



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

DECLARACION JURADA DE REVÁLIDA

DISPOSICIÓN ANMAT N° 9688/2019

N° rev: 646-44#0001

En nombre y representación de la firma AXIMPORT SRL , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 9688/19 I Anexo V para el producto médico inscripto bajo el Número de PM: 646-44

Disposición autorizante N° 7483 de fecha 06 diciembre 2013
Disposiciones modificatorias y reválidas N°: Disp. 10460/2019
Disp. 8871/2018

Datos Característicos del Producto Médico:

Nombre descriptivo: STENTS AUTO EXPANDIBLE JAGUAR CON SISTEMA DE LIBERACIÓN

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
20-430 ENDOPRÓTESIS (STENTS), VASCULARES, PERIFÉRICAS, AUTOEXPANSIBLES

Marca(s) de (los) producto(s) médico(s): Balton

Clase de Riesgo: III

Indicación/es autorizada/s: El stent autoexpandible Jaguar con sistema de liberación, está indicado para su uso en implantación intravascular percutánea en pacientes con lesiones ateroscleróticas, inducidas por radiación y postraumáticas que produzcan estenosis de los vasos, con una significancia hemodinámica importante e intratables con otro tipo de tratamiento. en otras formas de tratamiento. Indicado para uso en vasos en vasos periféricos

Modelos: JAGUAR

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Período de vida útil: 24 meses

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

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

Forma de presentación: Cada envase contiene una unidad estéril

Método de esterilización: Oxido de Etileno

Nombre del fabricante: BALTON Sp.z.o.o

Lugar de elaboración: Nowy Swiat 7/14

00-496 Varsovia

Polonia

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento que el producto médico no ha sufrido modificaciones según Artículo 11° Disposición 9688/19, que cumple y satisface los Requisitos Esenciales de Seguridad y Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 4306/99.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por disposición ANMAT N° 2318/02 y 9688/19


Responsable Legal
Firma y Sello
MAINARDI Ana Valentina

Responsable Técnico
Firma y Sello

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 9688/19, quedando inscripta la reválida en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a cargo de ANIMPORT SRL bajo el número PM 646-44 siendo su nueva vigencia hasta el 06 diciembre 2028 CUIL 278 70545716


GARCIA Mariela Andrea
CUIL 27247738822
Instituto Nacional de Productos Médicos ANMAT
Firma y Sello

El presente certificado será válido únicamente cuando se presente junto con las Disposiciones previas del PM enunciadas anteriormente y sea verificado con su código QR a través de la página de ANMAT.

Fecha de emisión: 23 noviembre 2023



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 53848

Tramitada por Expediente N°: 1-0047-3110-007031-23-1



Ministerio de Salud
Secretaría de Calidad en Salud
A.N.M.A.T.

CERTIFICADO DE AUTORIZACIÓN DE MODIFICACIÓN**N° rev: 646-44#0001**

El Instituto Nacional de Productos Médicos de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por AXIMPORT SRL, se autoriza la modificación en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), del PM 646-44 aprobado según:

Disposición autorizante N° 7483 de fecha 06 diciembre 2013
Disposiciones modificatorias y reválidas N°: Disp 10460/2019
Disp. 8871/2018
646-44#0001

Del siguiente/s dato/s característico/s:

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACION/RECTIFICACION AUTORIZADA
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Quedando el producto inscripto con los siguientes datos característicos:

Nombre descriptivo: STENTS AUTO EXPANDIBLE JAGUAR CON SISTEMA DE LIBERACIÓN

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
20-430 ENDOPRÓTESIS (STENTS), VASCULARES, PERIFÉRICAS, AUTOEXPANSIBLES

Marca(s) de (los) producto(s) médico(s): Balton

Clase de Riesgo: III

Indicación/es autorizada/s: El stent autoexpandible Jaguar con sistema de liberación, está indicado para su uso en implantación intravascular percutánea en pacientes con lesiones ateroscleróticas, inducidas por radiación y postraumáticas que produzcan estenosis de los vasos, con una significancia hemodinámica importante e intratables con otro tipo de tratamiento. en otras formas de tratamiento. Indicado para uso en vasos en vasos periféricos

Modelos: JAGUAR

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Período de vida útil: 24 meses

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: Cada envase contiene una unidad estéril

Método de esterilización: Oxido de Etileno

Nombre del fabricante: BALTON Sp.o.o.

Lugar de elaboración: Nowy Swiat 7/14
00-496 Varsovia
Polonia

AUTORIZADO

Habiéndose cumplimentado con lo previsto en la Disposición ANMAT N° 2318/02 y 9688/19, esta

Administración autoriza las modificaciones solicitadas en Argentina, Ciudad de Buenos Aires, 23 noviembre 2023.



BODNAR Andrea Veronica
Dirección Evaluación y Registro de Productos
Médicos
Firma y Sello



GARCIA Mariela Andrea
Instituto Nacional de Productos Médicos
ANMAT
Firma y Sello

El presente certificado será válido únicamente cuando se presente junto con las Disposiciones previas del PM enunciadas anteriormente y sea verificado con su código QR a través de la página de ANMAT. Este certificado no modifica el período de vigencia.

Fecha de emisión: 23 noviembre 2023



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 53856



ABRIOLA Leticia Adriana
CUIL 27323186494



República Argentina - Poder Ejecutivo Nacional

2019 - Año de la Exportación

Disposición

Número:

Referencia: 1-47-3110-7408-18-1

VISTO el Expediente N° 1-47-3110-7408-18-1 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones la firma AXIMPORT S.R.L. solicita la revalidación del Certificado de Inscripción en el RPPTM N° PM-646-44, denominado: STENTS AUTO EXPANDIBLE JAGUAR CON SISTEMA DE LIBERACIÓN, marca BALTON.

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 atribuciones conferidas por los Decretos N° 1490/92 y sus modificatorios.

Por ello;

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

DISPONE:

ARTÍCULO 1º.- Revalídese la fecha de vigencia del Certificado de Inscripción en el RPPTM N° PM-646-44, correspondiente al producto médico denominado: STENTS AUTO EXPANDIBLE JAGUAR CON SISTEMA DE LIBERACIÓN, propiedad de la firma AXIMPORT S.R.L. obtenido a través de la Disposición ANMAT N°7483 de fecha 06 de diciembre de 2013.

ARTÍCULO 2º.- Acéptase la Revalidación de la fecha de inscripción del Certificado de Inscripción en el RPPTM N° PM-646-44 la cual será 06 de diciembre de 2023.

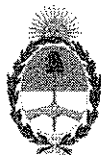
ARTICULO 3º.- Practíquese la atestación de la presente disposición al Certificado de Inscripción en el RPPTM N° PM-646-44.

ARTÍCULO 4º.- Regístrese; por el Departamento de Mesa de Entrada, notifíquese al interesado y hágasele entrega de la copia presente; gírese a la Dirección de Gestión de Información Técnica para que efectúe la agregación correspondiente. Cumplido, archívese.

Expediente N° 1-47-3110-7408-18-1

Digitally signed by CHIALE Carlos Alberto
Date: 2019.12.20 15:26:26 ART
Location: Ciudad Autónoma de Buenos Aires

Digitally signed by GESTION DOCUMENTAL
ELECTRONICA - GDE
Date: 2019.12.20 15:26:38 -03:00



República Argentina - Poder Ejecutivo Nacional
2018 - Año del Centenario de la Reforma Universitaria

Disposición

Número: DI-2018-8871-APN-ANMAT#MS

CIUDAD DE BUENOS AIRES
Miércoles 29 de Agosto de 2018

Referencia: 1-47-3110-4900-17-9

VISTO el Expediente N° 1-47-3110-4900-17-9 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones la firma AXIMPORT S.R.L. solicita la autorización de modificación del Certificado de Inscripción en el RPPTM N° PM-646-44, denominado: STENT AUTO-EXPANDIBLE CON SISTEMA DE ENTREGA "JAGUAR" SM, marca: BALTON.

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 la Dirección 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 Decreto N° 101 del 16 de diciembre de 2015.

Por ello;

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

DISPONE:

ARTÍCULO 1º.- Autorízase la modificación del Certificado de Inscripción en el RPPTM N° PM-646-44, denominado: STENT AUTO-EXPANDIBLE CON SISTEMA DE ENTREGA "JAGUAR" SM, marca:

BALTON, según Disposición Autorizante de (RPPTM) N° 7483/13 y tramitado por expediente N° 1-47-14170-10-7.

ARTÍCULO 2°.- Acéptase el Anexo de Autorización de Modificaciones documento N° IF-2018-38250907-APN-DNPM#ANMAT el que deberá agregarse al Certificado de Inscripción en el RPPTM N° PM-646-44.

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° 1-47-3110-4900-17-9

Carlos Alberto Chiale
Administrador
Administración Nacional de Medicamentos, Alimentos y Tecnología
Médica

ANEXO DE AUTORIZACIÓN DE MODIFICACIONES

El Administrador Nacional de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), autoriza a la firma AXIMPORT S.R.L. la modificación de los datos característicos correspondientes al Certificado de Inscripción en el RPPTM N° PM-646-44 de acuerdo con los datos que figuran en la tabla al pie, del producto:

Nombre genérico aprobado: STENT AUTO-EXPANDIBLE CON SISTEMA DE ENTREGA "JAGUAR" SM, marca: BALTON.

Disposición Autorizante de (RPPTM) N° 7483/13.

Tramitado por expediente N° 1-47-14170-10-7.

DATO IDENTIFICATORIO A MODIFICAR	DATO AUTORIZADO HASTA LA FECHA	MODIFICACIÓN RECTIFICACIÓN AUTORIZADA /
Modelos	JAGUAR, CÓDIGO: ZNSJ.	ZNSJ4x1518135 ZNSJ4x2018135 ZNSJ4x3018135 ZNSJ4x4018135 ZNSJ4x5018135 ZNSJ4x6018135 ZNSJ4x7018135 ZNSJ4x8018135 ZNSJ4x9018135 ZNSJ4x10018135 ZNSJ4x11018135 ZNSJ4x12018135 ZNSJ4x1535135 ZNSJ4x2035135 ZNSJ4x3035135 ZNSJ4x4035135 ZNSJ4x5035135 ZNSJ4x6035135 ZNSJ4x7035135 ZNSJ4x8035135 ZNSJ4x9035135

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Nombre Genérico	STENT AUTO-EXPANDIBLE CON SISTEMA DE ENTREGA "JAGUAR" SM	STENTS AUTO EXPANDIBLE JAGUAR CON SISTEMA DE LIBERACIÓN
Código de Identificación y nombre técnico UMDNS	17-461 ENDOPROTESIS (STENTS), VASCULARES.	20-430 ENDOPROTESIS (STENTS), VASCULARES, PERIFÉRICAS, AUTOEXPANSIBLES.

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

Expediente N° 1-47-3110-4900-17-9



Ministerio de Salud
Secretaría de Políticas,
Regulación e Institutos
A.N.M.A.T.

DISPOSICIÓN Nº 7483

BUENOS AIRES, 06 DIC 2013

VISTO el Expediente Nº 1-47-14170/10-7 del Registro de esta Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), y

CONSIDERANDO:

Que por las presentes actuaciones AXIMPORT SRL 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. Nº 40/00, incorporada al ordenamiento jurídico nacional por Disposición ANMAT Nº 2318/02 (TO 2004), y normas complementarias.

Que consta la evaluación técnica producida por el Departamento de Registro.

Que consta la evaluación técnica producida por la Dirección 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 los datos identificatorios característicos a ser transcritos en los proyectos de la Disposición Autorizante y del Certificado correspondiente, han sido convalidados por las áreas técnicas precedentemente citadas.

Que se ha dado cumplimiento a los requisitos legales y formales que contempla la normativa vigente en la materia.

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 los Artículos 8º, inciso II) y 10º, inciso i) del Decreto 1490/92 y por el Decreto 1271/13.



Ministerio de Salud
Secretaría de Políticas,
Regulación e Institutos
A.N.M.A.T.

DISPOSICIÓN Nº 7483

Por ello;

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

DISPONE:

ARTICULO 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 del producto médico de marca BALTON nombre descriptivo Stent autoexpandible con sistema de entrega "JAGUAR SM" y nombre técnico endoprótesis (stents), vasculares, de acuerdo a lo solicitado por AXIMPORT SRL, con los Datos Identificatorios Característicos que figuran como Anexo I de la presente Disposición y que forma parte integrante de la misma.

ARTICULO 2º - Autorízanse los textos de los proyectos de rótulo/s y de instrucciones de uso que obran a fojas 137 y 278-289 respectivamente, figurando como Anexo II de la presente Disposición y que forma parte integrante de la misma.

ARTICULO 3º - Extiéndase, sobre la base de lo dispuesto en los Artículos precedentes, el Certificado de Inscripción en el RPPTM, figurando como Anexo III de la presente Disposición y que forma parte integrante de la misma

ARTICULO 4º - En los rótulos e Instrucciones de uso autorizados deberá figurar la leyenda: Autorizado por la ANMAT, PM-646-44, con exclusión de toda otra leyenda no contemplada en la normativa vigente.

ARTICULO 5º- La vigencia del Certificado mencionado en el Artículo 3º será por cinco (5) años, a partir de la fecha impresa en el mismo.

ARTICULO 6º - Regístrese. Inscríbese en el Registro Nacional de Productores y Productos de Tecnología Médica al nuevo producto. Por Mesa de Entradas notifíquese al interesado, haciéndole entrega de copia autenticada de la presente Disposición, conjuntamente con sus Anexos I, II y III. Gírese al Departamento de



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DISPOSICIÓN Nº 7 4 8 3

Registro a los fines de confeccionar el legajo correspondiente. Cumplido,
archívese.

Expediente Nº 1-47-14170/10-7

DISPOSICIÓN Nº

7 4 8 3

Dr. OTTO A. ORSINGER
Sub Administrador Nacional
A.N.M.A.T.



Ministerio de Salud
Secretaría de Políticas,
Regulación e Institutos
A.N.M.A.T.

ANEXO I

DATOS IDENTIFICATORIOS CARACTERÍSTICOS del PRODUCTO MÉDICO
Inscrito en el RPPTM mediante DISPOSICIÓN ANMAT N°7483....

Nombre descriptivo: Stent auto-expandible con sistema de entrega "JAGUAR SM"

Código de identificación y nombre técnico UMDNS: 17-461 Endoprótesis (stents), vasculares

Marca de (los) producto(s) médico(s): BALTON

Clase de Riesgo: Clase III

Indicación/es autorizada/s: para uso en implantación intravascular percutánea en pacientes con lesiones ateroscleróticas, inducidas por radiación y lesiones postraumáticas que produzcan estenosis de los vasos, con una significancia hemodinámica importante e intratables con otro tipo de tratamiento. Indicado para uso en vasos periféricos.

Modelo/s: Modelos: JAGUAR, Código: ZNSJ

Período de vida útil: 2 años

Condición de expendio: venta exclusiva a profesionales e instituciones sanitarias

Nombre del fabricante: BALTON Sp.z.o.o,

Lugar/es de elaboración: 7 Nowy SEIT Street, apt. 14-00-496, Warsaw, Polonia

Expediente N° 1-47-14170/10-7

DISPOSICIÓN N°

7483

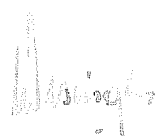
Dr. OTTO A. ORSINGER
Sub Administrador Nacional
A.N.M.A.T.



Ministerio de Salud
**Secretaría de Políticas,
Regulación e Institutos**
A.N.M.A.T.

ANEXO II

TEXTO DEL/LOS RÓTULO/S e INSTRUCCIONES DE USO AUTORIZADO/S del
PRODUCTO MÉDICO inscripto en el RPPTM mediante DISPOSICIÓN ANMAT N°
.....7483.....


Dr. OTTO A. ORSINGER
Sub Administrador Nacional
A.N.M.A.T.

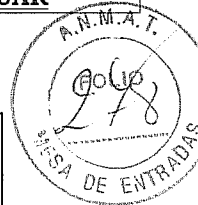
AXIIMPORT S.R.L.



INSTRUCCIONES DE USO

ANEXO III

A.N.M.A.T. - MESA DE ENTRADA
Retollado N° 292
STENT
AUTOEXPANDIBLE
JAGUAR



3.1- Rótulo

Fabricante: BALTON Sp. z o. o. Nowy Swiat 7/14 00-496 Warszawa – Polonia		Importador: AXIIMPORT S.R.L. Alsina 1535 4to. Piso of. 401 Capital Federal Tel: 4374-4482	
STENT AUTOEXPANDIBLE			
ESTERIL ATOXICO Y LIBRE DE APIRÓGENOS			
 PARA SER USADO SÓLO UNA VEZ			
TEMPERATURA COMPRENDIDA ENTRE 0° Y 40°C NO CONGELAR, NO HUMEDECER UTILIZAR INMEDIATAMENTE DESPUÉS DE ABRIR EL ENVASE PRIMARIO FRAGIL, MANEJAR CON CUIDADO NO UTILIZAR SI EL ENVASE NO ESTA ÍNTEGRO			
			
			
METODO DE ESTERILIZACIÓN: OE			
Director Técnico: Farm. Pablo Balduri MN 13402			
Venta exclusiva a profesionales e instituciones sanitarias			
Autorizado por la ANMAT PM-646-44			

3.2- Características

Los stents autoexpandibles están diseñados para el uso en implantación intravascular percutánea en pacientes con lesiones ateroscleróticas, inducidas por radiación y lesiones post traumáticas que produzcan estenosis de los vasos, con una significancia hemodinámica importante e intratables con otro tipo de tratamientos.

Los stent autoexpandibles se utilizan en los siguientes casos:

- Resultados insatisfactorios del procedimiento de ATP (estenosis residual)
- Delaminación de la membrana interna del vaso
- Desordenes de la elasticidad de la pared y presión desde afuera
- Estenosis recurrente o disminución de la permeabilidad luego de haber realizado procedimientos intravasculares.

El dispositivo consiste en un stent y un sistema introductor

Los diámetros fabricados de los Stent van desde 4mm a 10mm, y los largos en un rango de 15mm a 120mm. El largo del sistema introductor es de 80cm o 135cm.

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Argentina – Tel., Fax: 4374-2282 – Líneas Rotativas -info@axiimport.com.ar

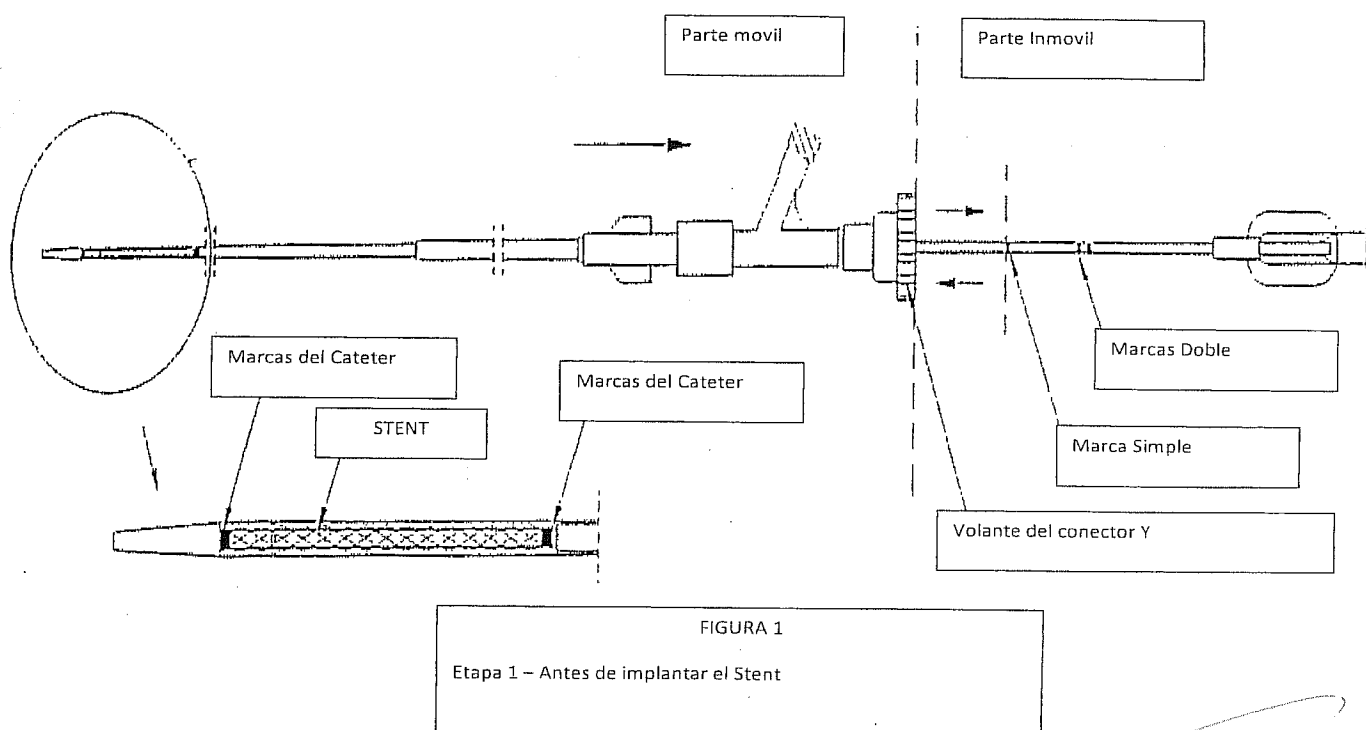
MARIO MARIANO
FARMACEUTICO
M.N. 1340

PABLO H. BALDURI
FARMACEUTICO
M.N. 1340



Los stent autoexpandibles fabricados por la compañía BALTON son hechos de alambre de nitinol (combinación de níquel y titanio). Estos son designados para usar como prótesis intravascular ayudando a mantener la permeabilidad de los vasos. El stent es colocado al final del sistema introductor. Una vez liberado del sistema introductor el stent se abre tomando la forma de un cilindro. Gracias a estas propiedades, restaura la forma deseado de la luz del vaso.

El sistema introductor consiste en una parte móvil y una inmóvil. El stent es liberado por deslizamiento de la parte móvil desde el extremo distal del sistema introductor. El stent es situado entre dos marcas del extremo distal en el sistema introductor (Figura 1).



El sistema introductor cuenta con dos canales: un canal central que es utilizado para introducir la guía en dónde es introducido el sistema introductor y otro canal externo, que constituye el espacio que separa la parte inmóvil que contiene el stent, de la parte móvil. Luego se debe comenzar a desenroscar el volante del conector "Y" (figura 1) que permite deslizar la parte móvil, para la liberación del stent.

Como el nitinol es apenas visible bajo fluoroscopia, las marcas de platino situadas en ambos extremos del stent ayudan a facilitar el despliegue del mismo durante el procedimiento (Figura 5). El sistema introductor es flexible y plegable, lo cual permite la implantación aún en vasos tortuosos. Las puntas redondeadas y flexibles del sistema introductor son atraumáticas para las paredes del vaso.

Durante la implantación del stent es posible corregir la locación de la parte desplegada en el vaso del stent.



El sistema introductor permite la reintroducción del stent dentro de la parte móvil. Esto se puede hacer cuando no más de la mitad del largo del stent ha sido desplegado (Figuras 3 y 4). Esta medida es proporcionada por la marca simple en el tubo de acero que constituye la parte inmóvil durante la implantación del stent. Esta simple marca representa el límite que muestra, cuando es excedida, que no va a ser posible la reintroducción del stent (Figura 3). La marca doble representa el lugar dónde el stent está completamente liberado del sistema introductor y desplegado (Figura 5).

Las siguientes etapas de la liberación del stent están representadas en las Figuras 1, 2, 3, 4 y 5.

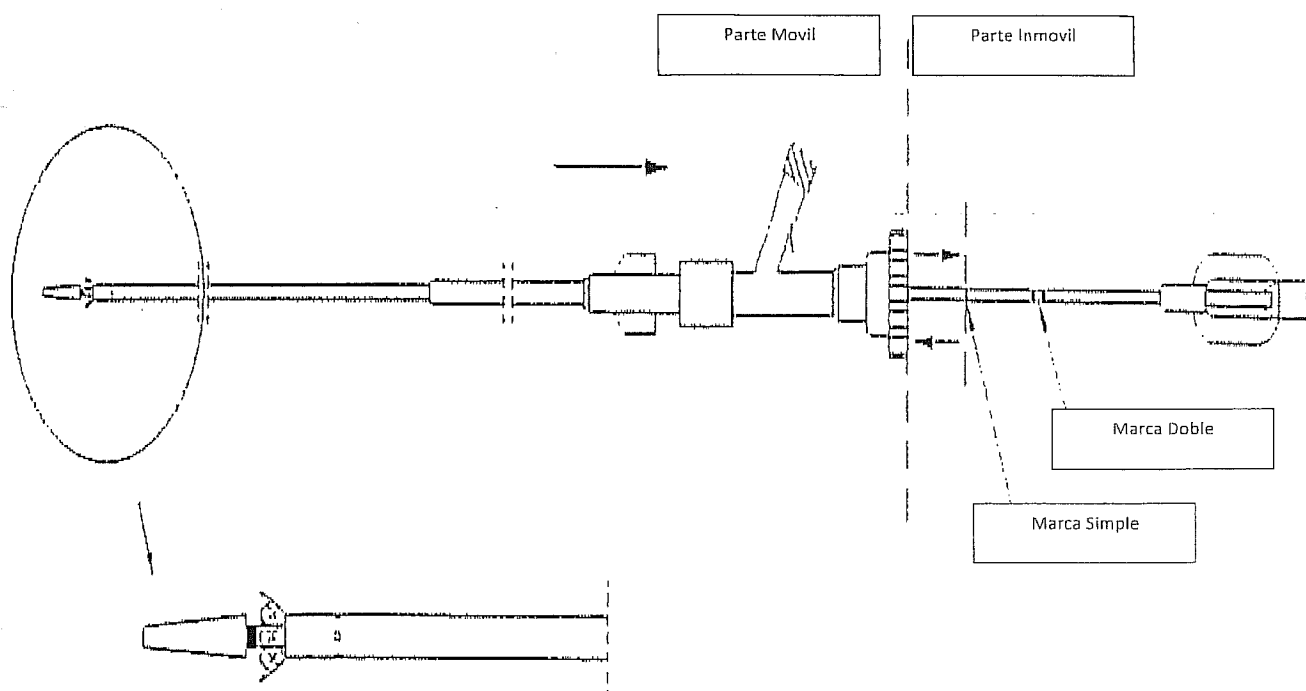


FIGURA 2

ETAPA 2 - LIBERACION DEL STENT

Pablo Maraviglia
PABLO MARAVIGLIA
SOCIO GERENTE

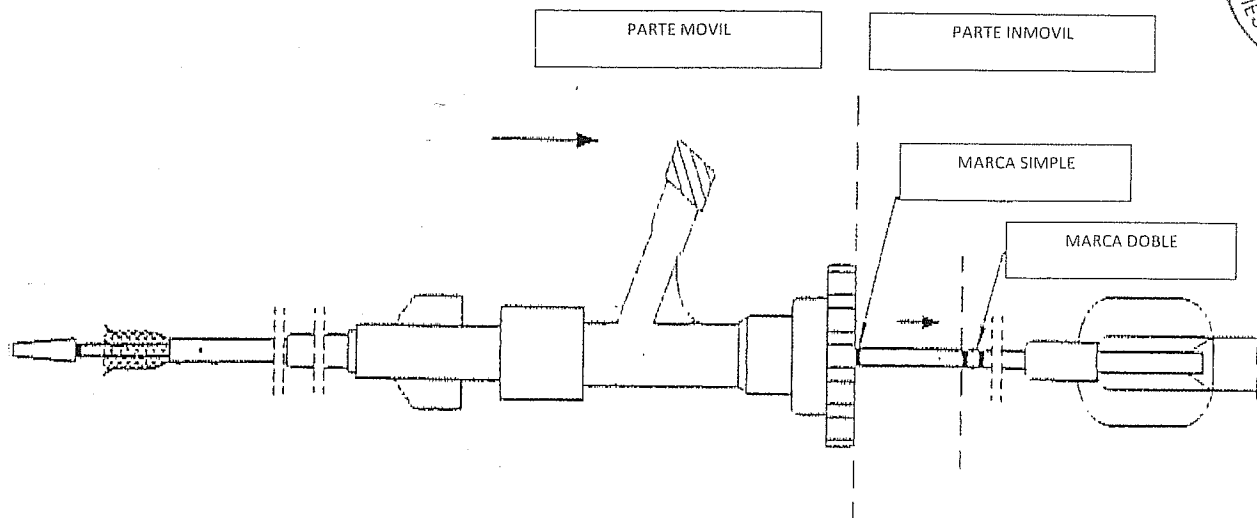


FIGURA 3

ETAPA 3 – POSICION DEL LIMITE DEL STENT EN DONDE TODAVIA ES POSIBLE CORREGIR SU DESPLIEGUE
(LA PARTE MOVIL SE SUPERPONE CON LA MARCA SIMPLE EN LA PARTE INMOVIL)

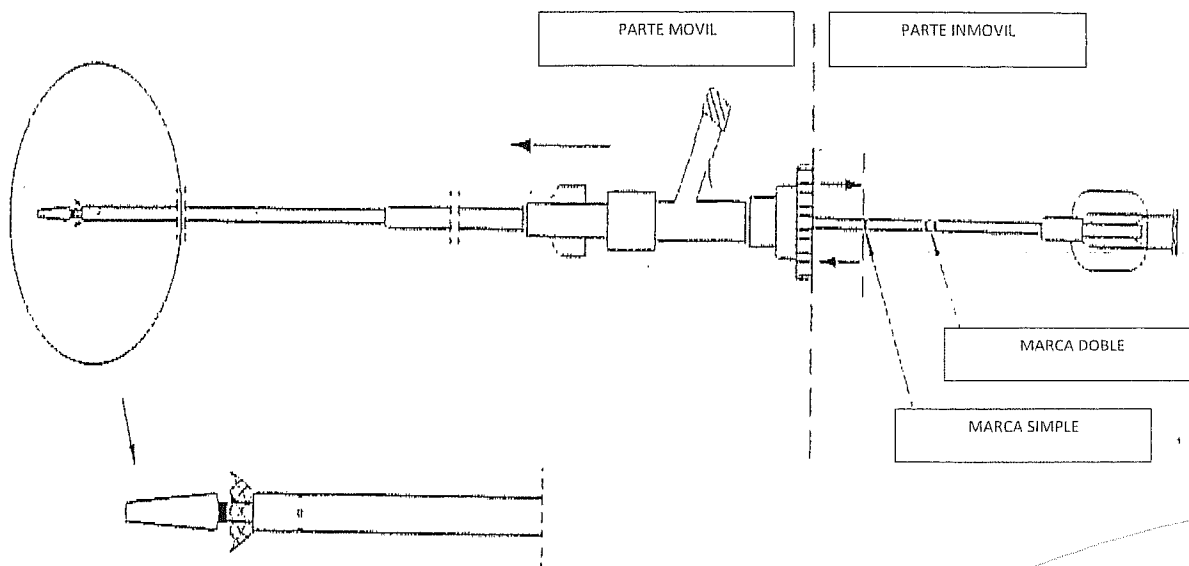
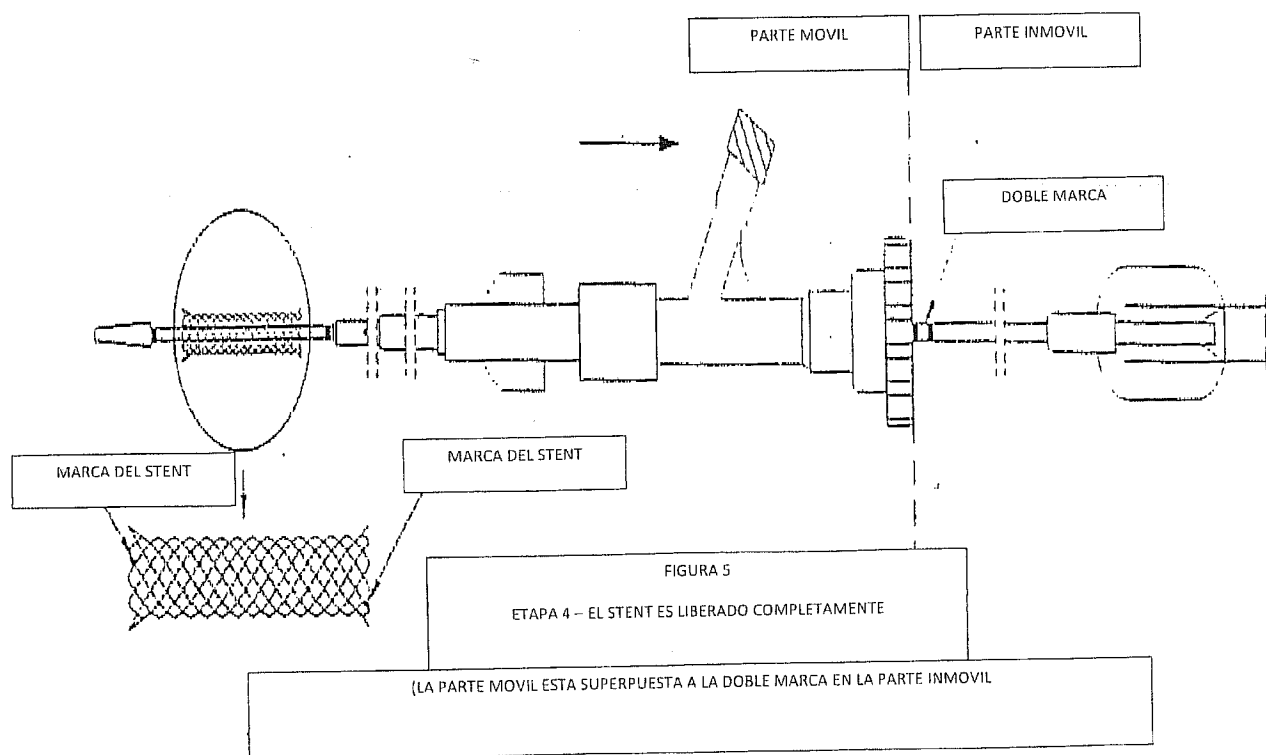


FIGURA 4

ETAPA 3 A – POSIBLE MODIFICACION DEL DESPLIEGUE DEL STENT

PABLO H. BALDURI
FARMACEUTICO
M.N. 1340

[Firma]
SOCIETA MARIATEGUIA
SOCIO GERENTE



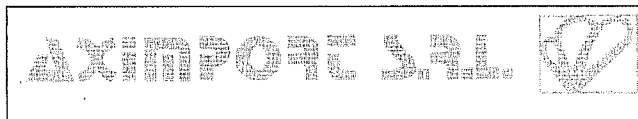
➤ Preparación antes del procedimiento

1- Selección del diámetro del Stent

Luego de la angiografía, es necesario determinar el diámetro del vaso y el mayor sitio de estenosis así como por debajo y encima de la lesión. El diámetro del stent debe exceder en 1 - 2mm el diámetro del vaso en la medida proximal y distal en relación con el lugar de la estenosis. Esto permitirá la correcta colocación del stent en las paredes del vaso. Si el diámetro del stent es muy pequeño el stent puede migrar o puede formarse un trombo.

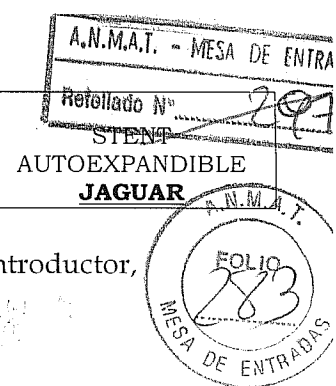
2- Selección del largo del Stent

El largo del stent es evaluado por la angiografía, se utiliza una escala especial en Gauge pegada al cuerpo del paciente, proyectando en el mismo en paralelo con el vaso alterado, o se introduce un catéter calibrado en lúmenes en el sitio de la estenosis. El largo del stent tiene que ser seleccionado de manera tal que la mayor estenosis quede situada exactamente en el medio del stent. Cuando es necesario implantar más de un stent, el stent distal será colocado primero. El proximal debe ser encerrado con el stent distal y presionar contra la pared del vaso en una circunferencia mínima de 5mm.



INSTRUCCIONES DE USO

ANEXO III



El stent autoexpandible, después de haber sido liberado del sistema introductor, alcanza su largo dependiendo del diámetro del vaso.

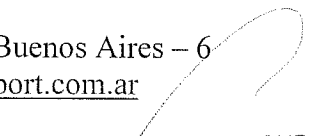
3- La preparación del Sistema Introductor

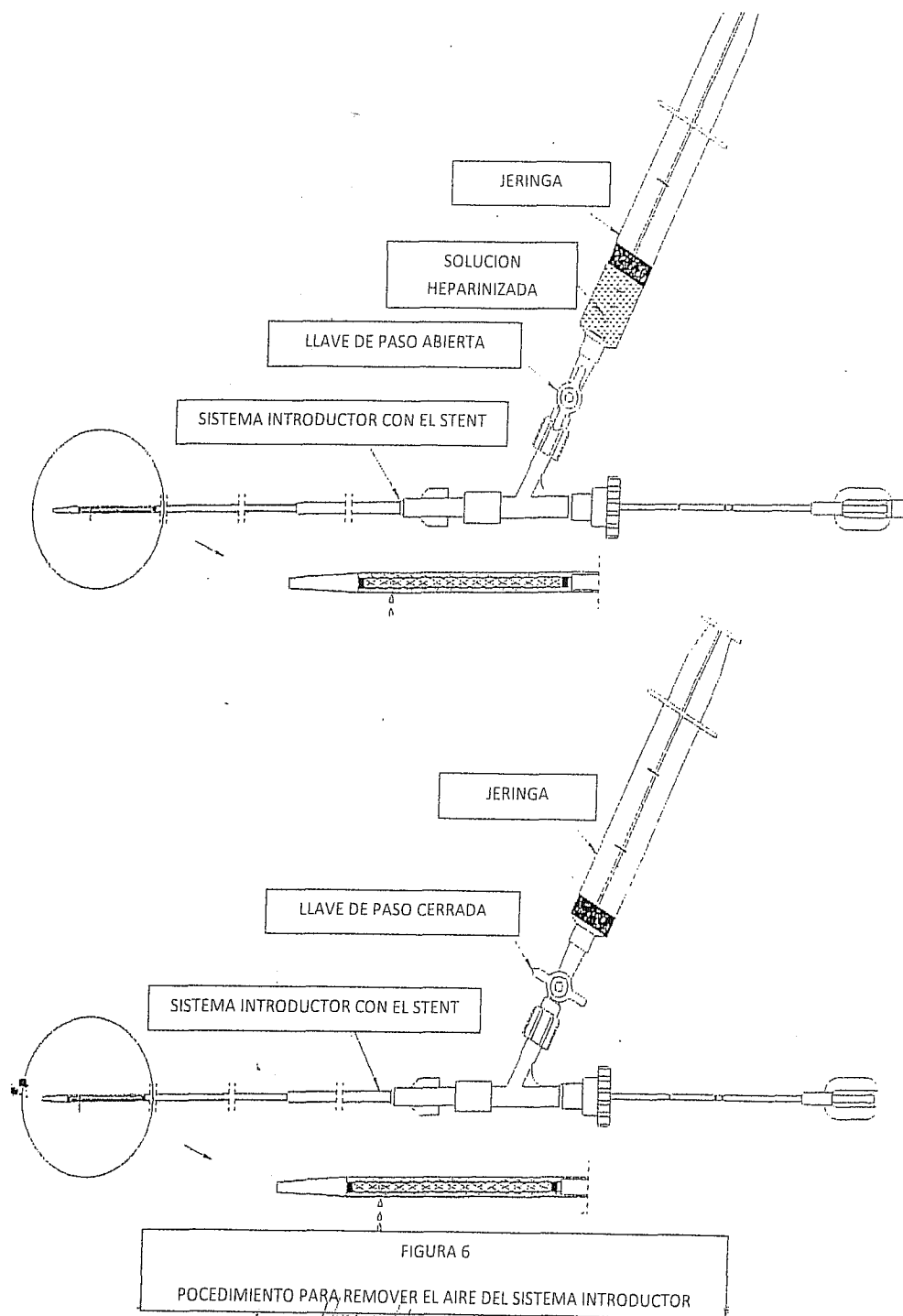
Una vez que el stent adecuado ha sido seleccionado, hay que sacarlo de su empaque conjuntamente con el sistema introductor e inspeccionar y verificar que no haya ni daños ni fallas visibles. Luego:

- Retirar la caja protectora del stent
- Libere el stent parcialmente del sistema introductor, no exceda la marca simple (Figura 2), y luego, vuelva a colocar el stent en el sistema introductor,
- Sacar el mandril de refuerzo de la luz del sistema introductor
- Luego abrir la llave de paso, y limpiar la luz con solución heparinizada, para remover el aire, gotas del líquido deben aparecer en la punta del sistema introductor justo sobre el stent. (Figura 6),
- Cerrar la llave de paso.
- Asegurarse que el conjunto del stent esté adjunto al sistema introductor.


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PABLO H. BALDURI
FARMACEUTICO
M.N. 1340



➤ **Inserción del stent en el vaso**

El stent es insertado en el vaso junto al sistema introductor a lo largo del alambre guía exclusivamente por medio de un introductor adecuadamente seleccionado con una válvula hemostática.

El tamaño del introductor depende del diámetro del sistema introductor.

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Luego de este procedimiento, a fin de evitar cualquier error en la selección del diámetro, es necesario estar seguro que el diámetro se ajusta al tamaño del introductor.

Es recomendable que el sistema sea introducido en el sistema vascular a través de una apertura de la válvula, que se adjunta al stent. Su función consiste en vencer la resistencia de la válvula hemostática y facilitar la introducción del stent. Debido a la apertura de la válvula el sistema introductor debe pasar suavemente a través del introductor. Luego de la introducción del sistema el abridor de la válvula debe ser retirado del mismo, de lo contrario la válvula se fuga y la sangre fluirá. El stent con los elementos necesarios para realizar el procedimiento están representados en la figura 7.

NOTA: LA VALVULA HEMOSTATICA, LA LLAVE DE PASO ONE-WAY Y LA GUIA NO SON COMPONENTES DEL SET

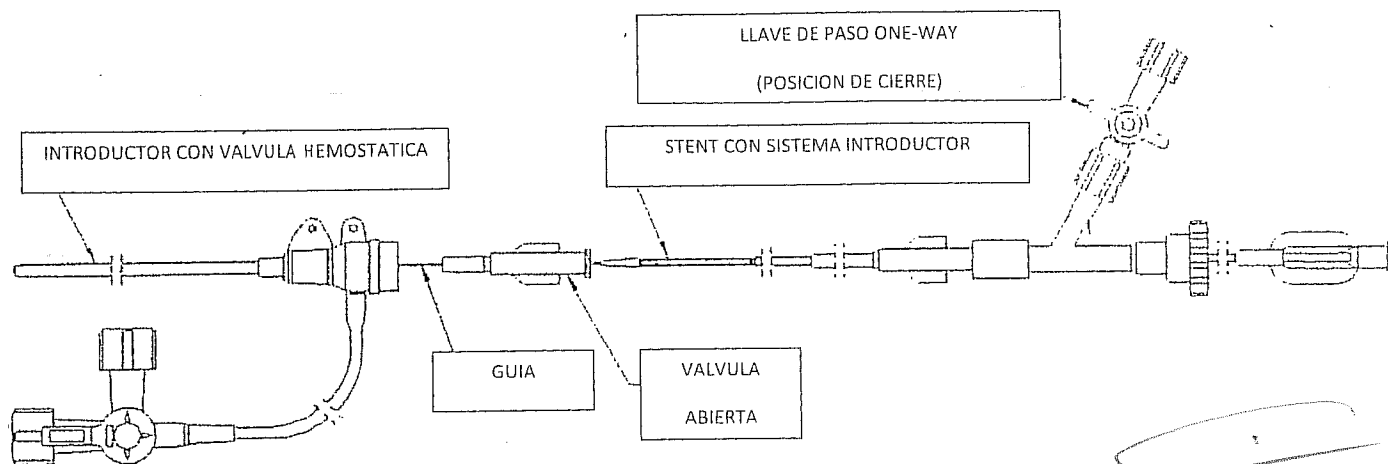


FIGURA 7

EL SET DE ELEMENTOS NECESARIOS PARA REALIZAR EL PROCEDIMIENTO

ATENCION: Si se encuentra resistencia al insertar el stent con el sistema introductor el mismo debe ser retirado. Entonces será necesario evaluar la situación y tomar la decisión de usar un stent diferente.

Cuando la guía se ha colocado dentro de cierta distancia de la sección del vaso afectado en la lesión, el sistema con el stent premontado debe insertarse a través de él y desplegarse de tal manera que los marcadores colocados en la punta del sistema introductor, visibles bajo fluoroscopia, comprometan el vaso lesionado. Luego el sistema introductor y la guía son inmovilizados. A continuación, el volante en el conector "Y" se apaga, después de asegurarse de que el stent se despliega correctamente, la liberación ha iniciado.

Para liberar el stent es necesario sostener el tubo de acero con una mano de tal manera que la marca simple y la doble permanezcan a la vista.

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Mano de la maravilla
MANO MARAVILLA
SOCIO GERENTE

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ATENCIÓN: Hay que recordar que esta porción del sistema deberá permanecer inmóvil durante la implantación.

Luego, con la otra mano, la parte móvil comienza a deslizarse viendo su posicionamiento.

NOTA: Si aparece una dificultad al liberar el stent, es necesario dejar la guía en el lugar, y remover el stent completo del sistema vascular, y luego hacer otro intento con un nuevo stent.

Durante la implantación del stent es posible corregir la posición del stent cuando está parcialmente expandido en el vaso. El sistema introductor permite la re-introducción del stent dentro de la parte móvil. Esto es posible cuando no más de la mitad del stent ha sido expandido (Figuras 3 y 4)

La información necesaria puede ser encontrada en la marca simple sobre el tubo de hierro que constituye la parte inmóvil durante la implantación del sistema introductor. La marca simple es el límite, con la cual, si se cruza, el stent no podrá plegarse nuevamente (Figura 3). La marca doble representa el lugar en dónde el stent está completamente liberado del sistema introductor y desplegado (Figura 5)

En las figuras 1, 2, 3, 4 y 5 está representadas las sucesivas etapas del stent.

Después de asegurarse que el stent está completamente liberado, hay que tener cuidado al retirar el sistema introductor y la guía dejarla en posición en el sistema vascular, circunferencialmente del stent implantado.

Si se encuentra con que el stent no dilata lo suficiente, este puede ser ampliado con un balón, el cual puede ser introducido sobre la guía dejada.

El diámetro del balón no debe exceder el diámetro del stent.

ATENCIÓN: La guía no debe ser removida del vaso hasta que el procedimiento haya concluido!

➤ Tratamiento Anticoagulante

La preparación de un paciente para la colocación del stent y su gestión durante y después del procedimiento no son objeto de estas instrucciones. El método de tratamiento y la dosis de los medicamentos anticoagulantes dependen de los patrones establecidos en los procedimientos elaborados, y de la experiencia del centro médico dónde se realizan los procedimientos intravasculares.

3.3- Equipo y material requerido para la colocación del Stent:

- Introductor/es apropiado/s
- 2 - 3 jeringas de 10-20ml
- Solución salina estéril heparinizada
- Alambre guía apropiado
- Conector con válvula hemostática rotativa de diámetro adecuado.
- Medio de contraste diluido con solución salina 1:1
- Inyector de alta presión
- Válvula de 3 vías
- Soluciones antiplaquetarias y antitrombóticas adecuadas.

NOTA: Si bien el producto no incluye todos estos materiales, los mismos son necesarios para la colocación del insumo médico en cuestión.

**3.4- Efectiva colocación del Stent:**

Para confirmar la buena colocación del stent se debe inyectar medio de contraste a través del catéter guía y realizarse posteriormente una angiografía. El diámetro final del vaso debe corresponderse con el diámetro de referencia de pago.

3.5- Precauciones necesarias

Solamente los especialistas en Radiología, Intervenciones Cardiológicas o cirugía cardiovascular deben llevar a cabo los procedimientos que consisten en la implantación del stent con sistema introductor. Tales procedimientos pueden considerarse seguros cuando se utiliza un sistema de angiografía de alta calidad.

Los empaques que contienen los stent deben ser conservados en la oscuridad, en una habitación seca y a temperatura de ambiente.

El stent no puede ser usado luego de la fecha de vencimiento especificada en el empaque.

Los stent que despiertan alguna sospecha de que el empaque esté dañado no deben ser usados.

➤ Precauciones:

- La implantación del stent debe ser realizada sólo por médicos que hayan sido entrenados apropiadamente.
- La colocación del stent debe realizarse sólo en hospitales donde el procedimiento de revascularización quirúrgica de emergencia pueda llevarse a cabo rápidamente.
- La restenosis subsecuente en un vaso con stent puede requerir que se repita la dilatación del segmento arterial que contiene al stent.
- No puede implantarse stents hechos de metales diferentes.
- No exponer el sistema introductor a la acción de solventes orgánicos como alcoholes.
- Mantener en lugar fresco y seco.
- No exponer a temperaturas inferiores a 0°C o superiores a 40°C.

b) Precauciones Especiales:

Antes de tomar la decisión concerniente a la implantación del stent deben considerarse los potenciales riesgos y beneficios individualmente para cada paciente.

Los siguientes factores de riesgo deben considerarse especialmente:

- Riesgo del tratamiento antiplaquetario.
- Gastritis activa o úlcera gástrica
- Diabetes, falla renal, obesidad
- Ubicación del vaso, tamaño del vaso de referencia, longitud de la lesión.

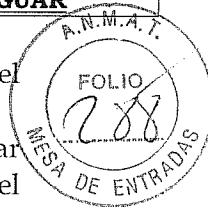
c) Precauciones en la manipulación del Stent:

- No extraer el stent del sistema introductor ya que al retirarlo puede dañarse y conducir luego a una trombosis.

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- No utilizar presión negativa en el catéter guía antes de colocar el stent en el lugar de la lesión ya que podría soltarse prematuramente del balón.
- El stent aferrado al balón debe manipularse con extremo cuidado para evitar posibles daños. Debe tenerse especial cuidado cuando se retira el catéter del envoltorio.
- Toda manipulación del stent situado en el balón puede hacer disminuir la adhesión del stent.
- Mezclar el medio de contraste sólo con solución salina
- No utilizar aire o cualquier otro medio gaseoso para inflar el balón.
- No expandir el stent a menos que se encuentre apropiadamente posicionado en el vaso.

➤ Contraindicaciones

- Flujo sanguíneo insatisfactorio por debajo de la posible ubicación del stent.
- Imposibilidad de pasar a través del sitio de la estenosis u ocleración con la guía o el catéter con el balón.
- Hipercoagulación en un paciente anémico.
- Riesgo de cerrar con un stent vasos del sistema circulatorio colateral
- Placas arterioescleróticas extremadamente calcificadas pueden dañar el stent.
- Presencia de nuevos trombos.
- Pacientes con contraindicaciones para tomar medicamentos antitrombóticos.
- Sangrado actual del tracto intestinal, accidente cerebro vascular reciente.
- Alergia al medio de contraste
- Alergia al nitinol

Posibles Complicaciones

- Punción del vaso
- Laminación del interior de la membrana del vaso.
- Espasmos
- Trombos en el stent recientemente implantado
- Trombosis periféricas
- Sangrado y hematomas en el lugar de inserción del sistema introductor.
- Falso aneurisma el lugar de inserción
- Migración del stent
- Reacción alérgica al medio de contraste o al nitinol

3.6- Riesgos de interferencia:

Para evitar la deformación o desplazamiento de un stent recientemente implantado debe tenerse extremo cuidado al pasar a través del mismo con cualquier otro instrumento como ser: sistema introductor, otro stent, balón, catéter intravascular de ultrasonido, alambre guía coronario, etc.

No realizar RNM en pacientes luego de la implantación de stent hasta que los mismos estén completamente recubiertos de endotelio (8 semanas), para minimizar un

AXIMPORT S.A.



INSTRUCCIONES DE USO

ANEXO III

A.N.M.A.T. - MESA DE ENTRADAS

Refollado N° STENT 202
AUTOEXPANDIBLE

JAGUAR A.N.M.A.T.



potencial desplazamiento. El stent puede provocar artefactos en RNM debido a la distorsión del campo magnético.

3.7- Esterilización:

No utilizar si el embalaje está abierto o dañado.

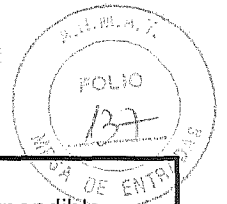
El STENT AUTOEXPANDIBLE está diseñado para ser usado una única vez. No puede esterilizarse y/o utilizarse nuevamente.

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M.N. 1340

7483



 AXIIMPORT S.R.L.	PROYECTO DE ROTULO Anexo III.B punto 2	Stent Autoexpandible JAGUAR
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2.1	Fabricante: BALTON Sp. zo. O. Nowy Swiat 7/14 00-496 Warszawa - Polonia	Importador: AXIIMPORT S.R.L. Alsina 1535 4to. Piso Capital Federal Tel: 4374-4482
2.2	STENT AUTOEXPANDIBLE	
2.3		
	Modelo: Ver envase Código: Ver en el envase	
2.4	ESTERIL, ATOXICO Y LIBRE DE APIROGENOS	
2.5	 Ver en el envase	 Ver en el envase
2.6	 PARA SER USADO SÓLO UNA VEZ	
2.7	TEMPERATURA COMPRENDIDA ENTRE 0° Y 40°C NO CONGELAR, NO HUMEDECER UTILIZAR INMEDIATAMENTE DESPUÉS DE ABRIR EL ENVASE PRIMARIO FRAGIL, MANEJAR CON CUIDADO NO UTILIZAR SI EL ENVASE NO ESTA ÍNTEGRO	
2.8		
2.9	   	
2.10	METODO DE ESTERILIZACIÓN: OE	
2.11	Director Técnico: Farm. Pablo Balduri MN 13402	
	Venta exclusiva a profesionales e instituciones sanitarias	
2.12	Autorizado por la ANMAT PM-646-44	


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Ministerio de Salud
**Secretaría de Políticas,
Regulación e Institutos**
A.N.M.A.T.

ANEXO III

CERTIFICADO

Expediente N°: 1-47-14170/10-7

El Administrador de la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que, mediante la Disposición N° **7483**, y de acuerdo a lo solicitado por AXIMPORT S.R.L, se autorizó 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: Stent auto-expandible con sistema de entrega "JAGUAR SM"

Código de identificación y nombre técnico UMDNS: 17-461 Endoprótesis (stents), vasculares

Marca de (los) producto(s) médico(s): BALTON

Clase de Riesgo: Clase III

Indicación/es autorizada/s: para uso en implantación intravascular percutánea en pacientes con lesiones ateroscleróticas, inducidas por radiación y lesiones postraumáticas que produzcan estenosis de los vasos, con una significancia hemodinámica importante e intratables con otro tipo de tratamiento. Indicado para uso en vasos periféricos.

Modelo/s: Modelos: JAGUAR, Código: ZNSJ

Período de vida útil: 2 años

Condición de expendio: venta exclusiva a profesionales e instituciones sanitarias

Nombre del fabricante: BALTON Sp.z.o.o,

Lugar/es de elaboración: 7 Nowy SEIT Street, apt. 14-00-496, Warsaw, Polonia

Se extiende a AXIMPORT SRL el Certificado PM-646-44, en la Ciudad de Buenos Aires, a **06 DIC 2013**, siendo su vigencia por cinco (5) años a contar de la fecha de su emisión.

DISPOSICIÓN N°

7 483


Dr. OTTO A. ORSINGER
Sub Administrador Nacional
A.N.M.A.T.