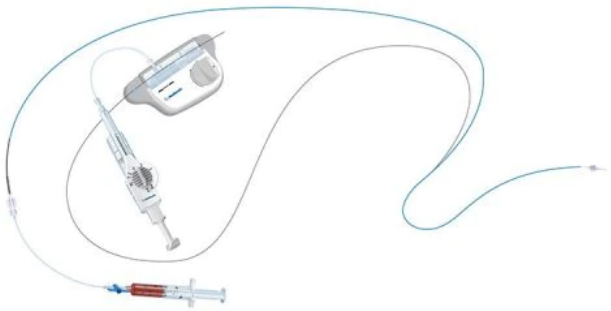
Medtronic

HEALTHCARE STAFF

GuardWire

Temporary Occlusion and Aspiration System



INDICATIONS, SAFETY, AND WARNINGS

INDICATIONS AND INTENDED USE

The GuardWire Temporary Occlusion and Aspiration System is indicated for use in the coronary saphenous vein bypass grafts (2.5 - 5.0 mm) to:

- Contain and aspirate embolic material (thrombus / debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse / deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

- The safety and effectiveness of the device as an embolic protection system has not been established in treating patients with acute myocardial infarction.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating native coronaries.

The Guardwire 3-6 Temporary Occlusion and Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus / debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures
- To subselectively infuse / deliver diagnostic or therapeutic agents with or without vessel occlusion
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

WARNINGS

- Use of the GuardWire Temporary Occlusion and Aspiration System requires an experiential learning curve needed to achieve familiarity with the proper use of the device. Prior to using the physician should have completed a training program regarding proper use of this device. Please see the Physician Training Section for further details.
- Prior to use, the packaging and product should be inspected for signs of damage. Never use damaged product or product from a damaged package.
- The GuardWire catheter should be handled carefully. Prior to use and when possible during the procedure, inspect the GuardWire catheter carefully for bends, kinks, or other damage. Do not use a damaged GuardWire catheter because failure to inflate or deflate the balloon, vessel damage and / or inaccurate torque response may occur.
- The EZ flator device contains a full range of volume designed exclusively for the GuardWire catheter. WHEN INFLATING THE GUARDWIRE BALLOON, USE ON THE EZ FLATOR inflation device. Do not over-inflate the GuardWire balloon after fully occluding the vessel. THE INFLATION DIAL SHOULD NOT BE TURNED GREATER THAN 1 MM BEYOND THE VESSEL SIZE, AS BALLOON RUPTURE MAY OCCUR.
- The GuardWire catheter is not recommended for ostial lesion use.

PRECAUTIONS

- Confirm the compatibility of other devices with the GuardWire catheter before actual use.
- Use only with devices that are approved for their intended use.

- The GuardWire Temporary Occlusion Catheter and accessories should be used in conjunction with fluoroscopic guidance and proper anticoagulation agents.
- Use only diluted contrast as the balloon inflation medium 60% contrast diluted 1:3 with heparinized normal saline or 76% contrast diluted 1:3 (1 part contrast 3 parts heparinized normal saline). Never use air or any gaseous medium to inflate the balloon.
- When using the Export Catheter for fluid delivery, do not exceed the maximum flow rate specified for the device (see Table 16 of IFU).

CAUTION: If there is an angle in the saphenous vein graft more acute than 60° distal to the target stenosis, the stent placement should stop approximately 10 mm before the vessel angle or the stent should extend completely around the angulated segment. In the event that resistance is met in removing the deflated GuardWire Catheter, a 5Fr straight coronary guide catheter with an inner luminal diameter of 0.055°/5Fr and a length of >125 cm in length may be advanced over the GuardWire Catheter used to encase the deflated occlusion balloon and allow it to be retracted slowly through a fully deployed stent and back into the guide catheter for complete removal.

- The system has been tested to 6 inflation/deflation cycles. Following proper preparation, it is NOT recommended that the system be inflated/deflated more than 6 times.
- The device is designed and intended for single patient use only. Do NOT resterilize and/reuse it.
- Always advance and withdraw the GuardWire Catheter slowly. Never push, withdraw or torque a GuardWire Catheter that meets resistance.
- The GuardWire occlusion balloon once inflated should be observed under fluoroscopy during catheter exchange to be sure the balloon does not move. The GuardWire Catheter should be treated like any standard coronary wire during catheter exchanges
- As in any elective coronary intervention, it is recommended that the patient have a mean systolic blood pressure greater than or equal to 90 mm Hg in concomitant of IV pressors or intra-Aortic Balloon Pump augmentation.
- Use caution when using the GuardWire Temporary Occlusion and Aspiration System in conjunction with a Rotating Hemostatic Valve (RHV), which utilizes a compression gasket to tighten onto the GuardWire catheter. This type of RHV does not rely on a manual tightening, unlike standard RHV's, and as a result, may place additional grip force on the GuardWire catheter such that inadvertent movement of the distal occlusion balloon may occur. An RHV of this type is the Guidant Copilot™ RHV.

- Avoid over tightening of wire torquing devices on the GuardWire catheter as it may result in damage to the hollow hypotube.

Important Information: Prior to use, refer to the Instructions for Use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions.

Caution: Swedish law restrictions this device to be ordered by, and sold to, a physician or medical institution only. See package insert for full product information.

RELATED LINKS

- Overview