



República Argentina - Poder Ejecutivo Nacional
2021 - Año de Homenaje al Premio Nobel de Medicina Dr. César Milstein

Disposición

Número:

Referencia: 1-47-3110-41-21-8

VISTO el Expediente N° 1-47-3110-41-21-8 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones Suvanza S.A.S., solicita se autorice la inscripción en el Registro Productores y Productos de Tecnología Médica (RPPTM) de esta Administración Nacional, de un nuevo producto médico.

Que las actividades de elaboración y comercialización de productos médicos se encuentran contempladas por la Ley 16463, el Decreto 9763/64, y MERCOSUR/GMC/RES. N° 40/00, incorporada al ordenamiento jurídico nacional por Disposición ANMAT N° 2318/02 (TO 2004), y normas complementarias.

Que consta la evaluación técnica producida por el Instituto Nacional de Productos Médicos, en la que informa que el producto estudiado reúne los requisitos técnicos que contempla la norma legal vigente, y que los establecimientos declarados demuestran aptitud para la elaboración y el control de calidad del producto cuya inscripción en el Registro se solicita.

Que corresponde autorizar la inscripción en el RPPTM del producto médico objeto de la solicitud.

Que se actúa en virtud de las facultades conferidas por el Decreto N° 1490/92 y sus modificatorios.

Por ello;

EL ADMINISTRADOR NACIONAL DE LA ADMINISTRACIÓN NACIONAL DE
MEDICAMENTOS, ALIMENTOS Y TECNOLOGÍA MÉDICA

DISPONE:

ARTÍCULO 1º.- Autorízase la inscripción en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM) de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) del producto médico marca Da: all, nombre descriptivo Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir y nombre técnico Suturas, de Polidioxanona, de acuerdo con lo solicitado por Suvanza S.A.S., con los Datos Identificatorios Característicos que figuran al pie de la presente.

ARTÍCULO 2º.- Autorízase los textos de los proyectos de rótulo/s y de instrucciones de uso que obran en documento N° IF-2021-17254029-APN-INPM#ANMAT.

ARTÍCULO 3º.- En los rótulos e instrucciones de uso autorizados deberá figurar la leyenda “Autorizado por la ANMAT PM-2556-3”, con exclusión de toda otra leyenda no contemplada en la normativa vigente.

ARTICULO 4º.- Extiéndase el Certificado de Autorización e Inscripción en el RPPTM con los datos característicos mencionados en esta disposición.

ARTÍCULO 5º.- La vigencia del Certificado de Autorización será de cinco (5) años, a partir de la fecha de la presente disposición.

ARTÍCULO 6º.- Regístrese. Inscríbese en el Registro Nacional de Productores y Productos de Tecnología Médica al nuevo producto. Por el Departamento de Mesa de Entrada, notifíquese al interesado, haciéndole entrega de la presente Disposición, conjuntamente con rótulos e instrucciones de uso autorizados y el Certificado mencionado en el artículo 4º. Gírese a la Dirección de Gestión de Información Técnica a los fines de confeccionar el legajo correspondiente. Cumplido, archívese.

DATOS IDENTIFICATORIOS CARACTERISTICOS

Nombre descriptivo: Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir.

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):

16-584 Suturas, de Polidioxanona

Marca(s) de (los) producto(s) médico(s): Da: all

Clase de Riesgo: IV

Indicación/es autorizada/s:

Este dispositivo está diseñado para fijar tejido subdérmico en una posición elevada en cirugía plástica y cirugía reconstructiva. La sutura de polidioxanona proporciona soporte a la herida durante más tiempo en comparación

con otra sutura sintética absorbible.

Modelos:

Sutura general con aguja

M2160S-0090 M2950S-W6070 MS2670S-60110 MS2950S-W6080 D2638S-W7050 DS2550SG5080

M2338S-3050 M2950S-W6080 MS2690S-60150 MS2960S-W6090 D2638S-W7060 DS2560SG5090

M2350S-3080 M2960S-W6090 MS2738S-5050 MS3025S-W7030 D2650S-W7080 DS2570SG50110

M2360S-3090 M2990S-W60150 MS2750S-5070 MS3030S-W7040 D2660S-W7090 DS2590SG50150

M2390S-30150 M3025S-W6030 MS2750S-5080 MS3038S-W7050 D2690S-W70150 DS2538S G6050

M2538S-4050 M3025S-W7030 MS2760S-5090 MS3038S-W7060 D2738S-W7050 DS2550SG6080

M2550S-4080 M3030S-W7040 MS2770S-50110 MS2338S-G3050 D2750S-W7080 DS2560SG6080

M2560S-4080 M3038S-W7060 MS2790S-50150 MS2350S-G3080 D2760S-W7090 DS2560SG6090

M2560S-4090 M2160S-G0090 MS2825S-5030 MS2360S-G3090 D2538S-G6050 DS2570SG60110

M2590S-40140 M2338S-G3050 MS2830S-5040 MS2370S-G30110 D2550S-G7080 DS2590SG60150

M2590S-40150 M2350S-G3080 MS2838S-5050 MS2390S-G30150 D2638S-G6050 DS2638SG5050

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M2938S-W6060 MS2660S-6090 MS2950S-W6070 D2660S-W6090 DS2538S-G5050 3B2560SG7080

Sutura general con aguja despuntada

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P2B21100A-70150
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P2B21100A-70180
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P9B2360A-7020
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P9B2360A-7060
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Sutura dentada con aguja

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Sutura dentada con aguja despuntada

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Sutura dentada con aguja simple brazo

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MP4HS26S20-201

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MP4HS26S20-401

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M9RS40S00-401 MP4RS17S30-401	M9RS17S30-G401	MSRS40S00-G401	MP2RS17S30-W401	MP3RS40S00-	W401
M9HS17S20-201 MP4HS26S30-201	M9HS26S30-G201	MSHS17S20-G201	MP2HS26S30-W201	MP3HS17S20-	W201
M9HS17S20-401 MP4HS26S30-401	M9HS26S30-G401	MSHS17S20-G401	MP2HS26S30-W401	MP3HS17S20-	W401
M9RS17S20-201 MP4RS26S30-201	M9RS26S30-G201	MSRS17S20-G201	MP2RS26S30-W201	MP3RS17S20-	W201
M9RS17S20-401 MP4RS26S30-401	M9RS26S30-G401	MSRS17S20-G401	MP2RS26S30-W401	MP3RS17S20-	W401
M9HS26S20-201 MP4HS26S00-W201	MSHS26S00-201	MSHS26S20-G201	MP2HS26S00-G201	MP3HS26S20-	W201
M9HS26S20-401 MP4HS26S00-W401	MSHS26S00-401	MSHS26S20-G401	MP2HS26S00-G401	MP3HS26S20-	W401
M9RS26S20-201 MP4RS26S00-W201	MSRS26S00-201	MSRS26S20-G201	MP2RS26S00-G201	MP3RS26S20-	W201
M9RS26S20-401 MP4RS26S00-W401	MSRS26S00-401	MSRS26S20-G401	MP2RS26S00-G401	MP3RS26S20-	W401
M9HS17S30-201 MP4HS40S00-W201	MSHS40S00-201	MSHS17S30-G201	MP2HS40S00-G201	MP3HS17S30-	W201
M9HS17S30-401 MP4HS40S00-W401	MSHS40S00-401	MSHS17S30-G401	MP2HS40S00-G401	MP3HS17S30-	W401
M9RS17S30-201	MSRS40S00-201	MSRS17S30-G201	MP2RS40S00-G201	MP3RS17S30-	W201

MP4RS40S00-W201

M9RS17S30-401 MSRS40S00-401 MSRS17S30-G401 MP2RS40S00-G401 MP3RS17S30- W401
MP4RS40S00-W401

M9HS26S30-201 MSHS17S20-201 MSHS26S30-G201 MP2HS17S20-G201 MP3HS26S30- W201
MP4HS17S20-W201

M9HS26S30-401 MSHS17S20-401 MSHS26S30-G401 MP2HS17S20-G401 MP3HS26S30- W401
MP4HS17S20-W401

M9RS26S30-201 MSRS17S20-201 MSRS26S30-G201 MP2RS17S20-G201 MP3RS26S30- W201
MP4RS17S20-W201

M9RS26S30-401 MSRS17S20-401 MSRS26S30-G401 MP2RS17S20-G401 MP3RS26S30- W401
MP4RS17S20-W401

M9HS26S00-W201 MSHS26S20-201 MP2HS26S00-201 MP2HS26S20-G201 MP3HS26S00- G201
MP4HS26S20-W201

M9HS26S00-W401 MSHS26S20-401 MP2HS26S00-401 MP2HS26S20-G401 MP3HS26S00- G401
MP4HS26S20-W401

M9RS26S00-W201 MSRS26S20-201 MP2RS26S00-201 MP2RS26S20-G201 MP3RS26S00- G201
MP4RS26S20-W201

M9RS26S00-W401 MSRS26S20-401 MP2RS26S00-401 MP2RS26S20-G401 MP3RS26S00-G401
MP4RS26S20-W401

M9HS40S00-W201 MSHS17S30-201 MP2HS40S00-201 MP2HS17S30-G201 MP3HS40S00-G201
MP4HS17S30-W201

M9HS40S00-W401 MSHS17S30-401 MP2HS40S00-401 MP2HS17S30-G401 MP3HS40S00-G401
MP4HS17S30-W401

M9RS40S00-W201 MSRS17S30-201 MP2RS40S00-201 MP2RS17S30-G201 MP3RS40S00-G201
MP4RS17S30-W201

M9RS40S00-W401 MSRS17S30-401 MP2RS40S00-401 MP2RS17S30-G401 MP3RS40S00-G401
MP4RS17S30-W401

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MP4HS26S30-W201

M9HS17S20-W401 MSHS26S30-401 MP2HS17S20-401 MP2HS26S30-G401 MP3HS17S20-G401
MP4HS26S30-W401

M9RS17S20-W201 MSRS26S30-201 MP2RS17S20-201 MP2RS26S30-G201 MP3RS17S20-G201
MP4RS26S30-W201

M9RS17S20-W401 MP4RS26S30-W401	MSRS26S30-401	MP2RS17S20-401	MP2RS26S30-G401	MP3RS17S20-G401
M9HS26S20-W201 MP4HS26S00-G201	MSHS26S00-W201	MP2HS26S20-201	MP3HS26S00-201	MP3HS26S20-G201
M9HS26S20-W401 MP4HS26S00-G401	MSHS26S00-W401	MP2HS26S20-401	MP3HS26S00-401	MP3HS26S20-G401
M9RS26S20-W201 MP4RS26S00-G201	MSRS26S00-W201	MP2RS26S20-201	MP3RS26S00-201	MP3RS26S20-G201
M9RS26S20-W401 MP4RS26S00-G401	MSRS26S00-W401	MP2RS26S20-401	MP3RS26S00-401	MP3RS26S20-G401
M9HS17S30-W201 MP4HS40S00-G201	MSHS40S00-W201	MP2HS17S30-201	MP3HS40S00-201	MP3HS17S30-G201
M9HS17S30-W401 MP4HS40S00-G401	MSHS40S00-W401	MP2HS17S30-401	MP3HS40S00-401	MP3HS17S30-G401
M9RS17S30-W201 MP4RS40S00-G201	MSRS40S00-W201	MP2RS17S30-201	MP3RS40S00-201	MP3RS17S30-G201
M9RS17S30-W401 MP4RS40S00-G401	MSRS40S00-W401	MP2RS17S30-401	MP3RS40S00-401	MP3RS17S30-G401
M9HS26S30-W201 MP4HS17S20-G201	MSHS17S20-W201	MP2HS26S30-201	MP3HS17S20-201	MP3HS26S30-G201
M9HS26S30-W401 MP4HS17S20-G401	MSHS17S20-W401	MP2HS26S30-401	MP3HS17S20-401	MP3HS26S30-G401
M9RS26S30-W201 MP4RS17S20-G201	MSRS17S20-W201	MP2RS26S30-201	MP3RS17S20-201	MP3RS26S30-G201
M9RS26S30-W401 MP4RS17S20-G401	MSRS17S20-W401	MP2RS26S30-401	MP3RS17S20-401	MP3RS26S30-G401
M9HS26S00-G201 MP4HS26S20-G201	MSHS26S20-W201	MP2HS26S00-W201	MP3HS26S20-201	MP4HS26S00-201
M9HS26S00-G401 MP4HS26S20-G401	MSHS26S20-W401	MP2HS26S00-W401	MP3HS26S20-401	MP4HS26S00-401
M9RS26S00-G201 MP4RS26S20-G201	MSRS26S20-W201	MP2RS26S00-W201	MP3RS26S20-201	MP4RS26S00-201
M9RS26S00-G401	MSRS26S20-W401	MP2RS26S00-W401	MP3RS26S20-401	MP4RS26S00-401

MP4RS26S20-G401

M9HS40S00-G201 MSHS17S30-W201 MP2HS40S00-W201 MP3HS17S30-201 MP4HS40S00-201
MP4HS17S30-G201

M9HS40S00-G401 MSHS17S30-W401 MP2HS40S00-W401 MP3HS17S30-401 MP4HS40S00-401
MP4HS17S30-G401

M9RS40S00-G201 MSRS17S30-W201 MP2RS40S00-W201 MP3RS17S30-201 MP4RS40S00-201
MP4RS17S30-G201

M9RS40S00-G401 MSRS17S30-W401 MP2RS40S00-W401 MP3RS17S30-401 MP4RS40S00-401
MP4RS17S30-G401

M9HS17S20-G201 MSHS26S30-W201 MP2HS17S20-W201 MP3HS26S30-201 MP4HS17S20-201
MP4HS26S30-G201

M9HS17S20-G401 MSHS26S30-W401 MP2HS17S20-W401 MP3HS26S30-401 MP4HS17S20-401
MP4HS26S30-G401

M9RS17S20-G201 MSRS26S30-W201 MP2RS17S20-W201 MP3RS26S30-201 MP4RS17S20-201
MP4RS26S30-G201

M9RS17S20-G401 MSRS26S30-W401 MP2RS17S20-W401 MP3RS26S30-401 MP4RS17S20-401
MP4RS26S30-G401

Sutura dentada sin aguja

AN00-91 AN00-W92 AN00-G172B CN00-W172B CN02-G172B ZN01-W172B

AN00-92 AN00-W172B AN00-G172 CN01-W172B ZN00-172B ZN02-W172B

AN00-172B AN00-W172 CN00-172B CN02-W172B ZN01-172B ZN00-G172B

AN00-172 AN00-G91 CN01-172B CN00-G172B ZN02-172B ZN01-G172B

AN00-W91 AN00-G92 CN02-172B CN01-G172B ZN00-W172B ZN02-G172B

Período de vida útil: 2 años desde la fecha de esterilización

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biotecnológico: N/A

Forma de presentación: Presentación en caja

Caja por 5/10 envases unitarios

Método de esterilización: Esterilizado por ETO

Nombre del fabricante:

METABIOMED Co., Ltd

Lugar de elaboración:

270, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

Expediente N° 1-47-3110-41-21-8

Digitally signed by GARAY Valeria Teresa
Date: 2021.03.02 23:55:48 ART
Location: Ciudad Autónoma de Buenos Aires

Digitally signed by Gestion Documental
Electronica
Date: 2021.03.02 23:55:51 -03:00

PROYECTO DE ROTULO

Anexo III.B – Disposición ANMAT N° 2318/02 (t.o. 2004)

Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir.

Fabricante: Metabiomed Co., Ltd.,
270, Osongsaengmyeong 1-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,
Corea

Importador: Suvanaza SAS, Gaspar Melchor de
Jovellanos 1527-1529, PB, Cod. Postal 1269,
Ciudad Autónoma de Buenos Aires, Argentina.

Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir.

Da: all

Modelo: según corresponda

Cantidad: xx

LOT

XXXXXXX

Fecha fabricación: YYYY.mm.dd

Fecha de vencimiento: YYYY.mm.dd

REF

Hebra [...color...] [...calibre (USP)...] [...largo sutura...] **Aguja** [...tipo, punta...] [...código aguja...] [...largo...]

Producto estéril. Esterilizado por ETO.

No utilizar si el envase está dañado

Producto medico desechable de un solo uso. No reutilizar



Lea las Instrucciones de Uso

Ver Precauciones, Advertencias y Contraindicaciones en Instrucciones de Uso

Evite la luz solar directa y manténgase seco. Temperatura de almacenamiento: 1 - 25 °C

Director Técnico: Farm. Sergio Angelucci MN 10744

Autorizado por la ANMAT PM 2556-3

Uso exclusivo a profesionales e instituciones sanitarias

Nota: el presente modelo de rotulo es válido para todos los productos que integran la familia: Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir

INSTRUCCIONES DE USO

Anexo III.B – Disposición ANMAT N° 2318/02 (t.o. 2004)

Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir.

Fabricante: Metabiomed Co., Ltd., 270, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Corea.	Importador: Suvanza SAS, Gaspar Melchor de Jovellanos 1527-1529, PB, Cod. Postal 1269, Ciudad Autónoma de Buenos Aires, Argentina.
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Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir.

Da: all

Modelo: según corresponda

Cantidad: xx

REF Hebra [...calibre (USP)...] [...largo sutura...] **Aguja** [...tipo, punta...] [...código aguja...] [...largo...]

Producto estéril. Esterilizado por ETO

No utilizar si el envase está dañado

Producto medico desechable de un solo uso. No reutilizar



Lea las Instrucciones de Uso

Ver Precauciones, Advertencias y Contraindicaciones en Instrucciones de Uso

Evite la luz solar directa y manténgase seco. Temperatura de almacenamiento: 1 - 25 °C

Director Técnico: Farm. Sergio Angelucci MN 10744

Autorizado por la ANMAT PM 2556-3

Uso exclusivo a profesionales e instituciones sanitarias

Nota: el presente modelo es válido para todos los productos que integran la familia: Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir

DESCRIPCION DEL DISPOSITIVO

“Sutura de polidioxanona absorbible (POD) con aguja y sin aguja, teñida o sin teñir” consta de aguja, capuchón de la aguja, cono, esponja, tubo de silicona y sutura de polidioxanona (PDO), y se esteriliza con gas OET. La seguridad y eficacia de la polidioxanona (DOP) está demostrada.

Esta sutura de polidioxanona (PDO) es una sutura absorbible y ya se ha utilizado para coser la herida en el hospital normal desde 2001 y la aguja también se ha utilizado en el hospital. Materiales utilizados en este dispositivo también se han utilizado en muchos dispositivos médicos como jeringas y dispositivos médicos desechables.

La sutura de polidioxanona se inserta en el tejido blando usando una aguja y luego, el hilo de sutura solo quedará en el tejido blando después de retirar la aguja. Cuando se saca la aguja del tejido blando, el hilo de sutura no ha salido con la aguja.

Para asegurar y aumentar la eficacia, fueron diseñados varios tipos y barbas para sutura dentada con aguja Tipo A, Tipo B, Tipo C. De esta manera la sutura insertada no se mueve a mano fuerte hacia atrás y puede ser atada sin deslizamiento. Así, el cierre y la cohesión entre tejido y tejido se hacen más firmes y la eficacia de la sutura para el tratamiento puede ser mejorada. Y, mediante el uso de la aguja

sin punta, la aguja y la sutura barbada puede insertarse en el tejido blando con una pequeña lesión del tejido.

USO PREVISTO

Este dispositivo está diseñado para fijar tejido subdérmico en una posición elevada en cirugía plástica y cirugía reconstructiva. La sutura de polidioxanona proporciona soporte a la herida durante más tiempo en comparación con otra sutura sintética absorbible.

PREPARACION ANTES DEL USO

- a) Antes de la cirugía, el estado del paciente debe ser estable y luego debe ser operado.
- b) Prepare algodones con alcohol.
- c) Prepare la "sutura de polidioxanona absorbible (DOP) de un solo uso, con aguja y sin aguja, teñida o sin teñir" que se envasa por esterilización.
- d) Verifique el modelo adecuado.
- e) Verifique el período de validez.
- f) Compruebe si el embalaje está dañado.
- g) Úselo después de comprender completamente cómo usar este producto.

INSTRUCCIONES DE USO

- a) Confirmar el contenido y estado de empaque del producto.
- b) Conozca las instrucciones de uso a fondo.
- c) Utilice productos envasados para esterilización.
- d) Retire el embalaje del producto y saque la "sutura de polidioxanona absorbible con aguja y sin aguja, teñida o sin teñir" cuidadosamente.
- e) Confirme si hay transformaciones, fallas o grietas en el producto.
- f) Este producto debe ser utilizado por un cirujano.
- g) La parte para insertar de "Sutura de polidioxanona absorbible con aguja y sin aguja, teñida o sin teñir" debe esterilizarse con algodones con alcohol.
- h) Inserte la "sutura de polidioxanona absorbible con aguja y sin aguja, teñida o sin teñir" en la piel o los músculos que necesita tratar correctamente.
- i) No lo inserte más de dos tercios de la aguja.
- j) Retire la "Sutura de polidioxanona absorbible con aguja y sin aguja, teñida o sin teñir" lenta y suavemente.
- k) Si solo necesita usar "Sutura de polidioxanona absorbible sin aguja, teñida o sin teñir", haga una incisión en la piel e inserte la aguja guía. Y luego, coloque la sutura a lo largo de la aguja guía en los músculos de la piel que necesita para tratar correctamente. Retire la aguja guía.

l) No lo reutilice, porque este producto es de un solo uso.

MANEJO DESPUÉS DEL USO

- a) Desechar el producto que fue una vez abierto.
- b) Debido a que este producto es un producto de un solo uso, no debe reutilizarse.
- c) Desechar el producto usado en un lugar seguro designado.

CONTRAINDICACIONES

- a) Este dispositivo no debe usarse en ninguna persona que tenga hipersensibilidad a cualquiera de los componentes de este dispositivo.
- b) Este producto no debe utilizarse en caso de enfermedad cutánea aguda o crónica (infección o inflamación) cerca del área a tratar.
- c) La pieza no se utiliza si tiene una tensión a largo plazo sobre la aproximación de tejidos (más de 6 semanas). El dispositivo protésico que no es de absorción característica no se utiliza para una fijación de dispositivos protésicos (es decir, válvulas cardíacas o trasplantes artificiales).

ADVERTENCIAS

- 1) Los siguientes pacientes deben seguir las instrucciones de un cirujano.
 - a) Pacientes con desnutrición
 - b) Paciente debilitado
 - c) El paciente que puede retrasar la recuperación de la herida.
- 2) Como sutura absorbible, puede actuar temporalmente como un cuerpo extraño.

EFECTOS SECUNDARIOS

Si se han producido efectos secundarios como los siguientes, debe dejar de usarse y debe ser utilizado de acuerdo con la guía o instrucción de un cirujano.

- a) Inflamación y reacción a un cuerpo extraño.

PRECAUCIONES

- a) Este producto debe ser utilizado únicamente por un cirujano.
- b) No utilice el producto con el período de vencimiento finalizado.
- c) No utilice el producto cuyo embalaje esté dañado.
- d) Este producto no se utiliza para otros fines que no sean el uso previsto.
- e) Este producto debe ser utilizado únicamente por un profesional médico, un cirujano.
- f) Si hay un sitio de tratamiento con inflamación u otras infecciones, no se utilizará.

g) Debido a que esta es una sutura absorbible, los cirujanos deben considerar si utilizan o no suturas no absorbibles como soporte adicional para el cierre de áreas que puedan agrandarse, estirarse o distenderse, o que puedan necesitar un sitio de apoyo adicional.

PROHIBICIÓN

a) Antes de la operación, durante aproximadamente una semana, deje de tomar anticoagulantes (como aspirina, warfarina, potenciador de la circulación sanguínea y eliminador de coágulos) con asistencia médica.

b) Antes y después de la operación, deje de fumar y beber.

c) Enfermedades imprevistas como el resfriado o la fiebre alta pueden causar un problema de anestesia; por lo tanto, consiga asesoramiento con un cirujano.

ALMACENAMIENTO

a) Evite la luz solar directa y manténgase seco.

b) Temperatura de almacenamiento: 1 - 25 °C

FECHA DE CADUCIDAD

a) Fecha de caducidad: 2 años desde la fecha de esterilización.

SIMBOLOS

	Caution		Do not rest
	Date of manufacture		Do not use if package is damaged
	Manufacturer		Temperatur
	Sterilized using ethylene oxide		Consult insti for use
	Authorised representative in the European Community	SIZE	Cannula s
	Batch code		Keep away f sunlight
	Use by		Keep dry



República Argentina - Poder Ejecutivo Nacional
2021 - Año de Homenaje al Premio Nobel de Medicina Dr. César Milstein

Hoja Adicional de Firmas
Anexo

Número:

Referencia: rot, e, inst, de uso-Suvanza S.A.S.,

El documento fue importado por el sistema GEDO con un total de 5 pagina/s.

Digitally signed by Gestion Documental Electronica
Date: 2021.02.26 21:22:18 -03:00

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Electronica
Date: 2021.02.26 21:22:19 -03:00



República Argentina - Poder Ejecutivo Nacional
2021 - Año de Homenaje al Premio Nobel de Medicina Dr. César Milstein

Certificado - Redacción libre

Número:

Referencia: 1-47-3110-41-21-8

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N°: 1-47-3110-41-21-8

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por Suvanza S.A.S., se autoriza la inscripción en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), de un nuevo producto con los siguientes datos identificatorios característicos:

Nombre descriptivo: Sutura de Polidioxanona absorbible estéril, con aguja y sin aguja, teñida o sin teñir.

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):

16-584 Suturas, de Polidioxanona

Marca(s) de (los) producto(s) médico(s): Da: all

Clase de Riesgo: IV

Indicación/es autorizada/s:

Este dispositivo está diseñado para fijar tejido subdérmico en una posición elevada en cirugía plástica y cirugía reconstructiva. La sutura de polidioxanona proporciona soporte a la herida durante más tiempo en comparación con otra sutura sintética absorbible.

Modelos:

Sutura general con aguja

M2160S-0090 M2950S-W6070 MS2670S-60110 MS2950S-W6080 D2638S-W7050 DS2550SG5080

M2338S-3050 M2950S-W6080 MS2690S-60150 MS2960S-W6090 D2638S-W7060 DS2560SG5090
M2350S-3080 M2960S-W6090 MS2738S-5050 MS3025S-W7030 D2650S-W7080 DS2570SG50110
M2360S-3090 M2990S-W60150 MS2750S-5070 MS3030S-W7040 D2660S-W7090 DS2590SG50150
M2390S-30150 M3025S-W6030 MS2750S-5080 MS3038S-W7050 D2690S-W70150 DS2538S G6050
M2538S-4050 M3025S-W7030 MS2760S-5090 MS3038S-W7060 D2738S-W7050 DS2550SG6080
M2550S-4080 M3030S-W7040 MS2770S-50110 MS2338S-G3050 D2750S-W7080 DS2560SG6080
M2560S-4080 M3038S-W7060 MS2790S-50150 MS2350S-G3080 D2760S-W7090 DS2560SG6090
M2560S-4090 M2160S-G0090 MS2825S-5030 MS2360S-G3090 D2538S-G6050 DS2570SG60110
M2590S-40140 M2338S-G3050 MS2830S-5040 MS2370S-G30110 D2550S-G7080 DS2590SG60150
M2590S-40150 M2350S-G3080 MS2838S-5050 MS2390S-G30150 D2638S-G6050 DS2638SG5050
M2638S-4050 M2360S-G3090 MS2850S-5080 MS2538S-G4050 D2638S-G6060 DS2650SG5080
M2650S-4080 M2390S-G30150 MS2860S-5090 MS2550S-G4080 D2660S-G6090 DS2660SG5090
M2660S-4090 M2538S-G4050 MS2838S-6060 MS2560S-G4090 D2638S-G7050 DS2570SG50110
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M2638S-5050 M2560S-G4080 MS2930S-5040 MS2590S-G40140 D2650S-G7080 DS2638SG6050
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Sutura dentada con aguja despuntada

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Sutura dentada con aguja simple brazo

M9HS26S00-201 MP4HS26S20-201	M9HS26S20-G201	MSHS26S00-G201	MP2HS26S20-W201	MP3HS26S00-	W201
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MP4HS17S30-201

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MP4HS17S30-401

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MP4RS17S30-201

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M9HS17S30-W401 MP4HS40S00-G401	MSHS40S00-W401	MP2HS17S30-401	MP3HS40S00-401	MP3HS17S30-G401
M9RS17S30-W201 MP4RS40S00-G201	MSRS40S00-W201	MP2RS17S30-201	MP3RS40S00-201	MP3RS17S30-G201
M9RS17S30-W401 MP4RS40S00-G401	MSRS40S00-W401	MP2RS17S30-401	MP3RS40S00-401	MP3RS17S30-G401
M9HS26S30-W201 MP4HS17S20-G201	MSHS17S20-W201	MP2HS26S30-201	MP3HS17S20-201	MP3HS26S30-G201
M9HS26S30-W401 MP4HS17S20-G401	MSHS17S20-W401	MP2HS26S30-401	MP3HS17S20-401	MP3HS26S30-G401
M9RS26S30-W201 MP4RS17S20-G201	MSRS17S20-W201	MP2RS26S30-201	MP3RS17S20-201	MP3RS26S30-G201
M9RS26S30-W401 MP4RS17S20-G401	MSRS17S20-W401	MP2RS26S30-401	MP3RS17S20-401	MP3RS26S30-G401
M9HS26S00-G201 MP4HS26S20-G201	MSHS26S20-W201	MP2HS26S00-W201	MP3HS26S20-201	MP4HS26S00-201
M9HS26S00-G401 MP4HS26S20-G401	MSHS26S20-W401	MP2HS26S00-W401	MP3HS26S20-401	MP4HS26S00-401
M9RS26S00-G201 MP4RS26S20-G201	MSRS26S20-W201	MP2RS26S00-W201	MP3RS26S20-201	MP4RS26S00-201
M9RS26S00-G401 MP4RS26S20-G401	MSRS26S20-W401	MP2RS26S00-W401	MP3RS26S20-401	MP4RS26S00-401
M9HS40S00-G201 MP4HS17S30-G201	MSHS17S30-W201	MP2HS40S00-W201	MP3HS17S30-201	MP4HS40S00-201
M9HS40S00-G401 MP4HS17S30-G401	MSHS17S30-W401	MP2HS40S00-W401	MP3HS17S30-401	MP4HS40S00-401

M9RS40S00-G201 MP4RS17S30-G201	MSRS17S30-W201	MP2RS40S00-W201	MP3RS17S30-201	MP4RS40S00-201
M9RS40S00-G401 MP4RS17S30-G401	MSRS17S30-W401	MP2RS40S00-W401	MP3RS17S30-401	MP4RS40S00-401
M9HS17S20-G201 MP4HS26S30-G201	MSHS26S30-W201	MP2HS17S20-W201	MP3HS26S30-201	MP4HS17S20-201
M9HS17S20-G401 MP4HS26S30-G401	MSHS26S30-W401	MP2HS17S20-W401	MP3HS26S30-401	MP4HS17S20-401
M9RS17S20-G201 MP4RS26S30-G201	MSRS26S30-W201	MP2RS17S20-W201	MP3RS26S30-201	MP4RS17S20-201
M9RS17S20-G401 MP4RS26S30-G401	MSRS26S30-W401	MP2RS17S20-W401	MP3RS26S30-401	MP4RS17S20-401

Sutura dentada sin aguja

AN00-91 AN00-W92 AN00-G172B CN00-W172B CN02-G172B ZN01-W172B

AN00-92 AN00-W172B AN00-G172 CN01-W172B ZN00-172B ZN02-W172B

AN00-172B AN00-W172 CN00-172B CN02-W172B ZN01-172B ZN00-G172B

AN00-172 AN00-G91 CN01-172B CN00-G172B ZN02-172B ZN01-G172B

AN00-W91 AN00-G92 CN02-172B CN01-G172B ZN00-W172B ZN02-G172B

Período de vida útil: 2 años desde la fecha de esterilización

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biotecnológico: N/A

Forma de presentación: Presentación en caja

Caja por 5/10 envases unitarios

Método de esterilización: Esterilizado por ETO

Nombre del fabricante:

METABIOMED Co., Ltd

Lugar de elaboración:

270, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

Se extiende el presente Certificado de Autorización e Inscripción del PM-2556-3, con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

Expediente N° 1-47-3110-41-21-8

Digitally signed by Gestion Documental Electronica
Date: 2021.03.02 23:53:32 -03:00

Digitally signed by Gestion Documental
Electronica
Date: 2021.03.02 23:53:33 -03:00