

# Exhibit 25

**Boston  
Scientific**

## **Guidezilla™**

Guide Extension Catheter (5-in-6)

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# Guidezilla™

## Guide Extension Catheter (5-in-6)

**Rx ONLY**

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

**WARNING**

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

**DEVICE DESCRIPTION**

The Guidezilla guide extension catheter is a single lumen rapid exchange catheter compatible with 6F guide catheters and may be placed over an exchanged length 180 cm guidewire. The 145 cm device has a stainless steel proximal shaft with a 25 cm single lumen distal guide segment with a hydrophilic coating.

The Guidezilla device has two platinum-iridium marker bands, which enable visibility while using standard fluoroscopic methods. The distal marker band is located 2 mm from the distal tip. The proximal marker band is located 3 mm distal to the opening of the guide segment. The device has two positioning marks located at 90 cm (single mark) and 100 cm (double mark) from the distal tip, respectively.

The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter. The Guidezilla device has a proximal tab which indicates inner diameter and guide catheter compatibility.

**Table 1. Compatibility Information**

Model	Compatible Guidewire	Compatible Guide Catheter	Guidezilla Min. I.D.
6F (5-in-6)	≤ 0.014 in (0.36 mm)	≥ 6F / ≥ 0.070 in I.D. (1.78 mm)	.057 in (1.45 mm)

**CONTENTS**

Qty	Material
One (1)	Single-use Guidezilla guide extension catheter

**INTENDED USE/INDICATIONS FOR USE**

The Guidezilla guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

**CONTRAINDICATIONS**

- Vessels less than 2.5 mm in diameter.
- Vessels in the neurovasculature and the venous system.

**WARNINGS**

- Use prior to the "use by" date as indicated on the label.
- Never advance the Guidezilla device into a vessel without a leading guidewire or without confirming location using fluoroscopic guidance. Vessel dissection or perforation may result.
- Due to the size and non-tapered tip of the Guidezilla device, extreme care must be taken to avoid vessel ischemia or vascular damage.
- Where there is limited clearance between interventional devices and the distal guide segment lumen, those devices must be advanced and withdrawn slowly with the hemostasis valve open to reduce the risk of embolism.
- This is a non-torqueable device. Torquing the device may result in wire wrap or damage to the device or vessel.
- Never advance the Guidezilla device into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the Guidezilla catheter, withdraw the Guidezilla catheter until the pressure returns to normal.

**PRECAUTIONS**

- Inspect the device prior to use for any bends or kinks. Any device damage may decrease the desired performance characteristics.
- The device lumen should be thoroughly flushed with heparinized saline prior to use.
- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.
- Exercise care in handling of the device during a procedure to reduce the possibility of accidental breakage, bending or kinking.
- When the device is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the device without observing the resultant tip response.
- Never advance the Guidezilla device more than 15 cm beyond the tip of the guide catheter. Further distal advancement of the Guidezilla device could cause the entire guide segment to track outside of the guide catheter and impede withdrawal of the device.
- If strong resistance is encountered during manipulation of the devices, do not force passage. Determine the cause of the resistance before proceeding. If the cause cannot be removed, withdraw all devices simultaneously.

**ADVERSE EVENTS**

The adverse events include, but are not limited to:

- Vessel trauma (e.g., perforation, dissection)
- Vascular complication (e.g., puncture site complication)
- Thrombus
- Renal failure
- Slow-flow/occlusion
- Allergic reaction
- Death
- Emboli
- Hemorrhage/hematoma (e.g., vascular access complication)
- Infection
- Myocardial infarction
- Arterial spasm
- Intimal disruption

**HOW SUPPLIED**

Packaging is designed to maintain sterility according to expiration date on the label. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Other items required but not provided:

- Guide catheter with an inner diameter large enough to accommodate the Guidezilla™ device
- Y-adaptor with hemostasis valve
- Guidewire with diameter ≤ 0.014 in (0.36 mm)
- Sterile syringe (for system flushing)
- Sterile heparinized saline (for system flushing)

**Handling and Storage**

Store in a cool, dry, dark place.

**OPERATIONAL INSTRUCTIONS**

**Preparations for Use**

1. Prior to use, carefully inspect the Guidezilla device packaging and components for damage.
2. Using sterile technique, transfer the protective tubing with the Guidezilla device into the sterile field.
3. Carefully remove the Guidezilla device from its protective tubing. Do not bend or kink the device during removal.
4. Immerse the distal guide segment in heparinized saline solution.

**Delivery Procedure**

Deliver the Guidezilla device according to the following steps:

1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve.
2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter.

3. Under fluoroscopy, advance the Guidezilla device up to a maximum of 15 cm beyond the distal tip of the guide catheter and into the desired location within the vessel.

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**Warning:** Due to the size and non-tapered tip of the Guidezilla device, extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.

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**Warning:** Never advance the Guidezilla device into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the Guidezilla catheter, withdraw the Guidezilla catheter until the pressure returns to normal.

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4. Using fluoroscopy, confirm the desired position of the Guidezilla device in the vessel.
5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space.

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**Note:** Use caution when advancing the interventional device into the distal guide segment.

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6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guidezilla device to prevent back-bleeding.
7. Perform the catheterization procedure. After completing the procedure, remove the Guidezilla device prior to removing the guide catheter from the vessel.

**WARRANTY**

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

# Guidezilla™

## Catéter guía con extensión (5 en 6)

### Rx ONLY

**Precaución:** las leyes federales de los Estados Unidos sólo permiten la venta de este dispositivo bajo prescripción facultativa.

### ADVERTENCIA

El contenido se suministra ESTÉRIL mediante óxido de etileno (OE). No usar si la barrera estéril está dañada. Si se encuentran daños, llamar al representante de Boston Scientific.

Para un solo uso. No reutilizar, reprocesar o reesterilizar. La reutilización, el reprocesamiento o la reesterilización pueden comprometer la integridad estructural del dispositivo y/o causar su fallo, lo que a su vez puede resultar en lesiones al paciente, enfermedad o la muerte. La reutilización, el reprocesamiento o la reesterilización pueden también crear el riesgo de contaminación del dispositivo y/o causar infección o infección cruzada al paciente, que incluye, entre otros, la transmisión de enfermedades infecciosas de un paciente a otro. La contaminación del dispositivo puede causar lesiones, enfermedad o la muerte del paciente.

Después de su uso, desechar el producto y su envase de acuerdo a las normas del hospital, administrativas y/o de las autoridades locales.

### DESCRIPCIÓN DEL DISPOSITIVO

El catéter guía con extensión Guidezilla es un catéter de intercambio rápido de un solo lumen compatible con catéteres guía de 6 F y puede colocarse sobre una guía de 180 cm o de longitud intercambiable. El dispositivo de 145 cm tiene un cuerpo proximal de acero inoxidable con un segmento guía distal de un solo lumen de 25 cm y revestimiento hidrófilo.

El dispositivo Guidezilla tiene dos bandas marcadoras de platino-iridio, que le proporcionan visibilidad durante la utilización de métodos fluoroscópicos estándar. La banda marcadora distal está situada a 2 mm de la punta distal. La banda marcadora proximal está situada a 3 mm de la abertura del segmento guía. El dispositivo dispone de dos marcas de posición situadas a 90 cm (marca única) y 100 cm (marca doble) de la punta distal, respectivamente.

El dispositivo Guidezilla se introduce a través de un catéter guía, dando lugar a un diámetro interno de aproximadamente 1 French menos que el catéter guía. El dispositivo Guidezilla tiene una lengüeta proximal que indica el diámetro interno y la compatibilidad del catéter guía.

Tabla 1. Información sobre compatibilidad

Modelo	Guía compatible	Catéter guía compatible	D.I. min. de Guidezilla
6 F (5 en 6)	≤ 0,014 in (0,36 mm)	≥ 6 F / ≥ D.I. de 0,070 in (1,78 mm)	0,057 in (1,45 mm)

### CONTENIDO

#### Cant. Material

Un (1) catéter guía con extensión de un solo uso Guidezilla

### USO INDICADO / INDICACIONES DE USO

El catéter guía con extensión Guidezilla está indicado para utilizarse junto con catéteres guía para acceder a regiones aisladas de la vasculatura periférica o coronaria, y para facilitar la colocación de dispositivos quirúrgicos.

### CONTRAINDICACIONES

- Vasos de diámetro inferior a 2,5 mm.
- Vasos de la neurovasculatura y del sistema venoso.

### ADVERTENCIAS

- Utilice este producto antes de la fecha de caducidad indicada en la etiqueta.
- No haga avanzar nunca un dispositivo Guidezilla en un vaso sin una guía de dirección o sin confirmar la ubicación mediante orientación fluoroscópica. Puede provocar disección o perforación vascular.
- Debido al tamaño y la punta no cónica del dispositivo Guidezilla, se debe actuar con suma precaución para evitar daños o isquemias vasculares.
- Cuando el espacio existente entre los dispositivos quirúrgicos y el lumen del segmento guía distal es limitado, dichos dispositivos deben hacerse avanzar y retirarse lentamente con la válvula hemostática abierta para reducir el riesgo de embolia.
- Este dispositivo no se puede torcer. La torsión del dispositivo puede provocar el enroscamiento de la guía o daños en el dispositivo o vaso.
- No introduzca nunca el dispositivo Guidezilla en un vaso de diámetro efectivo inferior a 2,5 mm. Puede ocasionarse una lesión, isquemia y/u oclusión vascular. Si la presión de un vaso desciende después de insertar el catéter Guidezilla, extráigalo hasta que la presión vuelva a ser normal.

### PRECAUCIONES

- Inspeccione el dispositivo antes de utilizarlo para verificar que no tiene pliegues ni acodamientos. Cualquier daño en el dispositivo puede disminuir el rendimiento del procedimiento.
- El lumen del dispositivo debe irrigarse completamente con solución salina heparinizada antes de utilizarse.
- Solo los médicos debidamente preparados en la realización de intervenciones y técnicas percutáneas e intravasculares deben utilizar este dispositivo.
- Cuando se usen catéteres en el sistema vascular, deberán tomarse precauciones para evitar o reducir la coagulación. Debe considerarse el uso de heparinización sistémica y solución salina heparinizada.
- Manipule el dispositivo con cuidado durante la intervención para reducir la posibilidad de acodamientos, dobleces o roturas accidentales.
- Cuando el dispositivo esté dentro del cuerpo, solo debe manipularse bajo fluoroscopia. No intente mover el dispositivo sin observar la respuesta correspondiente de la punta.
- No haga avanzar nunca el dispositivo Guidezilla más de 15 cm más allá de la punta del catéter guía. Si el dispositivo Guidezilla se hace avanzar a más profundidad en dirección distal, el segmento guía completo podría soltarse del catéter guía e impedir la extracción del dispositivo.

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