



República Argentina - Poder Ejecutivo Nacional

Año de la Grandeza Argentina

Certificado - Redacción libre

Número:

Referencia: 1-0047-3110-008912-25-5

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

Expediente N° 1-0047-3110-008912-25-5

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que de acuerdo con lo solicitado por Angiocor S.A. ; se autoriza la inscripción en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), de un nuevo producto con los siguientes datos identificatorios característicos:

DATOS IDENTIFICATORIOS CARACTERÍSTICOS

PM: 416-188

Nombre descriptivo: Sistema de injerto de stent torácico

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
15-784 Endoprotesis (stents)

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

Modelos:

Sistema de injerto de stent torácico

PTBS2222080, PTBS2424080, PTBS2626080, PTBS2828080, PTBS3030080, PTBS3232080, PTBS3434080,
PTBS3636080, PTBS3838080, PTBS4040080, PTBS4242080, PTBS4444080, PTBS4646080, PTBS2222150,

PTBS2424150, PTBS2626150, PTBS2828150, PTBS3030150, PTBS3232150, PTBS3434150, PTBS3636150, PTBS3838150, PTBS4040150, PTBS4242150, PTBS4444150, PTBS4646150, PTBS2222180, PTBS2424180, PTBS2626180, PTBS2828180, PTBS3030180, PTBS3232180, PTBS3434180, PTBS3636180, PTBS3838180, PTBS4040180, PTBS4242180, PTBS4444180, PTBS4646180, PTBS2222210, PTBS2424210, PTBS2626210, PTBS2828210, PTBS3030210, PTBS3232210, PTBS3434210, PTBS3636210, PTBS3838210, PTBS4040210, PTBS4242210, PTBS4444210, PTBS4646210, PTBS2222240, PTBS2424240, PTBS2626240, PTBS2828240, PTBS3030240, PTBS3232240, PTBS3434240, PTBS3636240, PTBS3838240, PTBS4040240, PTBS4242240, PTBS4444240, PTBS4646240

Sistema de injerto de stent torácico

PTBS2622150, PTBS2822150, PTBS2824150, PTBS3022150, PTBS3024150, PTBS3026150, PTBS3222150, PTBS3224150, PTBS3226150, PTBS3228150, PTBS3424150, PTBS3426150, PTBS3428150, PTBS3430150, PTBS3626150, PTBS3628150, PTBS3630150, PTBS3632150, PTBS3828150, PTBS3830150, PTBS3832150, PTBS3834150, PTBS4030150, PTBS4032150, PTBS4034150, PTBS4036150, PTBS4232150, PTBS4234150, PTBS4236150, PTBS4238150, PTBS4434150, PTBS4436150, PTBS4438150, PTBS4440150, PTBS4636150, PTBS4638150, PTBS4640150, PTBS4642150, PTBS2622180, PTBS2822180, PTBS2824180, PTBS3022180, PTBS3024180, PTBS3026180, PTBS3222180, PTBS3224180, PTBS3226180, PTBS3228180, PTBS3424180, PTBS3426180, PTBS3428180, PTBS3430180, PTBS3626180, PTBS3628180, PTBS3630180, PTBS3632180, PTBS3828180, PTBS3830180, PTBS3832180, PTBS3834180, PTBS4030180, PTBS4032180, PTBS4034180, PTBS4036180, PTBS4232180, PTBS4234180, PTBS4236180, PTBS4238180, PTBS4434180, PTBS4436180, PTBS4438180, PTBS4440180, PTBS4636180, PTBS4638180, PTBS4640180, PTBS4642180, PTBS2622210, PTBS2822210, PTBS2824210, PTBS3022210, PTBS3024210, PTBS3026210, PTBS3222210, PTBS3224210, PTBS3226210, PTBS3228210, PTBS3424210, PTBS3426210, PTBS3428210, PTBS3430210, PTBS3626210, PTBS3628210, PTBS3630210, PTBS3632210, PTBS3828210, PTBS3830210, PTBS3832210, PTBS3834210, PTBS4030210, PTBS4032210, PTBS4034210, PTBS4036210, PTBS4232210, PTBS4234210, PTBS4236210, PTBS4238210, PTBS4434210, PTBS4436210, PTBS4438210, PTBS4440210, PTBS4636210, PTBS4638210, PTBS4640210, PTBS4642210, PTBS2622240, PTBS2822240, PTBS2824240, PTBS3022240, PTBS3024240, PTBS3026240, PTBS3222240, PTBS3224240, PTBS3226240, PTBS3228240, PTBS3424240, PTBS3426240, PTBS3428240, PTBS3430240, PTBS3626240, PTBS3628240, PTBS3630240, PTBS3632240, PTBS3828240, PTBS3830240, PTBS3832240, PTBS3834240, PTBS4030240, PTBS4032240, PTBS4034240, PTBS4036240, PTBS4232240, PTBS4234240, PTBS4236240, PTBS4238240, PTBS4434240, PTBS4436240, PTBS4438240, PTBS4440240, PTBS4636240, PTBS4638240, PTBS4640240, PTBS4642240

Sistema de injerto de stent torácico

PTCW2222070, PTCW2424070, PTCW2626070, PTCW2828070, PTCW3030070, PTCW3232070, PTCW3434070, PTCW3636070, PTCW3838070, PTCW4040070, PTCW4242070, PTCW4444070, PTCW4646070, PTCW2222150, PTCW2424150, PTCW2626150, PTCW2828150, PTCW3030150, PTCW3232150, PTCW3434150, PTCW3636150, PTCW3838150, PTCW4040150, PTCW4242150, PTCW4444150, PTCW4646150, PTCW2222180, PTCW2424180, PTCW2626180, PTCW2828180, PTCW3030180, PTCW3232180, PTCW3434180, PTCW3636180, PTCW3838180, PTCW4040180, PTCW4242180, PTCW4444180, PTCW4646180, PTCW2222210, PTCW2424210, PTCW2626210, PTCW2828210, PTCW3030210, PTCW3232210, PTCW3434210, PTCW3636210, PTCW3838210, PTCW4040210, PTCW4242210, PTCW4444210, PTCW4646210, PTCW2222240, PTCW2424240, PTCW2626240, PTCW2828240, PTCW3030240, PTCW3232240, PTCW3434240, PTCW3636240, PTCW3838240, PTCW4040240, PTCW4242240, PTCW4444240, PTCW4646240

Sistema de injerto de stent torácico

PTCW2622150, PTCW2822150, PTCW2824150, PTCW3022150, PTCW3024150, PTCW3026150,
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PTCW4434240, PTCW4436240, PTCW4438240, PTCW4440240, PTCW4636240, PTCW4638240,
PTCW4640240, PTCW4642240

Clase de Riesgo: IV

Indicación/es autorizada/s:

El sistema de endoprótesis cubierta torácica Percutek está indicado para el tratamiento endovascular de pacientes con enfermedades de la aorta torácica descendente, incluidos, entre otros, aneurismas y disecciones, que presenten las siguientes condiciones.

- Abordaje ilíaco / femoral apropiado;
- Enfermedades de la aorta torácica descendente, y diámetro del cuello de 20-44 mm
- La longitud de la zona de aterrizaje proximal mayor o igual a 10 mm, sin calcificación significativa y / o trombosis significativa;
- Tener una morfología anatómica adecuada para la reparación endovascular.

Período de vida útil: 3 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Fuente de obtención de la materia prima de origen biológico: No corresponde.

Forma de presentación: -Sistema de endoprótesis torácica (1 sistema).

Método de esterilización: Óxido de etileno

Nombre del fabricante:

Beijing Percutec Therapeutics Inc.

Lugar de elaboración:

Room 401, Floor 4, Building 14, No. 26 Yongwang West Rd, Bioengineering & Medical Industry Base, Daxing District, Beijing, China

Se extiende el presente Certificado de Autorización e Inscripción del PM 416-188 , con una vigencia cinco (5) años a partir de la fecha de la Disposición autorizante.

Expediente 1-0047-3110-008912-25-5

Nº Identificador Trámite: 73563

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