General Overview of Embolic Protection Devices
Distal Protection Devices

- Balloon occlusion and aspiration systems
  - The PercuSurge (MDT) GuardWire
  - The Kensey Nash TriActiv system
- Catheter-based filters
  - The EPI (BSC) FilterWire
  - The Microvena (EV3) Trap
  - The Cordis Angioguard
  - The Mednova CardioShield and NeuroShield
  - The Guidant Accunet and Net II
  - The Medtronic Filter
PercuSurge Distal Protection System
PercuSurge GuardWire System

Consists of 4 components: the GuardWire®, the EZ-Flator™, the MicroSeal® Adapter, and the Export® catheter.
PercuSurge GuardWire System

Inflated GuardWire balloon and Export aspiration catheter
Balloon Occlusion Based Distal Protection

A. Lesion crossed with GuardWire

B. GuardWire balloon inflated and PCI performed under distal protection
Balloon Occlusion Based Distal Protection

C. Export aspirates emboli & thrombus with slow distal to proximal pullback

D. GuardWire balloon deflated
Kensey Nash TriActiv System

Compliant balloon, variable sizing from 3.0mm - 5.0mm

0.014” steerable guidewire, lubricious coating

3F Flush Catheter, side attachable design

TriActiv Balloon Guidewire and Catheter
Balloon Occlusion System

Advantages

- Complete control of the microcirculation
  - Small as well as large particles retrieved
  - Neurohumoral substances aspirated
- Low profile
  - Advantageous in tight lesions, native circulation
- No limit to amount of retrieved material
- Efficacy proven in SVG RCT
Ischemia
  • Excludes or compromises high risk pts
  • Need capable (fast) operators

PCI can be difficult with no forward flow

Manufacturing/technical challenges

Don’t steer or support like a 0.014” wire

Directs flow toward side branches

Can’t protect lesions in distal vessel
Filter Based Distal Protection

- **Insertion**
- **Stent**
- **Deployment and PTCA**
- **Retrieval**
Filter Based Distal Protection

The AngioGuard Filter

The EPI FilterWire EX
Filter Based Distal Protection

The Microvena TRAP

The Guidant NET II Filter

The MedNova Filter

The Medtronic INFERCEPTR
Extraction Using Filter Wire
Extraction Using Trap Device
Problems of FilterWire

Poor Apposition
Problems of FilterWire

Lack of Apposition

6.0 mm Angioguard in 5.5 mm round tube

6.0 mm Angioguard in a 5.0 mm asymmetrical tube

Lack of circumferential wall apposition between struts

The asymmetrical shape causes struts to pull farther away from wall
Problems of FilterWire

Capture Efficacy

MedNova filter capture efficiency in an ex vivo model (all filters have <100% capture efficiency depending on the particle size and model conditions)

Number and Size of Embolic Particles

Problems of FilterWire

Extruded Debris

Cordis AngioGuard Cases

(But can happen with all filters depending on pore size and retrieval mechanism)
Problems of FilterWire

Too Distal Lesion

FilterWire compressed in small native

Risks:
- Not completely open
- Branch unprotected

Pre | Filter deployed
Problems of FilterWire

Device Profile

Can inhibit lesion crossing, or result in embolization during passage

Angioguard 4.7 F

EPI FilterWire EX 3.9 F

GuardWire 2.7 F
Filter System

Advantages

- Continuous perfusion in most patients
  - First choice for the hemodynamically compromised patients
  - Contrast flow facilitates accurate PCI
  - Comfort level for patient and operator
- Simple to use
Filter System

Disadvantages

- Relatively high profile, crossing can lead to embolization
- Small particle and vasoactive substances can pass
- Debris can block flow, lead to ischemia
- No reflow, lead to no perfusion drive (? Need aspiration)
- Don’t steer or support like a 0.014” wire
- Genometric challenges, operator/technical considerations
- Directs flow toward side branches (esp, when occluded)
- Capacity limit; retrieval challenges
- Can’t protect lesions in small or distal vessels
Future of **Distal Protection Devices**

- It might be the standard of care during PCI of SVG disease, AMI and thrombotic lesions, carotid and renal intervention.

- Balloon occlusion system will continue to set the pace. Given their earlier introduction, positive results of trials (SAFER), low profile and total control of the distal microcirculation.

- Given maintained perfusion, ease of use issue, and anticipating future design enhancements, filter devices will assume an increasingly important role if their equivalence to balloon occlusion and aspiration system is demonstrated.
Distal Protection
With
The GuardWire Plus™ System
Learning Objectives

- Describe the clinical effects of microembolization on the myocardium.

- Explain how the GuardWire Plus provides protection from distal embolization.

- Demonstrate the sequence of steps required to prepare and use the GuardWire Plus System.
Microembolization occurs when particles from atherosclerotic lesions or other sources pass into the distal capillary beds possibly causing microvascular obstruction.
Distal embolization leads to microvascular obstruction, resulting in microinfarcts.
Microembolization

Where Do The Emboli Come From?

- **Spontaneous occurrence**
  - Plaque rupture
    - Unstable angina
    - Acute MI

- **Mechanically-induced event**
  - Interventions
Microembolization

Therapeutic Options

- Treatments aimed at minimizing the effects of distal embolization:
  - Restoration of distal flow by clot lysis, platelet disaggregation, vasodilation

- Preventative measures:
  - Anticoagulation
  - Anti-platelet therapy
  - Lipid-lowering drugs (plaque stabilization)
  - Distal protection
There is an atheroma component to embolization that cannot be managed with pharmacologic agents. Adjunctive distal protection will likely prove beneficial.
Microembolization

Patient Subsets at Risk

- Saphenous Vein Graft Interventions
- Acute Coronary Syndromes
- Carotid Artery Angioplasty/Stenting
- Renal Artery Stenting
- Any Percutaneous Intervention??
Coronary Artery Bypass With Saphenous Vein Grafts (SVGs)

Proximal Anastamosis

Vein Graft Body

Distal Anastamosis
Distal Protection in SVGs

- The average longevity of an SVG graft is 8-10 years
  - 40% occlude and 75% develop severe narrowing

- SVG atherosclerosis is diffuse and friable
  - Intervention may cause distal embolization
  - Embolization compromises the distal microcirculation

- SVG adverse events:
  - AHA - November 1998. Kalon Ho, MD
  - 415 stented SVGs at Beth Israel and Washington Hospital Center
  - **17.8% MACE**: Q-MI, non-Q MI, Death, E-CABG
  - CKMB >3x normal: 30 day mortality increase from 0.9% to 14%

A device that could capture and remove embolic particles before they reach the myocardium could reduce these complications…………….
The GuardWire Plus Solution for Protected SVG Interventions

A. Cross the lesion with the GuardWire Plus.

B. Inflate the GuardWire Plus.

C. Treat the lesion while GuardWire Plus provides distal protection.

D. Introduce the Export® catheter to aspirate embolic particles.

E. Deflate the GuardWire Plus.
John Webb, MD – Canadian Feasibility Study
- 27 patients, 1 site, non-randomized
- MACE = 3.7% vs. 17.8% (historical control)
- 79% treatment effect

These data provided the foundation for embarking on a multicenter, non-randomized trial in Europe...
SAFE – European Multi-Center Study

Saphenous Vein Graft Angioplasty Free of Emboli

- 103 patients, 8 sites, non-randomized
- MACE = 4.9% vs. 17.8% (historical control)
- 73% reduction in adverse events (death, MI, CABG, repeat revascularization)

The SAFE data provided the framework for a large multicenter, randomized trial in the US called SAFER…
SAFER – U.S. Multi-Center Randomized Study
Saphenous Vein Graft Angioplasty Free of Emboli Randomized

- 801 patients, 73 sites, randomized against standard care
- MACE = 9.6% vs. 16.5%
- 42% reduction in adverse events
The GuardWire Plus Distal Balloon Protection System

System Components

A. The GuardWire Plus Temporary Occlusion Balloon

B. The MicroSeal® Adapter and EZ Flator™

C. The Export Aspiration Catheter

Inflation/Deflation System
The Distal Occlusion Balloon Concept

- **Dual Role of the GuardWire**
  - Primary PTCA wire
  - Temporary occlusion balloon for distal protection

- **Unique Requirement**
  - Inflate distal occlusion balloon
  - Remove the inflation device
  - Balloon must remain inflated

- **Design elements that permits the device to function this way**
  - MicroSeal plug seals & unseals the inflation lumen
  - The MicroSeal Adapter simply opens & closes the MicroSeal plug
Moving the MicroSeal® back and forth opens and closes the Inflation port to allow inflation and deflation of the balloon. Note: The device illustrated here is in the “closed” position.
The MicroSeal® Adapter

GuardWire Plus

MicroSeal®
Plug

Gold
Marker
Band

MicroSeal®
Adapter

Inflation Port

Blue
Clip

Gray
Clip

Gray
Clip

Inflation
Seal

Movable
Gripper
Pads

Marker
Band

MicroSeal®
Plug
The GuardWire Plus

Ultra Low Entry & Exit Balloon Profiles:
- 3.0-6.0mm = 0.036”

Occlusion Balloon:
- 3.0-6.0 occlusion diameter range
- Proximal balloon marker

Lengths: 200 & 300 cm

2.5 cm shapeable tip
The Export® Aspiration Catheter

Length: 145 cm
Design: Rapid Exchange
- 35cm GW exit
Aspiration Lumen: 1mm
Prepping the GuardWire Plus

- Insert the GuardWire Plus™ into the MicroSeal® Adapter
- Align gold marker in blue clip
- Flush fluid into the inflation window area while closing clamshell, latch
Prepping the GuardWire Plus

- Turn the gray knob on the Adapter to ‘OPEN’
- Pull negative with EZ Flator x 30 seconds
- Return the handle to ambient (neutral position)
Prepping the GuardWire Plus

- Test inflate the balloon by slowly turning the dial on the EZ Flator to ‘5’

  *Note that the balloon will NOT reach its stated size on this test inflation, but WILL upon second inflation*
The GuardWire Plus

3-6mm Guardwire Plus Compliance Graph
(rd110200)

Volume (cc)
Balloon OD (mm)

1st Inflation (no prep inflation)
1st Inflation (prep per IFU)
Size
The GuardWire Plus

Inflation in a 3.0mm glass tube

Balloon inflated to 3.0mm
NO prep inflation

Balloon inflated to 3.5mm
NO prep inflation

Balloon inflated to 3.0mm
After prep inflation
Prepping the GuardWire Plus

- After confirming balloon inflation, turn the EZ Flator dial back to ‘0’
- Deflate the balloon by pulling negative on the EZ Flator handle until the balloon deflates
- Return the handle to ambient (neutral position)
Prepping the GuardWire Plus

- Turn the gray knob to ‘CLOSE MICROSEAL’
  - This pushes the MicroSeal plug back into the hypotube, sealing the inflation/deflation lumen closed
- Unlatch and open the Adapter - remove the wire from the blue clip first
- Prep is complete
Prepping the Export Catheter

- Connect the aspiration syringe to the extension tubing and draw 10cc of heparinized saline into the syringe
- Connect to the Export catheter and flush completely
- Turn the blue stopcock off to the extension tubing and pull back the syringe plunger until it locks in the vacuum position – it will snap in place
- Flush the rapid exchange guidewire lumen just prior to use
Distal Protection Procedure
Crossing the Lesion

- Cross lesion with GuardWire Plus
- Position distal occlusion balloon proximal to anastomosis
- Advance stent/balloon to tip of guide
- Insert proximal wire into Adapter
Occluding the Vessel

- Inflate distal occlusion balloon until vessel is occluded (may require 0.5mm greater than reference)
- Confirm occlusion
Treating the Lesion

- Close the MicroSeal plug
- Unlatch the Adapter and remove the wire
- Advance the interventional catheter and treat the lesion
Aspirating Particulate Debris

A. Load

B. Advance

C. Aspirate
Deflating the Balloon

- Apply Adaptor
- Open MicroSeal
- Pull negative to deflate
Hints for Minimizing Occlusion Time

- Have a clear strategy mapped out for deploying the GuardWire Plus and treating the lesion.

- Make certain the entire team understands the sequence of events.

- Have all equipment prepped and ready.

- Advance the therapy catheter to the distal end of the guiding catheter before inflating the occlusion balloon.

- Load the GuardWire Plus into the Adapter during the aspiration sequence so the balloon may be deflated as soon as aspiration is completed.
Hints for Minimizing Occlusion Time

**PROTECT**

**Operator 1**
Advance GuardWire across lesion and position in appropriate landing zone.

Load stent delivery catheter onto GuardWire and advance to distal end of guiding catheter.

**Operator 2**
Load GuardWire into Adapter.
Inflate balloon to occlude vessel.
Close MicroSeal and remove Adapter.

**TREAT**

**Operator 1**
Advance stent across lesion.
Deploy stent.
Remove stent delivery catheter.

**Operator 2**
Have Export Aspiration system ready.

**ASPIRATE**

**Operator 1**
Load Export onto GuardWire.
Advance Export to occlusion balloon.

**Operator 2**
Load GuardWire into Adapter, but DO NOT turn gray knob to ‘open’.

**Operator 1**
Initiate aspiration.
Perform 2-3 aspiration runs.

**Operator 2**
Only after aspiration is complete, turn Adapter knob to ‘open’ and deflate the balloon.
Troubleshooting

Tips & Tricks

- If the GuardWire Plus appears bent or kinked during prep, DO NOT USE: failure to inflate or deflate may occur.

- The GuardWire Plus is similar to a fixed wire balloon catheter – DO NOT rotate the device more than two complete turns in any one direction.

- Be sure to flush the guidewire lumen of all catheters and gently wipe the GuardWire Plus with a wet gauze between catheter exchanges.
Troubleshooting

Tips & Tricks

- When wiping the GuardWire Plus, do so GENTLY – DO NOT grasp the wire too tightly. Grasping too tightly may dislodge the MicroSeal plug, inadvertently deflating the balloon.

- DO NOT attempt to reposition the GuardWire Plus while the distal balloon is inflated. Sterile towels may be used to help stabilize the MicroSeal Adapter and keep it from tipping over.

- DO NOT attempt to treat an ostial lesion. There is a risk for dragging particulate debris into the aorta during catheter exchanges.
Troubleshooting

Lesion Visualization

- Perform test injections prior to inflating the balloon. Once the balloon occludes flow, contrast injections will not be helpful.

- If the lesion is in the ostium or very proximal segment of a vessel, do not perform a contrast injection after the intervention and before aspiration as this may dislodge particles into the aorta.
  - Balloon apposition may be confirmed by observing a squared-off appearance of the balloon in the vessel on fluoroscopy.
Troubleshooting

Lesion Visualization

- As the GuardWire Plus balloon is inflating, it is possible to gently inject a small amount of contrast into the vessel. Once the balloon is fully apposed to the vessel wall, the contrast will remain trapped in the vessel, providing a road map during the interventional procedure as well as confirmation of complete occlusion/protection.

- Consider selecting a stent length that will comfortably and completely cover the entire lesion length – slightly longer stents will facilitate stent positioning.
Troubleshooting
Defining the Balloon Landing Zone

- Inflate the GuardWire Plus balloon in an angiographically non-disease vessel segment.
- Position the GuardWire Plus marker band at least 3cm beyond the distal margin of the lesion.
- The inflated GuardWire Plus is NOT intended to act as an anchor in the vessel. Stabilize the wire by holding it and observing the tip on fluoroscopy during catheter exchanges.
  - Balloon movement in the vessel while inflated will increase the risk of vessel dissection.
Troubleshooting
Defining an ‘Ideal’ Balloon Landing Zone

Ideal Landing Zone

Improper Landing Zone
• Proximity too close to the lesion leads to incomplete lesion coverage
**Troubleshooting**

**If the Inflated Balloon is not Visible**

- Always test the system outside the body before introducing it in the vasculature.

- If the balloon fails to inflate during the test, replace the system.

- It is possible that the balloon was accidentally inflated with saline containing no contrast. Do not add additional volume to the balloon.
  - Perform a small test injection of contrast through the guide catheter to determine if the vessel is occluded.
  - Deflate the balloon, remove the wire, confirm inflation mixture of saline and contrast and re-prep the balloon outside the body.

- It may be possible that air is present in the balloon. Deflate the balloon using standard procedure, remove from the body and re-prep the balloon outside of the body.
Although the GuardWire Plus is made of nitinol, a material which is resistant to kinking, it is also a hypotube. The wire should be handled with care to avoid kinking.

If the GuardWire Plus kinks, try to gently remove the therapy catheter from it. Follow the removal of the therapy catheter by aspirating using the Export catheter, and then deflate the GuardWire Plus. Replace it with a new system to complete the procedure.

If the kink does not allow the removal of the therapy catheter, you may cut the wire and remove the therapy balloon. Once you have removed the therapy balloon, introduce the Export rail-like catheter and aspirate. Deflate the GuardWire Plus using standard technique and replace by a new system to complete the procedure.
Troubleshooting

Failure to Aspirate

- During aspiration, the system relies on the sumping of blood from the parent vessel (e.g. the aorta), through the ostium of the target vessel, and into the aspiration lumen of the Export catheter.

- Confirm that the guide catheter is not occlusively lodged in the ostium of the target vessel by withdrawing it slightly to allow blood flow around the catheter tip or through side holes.

- Move the Export catheter back and forth to facilitate aspiration of large deformable particles that may be lodged at the distal aspiration tip.

- Should none of these techniques work, close off the stopcock to the catheter and remove the catheter. This will prevent the dislodgment of any particles that may be stuck in the lumen of the Export catheter. Introduce a new Export catheter and aspirate per standard technique.
Troubleshooting

Failure of the Balloon to Deflate

- Check that the GuardWire Plus is properly positioned within the MicroSeal adapter. Repeat the deflation procedure.

- If you are using a torque device, unlock the torque device from the wire and attempt to deflate the balloon once again.

- Check for any kinks along the GuardWire Plus, specifically around the MicroSeal section. If there is a kink, try to gently straighten the wire and repeat the deflation procedure using the MicroSeal Adapter per IFUs.
Troubleshooting

Failure of the Balloon to Deflate

- If none of these work, or if the extension wire fractures, cut the GuardWire Plus approximately 4 cm distal to the gold marker band. This will allow the balloon to slowly deflate.

- To increase the rate of deflation of the cut wire, place the cut end in the MicroSeal Adapter so that it sits within the rubber ring of the inflation/deflation port. Deflate by following the IFU instructions.