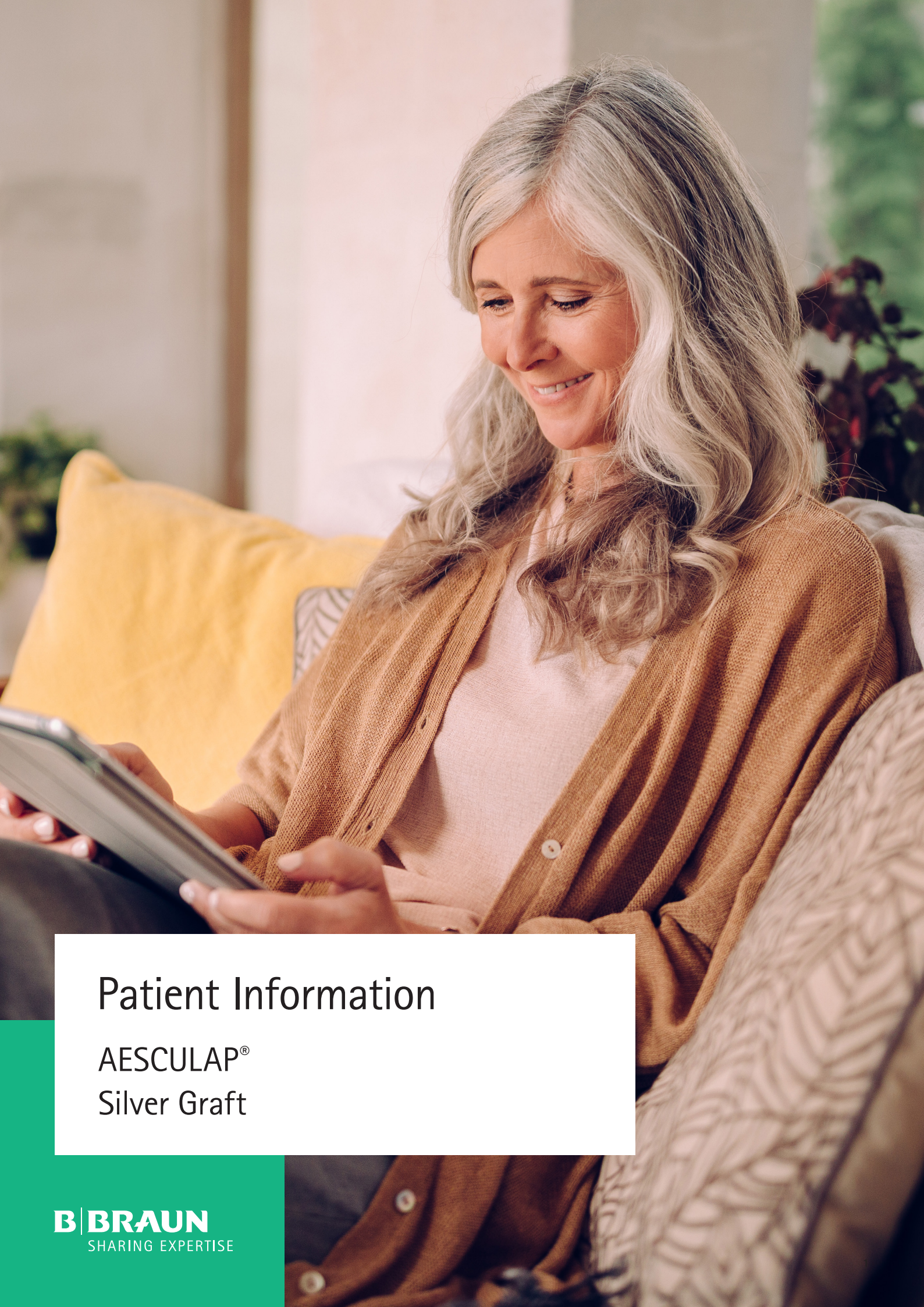


Patient Information

AESCULAP®
Silver Graft

B BRAUN
SHARING EXPERTISE

AESCULAP® Silver Graft
Patient information

en	Patient information	3
de	Patienteninformation	4
fr	Information du patient	5
es	Información para el paciente	6
it	Informazioni per il paziente	7
pt	Informações do doente	8
nl	Informatie ten behoeve van de patiënt	9
da	Patientinformation	10
no	Pasientinformasjon	11
sv	Patientinformation	12
fi	Tiedon välittäminen potilaalle	13
et	Patsiendi teavitamine	14
lv	Informācija pacientam	15
lt	Pacientų švietimas	16
cs	Informace pro pacienty	17
pl	Informacja dla pacjenta	18
sk	Informácia pre pacientov	19
hu	A betegek oktatása	20
sl	Izobraževanje bolnikov	21
hr	Edukacija pacijenata	22
ro	Instruirea pacientului	23
bg	Образование на пациента	24
tr	Hasta bilgisi	25
el	Εκπαίδευση ασθενή	26

Silver Graft

AESCULAP® Patient Information

en

What does your body come into contact with after Silver Graft implantation?

Materials and substances

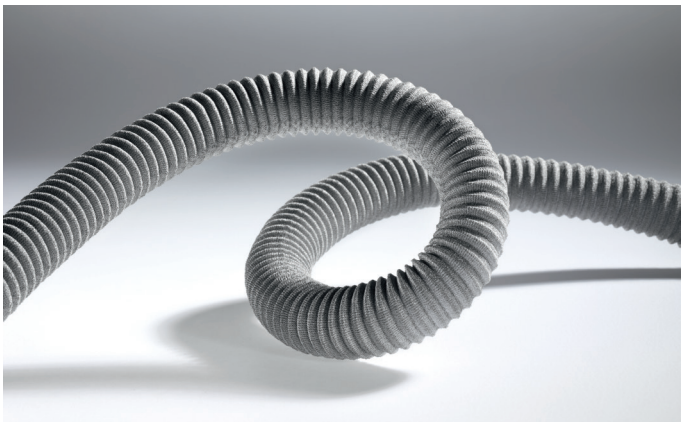
Silver Graft is a warp-knitted, double-velour vascular prosthesis, made of polyethylene terephthalate (polyester), for reconstructive procedures on the aorta and arteries in the peripheral area. Silver Graft is impregnated with absorbable modified bovine gelatine for temporary sealing. The outer surface of Silver Graft is coated with a metallic silver layer to inhibit microbial adhesion. Other ingredients are glycerol and hexamethylene diisocyanate (crosslinker for gelatine), Palladium and Titanium. In case of Silver Graft Helix additionally a polypropylene thread is included to protect the prosthesis against mechanical pressure from outside and increase the kink-stability.

How long will your implanted Silver Graft last?

Expected lifespan

The use of gelatine-coated, silver-impregnated polyester grafts such as Silver Graft as effective arterial substitutes has been assessed in both in vivo (animal) and in vitro (laboratory) experiments (1-4). Polyester is commonly used for vascular grafts in procedures such as bypass surgeries (5). Its durability and compatibility with the human body make it a preferred choice for many surgeons. The implant is not broken down by the body.

Therefore, Silver Graft remains implanted for the rest of the patient's life, if no adverse events occur. After implantation, the body's own connective tissue cells migrate into the implant.



What you and your doctor should look out for!

Interactions with environmental conditions

Magnetic resonance imaging (MRI) can be safely done in patients with implanted Silver Graft vascular prostheses under the following conditions:

- Static magnetic field: 1.5 T and 3 T
- Maximum spatial field gradient: 6.6 T/m
- Whole body averaged specific absorption rate (SAR): 2 W/kg

However, it is recommended to inform the treating physician about any implants prior to an MRI examination. Show your implant card!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Patienteninformation

de

Womit kommt Ihr Körper nach der Implantation von Silver Graft in Kontakt?

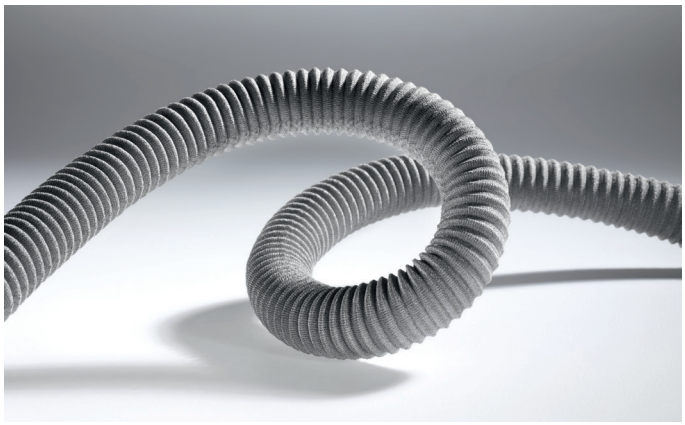
Materialien und Substanzen

Silver Graft ist eine gewebte und mit doppeltem Velours versehene Gefäßprothese aus Polyethylenterephthalat (Polyester) für rekonstruktive Eingriffe an der Aorta und den Arterien im peripheren Bereich. Silver Graft ist zur vorübergehenden Versiegelung mit resorbierbarer modifizierter Rindergelatine imprägniert. Die äußere Oberfläche von Silver Graft ist mit einer metallischen Silberschicht beschichtet, um die Anhaftung von Mikroben zu verhindern. Weitere Bestandteile sind Glycerin und Hexamethylendiisocyanat (Vernetzer für Gelatine), Palladium und Titan. Bei Silver Graft Helix ist zusätzlich ein Polypropylenfaden eingearbeitet, um die Prothese gegen mechanischen Druck von außen zu schützen und die Knickstabilität zu erhöhen.

Wie lange wird Ihr implantiertes Silver Graft halten?

Erwartete Lebensdauer

Die Verwendung von gelatinebeschichteten, silberimprägnierten Polyestertransplantaten wie Silver Graft als wirksamer Arterienersatz wurde sowohl in vivo (Tierversuche) als auch in vitro (Laborversuche) untersucht (1-4). Bei Verfahren wie Bypass-Operationen wird häufig Polyester für Gefäßprothesen verwendet (5). Seine Langlebigkeit und Kompatibilität mit dem menschlichen Körper machen es für viele Chirurgen zur ersten Wahl. Das Implantat wird vom Körper nicht abgebaut. Daher bleibt Silver Graft für den Rest des Lebens des Patienten implantiert, sofern keine unerwünschten Ereignisse auftreten. Nach der Implantation migrieren körpereigene Bindegewebszellen in das Implantat.



Auf was Sie und Ihr Arzt achten sollten!

Interaktionen mit Umweltbedingungen

Magnetresonanztomographie (MRT) kann bei Patienten mit implantierten Gefäßprothesen aus Silber unter folgenden Bedingungen sicher durchgeführt werden:

- Statisches Magnetfeld: 1,5 T und 3 T
- Maximaler räumlicher Feldgradient: 6,6 T/m
- Durchschnittliche spezifische Absorptionsrate des gesamten Körpers (SAR): 2 W/kg

Es wird jedoch empfohlen, den behandelnden Arzt vor einer MRT-Untersuchung über alle Implantate zu informieren. Zeigen Sie Ihren Implantatausweis!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Information du patient

fr

Avec quoi votre corps entre-t-il en contact après l'implantation de Silver Graft ?

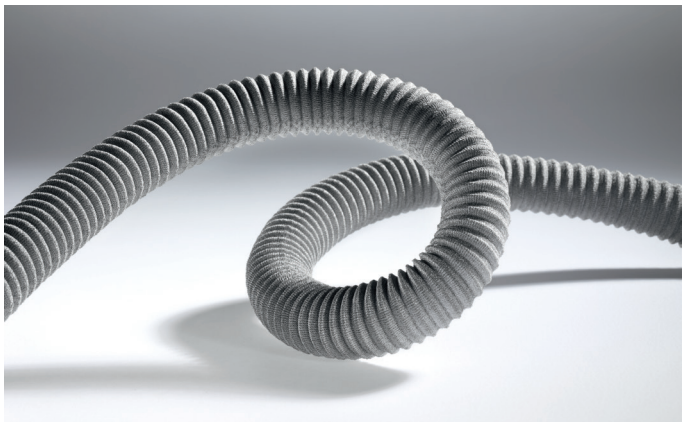
Matériaux et substances

Silver Graft est une prothèse vasculaire en mailles de polyéthylène téréphtalate (polyester) tricotées en chaîne, à double contour, destinée aux procédures de reconstruction de l'aorte et des artères de la zone périphérique. Silver Graft est imprégné de gélatine bovine modifiée absorbable pour un scellement temporaire. La surface extérieure de Silver Graft est recouverte d'une couche d'argent métallique qui empêche les microbes d'adhérer. Les autres ingrédients sont le glycérol et le diisocyanate d'hexaméthylène (réticulant pour la gélatine), le palladium et le titane. Dans le cas de Silver Graft Helix, un fil de polypropylène est également inclus pour protéger la prothèse contre les pressions mécaniques extérieures et augmenter sa stabilité.

Quelle est la durée de vie de votre Silver Graft une fois implanté ?

Durée de vie prévue

L'utilisation de greffons en polyester recouverts de gélatine et imprégnés d'argent, comme le Silver Graft, jouant le rôle de substituts artériels efficaces, a été évaluée dans des expériences in vivo (sur des animaux) et in vitro (en laboratoire) (1-4). Le polyester est couramment utilisé pour les greffes vasculaires dans des procédures telles que les pontages (5). Sa durabilité et sa compatibilité avec le corps humain en font un choix privilégié pour de nombreux chirurgiens. L'implant n'est pas décomposé par l'organisme. Par conséquent, Silver Graft reste implanté pour le reste de la vie du patient , si aucun événement indésirable ne se produit. Après l'implantation, des cellules de tissu conjonctif du corps migrent dans l'implant.



Ce que vous et votre médecin devez surveiller !

Interactions avec les conditions environnementales

L'imagerie par résonance magnétique (IRM) peut être réalisée en toute sécurité chez les patients porteurs de prothèses vasculaires implantées en argent dans les conditions suivantes:

- Champ magnétique statique : 1,5 T et 3 T
- Gradient de champ spatial maximum : 6,6 T/m
- Taux d'absorption spécifique (TAS) moyen du corps entier : 2 W/kg

Cependant, il est recommandé d'informer le médecin traitant de tout implant avant un examen IRM. Présentez votre carte d'implant !

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Información para el paciente

es

¿Con qué entra en contacto su cuerpo después de la implantación de un Silver Graft?

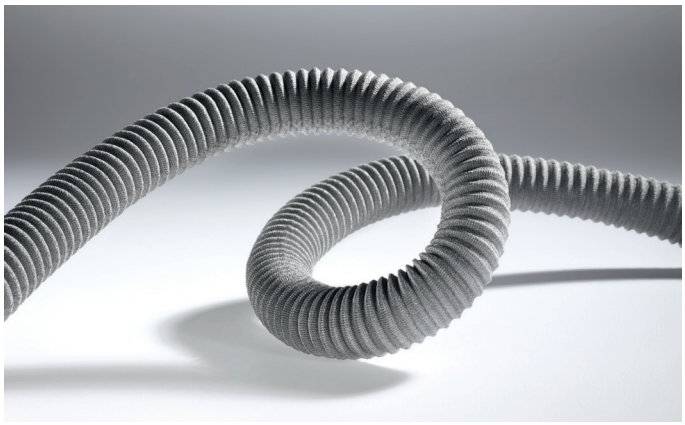
Materiales y sustancias

Silver Graft es una prótesis vascular de doble velur tejida por urdimbre fabricada con tereftalato de polietileno (poliéster) para intervenciones reconstructivas en la aorta y las arterias de la zona periférica. Silver Graft está impregnada de gelatina bovina modificada absorbible para un sellado temporal. La superficie exterior de Silver Graft está recubierta con una capa de plata metálica para inhibir la adhesión microbiana. Otros ingredientes son glicerol y diisocianato de hexametileno (reticulante de la gelatina), paladio y titanio. En el caso de Silver Graft Helix, se incluye adicionalmente un hilo de polipropileno para proteger la prótesis contra la presión mecánica del exterior y aumentar la estabilidad de la curva.

¿Cuánto durará el Silver Graft implantado?

Vida útil prevista

El uso de injertos de poliéster recubiertos de gelatina e impregnados de plata, como Silver Graft, como sustitutos arteriales eficaces se ha evaluado tanto en experimentos in vivo (animales) como in vitro (laboratorio) (1-4). El poliéster se utiliza habitualmente para injertos vasculares en procedimientos como las cirugías de bypass (5). Su durabilidad y compatibilidad con el cuerpo humano lo convierten en la opción preferida de muchos cirujanos. El implante se mantiene permanentemente en el organismo. Por lo tanto, Silver Graft permanece implantado durante el resto de la vida del paciente si no se producen acontecimientos adversos. Después de la implantación, las células de tejido conjuntivo del propio organismo migran al implante.



Lo que usted y su médico deberán tener en cuenta!

Interacciones con condiciones ambientales

La obtención de imágenes por resonancia magnética (RM) puede realizarse de forma segura en pacientes con prótesis vasculares Silver Graft implantadas en las condiciones siguientes:

- Campo magnético estático: 1,5 T y 3 T
- Gradiente máximo del campo espacial: 6,6 T/m
- Tasa de absorción específica media de todo el cuerpo (SAR): 2 W/kg

Sin embargo, se recomienda informar al médico responsable de cualquier implante antes de realizar una exploración por RM. ¡Muestre su tarjeta de implante!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informazioni per il paziente

it

Con che cosa viene a contatto il corpo dopo l'impianto di Silver Graft?

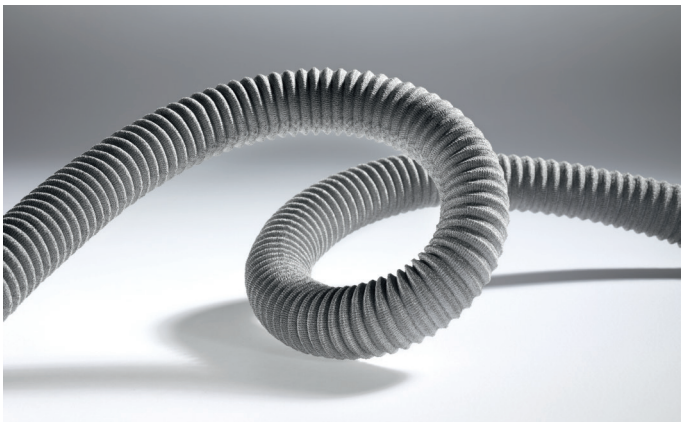
Materiali e sostanze

Silver Graft è una protesi vascolare indemagliabile, in doppio velour, realizzata in polietilene tereftalato (poliestere), per interventi ricostruttivi dell'aorta e delle arterie nell'area periferica. Silver Graft è stata impregnata con gelatina bovina modificata assorbibile per la chiusura temporanea. La superficie esterna della Silver Graft è rivestita con uno strato di argento metallico per inibire l'adesione microbica. Altri ingredienti sono il glicerolo e l'esametilene diisocianato (reticolante per gelatina), Palladio e Titanio. Nel caso di Silver Graft Helix è incluso anche un filo di polipropilene per proteggere la protesi da pressioni meccaniche esterne e aumentare la stabilità alle pieghe.

Quanto durerà l'impianto della Silver Graft?

Durata di vita prevista

L'uso di innesti in poliestere rivestiti di gelatina e impregnati d'argento, come Silver Graft, come efficaci sostituti arteriosi è stato valutato sia in esperimenti in vivo (animali) che in vitro (laboratorio) (1-4). Il poliestere è comunemente utilizzato per gli innesti vascolari in interventi come i bypass (5). La sua durata e compatibilità con il corpo umano ne fanno una scelta privilegiata per molti chirurghi. L'impianto non viene assorbito dal corpo. Pertanto, Silver Graft rimane impiantato per il resto della vita del paziente , se non si verificano eventi avversi. Dopo l'impianto, le cellule del tessuto connettivo del corpo stesso migrano nell'impianto.



A cosa dovreste fare attenzione tu e il tuo medico!

Interazioni con condizioni ambientali

La risonanza magnetica (RM) può essere eseguita in sicurezza in pazienti con impianto di protesi vascolari Silver Graft nelle seguenti condizioni:

- Campo magnetico statico: 1,5 T e 3 T
- Gradiente di campo spaziale massimo: 6,6 T/m
- Tasso di assorbimento specifico (SAR) mediato su tutto il corpo: 2 W/kg

Tuttavia, si consiglia di informare il medico curante di eventuali impianti prima di un esame RM. Mostra la tua scheda dell'impianto!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informações do doente

pt

O seu corpo entra em contacto com o quê após a implantação do Silver Graft?

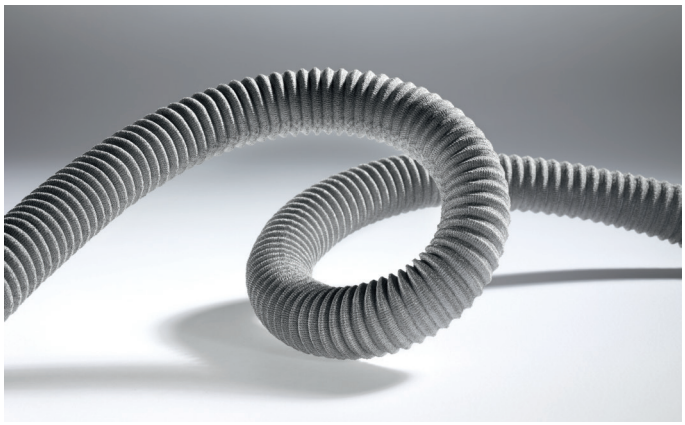
Materiais e substâncias

Silver Graft é uma prótese vascular de duplo velame, tricotada em teia, fabricada em politereftalato de etileno (poliéster), para procedimentos de reconstrução da aorta e das artérias da zona periférica. Silver Graft é impregnado com gelatina bovina modificada absorvível para vedação temporária. A superfície exterior do Silver Graft é revestida com uma camada de prata metálica para inibir a adesão microbiana. Outros ingredientes são o glicerol e o diisocianato de hexametileno (agente de reticulação para a gelatina), o paládio e o titânio. No caso da Silver Graft Helix, é incluído adicionalmente um fio de polipropileno para proteger a prótese contra a pressão mecânica do exterior e aumentar a estabilidade da ligação.

Quanto tempo durará o enxerto Silver Graft?

Tempo de vida previsto

A utilização de enxertos de poliéster revestidos com gelatina e impregnados a prata, como o Silver Graft, como substitutos arteriais eficazes, foi avaliada em experiências in vivo (em animais) e in vitro (em laboratório) (1-4). O poliéster é normalmente utilizado para enxertos vasculares em procedimentos como as cirurgias de bypass (5). A sua durabilidade e compatibilidade com o corpo humano fazem dele a escolha preferida de muitos cirurgiões. O implante não é decomposto pelo corpo. Por conseguinte, o Silver Graft permanece implantado para o resto da vida do paciente, se não ocorrerem eventos adversos. Após a implantação, as células do tecido conjuntivo do próprio corpo imigram para o implante.



O que é que o paciente e o médico devem procurar!

Interações com as condições ambientais

A imagiologia por ressonância magnética (IRM) pode ser realizada em segurança em doentes com prótese vascular Silver Graft implantada sob as seguintes condições:

- Campo magnético estático: 1,5 T e 3 T
- Gradiente máximo do campo espacial: 6,6 T/m
- Taxa de absorção específica da média da totalidade do corpo (SAR): 2 W/kg

No entanto, recomenda-se que informe o médico assistente sobre quaisquer implantes antes de um exame de IRM. Mostre o seu cartão de implante!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informatie ten behoeve van de patiënt

nl

Waarmee komt u lichaam in contact, na de implantatie van Silver Graft?

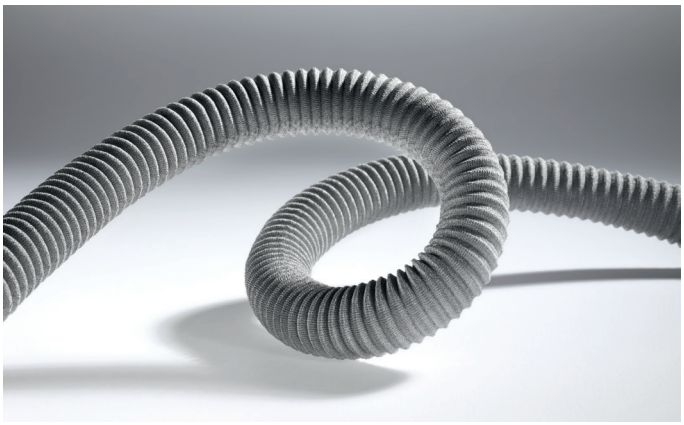
Materialen en stoffen

Silver Graft is een kettinggebreide, dubbelwandige vasculaire prothese van polyethyleentereftalaat (polyester) voor reconstructieve ingrepen aan de aorta en slagaders in het perifere gebied. Silver Graft is geïmpregneerd met resorbeerbare gemodificeerde rundergelatine voor tijdelijke afdichting. Het buitenoppervlak van Silver Graft is gecoat met een metallic zilverlaag om microbiële aanhechting tegen te gaan. Andere ingrediënten zijn glycerol en hexamethyleendiisocyanaat (crosslinker voor gelatine), palladium en titanium. In het geval van Silver Graft Helix is er bovendien een polypropyleendraad toegevoegd om de prothese te beschermen tegen mechanische druk van buitenaf en de knikstabiliteit te vergroten.

Hoe lang gaat uw geïmplanteerde Silver Graft mee?

Verwachte levensduur

Het gebruik van met gelatine gecoate, met zilver geïmpregneerde polyester transplantaten zoals Silver Graft als effectieve arteriële substituten is beoordeeld in zowel in vivo (dier) als in vitro (laboratorium) experimenten (1-4). Polyester wordt vaak gebruikt voor vasculaire transplantaten bij procedures zoals bypassoperaties (5). De duurzaamheid en compatibiliteit met het menselijk lichaam maken het tot een favoriete keuze voor veel chirurgen. Het implantaat wordt niet door het lichaam afgebroken. Daarom blijft de Silver Graft voor de rest van het leven van de patiënt geïmplanteerd, tenzij bijwerkingen optreden. Na implantatie zullen de lichaamseigen bindweefselcellen immigreren in het implantaat.



Waar u en uw arts op moeten letten!

Interacties met omgevingsfactoren

Magnetic Resonance Imaging (MRI) kan veilig worden uitgevoerd bij patiënten met geïmplanteerde Silver Graft vasculaire prothesen onder de volgende omstandigheden:

- Statisch magnetisch veld: 1,5 T en 3 T
- Maximale ruimtelijke veldgradiënt: 6,6 T/m
- Gemiddelde specifieke absorptiesnelheid (SAR) voor het hele lichaam: 2 W/kg

Het wordt echter aanbevolen om de behandelend arts voorafgaand aan een MRI-onderzoek te informeren over eventuele implantaten. Toon uw implantaatkaart!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Patientinformation

da

Hvad kommer din krop i kontakt med efter implantationen af Silver Graft?

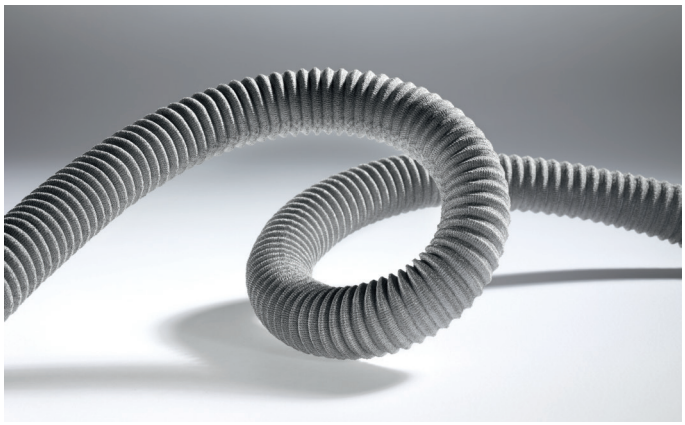
Materialer og stoffer

Silver Graft er en kædestrikket, dobbeltvelour vaskulær protese, fremstillet af polyethylenterephthalat (polyester), til rekonstruktive procedurer på aorta og arterier i det perifere område. Silver Graft er imprægneret med absorberbar modificeret bovin gelatine til midlertidig forsegling. Den ydre overflade af Silver Graft er belagt med et metallisk sølvlag for at hæmme mikrobiel vedhæftning. Andre ingredienser er glycerol og hexamethylendiisocyanat (tværbindingsmiddel til gelatine), Palladium og titanium. I tilfælde af Silver Graft Helix er der desuden inkluderet en polypropylentråd for at beskytte protesen mod mekanisk tryk udefra og øge kink-stabiliteten.

Hvor længe vil dit implanterede Silver Graft holde?

Forventet levetid

Brugen af gelatineovertrukne, sølvimprægnerede polyestertransplantater som Silver Graft som effektive arteriesubstitutter er blevet vurderet i både in vivo (dyreforsøg) og in vitro (laboratorieforsøg) (1-4). Polyester bruges ofte til vaskulære transplantater i procedurer som f.eks. bypass-operationer (5). Dens holdbarhed og kompatibilitet med menneskekroppen gør den til et foretrukket valg for mange kirurger. Implantatet nedbrydes ikke af kroppen. Derfor forbliver Silver Graft indopereret resten af patientens liv, hvis der ikke opstår bivirkninger. Efter implantationen immigrerer kroppens egne bindevævsceller ind i implantatet.



Det skal du og din læge holde øje med!

Interaktioner med miljømæssige betingelser

Magnetisk resonansbilleddannelse (MRI) kan udføres sikkert hos patienter med implanteret vaskulære Silver Graft-proteser under følgende forhold:

- Statisk magnetfelt: 1,5 T og 3 T
- Maksimal rumlig feltgradient: 6,6 T/m
- Gennemsnitlig specifik absorptionshastighed (SAR) for hele kroppen: 2 W/kg

Det anbefales dog at informere den behandlende læge om eventuelle implantater før en MRI-scanning. Vis dit implantatkort!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Pasientinformasjon

no

Hva kommer kroppen din i kontakt med etter implantasjon av Silver Graft?

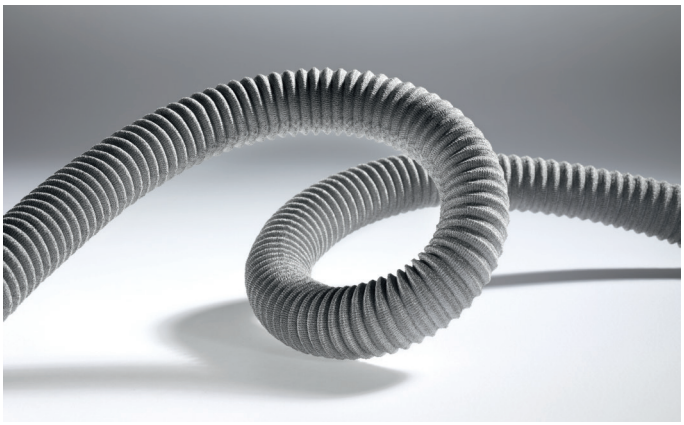
Materialer og stoffer

Silver Graft er en varpstrikket, dobbeltvelurs vaskulær protese, laget av polyetylentereftalat (polyester), for rekonstruktive inngrep på aorta og arterier i det perifere området. Silver Graft er impregnert med absorberbar modifisert bovin gelatin for midlertidig forsegling. Den ytre overflaten av Silver Graft er belagt med et metallisk sølvlag for å hindre mikrobiell adhesjon. Andre ingredienser er glyserol og heksametylendiisocyanat (tverrbindingsmiddel for gelatin), palladium og titan. Silver Graft Helix har i tillegg en polypropylentråd for å beskytte protesen mot mekanisk trykk utenfra og øke kinkstabiliteten.

Hvor lenge vil ditt implanterte Silver Graft vare?

Forventet levetid

Bruken av gelatinbelagte, sølvimpregnerte polyestertransplantater som Silver Graft som effektive arteriesubstitutter har blitt vurdert i både in vivo (dyreforsøk) og in vitro (laboratorieforsøk) (1-4). Polyester brukes ofte til vaskulære transplantater i prosedyrer som bypassoperasjoner (5). Holdbarheten og kompatibiliteten med menneskekroppen gjør den til et foretrukket valg for mange kirurger. Implantatet brytes ikke ned av kroppen. Derfor forblir Silver Graft implantert resten av pasientens liv, hvis det ikke oppstår uønskede hendelser. Etter implantering migrerer kroppens egne bindevevsceller inn i implantatet.



Hva du og legen din bør se etter!

Interaksjoner med miljøbetingelser

Magnetresonanstomografi (MR) kan trygt utføres hos pasienter med implanterte Silver Graft vaskulære proteser under følgende forhold:

- Statisk magnetfelt: 1,5 T og 3 T
- Maksimal romlig feltgradient: 6,6 T/m
- Gjennomsnittlig spesifikk absorpsjonsrate (SAR) for hele kroppen: 2 W/kg

Det anbefales imidlertid å informere behandlende lege om eventuelle implantater før en MR-undersøkelse. Vis implantatkortet ditt!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Patientinformation

sv

Vad kommer din kropp i kontakt med efter implantationen av Silver Graft?

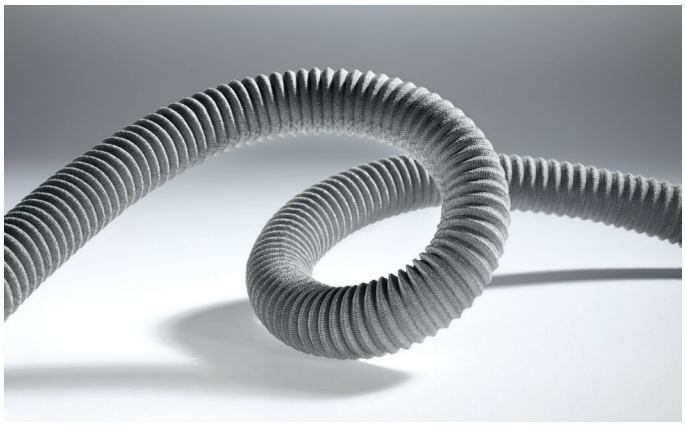
Material och ämnen

Silver Graft är en varpstickad vaskulärprotes med dubbel velour tillverkad av polyetylentereftalat (polyester), för rekonstruktiva ingrepp på aorta och artärer i det perifera området. Silver Graft är impregnerat med absorberbart modifierat bovint gelatin för tillfällig försegling. Den yttre ytan av Silver Graft är belagd med ett metalliskt silverskikt för att förhindra mikrobiell vidhäftning. Övriga ingredienser är glycerol och hexametylendiisocyanat (tvärbindare för gelatin), Palladium och titan. För Silver Graft Helix ingår dessutom en polypropylentråd för att skydda protesen mot mekaniskt tryck utifrån och öka motståndskraften mot böjning.

Hur länge kommer ditt implanterade Silver Graft att hålla?

Förväntad livslängd

Användningen av gelatinbelagda, silverimpregnerade polyestergrafter som Silver Graft som effektiva arteriella substitut har utvärderats i både in vivo- (djur) och in vitro-experiment (laboratorium) (1-4). Polyester används ofta som kärlgraft vid t.ex. bypassoperationer (5). Dess hållbarhet och kompatibilitet med människokroppen gör den till ett förstahandsval för många kirurger. Implantatet bryts inte ner av kroppen. Silver Graft förblir därför implanterat under resten av patientens liv, om inga negativa händelser inträffar. Efter implantationen infiltrerar kroppens egna bindvävsceller implantatet.



Det här ska du och din läkare vara uppmärksamma på!

Interaktioner med miljöförhållanden

Magnetisk resonanstomografi (MRT) kan utföras på ett säkert sätt på patienter med implanterade Silver Graft-kärlproteser under följande förhållanden::

- Statiskt magnetfält: 1,5 T och 3 T
- Maximal spatial fältgradient: 6,6 T/m
- Genomsnittlig specifik absorptionshastighet (SAR) för hela kroppen: 2 W/kg

Till den behandlande läkaren rekommenderas dock att informera om eventuella implantat före en MRT-undersökning. Visa ditt implantatkort!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Tiedon välittäminen potilaalle

fi

Mihin elimistösi on kosketuksissa Silver Graft-implantoinnin jälkeen?

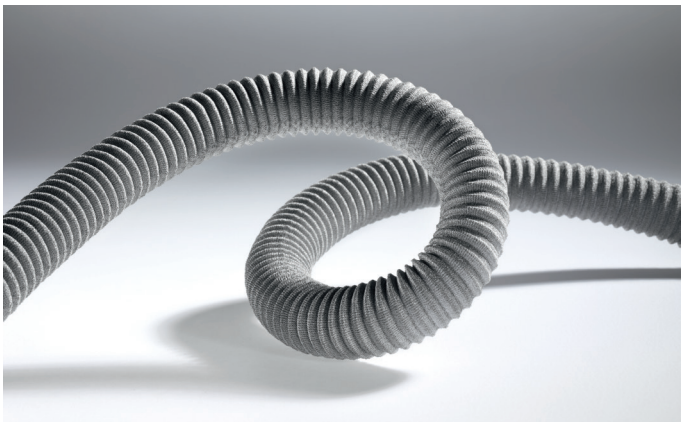
Materiaalit ja aineet

Silver Graft on loimikudottu, kaksoisveluurista valmistettu verisuoniproteesi polyeteenitereftalaatista (polyesteri). Se on tarkoitettu aortan ja perifeeristen valtimoiden korjaaviin toimenpiteisiin. Silver Graft on kyllästetty imeytyvällä modifioidulla naudanlihagelatiinilla väliaikaista sulkemista varten. Silver Graftin ulkopinta on päällystetty metallisella hopeakerroksella mikrobien tarttumisen estämiseksi. Muita ainesosia ovat glyseroli ja heksametyleenidi-isosyanaatti (gelatiinin silloitin), palladium ja titaani. Silver Graft Helix sisältää lisäksi polypropeenikuituja, jotka suojaavat proteesia ulkoisilta mekaaniselta paineelta ja parantavat taivutuskestävyyttä.

Kuinka kauan implantoitu Silver Graft kestää?

Odotettu käyttöikä

Gelatiinipinnoitettujen, hopeakyllästettyjen polyesterisiirteiden, kuten Silver Graftin, käyttöä tehokkaina valtimoiden korvikkeina on arvioitu sekä in vivo (eläinkokeissa) että in vitro (laboratoriokokeissa) (1-4). Polyesteriä käytetään yleisesti verisuonisiirteissä esimerkiksi ohitusleikkauksissa (5). Sen kestävyys ja yhteensopivuus ihmiskehon kanssa tekevät siitä monien kirurgien suosiman valinnan. Keho ei hajota implanttia. Näin ollen Silver Graft pysyy implantoituna potilaan koko loppuelämän ajan, jos haittatapahtumia ei esiinny. Implantoinnin jälkeen kehon omat sidekudossolut siirtyvät implanttiin.



Mitä sinun ja lääkärisi tulee ottaa huomioon!

Ympäristöolosuhteiden huomioiminen

Magneettikuvaus (MRI) voidaan tehdä turvallisesti potilailla, joille on implantoitu Silver Graft -verisuoniproteesi seuraavissa olosuhteissa:

- Staattinen magneettikenttä: 1,5 T ja 3 T
- Suurin tilakentän kaltevuus 6,6 T/m
- Koko kehon keskimääräinen ominaisabsorptionopeus (SAR): 2 W/kg

On kuitenkin suositeltavaa kertoa hoitavalle lääkärille mahdollisista implanteista ennen magneettikuvausta. Näytä implanttikorttisi!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Patsiendi teavitamine

et

Millega teie keha kokku puutub pärast Silver Graft-i implanteerimist?

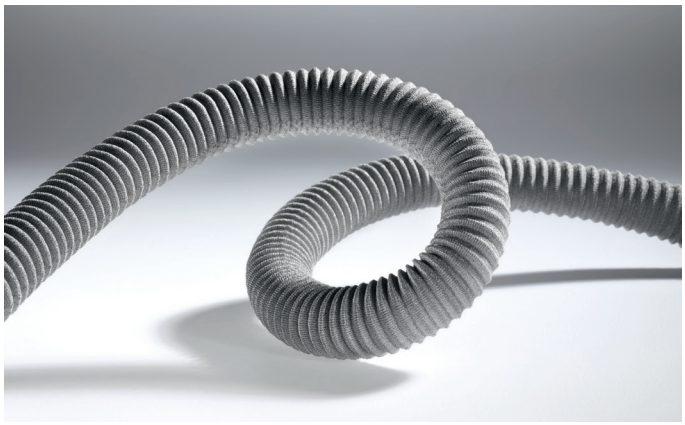
Materjalid ja ained

Silver Graft on polüetüleentereftalaadist (polüestrist) valmistatud kootud kahekordsest veluurist veresoonteprotees, mis on mõeldud aordi ja perifeerse piirkonna arterite rekonstruktsiooniprotseduurideks. Silver Graft on ajutiseks tihendamiseks impregneeritud imenduva modifitseeritud veiseželatiiniga . Silver Graft'i välispind on kaetud metallilik-hõbekihiga, mis takistab mikroobide kinnitumist. Muud koostisosad on glütserool ja heksametüleen-diisotsüanaat (želatiini ristsiduja), pallaadium ja titaan. Silver Graft Helixi puhul on lisatud ka polüpropüleenist niit, mis kaitseb proteesi väljastpoolt tulevate mehaaniliste surveteguritе eest ja suurendab väändestabiilsust.

Kui kaua teie implanteeritud Silver Graft vastu peab?

Eeldatav eluiga

Želatiiniga kaetud, hõbedaga immutatud polüestersiirikute, nagu Silver Graft, kasutamist tõhusate arteri asendustena on hinnatud nii in vivo (loomkatsetes) kui ka in vitro (laboratoorsetes) katsetes (1-4). Polüestrit kasutatakse tavaliselt veresoonesiirikutena sellistes protseduurides nagu šuntimisoperatsioonid (5). Selle vastupidavus ja okkusobivus inimkehaga teevad sellest paljude kirurgide eelistatud valiku. Keha ei lagunda implantaati. Seetõttu jääb Silver Graft implanteerituks kogu ülejäänud eluks, kui kõrvaltoimeid ei esine, . Pärast implanteerimist liiguvad implantaati keha enda sidekoe rakud.



Millele peaksite koos arstiga tähelepanu pöörama!

Koostoimed keskkonnatingimustega

Silver Grafti implanteeritud vaskulaarproteesidega patsientidele võib magnetresonantstomograafia uuringuid (MRT) teha järgmistel tingimustel:

- Staatiline magnetväli: 1,5 T ja 3 T
- Maksimaalne ruumiline väljagradient: 6,6 T/m
- Kogu keha keskmistatud erineelduvuskiirus (SAR): 2 W/kg

Siiski on soovitatav teavitada raviarsti implantaatidest enne MRT-uuringut. Näidake oma implantaadikaarti!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informācija pacientam

lv

Ar ko jūsu ķermenis nonāk kontaktā pēc Silver Graft implantācijas?

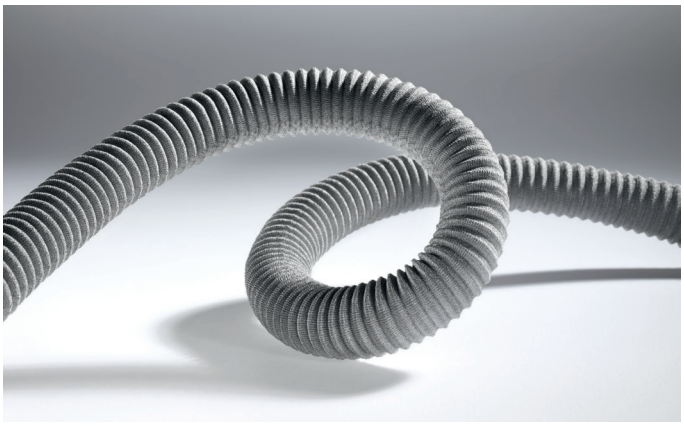
Materiāli un vielas

Silver Graft ir vītņadīta, dubultā velūra asinsvadu protēze no polietilēna tereftalāta (poliestera), kas paredzēta aortas un perifēro artēriju rekonstruktīvajām operācijām. Silver Graft ir piesūcināts ar absorbējamu modificētu liellopu želatīnu, lai nodrošinātu pagaidu blīvējumu. Silver Graft ārējā virsma ir pārklāta ar metālisku sudraba slāni mikroorganismu adhesijas samazināšanai. Citas sastāvdaļas ir glicerīns un heksametilēndiizocianāts (želatīna saistviela), palādijs un titāns. Silver Graft Helix protēzē iebūvēts polipropilēna pavediens ārējā mehāniskā spiediena ierobežošanai un liekšanās stabilitātes nodrošināšanai.

Cik ilgi kalpos implantētais Silver Graft?

Paredzamais kalpošanas ilgums

Ar želatīnu pārklātu, ar sudrabu piesūcinātu poliestera transplantātu, piemēram, Silver Graft, kā efektīvu arteriālu aizstājēju izmantošana ir novērtēta gan in vivo (dzīvnieki), gan in vitro (laboratorijas) eksperimentos (1–4). Poliesteris parasti tiek izmantots asinsvadu transplantātiem, piemēram, šuntēšanas operācijās (5). Pateicoties tā izturībai un bioloģiskajai saderībai ar cilvēka organismu, poliesteris ir kļuvis par bieži izmantotu materiālu ķirurģijā. Implants organismā nesadalās. Tāpēc Silver Graft paliek implantēts visu atlikušo pacienta mūžu, ja vien nav nevēlamu blakusparādību. Pēc implantācijas ķermeņa paša saistaudu šūnas pārvietojas implantā.



No kā būtu jāuzmanās jums un jūsu ārstam!

Mijiedarbība ar vides apstākļiem

Magnētiskās rezonanses attēlveidošanu (MRI) var droši veikt pacientiem ar implantētām sudraba transplantāta asinsvadu protēzēm šādos apstākļos:

- Statiskais magnētiskais lauks: 1,5 T un 3 T
- Maksimālais telpiskā lauka gradients: 6,6 T/m
- Visa ķermeņa vidējais īpatnējais absorbcijas ātrums (SAR): 2 W/kg

Tomēr pirms MRI izmeklējuma ieteicams informēt ārstējošo ārstu par visiem implantiem. Parādiet savu implanta karti!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Pacientų švietimas

lt

Prie ko liečiasi jūsų kūnas implantavus Silver Graft?

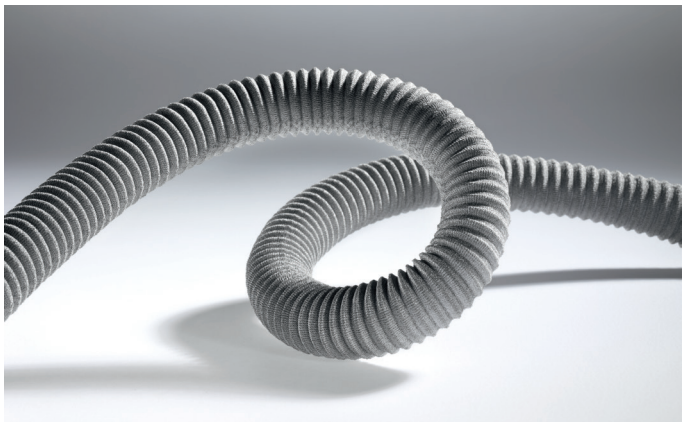
Medžiagos

Silver Graft yra metmeniniu būdu megztas, dvigubo veliūro kraujagyslių protezas iš polietileno tereftalato (poliesterio), skirtas aortos ir periferinių arterijų rekonstrukcinėms procedūroms. Silver Graft impregnuotas absorbuojama modifikuota galvijų želatina , skirta laikinam užsandarinimui. Išorinis Silver Graft paviršius padengtas metalinio sidabro sluoksniu, kuris stabdo mikrobų sukibimą. Kitos sudedamosios dalys yra glicerolis ir heksametileno diizocianatas (želatinos rišančioji medžiaga), paladis ir titanas. Silver Graft Helix atveju papildomai pridedamas polipropileno siūlas, kad protezas būtų apsaugotas nuo mechaninio spaudimo iš išorės ir padidėtų jo stabilumas lenkiant.

Kiek laiko tarnaus jūsų implantuotas Silver Graft?

Numatomas tarnavimo laikas

Želatina padengtų, sidabru impregnuotų poliesterio transplantatų, tokių kaip Silver Graft, kaip veiksmingų arterijų pakaitalų naudojimas buvo įvertintas tiek in vivo (su gyvūnais), tiek in vitro (laboratorijoje) eksperimentų metu (1–4). Poliesteris paprastai naudojamas kraujagyslių transplantatams, pavyzdžiui, atliekant apylankos operacijas (5). Dėl patvarumo ir suderinamumo su žmogaus kūnu jį renkasi daugelis chirurgų. Implantas organizme nesuyra. Todėl Silver Graft lieka implantuotas visą likusį paciento gyvenimą, jei neatsiranda nepageidaujamų reiškinių. Po implantavimo kūno jungiamojo audinio ląstelės įsiskverbia į implantą.



Į ką turite atkreipti dėmesį jūs ir jūsų gydantysis gydytojas!

Sąveika su aplinkos sąlygomis

Magnetinio rezonanso tomografija (MRT) gali būti saugiai atliekama pacientams su implantuotais „Silver Graft" kraujagyslių protezais, jei yra laikomasi šių sąlygų:

- Statinis magnetinis laukas: 1.5 T ir 3 T
- Didžiausias erdvinis lauko gradientas: 6,6 T/m
- Viso kūno vidurkio specifinis absorbcijos greitis (SAR): 2 W/kg

Tačiau prieš atliekant MRT tyrimą rekomenduojama informuoti gydantįjį gydytoją apie bet kokius implantus. Parodykite savo implanto kortelę!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informace pro pacienty

cs

S čím vaše tělo přichází do kontaktu po implantaci Silver Graft?

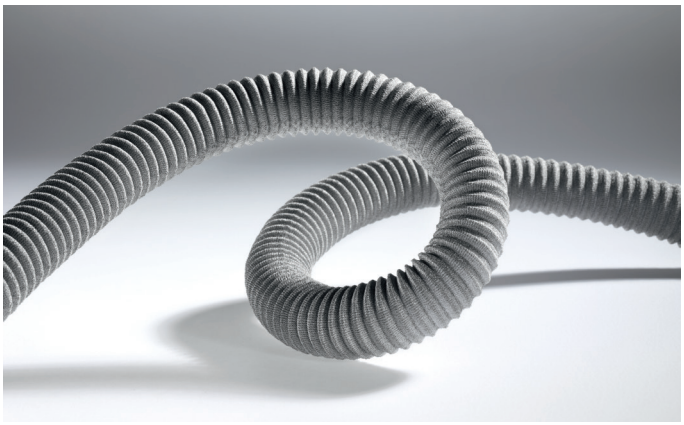
Materiály a látky

Silver Graft je dvojitě pletená cévní protéza z polyetylentereftalátu (polyesteru) pro rekonstrukční zákroky na aortě a tepnách v periferní oblasti. Výrobek Silver Graft je impregnován vstřebatelnou modifikovanou hovězí želatinou pro dočasné utěsnění. Vnější povrch Silver Graft je potažen kovovou stříbrnou vrstvou, která brání adhezi mikrobů. Dalšími složkami jsou glycerol a hexamethylen diizokyanát (zesíťovač želatiny), palladium a titan. V případě Silver Graft Helix je navíc součástí polypropylenové vlákno, které chrání protézu před mechanickým tlakem zvenčí a zvyšuje stabilitu kloubu.

Jak dlouho implantovaný Silver Graft vydrží?

Předpokládaná životnost

Použití polyesterových štěpů potažených želatinou a impregnovaných stříbrem, jako je Silver Graft, jako účinných tepenných náhrad bylo hodnoceno v pokusech in vivo (na zvířatech) i in vitro (v laboratoři) (1-4). Polyester se běžně používá pro cévní štěpy při operacích, jako jsou bypassy (5). Díky své trvanlivosti a kompatibilitě s lidským tělem je preferovanou volbou mnoha chirurgů. Implantát se v těle nerozkládá.
Pokud tedy nedojde k nežádoucím příhodám, zůstane štěp Silver Graft implantován po zbytek života pacienta. Po implantaci se do implantátu přemístí tělu vlastní buňky pojivové tkáně.



Co by vás a vašeho lékaře mělo zajímat!

Interakce s podmínkami prostředí

Magnetickou rezonanci (MRI) lze u pacientů s implantovanými cévními protézami Silver Grft bezpečně provést za následujících podmínek:

- Statické magnetické pole: 1,5 T a 3 T
- Maximální prostorový gradient pole: 6,6 T/m
- Průměrná specifická celotělová míra absorpce (SAR): 2 W/kg

Doporučuje se však informovat ošetřujícího lékaře o jakýchkoli implantátech před vyšetřením MRI. Ukažte svou kartu implantátu!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.
(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.
(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.
(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.
(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informacja dla pacjenta

pl

Z czym ma kontakt twój organizm po implantacji Silver Graft?

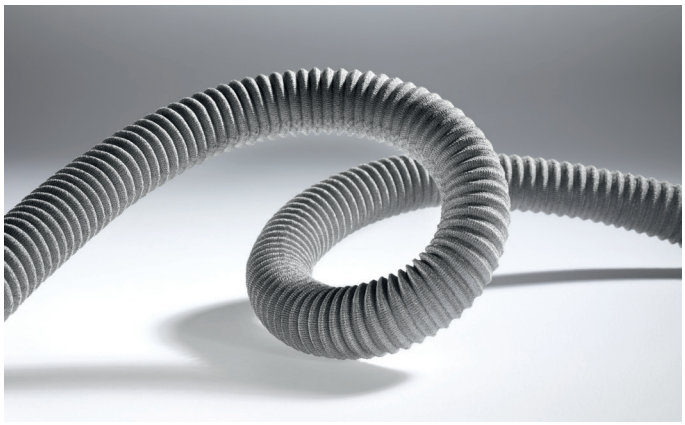
Materiały i substancje

Silver Graft to proteza naczyniowa o podwójnym splocie z dzianiny osnowowej, wykonana z politereftalanu etylenu (poliestru), przeznaczona do zabiegów rekonstrukcyjnych aorty i tętnic obwodowych. Silver Graft jest impregnowany wchłanialną modyfikowaną żelatyną wołową w celu tymczasowego uszczelnienia. Zewnętrzna powierzchnia Silver Graft jest pokryta metaliczną warstwą srebra, która hamuje adhezję drobnoustrojów. Inne składniki to glicerol i diizocyjanian heksametylenu (substancja sieciująca żelatynę), pallad i tytan. W przypadku Silver Graft Helix dodatkowo dołączona jest nić polipropylenowa chroniąca protezę przed mechanicznym naciskiem z zewnątrz i zwiększająca stabilność protezy.

Jak długo wytrzyma wszczepiony implant Silver Graft?

Przewidywany okres użytkowania

Zastosowanie pokrytych żelatyną, impregnowanych srebrem przeszczepów poliestrowych, takich jak Silver Graft, jako skutecznych substytutów tętnic zostało ocenione zarówno w doświadczeniach in vivo (na zwierzętach), jak i in vitro (laboratoryjnych) (1-4). Poliester jest powszechnie stosowany do przeszczepów naczyniowych w procedurach takich jak operacje pomostowania (5). Jego trwałość i kompatybilność z ludzkim ciałem sprawiają, że jest to preferowany wybór dla wielu chirurgów. Implant nie jest niszczony przez organizm. Dlatego Silver Graft pozostaje wszczepiony do końca życia pacjenta , jeśli nie wystąpią żadne zdarzenia niepożądane. Po implantacji własne komórki tkanki łącznej ciała migrują do wnętrza implantu.



Na co ty i twój lekarz powinniście uważać!

Interakcje z warunkami środowiskowymi

Obrazowanie metodą rezonansu magnetycznego (MRI) można bezpiecznie wykonać u pacjentów z wszczepionymi protezami naczyniowymi Silver Graft w następujących warunkach:

- Statyczne pole magnetyczne: 1,5 T i 3 T
- Maksymalny gradient przestrzenny pola: 6,6 T/m
- Specyficzny współczynnik absorpcji (SAR) uśredniony dla całego ciała: 2 W/kg

Zaleca się jednak poinformowanie lekarza prowadzącego o wszelkich implantach przed badaniem MRI. Pokaż swoją kartę implantu!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Informácia pre pacientov

sk

S čím prichádza vaše telo do kontaktu po implantácii Silver Graft?

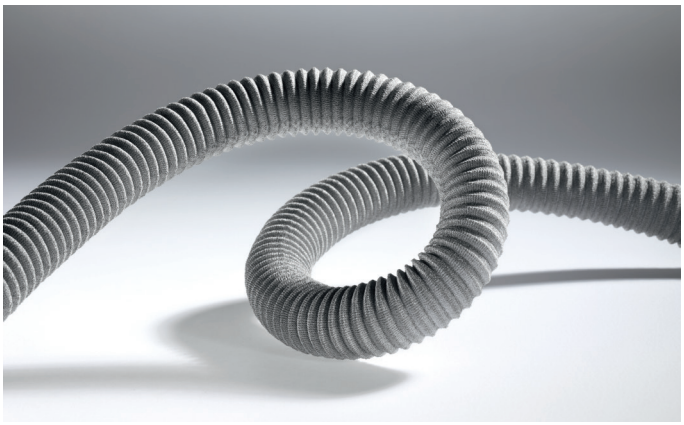
Materiály a látky

Silver Graft je dvojvrstvová cievna protéza vyrobená z polyetyléntereftalátu (polyesteru) na rekonštrukčné zákroky na aorte a tepnách v periférnej oblasti. Výrobok Silver Graft je impregnovaný vstrebateľnou modifikovanou hovädzou želatínou na dočasné utesnenie. Vonkajší povrch Silver Graft je potiahnutý kovovou striebornou vrstvou, ktorá zabraňuje priľnutiu mikroorganizmov. Ďalšími zložkami sú glycerol a hexametyléndiizokyanát (zosieťovač želatíny), paládium a titán. V prípade Silver Graft Helix je navyše súčasťou polypropylénové vlákno, ktoré chráni protézu pred mechanickým tlakom zvonku a zvyšuje stabilitu pri prekrývaní.

Ako dlho implantovaný Silver Graft vydrží?

Predpokladaná životnosť

Použitie polyesterových štepov potiahnutých želatínou a impregnovaných striebrom, ako je Silver Graft, ako účinných arteriálnych náhrad bolo hodnotené v experimentoch in vivo (na zvieratách) aj in vitro (v laboratóriu) (1-4). Polyester sa bežne používa na cievne štepy pri zákrokoch, ako sú bypassy (5). Vďaka svojej odolnosti a kompatibilite s ľudským telom je preferovanou voľbou mnohých chirurgov. Implantát sa v tele nerozkladá.
Ak sa nevyskytnú žiadne nežiaduce udalosti, Silver Graft zostane implantovaný do konca života pacienta . Po implantácii do implantátu migrujú vlastné spojivové tkanivové bunky tela.



Na čo si máte dávať pozor vy a váš lekár!

Interakcie s environmentálnymi podmienkami

Pri pacientoch s implantovanými cievnymi protézami Silver Graft sa môže bezpečne vykonávať zobrazovanie magnetickou rezonanciou (MRI) za nasledujúcich podmienok:

- Statické magnetické pole: 1,5 T a 3 T
- Maximálny priestorový gradient poľa: 6,6 T/m
- Celotelová priemerná špecifická rýchlosť absorpcie (SAR): 2 W/kg

Odporúča sa však informovať ošetrujúceho lekára o akýchkoľvek implantátoch pred vyšetrením MRI. Ukážte svoju kartu implantátu!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.
(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.
(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.
(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.
(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® A betegek oktatása

hu

Mivel kerül érintkezésbe szervezete a Silver Graft beültetését követően?

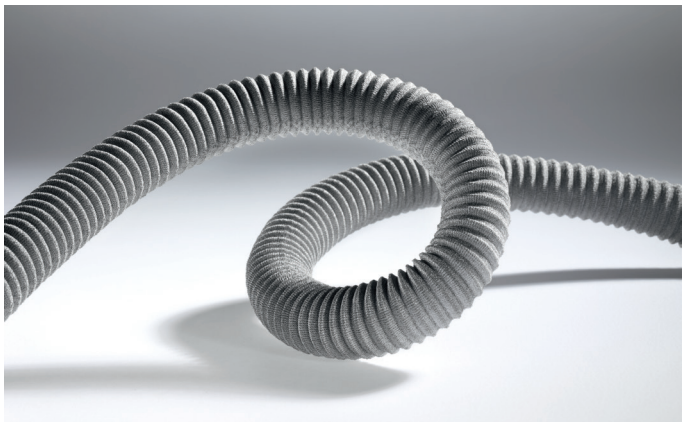
Anyagok és összetevők

A Silver Graft polietilén-tereftalátból (poliészter) készült, lánchurkolt, kétrétegű érprotézis, amely az aorta és a perifériás artériák helyreállító eljárásaihoz használható. A Silver Graft felszívódó, módosított szarvasmarha-zselatinnal impregnált a protézis ideiglenes vérzáróvá tételéhez. A Silver Graft külső felülete egy fém ezüst bevonattal rendelkezik, amely megakadályozza a mikrobiális megtapadást. Egyéb összetevők: glicerin, hexametilén-diizocianát (a zselatin térhálósítója), palládium és titánium. A Silver Graft Helix ezeken felül egy polipropilén szálat is tartalmaz a protézis külső mechanikai nyomás elleni védelmére és a gyűrődés elleni stabilitás növelésére.

Mennyi ideig fog tartani a Silver Graft impalntátum?

Várható élettartam

A zselatinbevonatú, ezüsttel impregnált poliészter graftok, például a Silver Graft hatékony artériapótlóként való alkalmazását mind in vivo (állat), mind in vitro (laboratóriumi) kísérletekben értékelték (1-4). A poliésztert gyakran használják vaszkuláris graftokhoz, például bypass- műtéteknél (5). Tartóssága és az emberi testtel való kompatibilitása miatt sok sebész számára előnyös választás. Az implantátumot a szervezet nem bontja le. Ezért, ha nem fordulnak elő mellékhatások, a Silver Graft a páciens élete végéig a testben maradhat. A beültetést követően a szervezet saját kötőszöveti sejtjei bevándorolnak az implantátumba.



Amire önnek és orvosának figyelnie kell!

Kölcsönhatások környezeti tényezőkkel

Mágneses rezonanciás képalkotás (MRI) biztonságosan végezhető beültetett ezüstgraft érrendszeri protézisben szenvedő betegeknél a következő feltételek mellett:

- Statikus mágneses mező: 1,5 T és 3 T
- Maximális térbeli grádiens: 6,6 T/m
- Teljes test átlagos fajlagos abszorpciós ráta (SAR): 2 W/kg

Azonban javasolt, hogy az MRI-vizsgálat előtt tájékoztassa a kezelőorvost az implantátumokról. Mutassa meg az implantátumkártyáját!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Izobraževanje bolnikov

sl

S čim pride vaše telo v stik po vsaditvi izdelka Silver Graft?

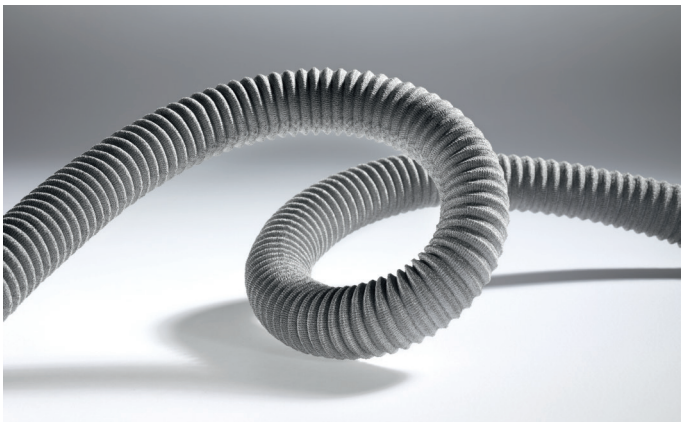
Materiali in snovi

Silver Graft je snutkovno pletena dvojno veluracijska žilna proteza iz polietilen tereftalata (poliestra) za rekonstrukcijske posege na aorti in perifernih arterijah. Silver Graft je impregniran z vpojno modificirano govejo želatino za začasno zatesnitev. Zunanja površina izdelka Silver Graft je prekrita s kovinsko srebrno plastjo, ki preprečuje prijemanje mikrobov. Druge sestavine so glicerol in heksametilen diizocianat (sredstvo za križno vezavo želatine), paladij in titan. Pri različici Silver Graft Helix je dodatno vključena polipropilenska nit, ki protezo ščiti pred mehanskim pritiskom od zunaj in povečuje stabilnost vsadka.

Kako dolgo bo vaš vsajeni Silver Graft zdržal?

Pričakovana življenjska doba

Uporaba z želatino prevlečenih in s srebrom impregniranih poliestrskih presadkov, kot je Silver Graft, kot učinkovitih arterijskih nadomestkov je bila ocenjena v poskusih in-vivo (na živalih) in in-vitro (v laboratoriju) (1-4). Poliester se pogosto uporablja za žilne presadke pri posegih, kot so obvodi (5). Zaradi svoje trajnosti in združljivosti s človeškim telesom je prednostna izbira številnih kirurgov. Telo vsadka ne razgradi. Če se ne pojavijo neželeni dogodki, ostane presadek Silver Graft lahko vsajen do konca bolnikovega življenja. Po vsaditvi se celice lastnega vezivnega tkiva telesa povežejo z vsadkom.



Na kaj morate biti pozorni vi in vaš zdravnik!

Medsebojni vpliv z okoljskimi pogoji

Slikanje z magnetno resonanco (MRI) je pri bolnikih z vsajenimi žilnimi protezami Silver Graft mogoče varno opraviti pod naslednjimi pogoji:

- Statično magnetno polje: 1,5 T in 3 T
- Največji gradient prostorskega polja: 6,6 T/m
- Povprečna specifična stopnja absorpcije celotnega telesa (SAR): 2 W/kg

Vendar pa je priporočljivo, da lečečega zdravnika pred preiskavo z MRI obvestite o morebitnih vsadkih. Pokažite svojo kartico vsadka!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Edukacija pacijenata

hr

S čime vaše tijelo dolazi u kontakt nakon implantacije proizvoda Silver Graft?

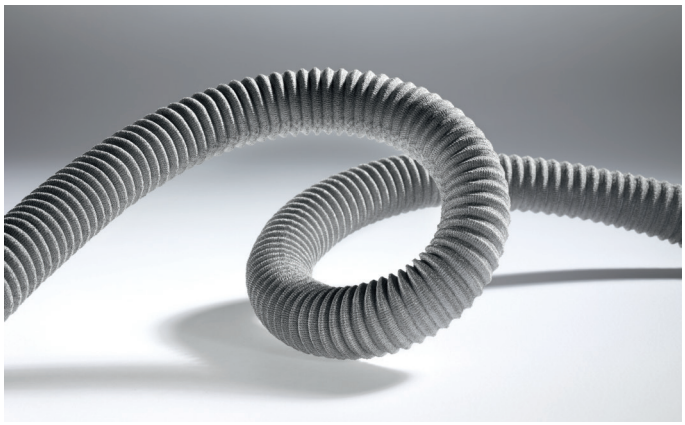
Materijali i tvari

Silver Graft je vaskularna proteza izrađena tehnikom pletenja osnove, s dvostrukim velurom, izrađena od polietilen tereftalata (poliestera), za rekonstrukcijske zahvate na aorti i arterijama u perifernom području. Silver Graft impregniran je apsorbirajućom modificiranom goveđom želatinom radi privremenog brtvljenja. Vanjska površina Silver Grafta obložena je metalnim srebrnim slojem kako bi se spriječila mikrobna adhezija. Drugi sastojci su glicerol i heksametilen diizocijanat (sredstvo za umrežavanje želatine), paladij i titanij. U slučaju Silver Graft Helix dodatno je uključen polipropilenski navoj koji štiti protezu od mehaničkog pritiska izvana i povećava stabilnost tinte.

Koliki je vijek trajanja vašeg implantiranog proizvoda Silver Graft?

Očekivani životni vijek

Uporaba želatinom obloženih, srebrom impregniranih poliesterskih presadaka kao što je Silver Graft kao učinkovitih nadomjestaka za arterije procijenjena je u in vivo (životinjskim) i in vitro (laboratorijskim) pokusima (1-4). Poliester se obično upotrebljava za vaskularne presatke u postupcima kao što su operacije premosnice (5). Njegova izdržljivost i kompatibilnost s ljudskim tijelom čine ga preferiranim izborom za mnoge kirurge. Tijelo ne razgrađuje implantat. Stoga, ako se ne pojave štetni događaji, Silver Graft ostaje implantiran do kraja života pacijenta. Nakon implantacije stanice vezivnog tkiva tijela migriraju u implantat.



Na što biste vi i vaš liječnik trebali pripaziti?

Interakcije s okolišnim uvjetima

Snimanje magnetskom rezonancijom (MRI) može se na siguran način obavljati u pacijenata s implantiranim vaskularnim protezama Silver Graft u sljedećim uvjetima:

- Statičko magnetsko polje: 1,5 T i 3 T
- Maksimalni prostorni gradijent polja: 6,6 T/m
- Specifična stopa apsorpcije za cijelo tijelo (SAR): 2 W/kg

Međutim, preporučuje se obavijestiti nadležnog liječnika o bilo kakvim implantatima prije pregleda magnetskom rezonancijom. Pokažite svoju karticu implantata!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Instruirea pacientului

ro

Cu ce vine corpul dvs. în contact după implantarea Silver Graft?

Materiale și substanțe

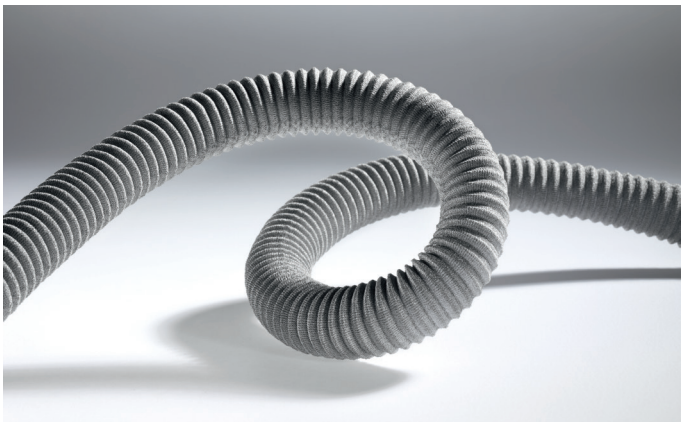
Silver Graft este o proteză vasculară din polietilen tereftalat (poliester), tricotată în urzeală, cu două nervuri, pentru proceduri de reconstrucție a aortei și a arterelor din zona periferică. Silver Graft este impregnată cu gelatină bovină modificată absorbabilă pentru sigilare temporară. Suprafața exterioară a Silver Graft este acoperită cu un strat de argint metalic pentru a inhiba aderența microbiană. Alte ingrediente sunt glicerolul și diizocianatul de hexametilenă (reticulant pentru gelatină), paladiul și titanul. În cazul Silver Graft Helix este inclus în plus un fir de polipropilenă pentru a proteja proteza împotriva presiunii mecanice din exterior și pentru a crește stabilitatea la răsucire.

Cât va rezista implantul dumneavoastră Silver Graft?

Durata de viață preconizată

Utilizarea grefelor de poliester acoperite cu gelatină și impregnate cu argint, cum ar fi Silver Graft, ca înlocuitori arteriali eficienți, a fost evaluată atât în experimente in vivo (animale), cât și in vitro (laborator) (1-4). Poliesterul este utilizat în mod obișnuit pentru grefele vasculare în proceduri precum operațiile de bypass (5). Durabilitatea și compatibilitatea cu corpul uman îl transformă într-o alegere preferată pentru mulți chirurgi. Implantul nu este absorbit de corp.

Prin urmare, Silver Graft rămâne implantat pentru tot restul vieții pacientului , dacă nu apar evenimente adverse. După implantare, celulele de țesut conjunctiv ale corpului imigrează în implant.



Ce trebuie să aveți în vedere dvs. și doctorul dvs.!

Interacțiuni cu condițiile de mediu

Imagistica prin rezonanță magnetică (IRM) poate fi efectuată în siguranță la pacienții cu proteze vasculare Silver Graft implantate, în următoarele condiții:

- Câmp magnetic static: 1,5 T sau 3 T
- Gradient spațial maxim al câmpului: 6,6 T/m
- Rata specifică de absorbție mediată pe întreg corpul (RSA): 2 W/kg

Cu toate acestea, se recomandă să informați medicul curant cu privire la orice implanturi înainte de efectuarea unei examinări RMN. Prezentați-vă cardul de implant!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Образование на пациента

bg

С какво влиза в контакт вашето тяло след имплантирането на Silver Graft?

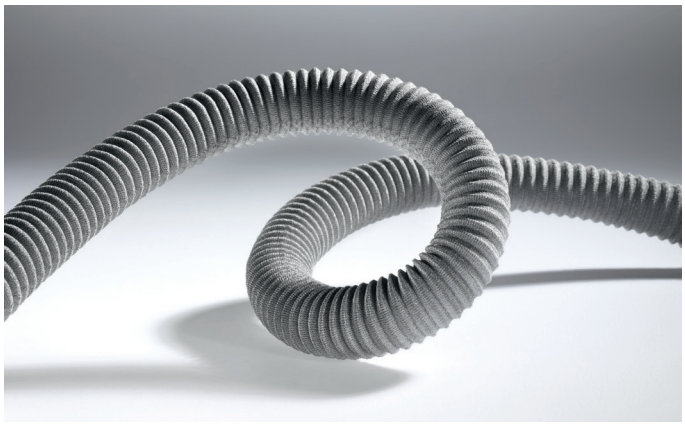
Материали и вещества

Silver Graft е съдова протеза от полиетилен терефталат (полиестер) с двойно покритие, изработена с едра плетка двойно изплетена с велурена нишка, за реконструктивни процедури на аортата и артериите в периферната област. Silver Graft е импрегнирана с абсорбиращ се модифициран говежди желатин за временно уплътняване. Външната повърхност на Silver Graft е покрита с метален сребърен слой, който инхибира микробната адхезия. Другите съставки са глицерол и хексаметилен диизоцианат (омрежващ агент за желатин), паладий и титан. При Silver Graft Helix допълнително е включена полипропиленова нишка, за да се предпази протезата от механичен натиск отвън и да се увеличи стабилността на прегъване.

Каква е трайността на имплантираната Silver Graft?

Очакван експлоатационен живот

Използването на покрити с желатин, импрегнирани със сребро полиестерни присадки, като Silver Graft, като ефективни артериални заместители е оценено както в експерименти in vivo (при животни), така и in vitro (в лабораторни условия) (1-4). Полиестерът често се използва за съдови присадки при процедури като байпас хирургия (5). Неговата издръжливост и съвместимост



с човешкото тяло го правят предпочитан избор за много хирурзи. Имплантът не се разгражда от тялото. Поради това, ако не настъпят нежелани събития, Silver Graft остава имплантирана до края на живота на пациента. След имплантирането клетките на собствената съединителна тъкан в тялото мигрират в импланта.

За какво трябва да внимавате вие и вашият лекар!

Взаимодействия с условията на околната среда

Ядрено-магнитен резонанс (ЯМР) може да се извърши безопасно при пациенти с имплантирани съдови протези Silver Graft при следните условия:

- Статично магнитно поле: 1,5 T и 3 T
- Максимален пространствен градиент на полето: 6,6 T/m
- Средна специфична степен на поглъщане (SAR) за цялото тяло: 2 W/kg

Препоръчва се обаче лекуващият лекар да бъде информиран за всички импланти преди ЯМР изследване. Покажете Вашата имплантна карта!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Hasta bilgisi

tr

Silver Graft implante edildikten sonra vücudunuz neye temas eder?

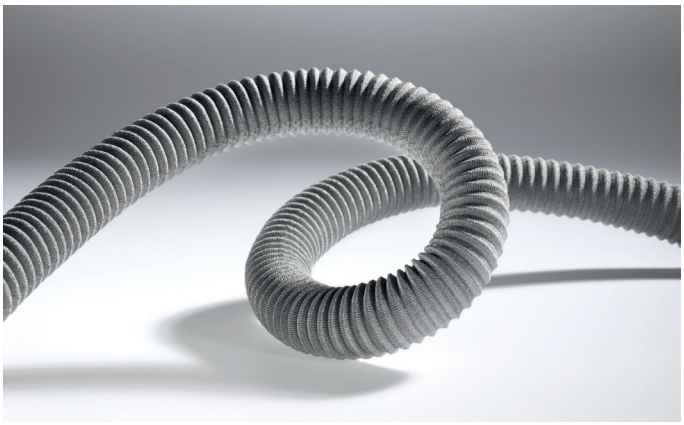
Malzemeler ve Maddeler

Silver Graft, aort ve periferik arterlerdeki rekonstrüktif işlemler için kullanılan, polietilen tereftalat (polyester) malzemeden üretilmiş, çözgü örme teknolojisiyle üretilen çift yüzeyli velur yapıya sahip bir damar protezidir. Silver Graft, geçici sızdırmazlık sağlamak amacıylaemilebilir modifiye edilmiş sığır jelatini ile emprenye edilmiştir. Silver Graft'ın dış yüzeyi mikrobiyal yapışmayı önlemek için metalik gümüş bir tabaka ile kaplanmıştır. Diğer bileşenler arasında gliserol, heksametilen diizosiyanat (jelatin için çapraz bağlayıcı), Paladyum ve Titanyum bulunmaktadır. Silver Graft Helix modelinde ise, protezi dışarıdan gelebilecek mekanik baskılara karşı korumak ve kıvrılma direncini artırmak amacıyla ayrıca bir polipropilen iplik kullanılmaktadır.

İmplante edilen Gümüş Greftiniz ne kadar vücutta kalır?

Beklenen kullanım ömrü

Silver Graft gibi jelatin kaplı ve gümüş emprenyeli polyester greftlerin etkili arteriyel yedekler olarak kullanımı, hem in vivo (hayvan) hem de in vitro (laboratuvar) deneylerle değerlendirilmiştir (1-4). Polyester, bypass ameliyatları gibi damar cerrahisi işlemlerinde yaygın olarak kullanılan bir malzemedir (5). Dayanıklılığı ve insan vücuduyla uyumu, onu birçok cerrah için tercih edilen bir seçenek haline getirmektedir. İmplant vücut tarafından parçalanmaz. Bu nedenle Silver Graft, herhangi bir advers olay gelişmediği sürece hastanın yaşamı boyunca vücutta kalır. İmplantasyondan sonra vücudun kendi bağdoku hücreleri implantın içine yerleşir.



Siz ve doktorunuz nelere dikkat etmelisiniz!

Çevresel koşullarla etkileşimler

Manyetik rezonans görüntüleme (MRI), aşağıdaki koşullar altında implante edilmiş Gümüş Greft vasküler protezleri olan hastalarda güvenle yapılabilir:

- Statik manyetik alan: 1,5 T ve 3 T
- Maksimum boyutsal alan eğimi: 6,6 T/m
- Tüm vücut ortalaması alınmış özgül abzorbsiyon oranı (SAR): 2 W/kg

Bununla birlikte, bir MRI muayenesinden önce tedavi eden hekimin implantlar hakkında bilgilendirilmesi önerilir. İmplant kartınızı gösterin!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

Silver Graft

AESCULAP® Εκπαίδευση ασθενή

el

Με τι ερχεται σε επαφη το σωμα σας μετα την εμφυτευση του Silver Graft?

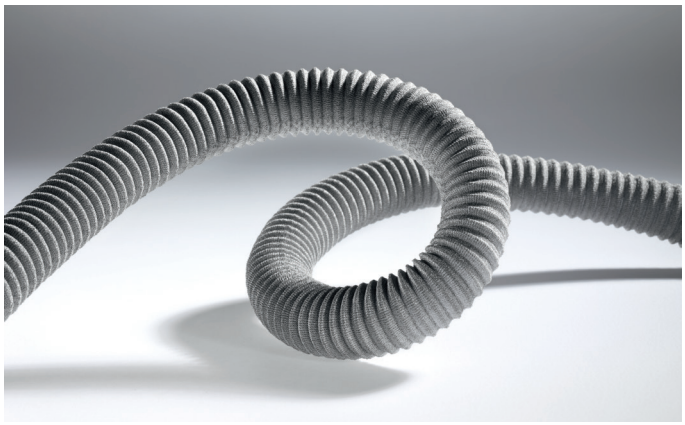
Υλικά και ουσίες

Το Silver Graft είναι μια αγγειακή πρόθεση από τερεφθαλικό πολυαιθυλένιο (πολυεστέρα), διπλής πλέξης, για επεμβάσεις αποκατάστασης της αορτής και των αρτηριών στην περιφερική περιοχή. Το Silver Graft είναι εμποτισμένο με απορροφήσιμη τροποποιημένη ζελατίνη βοοειδών για προσωρινή έμφραξη. Η εξωτερική επιφάνεια του Silver Graft είναι επικαλυμμένη με ένα στρώμα μεταλλικού αργύρου, ώστε να παρεμποδίζει την προσκόλληση μικροβίων. Άλλα συστατικά είναι γλυκερίνη και διισοκυανικό εξαμεθυλένιο (διασυνδετικός παράγοντας για τη ζελατίνη), παλλάδιο και τιτάνιο. Στην περίπτωση του Silver Graft Helix περιλαμβάνεται επιπλέον ένα νήμα πολυπροπυλενίου για την προστασία της πρόθεσης από μηχανική πίεση από εξωγενείς παράγοντες και για την αύξηση της σταθερότητας του πηκτώματος.

Πόσο καιρό θα διαρκέσει το εμφυτευμένο αργυρό μόσχευμα?

Προβλεπόμενη διάρκεια ζωής

Η χρήση πολυεστερικών μοσχευμάτων με επικάλυψη ζελατίνης, που έχουν εμποτιστεί με άργυρο, όπως το Silver Graft, ως αποτελεσματικών αρτηριακών υποκατάστατων, έχει αξιολογηθεί τόσο σε in vivo (σε ζώα) όσο και σε in vitro (εργαστηριακά) πειράματα (1-4). Ο πολυεστέρας χρησιμοποιείται συνήθως για αγγειακά μοσχεύματα σε διαδικασίες όπως οι χειρουργικές επεμβάσεις



παράκαμψης (5). Η αντοχή και η συμβατότητά του με το ανθρώπινο σώμα το καθιστούν μια από τις πρώτες επιλογές πολλών χειρουργών. Το εμφύτευμα δεν διασπάται από το σώμα. Ως εκ τούτου, το Silver Graft παραμένει εμφυτευμένο για το υπόλοιπο της ζωής του ασθενούς, εάν δεν εμφανιστούν ανεπιθύμητες παρενέργειες. Μετά την εμφύτευση, τα κύτταρα του συνδετικού ιστού του σώματος του μεταναστεύουν στο εμφύτευμα.

Τι θα πρεπει να προσεξετε εσεις και ο ιατρος σας!

Αλληλεπιδρασεις με τις περιβαλλοντικες συνθηκες

Η μαγνητική τομογραφία (MRI) μπορεί να πραγματοποιηθεί με ασφάλεια σε ασθενείς με εμφυτευμένες αγγειακές προθέσεις Silver Graft υπό τις ακόλουθες συνθήκες:

- Στατικό μαγνητικό πεδίο: 1,5 T και 3 T
- Μέγιστη διαβάθμιση χωρικού πεδίου: 6,6 T/m
- Μέσος ρυθμός ειδικής απορρόφησης ολόκληρου του σώματος (SAR): 2 W/kg

Ωστόσο, συνιστάται ο θεράπων ιατρός να ενημερώνεται για τυχόν εμφυτεύματα πριν από εξέταση μαγνητικής τομογραφίας. Δείξτε την κάρτα εμφυτεύματός σας!

(1) Zegelman M, Guenther G, Florek HJ, Orend KH, Zuehlke H, Liewald F et al. Results from the first in man german pilot study of the silver graft, a vascular graft impregnated with metallic silver. Vascular. 2009;17(4):190–6. DOI: 10,2310/6670.2009.00034.

(2) Zegelman M, Guenther G, Waliszewski M, Pukacki F, Stanisic MG, Piquet P et al. Results from the International Silver Graft Registry for high-risk patients treated with a metallic-silver impregnated vascular graft. Vascular. 2013;21(3):137–47. DOI: 10,1177/1708538113478773.

(3) Ueberrueck T, Zippel R, Tautenhahn J, Gastinger I, Lippert H, Wahlers T. Vascular graft infections: in vitro and in vivo investigations of a new vascular graft with longterm protection. J Biomed Mater Res B Appl Biomater. 2005;74(1):601-7.

(4) Ueberrueck T, Meyer L, Zippel R, Nestler G, Wahlers T, Gastinger I. Healing Characteristics of a New Silver-Coated, Gelatine Impregnated Vascular Prosthesis in the Porcine Model. Zentralbl Chir. 2005;130:71–6.

(5) Li, Y., Wu, Z. Prosthetic Vascular Grafts: Past, Present, and Future. In: Tang, YD., Yang, J., Zheng, Y., Li, Y., Zeng, Y. (eds) Application of Biomaterials in the Treatment of Cardiovascular Diseases. 2024. Springer, Singapore.

AESCULAP® – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-2600 | www.bbraun.com

The main product trademark "Aesculap" and the product trademarks "Prospace", "S4" and "activL®" are registered trademarks of Aesculap AG.

Subject to technical changes. All rights reserved. This brochure may only be used for the exclusive purpose of obtaining information about our products. Reproduction in any form partial or otherwise is not permitted.

L06599 0726/PDF/2