



República Argentina - Poder Ejecutivo Nacional
2019 - Año de la Exportación

Disposición

Número: DI-2019-8378-APN-ANMAT#MSYDS

CIUDAD DE BUENOS AIRES
Jueves 10 de Octubre de 2019

Referencia: 1-47-3110-1282-19-9

VISTO el Expediente N° 1-47-3110-1282-19-9 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones la firma SOUTH AMERICA IMPLANTS S.A. solicita la autorización de modificación del Certificado de Inscripción en el RPPTM N° PM-2022-72, denominado: Artroscopia de Rodilla de Titanio, marca ConMed® Linvatec®.

Que lo solicitado se encuadra dentro de los alcances de la Disposición ANMAT N° 2318/02, sobre el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM).

Que la documentación aportada ha satisfecho los requisitos de la normativa aplicable.

Que el Instituto Nacional de Productos Médicos ha tomado la intervención que le compete.

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 1°.- Autorízase la modificación del Certificado de Inscripción en el RPPTM N° PM-2022-72,

denominado Artroscopia de Rodilla de Titanio, marca ConMed® Linvatec® según Disposición Autorizante de (RPPTM) N° DI-2018-9087-APN-ANMAT#MS y tramitado por expediente N° 1-47-3110-1574-18-6

ARTÍCULO 2°.- Acéptase el Anexo de Autorización de Modificaciones documento N° IF-2019-76852299-APN-DNPM#ANMAT el que deberá agregarse al Certificado de Inscripción en el RPPTM N° PM-2022-72.

ARTICULO 3°.- En los rótulos e instrucciones de uso deberán constar la modificación autorizadas.

ARTÍCULO 4°.- Regístrese; por el Departamento de Mesa de Entrada, notifíquese al interesado y hágasele entrega de copia autenticada de la presente Disposición conjuntamente con su Anexo, gírese a la Dirección de Gestión de Información Técnica para que efectúe la agregación del Anexo de Modificaciones al certificado. Cumplido, archívese.

Expediente N° 1-47-3110-1282-19-9

Digitally signed by BELLOSO Waldo Horacio
Date: 2019.10.10 15:22:36 ART
Location: Ciudad Autónoma de Buenos Aires

Waldo HORACIO BELLOSO
SubAdministrador
Administración Nacional de Medicamentos, Alimentos y Tecnología
Médica

Digitally signed by GESTION DOCUMENTAL
ELECTRÓNICA - GDE
Date: 2019.10.10 15:22:38 -03:00

ANEXO DE AUTORIZACION DE MODIFICACIONES

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), autoriza a la firma SOUTH AMERICA IMPLANTS S.A. la modificación de los datos característicos correspondientes al Certificado de Inscripción en el RPPTM N° PM-2022-72 de acuerdo con los datos que figuran en tabla al pie, del producto:

Nombre genérico aprobado: Artroscopía de Rodilla de Titanio

Marca: ConMed® Linvatec®

Disposición Autorizante de (RPPTM) N° DI-2018-9087-APN-ANMAT#MS

Tramitado por expediente N° 1-47-3110-1574-18-6

| DATO IDENTIFICATORIO A MODIFICAR | DATO AUTORIZADO HASTA LA FECHA | MODIFICACIÓN / RECTIFICACIÓN AUTORIZADA |
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| Modelo/s | <u>IMPLANTES:</u> 255015-5.0 X 15MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 15MM 255020-5.0 X 20MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 20MM 255025-5.0 X 25MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 25MM 255030-5.0 X 30MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 30MM 255515-5.5 X 15MM | <u>IMPLANTES:</u> 255015-5.0 X 15MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 15MM 255020-5.0 X 20MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 20MM 255025-5.0 X 25MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 25MM 255030-5.0 X 30MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,0 X 30MM 255515-5.5 X 15MM |

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| | <p>GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 15MM 255520-5.5 X 20MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 20MM 255525-5.5 X 25MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 25MM 255530-5.5 X 30MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 30MM 256015-6.0 X 15MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 15MM 256020-6.0 X 20MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 20MM 256025-6.0 X 25MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 25MM 256030-6.0 X 30MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 30MM 8960S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 9MM X 20MM - TORNILLO INTERFERENCIAL</p> | <p>GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 15MM 255520-5.5 X 20MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 20MM 255525-5.5 X 25MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 25MM 255530-5.5 X 30MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 5,5 X 30MM 256015-6.0 X 15MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 15MM 256020-6.0 X 20MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 20MM 256025-6.0 X 25MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 25MM 256030-6.0 X 30MM GUARDSMAN INTERFERENCE SCREW - TORNILLO INTERFERENCIAL GUARDSMAN 6,0 X 30MM 8960S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 9MM X 20MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 9MM X</p> |
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| | <p>CANULADO CON GUÍA 9MM X 20MM 8961S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 9MM X 25MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 9MM X 25MM 8962S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 9MM X 30MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 9MM X 30MM 8970S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 7MM X 20MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 7MM X 20MM 8971S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 7MM X 25MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 7MM X 25MM 8972S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 7MM X 30MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 7MM X 30MM 9742-2.4 X 229MM (3/32 INCH X 9INCH) HIGH STRENGTH PIN, QTY 5 - PERNO DE ALTA RESISTENCIA 2,4 X 229MM (3/32 PULGADAS X 9 PULGADAS), CANTIDAD 5</p> | <p>20MM 8961S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 9MM X 25MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 9MM X 25MM 8962S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 9MM X 30MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 9MM X 30MM 8970S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 7MM X 20MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 7MM X 20MM 8971S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 7MM X 25MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 7MM X 25MM 8972S-CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE 7MM X 30MM - TORNILLO INTERFERENCIAL CANULADO CON GUÍA 7MM X 30MM C2610-CANCELLOUS SCREW 6.5MM X 25MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 25MM C2611-CANCELLOUS SCREW 6.5MM X 30MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 30MM C2612-CANCELLOUS SCREW 6.5MM X 35MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 35MM C2613-CANCELLOUS SCREW</p> |
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| | <p>9742D-HIGH STRENGTH GUIDE PIN, 9 IN, STERILE, 2.4 X 229MM (.093 X 9IN) - PERNO GUÍA DE ALTA RESISTENCIA, 9 PULGADAS, ESTÉRIL, 2,4 X 229MM (0,093 X 9 PULGADAS)</p> <p>9743-2.4 X 229MM (3/32IN X 9IN) HEWSON BREAK AWAY PIN, 5 EA - PERNO DESMONTABLE HEWSON, 2,4 X 229MM (3/32 PULGADAS X 9 PULGADAS), CANTIDAD 5</p> <p>9743D-HIGH STRENGTH BREAKAWAY GUIDE PIN, 9 IN, STERILE, 2.4 X 229MM (.093 X 9IN) - PERNO GUÍA DESMONTABLE DE ALTA RESISTENCIA, 9 PULGADAS, ESTÉRIL, 2,4 X 229MM</p> <p>9744-3/32 IN. X 14 IN. HIGH STRENGTH PIN, QTY 5 - PERNO DE ALTA RESISTENCIA 3/32 PULGADAS X 14 PULGADAS, CANTIDAD 5</p> <p>9744D-HIGH STRENGTH GUIDE PIN, 14 IN, STERILE, 2.4 X 356MM (.093 X 14IN) - PERNO GUÍA DE ALTA RESISTENCIA, 14 PULGADAS, ESTÉRIL, 2,4 X 356MM (0,093 X 14 PULGADAS)</p> <p>9745D-HIGH STRENGTH GUIDE PIN, 12 IN, STERILE, 2.4 X 305MM (.093 X 12IN) - PERNO GUÍA DE ALTA RESISTENCIA, 12 PULGADAS, ESTÉRIL, 2,4 X 305MM (0,093 X 12</p> | <p>6.5MM X 40MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 40MM</p> <p>C2614-CANCELLOUS SCREW 6.5MM X 45MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 45MM</p> <p>C2615-CANCELLOUS SCREW 6.5MM X 50MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 50MM</p> <p>C2616-CANCELLOUS SCREW 6.5MM X 55MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 55MM</p> <p>C2617-CANCELLOUS SCREW 6.5MM X 60MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 60MM</p> <p>C2618-CANCELLOUS SCREW 6.5MM X 65MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 65MM</p> <p>C2620-14MM SPIKED WASHER, 1.3MM POST - ARANDELA MARCADA 14MM, CLAVIA DE 1,3MM</p> <p>C2621-17MM SPIKED WASHER, 1.3MM POST - ARANDELA MARCADA 17MM, CLAVIA DE 1,3MM</p> <p>C2622-20MM SPIKED WASHER, 1.3MM POST - ARANDELA MARCADA 20MM, CLAVIA DE 1,3MM</p> <p>C2630-14MM SPIKED WASHER, 2.5MM POST - ARANDELA MARCADA 14MM, CLAVIA DE 2,5MM</p> <p>C2631-17MM SPIKED WASHER, 2.5MM POST - ARANDELA MARCADA 17MM, CLAVIA DE 2,5MM</p> <p>C2632-20MM SPIKED WASHER,</p> |
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| | <p>PULGADAS) C2610-CANCELLOUS SCREW 6.5MM X 25MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 25MM C2611-CANCELLOUS SCREW 6.5MM X 30MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 30MM C2612-CANCELLOUS SCREW 6.5MM X 35MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 35MM C2613-CANCELLOUS SCREW 6.5MM X 40MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 40MM C2614-CANCELLOUS SCREW 6.5MM X 45MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 45MM C2615-CANCELLOUS SCREW 6.5MM X 50MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 50MM C2616-CANCELLOUS SCREW 6.5MM X 55MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 55MM C2617-CANCELLOUS SCREW 6.5MM X 60MM - TORNILLO PARA HUESO ESPONJOSO 6,5MM X 60MM C2618-CANCELLOUS SCREW 6.5MM X 65MM - TORNILLO PARA HUESO</p> | <p>2.5MM POST - ARANDELA MARCADA 20MM, CLAVIJA DE 2,5MM C2830-CORTICAL SCREW 4.5MM X 30MM - TORNILLO CORTICAL 4,5MM X 30MM C2832-CORTICAL SCREW 4.5MM X 32MM - TORNILLO CORTICAL 4,5MM X 32MM C2834-CORTICAL SCREW 4.5MM X 34MM - TORNILLO CORTICAL 4,5MM X 34MM C2836-CORTICAL SCREW 4.5MM X 36MM - TORNILLO CORTICAL 4,5MM X 36MM C2838-CORTICAL SCREW 4.5MM X 38MM - TORNILLO CORTICAL 4,5MM X 38MM C2840-CORTICAL SCREW 4.5MM X 40MM - TORNILLO CORTICAL 4,5MM X 40MM C2842-CORTICAL SCREW 4.5MM X 42MM - TORNILLO CORTICAL 4,5MM X 42MM C2844-CORTICAL SCREW 4.5MM X 44MM - TORNILLO CORTICAL 4,5MM X 44MM C2846-CORTICAL SCREW 4.5MM X 46MM - TORNILLO CORTICAL 4,5MM X X46MM C2848-CORTICAL SCREW 4.5MM X 48MM - TORNILLO CORTICAL 4,5MM X 48MM C2850-CORTICAL SCREW 4.5MM X 50MM - TORNILLO CORTICAL 4,5MM X 50MM C2852-CORTICAL SCREW 4.5MM X 52MM - TORNILLO CORTICAL 4,5MM X 52MM C2854-CORTICAL SCREW 4.5MM X 54MM - TORNILLO CORTICAL 4,5MM X 54MM C2856-CORTICAL SCREW 4.5MM X 56MM - TORNILLO CORTICAL</p> |
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| <p> ESPONJOSO 6,5MM X 65MM C2620-14MM SPIKED WASHER, 1.3MM POST - ARANDELA MARCADA 14MM, CLAVIJA DE 1,3MM C2621-17MM SPIKED WASHER, 1.3MM POST - ARANDELA MARCADA 17MM, CLAVIJA DE 1,3MM C2622-20MM SPIKED WASHER, 1.3MM POST - ARANDELA MARCADA 20MM, CLAVIJA DE 1,3MM C2630-14MM SPIKED WASHER, 2.5MM POST - ARANDELA MARCADA 14MM, CLAVIJA DE 2,5MM C2631-17MM SPIKED WASHER, 2.5MM POST - ARANDELA MARCADA 17MM, CLAVIJA DE 2,5MM C2632-20MM SPIKED WASHER, 2.5MM POST - ARANDELA MARCADA 20MM, CLAVIJA DE 2,5MM C2830-CORTICAL SCREW 4.5MM X 30MM - TORNILLO CORTICAL 4,5MM X 30MM C2832-CORTICAL SCREW 4.5MM X 32MM - TORNILLO CORTICAL 4,5MM X 32MM C2834-CORTICAL SCREW 4.5MM X 34MM - TORNILLO CORTICAL 4,5MM X 34MM C2836-CORTICAL SCREW 4.5MM X 36MM - TORNILLO CORTICAL 4,5MM X 36MM C2838-CORTICAL SCREW 4.5MM X 38MM - </p> | <p> 4,5MM X 56MM C2858-CORTICAL SCREW 4.5MM X 58MM - TORNILLO CORTICAL 4,5MM X 58MM C2860-CORTICAL SCREW 4.5MM X 60MM - TORNILLO CORTICAL 4,5MM X 60MM C2862-CORTICAL SCREW 4.5MM X 62MM - TORNILLO CORTICAL 4,5MM X 62MM C2864-CORTICAL SCREW 4.5MM X 64MM - TORNILLO CORTICAL 4,5MM X 64MM C2866-CORTICAL SCREW 4.5MM X 66MM - TORNILLO CORTICAL 4,5MM X 66MM C2868-CORTICAL SCREW 4.5MM X 68MM - TORNILLO CORTICAL 4,5MM X 68MM C2870-CORTICAL SCREW 4.5MM X 70MM - TORNILLO CORTICAL 4,5MM X 70MM C2872-CORTICAL SCREW 4.5MM X 72MM - TORNILLO CORTICAL 4,5MM X 72MM C2874-CORTICAL SCREW 4.5MM X 74MM - TORNILLO CORTICAL 4,5MM X 74MM C2876-CORTICAL SCREW 4.5MM X 76MM - TORNILLO CORTICAL 4,5MM X 76MM C2878-CORTICAL SCREW 4.5MM X 78MM - TORNILLO CORTICAL 4,5MM X 78MM C2880-CORTICAL SCREW 4.5MM X 80MM - TORNILLO CORTICAL 4,5MM X 80MM C8320-7mm X 20mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7mm x 20mm C8325-7mm X 25mm </p> |
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| TORNILLO CORTICAL 4,5MM X 38MM C2840-CORTICAL SCREW 4.5MM X 40MM - | GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7mm x 25mm C8330-7mm X 30mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X 40MM C2842-CORTICAL SCREW 4.5MM X 42MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7mm x 30mm C8420-8mm X 20mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X 42MM C2844-CORTICAL SCREW 4.5MM X 44MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8mm x 20mm C8425-8mm X 25mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X 44MM C2846-CORTICAL SCREW 4.5MM X 46MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8mm x 25mm C8430-8mm X 30mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X X46MM C2848-CORTICAL SCREW 4.5MM X 48MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8mm x 30mm C8520-9mm X 20mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X 48MM C2850-CORTICAL SCREW 4.5MM X 50MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9mm x 20mm C8525-9mm X 25mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X 50MM C2852-CORTICAL SCREW 4.5MM X 52MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9mm x 25mm C8530-9mm X 30mm GUARDSMAN FEMORAL INTERFERENCE SCREW - |
| TORNILLO CORTICAL 4,5MM X 52MM C2854-CORTICAL SCREW 4.5MM X 54MM - | |
| TORNILLO CORTICAL 4,5MM X 54MM C2856-CORTICAL SCREW 4.5MM X 56MM - | |
| TORNILLO CORTICAL 4,5MM X 56MM C2858-CORTICAL SCREW 4.5MM X 58MM - | |
| TORNILLO CORTICAL 4,5MM X 58MM C2860-CORITCAL SCREW 4.5MM X 60MM - | |

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| TORNILLO CORTICAL 4,5MM X 60MM C2862-CORTICAL SCREW 4.5MM X 62MM - | TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9mm x 30mm C8600-9MM X 20MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 62MM C2864-CORTICAL SCREW 4.5MM X 64MM - | INTERFERENCIAL CANULADO PROPEL 9MM X 20MM C8610-9MM X 25MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 64MM C2866-CORTICAL SCREW 4.5MM X 66MM - | INTERFERENCIAL CANULADO PROPEL 9MM X 25MM C8620-9MM X 30MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 66MM C2868-CORTICAL SCREW 4.5MM X 68MM - | INTERFERENCIAL CANULADO PROPEL 9MM X 30MM C8700-7MM X 20MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 68MM C2870-CORTICAL SCREW 4.5MM X 70MM - | INTERFERENCIAL CANULADO PROPEL 9MM X 20MM C8710-7MM X 25MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 70MM C2872-CORTICAL SCREW 4.5MM X 72MM - | INTERFERENCIAL CANULADO PROPEL 7MM X 20MM C8720-7MM X 30MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 72MM C2874-CORTICAL SCREW 4.5MM X 74MM - | INTERFERENCIAL CANULADO PROPEL 7MM X 25MM C8800-8MM X 20MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 74MM C2876-CORTICAL SCREW 4.5MM X 76MM - | INTERFERENCIAL CANULADO PROPEL 7MM X 30MM C8810-8MM X 25MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO |
| TORNILLO CORTICAL 4,5MM X 76MM C2878-CORTICAL SCREW 4.5MM X 78MM - | INTERFERENCIAL CANULADO PROPEL 8MM X 20MM C8820-8MM X 30MM PROPEL |
| TORNILLO CORTICAL 4,5MM X 78MM C2880-CORTICAL SCREW 4.5MM X 80MM - | |
| TORNILLO CORTICAL 4,5MM X 80MM C8320-7mm X 20mm GUARDSMAN FEMORAL | |

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| <p>INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7mm x 20mm C8325-7mm X 25mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7mm x 25mm C8330-7mm X 30mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7mm x 30mm C8420-8mm X 20mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8mm x 20mm C8425-8mm X 25mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8mm x 25mm C8430-8mm X 30mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8mm x 30mm C8520-9mm X 20mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9mm x 20mm C8525-9mm X 25mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL</p> | <p>CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 8MM X 30MM C8920-7MM X 20MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7MM X 20MM C8921-7MM X 25MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7MM X 25MM C8922-7MM X 30MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7MM X 30MM C8923-8MM X 20MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8MM X 20MM C8924-8MM X 25MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8MM X 25MM C8925-8MM X 30MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8MM X 30MM C8926-9MM X 20MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL</p> |
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| | <p>FEMORAL GUARDSMAN 9mm x 25mm C8530-9mm X 30mm GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9mm x 30mm C8600-9MM X 20MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 9MM X 20MM C8610-9MM X 25MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 9MM X 25MM C8620-9MM X 30MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 9MM X 30MM C8700-7MM X 20MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 7MM X 20MM C8710-7MM X 25MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 7MM X 25MM C8720-7MM X 30MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 7MM X 30MM</p> | <p>FEMORAL GUARDSMAN 9MM X 20MM C8927-9MM X 25MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9MM X 25MM C8928-9MM X 30MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9MM X 30MM C8940-7MM X 20MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 7MM X 20MM C8941-7MM X 25MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 7MM X 25MM C8942-7MM X 30MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 7MM X 30MM C8943-8MM X 20MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 8MM X 20MM C8944-8MM X 25MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 8MM X 25MM C8945-8MM X 30MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 8MM X 30MM C8946-9MM X 20MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 9MM X 20MM C8947-9MM X 25MM PROPEL INTERFERENCE SCREW -</p> |
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| C8800-8MM X 20MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 8MM X 20MM | TORNILLO INTERFERENCIAL PROPEL 9MM X 25MM C8948-9MM X 30MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 9MM X 30MM |
| C8810-8MM X 25MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 8MM X 25MM | C8950-8MM X 20MM CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE - TORNILLO INTERFERENCIAL CANULADO 8MM X 20MM CON GUÍA |
| C8820-8MM X 30MM PROPEL CANNULATED INTERFERENCE SCREW - TORNILLO INTERFERENCIAL CANULADO PROPEL 8MM X 30MM | C8951-8MM X 25MM CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE - TORNILLO INTERFERENCIAL CANULADO 8MM X 25MM CON GUÍA |
| C8920-7MM X 20MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7MM X 20MM | C8952-8MM X 30MM CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE - TORNILLO INTERFERENCIAL CANULADO 8MM X 30MM CON GUÍA |
| C8921-7MM X 25MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7MM X 25MM | KS-ALB-GRAFTMAX BUTTON ALB (ADJUSTABLE LOOP BUTTON) - BOTÓN ALB (BOTÓN CON BUCLE AJUSTABLE) GRAFTMAX |
| C8922-7MM X 30MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 7MM X 30MM | KS-BCA-GRAFTMAX BUTTON CRADLE - EXTENSOR DEL BOTÓN GRAFTMAX |
| C8923-8MM X 20MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8MM X 20MM | KS-BTB-GRAFTMAX BUTTON BTB (BONE TENDON BONE) - BOTÓN BTB (HUESO TENDÓN HUESO) GRAFTMAX |
| C8924-8MM X 25MM GUARDSMAN FEMORAL | T5015-15MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 15MM CON BUCLE CONTINUO |
| | T5020-20MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 20MM CON BUCLE CONTINUO |
| | T5025-25MM XO BUTTON WITH |

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| <p>INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8MM X 25MM C8925-8MM X 30MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 8MM X 30MM C8926-9MM X 20MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9MM X 20MM C8927-9MM X 25MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9MM X 25MM C8928-9MM X 30MM GUARDSMAN FEMORAL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL FEMORAL GUARDSMAN 9MM X 30MM C8940-7MM X 20MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 7MM X 20MM C8941-7MM X 25MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 7MM X 25MM C8942-7MM X 30MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 7MM X 30MM C8943-8MM X 20MM</p> | <p>CONTINUOUS LOOP - XO BUTTON 25MM CON BUCLE CONTINUO T5030-30MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 30MM CON BUCLE CONTINUO T5035-35MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 3MM CON BUCLE CONTINUO T5040-40MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 40MM CON BUCLE CONTINUO T5045-45MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 45MM CON BUCLE CONTINUO T5050-50MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 50MM CON BUCLE CONTINUO T5055-55MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 55MM CON BUCLE CONTINUO T5060-60MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 60MM CON BUCLE CONTINUO EZ0615T EZStart Interference Screw. 6mm x 15mm - Tornillo de interferencia EZStart 6mm x 15mm EZ0620T EZStart Interference Screw. 6mm x 20mm - Tornillo de interferencia EZStart 6mm x 20mm EZ0720T EZStart Interference Screw. 7mm x 20mm - Tornillo de interferencia EZStart 7mm x 20mm</p> |
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| <p>PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 8MM X 20MM C8944-8MM X 25MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 8MM X 25MM C8945-8MM X 30MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 8MM X 30MM C8946-9MM X 20MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 9MM X 20MM C8947-9MM X 25MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 9MM X 25MM C8948-9MM X 30MM PROPEL INTERFERENCE SCREW - TORNILLO INTERFERENCIAL PROPEL 9MM X 30MM C8950-8MM X 20MM CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE - TORNILLO INTERFERENCIAL CANULADO 8MM X 20MM CON GUÍA C8951-8MM X 25MM CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE - TORNILLO INTERFERENCIAL CANULADO 8MM X 25MM CON GUÍA C8952-8MM X 30MM</p> | <p>EZ0725T EZStart Interference Screw. 7mm x 25mm - Tornillo de interferencia EZStart 7mm x 25mm EZ0730T EZStart Interference Screw. 7mm x 30mm - Tornillo de interferencia EZStart 7mm x 30mm EZ0820T EZStart Interference Screw. 8mm x 20mm - Tornillo de interferencia EZStart 8mm x 20mm EZ0825T EZStart Interference Screw. 8mm x 25mm - Tornillo de interferencia EZStart 8mm x 25mm EZ0830T EZStart Interference Screw, 8mm x 30mm - Tornillo de interferencia EZStart, 8 mm x 30 mm EZ0920T EZStart Interference Screw, 9mm x 20mm - Tornillo de interferencia EZStart, 9mm x 20mm EZ0925T EZStart Interference Screw, 9mm x 25mm - Tornillo de interferencia EZStart, 9mm x 25mm EZ0930T EZStart Interference Screw, 9mm x 30mm - Tornillo de interferencia EZStart, 9mm x 30mm <u>INSTRUMENTAL ASOCIADO</u></p> |
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| | <p>CANNULATED INTERFERENCE SCREW WITH GUIDEWIRE - TORNILLO INTERFERENCIAL CANULADO 8MM X 30MM CON GUÍA KS-ALB-GRAFTMAX BUTTON ALB (ADJUSTABLE LOOP BUTTON) - BOTÓN ALB (BOTÓN CON BUCLE AJUSTABLE) GRAFTMAX KS-BCA-GRAFTMAX BUTTON CRADLE - EXTENSOR DEL BOTÓN GRAFTMAX KS-BTB-GRAFTMAX BUTTON BTB (BONE TENDON BONE) - BOTÓN BTB (HUESO TENDÓN HUESO) GRAFTMAX T5015-15MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 15MM CON BUCLE CONTINUO T5020-20MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 20MM CON BUCLE CONTINUO T5025-25MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 25MM CON BUCLE CONTINUO T5030-30MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 30MM CON BUCLE CONTINUO T5035-35MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 3MM CON BUCLE CONTINUO T5040-40MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 40MM CON BUCLE CONTINUO</p> | |
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| | <p>T5045-45MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 45MM CON BUCLE CONTINUO</p> <p>T5050-50MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 50MM CON BUCLE CONTINUO</p> <p>T5055-55MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 55MM CON BUCLE CONTINUO</p> <p>T5060-60MM XO BUTTON WITH CONTINUOUS LOOP - XO BUTTON 60MM CON BUCLE CONTINUO</p> <p><u>INSTRUMENTAL</u> <u>ASOCIADO</u></p> | |
| Vida Útil | 5 años | <p>18 meses para los modelos EZStart: EZ0615T, EZ0620T, EZ0720T, EZ0725T, EZ0730T, EZ0820T, EZ0825T, EZ0830T, EZ0920T, EZ0925T, EZ0930T. Para el resto de los productos, 5 años.</p> |

El presente sólo tiene valor probatorio anexado al certificado de Autorización antes mencionado.

EXPEDIENTE Nº 1-47-3110-1282-19-9



República Argentina - Poder Ejecutivo Nacional
2019 - Año de la Exportación

Hoja Adicional de Firmas
Anexo

Número: IF-2019-76852299-APN-DNPM#ANMAT

CIUDAD DE BUENOS AIRES
Lunes 26 de Agosto de 2019

Referencia: 1-47-3110-1282-19-9

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Date: 2019.08.26 15:34:24 -0300'

Mariano Pablo Manenti
Jefe I
Dirección Nacional de Productos Médicos
Administración Nacional de Medicamentos, Alimentos y Tecnología
Médica

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