

# Instructions for Use

## TorFlex™ Transseptal Guiding Sheath

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**English**  
Carefully read all instructions prior to use. Observe all warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the procedure.

**CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**

**I. DEVICE DESCRIPTION**

The TorFlex™ Transseptal Guiding Sheath Kit consists of three components: a sheath, a dilator, and a J-tipped guidewire. The TorFlex™ Transseptal Guiding Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The radiopaque tip maximizes visualization of the sheath during manipulation. The dilator provides support for the sheath and has a tapered tip.

**II. INDICATIONS FOR USE**

The TorFlex™ Transseptal Guiding Sheath is used for the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal perforation / puncture.

**III. WARNINGS**

Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.

- The TorFlex™ Transseptal Guiding Sheath Kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath Kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another.
- Failure to do so may result in patient complications
- The TorFlex™ Transseptal Guiding Sheath Kit is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- Care should be taken to ensure that all air is removed from the sheath before infusing through the side port.
- Care should be taken when removing the dilator and catheters from the sheath.
- Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury.
- Damage to guidewire may result if withdrawn through a metal needle cannula.
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance.

**IV. PRECAUTIONS**

- Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
- The sterile packaging and sheath should be visually inspected prior to use. Do not use the device if it has been compromised or damaged.
- Do not attempt to use the TorFlex™ Transseptal Guiding Sheath Kit before thoroughly reading the accompanying Instructions for Use.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Note product "Use By" date.
- TorFlex™ SuperStrong™ Transseptal Dilator is not compatible with the "NRG" Transseptal Needle.

**V. ADVERSE EVENTS**

Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath include:

- Infection
- Air embolus
- Local nerve damage
- Vasovagal reaction
- Dissection
- Vessel spasm
- AV fistula formation
- Atrial septal defect
- Pseudoaneurysm
- Aortic puncture
- Arrhythmias
- Perforation and/or tamponade
- Hematoma
- Hemorrhage
- Catheter entrapment
- Thromboembolic events
- Stroke
- Valve damage
- Myocardial infarction
- Pacemaker/defibrillator lead displacement
- Pulmonary edema
- Coronary artery spasm and/or damage
- Vessel trauma
- Pericardial/pleural effusion

**VI. INSPECTION PRIOR TO USE**

Prior to use of the TorFlex™ Transseptal Guiding Sheath Kit, the individual components should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the device.

**VII. EQUIPMENT REQUIRED**

Intracardiac puncture procedures should be performed in a sterile environment in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

**VIII. SUGGESTED DIRECTIONS FOR USE**

- Carefully read all instructions prior to use. Failure to do so may result in complications.
- Thoroughly flush the sheath, guidewire and dilator with heparinized saline solution prior to use.
- Perform a standard vein puncture of the right femoral vein using an access needle (not supplied).
- Introduce the guidewire and advance to required depth. If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of resistance before proceeding.
- Leaving the guidewire in place, withdraw the needle.
- Enlarge the cutaneous puncture site as necessary.
- Assemble the dilator and sheath until the dilator hub locks into the sheath hub.
- Thread the dilator/sheath assembly over the guidewire using a slight twisting motion into the superior vena cava (SVC) under fluoroscopic guidance.
- Use standard technique to position the sheath/dilator assembly into the desired heart chamber.
- If transseptal puncture is required, refer to the Instructions for Use of the transseptal puncture device.
- Ensure the sheath is clear of air. To separate blood, use the sheath side port.
- Monitor the location of the radiopaque tip frequently under fluoroscopy.
- Deliver a continuous heparinized solution infusion or aspirate periodically. This may help reduce the risk of thromboembolic complications due to thrombus formation, as there may be a possibility of thrombus development at the distal sheath tip or inside the sheath lumen. Also aspirate when removing the transseptal device or dilator.
- After removal of the dilator and sheath until the dilator hub locks into the sheath hub.

**IX. CLEANING AND STERILIZATION INSTRUCTIONS**

Do not clean or re-sterilize the TorFlex™ Transseptal Guiding Sheath kit. The TorFlex™ Transseptal Guiding Sheath kit is intended for single use only.

**X. CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION**

Intracardiac puncture procedures should be performed in a sterile environment in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

If you have any problems with or questions about Baylis Medical Equipment contact our technical support personnel.  
**Baylis Medical Company Inc.**  
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 Montreal, Quebec, Canada, H4T 1A1  
 Phone: (514) 488-9801 / (800) 850-9801  
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 www.baylismedical.com

**NOTES:**

- In order to return products you must have a return authorization number before shipping the products back to Baylis Medical Company. Product Return Instructions will be provided at this time.
- Ensure that any product being returned to Baylis Medical has been cleaned, decontaminated and/or sterilized as indicated in the Product Return Instruction before returning it for warranted service. Baylis Medical will not accept any piece of used equipment that has not been properly cleaned or decontaminated as per the Product Return Instructions.

**XI. LABELING AND SYMBOLS**

	Manufacturer	<b>Rx ONLY</b>	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Sterile using ethylene oxide		Single Use – Do not reuse
	Use By		Lot Number
	EU Authorized Representative		Do Not Use If Packaging is Damaged
	Caution		Keep Away from Sunlight
	Consult Instructions for Use		Keep Dry
	Model number	<b>Max Guidewire O.D.</b>	Maximum guidewire outside diameter that can be used with this device
	Non-Pyrogenic		

**XII. LIMITED WARRANTY – Disposables and Accessories**

Baylis Medical Company Inc. (BMC) warrants its Disposable and Accessory products against defects in materials and workmanship. BMC warrants that sterile products will remain sterile for a period of time as shown on the label as long as the original package remains intact. Under this Limited Warranty, if any covered product is proved to be defective in materials or workmanship, BMC will replace or repair, in its absolute and sole discretion, any such product, less any charges to BMC for transportation and labor costs incidental to inspection, removal or restocking of product. The length of the warranty is: (i) for the Disposable products, the shelf life of the product, and (ii) for the Accessory products, 90 days from shipment date. This limited warranty applies only to new original factory delivered products that have been used for their normal and intended uses. BMC's Limited Warranty shall not apply to BMC products which have been resterilized, repaired, altered, or modified in any way and shall not apply to BMC products which have been improperly stored or improperly cleaned, installed, operated or maintained contrary to BMC's instructions.

**DISCLAIMER AND LIMITATION OF LIABILITY**

THE LIMITED WARRANTY ABOVE IS THE SOLE WARRANTY PROVIDED BY SELLER. SELLER DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. THE REMEDY SET FORTH HEREIN SHALL BE THE EXCLUSIVE REMEDY FOR ANY WARRANTY CLAIM AND ADDITIONAL DAMAGES, INCLUDING CONSEQUENTIAL DAMAGES OR DAMAGES FOR BUSINESS INTERRUPTION OR LOSS OF PROFIT, REVENUE, MATERIALS, ANTICIPATED SAVINGS, DATA, CONTRACT, GOODWILL OR THE LIKE (WHETHER DIRECT OR INDIRECT IN NATURE) OR FOR ANY OTHER FORM OF INCIDENTAL, OR INDIRECT DAMAGES OF ANY KIND, SHALL NOT BE AVAILABLE. SELLER'S MAXIMUM CUMULATIVE LIABILITY RELATIVE TO ALL OTHER CLAIMS AND LIABILITIES, INCLUDING OBLIGATIONS UNDER ANY INDEMNITY, WHETHER OR NOT INSURED, WILL NOT EXCEED THE COST OF THE PRODUCT(S) GIVING RISE TO THE CLAIM OR LIABILITY. SELLER DISCLAIMS ALL LIABILITY RELATIVE TO GRATUITOUS INFORMATION OR ASSISTANCE PROVIDED BY, BUT NOT REQUIRED OF SELLER HEREUNDER. ANY ACTION AGAINST SELLER MUST BE BROUGHT WITHIN EIGHTEEN (18) MONTHS AFTER THE CAUSE OF ACTION ACCRUES. THESE DISCLAIMERS AND LIMITATIONS OF LIABILITY WILL APPLY REGARDLESS OF ANY OTHER CONTRARY PROVISION HEREOF AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, AND FURTHER WILL EXTEND TO THE BENEFIT OF SELLER'S VENDORS, APPOINTED DISTRIBUTORS AND OTHER AUTHORIZED RESELLERS AS THIRD-PARTY BENEFICIARIES. EACH PROVISION HEREOF WHICH PROVIDES FOR A LIMITATION OF LIABILITY, DISCLAIMER OF WARRANTY OR CONDITION OR EXCLUSION OF DAMAGES IS SEVERABLE AND INDEPENDENT OF ANY OTHER PROVISION AND IS TO BE ENFORCED AS SUCH. IN ANY CLAIM OR LAWSUIT FOR DAMAGES ARISING FROM ALLEGED BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, PRODUCT LIABILITY OR ANY OTHER LEGAL OR EQUITABLE THEORY, THE BUYER SPECIFICALLY AGREES THAT BMC SHALL NOT BE LIABLE FOR DAMAGES OR FOR LOSS OF PROFITS, WHETHER FROM BUYER OR BUYER'S CUSTOMERS. BMC'S LIABILITY SHALL BE LIMITED TO THE PURCHASE COST TO BUYER OF THE SPECIFIED GOODS SOLD BY BMC TO BUYER WHICH GIVE RISE TO THE CLAIM FOR LIABILITY. No agent, employee or representative of Baylis Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product. This warranty is valid only to the original purchaser of Baylis Medical products directly from a Baylis Medical authorized agent. The original purchaser cannot transfer the warranty. Use of any BMC product shall be deemed acceptance of the terms and conditions herein. The warranty periods for Baylis Medical products are as follows:

Disposable Products	The shelf life of the product
Accessory Products	90 days from the shipment date

**Français**  
 Lire attentivement toutes les directives avant l'utilisation. Respectez toutes les contre-indications, avertissements et précautions indiqués dans ces directives. Lire non-respect risque de causer des complications pour le patient.  
 La compagnie Baylis Médical se fie sur le médecin pour déterminer, évaluer et communiquer à chaque patient tous les risques potentiels de la procédure.  
**AVERTISSEMENT : EN VERTU DE LA LOI FÉDÉRALE AMÉRICAINNE, CE DISPOSITIF NE PEUT ÊTRE VENDU QUE PAR UN MÉDECIN OU SUR L'AVIS D'UN MÉDECIN**

**DESCRIPTION DU DISPOSITIF**

La TorFlex™ Transseptal Guiding Sheath Kit est munie de trois composantes : une gaine, un dilateur et un fil guide avec un bout-J.  
 La TorFlex™ Transseptal Guiding Sheath est conçue pour facilement et sûrement effectuer des cathétérisations et des angiographies de localisations et chambres spécifiques du cœur. La gaine fournit un contrôle supérieur du torque et est flexible. Le bout radiopaque maximise la visualisation de la gaine durant sa manipulation.  
 Le dilateur fournit un support pour la gaine et a un bout conique.



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Lea con atención las instrucciones antes de la utilización del material. Verifique todas las contra-indicaciones, avisos e precauciones descritas en estas instrucciones. A não observância destes princípios pode causar complicações ao doente.

**Portugues**  
**Leia com atenção as instruções antes da utilização do material. Verifique todas as contra-indicações, avisos e precauções descritas nestas instruções. A não observância destes princípios pode causar complicações ao doente.**  
**A ToxFlex™ Transseptal Guiding Sheath Kit de responsabilidade do médico assistente a decisão, avaliação e a comunicação dos riscos previsíveis do procedimento a cada doente individualmente.**  
**PRECAUÇÕES: AS LEIS FEDERAIS DOS EUA RESTRINGEM A VENDA DESTES DISPOSITIVO APENAS A MÉDICOS OU A PEDIDO DESTES**

**I. DESCRIÇÃO DO DISPOSITIVO**  
 El ToxFlex™ Transseptal Guiding Sheath Kit está compuesto por tres elementos: una vaina, un dilatazor y un alambre guía con la punta en forma de J.

**II. INSTRUCCIONES DE USO**  
 La ToxFlex™ Transseptal Guiding Sheath se utiliza para la introducción percutánea de varios tipos de catéteres cardiovasculares en todas las cámaras del corazón, incluida la aurícula izquierda a través de una punción/perforación transseptal.

**III. ADVERTENCIAS**

**IV. PRECAUCIONES**

**V. REACCIONES ADVERSAS**

**VI. INSPECCIÓN ANTES DE SU USO**

**VII. EQUIPO NECESARIO**

**VIII. INSTRUCCIONES DE USO RECOMENDADAS**

**IX. INSTRUCCIONES DE LIMPIEZA Y ESTERILIZACIÓN**

**X. SERVICIO DE ATENCIÓN AL CLIENTE Y DEVOLUCIÓN DE LOS PRODUCTOS INFORMACION**

**XI. ETIQUETAJE Y SÍMBOLOS**

**XII. GARANTÍA LIMITADA - Desechables y accesorios**

**Garantía Limitada - Descartables y Accesorios**

**DECLARACIÓN Y LIMITACIÓN DE RESPONSABILIDAD A GARANTÍA LIMITADA ACIMA É A ÚNICA GARANTIA FORNECIDA PELO**

**VEICULO**

**NOTAS:**

**1.** Para devolver produtos a Baylis Medical Company deve obter um número de autorização de devolução antes de enviar o produto de volta. As instruções de devolução do produto se encontram no anexo fornecido.

**2.** Assegure-se de que se ha enviado o produto esterilizado e não contaminado e/ou esterilizado tal como indicado nas Instruções de Devolução do Produto antes de devolvê-lo para o serviço de garantia. A Baylis Medical não aceita qualquer peça de equipamento usado que não tenha sido limpa adequadamente ou descontaminada de acordo com as instruções de Devolução.

**XI. ETIQUETAJE Y SÍMBOLOS**

Simbolo	Descrição	Simbolo	Descrição
	Esterilizado por meio de óxido de etileno		Número de lote
	Representante autorizado na UE		Mantener alejado de la luz del sol
	Advertencia		Mantener alejado de la luz del sol
	Consultar Instrucciones de Uso		Manter Seco
	Número de catálogo		Mantener em lugar seco
	No-progénico		

**XII. GARANTÍA LIMITADA - Desechables y accesorios**

A Baylis Medical Company Inc. (BMC) garantiza sus productos desechables y accesorios contra defectos en materiales y mano de obra.

**Garantía Limitada - Descartables y Accesorios**

A Baylis Medical Company Inc. (BMC) garante a Eliminação e Produtos de Acesso contra defeitos em materiais e mão-de-obra.

**DECLARACIÓN Y LIMITACIÓN DE RESPONSABILIDAD A GARANTÍA LIMITADA ACIMA É A ÚNICA GARANTIA FORNECIDA PELO**

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