[<< Atras]

Datos Generales del Producto

Expediente Sanitario	20089522	Nombre producto	RESOLUTE ONYX / STENT CORONARIO CON LIBERACIÓN DE ZOTAROLIMUS				
Registro Sanitario	INVIMA 2015DM-0013116	Vencimiento	2025/06/12	Modalidad	IMPORTAR Y VENDER	Estado Registro	Vigente
Observaciones	EL PRESENTE REGISTRO SANITARIO AMPARA LAS SIGUIENTES REFERENCIAS: RONYX45012XRONYX45015XRONYX45018XRONYX45022XRONYX45026XRONYX45030XRONYX50012XRONYX50015XRONYX50018XRONYX50022XRONYX50026XRONYX50030X RSINT22508X, RSINT22512X, RSINT22514X, RSINT22518X, RSINT22522X, RSINT22526X, RSINT22530X, RSINT25008X, RSINT25012X, RSINT25014X, RSINT25018X, RSINT25022X, RSINT25026X, RSINT25030X, RSINT27508X, RSINT27512X, RSINT27514X, RSINT27518X, RSINT27522X, RSINT27526X, RSINT27530X, RSINT30009X, RSINT30012X, RSINT30015X, RSINT30018X, RSINT30022X, RSINT30026X, RSINT30030X, RSINT30034X, RSINT30038X, RSINT35009X, RSINT35012X, RSINT35015X, RSINT35018X, RSINT35022X, RSINT35026X, RSINT35030X, RSINT35034X, RSINT35038X, RSINT40009X, RSINT40012X, RSINT40015X RSINT40018X, RSINT40022X, RSINT40026X, RSINT40030X, RSINT40034X, RSINT40038X, TRCR22508X,TRCR22512X, TRCR22515X, TRCR22518X, TRCR22522X, TRCR22526X, TRCR22530X, TRCR22534X, TRCR22538X, TRCR25008X, TRCR25012X, TRCR25015X, TRCR25018X, 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Marcas	ONYX, ONYX TRUCOR / STENT CORONARIO CON LIBERACIÓN DE ZOTAROLIMUS, ONYX TRUSTAR / STENT CORONARIO CON LIBERACIÓN DE ZOTAROLIMUS

Datos de Interes

Vida Util	3 AÑOS	Miembros Comprometidos	CORAZÓN
Usos	FIN PREVISTO EL STENT RESOLUTE ONYX ESTÁ DISEÑADO PARA AUMENTAR EL DIÁMETRO LUMINAL CORONARIO DE UNO O VARIOS VASOS COMO MEDIDA COMPLEMENTARIA EN LAS INTERVENCIONES CORONARIAS Y PARA REDUCIR LAS REESTENOSIS. EL STENT ESTÁ DISEÑADO PARA UTILIZARSE COMO DISPOSITIVO DE IMPLANTACIÓN PERMANENTE. INDICACIONES EL SISTEMA DE STENT RESOLUTE ONYX ESTÁ INDICADO PARA USO EN PACIENTES APTOS PARA ANGIOPLASTIA CORONARIA TRANSLUMINAL PERCUTÁNEA (ACTP) CON UN DIÁMETRO DE VASO DE REFERENCIA DE 2,0 MM A 5,0 MM. EL STENT RESOLUTE ONYX ESTÁ INDICADO PARA EL TRATAMIENTO DE LOS SIGUIENTES SUBCONJUNTOS DE PACIENTES Y LESIONES: • DIABETES MELLITUS • REESTENOSIS INTRASTENT (RIS) • ENFERMEDAD DE VARIOS VASOS • OCLUSIONES TOTALES CRÓNICAS (OTC) • SÍNDROME CORONARIO AGUDO (SCA) • OCLUSIONES TOTALES (OT) • INFARTO AGUDO DE MIOCARDIO (IAM) • ARTERIA CORONARIA PRINCIPAL IZQUIERDA (ACPI) • ANGINA INESTABLE (AI) • VASO PEQUEÑO (VP) • LESIONES EN BIFURCACIONES • UN MES DE TRATAMIENTO ANTIAGREGANTE PLAQUETARIO DOBLE (DAPT) EN PACIENTES CON ALTO RIESGO DE HEMORRAGIA (ARH), INCLUIDOS PACIENTES QUE NO TOLERAN UN DAPT PROLONGADO	Riesgo	III

Presentaciones Comerciales

Presentacion Comercial
CAJA DE CARTON CONTENIENDO EL SISTEMA DE STENT CORONARIO

Roles por Producto

Rol	Nombre / Razon Social	Direccion	Pais	Depto	Ciudad	Email
ACONDICIONADOR	BIOMEDICAL DISTRIBUTION COLOMBIA SL LTDA	Cra 47 N° 132-54	COLOMBIA	D.C.	BOGOTA	mariavictoriaussa@arunasesores.com
ACONDICIONADOR	BIOMEDICAL DISTRIBUTION COLOMBIA S.L. LTDA	KILOMETRO 1,5 VIA SIBERIA - TENJO BODEGAS 6,7,8,9 Y 10 TERMINALES LOGISTICOS DE COLOMBIA	COLOMBIA	CUNDINAMARCA	COTA	
FABRICANTE	MEDTRONIC IRELAND	Parkmore Business Park West, Galway, Irlanda	IRLANDA			ariasfajardo@registrosencolombia.com
FABRICANTE	MEDTRONIC INC.	710 MEDTRONIC PARKWAY - MN 55432, MINNEAPOLIS	ESTADOS UNIDOS DE AMÉRICA			
IMPORTADOR	MEDTRONIC LATINAMERICA INC SUCURSAL COLOMBIA	Calle 116 No. 7-15 Piso 10 OFC 1001	COLOMBIA	D.C.	BOGOTA	ariasfajardo@telecom.com.co
IMPORTADOR	MEDTRONIC COLOMBIA S.A	AVENIDA CALLE 116 NO. 7-15, PISO 11 OFICINA 1101	COLOMBIA	D.C.	BOGOTA	
TITULAR	MEDTRONIC INC.	710 MEDTRONIC PARKWAY - MN 55432, MINNEAPOLIS	ESTADOS UNIDOS DE AMÉRICA			

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