

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing ETHIBOND EXCEL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used.

WARNINGS

None known.

CONTRAINDICATIONS

pharmacologically inactive.

polyester fiber suture material and the polybutilate coating are not meaningful decline in polyester suture strength over time. Both by fibrous connective tissue. Implantation studies in animals show reaction in tissue, followed by a gradual encapsulation of the suture ETHIBOND EXCEL suture elicits a minimal acute inflammatory

ACTIONS

ophthalmic and neurological procedures.

ETHIBOND EXCEL suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ETHIBOND EXCEL suture is indicated for use in general soft tissue

INDICATIONS

ETHIBOND EXCEL suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, and for good visibility in the surgical field, are dyed green. ETHIBOND EXCEL sutures are braided for optimal handling properties, MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P. U.S.P. SUTURE SIZE DESIGNATION (mm) MAXIMUM OVERSIZE (mm) 0.024

DESCRIPTION

ETHIBOND EXCEL polyester suture is a nonabsorbable, braided, sterile, surgical suture composed of Poly (ethylene terephthalate). It is prepared from fibers of high molecular weight, long-chain, linear poly (oxy-1, 4 butanedioldioxy (1, 6-dioxo-1, 6 hexanediyl)). The ETHIBOND EXCEL suture is uniformly coated with polybutilate or poly (oxy-1, 4 butanedioldioxy (1, 6-dioxo-1, 6 hexanediyl)). The polybutilate coating is a relatively nonabsorbable compound which acts as a lubricant to suture by improving ease of passage through tissues and by providing overall improved handling qualities as contrasted to the braided, uncoated fiber. ETHIBOND EXCEL sutures are braided for optimal handling properties, MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P. U.S.P. SUTURE SIZE DESIGNATION (mm) MAXIMUM OVERSIZE (mm) 0.024

NONABSORBABLE SURGICAL SUTURE, U.S.P.	Except for size 6-0 diameter
ETHIBOND® EXCEL	POLYESTER SUTURE
ETHIBOND® EXCEL	POLYESTER SUTURE
English	

Não reesterilizar. Rejeitar embalagens abertas e fios de sutura não utilizados.

Como acontece com todos os corpos estranhos, o contacto prolongado do fio de sutura com soluções salinas (ao nível das vias urinárias ou biliares, por exemplo) pode conduzir à formação de cálculos. Devem ser seguidas práticas cirúrgicas aceitáveis para o tratamento de feridas infectadas ou contaminadas.

PRECAUÇÕES

Quando se manusear este ou qualquer outro material de sutura, deve tomar-se precaução para evitar danos decorrentes do manuseamento. Evitar danos por esmagamento ou compressão devido à aplicação de instrumentos cirúrgicos como pinças ou porta-agulhas.

À semelhança do verificado com qualquer material de sutura, a segurança adequada dos nós exige técnicas habituais de sutura e de nós cirúrgicos com nós de reforço, de acordo com a circunstância cirúrgica e a experiência do cirurgião.

Para evitar danos na ponta da agulha e áreas de fixação do fio, agarrar na agulha numa área de entre um terço (1/3) e metade (1/2) da distância entre a extremidade de fixação e a ponta. Moldar as agulhas pode fazer com que estas percam força e fiquem menos resistentes à flexão e fractura. Os utilizadores devem tomar precaução quando manusearem agulhas cirúrgicas, para evitarem lesões por picadas accidentais. Eliminar as agulhas usadas em recipientes próprios para “objetos cortantes”.

REAÇÕES ADVERSAS

Entre os efeitos adversos associados à utilização deste dispositivo inclui-se deiscência da ferida, formação de cálculos no aparelho urinário e vias biliares quando ocorre um contacto prolongado com soluções salinas, tais como a urina e bilis, infecção, reacção tecidual inflamatória aguda mínima e irritação local transitória no local da ferida. Agulhas partidas podem originar o prolongamento do tempo operativo ou obrigar a cirurgia adicional ou associar-se a corpos estranhos residuais. Picadas accidentais com agulhas cirúrgicas contaminadas podem originar a transmissão de agentes patogénicos por via sanguínea.

APRESENTAÇÃO

As suturas ETHIBOND EXCEL estão disponíveis sob a forma de fios esterilizados, entrançados, verdes e incolores (brancos) em calibres de 7-0 a 5 (métricos de 0,5 a 7), numa ampla variedade de comprimentos, armados com agulhas permanentes ou sem agulhas.

Os fios de sutura ETHIBOND EXCEL, verdes, entrançados, nos calibres de 4-0 a 1 (métricos de 1,5 a 4), também estão disponíveis armados com agulhas amovíveis CONTROL RELEASE®.

Os fios de sutura ETHIBOND EXCEL, verdes e incolores, também estão disponíveis armados com compressas de polímero TFE de 3,0 mm x 3,0 mm x 1,5 mm; 7,0 mm x 3,0 mm x 1,5 mm.

Os fios de sutura ETHIBOND EXCEL estão disponíveis em caixas de uma, duas e três dúzias.

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*Trademark

ETHIBOND EXCEL sutures are available in one, two and three dozen boxes.

ETHIBOND EXCEL sutures are available in one, two and three dozen boxes. (metric sizes 1.5-4) are also available attached to CONTROL RELEASE® removable needles.

ETHIBOND EXCEL sutures, green, braided, in sizes 4-0 through 1 (metric lengths, with and without permanently attached needles. ETHIBOND EXCEL sutures are available as sterile, braided, green and undyed (white) strands in sizes 7-0 through 5 (metric sizes 0.5-7) in a variety of lengths, with and without permanently attached needles.

HOW SUPPLIED

ETHIBOND EXCEL sutures are available as sterile, braided, green and undyed (white) strands in sizes 7-0 through 5 (metric sizes 0.5-7) in a variety of lengths, with and without permanently attached needles. Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies.

As with any suture material, adequate knot security requires the accepted surgical technique of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the point to the point. 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 sticks. Discard used needles in “sharp” containers.

PRECAUTIONS

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Português	
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FIO DE SUTURA DE POLIÉSTER	ETHIBOND® EXCEL
FIO DE SUTURA CIRÚRGICO NÃO ABSORVÍVEL, U.S.P.	FIO DE SUTURA CIRÚRGICO NÃO ABSORVÍVEL, U.S.P.
À excepção do diâmetro do calibre 6-0	

DESCRIÇÃO

O fio de sutura de poliéster ETHIBOND® EXCEL consiste numa sutura cirúrgica esterilizada, entrançada e não absorvível constituída por poli (etileno tereftalato). É fabricado a partir de fibras de poliésteres lineares de cadeia longa e peso molecular elevado, apresentando anéis aromáticos recorrentes como componente integral. O fio de sutura ETHIBOND EXCEL é revestido uniformemente com polibutilato ou poli (oxi-1, 4 butanediolxi (1, 6-dioxo-1, 6 hexanediil)). A camada altamente aderente consiste num composto não absorvível relativamente não reactivo, que actua como lubrificante para melhorar mecanicamente as propriedades físicas do fio de sutura não revestido, ao melhorar a facilidade de passagem através dos tecidos e ao conferir qualidades de manuseamento globalmente melhoradas, em contraste com a fibra entrançada não revestida. Os fios de sutura ETHIBOND EXCEL são entrançados para disporem de propriedades de manuseamento ideais e são coloridos de verde para uma boa visibilidade no campo cirúrgico.

Os fios de sutura ETHIBOND EXCEL de calibre 6-0 estão em conformidade com a U.S.P., à excepção do diâmetro.

EXCESSO DE FIO DE SUTURA MÁXIMO EM DIÂMETRO (mm) RELATIVAMENTE À U.S.P.	
DESIGNAÇÃO DO CALIBRE DO FIO DE SUTURA DA U.S.P.	EXCESSO MÁXIMO (mm)
6-0	0,024

INDICAÇÕES

O fio de sutura ETHIBOND EXCEL está indicado para ser utilizado na coaptação e/ou laqueação dos tecidos moles em geral, incluindo utilização em procedimentos cardiovasculares, oftalmológicos e neurológicos.

ACTUAÇÃO

O fio de sutura ETHIBOND EXCEL provoca uma reacção inflamatória aguda mínima dos tecidos, que é seguida de um encapsulamento gradual da sutura por tecido conjuntivo fibroso. Estudos de implantação efectuados nos animais não mostram qualquer declínio significativo da força da sutura de poliéster no decurso do tempo. O material do fio de sutura em fibra de poliéster e o revestimento de polibutilato são farmacologicamente inactivos.

CONTRA-INDICAÇÕES

Nenhuma conhecida.

ADVERTÊNCIAS

O utilizador deve dominar as técnicas cirúrgicas que envolvem o uso de suturas não absorvíveis antes de utilizar o fio de sutura ETHIBOND EXCEL, pois o risco de deiscência varia consoante o local de aplicação e o tipo de material de sutura utilizado.

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ETHIBOND EXCEL sutures are available in one, two and three dozen boxes. (metric sizes 1.5-4) are also available attached to CONTROL RELEASE® removable needles.

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Français	
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English	
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FIL DE SUTURE EN POLYESTER	ETHIBOND® EXCEL
FIL DE SUTURE CHIRURGICAL NON RÉSORBABLE, AUX NORME DE LA PHARMACOPÉE DES ÉTATS-UNIS (U.S.P.)	FIL DE SUTURE CIRÚRGICO NÃO RESORVÁVEL, U.S.P.
Excepté pour les calibres de diamètre 6/0	

DESCRIPTION

Le fil de sutura chirurgical en polyester ETHIBOND® EXCEL est non résorbable, tressé, stérile et composé de Poly (éthylène téréphtalate). Il est préparé à partir de fibres de haut poids moléculaires, à longues chaînes de polyesters linéaires possédant des anneaux aromatiques récurrents en tant que composants à part entière. Le fil de sutura ETHIBOND EXCEL est uniformément enduit de polybutilato ou de poly (oxy-1, 4 butanedioldioxy (1, 6-dioxo-1, 6 hexanediyl)). Le revêtement fortement adhérent est un composé relativement non réactif et non résorbable, qui agit en tant que lubrifiant pour améliorer mécaniquement les propriétés physiques du fil de sutura non recouvert, en facilitant son passage à travers les tissus, et surtout en conférant des facilités de manipulation par rapport à la fibre tressée non recouverte.

Les fils de sutura ETHIBOND EXCEL sont tressés afin d'avoir des propriétés de manipulation optimales, et sont teints en vert pour leur donner une bonne visibilité dans le champ chirurgical.

Les fils de sutures de calibre 6/0 ETHIBOND EXCEL sont aux normes U.S.P., excepté pour leur diamètre.

DIAMÈTRE (mm) DU CALIBRE MAXIMUM ADMIS PAR L'U.S.P. POUR UN FIL DE SUTURE	
DÉSIGNATION U.S.P. DU CALIBRE D'UN FIL DE SUTURE	CALIBRE MAXIMUM (mm)
6/0	0,024

INDICATIONS

Le fil de sutura ETHIBOND EXCEL est indiqué d'une façon générale pour le rapprochement des tissus mous et/ou pour les ligatures, notamment lors des interventions cardiovasculaires, ophtalmiques et neurologiques.

COMPORTEMENT

Le fil de sutura ETHIBOND EXCEL provoque une réaction inflammatoire tissulaire aigüe minime, suivie d'une encapsulation progressive de la sutura par du tissu conjonctif fibreux. Les études d'implant chez l'animal ne montrent aucune disparition significative de la force du fil en polyester au cours du temps. Aussi bien le matériel de la fibre de sutura en polyester que le polybutilato recouvrant sont pharmacologiquement inactifs.

CONTRE-INDICATIONS

Aucune connue.

AVERTISSEMENTS

Les utilisateurs doivent être familiarisés avec les techniques et procédures chirurgicales faisant appel aux fils de sutura non résorbables avant d'employer le fil de sutura ETHIBOND EXCEL pour la fermeture de la plaie,

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*Marque commerciale	

리에스데은 용합사
수용용 용합사, U.S.P.
조 6-0 직경 제외

符合美國藥典對不可吸收之手術縫合線之要求
(規格6-0의直徑除外)

符合美國藥典對不可吸收之手術縫合線之要求
(0-規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

符合美國藥典對不可吸收之手術縫線之要求
(規格除外)

English	
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Português	
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FIL DE SUTURE EN POLYESTER	ETHIBOND® EXCEL
FIL DE SUTURE CHIRURGICAL NON RÉSORBABLE, AUX NORME DE LA PHARMACOPÉE DES ÉTATS-UNIS (U.S.P.)	FIL DE SUTURE CIRÚRGICO NÃO RESORVÁVEL, U.S.P.
Excepté pour les calibres de diamètre 6/0	

DESCRIPTION

Le fil de sutura chirurgical en polyester ETHIBOND® EXCEL est non résorbable, tressé, stérile et composé de Poly (éthylène téréphtalate). Il est préparé à partir de fibres de haut poids moléculaires, à longues chaînes de polyesters linéaires possédant des anneaux aromatiques récurrents en tant que composants à part entière. Le fil de sutura ETHIBOND EXCEL est uniformément enduit de polybutilato ou de poly (oxy-1, 4 butanedioldioxy (1, 6-dioxo-1, 6 hexanediyl)). Le revêtement fortement adhérent est un composé relativement non réactif et non résorbable, qui agit en tant que lubrifiant pour améliorer mécaniquement les propriétés physiques du fil de sutura non recouvert, en facilitant son passage à travers les tissus, et surtout en conférant des facilités de manipulation par rapport à la fibre tressée non recouverte.

Les fils de sutura ETHIBOND EXCEL sont tressés afin d'avoir des propriétés de manipulation optimales, et sont teints en vert pour leur donner une bonne visibilité dans le champ chirurgical.

Les fils de sutures de calibre 6/0 ETHIBOND EXCEL sont aux normes U.S.P., excepté pour leur diamètre.

DIAMÈTRE (mm) DU CALIBRE MAXIMUM ADMIS PAR L'U.S.P. POUR UN FIL DE SUTURE	
DÉSIGNATION U.S.P. DU CALIBRE D'UN FIL DE SUTURE	CALIBRE MAXIMUM (mm)
6/0	0,024

INDICATIONS

Le fil de sutura ETHIBOND EXCEL est indiqué d'une façon générale pour le rapprochement des tissus mous et/ou pour les ligatures, notamment lors des interventions cardiovasculaires, ophtalmiques et neurologiques.

COMPORTEMENT

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CONTRE-INDICATIONS

Aucune connue.

AVERTISSEMENTS

Les utilisateurs doivent être familiarisés avec les techniques et procédures chirurgicales faisant appel aux fils de sutura non résorbables avant d'employer le fil de sutura ETHIBOND EXCEL pour la fermeture de la plaie,

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