

## ScoutPro Guide Wire, ScoutPro Hemostatic Valve, ScoutPro Slitter Tool Advanced

### Accessories for the ScoutPro CS Lead Introducer System

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BIOTRONIK GmbH & Co. KG  
Woermannkehe 1  
12359 Berlin · Germany  
Tel +49 (0) 30 68905-0  
Fax+49 (0) 30 6852804  
sales@biotronik.com  
www.biotronik.com

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# BIOTRONIK

## General Considerations

### Intended use

The ScoutPro Guide Wire, the ScoutPro Hemostatic Valve, and the ScoutPro Slitter Tool Advanced are solely intended for use in conjunction with BIOTRONIK's ScoutPro CS Lead Introducer System or the separately available BIOTRONIK ScoutPro guiding catheters for implanting a CS lead via the coronary sinus.

(CS is the abbreviation of Coronary Sinus)

**Note:** When using the implantation accessories described above, refer to the detailed accompanying technical manual for the ScoutPro CS Lead Introducer System and the separately available ScoutPro guiding catheters.

### Guide wire

After puncture, the guide wire facilitates the introduction of the introducer sheath and the guiding catheter into the atrium and in doing so straightens the pre-shaped guiding catheter.

### Hemostatic valve

The hemostatic valve is suitable for legally marketed polyurethane or polyurethane-coated leads with a diameter of less than 7.8 F.

The valve prevents the return flow of blood at the proximal end of the guiding catheter with or without an inserted catheter (lead, dilator, guide wire, probing catheter).

### Slitter tool

The slitter tool is used to remove the guiding catheter after the CS lead has been successfully anchored.

The slitter tool is designed to remove catheters from CS leads with an outer diameter of 4.1 to 7.2 F.

## Indications

The guide wire, the hemostatic valve, and the slitter tool are used in conjunction with the ScoutPro CS Lead Introducer System to facilitate lead implantation in the left of the heart via the coronary sinus.

## Contraindications

The use of the ScoutPro CS Lead Introducer System and its separately sold accessories is contraindicated for the following:

- Patients with an existing or possible occlusion of the coronary vessels or inadequate anatomy of the coronary veins
- Patients with active systemic infection

## Potential Negative Side Effects

Possible complications are as follows:

- Allergic reaction to contrast media
- Hematoma
- Bleeding
- Infection
- Air embolism
- Pneumothorax
- Cardiac tamponade
- Myocardial damage
- Venous or cardiac perforation
- Local tissue reaction, formation of fibrotic tissue
- Thromboembolism
- Damage to the heart valve
- Vascular occlusion
- Chronic nerve damage

## Packaging and Sterility

The guide wire, the hemostatic valve, and the slitter tool are sealed in sterile bags and sterilized with ethylene oxide.

The sterile bags are packaged in a container that carries a quality control seal and a product information label. The label lists the model type, technical data, serial number, use-before date, and information about sterility and storage of the package.

- 1 Examine the package for damage before opening to ensure sterility.
- 2 Return the package and its contents to BIOTRONIK, if you suspect that a sterile bag has been opened or damaged.

**Note:** The guide wire, the hemostatic valve, and the slitter tool are intended for single use only.

### Disposal

Used ScoutPro implantation accessories can be properly disposed with contaminated hospital refuse. They do not contain any materials that require special waste disposal.

## Handling the Guide Wire

### Preparation

- In a non-sterile area: Remove the sterile bag from the box and open it.
- In a sterile area: Remove the guide wire.

### Application of the guide wire during an implantation

- 1 After the successful puncture of the chosen vein, remove the syringe body while leaving the cannula in position.
- 2 Using X-ray detection, introduce the guide wire through the cannula into the vein and advance it up to the atrium. Remove the cannula.
- 3 Additionally, when using the peel-away introducer with dilator:
  - Advance the introducer with the entirely introduced dilator over the guide wire into the vessel.
  - Remove the dilator. The introducer sheath will remain in the vessel.
- 4 Insert the selected guiding catheter with dilator and mounted hemostatic valve over the guide wire. Advance the guiding catheter up to the atrium.

**Caution: Carefully advance the guiding catheter to prevent damage to the vessel walls!**

**Note:** To inhibit blood clotting, BIOTRONIK recommends intravenously administering 50-100 I.U. heparin per kg body weight if the patient is not otherwise anticoagulated. The heparin may be directly administered through the ScoutPro guiding catheter or a different venous access point. In this case please flush with sufficient physiological NaCl solution to guarantee that the heparin completely enters the patient's circulation.

- 5 Remove the dilator and the guide wire. The guide wire will then resume its curved pre-formed shape.

## Handling the Hemostatic Valve

### Preparation

- Opening the sterile container:
  - In a non-sterile area: Remove the outer sterile bag from the box and open it.
  - In a sterile area: Remove and open the inner sterile bag.
- Rinse, aspirate, and vent the hemostatic valve thoroughly. Then connect the hemostatic valve to the selected ScoutPro guiding catheter.
- The valve position can be set with the front rotation ring. Select the setting so that the dilator can be guided through the hemostatic valve. Insert the guiding catheter with dilator and mounted hemostatic valve using the guidewire.

**Note:** To inhibit blood clotting, BIOTRONIK recommends intravenously administering 50-100 IU heparin per kg body weight if the patient is not otherwise anticoagulated. The heparin may be directly administered through the ScoutPro guiding catheter or a different venous access point. In this case please flush with sufficient physiological NaCl solution to guarantee that the heparin completely enters the patient's circulation.

### Removing implantation accessories

After the lead has been successfully positioned, twist off the hemostatic valve by rotating and sliding it over the proximal end of the lead. Then remove the guiding catheter and, if necessary, the introducer sheath.

## Handling the Slitter Tool

### Preparation

In a non-sterile area:

- Remove the outer sterile bag from the outer container and open it.

In a sterile area:

- Remove and open the inner sterile bag.
- Remove the clear bag (PE) with the slitter tool and take the slitter tool out of the clear bag.

**Note:** The guiding catheters from the BIOTRONIK ScoutPro CS Lead Introducer System cannot be lacerated by hand using the peel-away technique. These catheters must be removed with a slitter tool.

### Removing the guiding catheter with the slitter tool

After the lead has been successfully positioned and anchored:

- Detach the hemostatic valve and peel off over the proximal end of the lead.
- Carefully tear approx. 15mm into the proximal part of the guiding catheter using the peel-away handles.
- Insert the lead in the guiding channel of the slitter tool and anchor it with your thumbs.

**Note:** The tip (blade) of the slitter tool should point at the open area of the catheter. (see Fig. 1)



Fig. 1: Anchor the lead to the slitter tool

- Continue to hold the slitter tool and the lead, (Recommendation: while doing this, rest your hand on a firm base) and pull the guiding catheter along the steel blade of the slitter tool with your other hand, thus slitting it open. (Recommendation: simultaneously hold both open peel-away handles between your thumb, index finger and middle finger)

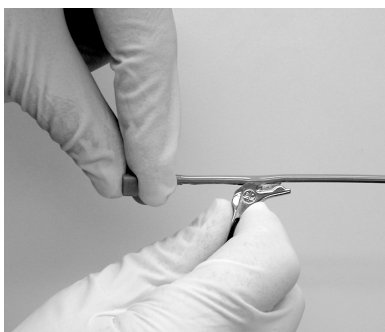


Fig. 2: Pull the catheter against the blade of the slitter tool

- If an introducer was used, then it must be removed. Either do this by hand (peel-away technique) or by using the slitter tool.

**Note:** Avoid sharp bends in the lead and the catheter close to the slitter tool! The movement between the catheter and the slitter tool should proceed in the straightest possible manner.

### Disclaimer

The BIOTRONIK ScoutPro CS Lead Introducer System (including all separately sold accessories), which is used in conjunction with devices for implantation in the coronary sinus, has been qualified, manufactured, and inspected according to accepted standards and procedures.

However, the physician must be aware that the accessories may be easily damaged through improper handling or use.

For this reason, BIOTRONIK does not grant any further explicit or implied warranty for its accessories with the exception of the guaranty stated in the "limited warranty".

## Key to the Label



Date of manufacture of the device



Expiration date, only valid if sterile package is undamaged! Never use outdated devices!



Permitted storage temperature range



BIOTRONIK order number



Lot number



Sterilized with ethylene oxide



Do not re-sterilize!



Single use only. No re-use!



Non-sterile



Consult operating instructions



Contents



Do not use if packaging is damaged



European approval mark



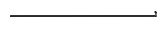
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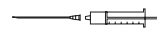
External diameter



Overall length



Guide wire



Needle and syringe



Peel away lead introducer LI



Dilator



Guiding catheter



Hemostatic valve



Slitter Tool Advanced

## CE Mark

This product complies with EC Directive 90/385/EEC relating to active implantable medical devices. It is therefore designated with the CE mark. The product may be used in all European Union countries as well as in countries that recognize the above-mentioned directive.

