Passeo-18

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

STERILE EO

BIOTRONIK
excellence for life

Sizes/Größen/Tailles/Misure/Tamaños/Размери/Veličine/Velikosti/Størrelser/Maten/Koot/Μεγέθη/Méretek/Izmēri/Dydžiai/Størrelser/Rozmiary/Tamanhos/Dimensiuni/Размеры/Veľkosti/Velikosti/Storlekar/Büyüklükler

Balloon Length (mm) [BL]		20			40			60			80			120			150			170			200			220		
Usable Length (cm) [UL]		90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150	90	130	150
Nominal Balloon Ø (mm) [NB Ø]	2	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x
	2.5	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	3	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	3.5	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	4	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	5	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	6	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	
	7	x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x		x	x	

Abbreviations/Abkürzungen/Abréviations/Abbreviazioni/Abreviaturas/Абревиатури/Kratice/Zkratky/Forkortelser/Afkortingen/Lyhenteet/Συντμήσεις/Rövidítések/Saīsinājumi/Santrumpos/Forkortelser/Skróty/Abreviaturas/Abrevieri/Сокращения/Skratky/Okrajšave/Förkortningar/Kısaltmalar

Deutsch:
BL: Ballonlänge (mm)
UL: Nutzlänge (cm)
NB Ø: Nenndurchmesser des Ballons (mm)

Français:
BL : longueur du ballonnet (mm)
UL : longueur utile (cm)
NB Ø : Ø nominal du ballonnet (mm)

Italiano:
BL: Lunghezza del palloncino (mm)
UL: Lunghezza utile (cm)
Ø NB: Diametro nominale del palloncino (mm)

Español:
BL: Longitud del balón (mm)
UL: Longitud útil (cm)
NB Ø: Ø nominal del balón (mm)

Български:
BL: Дължина на балона (mm)
UL: Работна дължина (cm)
NB Ø: Номинален диаметър на балона (mm)

Hrvatski:
BL: Duljina balona (mm)
UL: Korisna duljina (cm)
NB Ø: Nominalni promjer balona (mm)

Česky:
BL: Délka balonku (mm)
UL: Použitelná délka (cm)
NB Ø: Nominální Ø balonku (mm)

Dansk:
BL: Ballonlængde (mm)
UL: Anvendelig længde (cm)
NB Ø: Nominel ballondiameter (mm)

Nederlands:
BL: Ballonlengte (mm)
UL: Bruikbare lengte (cm)
NB Ø: Nominale ballondiameter (mm)

Suomi:
BL: Pallon pituus (mm)
UL: Työpituus (cm)
NB Ø: Pallon nimellinen Ø (mm)

Ελληνικά:
BL: Μήκος μπαλονιού (mm)
UL: Χρησιμοποιήσιμο μήκος (cm)
NB Ø: Ονομαστική διάμετρος μπαλονιού (mm)

Magyar:
BL: Ballon hossza (mm)
UL: Hasznos hossz (cm)
NB Ø: Névleges ballonátmérő (mm)

Latviešu:
BL: balona garums (mm)
UL: lietojamais garums (cm)
NB Ø: nominālais balona Ø (mm)

Lietuvių:
BL: balionėlio ilgis (mm)
UL: naudojamas ilgis (cm)
NB Ø: nominalusis balionо skersmuo Ø (mm)

Norsk:
BL: Ballonglengde (mm)
UL: Arbeidslengde (cm)
NB Ø: Nominell ballongdiameter (mm)

Polski:
BL: Długość balonu (mm)
UL: Długość użytkowa (cm)
NB Ø: Nominalna Ø balonu (mm)

Português:
BL: Comprimento do balão (mm)
UL: Comprimento útil (cm)
NB Ø: Ø nominal do balão (mm)

Română:
LB: Lungimea balonului (mm)
LU: Lungime utilă (cm)
Ø NB: Ø nominal balon (mm)

Русский:
BL: Длина баллона (мм)
UL: Рабочая длина (см)
NB Ø: Номинальный диаметр баллона (мм)

Slovenčina:
BL: Dĺžka balónika (mm)
UL: Pracovná dĺžka (cm)
NB Ø: Nominálny priemer balónika (mm)

Slovenščina:
BL: dolžina balona (mm)
UL: uporabna dolžina (cm)
NB Ø: nominalni Ø balona (mm)

Svenska:
BL: Ballonglängd (mm)
UL: Arbetslängd (cm)
NB Ø: Nominell ballong-Ø (mm)

Türkçe:
BL: Balon Uzunluğu (mm)
UL: Çalışma Uzunluğu (cm)
NB Ø: Nominal Balon Ø (mm)

Symbol Legend/Symbollegende/Légende des symboles/Legenda dei simboli/Leyenda de símbolos/Легенда на символите/Legenda simbola/Popis symbolů/Symbolforklaring/Verklaring van symbolen/Symbolien selitykset/Επεξήγηση συμβόλων/Jelmagyarázat/Simbolu skaidrojums/Simbolių reikšmės/Symbolforklaring/Wyjaśnienie symboli/Legenda dos símbolos/Legenda simbolurilor/Условные обозначения/Legenda k symbolom/Legenda simbolov/Symbolförklaring/Sembol açıklaması

STERILE EO

Sterilized using ethylene oxide
Sterilisation mit Ethylenoxid
Stérilisé à l'oxyde d'éthylène
Sterilizzato mediante ossido di etilene
Producto esterilizado con óxido de etileno
Стерилизирано с етиленов оксид
Sterilizirano etilen oksidom
Sterilizováno ethylenoxidem
Steriliseret med ethylenoxid
Gesteriliseerd met ethyleenoxide
Steriloitu etyleenioksidilla
Αποστειρωμένο με χρήση οξειδίου του αιθυλενίου
Etilén-oxiddal sterilizálva
Sterilizēts, izmantojot etilēna oksīdu
Sterilizuota etileno oksidu
Steriliserl med etylenoksid
Sterylizowano tlenkiem etylenu
Esterilizado com óxido de etileno
Sterilizat cu oxid de etilenă
Стерилизовано оксидом этилена
Sterilizované etylénoxidom
Sterilizirano z etilenoksidom
Steriliserad med etylenoxid
Etilen oksitle sterilize edilmiştir

Keep dry
Trocken aufbewahren
Conserver au sec
Tenere all'asciutto
Mantener seco
Да се пази от влага
Držati na suhom
Uchovávejte v suchu
Holdes tør
Droog houden
Pidettävä kuivana
Διατηρήστε το στεγνό
Szárazon tartandó
Uzturēt sausu
Laikyti sausai
Holdes tørt
Chronić przed wilgocią
Manter em local seco
A se păstra în stare uscată
Хранить в сухом месте
Uchovávajte v suchu
Shranjujte na suhem
Förvaras torrt
Kuru tutun

Do not resterilize
Nicht resterilisieren
Ne pas restériliser
Non risterilizzare
No reesterilizar
Да не се стерилизира повторно
Nemojte ponovno sterilizirati
Neresterilizujte
Må ikke resteriliseres
Niet opnieuw steriliseren
Ei saa steriloida uudelleen
Μην επαναποστειρώνετε
Tilos újrasterilizálni!
Nesterilizēt atkārtoti
Nesterilizuoti pakartotinai
Skal ikke resteriliseres
Nie sterylizować ponownie
Não reesterilizar
Nu resterilizați
Не подвергайте повторной стерилизации
Nesterilizujte opakovane
Ne sterilizirajte ponovno
Får inte omsteriliseras
Tekrar sterilize etmeyin

Consult instructions for use
Gebrauchsanweisung beachten
Consulter le mode d'emploi
Consultare le istruzioni per l'uso
Consultar las instrucciones de uso
Вижте инструкциите за употреба
Pogledajte upute za uporabu
Řiďte se návodem k použití
Se brugsanvisningen
Gebruiksaanwijzing raadplegen
Kalso käyttöohjeet
Συμβουλευτείτε τις οδηγίες χρήσης
Olvassa el a használati utasítást
Iepazīstieties ar lietošanas instrukciju
Skaityti naudojimo instrukcijas
Se bruksanvisningen
Sprawdź w instrukcji użycia
Consultar as instruções de utilização
Consultați instrucțiunile de utilizare
Смотрите инструкцию по применению
Pozrite si návod na použitie
Glejte navodila za uporabo
Se bruksanvisningen
Kullanma talimatına başvurun

Do not reuse
Nicht zur Wiederverwendung
Ne pas réutiliser
Non riutilizzare
No reutilizar
Да не се използва повторно
Nemojte ponovno upotrebljavati
Nepoužívejte opakovaně
Må ikke genbruges
Niet opnieuw gebruiken
Ei saa käyttää uudelleen
Μην το επαναχρησιμοποιείτε
Tilos újra felhasználni!
Nelietot atkārtoti
Nenaudoti pakartotinai
Skal ikke brukes flere ganger
Nie używać ponownie
Não reutilizar
A nu se refolosi
Не использовать повторно
Nepoužívajte opakovane
Ne uporabite ponovno
Får ej återanvändas
Tekrar kullanmayın

Keep away from sunlight
Vor Sonnenlicht schützen
Conserver à l'abri de la lumière du soleil
Mantenere al riparo dalla luce solare
Mantener lejos de la luz solar
Да се пази от слънчева светлина
Ne izlažite sunčevoj svjetlosti
Chraňte před slunečním světlem
Må ikke udsælles for sollys
Niet blootstellen aan zonlicht
Suojattava auringonvalolta
Διατηρήστε το μακριά από το φως
Napsugárzástól védve tartandó
Sargāt no saules gaismas
Laikyti atokiau nuo saulės spindulių
Må ikke utsælles for sollys
Chronić przed światłem
Manter afastado da luz solar
A se feri de lumină
Хранить в защищенном от солнечного света месте
Uchovávajte mimo slnečného žiarenia
Zaščitite pred sončno svetlobo
Får inte utsättas för solljus
Güneş ışığından uzak tutun

Date of manufacture
Herstellungsdatum
Date de fabrication
Data di fabbricazione
Fecha de fabricación
Дата на производство
Datum proizvodnje
Datum výroby
Fremstillingsdato
Productiedatum
Valmistuspäivämäärä
Ημερομηνία κατασκευής
Gyártási dátum
Ražošanas datums
Pagaminimo data
Produksjonsdato
Data produkcji
Data de fabrico
Data fabricației
Дата изготовления
Dátum výroby
Datum izdelave
Tillverkningsdatum
Üretim tarihi

Manufacturer
Hersteller
Fabricant
Fabbricante
Fabricante
Производител
Proizvođač
Výrobce
Fabrikant
Fabrikant
Valmistaja
Κατασκευαστής
Gyártó
Ražotājs
Gamintojas
Produsent
Wytwórca
Fabricante
Producător
Изготовитель
Výrobca
Izdelovalec
Bruksanvisning
Üretici

Caution
Vorsicht
Attention
Attenzione
Aviso
Внимание
Oprez
Upozornění
Forsigtig
Let op
Huomio
Προσοχή
Figyelem
Piesardzība
Dėmesio
Forsiktig
Przestroga
Cuidado
Atenție
Не использовать повторно
Upozornenie
Pozor
Laktta försiktighet
Dikkat

Use by
Vorwendbar bis
À utiliser avant le
Utilizzare entro il
Fecha de caducidad
Срок на годност
Rok uporabe
Použít do
Anvendes før
Te gebruiken voor
Käytettävä ennen
Ημερομηνία λήξης
Felhasználható a következő időpontig
Derīguma termiņš
Naudoti iki
Brukes innen
Użyć przed
Validade
Data expirării
Срок годности
Použite do
Uporabite do
Sista förbrukningsdag
Son kullanma tarihi

LOT

Batch code
Chargenbezeichnung
Code de lot
Numero di lotto
Código de lote
Партиден номер
Oznaka serije
Kód šarže
Batch-kode
Batchcode
Eräkoodi
Κωδικός παρτίδας
Gyártási tétel kódja
Sērijas kods
Partijos kodas
Partikode
Numer serii
Código do lote
Cod lot
Код партии
Kód šarže
Koda serije
Satskod
Seri kodu

REF

Catalogue number
Bestellnummer
Référence
Codice
Número de catálogo
Каталожен номер
Kataloški broj
Číslo v katalogu
Katalognummer
Catalogusnummer
Luettelonumero
Αριθμός καταλόγου
Katalógusszám
Kataloga numurs
Katalogo numeris
Katalognummer
Numer katalogowy
Número do catálogo
Număr de catalog
Номер по каталогу
Katalógové číslo
Katalóška številka
Katalognummer
Katalog numarası

NP	RBP		
Nominal pressure	Rated burst pressure	Temperature limitation	Do not use if package is damaged
Nenndruck	Nennberstdruck	Temperaturgrenze	Inhalt bei beschädigter Verpackung nicht verwenden
Pression nominale	Pression de rupture nominale	Limite de température	Ne pas utiliser si l'emballage est endommagé
Pressione nominale	Pressione nominale di rottura	Limiti di temperatura	Non utilizzare se la confezione è danneggiata
Presión nominal	Presión máxima de hinchado	Límites de temperatura	No utilizar si el envase está dañado
Номинално налягане	Номинално налягане на спукване	Ограничение на температурата	Да не се използва, ако опаковката е повредена
Nominalni tlak	Maksimalni dopušteni tlak	Temperaturno ograničenje	Nemojte koristiti ako je pakiranje oštećeno
Jmenovitý tlak	Poruchový tlak	Teplotní omezení	Nepoužívejte, je-li obal poškozen
Nominelt tryk	Nominelt sprængtryk	Temperaturbegrænsning	Anvendes ikke, hvis emballagen er beskadiget
Nominale druk	Nominale barstdruk	Temperatuurgrenzen	Niet gebruiken indien de verpakking beschadigd is
Nimellispaine	Nimellinen repeämispaine	Lämpötilarajoitus	Ei saa käyttää, jos pakkaus on vahingoittunut
Ονομαστική πίεση	Ονομαστική πίεση ρήξης	Περιορισμός θερμοκρασίας	Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί φθορά
Névleges nyomás	Névleges szétrepedési nyomás	Hőmérséklethatár	Ne használja, ha a csomagolás sérült
Nominālais spiediens	Nominālais pārraušanas spiediens	Temperatūras ierobežojumi	Nelietot, ja iepakojums bojāts
Vardinis slėgis	Vardinis trūkimo slėgis	Temperatūros ribos	Nenaudoti, jei pakuotė pažeista
Nominelt trykk	Nominelt sprengtrykk	Temperaturbegrensning	Skal ikke brukes hvis emballasjen er skadet
Ciśnienie nominalne	Nominalne ciśnienie rozrywające	Ograniczenia temperatury	Nie stosować, jeżeli opakowanie jest uszkodzone
Pressão nominal	Pressão de rotura nominal	Limites de temperatura	Não utilizar se a embalagem estiver danificada
Presiune nominală	Presiune de spargere nominală	Limitare de temperatură	Nu utilizați dacă ambalajul este deteriorat
Номинальное давление	Номинальное давление разрыва	Ограничения температуры	Не использовать, если упаковка повреждена
Nominálny tlak	Nominálny tlak roztrhnutia	Teplotné obmedzenie	Nepoužívajte, ak je poškodený obal
Nazivni tlak	Nazivni porušitveni tlak	Temperaturne omejitve	Ne uporabljajte, če je ovojnina poškodovana
Nominellt tryck	Beräknat sprängtryck	Temperaturbegränsning	Får ej användas om förpackningen skadats
Nominal basınç	Anma patlama basıncı	Sıcaklık sınırlaması	Ambalaj hasarlıysa kullanmayın

English

Description

The Passeo-18 peripheral dilatation catheter is intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae. The dilatation balloon is designed to inflate to a known diameter at a specific inflation pressure consistent with the compliance chart on the label. One radiopaque marker is located at each end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon catheter towards and across the lesion.
The dilatation catheter includes a soft tapered tip to facilitate advancement of the catheter. The dilatation catheter has two Luer-ports at the proximal end. One port (inflation port) serves for connecting an inflation device to inflate/deflate the balloon. The other port enables flushing of the guide wire lumen. The dilatation catheter has a hydrophobic silicone coating on the shaft outer surface and a hydrophobic patchwork coating on the balloon.
The dilatation catheter is compatible with guide wire and introducer sheath sizes according to the recommendations on the label.
Caution: Non-clinical testing with the following introducer sheaths "Cordis Avanti+", "Terumo Radifocus", "Cook Flexor Check-Flo Performer" and "BIOTRONIK Fortress" has demonstrated that the BIOTRONIK Passeo-18 balloon catheter is compatible with the indicated minimum introducer sheath sizes. If Passeo-18 is used in conjunction with other, long and/or braided introducer sheaths a larger French size than indicated on the label may be necessary to reduce friction.

How Supplied

Sterile. Non-pyrogenic. Device is sterilized with ethylene oxide.
DO NOT use if the package is opened or damaged, or if any information provided is obscured or damaged.

Contents

- One (1) Passeo-18 peripheral dilatation catheter in a sealed, peel-open pouch.
- One (1) Instructions for Use Manual.

Storage

Store in a dark, dry location between 10°C and 40°C / 50°F and 104°F.

Indications

The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications

Contraindications for this device and peripheral dilatation catheters in general are:
- Inability to cross the target lesion with a guide wire
- Bleeding diathesis

Warnings

- The Passeo-18 peripheral dilatation catheter is not indicated for use in coronary, cervical and intracranial arteries.
- This device is designed and intended for single use only. DO NOT resterilize and/or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. BIOTRONIK will not be responsible for any direct, incidental or consequential damages resulting from resterilization or reuse.
- The inflated diameter of the balloon should never exceed the original diameter of the vessel proximal and distal to the lesion.
- Balloon pressure should not exceed the given rated burst pressure (RBP). The use of a pressure monitoring device is mandatory to prevent overpressurization.
- Use only an appropriate balloon inflation medium, (e.g. 50:50 mixture by volume of contrast medium and saline). Never use air or any gaseous medium to inflate the balloon.
- Do not expose the catheter to organic solvents, e. g. alcohol.
- When the dilatation catheter is in the body, it should be manipulated whilst under sufficient and/or high-quality fluoroscopy.
- Precautions to prevent or reduce clotting should be taken. Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution prior to use. The use of systemic heparinization during the procedure is recommended.

Precautions

- Do not use the Passeo-18 peripheral dilatation catheter if either the outer or inner package is damaged or opened.
- Only physicians thoroughly trained and educated in the performance of percutaneous transluminal angioplasty (PTA) should use the dilatation catheter.
- Use prior to the "use by" date.
- Use only guide wires with a maximum 0.018" (0.46 mm) diameter. Use only with introducers of an appropriate size as specified on the label.
- Non-clinical testing with the following introducer sheaths "Cordis Avanti+", "Terumo Radifocus", "Cook Flexor Check-Flo Performer" and "BIOTRONIK Fortress" has demonstrated that the BIOTRONIK Passeo-18 balloon catheter is compatible with the indicated minimum introducer sheath sizes. If Passeo-18 is used in conjunction with other, long and/or braided introducer sheaths a larger French size than indicated on the label may be necessary to reduce friction.
- Exercise care during handling to reduce the possibility of accidental breakage, bending or kinking of the catheter shaft.
- Prior to commencing the procedure, the dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.
- If strong resistance is experienced during manipulation, stop the procedure and determine the cause of the resistance before proceeding.
- Balloons exceeding 3.5 mm diameter and 60 mm length should be deflated for at least 90 seconds to assure that all inflation medium was completely removed. It is recommended to maintain vacuum whenever the dilatation catheter is subsequently advanced or withdrawn. Failure to do so may result in difficulties pulling back the balloon through the introducer sheath.
- Disposal of packaging materials can be handled per normal industrial/local standards. The used device shall be handled according to hospital procedure.

Potential Adverse Events/Complications

Possible complications include, but are not limited to:
- Death
- Injury to the vessel wall, intimal tear
- Arteriovenous fistula
- Embolization of air, thrombotic or atherosclerotic material
- Pseudoaneurysm formation
- Vessel spasm
- Restenosis of the dilated vessel
- Total occlusion of the vessel
- Infection
- Hemorrhage or hematoma
- Embolism
- Thrombosis
- Allergic reactions to contrast media, antiplatelets, anticoagulants
- Balloon catheter events: Failure to reach or cross the lesion, inflation difficulties, rupture or pinhole of the balloon, deflation difficulties, withdrawal difficulties, embolization of catheter material.

Directions for Use

Dilatation catheter preparation

1. Remove the dilatation catheter protection ring from the package and place it onto a sterile field.
2. Gently withdraw the dilatation catheter from the protection ring.
3. Carefully remove the balloon protector by pulling on the very distal end of the protector.

Flush guide wire lumen

4. Connect a 10 ml or 20 ml syringe containing sterile saline to the Luer port of the guide wire lumen at the proximal end of the dilatation catheter.
5. Flush the guide wire lumen.
6. Remove the syringe.

Insertion technique

7. Position the guide wire, under fluoroscopic guidance, in accordance with standard percutaneous transluminal angioplasty (PTA) techniques.
8. Insert the distal tip of the dilatation catheter onto the proximal end of the guide wire and advance until the guide wire exits the Luer lock at the proximal end of the catheter.
9. Carefully insert the dilatation catheter through the introducer.
10. Advance the dilatation catheter over the guide wire towards the lesion.
11. Position the balloon across the lesion using the balloon radiopaque markers as reference points.

Purge air from catheter inflation lumen

12. Fill a 20 ml capacity inflation device with 6 ml of contrast solution. Use 10 ml of contrast solution for balloons exceeding 5 mm diameter and 120 mm length.
13. Remove air from the inflation device according to the manufacturer's recommendations and instructions.
14. Attach the inflation device to the inflation port of the dilatation catheter.

Caution: Do not permit air to enter the system.
15. Pull back on the plunger and aspirate for 30 seconds until no bubbles appear inside the barrel of the inflation device during aspiration. Repeat this process several times if necessary.
16. Return to neutral pressure.

Balloon inflation/deflation

17. Inflate the balloon with the inflation device to dilate the lesion using standard PTA techniques.

Caution: Do not exceed the RBP stated on the label.
18. To deflate the balloon completely pull back the plunger of the inflation device and lock it in this position. Apply vacuum to the balloon under fluoroscopic control for at least 30-90 seconds depending on the balloon size.

Caution: Balloons exceeding 3.5 mm diameter and 60 mm length should be deflated for at least 90 seconds to assure that all inflation medium was completely removed.
Caution: It is recommended to maintain vacuum whenever the dilatation catheter is subsequently advanced or withdrawn.

Dilatation catheter removal

19. While maintaining a vacuum with the inflation device and stable guide wire position across the lesion, withdraw the dilatation catheter carefully from the lesion and out through the introducer sheath.

Caution: Failure to do so may result in difficulties pulling back the balloon through the introducer sheath.
Note: If the balloon has been dilated several times, there may be some resistance as it is pulled back into the introducer sheath. In case of difficulties, pull out the dilatation catheter and the introducer sheath together.
20. Completely remove the dilatation catheter from the guide wire.

Warranty/Liability

This product and each of its components (hereinafter product) were designed, manufactured, tested and packaged with all reasonable care. However, since BIOTRONIK does not have control over the conditions under which the product is used, the contents of this Instructions For Use (IFU) are to be considered as an integral part of this disclaimer for cases when a disturbance of the product's intended function may occur for various reasons.
BIOTRONIK does not guarantee that the following events will not occur:
- Product malfunctions or failures
- Patient's immune response to the product
- Medical complications during the use of the product or as a consequence of the product being in contact with the patient's body

BIOTRONIK does not assume any liability for:
- The use of the product that is not in accordance with the stated intended use/indication, contraindications, warnings, precautions and the directions for use of this IFU
- Modification to the original product
- Events which could not have been foreseen at the time of product delivery using the available levels of science and technology
- Events originating from other BIOTRONIK products or products not from BIOTRONIK
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