VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM – ENDOPRÓTESIS VASCULAR DE AÓRTA TORÁCICA DESCENDIENTE

1. Información General



Producto (Según Registro Sanitario)	Valiant thoracic stent graft with the captivia delivery system – endoprótesis vascular de aórta torácica descendiente
Nombre Comercial	Valiant thoracic stent graft with the captivia delivery system
Marcas	Medtronic
Fabricante Legal	Medtronic Inc, USA
Número de Registro Sanitario	INVIMA 2019DM-0019255
Fecha de expiración del Registro Sanitario	21 de enero de 2029
Clasificación del riesgo	IIB
Código GMDN	48060

2. Especificaciones

Composición	**Stent Graft:** Nitinol, Poliester, Platino-iridio **Catéter de inserción:** Acrilonitrilo butadieno estireno, nylon, Acero inoxidable, policarbonato, Adhesivo Loctite, Copolímero de poliamida – polieter (PEBAX), Sulfato de bario, Polietetercetona, Polietileno de alta densidad, Caucho etileno propileno, Tungsteno, Lubricante de silicona, Recubrimiento Hidrofílico.
Presentación Comercial	Caja por 1 unidad
Condiciones de Almacenamiento	Debe almacenarse en un lugar fresco, seco y protegido de la luz.
Método de esterilización	Haz de electrones
Vida Útil	2 años
Referencias	

Referencias	Descripción
VAMC2222B100TE	Valiant thoracic stent graft with the captivia delivery system

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3. Descripción del Producto	
Indicaciones de Uso	Está diseñada para tratar enfermedades de la aorta torácica descendente, incluyendo, de modo no exhaustivo, aneurisma y disecciones, excluir el aneurisma, el falso lumen o punto de rotura y para restaurar el flujo sanguíneo mediante el lumen de la prótesis de stent.

DESCRIPCIÓN

La endoprótesis torácica Valiant con el sistema de liberación Captivia consta de los siguientes componentes: la endoprótesis torácica Valiant, el sistema de liberación Captivia.

Endoprótesis

La endoprótesis torácica Valiant está disponible en una amplia gama de configuraciones. La endoprótesis torácica Valiant es una endoprótesis tubular autoexpansible compuesta de un tejido de poliéster y de una estructura de stents elaborada con alambres de nitinol. La estructura metálica está constituida por una serie de ministents enrollados y apilados en una configuración tubular. Los stents están unidos al tejido de poliéster mediante suturas no reabsorbibles. Unas marcas radiopacas de platino-iridio que están cosidas al tejido permiten visualizar radiográficamente el borde del material de la endoprótesis y proporcionan una orientación con respecto a la distancia mínima de solapamiento necesaria cuando se utilizan varias endoprótesis. Las cuatro marcas proximales Figur8 (con forma de ocho) y las dos marcas distales Zer0 (con forma de cero) indican los extremos de la endoprótesis cubierta. Durante el proceso de fabricación, la endoprótesis torácica Valiant se precarga en el sistema de liberación Captivia.

La endoprótesis torácica Valiant es un dispositivo modular que permite utilizar secciones adicionales. Dependiendo de la configuración de la vasculatura, puede ser necesario utilizar un solo componente o varios componentes para lograr la cobertura suficiente (determinada por el médico). Cuando se utilizan varios componentes, tres marcas de alineación indican el solapamiento mínimo con la endoprótesis hermana (consulte la Figura 19 y la Figura 20). Con el fin de garantizar un solapamiento suficiente, las marcas Zer0 de la

endoprótesis proximal deben alinearse con la marca única (entre el tercer y cuarto stent cubierto) de la endoprótesis distal.

Sistema de liberación

El sistema de liberación Captivia consta de un catéter desechable de un solo uso con un mango integrado que permite al usuario realizar un despliegue controlado.

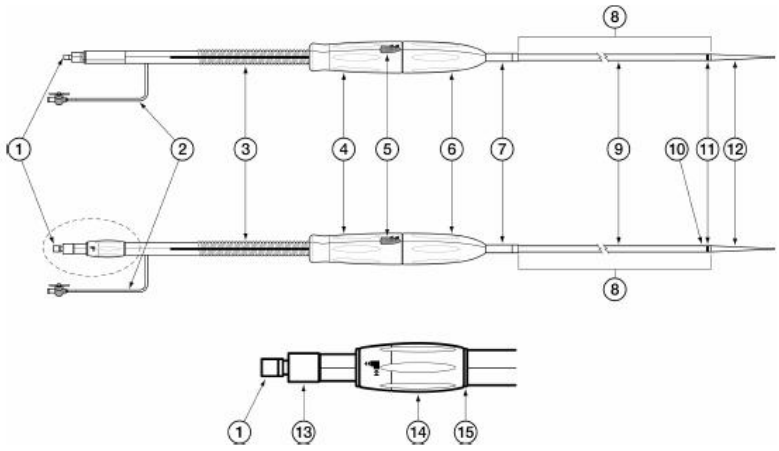


Figura 10. Sistema de liberación Captivia (sistema de liberación de endoprótesis Closed Web en la parte superior, sistema de liberación de endoprótesis FreeFlo en la parte inferior)

1. Conector lúer
2. Extensión de puerto lateral
3. Engranaje helicoidal
4. Deslizador/Mango
5. Activador
6. Empuñadura frontal
7. Protección contra tensiones
8. Cubierta de la endoprótesis (introductor)
9. Tope del stent
10. Mecanismo de captura de punta
11. Marca radiopaca
12. Punta cónica
13. Mecanismo de bloqueo posterior
14. Mango de liberación del mecanismo de captura de punta
15. Anillo de clampado

NOTA: PARA LA CORRECTA UTILIZACION DEL DISPOSITIVO POR FAVOR LEER EL INSERTO DEL PRODUCTO

Originado por: Nombre: Juliana Andrea Trujillo Cargo: Regulatory Affairs Specialist	Fecha: 10-Dec-19	Aprobado por: Nombre: Juan Bolaños Cargo: Regulatory Affairs Manager	Fecha: 10-Dec-19
Revisado por: Nombre: Andrea Romero Cargo: Sr. Market Dev Specialist	Fecha: 10-Dec-19		