



República Argentina - Poder Ejecutivo Nacional
AÑO DE LA RECONSTRUCCIÓN DE LA NACIÓN ARGENTINA

Disposición

Número:

Referencia: 1-0047-3110-005896-24-1

VISTO el Expediente N° 1-0047-3110-005896-24-1 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y:

CONSIDERANDO:

Que por las presentes actuaciones Bio Lap S.A 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° 64/25, 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;

LA ADMINISTRADORA 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 GLOBUS MEDICAL nombre descriptivo Espaciador lumbar e instrumental asociado y nombre técnico Sistemas Ortopédicos de Fijación Interna, para Columna Vertebral , de acuerdo con lo solicitado por Bio Lap S.A , con los Datos Identificatorios Característicos que figuran al pie de la presente.

ARTÍCULO 2º.- Autorízanse los textos de los proyectos de rótulo/s y de instrucciones de uso que obran en documento GEDO N° IF-2025-118461904-APN-INPM#ANMAT .

ARTÍCULO 3º.- En los rótulos e instrucciones de uso autorizados deberá figurar la leyenda "Autorizado por la ANMAT PM 1882-86 ", 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. Inscribese 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 CARACTERÍSTICOS

PM: 1882-86

Nombre descriptivo: Espaciador lumbar e instrumental asociado

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
15-766-Sistemas Ortopédicos de Fijación Interna, para Columna Vertebral

Marca(s) de (los) producto(s) médico(s): GLOBUS MEDICAL

Modelos:

Rise Spacers and Orthopedic Manual Surgical Instruments

193.001 RISE Spacer, 8x22mm, 7-13mm
193.001S RISE Spacer, 8x22mm, 7-13mm
193.002 RISE Spacer, 8x26mm, 7-14mm
193.002S RISE Spacer, 8x26mm, 7-14mm
193.003 RISE Spacer, 8x30mm, 7-14mm
193.003S RISE Spacer, 8x30mm, 7-14mm
193.004 RISE Spacer, 8x34mm, 7-14mm
193.004S RISE Spacer, 8x34mm, 7-14mm
193.005 RISE Spacer 8x38mm, 7-14mm
193.005S RISE Spacer, 8x38mm, 7-14mm
193.011 RISE Spacer, 8x22mm, 11-17mm
193.011S RISE Spacer, 8x22mm, 11-17mm
193.012 RISE Spacer 8x26mm, 10-17mm
193.012S RISE Spacer, 8x26mm, 10-17mm
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193.015 RISE Spacer 8x38mm, 10-17mm
193.015S RISE Spacer 8x38mm, 10-17mm
193.021 RISE Spacer, 8x22mm, 8-14mm, 10°
193.021S RISE Spacer, 8x22mm, 8-14mm, 10°
193.022 RISE Spacer 8x26mm, 8-15mm, 10°
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193.023 RISE Spacer 8x30mm, 8-15mm, 10°
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193.031S RISE Spacer, 8x22mm, 9-15mm, 15°
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193.045 RISE Spacer 8x38mm, 10-17mm, 15°
193.045S RISE Spacer, 8x38mm, 10-17mm, 15°
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193.105 RISE Spacer 10x38mm, 7-14mm
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193.201 RISE Spacer 12x22mm, 7-13mm
193.201S RISE Spacer, 12x22mm, 7-13mm
193.202 RISE Spacer, 12x26mm, 7-14mm
193.202S RISE Spacer, 12x26mm, 7-14mm

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193.303S RISE-L Spacer, 18x45mm, 7-14mm

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193.404 RISE-L Spacer, 22x50mm, 7-14mm
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193.405 RISE-L Spacer, 22x55mm, 7-14mm
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193.411 RISE-L Spacer, 22x35mm, 10-17mm
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193.413S RISE-L Spacer, 22x45mm, 10-17mm
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193.414S RISE-L Spacer, 22x50mm, 10-17mm
193.415 RISE-L Spacer, 22x55mm, 10-17mm
193.415S RISE-L Spacer, 22x55mm, 10-17mm
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193.424 RISE-L Spacer, 22x50mm, 8-15mm, 6°
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193.425 RISE-L Spacer, 22x55mm, 8-15mm, 6°
193.425S RISE-L Spacer, 22x55mm, 8-15mm, 6°
193.426 RISE-L Spacer, 22x60mm, 8-15mm, 6°
193.426S RISE-L Spacer, 22x60mm, 8-15mm, 6°
193.427 RISE-L Spacer, 22x65mm, 8-15mm, 6°
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193.502 RISE-L Spacer, 18x40mm, 7-14mm, 3-15°
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193.602 RISE-L Spacer, 22x40mm, 7-14mm, 3-15°
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193.603S RISE-L Spacer, 22x45mm, 7-14mm, 3-15°
193.604 RISE-L Spacer, 22x50mm, 7-14mm, 3-15°
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193.605S RISE-L Spacer, 22x55mm, 7-14mm, 3-15°
193.606 RISE-L Spacer, 22x60mm, 7-14mm, 3-15°
193.606S RISE-L Spacer, 22x60mm, 7-14mm, 3-15°
193.607 RISE-L Spacer, 22x65mm, 7-14mm, 3-15°
193.607S RISE-L Spacer, 22x65mm, 7-14mm, 3-15°
693.051S Needle, Stylette, K-Wire
693.055S Coated K-Wire
693.056S Coated K-Wire, Trocar
693.057S Coated K-Wire, Trocar

693.058S Coated K-Wire, Blunt
693.059S Coated K-Wire, Blunt
693.060S Coated K-Wire, Blunt
693.061S K-Wire Stimulation Lead
693.351S Disc Prep Brush (1x)
693.352S Disc Prep Brush (2x)
693.355S Disc Prep Brush (5x)
693.371S Disc Prep Brush (No Hard Stop) (1x)
693.372S Disc Prep Brush (No Hard Stop) (2x)
693.375S Disc Prep Brush (No Hard Stop) (5x)
693.210 Adjustable Trial 8x22, 7-13mm
693.211 Adjustable Trial, 8x26, 7-14mm
693.212 Adjustable Trial, 10x26, 7-14mm
693.215 Adjustable Trial, 10x26, 8-15mm, 15°
693.216 Adjustable Trial, 8x26, 7-14mm
693.001 Inserter Base
693.002 Torque Limiting Implant Driver
693.003 Torque Limiting Palm Handle, 3.0Nm
693.011 Inserter Fork, 8mm
693.012 Inserter Fork, 10mm
693.013 Inserter Fork, 12mm
693.014 Inserter Fork, 8mm
693.015 Inserter Fork, 10mm
693.021 Inserter Tube
693.022 Inserter Tube
693.031 Inserter QC Shaft
693.071 Impaction Cap #1
693.072 Impaction Cap #2
693.073 Impaction Cap #3
693.102 Dilator, 7mm
693.103 Dilator, 6mm Transition
693.104 Dilator, 8.5mm
693.106 Dilator, 6mm
693.108 Dilator, 8mm
693.110 Dilator, 10mm
693.112 Cannula, Working (7mm ID)
693.114 Cannula, 8.5mm
693.122 Sleeve Impactor, Working (7mm ID)
693.124 Sleeve Impactor, 8.5mm
693.132 Fluid Adapter, 7mm
693.134 Fluid Adapter, 8.5mm
693.141 Slap Hammer
693.201 Adjustable Scraper, 7-14mm
693.203 Adjustable Scraper, 7-14mm
693.301 Articulating Curette, Short
693.302 Articulating Curette, Long

693.310 160° Sweep
693.311 Articulating Ring Curette, SHORT
693.312 Articulating Ring Curette, LONG
693.313 Articulating Cup Curette, LEFT
693.314 Articulating Cup Curette, RIGHT
693.315 Articulating Rake
693.316 Pituitary, Single Action
693.317 Pituitary, Double Action
693.402 Funnel, 7mm
693.404 Funnel, 8.5mm
693.412 Plunger, 7mm
693.414 Plunger/Trial, 8.5mm
693.415 Plunger/Trial, 8mm
693.416 Plunger/Trial, 10mm
693.420 6.5mm Drill
693.501 5mm Rongeur
693.502 5mm Rongeur, Double Acting
693.558 8mm Cannula
693.559 9mm Cannula
693.560 10mm Cannula
693.572 2Nm Torque Limiting Implant Driver
693.580 Adjustable Stop
693.581 Funnel Attachment
693.600 Lateral Torque Limiting Driver, 3.0Nm
693.601 Lateral Inserter
693.602 Lateral Angled Inserter
693.603 Graft Sleeve, 7mm
693.604 Graft Sleeve, 10mm
693.610 Threaded Funnel Shaft
693.611 Graft Plunger
693.612 Spanner Wrench
693.613 Removal Tool
693.614 Inserter Wrench
693.707 Extractor
993.001 RISE IntraLIF Graphic Case
993.002 RISE IntraLIF Implant Module
993.003 RISE Instrument Graphic Case
993.004 RISE 8mm Implant Module
993.005 RISE 10mm Implant Module
993.006 RISE 12mm Implant Module
993.007 RISE Implant Graphic Case
993.010 RISE-L Implant Caddie
993.014 RISE 8mm Soft Case
993.015 RISE 10mm Soft Case
993.016 RISE 12mm Soft Case
993.018 RISE-L 18mm Module

993.019 RISE-L Instruments Graphic Case
993.020 RISE-L Implants Graphic Case
993.022 RISE-L 22mm Module
993.028 RISE-L Sterile Implant Set Soft Case
993.031 IntraLIF Instrument Graphic Case
993.032 RISE Inserter Instrument Graphic Case
993.052 Rise IntraLIF Implants
993.054 Rise 8mm Implants
993.055 Rise 10mm Implants
993.056 Rise 12mm Implants

Altera Spacers

1124.1001 ALTERA Spacer, 10x26mm, 8-12mm, 0deg
1124.1002 ALTERA Spacer, 10x26mm, 9-13mm, 0deg
1124.1003 ALTERA Spacer, 10x26mm, 10-14mm, 0deg
1124.1004 ALTERA Spacer, 10x26mm, 11-15mm, 0deg
1124.1005 ALTERA Spacer, 10x26mm, 12-16mm, 0deg
1124.1006 ALTERA Spacer, 10x26mm, 13-17mm, 0deg
1124.1007 ALTERA Spacer, 10x26mm, 14-18mm, 0deg
1124.1011 ALTERA Spacer, 10x26mm, 8-12mm, 8deg
1124.1012 ALTERA Spacer, 10x26mm, 9-13mm, 8deg
1124.1013 ALTERA Spacer, 10x26mm, 10-14mm, 8deg
1124.1014 ALTERA Spacer, 10x26mm, 11-15mm, 8deg
1124.1015 ALTERA Spacer, 10x26mm, 12-16mm, 8deg
1124.1016 ALTERA Spacer, 10x26mm, 13-17mm, 8deg
1124.1017 ALTERA Spacer, 10x26mm, 14-18mm, 8deg
1124.1032 ALTERA Spacer, 10x26mm, 9-13mm, 15deg
1124.1033 ALTERA Spacer, 10x26mm, 10-14mm, 15deg
1124.1034 ALTERA Spacer, 10x26mm, 11-15mm, 15deg
1124.1035 ALTERA Spacer, 10x26mm, 12-16mm, 15deg
1124.1036 ALTERA Spacer, 10x26mm, 13-17mm, 15deg
1124.1037 ALTERA Spacer, 10x26mm, 14-18mm, 15deg
1124.1101 ALTERA Spacer, 10x31mm, 8-12mm, 0deg
1124.1102 ALTERA Spacer, 10x31mm, 9-13mm, 0deg
1124.1103 ALTERA Spacer, 10x31mm, 10-14mm, 0deg
1124.1104 ALTERA Spacer, 10x31mm, 11-15mm, 0deg
1124.1105 ALTERA Spacer, 10x31mm, 12-16mm, 0deg
1124.1106 ALTERA Spacer, 10x31mm, 13-17mm, 0deg
1124.1107 ALTERA Spacer, 10x31mm, 14-18mm, 0deg
1124.1111 ALTERA Spacer, 10x31mm, 8-12mm, 8deg
1124.1112 ALTERA Spacer, 10x31mm, 9-13mm, 8deg
1124.1113 ALTERA Spacer, 10x31mm, 10-14mm, 8deg
1124.1114 ALTERA Spacer, 10x31mm, 11-15mm, 8deg
1124.1115 ALTERA Spacer, 10x31mm, 12-16mm, 8deg
1124.1116 ALTERA Spacer, 10x31mm, 13-17mm, 8deg
1124.1117 ALTERA Spacer, 10x31mm, 14-18mm, 8deg
1124.1132 ALTERA Spacer, 10x31mm, 9-13mm, 15deg

1124.1133 ALTERA Spacer, 10x31mm, 10-14mm, 15deg
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1124.1136 ALTERA Spacer, 10x31mm, 13-17mm, 15deg
1124.1137 ALTERA Spacer, 10x31mm, 14-18mm, 15deg
1124.1201 ALTERA Spacer, 10x36mm, 8-12mm, 0deg
1124.1202 ALTERA Spacer, 10x36mm, 9-13mm, 0deg
1124.1203 ALTERA Spacer, 10x36mm, 10-14mm, 0deg
1124.1204 ALTERA Spacer, 10x36mm, 11-15mm, 0deg
1124.1205 ALTERA Spacer, 10x36mm, 12-16mm, 0deg
1124.1206 ALTERA Spacer, 10x36mm, 13-17mm, 0deg
1124.1207 ALTERA Spacer, 10x36mm, 14-18mm, 0deg
1124.1211 ALTERA Spacer, 10x36mm, 8-12mm, 8deg
1124.1212 ALTERA Spacer, 10x36mm, 9-13mm, 8deg
1124.1213 ALTERA Spacer, 10x36mm, 10-14mm, 8deg
1124.1214 ALTERA Spacer, 10x36mm, 11-15mm, 8deg
1124.1215 ALTERA Spacer, 10x36mm, 12-16mm, 8deg
1124.1216 ALTERA Spacer, 10x36mm, 13-17mm, 8deg
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1124.1232 ALTERA Spacer, 10x36mm, 9-13mm, 15deg
1124.1233 ALTERA Spacer, 10x36mm, 10-14mm, 15deg
1124.1234 ALTERA Spacer, 10x36mm, 11-15mm, 15deg
1124.1235 ALTERA Spacer, 10x36mm, 12-16mm, 15deg
1124.1236 ALTERA Spacer, 10x36mm, 13-17mm, 15deg
1124.1237 ALTERA Spacer, 10x36mm, 14-18mm, 15deg
1124.1001S ALTERA Spacer, 10x26mm, 8-12mm, 0deg
1124.1002S ALTERA Spacer, 10x26mm, 9-13mm, 0deg
1124.1003S ALTERA Spacer, 10x26mm, 10-14mm, 0deg
1124.1004S ALTERA Spacer, 10x26mm, 11-15mm, 0deg
1124.1005S ALTERA Spacer, 10x26mm, 12-16mm, 0deg
1124.1006S ALTERA Spacer, 10x26mm, 13-17mm, 0deg
1124.1007S ALTERA Spacer, 10x26mm, 14-18mm, 0deg
1124.1011S ALTERA Spacer, 10x26mm, 8-12mm, 8deg
1124.1012S ALTERA Spacer, 10x26mm, 9-13mm, 8deg
1124.1013S ALTERA Spacer, 10x26mm, 10-14mm, 8deg
1124.1014S ALTERA Spacer, 10x26mm, 11-15mm, 8deg
1124.1015S ALTERA Spacer, 10x26mm, 12-16mm, 8deg
1124.1016S ALTERA Spacer, 10x26mm, 13-17mm, 8deg
1124.1017S ALTERA Spacer, 10x26mm, 14-18mm, 8deg
1124.1032S ALTERA Spacer, 10x26mm, 9-13mm, 15deg
1124.1033S ALTERA Spacer, 10x26mm, 10-14mm, 15deg
1124.1034S ALTERA Spacer, 10x26mm, 11-15mm, 15deg
1124.1035S ALTERA Spacer, 10x26mm, 12-16mm, 15deg
1124.1036S ALTERA Spacer, 10x26mm, 13-17mm, 15deg
1124.1037S ALTERA Spacer, 10x26mm, 14-18mm, 15deg
1124.1101S ALTERA Spacer, 10x31mm, 8-12mm, 0deg

1124.1102S ALTERA Spacer, 10x31mm, 9-13mm, 0deg
1124.1103S ALTERA Spacer, 10x31mm, 10-14mm, 0deg
1124.1104S ALTERA Spacer, 10x31mm, 11-15mm, 0deg
1124.1105S ALTERA Spacer, 10x31mm, 12-16mm, 0deg
1124.1106S ALTERA Spacer, 10x31mm, 13-17mm, 0deg
1124.1107S ALTERA Spacer, 10x31mm, 14-18mm, 0deg
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1124.1112S ALTERA Spacer, 10x31mm, 9-13mm, 8deg
1124.1113S ALTERA Spacer, 10x31mm, 10-14mm, 8deg
1124.1114S ALTERA Spacer, 10x31mm, 11-15mm, 8deg
1124.1115S ALTERA Spacer, 10x31mm, 12-16mm, 8deg
1124.1116S ALTERA Spacer, 10x31mm, 13-17mm, 8deg
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1124.1203S ALTERA Spacer, 10x36mm, 10-14mm, 0deg
1124.1204S ALTERA Spacer, 10x36mm, 11-15mm, 0deg
1124.1205S ALTERA Spacer, 10x36mm, 12-16mm, 0deg
1124.1206S ALTERA Spacer, 10x36mm, 13-17mm, 0deg
1124.1207S ALTERA Spacer, 10x36mm, 14-18mm, 0deg
1124.1211S ALTERA Spacer, 10x36mm, 8-12mm, 8deg
1124.1212S ALTERA Spacer, 10x36mm, 9-13mm, 8deg
1124.1213S ALTERA Spacer, 10x36mm, 10-14mm, 8deg
1124.1214S ALTERA Spacer, 10x36mm, 11-15mm, 8deg
1124.1215S ALTERA Spacer, 10x36mm, 12-16mm, 8deg
1124.1216S ALTERA Spacer, 10x36mm, 13-17mm, 8deg
1124.1217S ALTERA Spacer, 10x36mm, 14-18mm, 8deg
1124.1232S ALTERA Spacer, 10x36mm, 9-13mm, 15deg
1124.1233S ALTERA Spacer, 10x36mm, 10-14mm, 15deg
1124.1234S ALTERA Spacer, 10x36mm, 11-15mm, 15deg
1124.1235S ALTERA Spacer, 10x36mm, 12-16mm, 15deg
1124.1236S ALTERA Spacer, 10x36mm, 13-17mm, 15deg
1124.1237S ALTERA Spacer, 10x36mm, 14-18mm, 15deg
6124.0001 ALTERA Insert Base
6124.0002 ALTERA Insert Sleeve
6124.0003 ALTERA Insert Threaded Rod
6124.0004 ALTERA Insert Driver Shaft
6124.0005 ALTERA Impaction Cap
6124.0006 ALTERA Removal Threaded Rod
6124.0007 ALTERA Torque Limiting Palm Handle, Cannulated, 4.5Nm

6124.0008 ALTERA Spanner Wrench
6124.0009 ALTERA Removal Driver Shaft
6124.0010 Bone Funnel Tube
6124.0011 Bone Funnel Pusher
9124.0001 ALTERA Instrument Graphic Case
9124.0026 ALTERA Implant Module, 10 x 26mm
9124.0031 ALTERA Implant Module, 10 x 31mm
9124.0036 ALTERA 10x36mm Implant Module
9124.0020 ALTERA Sterile Implant Soft Case

Clase de Riesgo: III

Indicación/es autorizada/s:

El espaciador RISE® es un dispositivo de fusión intervertebral lumbar creado para su uso en pacientes con discopatía degenerativa (DDD) en uno o más niveles contiguos de la región lumbosacra (L2-S1) de la columna. La DDD se define como un dolor de espalda discógeno con degeneración discal confirmada por historial y estudios radiográficos. Los pacientes deberán ser esqueléticamente maduros y haber recibido tratamiento no quirúrgico durante seis (6) meses como mínimo. Además, estos pacientes pueden tener espondilolistesis o retrolistesis grado 1 en los niveles afectados.

El espaciador RISE® debe llenarse con material de injerto óseo autógeno, y utilizarse con fijación suplementaria, como los sistemas de estabilización REVERE® o REVOLVE®.

El espaciador ALTERA® es un dispositivo de fusión intersomática creado para el uso en pacientes con discopatía degenerativa (EDD, o DDD por sus siglas en inglés) en uno o más niveles contiguos de la columna lumbosacra (L2-S1). La EDD se define como dolor de espalda discógeno con degeneración discal confirmada por historial y estudios radiográficos. Los pacientes deberán ser esqueléticamente maduros y haber recibido tratamiento no quirúrgico durante seis (6) meses como mínimo.

Además, estos pacientes pueden tener espondilolistesis o retrolistesis de grado 1 como máximo en los niveles afectados.

El espaciador ALTERA® debe rellenarse con material de injerto óseo autólogo, prolongadores o sustitutos de injerto óseo.

El dispositivo está pensado para su uso con fijación complementaria.

Período de vida útil: Productos estériles para códigos terminados en S: 5 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biológico: NA

Forma de presentación: Unitaria

Método de esterilización: Implantes estériles: Radiación Gamma

Implantes no estériles: No aplica

Instrumental estéril: Radiación Gamma

Instrumental no estériles: No aplica

Nombre del fabricante:

GLOBUS MEDICAL, INC.

Lugar de elaboración:

2560 General Armistead Ave VALLEY FORGE BUSINESS CENTER
AUDUBON, PA USA 19403, Estados Unidos.

1-0047-3110-005896-24-1

Nº Identificadorio Trámite: 61360

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