

SECRETARÍA DE SALUD

COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS COMISIÓN DE AUTORIZACIÓN SANITARIA DIRECCIÓN EJECUTIVA DE AUTORIZACIÓN DE PRODUCTOS Y ESTABLECIMIENTOS SUBDIRECCIÓN EJECUTIVA DE SERVICIOS DE SALUD Y DISPOSITIVOS MÉDICOS

MODIFICACIÓN DEL REGISTRO SANITARIO No.

981C94 SSA

No. DE SOLICITUD 113300402A0619

Con fundamento en los Artículos 4 párrafo cuarto, 8, 14 y 16 de la Constitución Política de los Estados Unidos Mexicanos; 39 de la Ley Orgánica de la Administración Pública Federal; 1, 3 y 16 fracción X, de la Ley Federal de Procedimiento Administrativo; 3 fracción XXV, 4 fracción III, 17 bis fracción IV, 194 fracción II, 194 bis, 197, 262, 368, 376, 376 Bis, 378, 380 y 393 de la Ley General de Salud; 1 y 2 inciso C fracción X del Reglamento Interior de la Secretaria de Salud, 1, 3 fracción I inciso b, VII, 4 fracción II inciso c y 14 fracción I del Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios; 1, 82, 83, 153, 157, 181, 184, 188 y 189, del Reglamento de Insumos para la Salud; con fundamento en lo dispuesto por el artículo décimo octavo del Acuerdo por el que se delegan las facultades que se señalan en los Órganos Administrativos que en el mismo se indican de la Comisión Federal para la Protección contra Riesgos Sanitarios, publicado en el Diario Oficial de la Federación el 7 de abril de 2010; así como los relativos y aplicables del Acuerdo por el que se dan a conocer los trámites y servicios, así como los formatos que aplica la Secretaria de Salud, a través de la Comisión Federal para la Protección contra Riesgos Sanitarios, inscritos en el Registro Federal de Trámites y Servicios de la Comisión Federal de Mejora Regulatoria; publicado el 28 de enero de 2011, en el Diario Oficial de la Federación; se otorga la presente Modificación al Registro Sanitario bajo las siguientes condiciones:

Titular del registro:

SJ Medical México, S. de R.L. de C.V.

Domicilio:

Avenida Rubén Darío 945-B, Colonia Prados de Providencia, Guadalajara, C.P. 44670, Jalisco, México.

R.F.C.

SMM0809235UA

CARACTERÍSTICAS DEL PRODUCTO.

Denominación Distintiva:

Catéteres Introductores y Accesorios.

Denominación Genérica:

Catéter para introducción de catéteres cardiovasculares.

Tipo de Insumo para la Salud Art. 262 LGS:

Material de Curación

Clasificación del Insumo para la Salud Art. 83 RIS:

Clase II

Fabricado por:

1. St. Jude Medical.

2. Lake Region Manufacturing, Company Limited (Guias Guideright).

Domicilio:

1. 14901 De Veau Place, Minnetonka, MN 55345-2126, U.S.A.

2. Butlerslan New Ross, Co. Wexford, Irlanda.

Fabricado para:

St. Jude Medical.

Domicilio:

14901 De Veau Place, Minnetonka, MN 55345-2126, U.S.A.

Distribuido por.

SJ Medical México, S, de R, L, de C, V.

Domicilio:

Avenida Rubén Darío 945-B. Colonia Prados de Providencia, Guadalajara, C.I.

44670, Jalisco, México.

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MÉRIDA TUCATÁN MÉXICO. C.P. 97158 TELITAX: 01(599)924-77 81 / 176 61-22 PFC: NIE-070528-4N6



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Indicaciones de uso:

Caléter introductor, dispositivo auxiliar para la introducción de caléteres cardiovasculares, incluyendo dispositivos para biopsia, dentro del sistema vascular / intra - cardiaco

Descripción:

Catéter introductor radiopaco con curva especial en la porción distal, con y sin válvula de hemóstasis, puerto con llave de paso, dilatador y accesorios. Estéril y Desechable.

Presentaciones:

Envase secundario colectivo conteniendo: 5 ó 10 empaques individuales estériles.

MODELO	DESCRIPCIÓN
407200	BRK Transseptal Needle
407202	BRK Transseptal Needle
407201	BRK-1 Transseptal Needle
407203	BRK-2 Transseptal Needle
407205	BRK-2 Transseptal Needle
406331	Fast-Cath Duo Hemostasis Introducer
406307	Fast-Cath Duo Hemostasis Introducer
406301	Fast-Cath Duo Hemostasis Introducer
406333	Fast-Cath Duo Hemostasis Introducer
406315	Fast-Cath Duo Transseptal Guiding Introducer
406316	Fast-Cath Duo Transseptal Guiding Introducer
406291	Fast-Cath Duo Transseptal Guiding Introducer
406292	Fast-Cath Duo Transseptal Guiding Introducer
406844	Fast-Cath Guiding Introducer
406845	Fast-Cath Guiding Introducer
406846	Fast-Cath Guiding Introducer
406847	Fast-Cath Guiding Introducer
407404	Fast-Cath Guiding Introducer
407405	Fast-Cath Guiding Introducer
407406	Fast-Cath Guiding Introducer
407407	Fast-Cath Guiding Introducer
407408	Fast-Cath Guiding Introducer
406840	Fast-Cath Guiding Introducer
406841	Fast-Cath Guiding Introducer
406842	Fast-Cath Guiding Introducer
406850	Fast-Cath Guiding Introducer
406851	Fast-Calh Guiding Infroducer
406871	Fast-Cath Guiding Introducer
406868	Fast-Calh Guiding Introducer
406885	Fast-Cath Guiding Introducer
406894	Fast-Cath Guiding Introducer
406848	Fast-Cath Guiding Introducer
406846	Fast-Cath Guiding Introducer
406853	Fast-Cath Guiding Introducer
406854	Fast-Cath Guiding Introducer
406855	Fast-Cath Guiding Introducer



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MODELO	DESCRIPCIÓN DESCRIPCIÓN				
406856	Fast-Cath Guiding Introducer				
406857	Fast-Cath Guiding Introducer				
406898	Fast-Cath Guiding Introducer				
406843	Fast-Cath Guiding Introducer, Swartz SL Transseptal Series 7.5F				
405849	Fast-Cath Guiding Introducer, Swartz SL Transseptal Series 8F				
406650	Fast-Cath Hemostasis Introducer				
406651	Fast-Cath Hemostasis Introducer				
406562	Fast-Cath Hemostasis Introducer				
406549	Fast-Cath Hemostasis Introducer				
406712	Fast-Cath Hemostasis Introducer				
406560	Fast-Cath Hemostasis Introducer 70cm Sheath 8F				
406134	Fast-Cath Hemostasis Introducer, 10.5F, 12 cm				
406577	Fast-Cath Hemostasis Introducer, 10.5F, 12 cm, with obturator 9F				
406183	Fast-Cath Hemostasis Introducer, 10.5F, 30 cm	Jr.			
406592	Fast-Cath Hemostasis Introducer, 10.5F, 30 cm, with obturator 9F				
406120	Fast-Cath Hemostasis Introducer, 10F, 12 cm				
406576	Fast-Cath Hemostasis Introducer, 10F, 12 cm, with obturator 9F				
406125	Fast-Cath Hemostasis Introducer, 10F, 23 cm, no GW				
406180	Fast-Cath Hemostasis Introducer, 10F, 30 cm				
406591	Fast-Cath Hemostasis Introducer, 10F, 30 cm, with obturator 9F				
406599	Fast-Cath Hemostasis Introducer, 10F, 40 cm				
406124	Fast-Cath Hemostasis Introducer, 11F, 12 cm				
406578	Fast-Cath Hemostasis Introducer, 11F, 12 cm, with obturator 10F				
406182	Fast-Cath Hemostasis Infroducer, 11F, 30 cm				
406593	Fast-Cath Hemostasis Introducer, 11F, 30 cm, with obturator 10F				
406556	Fast-Cath Hemostasis Introducer, 11F, 75 cm				
406128	Fast-Cath Hemostasis Introducer, 12F, 12 cm				
406579	Fast-Cath Hemostasis Introducer, 12F, 12 cm, with obturator 11F				
406184	Fast-Cath Hemostasis Introducer, 12F, 30 cm				
406594	Fast-Cath Hemostasis Introducer, 12F, 30 cm, with obturator 11F				
406557	Fast-Cath Hemostasis Introducer, 12F, 75 cm				
406132	Fast-Cath Hemostasis Introducer, 13F, 12 cm				
406580	Fast-Cath Hemostasis Introducer, 13F, 12 cm, with obturator 12F				
406186	Fast-Cath Hemostasis Introducer, 13F, 30 cm				
406595	Fast-Cath Hemostasis Introducer, 13F, 30 cm, with obturator 12F				
406581	Fast-Cath Hemostasis Introducer, 14F, 12 cm, with obturator 13F				
406188	Fast-Cath Hemostasis Introducer, 14F, 30 cm				
406596	Fast-Cath Hemostasis Introducer, 14F, 30 cm, with obturator 13F				
406397	Fast-Cath Hemostasis Introducer, 4.5F, 12 cm, small GW				
406709	Fast-Cath Hemostasis Introducer, 4F, 12 cm, Cath-Lock				
406115	Fast-Cath Hemostasis Introducer, 4F, 12 cm, small GW				
406159	Fast-Cath Hemostasis Introducer, 4F, 5 cm				
406540	Fast-Cath Hemostasis Introducer, 4F, 8.5 cm				
406151	Fast-Cath Hemostasis Introducer, 5.5F, 12 cm	K			
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MODELO	DESCRIPCION
406703	Fast-Cath Hemostasis Introducer, 5.5F, 12 cm, Cath-Lock
406202	Fast-Cath Hemostasis Introducer, 5.5F, 12 cm, no GW
406100	Fast-Cath Hemostasis Introducer, 5F, 12 cm
406541	Fast-Cath Hemostasis Introducer, 5F, 12 cm
406700	Fast-Cath Hemostasis Introducer, 5F, 12 cm, Cath-Lock
406240	Fast-Cath Hemostasis Introducer, 5F, 12 cm, Luer-Lock
406200	Fast-Cath Hernostasis Introducer, 5F, 12 cm, no GW
406101	Fast-Cath Hemostasis Introducer, 5F, 12 cm, small GW
406138	Fast-Cath Hemostasis Introducer, 5F, 23 cm
406130	Fast-Cath Hemostasis Introducer, 5F, 23 cm, no GW
406195	Fast-Cath Hemostasis Introducer, 5F, 23 cm, with obturator 4F
406163	Fast-Cath Hemostasis Introducer, 5F, 5 cm
406542	Fast-Cath Hemostasis Introducer, 5F, 8.5 cm
406754	Fast-Catin Hemostasis Introducer, 6.5F, 110 cm, straight tip
406153	Fast-Cath Hemostasis Introducer, 6.5F, 12 cm
406206	Fast-Cath Hemostasis Introducer, 6.5F, 12 cm, no GW
406585	Fast-Cath Hemostasis Introducer, 6.5F, 12 cm, with obturator 5F
406744	Fast-Cath Hemostasis Introducer, 6.5F, 45 cm, 30 degrees
406104	Fast-Cath Hemostasis Introducer, 6F, 12 cm
406543	Fast-Cath Hemostasis Introducer, 6F, 12 cm
406701	Fast-Cath Hemostasis Introducer, 6F, 12 cm, Cath-Lock
406242	Fast-Cath Hemostasis Introducer, 6F, 12 cm, Luer-Lock
406204	Fast-Cath Hemostasis Introducer, 6F, 12 cm, no GW
406105	Fast-Cath Hemostasis Introducer, 6F, 12 cm, small GW
406103	Fast-Cath Hemostasis Introducer, 6F, 12 cm, with accessories
406110	Fast-Cath Hemostasis Introducer, 6F, 12 cm, with accessories, small GW
406584	Fast-Cath Hemostasis Introducer, 6F, 12 cm, with obturator 5F
406139	Fast-Cath Hemostasis Introducer, 6F, 23 cm
406724	Fast-Cath Hemostasis Introducer, 6F, 23 cm
406131	Fast-Cath Hemostasis Introducer, 6F, 23 cm, no GW
406197	Fast-Cath Hemostasis Introducer, 6F, 23 cm, with obturator 5F
406568	Fast-Cath Hemostasis Introducer, 6F, 40 cm
406784	Fast-Cath Hemostasis Introducer, 6F, 40 cm, 60 degrees
406743	Fast-Cath Hemostasis Introducer, 6F, 45 cm, 30 degrees
406165	Fast-Cath Hemostasis Introducer, 6F, 5 cm
406544	Fast-Cath Hemostasis Introducer, 6F, 8.5 cm
406567	Fast-Cath Hemostasis Introducer, 6F, 90 cm
406564	Fast-Cath Hemostasis Introducer, 7.5F, 110 cm, 48 degrees
406119	Fast-Cath Hemostasis Introducer, 7.5F, 12 cm
406705	Fast-Cath Hemostasis Introducer, 7.5F, 12 cm, Cath-Lock
406203	Fast-Calh Hemostasis Introducer, 7.5F, 12 cm, no GW
406571	Fast-Cath Hemostasis Introducer, 7.5F, 12 cm, with obturator 6F
406141	Fast-Cath Hemostasis Introducer, 7.5F, 23 cm
406127	Fast-Cath Hemostasis Introducer, 7.5F, 23 cm, no GW



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406191	DESCRIPCIÓN Facil Caih Hamadagia Introducar, 7.65, 23 am, with obturator 65
406561	Fast-Cath Hemostasis Introducer, 7.5F, 23 cm, with obturator 6F
406108	Fast-Cath Hemostasis Introducer, 7.5F, 90 cm
406545	Fast-Cath Hemostasis Introducer, 7F, 12 cm
406702	Fast-Cath Hemostasis Introducer, 7F, 12 cm
	Fast-Cath Hemostasis Introducer, 7F, 12 cm, Cath-Lock
406244	Fast-Cath Hemostasis Introducer, 7F, 12 cm, Luer-Lock
406208	Fast-Cath Hemostasis Introducer, 7F, 12 cm, no GW
406109	Fast-Cath Hemostasis Introducer, 7F, 12 cm, small GW
406107	Fast-Cath Hemostasis Introducer, 7F, 12 cm, with accessories
406111	Fast-Cath Hemostasis Introducer, 7F, 12 cm, with accessories, small GW
406570	Fast-Cath Hemostasis Introducer, 7F, 12 cm, with obturator 6F
406725	Fast-Cath Hemostasis Introducer, 7F, 23 cm
406140	Fast-Cath Hemostasis Introducer, 7F, 23 cm
406113	Fast-Cath Hemostasis Introducer, 7F, 23 cm, no GW
406190	Fast-Cath Hemostasis Introducer, 7F, 23 cm, with obturator 6F
406597	Fast-Cath Hemostasis Introducer, 7F, 40 cm
406783	Fast-Cath Hemostasis Introducer, 7F, 40 cm, 60 degrees
406772	Fast-Cath Hemostasis Introducer, 7F, 40 cm, GSPC
406742	Fast-Cath-Hemostasis Introducer, 7F, 45 cm, 30 degrees
406546	Fast-Cath Hemostasis Introducer, 7F, 8.5 cm
406764	Fast-Cath Hemostasis Introducer, 7F, 85 cm, 5 cm J tip
406765	Fast-Cath Hemostasis Introducer, 7F, 85 cm, 7 cm J tip
406787	Fast-Cath Hemostasis Introducer, 7F, 85 cm, GSPC
406773	Fast-Cath Hemostasis Introducer, 7F, 98 cm, 40 degrees
406707	Fast-Cath Hemostasis Introducer, 8.5F, 12 cm, Cath-Lock
406207	Fast-Cath Hemostasis Introducer, 8.5F, 12 cm, no GW
406137	Fast-Cath Hemostasis Introducer, 8.5F, 12 cm, with accessories
406573	Fast-Cath Hemostasis Introducer, 8.5F, 12 cm, with obturator 7F
406143	Fast-Cath Hemostasis Introducer, 8.5F, 23 cm
406129	Fast-Cath Hemostasis Introducer, 8.5F, 23 cm, no GW
406193	Fast-Cath Hemostasis Introducer, 8.5F, 23 cm, with obturator 7F
406714	Fast-Cath Hemostasis Introducer, 8F 35cm 135° Curve
406774	Fast-Cath Hemostasis Introducer, 8F 98cm 40° Curve (w/Curved Dilator)
406112	Fast-Cath Hemostasis Introducer, 8F, 12 cm
406706	Fast-Cath Hemostasis Introducer, 8F, 12 cm, Cath-Lock
406246	Fast-Cath Hemostasis Introducer, 8F, 12 cm, Luer-Lock
406212	Fast-Cath Hemostasis Introducer, 8F, 12 cm, no GW
406114	Fast-Cath Hemostasis Introducer, 8F, 12 cm, with accessories
406572	Fast-Cath Hemostasis Introducer, 8F, 12 cm, with obturator 7F
406726	Fast-Cath Hemostasis Introducer, 8F, 23 cm
406142	Fast-Cath Hemostasis Introducer, 8F, 23 cm
406117	Fast-Cath Hemostasis Introducer, 8F, 23 cm, no GW
406192	Fast-Cath Hemostasis Introducer, 8F, 23 cm, with obturator 7F
406598	Fast-Cath Hemostasis Introducer, 8F, 40 cm

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MODELO	DESCRIPCIÓN	
406768	Fast-Cath Hemostasis Introducer, 8F, 45 cm, 30 degrees	
406740	Fast-Cath Hemostasis Introducer, 8F, 85 cm, 5 cm J tip	
406741	Fast-Cath Hemostasis Introducer, 8F, 85 cm, 7 cm J tip	
406133	Fast-Cath Hemostasis Introducer, 9.5F, 12 cm	
406575	Fast-Cath Hemostasis Introducer, 9.5F, 12 cm, with obturator 8F	
406181	Fast-Cath Hemostasis Introducer, 9.5F, 30 cm	
406590	Fast-Cath Hemostasis Introducer, 9.5F, 30 cm, with obturator 8F	
406116	Fast-Cath Hemostasis Introducer, 9F, 12 cm	
406708	Fast-Cath Hemostasis Introducer, 9F, 12 cm, Cath-Lock	
406248	Fast-Cath Hemostasis Introducer, 9F, 12 cm, Luer-Lock	
406216	Fast-Cath Hemostasis Introducer, 9F, 12 cm, no GW	
406118	Fast-Cath Hemostasis Introducer, 9F, 12 cm, with accessories	
406574	Fast-Cath Hemostasis Introducer, 9F, 12 cm, with obturator 8F	
406144	Fast-Cath Hemostasis Introducer, 9F, 23 cm	
406121	Fast-Cath Hemostasis Introducer, 9F, 23 cm, no GW	
406194	Fast-Cath Hemostasis Introducer, 9F, 23 cm, with obturator 8F	
406530	Fast-Cath Hemostasis Introducer, Set 4F .021 G.W.	
406532	Fast-Cath Hemostasis Introducer, Set 5F .021 G.W.	
406534	Fast-Cath Hemostasis Introducer, Set 6F .021 G.W.	
406536	Fast-Cath Hemostasis Infroducer, Set 7F .025 G.W.	
406160	Fast-Cath Hemostasis Introducer, Wysham, 4F, 5 cm	
406164	Fast-Cath Hemostasis Introducer, Wysham, 6F, 5 cm	
406168	Fast-Cath Hemostasis Introducer, Wysham, 7F, 5 cm	
406170	Fast-Cath Hemostasis Introducer, Wysham, 8F, 5 cm	
406852	Fast-Cath Transseptal Guiding Introducer	i
407400	Fast-Cath Transseptal Guiding Introducer	!
407401	Fast-Cath Transseptal Guiding Introducer	
407402	Fast-Cath Transseptal Guiding Introducer	
407403	Fast-Cath Transseptal Guiding Introducer	
406876	Fast-Cath Transseptal Guiding Introducer	
406877	Fast-Cath Transseptal Guiding Introducer	
406878	Fast-Cath Transseptal Guiding Introducer	
406879	Fast-Cath Transseptal Guiding Introducer	
406800	Fast-Cath Transseptal Guiding Introducer	
406801	Fast-Cath Transseptal Guiding Introducer	
406802	Fast-Cath Transseptal Guiding Introducer	
406803	Fast-Cath Transseptal Guiding Introducer	
406553	Fast-Cath Transseptal Guiding Introducer	
406804	Fast-Cath Transseptal Guiding Introducer	
406805	Fast-Cath Transceptal Guiding Introducer	
406901	Fast-Cath Transseptal Guiding Introducer	
406308	Fast-Cath Trio Hemostasis Introducer	
406306	Fast-Cath Trio Hemostasis Introducer	
406303	Fast-Cath Trio Hemostasis Introducer	



MODELO	DESCRIPCIÓN
406335	Fast-Cath Trio Hemostasis Introducer
404556	GuideRight Guidewires
405041	GuideRight Guidewires
404558	GuideRight Guidewires
404842	GuideRight Guidewires
404845	GuideRight Guidewires
404871	GuideRight Guidewires
404872	GuideRight Guidewires
404875	GuideRight Guidewires
404614	GuideRight Guidewires
405024	GuideRight Guidewires
405040	GuideRight Guidewires
405023	GuideRight Guidewires
405014	GuideRight Guidewires - Heparin
405015	GuideRight Guidewires - Heparin /
405017	GuideRight GuideWires - Hepzrin /
405018	GuideRight Guidewires - Heparin
405016	GuideRight Guidewires - Heparin
405020	GuideRight Guidewires - Heparin
405021	GuideRight Guidewires - Heparin
405022	GuideRight Guidewires - Heparin
404550	GuideRight Guidewires, 50 cm, double distal J
404551	GuideRight Guidewires, 50 cm, double distal J
404552	GuideRight Guidewires, 50 cm, double distal J
404559	GuideRight Guidewires, 50 cm, double distal J
404553	GuideRight Guidewires, 50 cm, double distal J
404554	GuideRight Guidewires, 50 cm, double distal J
404613	GuldeRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404579	GuideRight Guidewires, PTFE coaled, fixed core, 180 cm, J tip
404555	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, double distal: J and
404CE7	straight ends
404557	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, double distal: J and
404584	straight ends GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404568	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404583	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404569	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404509	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404570	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404573	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404578	GuideRight Guidewires, PTFE coated, fixed core, 130 cm, 3 lip
404574	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404575	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404575	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
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MODELO	DESCRIPCION Cuida Diabt Cuida viica DTEE agreed fixed agree 150 agree 140 a
404610	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404612	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404615	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404582	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, J tip
404846	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
404847	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
404840	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
404841	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
404870	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
404873	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
404571	GuideRight Guidewires, PTFE coated, fixed core, 180 cm, J tip
404576	GuideRight Guidewires, PTFE coated, fixed core, 180 cm, J tip
404611	GuideRight Guidewires, PTFE coated, fixed core, 180 cm, J fip
404616	GuideRight Guidewires, PTFE coated, fixed core, 180 cm, J tip
404878	GuideRight Guidewires, PTFE coated, fixed core, 260 cm, J tip
404577	GuideRight Guidewires, PTFE coated, fixed core, 260 cm, J tip
404617	GuideRight Guidewires, PTFE coated, fixed core, 260 cm, J tip
404844	GuideRight Guidewires, PTFE coated, fixed core, 260 cm, straight tip
404874	GuideRight Guidewires, PTFE coated, fixed core, 260 cm, straight tip
404581	GuideRight Guidewires, PTFE coated, ixed core, 150 cm, J tip
404948	GuideRight Guidewires, PTFE coated, movable core, 150 cm, J tip
404949	GuideRight Guidewires, PTFE coated, movable core, 150 cm, J tip
404968	GuideRight Guidewires, PTFE coated, movable core, 150 cm, J tip
404969	GuideRight Guidewires, PTFE coated, movable core, 150 cm, J tip
404998	GuideRight Guidewires, PTFE coated, movable core, 150 cm, straight tip
404999	GuideRight Guidewires, PTFE coated, movable core, 150 cm, straight tip
405012	GuideRight Guidewires, PTFE coated, movable core, 150 cm, straight tip
405013	GuideRight Guidewires, PTFE coated, movable core, 150 cm, straight tip
405050	GuideRight Guidewires, PTFE coated, steerable, 150 cm, modified J tip
405051	GuideRight Guidewires, PTFE coated, steerable, 150 cm, straight tip
405052	GuideRight Guidewires, PTFE coated, steerable, 150 cm, straight tip
404560	GuideRight Guidewires, PTFE coaled, super stiff fixed core, 180 cm, J tip
404877	GuideRight Guidewires, PTFE coated, super stiff fixed core, 180 cm, straight tip
404876	GuideRight Guidewires, PTFE coated, super stiff fixed core, 260 cm, straight tip
404848	GuideRight Guidewires, PTFE coated, fixed core, 150 cm, straight tip
406404	Hemostasis Valve Adapter
406300	Hemostasis Valve Adapter
406304	Hemostasis Valve Adapter, Cath-Lock
406302	Hemostasis Valve Adapter, Luer-Lock
406261	Maximum Hemostasis Introducer
406345	Maximum Hemostasis Introducer
406346	Maximum Hemostasis Introducer
406254	Maximum Hemostasis Introducer
406662	Maximum Hemostasis Introducer



MODELO	DESCRIPCIÓN	
406664	Maximum Hemostasis Iniroducer	<u> </u>
406369	Maximum Hemostasis Introducer	
406666	Maximum Hemostasis Introducer	
406259	Maximum Hemostasis Introducer, 4F, 12 cm	
406351		
406255	Maximum Hemostasis Introducer, 4F, 5 cm Maximum Hemostasis Introducer, 4F, 8.5 cm	
406359	Maximum Hemostasis Introducer, 4F, 6.5 cm	
406250	Maximum Hemostasis Introducer, 4F-ACT, 12 cm	
406652	Maximum Hemostasis Introducer, 5F, 12 cm, with needle	
406660	Maximum Hemostasis Introducer, 5F, 23 cm	
406656	Maximum Hemostasis Introducer, 5F, 23 cm, with needle	
406353	Maximum Hemostasis Introducer, 5F, 5 cm	
406256	Maximum Hemostasis Introducer, 5F, 8.5 cm	
406357	Maximum Hemostasis Introducer, 5F, 6.5 cm	
406669 -	Maximum Hemostasis Introducer, 5F-ACT, 23 cm	
406251	Maximum Hemostasis Introducer, 6F, 12 cm	
408661	Maximum Hemostasis Introducer, 6F, 23 cm	
406657	Maximum Hemostasis Introducer, 6F, 23 cm, with needle	
406355	Maximum Hemostasis Introducer, 6F, 5 cm	
406257	Maximum Hemostasis Introducer, 6F, 8.5 cm	
406361	Maximum Hemostasis Introducer, 6F-ACT, 12 cm	
406371	Maximum Hemostasis Introducer, 6F-ACT, 23 cm	
406252	Maximum Hemostasis Introducer, 7F, 12 cm	
406667	Maximum Hemostasis Introducer, 7F, 12 cm, with needle	
406663	Maximum Hemostasis Introducer, 7F, 23 cm	
406668	Maximum Hemostasis Introducer, 7F, 23 cm, with needle	
406258	Maximum Hemostasis Introducer, 7F, 8.5 cm	
406363	Maximum Hemoslasis Introducer, 7F-ACT, 12 cm	
406373	Maximum Hemostasis Introducer, 7F-ACT, 23 cm	
406665	Maximum Hemostasis Introducer, 8F, 23 cm	
406375	Maximum Hemostasis Introducer, 8F-ACT, 23 cm	
406347	Maximum Hemostasis Introducer, 9F, 12 cm	
406684	Maximum Xtra Hemostasis Introducer, 4F, 12 cm	
406690	Maximum Xtra Hemostasis Introducer, 5.5F, 12 cm	
406681	Maximum Xtra Hemostasis Introducer, 5F, 12 cm	
406685	Maximum Xtra Hemostasis Introducer, 6.5F, 12 cm	
406682	Maximum Xtra Hemostasis Introducer, 6F, 12 cm	
406686	Maximum Xtra Hemostasis Introducer, 7.5F, 12 cm	· 1:
406688	Maximum Xtra Hemostasis Introducer, 8.5F, 12 cm	
406687	Maximum Xtra Hemostasis Introducer, 8F, 12 cm	
406689	Maximum Xtra Hemostasis Introducer, 9F, 12 cm	
404210	Perculaneous Catheter Introducer 8F .038 G.W	
404212	Percutaneous Catheter Introducer, 9F .038 G.W.	MACHANI
404214	Percutaneous Catheter Introducer, 4F .025 G.W.	<u> </u>
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MODELO	DESCRIPCIÓN
404114	· · · · · · · · · · · · · · · · · · ·
404115	Percutaneous Catheter Introducer, 4F, 12 cm, small GW
404113	Percutaneous Catheter Introducer, 4F, 8.5 cm
	Perculaneous Catheter Introducer, 5F .032 G.W.
404200	Perculaneous Catheter Introducer, 5F .038 G.W.
404100	Percutaneous Catheter Introducer, 5F, 12 cm
404101	Percutaneous Catheter Introducer, 5F, 12 cm, small GW
404116	Percutaneous Catheter Introducer, 5F, 8.5 cm
404205	Percutaneous Catheter Introducer, 6F .032 G.W.
404204	Percutaneous Catheter Introducer, 6F .038 G.W.
404104	Percutaneous Catheter Introducer, 6F, 12 cm
404105	Percutaneous Catheter Introducer, 6F, 12 cm, small GW
404117	Perculaneous Calheler Infroducer, 6F, 8.5 cm
404209	Percutaneous Catheter Introducer, 7F .032 G.W.
404208	Percutaneous Catheter Introducer, 7F .038 G.W.
404112	Percutaneous Catheter Introducer, 7F, 12 cm
404109	Percutaneous Catheter Introducer, 7F, 12 cm, small GW
404118	Percutaneous Catheter Introducer, 7F, 8.5 cm
404108	Percutaneous Catheter Introducer, 8F, 12 cm
404110	Percutaneous Catheter Introducer, 9F, 12 cm
406505	Repositioning Sleeve , 60 cm, Luer-Lock
406500	Repositioning Sleeve, 30 cm
406504	Repositioning Sleeve, 30 cm, Luer-Lock
406502	Repositioning Sleeve, 30 cm, Luer-Lock and Cath-Lock adapter
406501	Repositioning Sleeve, 60 cm
406503	Repositioning Sleeve, 60 cm, Luer-Lock and Cath-Lock adapter
407517	Seal-Away CS Introducer Kit
407518	Seal-Away CS Introducer Kit
407500	Seal-Away Introducer kit
407501	Seal-Away Introducer kit
407502	Seal-Away Introducer kit
407503	Seal-Away Introducer kit
407504	Seal-Away Introducer kit
407505	Seal-Away Introducer kit
407506	Seal-Away Introducer kit
407507	Seal-Away Introducer kit 14cm Sheath, 12F
406317	Sheath obturator
406320	Sheath obturator \
406322	Sheath obturator
406422	Sheath Obturator, 10F, 15 cm, Snap-Lock
406426	Sheath Obturator, 11F, 15 cm, Snap-Lock
406427	Sheath Obturator, 12F, 15 cm, Snap-Lock
406428	Sheath Obturator, 13F, 15 cm, Snap-Lock
406324	Sheath Obturator, 26CM 8F
406310	Sheath Obturator, 4F, 15 cm, Luer-Lock



MODELO	DESCRIPCIÓN		
406401	Sheath Obturator, 4F, 15 cm, Snap-Lock		
406419	Sheath Obturator, 4F, 26 cm, Snap-Lock		
406318	Sheath Obturator, 5F		
406309	Sheath Obturator, 5F, 15 cm, Luer-Lock		
406403	Sheath Obturator, 5F, 15 cm, Snap-Lock		
406402	Sheath Obturator, 5F, 26 cm, Snap-Lock		
406311	Sheath Obturator, 6F, 15 cm, Luer-Lock		
406405	Sheath Oblurator, 6F, 15 cm, Snap-Lock		
406312	Sheath Obturator, 7F, 15 cm, Luer-Lock		
406407	Sheath Oblurator, 7F, 15 cm, Snap-Lock		
406413	Sheath Oblurator, 7F, 26 cm, Snap-Lock		
406314	Sheath Obturator, 8F, 15 cm, Luer-Lock		
406411	Sheath Oblurator, 8F, 15 cm, Snap-Lock		
406420	Sheath Obturator, 8F, 15 cm, Snap-Lock		
406415	Sheath Obturator, 8F, 26 cm, Snap-Lock		
406326	Sheath Obturator, 9F		
406313	Sheath Obturator, 9F, 15 cm, Luer-Lock		
406409	Sheath Obturator, 9F, 15 cm, Snap-Lock		
406421	Sheath Obturator, 9F, 15 cm, Snap-Lock		
406417	Sheath Obturator, 9F, 26 cm, Snap-Lock		
406425	Sheath Obturator, Snap-Fit 10F		
406429	Sheath Obturator, Snap-Fit 11F		
406430	Sheath Obturator, Snap-Fit 12F		
406431	Sheath Obturator, Snap-Fit 13F		
406423	Sheath Obturator, Snap-Fit 8F		
406432	Shealh Oblurator, Snap-Fit 9F		
406424	Shealh Obturator, Snap-Fit 9F		
407900	Sistema introductor atrial izquierdo		
407901	Sistema introductor atrial izquierdo		
406410	SJM Contamination Cover/ Protective cap		
405300	SJM Peel-Away Introducer		
405304	SJM Peel-Away Introducer		
405308	SJM Peel-Away Introducer		
405400	SJM Peel-Away Introducer		
405404	SJM Peel-Away introducer		
405408	SJM Peel-Away Introducer		
405412	SJM Peel-Away Introducer		
405416	SJM Peel-Away Introducer	{	
405418	SJM Peel-Away Introducer		
405420	SJM Peel-Away Introducer		
405422	SJM Peel-Away Introducer		
405424	SJM Peel-Away Introducer		
405428	SJM Peel-Away Introducer	 	
405432	SJM Peel-Away Introducer	<u> 178(dl</u>)	

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MODELO	DESCRIPCIÓN
405436	SJM Peel-Away Introducer
405440	SJM Peel-Away Introducer
405444	SJM Peel-Away Introducer
405100	SJM Peel-Away Introducer
405104	SJM Peel-Away Introducer
405108	SJM Peel-Away Introducer
405112	SJM Peel-Away Introducer
405116	SJM Peel-Away Introducer
405118	SJM Peel-Away Introducer
405120	SJM Peel-Away Introducer
405122	SJM Peel-Away Introducer
405124	SJM Peel-Away Introducer
405128	SJM Peel-Away Introducer
405132	SJM Peel-Away Introducer
405136	SJM Peel-Away Introducer
405140	SJM Peel-Away Introducer
405254	SJM Peel-Away Introducer
405256	SJM Peel-Away Introducer
405258	SJM Peel-Away Introducer .
405259	SJM Peel-Away Introducer
405261	SJM Peel-Away Introducer
404215	SJM Transseptal catheter introducer
404216	SJM Transseptal catheter introducer
404217	SJM Transseptal catheter introducer
404225	SJM Transseptal catheter introducer
404226	SJM Transseptal catheter introducer
404227	SJM Transseptal catheter introducer
405561	SJM Transseptal Vessel Dilator
405562	SJM Transseptal Vessel Dilator
407605	Ultimum Hemostasis Introducer
407606	Ultimum Hemostasis Introducer
407607	Ultimum Hemostasis Introducer
407608	Ultimum Hemostasis Introducer
407609	Ultimum Hemostasis Introducer
407610	Ultimum Hemostasis Introducer
407611	Ultimum Hemostasis Introducer
407612	Ultimum Hemostasis Introducer
407613	Ultimum Hemostasis Introducer
407614	Ultimum Hemostasis Introducer
407616	Ultimum Hemostasis Introducer
407617	Ultimum Hemostasis Introducer
407618	Ultimum Hemostasis Introducer
407619	Ultimum Hemostasis Introducer
407621	Ultimum Hemostasis Introducer
	



MODELO · DESCRIPCIÓN 407622 Ultimum Hemostasis Introducer 407623 Ultimum Hemoslasis Introducer 407624 Ultimum Hemostasis Introducer 407616 Ultimum Hemostasis Introducer 407625 Ultimum Hemostasis Introducer 407626 Ultimum Hemostasis Introducer 407627 Ultimum Hemostasis Introducer 407628 Ultimum Hemostasis Introducer 407629 Ultimum Hemostasis Introducer 407630 Ultimum Hemostasis Introducer 407632 Ultimum Hemostasis Introducer 407633 Ultimum Hemostasis Introducer 407634 Ultimum Hemostasis Introducer 407635 Ultimum Hemostasis Introducer 407620 Ultimum Hemostasis Introducer 407636 Ultimum Hemostasis Introducer 407840 Ultimum Hemostasis Introducer, 4F, 12 cm 407841 Ultimum Hemostasis Introducer, 4F-ACT, 12 cm 407842 Ultimum Hernostasis Introducer, 5F, 12 cm 407843 Ultimum Hemostasis Introducer, 5F-ACT, 12 cm 407844 Ultimum Hemostasis Introducer, 6F, 12 cm 407845 Ultimum Hemostasis Introducer, 6F-ACT, 12 cm Ultimum Hemostasis Introducer, 7F, 12 cm 407846 407847 Ultimum Hemostasis Introducer, 7F-ACT, 12 cm 407848 Ultimum Hemostasis Introducer, 8F, 12 cm 407849 Ultimum Hemostasis Introducer, 8F-ACT, 12 cm 407850 Ultimum Hemostasis Introducer, 9F, 12 cm 405510 Vessel dilator 405532 Vessel Dilator 13F .038 G.W. 405540 Vessel Dilator 15F .038 G.W. 405501 Vessel Dilator 4F .021 G.W. 405502 Vessel Dilator 4F .025 G.W. 405503 Vessel Dilator 5F .025 G.W. 405511 Vessel Dilator 5F .035 G.W. 405505 Vessel Dilator 6F .032 G.W. 405513 Vessel Dilator 6F .035 G.W. 405506 Vessel Dilator 7F .032 G.W. 405507 Vessel Dilator 7F .035 G.W. Vessel Dilator 8F .035 G.W. 405509 Vessel Dilator, 10F, 19 cm 405520 405524 Vessel Dilator, 11F, 19 cm 405528 Vessel Dilator, 12F, 19 cm Vessel Dilator, 14F, 19 cm 405536

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405544

Vessel Dilator, 16F, 19 cm



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MODELO	DESCRIPCIÓN
405545	Vessel Dilator, 4F, 15 cm
405546	Vessel Dilator, 5F, 15 cm
405500	Vessel Dilator, 5F, 19 cm
405547	Vessel Dilator, 6F, 15 cm
405504	Vessel Dilator, 6F, 19 cm
405548	Vessel Dilator, 7F, 15 cm
405508	Vessel Dilator, 7F, 19 cm
405512	Vessel Dilator, 8F, 19 cm
405516	Vessel Dilator, 9F, 19 cm
406872	Fast-Cath Guiding Introducer
406870	Fast-Cath Guiding Introducer
406102	Fast-Cath Hemostasis Introducer, 5F, 12 cm, with accessories
406123	Fast-Cath hemostasis Introducer, 8.5F, 12 cm.
406162	Fast-Cath Hemostasis Introducer, Wysham, 5F, 5 cm.
404618	Guide Right Guidewires, PTFE coated, fixed core, 150 cm. J tip.
404843	Guide Right Guidewires, PTFE coated, fixed core, 150 cm, straight tip.
406998	Luer Cap
406249	Maximum Hemostasis Introducer, 4F, 12 cm.
406653	Maximum Hemostasis Introducer, 6F, 12 cm, with needle.
406253	Maximum Hemostasis Introducer, 8F, 12 cm.
406683	Maximum Xtra Hemostasis Introducer, 7F, 12 cm.
404212	Perculaneous Catheter Introducer, 9F, .038 G.W.
405144	SJM Peel-Away Introducer
407615	Ultimum Hemostasis Introducer
407631	Ultimum Hemostasis Introducer 7
406136	Fast-Cath Hemostasis Introducer, 14F, 12 cm.

Empaque primario: Charola de PVC termoformado con tapa de Tyvek y Bolsa de Tyvek/Mylar. Empaque secundario: Caja de cartulina.

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3 años, consérvese a temperatura ambiente.

Publicidad dirigida a:

Profesionales de la Salud.

Fecha de prórroga del Registro Sanitario:

25 de mayo de 2011.



Fecha de emisión:

05 de octubre de 2012,

Fecha de vencimiento:

25 de mayo de 2016

SUFRAGIO EFECTIVO. NO REELECCIÓN SUBDIRECCIÓN EJECUTIVA DE SERVICIOS DE SALUD Y DISPOSITIVOS MÉDICOS

DULCE MARÍA MARTÍNEZ HERNÁNDEZ

OBSERVACIONES AL REGISTRO:

El presente Registro Sanitario es un documento auténtico expedido per el gobierno mexicano. Es un requisito indispensable pero no suficiente para la comercialización del producto autorizado, por lo que se expide sin interierir con disposiciones de otras depandencias.

La presente autorización será revocada ante cualquier alteración a las condiciones y términos en la que fue otorgada, sin perjuicio de las sanciones que en su caso

3, La importación, exportación, acondicionamiento, venta o suministro al público del producto autorizado deberá estar de acuerdo a las condiciones en las que se ha aprobado, por lo que el solicitante debera especificar cada proceso, señalando el lugar en el cual se lleven a cabo (Razón Social y domicilio).

Las presentaciones para el Sector Salud deberán sujetarse a las disposiciones emitidas por el Consejo de Salubridad General por lo que su autorización no es competencia de esta Comisión.

La información contenida en las etiquetas o contraetiquetas se deberá sujetar a lo establacido en la Ley General de Salud, en el Reglamento de Insumos para la Salud y las Normas Oficiales Mexicanas, deberá estar en idioma español y corresponder a lo autorizado en el presente documento.

El contenido de los manuales e instructivos de uso presentados ante esta Comisión, son responsabilidad del fabricante y del titular del Registro, deblendo cumplir con las disposiciones y reglamentación vigente.

Se otorga un plazo de 120 días para agotar la existencia de material de envase y producto terminado previo a lá presente autorización.

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NASAW AROMAN MEXICO, C.P. 87188 Sec. - N. 19 (979) 924-77-81 / 176-61-22

RTC 111E-070528-4116

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