZORNENIE / sv-OBS / tr-DİKKAT / zh-cn-注意 / zh-tw-注意
	ar / cs-Výrobce / da-Producent / de-Hersteller / el-Κατασκευαστής / en-Manufacturer / es-Fabricante / fi-Valmistaja / fr-Fabricant / hu-Gyártó / it-Fabbricante / ko-제조사 / nl-Fabrikant / no-Produsent / pl-Producent / pt-Fabricante / ru-Производитель / sk-Výrobca / sv-Tillverkare / tr-İmalatçı / zh-cn-制造商 / zh-tw-製造廠



-ar / **cs**-Neresterilizujte / **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 / **ko**-재멸균하지 마십시오 / **nl**-Niet opnieuw steriliseren / **no**-Skal ikke resteriliseres / **pl**-Nie wyjaławiać powtórnie / **pt**-Não reesterilizar / **ru**-Не стерилизовать повторно / **sk**-Nesterilizujte opakovane / **sv**-Får ej omsteriliseras / **tr**-Tekrar steril etmeyin / **zh-cn**-不得重复灭菌 / **zh-tw**-不得重複滅菌

EC REP

-ar / **cs**-Autorizovaný 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 képviselő az Európai Közösségben / **it**-Rappresentante autorizzato nella Comunità europea / **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 / **ru**-Официальный представитель в ЕС / **sk**-Autorizovaný zástupca v Európskom spoločenstve / **sv**-Auktoriserad representant i Europeiska gemenskapen / **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 / **cs**-Nepoužívejte, je-li obal poškozený / **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 / **ko**-포장이 파손되어 있는 경우에는 사용하지 마십시오 / **nl**-Niet gebruiken als de verpakking beschadigd is / **no**-Må ikke brukes hvis pakningen er skadet / **pl**-Nie używać, jeśli opakowanie jest uszkodzone / **pt**-Não utilizar se a embalagem estiver danificada / **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, 请勿使用 / **zh-tw**-如果包裝有破損, 請勿使用

CE 0086

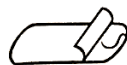
-ar-العلامة الخاصة بمطابقة المنتج لتوجيهات السوق الأوروبية المشتركة ورقم التعريف من قبل مجموعة/جهة ترخيص معترف بها من الاتحاد الأوروبي. وهذا يعني أن المنتج مطابق للشروط الأساسية للتوجيهات المتعلقة بالأجهزة الطبية الصادرة عن السوق الأوروبية المشتركة برقم 93/42/EEC

cs-Označení CE a identifikační číslo notifikované osoby. Výrobek odpovídá základním požadavkům směrnice 93/42/EHS pro zdravotnické prostředky / **da**-CE-mærkning og identifikationsnummer for bemyndiget organ. Produktet opfylder de væsentlige krav i Direktiv 93/42/EØF om medicinsk udstyr / **de**-CE-Kennzeichnung und Kennnummer der Benannten Stelle. Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie 93/42/EWG des Rates über Medizinprodukte / **el**-Σήμανση CE και αριθμός αναγνώρισης του κοινοποιημένου οργανισμού. Το προϊόν πληροί τις απαραίτητες απαιτήσεις της Οδηγίας 93/42/EOK περί ιατροτεχνολογικών προϊόντων / **en**-CE-mark and Identification number of Notified Body. The product meets the essential requirements of Medical Device Directive 93/42/EEC / **es**-Marca CE + número de identificación del organismo notificado. Este producto cumple los requisitos esenciales de la directiva de productos sanitarios 93/42/CEE



0086

fi-CE-merkintä ja ilmoitetun laitoksen tunnusnumero. Tuote noudattaa lääkinnällisistä laitteista annetun direktiivin 93/42/ETY säännöksiä / **fr**-Marquage CE et numéro d'identification de l'organisme notifié. Le produit est conforme aux exigences essentielles de la Directive sur les dispositifs médicaux 93/42/CEE / **hu**-CE-jel és a bejegyzett testület száma. A termék megfelel az orvosi készülékekről szóló 93/42/EGK számú irányelv előírásainak / **it**-Marchio CE e numero di identificazione dell'organismo notificato. Il prodotto è conforme ai requisiti essenziali della direttiva 93/42/CEE sui dispositivi medici / **ko**-CE 마크 및 인증기관의 식별번호. 제품은 의료기기지침 93/42/EEC 필수조건에 부합됩니다 / **nl**-CE-markering en identificatienummer van de aangemelde instantie. Het product is in overeenstemming met de essentiële eisen van de richtlijn voor medische hulpmiddelen 93/42/EEG / **no**-CE-merke og ID-nummer for bemyndiget organ. Produktet innfrir de vesentlige krav i direktivet 93/42/EØF for medisinsk utstyr / **pl**-Znak CE i numer identyfikacyjny jednostki notyfikowanej. Produkt spełnia wymagania zasadnicze zawarte w dyrektywie 93/42/EWG dotyczącej wyrobów medycznych / **pt**-Marca CE e número de identificação do organismo notificado. O produto cumpre os principais requisitos da diretiva sobre dispositivos médicos 93/42/CEE / **ru**-Знак сертификации «CE» и идентификационный номер уведомленного органа. Данное изделие отвечает основным требованиям директивы о медицинском оборудовании 93/42/ЕЭС / **sk**-Označenie CE a identifikačné číslo notifikovaného orgánu. Produkt spĺňa základné požiadavky smernice 93/42/EHS o zdravotníckych pomôckach / **sv**-CE-märke och identifieringsnummer för anmält organ. Produkten uppfyller de väsentliga kraven i direktivet för medicinsk utrustning, 93/42/EEG / **tr**-CE işareti ve onaylanmış kuruluşun kimlik numarası. Ürün, 93/42/AET sayılı Tıbbi Cihazlar Direktifi'nin başlıca gereklerine uygundur / **zh-cn**-CE 标志和认证机构的识别号。产品符合医疗设备指令93/42/EEC的基本要求 / **zh-tw**-CE 標誌和認證機構的識別號。產品符合醫療設備指令93/42/EEC的基本要求



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 / **ko**-제품 개수 / **nl**-Aantal eenheden / **no**-Antall enheter / **pl**-Liczba jednostek / **pt**-Número de unidades / **ru**-Число единиц / **sk**-Počet jednotiek / **sv**-Antal enheter / **tr**-Ünite sayısı / **zh-cn**-件数 / **zh-tw**-數量



(عدد الخيوط في كل عبلة=X) CONTROL RELEASE™-**ar** / **cs**-CONTROL RELEASE™ (X = počet vláken v jednom balení) / **da**-CONTROL RELEASE™ (X=antal af tråde pr. pakke) / **de**-CONTROL RELEASE™ (X=die Anzahl der Stränge pro Paket) / **el**-Σύστημα αφαίρεσης βελόνας CONTROL RELEASE™ (X=Ο αριθμός νημάτων ανά συσκευασία) / **en**-CONTROL RELEASE™ (X=The number of strands per packet) / **es**-CONTROL RELEASE™ (X=Número de hilos de sutura por paquete) / **fi**-CONTROL RELEASE™ (X = lankojen määrä pakkausta kohden) / **fr**-CONTROL RELEASE™ (X=nombre de brins par paquet) / **hu**-CONTROL RELEASE™ (X=A szálak száma csomagonként) / **it**-CONTROL RELEASE™ (X=numero di fili per confezione) / **ko**-CONTROL RELEASE™ (X=패킷당 가닥 수) / **nl**-CONTROL RELEASE™ (X = het aantal draden per verpakking) / **no**-CONTROL RELEASE™ (X = antall tråder i hver pakke) / **pl**-Odejmwane igły CONTROL RELEASE™ (X=Liczba pasm w opakowaniu) / **pt**-CONTROL RELEASE™ (X=O número de fios por embalagem) / **ru**-С контролируемым освобождением (CONTROL RELEASE™) (X=число нитей в пакете) / **sk**-CONTROL RELEASE™ (X = počet vláken na balenie) / **sv**-CONTROL RELEASE™ (X = antalet suturer per förpackning) / **tr**-CONTROL RELEASE™ (X=Paket başına iplik sayısı) / **zh-cn**-CONTROL RELEASE™ (X=每股线的数目) / **zh-tw**-控釋 (X=每股股數量)

MS/X

(X=عدد الخيوط في كل علبة) **-ar / cs**-Multistrand (X = počet vláken v jednom balení) / **da**-Flertrådet (X=antal af tråde pr. pakke) / **de**-Mehrfachstrang (X=die Anzahl der Stränge pro Paket) / **el**-Πολλαπλών νημάτων (X=Ο αριθμός νημάτων ανά συσκευασία) / **en**-Multistrand (X=The number of strands per packet) / **es**-Multihebra (X=Número de hilos de sutura por paquete) / **fi**-Monilankainen (X = lankojen määrä pakkausta kohden) / **fr**-Multibrins (X=nombre de brins par paquet) / **hu**-Többszálú (X=A szálak száma csomagonként) / **it**-Multifilo (X=numero di fili per confezione) / **ko**-다중가닥(X=패킷당 가닥 수) / **nl**-Meerdere draden (X=het aantal draden per verpakking) / **no**-Flertrådet (X = antall tråder i hver pakke) / **pl**-Wielopasmowy (X=Liczba pasm w opakowaniu) / **pt**-Multifios (X=0 número de fios por embalagem) / **ru**-Многониточный (X=число нитей в пакете) / **sk**-Viacvláknová (X = počet vláken na balenie) / **sv**-Multistrand (X = antalet suturer per förpackning) / **tr**-Çok iplikli (X=Paket başına iplik sayısı) / **zh-cn**-多股 (X=每包股线的数目) / **zh-tw**-多股 (X=每包股數量)



-ar / 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**-HÚZZA LE / EMELJE MEG / NYISSA FEL ITT / **it**-STRAPPARE/SOLLEVARE/APRIRE QUI / **ko**-여기를 떼내고/올리고/개봉하십시오 / **nl**-HIER OPENTREKKEN/OMHOOGTREKKEN/OPENEN / **no**-SKRELLES AV / LØFTES / ÅPNES HER / **pl**-ODERWAĆ/UNIEŚĆ/OTWIERAĆ TUTAJ / **pt**-PUXAR/LEVANTAR/ABRIR AQUI / **ru**-СНЯТЬ/ПРИПОДНЯТЬ/ОТКРЫТЬ ЗДЕСЬ / **sk**-ODLUPNÚŤ/NADVIHNÚŤ/TU OTVORIT / **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 / 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**-SZAKÍTSA LE ITT / **it**-ROMPERE QUI / **ko**-여기를 찢으십시오 / **nl**-HIER AFSCHIEUREN / **no**-RIVES HER / **pl**-ROZERWAĆ TUTAJ / **pt**-RASGAR AQUI / **ru**-ОТОРВАТЬ ЗДЕСЬ / **sk**-TU ODTRHNÚŤ / **sv**-RIV HÄR / **tr**-BURADAN YIRTIN / **zh-cn**-由此撕开 / **zh-tw**-在此撕開