Boston Scientific

MANTIS™

Clip

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MANTIS™
Clip

℞ ONLY

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

REUSE WARNING

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DEVICE DESCRIPTION

The MANTIS Clip consists of a radiopaque, single-use clip with an 11 mm clip opening, pre-loaded on a flexible, rotatable delivery system.

The MANTIS Clip is designed to be compatible with forward viewing endoscopes with working channels equal to or greater than 2.8 mm.

The radiopaque MANTIS Clip is engineered to enable opening and closing no more than five times prior to deployment, aiding in repositioning of the clip at the lesion site. Reopening, closing and rotation capability may be limited by clinical circumstances and patient anatomy, among other factors.

Contents

(1) MANTIS Clip, pre-loaded on a flexible, rotatable delivery system.

Operating Principle

MANTIS Clip is a single use rotatable mechanical clip with enhanced grasping capabilities which can be introduced in the GI tract through an endoscope to be deployed in a target site. The clip can then be positioned for deployment via manipulation of the scope and/or the device itself which may include rotation of the clip. Once the clip is positioned at the treatment site, the handle is actuated to deploy the clip and the delivery catheter is then withdrawn through the scope. The deployed clip remains at the treatment site and facilitates the treatment; the clip eventually passes naturally through the Gastrointestinal (GI) tract.

Materials

Materials and substances for which the patient can be exposed to, by the implantable portion of the medical device, are the following:

Implantable Material	% (wt) (Total assembly weight = 0.125g)
Stainless steel	75%
Cobalt-Chrome	22%
Styrene acrylonitrile copolymers	3%

Contains cobalt: CAS No. 7440-48-4; EN No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight.

Note: Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.

User Information

The MANTIS Clip should only be used by or under the supervision of a physician with a thorough understanding of the technical principles, clinical applications, and risks associated with MANTIS Clip.

INTENDED USE/ INDICATIONS FOR USE

The MANTIS Clip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:

1. Endoscopic marking
2. Hemostasis for: Mucosal/sub-mucosal defects < 3 cm, Bleeding ulcers, Arteries < 2 mm, Polyps < 1.5 cm in diameter, Diverticula in the colon, Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel
4. As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively

Clinical Benefit Statement

The clinical benefit of the MANTIS Clip is to enable endoscopic marking, provide acute and prophylactic hemostasis, anchor jejunal feeding tubes, and aid in closure of defects in the GI tract.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

CONTRAINDICATIONS

- Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
- Arteries greater than 2 mm.
- Polyps greater than 1.5 cm in diameter.
- Mucosal/Submucosal defects greater than 3 cm.

WARNINGS

- DO NOT FORCIBLY PULL BACK ON A CLIP THAT IS DEPLOYED AND HAS NOT DETACHED FROM THE COIL. THIS WILL TEAR THE TISSUE AND LIKELY RESULT IN SEVERE BLEEDING OR PERFORATION.

  A wire-cutter should be available on the endoscopy cart and used to cut the coil near the device handle if needed. The endoscope can then be removed leaving the clip and coil intact.

  The patient may require URGENT SURGERY to separate the clip from the coil without tearing tissue or to manage bleeding resulting from manipulating the imbedded clip.
- If the clip detaches prematurely, there is a risk of re-bleeding, unsuccessful anchoring to affix jejunal feeding tubes, unsuccessful marking, or insufficient perforation closure.
- Although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.
- The use of clips in the presence of bacterial contamination may potentiate or prolong infection.
- Clipping hard or severely fibrotic lesions may result in ineffective hemostasis, unsuccessful anchoring to affix jejunal feeding tubes, unsuccessful marking, or insufficient perforation closure. Additional interventions may be required to control bleeding, successfully anchor to affix jejunal feeding tube, successfully mark, or sufficiently close the perforation.
- Contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

- The MANTIS Clip is designed to be compatible with forward viewing endoscopes with working channels equal to or greater than 2.8 mm. Use with a side viewing scope may result in difficulty or inability to deploy, leading to patient injury.

NOTES

Limited studies indicate that:

- Lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward viewing endoscope.
- The number of clips required for hemostasis, anchoring, marking, or closure may vary depending upon the anatomical site, histology, lesion type, and patient condition and history.
- There is no clinical evidence to support the use of this device for clipping the neck of the diverticulum to treat bleeds.
- There is no clinical evidence to support the use of this device for clipping GI tract luminal perforations >20 mm.
- There is no clinical evidence to support the use of the device for esophageal varices.

PRECAUTIONS

- It is recommended that healthcare providers distribute patient implant cards with the name of the clip and date it was placed.
- Passage of the MANTIS Clip through a retroflexed or tortuous path, may result in the clip separating from the catheter and potentially kinking or damaging the device.
- Applying tangential pressure to an opened or closed clip may result in the clip separating from the catheter and potentially kinking or damaging the device.
- In a difficult scope position, it may be necessary to straighten the endoscope to facilitate the device passage, then reposition scope for treatment.
- If the catheter kinks or becomes damaged during insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product.

ADVERSE EVENTS

- Allergic reaction
- Burn
- Hemorrhage
- Infection
- Inflammation
- Pain
- Perforation
- Surgery
- Tissue Damage

HOW SUPPLIED

The device is supplied sterile by ethylene oxide gas sterilization and is intended for single use only.

Device Details

Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged.

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

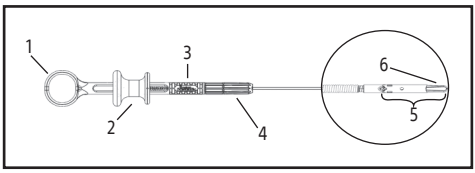
Immediately return damaged product to Boston Scientific Corporation.

Handling and Storage

Rotate inventory so that products are used prior to the expiration date on the package label.

This product has no special handling or storage requirements.

OPERATIONAL INSTRUCTIONS



[1] Thumb Ring [2] Slider [3] Handle [4] Rotation Control Knob [5] Clip [6] Clip Jaws

Figure 1. MANTIS Clip

Preparation

1. Open the pouch and remove the device.
2. Inspect the device for kink or damage.

Note: If the device shows any sign of damage, do not use it, call Boston Scientific Customer Service and return the product. Do not attempt to repair nonfunctional or damaged devices.

Device Insertion

1. Carefully insert the MANTIS Clip through the biopsy channel of the endoscope with short, deliberate 2 to 3 centimeter strokes.

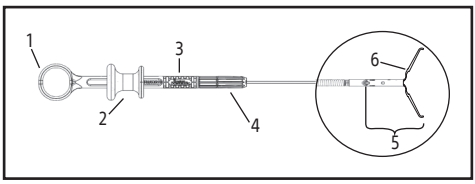
Caution: Do not advance an open clip through the endoscope working channel, otherwise endoscope working channel damage may result.

Note: Passage of the MANTIS Clip through a retroflexed or tortuous path may result in the clip separating from the catheter and potentially kinking or damaging the device. In a difficult scope position, it may be necessary to straighten the endoscope to facilitate the device passage, then reposition scope for treatment. If the device kinks or becomes damaged during insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product. Do not attempt to repair nonfunctional or damaged devices.

Procedure

Note: Applying tangential pressure to an opened or closed clip may result in the clip separating from the catheter and potentially kinking or damaging the device. Prior to permanently deploying the MANTIS Clip, visually confirm that the device has not kinked, separated from the catheter, or become damaged in any way. If the device shows any sign of damage, DO NOT USE IT. Call Boston Scientific Customer Service and return the product.

1. When the MANTIS Clip is at the desired location, gently move the slider distally (away from the thumb ring) to open the MANTIS Clip jaws, as shown in Figure 2.



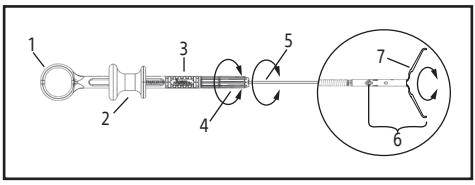
[1] Thumb Ring [2] Slider [3] Handle [4] Rotation Control Knob [5] Clip [6] Clip Jaws

Figure 2. Open the MANTIS Clip Jaws

2. If additional positioning is desired, the clip may be rotated in either of the following two methods (see Figure 3):
   a. The clip can be rotated by turning the rotation control knob in either direction. Typically, this is done by the nurse, technician, or assistant. Because the rotation control knob is separate from the handle, the user can keep his/her hand on the handle while rotating the knob with the other hand.
   b. The clip can be rotated by spinning the catheter between your fingers in either direction where it enters the scope channel. Typically, this would be done by the physician.

Note: It is not recommended to utilize both rotation methods at the same time, as the rotation performance may be compromised.

Note: If there is no rotation response, do not continue to rotate the device more than three full rotations. Failure to do so may result in difficulty removing and/or scope damage.

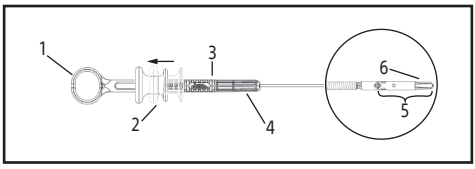


[1] Thumb Ring [2] Slider [3] Handle [4] Rotation Control Knob [5] Catheter [6] Clip [7] Clip Jaws

Figure 3. Rotating the Clip

3. To close the MANTIS Clip on the desired location, move the slider proximally until tactile resistance is felt in the handle, as shown in Figure 4. Clip position may now be assessed prior to deployment.

Caution: Do not continue moving the slider proximally beyond the tactile resistance until you are ready to deploy the clip, otherwise you may not be able to reopen the clip. If you hear or feel a click, the clip cannot be reopened, go to step 4 Option 2 to complete clip deployment.



[1] Thumb Ring [2] Slider [3] Handle [4] Rotation Control Knob [5] Clip [6] Clip Jaws

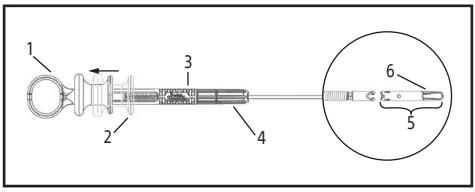
Figure 4. MANTIS Clip Closed

4. At this point, there are 2 options:
   - Option 1: The MANTIS Clip can be reopened, rotated, and repositioned to the desired location (See steps 1-3).

Note: The MANTIS Clip is engineered to enable opening and closing up to five times prior to deployment, aiding in repositioning of the clip at the lesion site. Reopening, closing, and rotation capability may be limited by clinical circumstances and patient anatomy, among other factors.

- Option 2: The MANTIS Clip can be permanently deployed. To permanently deploy the MANTIS Clip, continue moving the slider proximally beyond the tactile resistance point, at which point a first click may be heard or felt. Continue moving the slider proximally until a second tactile resistance point and/or click is heard or felt. Continue moving the slider proximally until it reaches the thumb ring, as shown in Figure 5.

Note: Do not attempt to reopen the clip once the initial tactile resistance point has been passed and/or the first click has been heard or felt. Reopening the clip may result in the clip separating from the catheter and potentially kinking or damaging the device. After the first tactile resistance point is passed and/or click is observed, do not attempt to move the slider distally until both clicks are heard or felt. Do not continue to move the slider towards the thumb ring after both clicks are heard.



[1] Thumb Ring [2] Slider [3] Handle [4] Rotation Control Knob [5] Clip [6] Clip Jaws

Figure 5. MANTIS Clip Permanently Deployed

5. Once the MANTIS Clip has been deployed, gently move the slider distally to separate the clip from the delivery device. Once the clip separates from the delivery device, release the slider.

Warning: Failure to release the slider after separation could result in patient injury.

If the MANTIS Clip has not been deployed, close the jaws, and withdraw the device slowly through the endoscope.

DEVICE REMOVAL

Withdraw the device slowly through the endoscope.

For partially deployed clip, attempt to fully deploy the clip. If unable to deploy clip, withdraw the scope and clip together.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device and packaging may contain biohazardous substances. Any device and packaging that came into contact with biohazardous substances should be treated and disposed of as biohazardous waste or be treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer and to the relevant local regulatory authority.

MRI SAFETY INFORMATION

MRI SAFETY INFORMATION
A person with the MANTIS Clip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	MANTIS Clip
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration / Temperature Rise	Under scan conditions defined above, MANTIS Clips are expected to have a temperature rise of less than 4°C and can be used for 60 minutes of continuous RF
MR Image Artifact	Image artifact caused by device may extend approximately 90 mm from the implant

Warning: Failure to follow the recommended MR Conditional labeling may result in a deployed GI hemoclip dislodging from tissue or heating of tissue at the GI hemoclip location. A GI hemoclip dislodgement may result in rebleeding requiring additional intervention or surgery, serious injury, or death.

Warning: This clip contains ferromagnetic material. Follow your institutional protocols to determine whether or not an x-ray should be performed prior to an MRI exam. There may be a small potential risk of clip dislodgement and rebleeding if the clip is used in friable or healing tissues due to magnetic forces acting on the clip when in or near an MRI scanner.

PATIENT COUNSELING INFORMATION

Provide the patient with the completed implant card to carry and explain that the Boston Scientific website has additional patient information with the summary of clip safety and clinical performance.

Inform the patient to present the implant card it to their Healthcare professionals (doctors, dentist, technicians) including at MRI scans so they can take the necessary precautions.

Inform the patient if any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.

Brief the patient on any relevant post-procedure instructions, contraindications, warnings, precautions and/or adverse events found within this Instructions for Use (IFU), pertaining to the patient.

Implantable Device Patient Information

Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

Implant Card Instructions

- Apply the peel-off label from the product onto the supplied patient implant card
- Fill in the implantation date, patient name, name and address of healthcare institution and/or physician information
- Give the completed card to the patient

WARRANTY

For device warranty information, visit www.bostonscientific.com/warranty.

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

INSTRUCTIONS FOR USE **en**

The Instructions for Use (IFU) for this product are supplied in electronic form over the Internet.

Visit www.IFU-BSCI.com to access the IFU using your internet browser. Information from the product labeling such as Product Code, UDI-DI or Product Name may be used to search for the specific IFU.

If you have difficulty accessing the IFU online, or would prefer to receive a paper copy, please contact Boston Scientific Customer Service or your local country contact. A copy will be sent to you at no charge and should arrive within seven days.

INSTRUCCIONES DE USO **es**

Las Instrucciones de uso de este producto se suministran en formato electrónico a través de Internet.

Utilice su navegador de internet para visitar www.IFU-BSCI.com y acceder a las instrucciones de uso (IFU). La información del etiquetado del producto (como el código de producto, el UDI-DI o el nombre del producto) puede utilizarse para buscar las instrucciones de uso específicas.

Si experimenta alguna dificultad para acceder a las Instrucciones de uso por Internet o si prefiere recibir un ejemplar impreso, diríjase al Servicio de Atención al Cliente de Boston Scientific o al representante en su país. Se le enviará un ejemplar gratuito, que debería recibir en un plazo de siete días.

MODE D'EMPLOI **fr**

Le mode d'emploi de ce produit est fourni sous forme électronique par Internet.

Consultez le site www.IFU-BSCI.com pour accéder au mode d'emploi à l'aide de votre navigateur Internet. Les informations figurant sur l'étiquette du produit, telles que le code produit, l'IUD-ID ou le nom du produit, peuvent être utilisées pour rechercher le mode d'emploi correspondant.

Si vous avez des problèmes pour accéder au mode d'emploi en ligne ou que vous préférez recevoir une copie papier, contacter le service clientèle de Boston Scientific ou votre représentant local. Un exemplaire vous sera envoyé gratuitement et devrait vous parvenir dans les sept jours.

GEBRAUCHSANWEISUNG **de**

Die Gebrauchsanweisung für dieses Produkt ist in elektronischer Form über das Internet verfügbar.

Sie können die Gebrauchsanweisung mit Ihrem Internetbrowser unter www.IFU-BSCI.com abrufen. Angaben auf der Produktkennzeichnung wie der Produktcode, die eindeutige Produktkennung (UDI-DI) oder der Produktname können zur Suche nach einer bestimmten Gebrauchsanweisung verwendet werden.

Wenn Sie Probleme haben, die Gebrauchsanweisung online aufzurufen, oder wenn Sie eine gedruckte Kopie der Gebrauchsanweisung wünschen, wenden Sie sich bitte an den Kundendienst von Boston Scientific in den oder die Vertretung in Ihrem Land. Die Kopie wird Ihnen kostenlos innerhalb von ca. sieben Tagen zugestellt.

ISTRUZIONI PER L'USO **it**

Le Istruzioni per l'uso (IFU) per questo prodotto vengono fornite in formato elettronico su Internet.

Visita www.IFU-BSCI.com per accedere alle IFU con il tuo browser Internet. Le informazioni riportate sull'etichetta del prodotto come Codice prodotto, UDI-DI o Nome prodotto possono essere utilizzate per la ricerca di IFU specifiche.

In caso di problemi di accesso alle Istruzioni per l'uso online o se si preferisce ricevere una copia cartacea, rivolgersi al Servizio clienti Boston Scientific o al contatto di zona. La copia sarà spedita gratuitamente e dovrebbe arrivare entro sette giorni.

INSTRUCTIES VOOR GEBRUIK **nl**

De instructies voor gebruik (IFU) voor dit product worden via internet in elektronisch formaat verstrekt.

Ga naar www.IFU-BSCI.com om via uw internetbrowser de gebruiksaanwijzing te openen. Informatie op de productetiketten, zoals de productcode, UDI-DI of productnaam, kan worden gebruikt om te zoeken naar de specifieke gebruiksaanwijzing.

Als het niet lukt om de GA online te bekijken of als u de voorkeur geeft aan een papieren exemplaar, neemt u contact op met Boston Scientific Customer Service of met de lokale contactpersoon in uw eigen land. Binnen zeven dagen wordt een gratis exemplaar naar u toe gestuurd.

BRUGSANVISNING **da**

Brugsanvisningen til dette produkt fås i elektronisk form via internettet.

Gå til www.IFU-BSCI.com for at få adgang til brugsanvisningen i din internetbrowser. Oplysninger fra produktmærkningen såsom produktkode, UDI-DI eller produktets navn kan bruges til at søge efter den pågældende brugsanvisning.

Hvis du har problemer med at få adgang til brugsanvisningen online, eller hvis du foretrækker at modtage en udskrevet kopi, bedes du kontakte Boston Scientifics kundeservice eller den lokale kontakt i dit land. Du vil modtage en kopi uden beregning i løbet af ca. en uge.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ **el**

Οι οδηγίες χρήσης (IFU) για αυτό το προϊόν παρέχονται σε ηλεκτρονική μορφή μέσω του Διαδικτύου.

Επισκεφθείτε τη διεύθυνση www.IFU-BSCI.com για να αποκτήσετε πρόσβαση στις Οδηγίες χρήσης χρησιμοποιώντας το πρόγραμμα περιήγησής σας στο διαδίκτυο. Πληροφορίες από την επισήμανση του προϊόντος, όπως ο κωδικός προϊόντος, το αναγνωριστικό τεχνολογικού προϊόντος UDI (UDI-DI) ή η ονομασία προϊόντος, μπορούν να χρησιμοποιηθούν για την αναζήτηση των συγκεκριμένων Οδηγιών χρήσης.

Εάν δυσκολεύεστε να αποκτήσετε πρόσβαση στις ηλεκτρονικές οδηγίες χρήσης (IFU) ή εάν προτιμάτε να λάβετε ένα εκτυπωμένο αντίγραφο, επικοινωνήστε με το τμήμα εξυπηρέτησης πελατών της Boston Scientific ή τον αρμόδιο υπεύθυνο επικοινωνίας για τη χώρα σας. Θα σας αποσταλεί ένα αντίγραφο χωρίς χρέωση, το οποίο θα λάβετε εντός επτά ημερών.

INSTRUÇÕES DE UTILIZAÇÃO **pt-EU**

As Instruções de Utilização (IDU) deste produto são fornecidas em formato eletrónico através da Internet.

Visite www.IFU-BSCI.com para aceder às Instruções de Utilização através do seu browser da Internet. As informações na rotulagem do produto como o Código do Produto, UDI-DI ou Nome do Produto podem ser utilizadas para pesquisar as Instruções de Utilização específicas.

Se tiver dificuldade em aceder às IDU online ou se preferir receber uma cópia em papel, contacte o Apoio ao cliente da Boston Scientific ou o seu representante nacional local. Ser-lhe-á enviada uma cópia sem qualquer custo, que deverá ser recebida no prazo de sete dias.

BRUKSANVISNING **sv**

Bruksanvisningen till denna produkt tillhandahålls i elektronisk form via internet.

Besök www.IFU-BSCI.com för att komma åt bruksanvisningen med hjälp av din webbläsare. Information från produktmärkningen, t.ex. produktkod, UDI-DI eller produktnamn, kan användas för att söka efter den specifika bruksanvisningen.

Om du har svårt att få tillgång till bruksanvisningen online eller föredrar ett pappersexemplar, kontakta Boston Scientifics kundtjänst eller en lokal representant i ditt land. Ett exemplar skickas ut utan extra kostnad och är dig normalt till handa inom sju arbetsdagar.

HASZNÁLATI UTASÍTÁS **hu**

A termék használati utasítása (IFU) elektronikus formában megtalálható az interneten.

A használati utasítás eléréséhez látogasson el a www.IFU-BSCI.com weboldalra az internetböngésző segítségével. A kívánt használati utasítás megkereséséhez felhasználhatók a termékcímkén található információk, például a termékkód, az UDI-DI vagy a termék neve.

Amennyiben nem sikerül hozzáférnie online a használati utasításhoz, vagy papíralapú példányt szeretne kapni, lépjen kapcsolatba a Boston Scientific ügyfélszolgálatával vagy az országában lévő helyi képviselettel. Térítésmentesen küldünk Önnek egy példányt, amelynek hét napon belül meg kell érkeznie.

NÁVOD K POUŽITÍ **cs**

Návod k použití (IFU) pro tento produkt je k dispozici v elektronickém formátu na internetu.

Ve svém webovém prohlížeči přejděte na web www.IFU-BSCI.com, kde získáte návod k použití. K vyhledání konkrétního návodu k použití můžete použít informace ze štítku produktu, jako je kód produktu, UDI-DI nebo název produktu.

Pokud máte problémy s on-line přístupem k návodu k použití nebo spíše upřednostňujete papírovou verzi, obraťte se na zákaznický servis společnosti Boston Scientific nebo na svého místního zástupce. Tištěnou kopii vám poskytneme bezplatně a budete ji mít k dispozici během sedmi dní.

SPOSÓB UŻYCIA **pl**

Instrukcja użytkowania dotycząca tego produktu jest dostarczana w formie elektronicznej przez Internet.

Wejdź na stronę www.IFU-BSCI.com za pomocą przeglądarki internetowej, aby zyskać dostęp do instrukcji użytkowania. Informacje z etykiety produktu, takie jak kod produktu, kod UDI-DI lub nazwa produktu mogą być wykorzystane do wyszukania konkretnej instrukcji użytkowania.

W przypadku problemów z dostępem do instrukcji użytkowania online lub jeśli preferowana jest papierowa wersja dokumentu, należy się skontaktować z działem obsługi klienta w Boston Scientific lub z przedstawicielem lokalnym. Wersja papierowa zostanie przesłana nieodpłatnie i powinna dotrzeć do adresata w ciągu siedmiu dni.

BRUKSANVISNING **no**

Bruksanvisningen for dette produktet er tilgjengelig i elektronisk format via Internett.

Bruk nettleseren din og gå til www.IFU-BSCI.com for å få tilgang til bruksanvisningen. Du kan bruke informasjon fra produktetiketten, f.eks. produktkode, unik produktidentifikator (UDI-DI) eller produktnavn for å søke etter en bestemt bruksanvisning.

Hvis du har problemer med å få tilgang til bruksanvisningen på Internett, eller hvis du foretrekker å ha den i papirformat, kan du kontakte Boston Scientifics kundeservice eller din nasjonale kontaktperson. Du vil få tilsendt en kopi uten omkostninger innen sju dager.

KULLANIM TALİMATLARI **tr**

Bu ürüne ait Kullanma Talimatları, İnternet üzerinden elektronik form şeklinde sağlanmaktadır.

İnternet tarayıcınızı kullanarak Kullanım Talimatlarına (IFU) erişmek için www.IFU-BSCI.com adresini ziyaret edin. Ürün etiketinde yer alan Ürün Kodu, UDI-DI veya Ürün Adı gibi bilgiler, belirli bir IFU'yu aramak için kullanılabilir.

Kullanım Talimatları'na çevrimiçi olarak erişmede güçlük çekerseniz ya da basılı bir kopyasını almayı tercih ederseniz lütfen Boston Scientific Müşteri Hizmetleri ya da yerel ülke temsilciniz ile iletişime geçin. Bir kopyası ücretsiz olarak size gönderilecektir ve bunun yedi gün içinde ulaşması gerekir.

INSTRUÇÕES DE USO **pt-BRA**

As instruções de uso deste produto são fornecidas em formato eletrônico pela Internet.

Visite www.IFU-BSCI.com para acessar as instruções de uso usando seu navegador de internet. Informações do rótulo do produto, como código do produto, UDI-DI (Identificador único do dispositivo e do fabricante) ou nome do produto, podem ser utilizadas para procurar as instruções de uso específicas.

Em caso de dificuldade para acessar as instruções de uso on-line ou preferir receber um exemplar impresso, entre em contato com o serviço de atendimento ao cliente da Boston Scientific ou com o representante no seu país. Você receberá um exemplar gratuito em até sete dias.

KÄYTTÖOHJEET **fi**

Tämän tuotteen käyttöohjeet (IFU) toimitetaan sähköisessä muodossa Internetin kautta.

Löydät käyttöohjeen käymällä verkkoselaimella osoitteessa www.IFU-BSCI.com. Tuotemerkinnöissä olevia tietoja, kuten tuotekoodia, UDI-DI:tä tai tuotenimeä, voidaan käyttää tietyn käyttöohjeen hakemiseen.

Jos sinulla on vaikeuksia lukea verkossa annettuja käyttöohjeita tai jos haluat käyttöohjeiden paperiversion, ota yhteyttä Boston Scientificin asiakaspalveluun tai oman maasi yhteyshenkilöön. Sinulle lähetetään ilmainen paperikopio, jonka pitäisi tulla perille seitsemän päivän kuluessa.

INSTRUCȚIUNI DE UTILIZARE **ro**

Instrucțiunile de utilizare pentru acest produs sunt oferite în format electronic prin internet.

Pentru a accesa instrucțiunile de utilizare, vizitați www.IFU-BSCI.com cu ajutorul browserului de internet. Informațiile de pe eticheta produsului, cum ar fi codul produsului, UDI-DI sau denumirea produsului, pot fi utilizate pentru a căuta instrucțiunile de utilizare specifice.

Dacă întâmpinați dificultăți în accesarea online a instrucțiunilor de utilizare sau preferați să primiți instrucțiunile pe hârtie, vă rugăm să contactați serviciul clienți Boston Scientific sau reprezentantul local. Vi se va expedia un exemplar gratuit care trebuie să sosească în șapte zile.

NÁVOD NA POUŽITIE **sk**

Návod na použitie k tomuto produktu v elektronickej podobe je k dispozícii na internete.

Navštívte www.IFU-BSCI.com, ak si chcete návod na použitie prečítať pomocou internetového prehliadača. Konkrétny návod na použitie môžete vyhľadať pomocou informácií z označenia výrobku, ako je kód výrobku, identifikačné číslo výrobku (UDI-DI) alebo názov výrobku.

Ak máte problémy s prístupom k návodu na použitie online alebo by ste radšej uprednostnili kópiu vo vytlačenej podobe, obráťte sa na zákaznícky servis spoločnosti Boston Scientific alebo miestneho zástupcu vo vašej krajine. Vytlačenú kópiu vám zašleme bezplatne do siedmich dní.

ИНСТРУКЦИИ ЗА УПОТРЕБА **bg**

Инструкциите за употреба за този продукт се предоставят в електронен формат по интернет.

Посетете www.IFU-BSCI.com за достъп до ИЗУ чрез вашия интернет браузър. Информацията от етикета на продукта, като например код на продукта, UDI-DI или име на продукта, може да се използва за търсене на конкретни ИЗУ.

Ако имате затруднения при достъпа до инструкциите за употреба онлайн или предпочитате да получите хартиен екземпляр, моля, обърнете се към отдела за обслужване на клиенти на Boston Scientific или към лицето за контакт за вашата страна. Безплатно ще ви бъде изпратен такъв екземпляр, който би трябвало да пристигне при вас в рамките на седем дни.

UPUTE ZA UPOTREBU **hr**

Upute za upotrebu ovog proizvoda isporučene su u elektroničkom obliku putem interneta.

Posjetite www.IFU-BSCI.com kako biste pristupili uputama za uporabu putem svog internetskog preglednika. Za traženje određenih uputa za uporabu mogu se upotrijebiti informacije s naljepnice na proizvodu poput šifre proizvoda, jedinstvenog identifikatora proizvoda (UDI-DI) ili naziva proizvoda.

Ako imate poteškoća s pristupom Uputama za upotrebu na mreži ili ako ih želite dobiti u papirnatom obliku, obratite se korisničkoj službi tvrtke Boston Scientific ili lokalnoj kontaktnoj osobi u svojoj zemlji. Poslat ćemo vam besplatan primjerak koji biste trebali dobiti u roku od sedam dana.

KASUTUSJUHISED **et**

Selle toote kasutusjuhised on saadaval elektroonilisel kujul internetis.

Kasutusjuhend on brauseris vaadatav saidilt www.IFU-BSCI.com, et pääseda kasutusjuhendile ligi oma veebilehitseja kaudu. Konkreetse kasutusjuhendi otsimiseks saab kasutada toote märgistusel toodud teavet, nagu tootekood, UDI-DI või tootenimi.

Kui teil on kasutusjuhistele internetis ligipääsemisega probleeme või eelistate paberkoopiat, võtke palun ühendust Boston Scientificu klienditeeninduse või oma riigi kohaliku kontaktisikuga. Teile saadetakse tasuta koopia ning see peaks saabuma seitsme päeva jooksul.

LIETOŠANAS INSTRUKCIJA **lv**

Šī izstrādājuma lietošanas instrukcija tiek piegādāta elektroniskā formā internetā.

Pārlūkprogrammā atveriet vietni www.IFU-BSCI.com. Lai meklētu konkrētu lietošanas instrukciju, izmantojiet izstrādājuma marķējumā sniegto informāciju, piemēram, izstrādājuma kodu, UDI-DI vai izstrādājuma nosaukumu.

Ja rodas problēmas ar piekļūšanu lietošanas instrukcijai tiešsaistē vai vēlaties saņemt drukātu eksemplāru, lūdzu, sazinieties ar Boston Scientific klientu apkalpošanas dienestu vai kontaktpersonu savā valstī. Eksemplārs tiks nosūtīts jums bez maksas, jūs to saņemsiet septiņu dienu laikā.

NAUDOJIMO INSTRUKCIJOS **lt**

Šio gaminio naudojimo instrukcijos teikiamos elektronine forma internete.

Apsilankykite svetainėje www.IFU-BSCI.com ir peržiūrėkite naudojimo instrukcijas savo interneto naršyklėje. Ieškoti konkrečios naudojimo instrukcijos galima naudojant tokią gaminio etiketėje esančią informaciją kaip gaminio kodas, unikalusis priemonės identifikatorius UDI-DI ar gaminio pavadinimas.

Jei negalite pasiekti naudojimo instrukcijų internete arba norite gauti popierinę kopiją, kreipkitės į „Boston Scientific" klientų aptarnavimo skyrių arba vietos kontaktinį asmenį savo šalyje. Kopija jums bus išsiųsta nemokamai; ją turėtumėte gauti per septynias dienas.

NAVODILA ZA UPORABO **sl**

Navodila za uporabo za ta izdelek so dobavljena v elektronski obliki prek spleta.

Za dostop do navodil za uporabo prek spletnega brskalnika obiščite www.IFU-BSCI.com. Za iskanje specifičnih navodil za uporabo lahko uporabite podatke z oznake izdelka, na primer šifro izdelka, UDI-DI ali ime izdelka.

Če imate težave pri dostopanju do navodil za uporabo prek spleta ali bi radi prejeli tiskano kopijo, se obrnite na službo za stranke Boston Scientific ali na lokalni stik za vašo državo. Kopijo vam bomo poslali brezplačno in bi morala prispeti v sedmih dneh.

PETUNJUK PENGGUNAAN **id**

Petunjuk Penggunaan (IFU) untuk produk ini disediakan dalam bentuk elektronik lewat Internet.

Kunjungi www.IFU-BSCI.com untuk mengakses IFU menggunakan browser internet Anda. Informasi dari pelabelan produk seperti Kode Produk, UDI-DI, atau Nama Produk dapat digunakan untuk mencari IFU tertentu.

Jika Anda kesulitan mengakses IFU secara online, atau lebih suka menerima salinan cetak, silakan hubungi Layanan Pelanggan Boston Scientific atau kontak negara setempat Anda. Anda akan dikirimi satu salinan secara gratis dan salinan akan sampai di alamat Anda dalam tujuh hari.

ІНСТРУКЦІЇ З ВИКОРИСТАННЯ **uk**

Інструкції з використання для цього продукту надають в електронній формі через Інтернет.

Відвідайте www.IFU-BSCI.com, щоб переглянути інструкції з використання за допомогою інтернет-браузера. Щоб знайти конкретні інструкції з використання, можна використовувати інформацію з етикетки продукту, як-от код продукту, номер UDI-DI чи назву продукту.

Якщо ви не можете завантажити інструкції з використання онлайн або хочете отримати паперовий примірник інструкцій, зверніться до служби підтримки клієнтів Boston Scientific чи місцевої контактної особи. Примірник буде надіслано безкоштовно. Ви маєте отримати його протягом семи днів.

Implant Card Instructions **en**
Record the institution name, patient details, and implant date. Add a peel-off label from product packaging. Provide to patient.

Instrucciones de la tarjeta del implante **es**
Anote el nombre de la institución, los detalles del paciente y la fecha del implante. Añada una etiqueta despegable del envase del producto. Facilítesela al paciente.

Instructions concernant la carte d'implant **fr**
Enregistrez le nom de l'établissement, les informations sur le patient et la date d'implantation. Ajoutez une étiquette de l'emballage du produit. Remettez au patient.

Anleitungen zur Implantatkarte **de**
Notieren Sie den Namen der Einrichtung, die Patientenangaben und das Implantationsdatum. Bringen Sie einen Aufkleber von der Produktverpackung an. Händigen Sie die Karte dem Patienten aus.

Istruzioni per l'uso della scheda di impianto **it**
Registrare il nome dell'istituto, i dettagli del paziente e la data dell'impianto. Aggiungere un'etichetta adesiva contenuta nella confezione del prodotto. Consegnare al paziente.

Instructies voor implantaatkaart **nl**
Vermeld de naam van de instelling, patiëntgegevens en datum implantatie. Bevestig een afneembaar etiket van de productverpakking. Geef aan de patiënt.

Anvisninger for implantatkort **da**
Registrer institutionens navn, patientoplysninger og dato for implantation. Påsæt en selvklæbende mærkat fra produktindpakningen. Giv det til patienten.

Οδηγίες για την κάρτα εμφυτεύματος **el**
Καταγράψτε το όνομα του ιδρύματος, τα στοιχεία ασθενούς και την ημερομηνία εμφύτευσης. Προσθέστε μια αποκολλούμενη ετικέτα από τη συσκευασία προϊόντος. Δώστε την κάρτα στον ασθενή.

Instruções do Cartão de Implante **pt-EU**
Registe o nome da instituição, os detalhes do paciente e a data do implante. Adicione uma etiqueta destacável da embalagem do produto. Dê o cartão ao paciente.

Anvisningar för implantatkort **sv**
Notera institutionens namn, patientens uppgifter och implantationsdatum. Klistra fast en löstagbar etikett från produktförpackningen. Lämna över kortet till patienten.

Az implantációs kártyára vonatkozó utasítások **hu**
Jegyezze fel rá az intézmény nevét, a beteg adatait és a beültetés dátumát. Helyezze el rajta a termék csomagolásáról lehúzható címkét. Adja át a betegnek.

Pokyny ke kartě s informacemi o implantátu **cs**
Zaznamenejte název instituce, podrobnosti o pacientovi a datum implantace. Přidejte nalepovací štítek dodávaný v balení s produktem. Předejte pacientovi.

Instrukcja dotycząca karty implantu **pl**
Zapisać nazwę instytucji, dane pacjenta i datę wszczepienia. Dołączyć odklejalną etykietę z opakowania produktu. Przekazać pacjentowi.

Instruksjoner for implantatkortet **no**
Registrer institusjonens navn, pasientinformasjonen og implantasjonsdatoen. Fest en avrivbar etikett fra produktemballasjen på kortet. Gi kortet til pasienten.

İmplant Kartı Talimatları **tr**
Kurum adını, hasta bilgilerini ve implant tarihini kaydedin. Ürün ambalajından bir soyulabilir etiket ekleyin. Hastaya verin.

Instruções do cartão de implante **pt-BRA**
Anote o nome da instituição, os detalhes do paciente e a data do implante. Adicione uma etiqueta adesiva retirada da embalagem do produto. Forneça ao paciente.

Implanttikortin ohjeet **fi**
Kirjaa ylös laitoksen nimi, potilaan tiedot ja asennuspäivämäärä. Lisää korttiin tuotepakkauksessa oleva tarra. Anna kortti potilaalle.

Instrucțiuni referitoare la cardul implant **ro**
Înregistrați denumirea instituției, detaliile pacientului și data implantării. Adăugați o etichetă detașabilă din ambalajul produsului. Înmânați cardul pacientului.

Pokyny ku karte implantátu **sk**
Zaznamenajte názov inštitúcie, podrobnosti o pacientovi a dátum implantácie. Pridajte odlepiteľný štítok z balenia produktu. Poskytnite pacientovi.

Инструкции за картата за имплант **bg**
Запишете името на институцията, подробностите за пациента и датата на имплантиране. Добавете отлепящия се етикет от опаковката на продукта. Дайте на пациента.

Upute za kartice implantata **hr**
Zabilježite naziv ustanove, detalje o pacijentu i datum implantacije. Dodajte naljepnicu s pakiranja proizvoda. Pružite pacijentu.

Implantaadi kaardi suunised **et**
Registreerige asutus nimi, patsiendi andmed ja implanteerimise kuupäev. Lisage toote pakendilt eemaldatav silt. Andke patsiendile.

Implantāta kartes norādījumi **lv**
Norādiet iestādes nosaukumu, pacienta datus un implantēšanas datumu. Pievienojiet izstrādājuma iepakojumā pieejamo uzlīmi. Iedodiet pacientam.

Implanto kortelės naudojimo instrukcijos **lt**
Įrašykite įstaigos pavadinimą, paciento duomenis ir implanto datą. Ant gaminio pakuotės pridėkite nuplėšiamą etiketę. Pateikite pacientui.

Navodila v zvezi s kartico vsadka **sl**
Navedite ime ustanove, podatke bolnika in datum vsaditve. Nalepite odstranljivo nalepko iz embalaže izdelka. Kartico dajte bolniku.

Petunjuk Kartu Implan **id**
Catat nama lembaga, detail pasien, dan tanggal implan. Tambahkan label dapat-lepas dari kemasan produk. Berikan kepada pasien.

Інструкції до картки імплантату **uk**
Запишіть назву закладу, дані пацієнта й дату імплантації. Додайте відривну етикетку з упаковки продукту. Надайте пацієнту. Щоб дізнатися більше, див.

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REF

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AR | REP

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