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

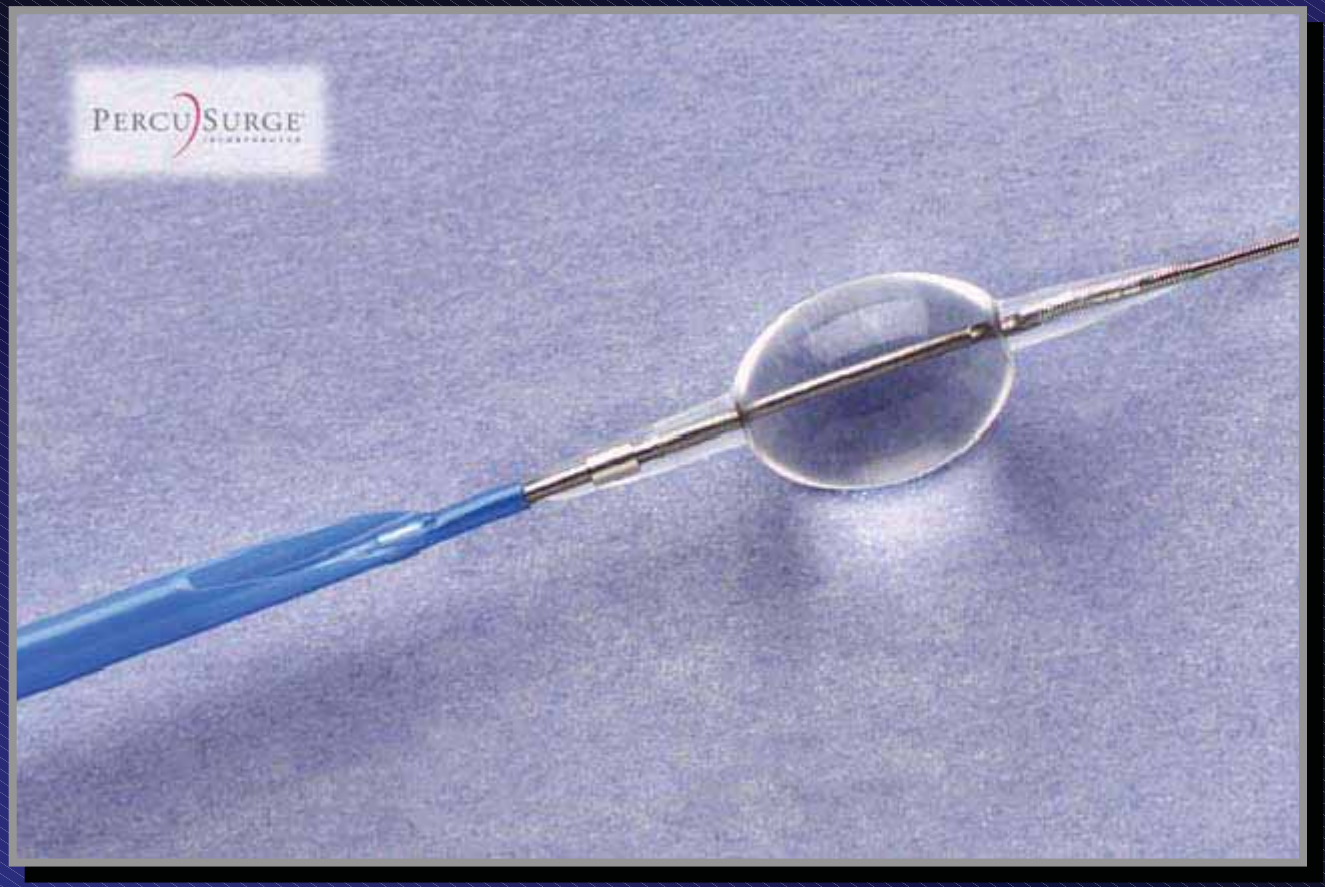
PercuSurge GuardWire System

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

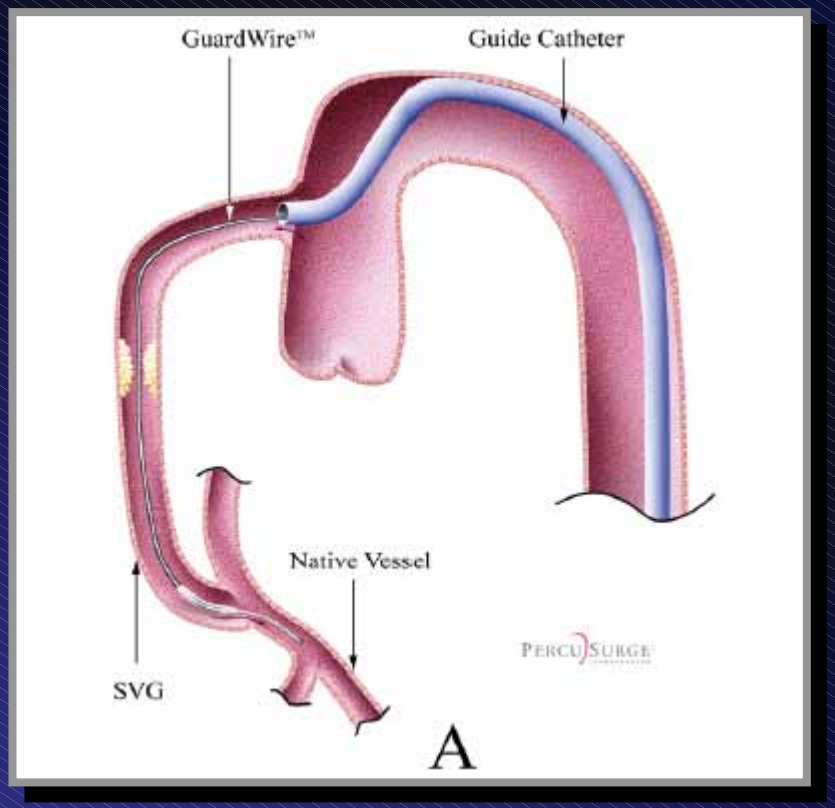
MicroSeal Adapter

PercuSurge GuardWire System

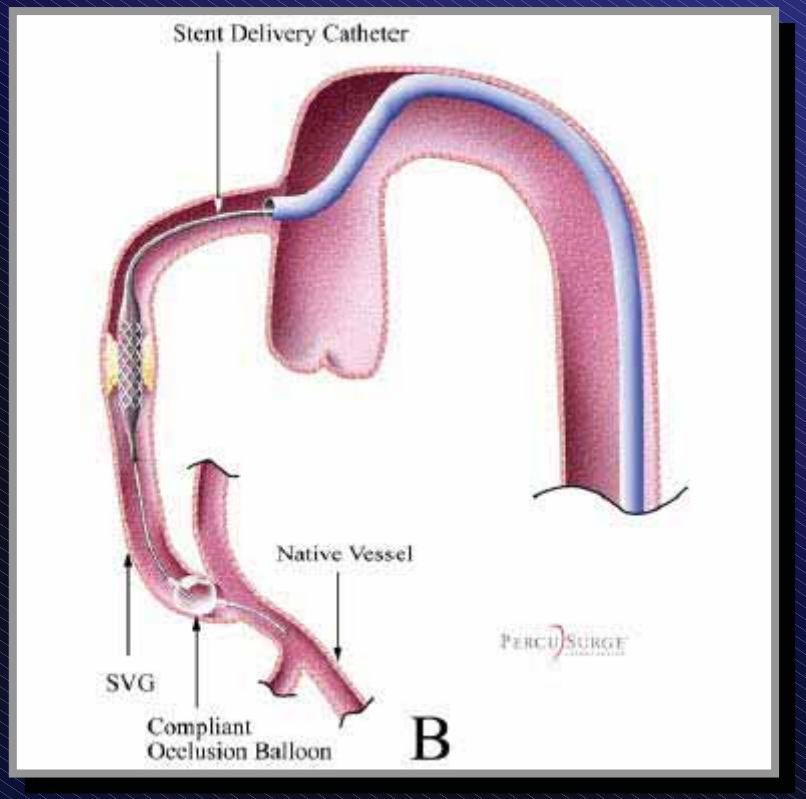
Inflated GuardWire balloon and Export aspiration catheter



Balloon Occlusion Based Distal Protection

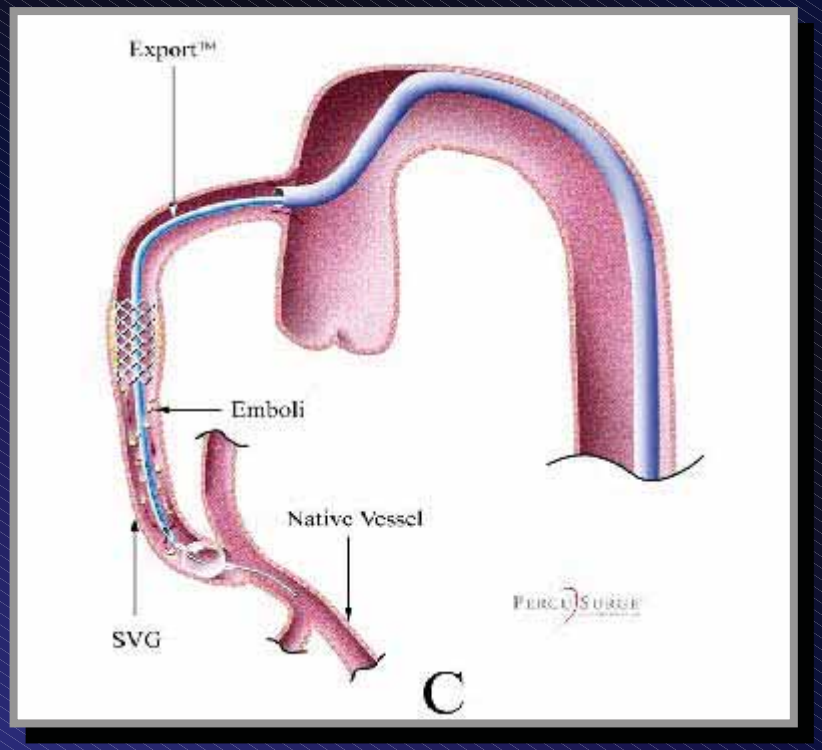


A. Lesion crossed with GuardWire

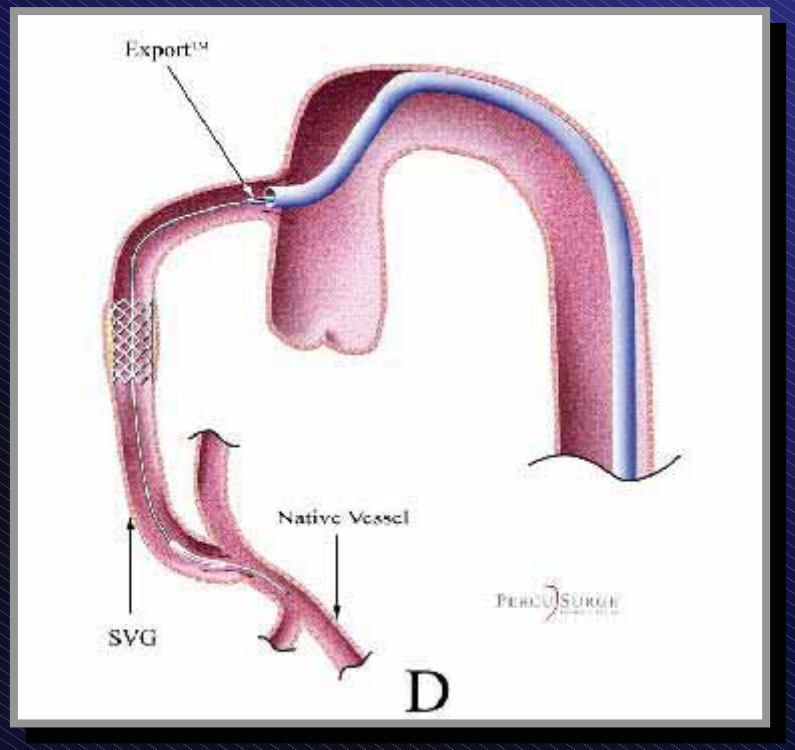


B. GuardWire balloon inflated and PCI performed under distal protection

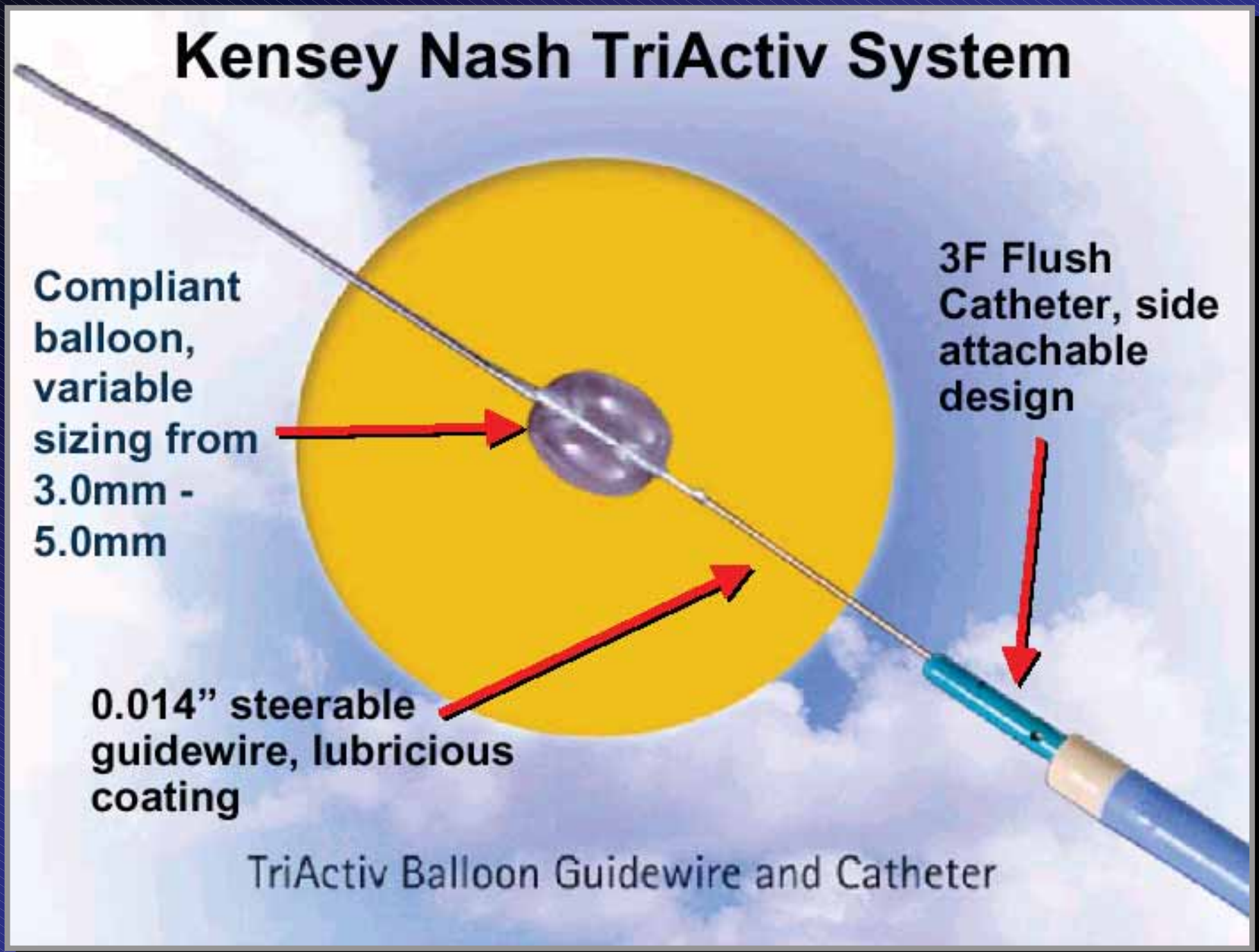
Balloon Occlusion Based Distal Protection



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
3F Flush Catheter, side attachable design
0.014” steerable guidewire, lubricious coating
TriActiv Balloon Guidewire and Catheter

Balloon Occlusion System

Advantages

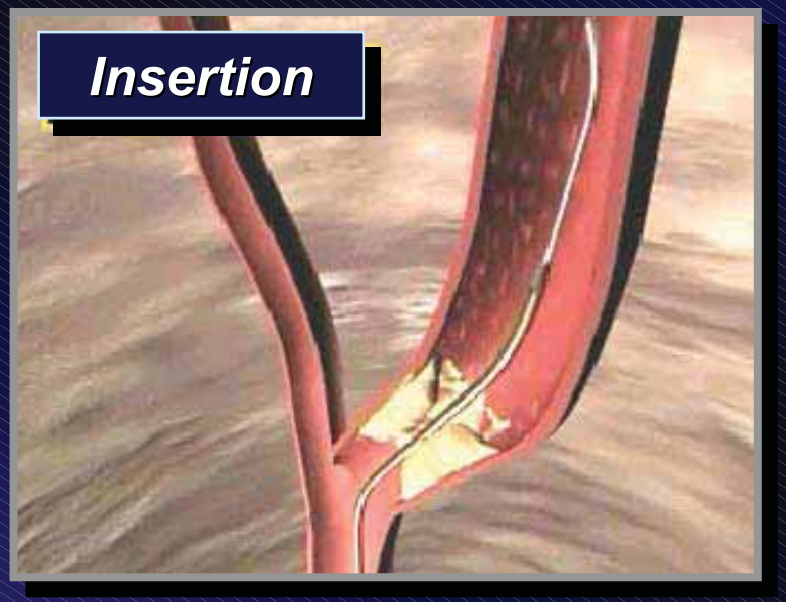
- Complete control of the microcirculation
  - Small as well as large particles retrieved
  - Neurohumoral substances aspirated
- Low profile
  - Advantageous in tight lesions, native circulation
- No limit to amount of retrieved material
- Efficacy proven in SVG RCT

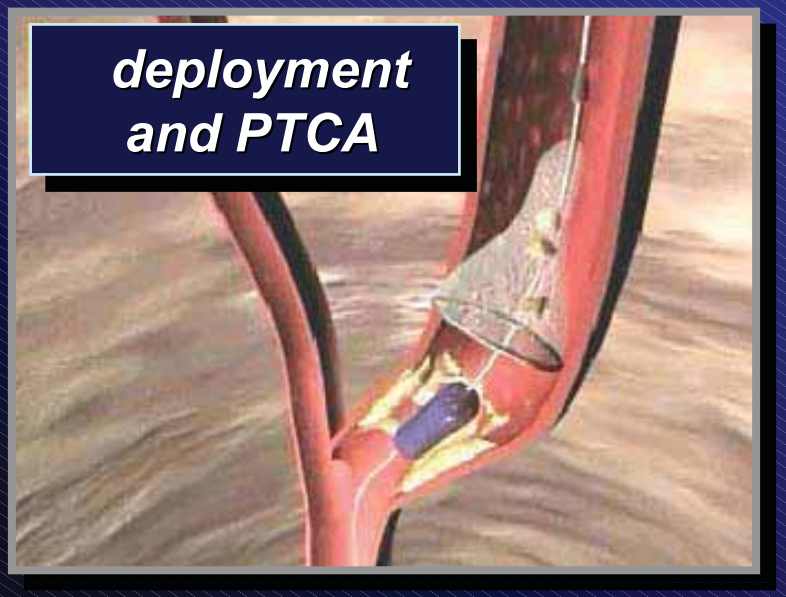
Balloon Occlusion System

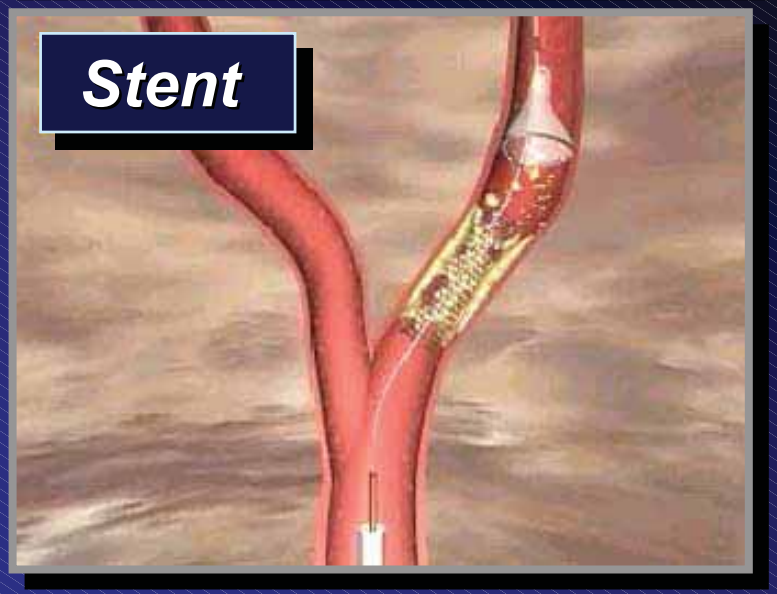
Disadvantages

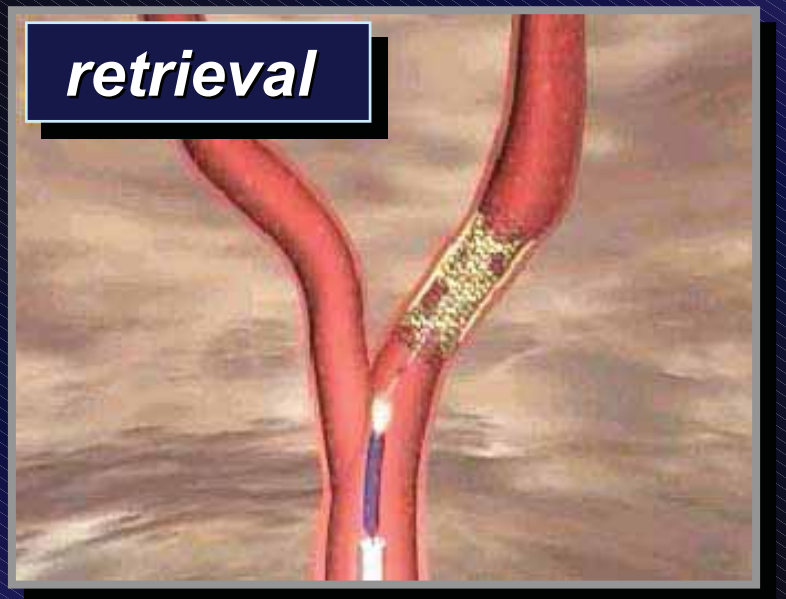
- **Ischemia**
  - **Excludes or compromises high risk pts**
  - **Need capable (fast) operators**
- **PCI can be difficult with no forward flow**
- **Manufacturing/technical challenges**
- **Don’t steer or support like a 0.014” wire**
- **Directs flow toward side branches**
- **Can’t protect lesions in distal vessel**

Filter Based Distal Protection



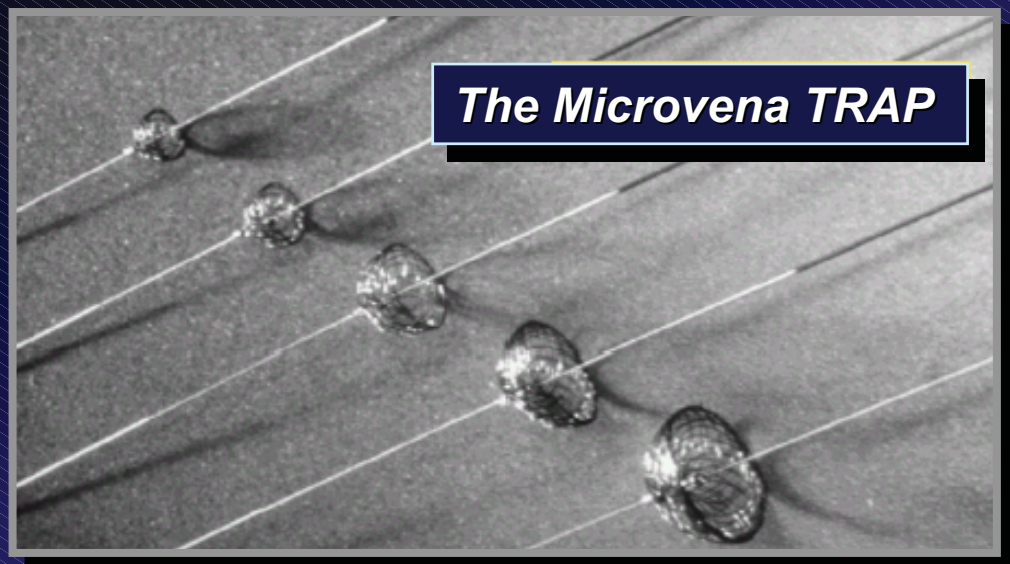


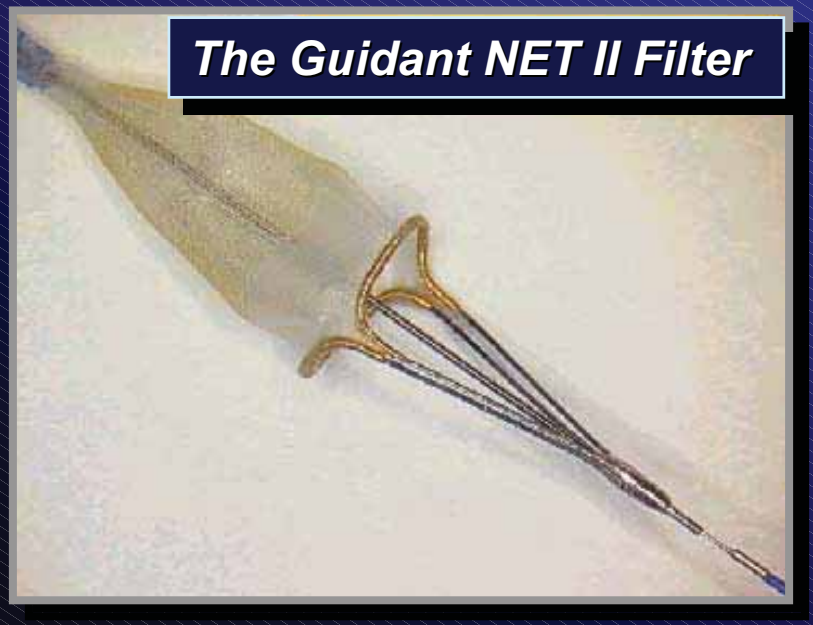


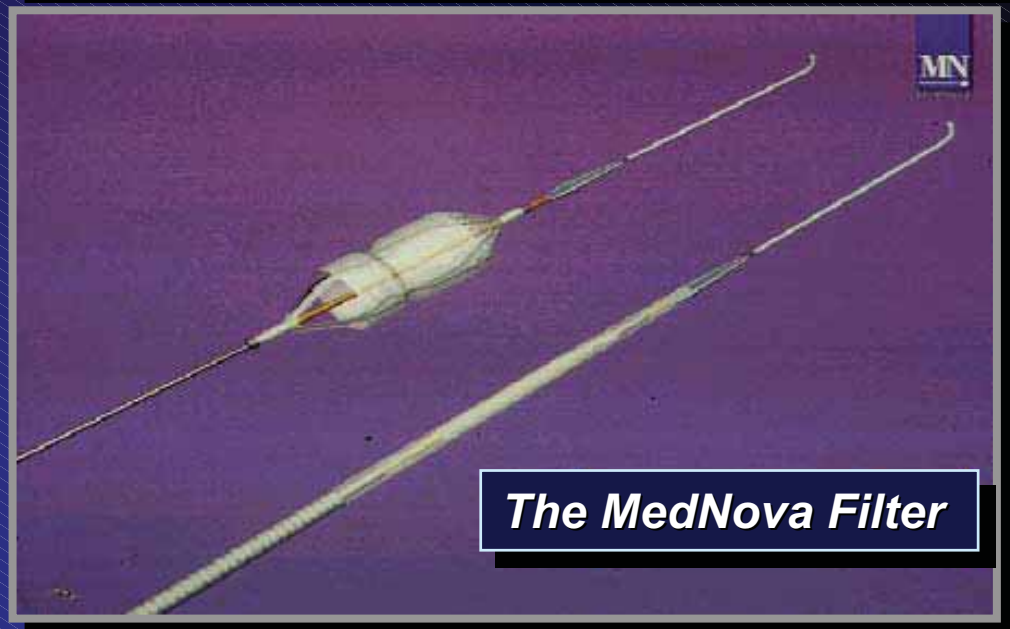


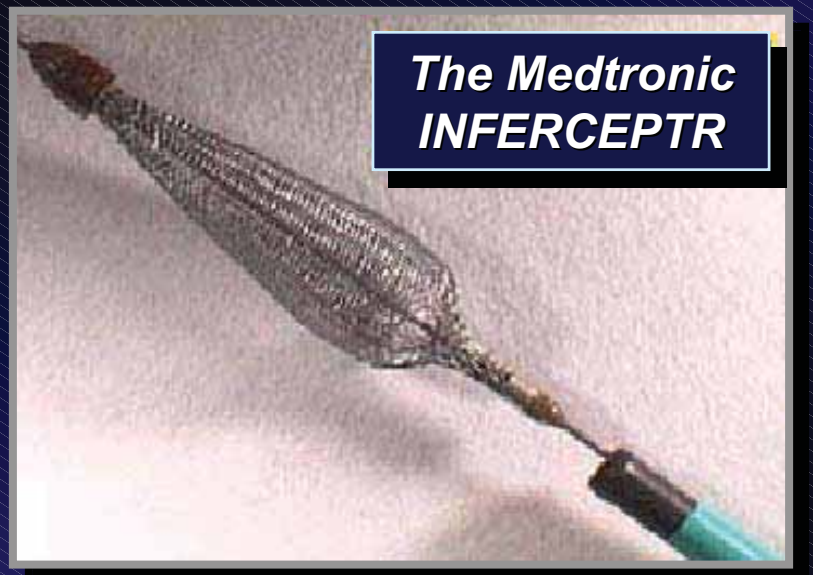
Filter Based Distal Protection

Filter Based Distal Protection



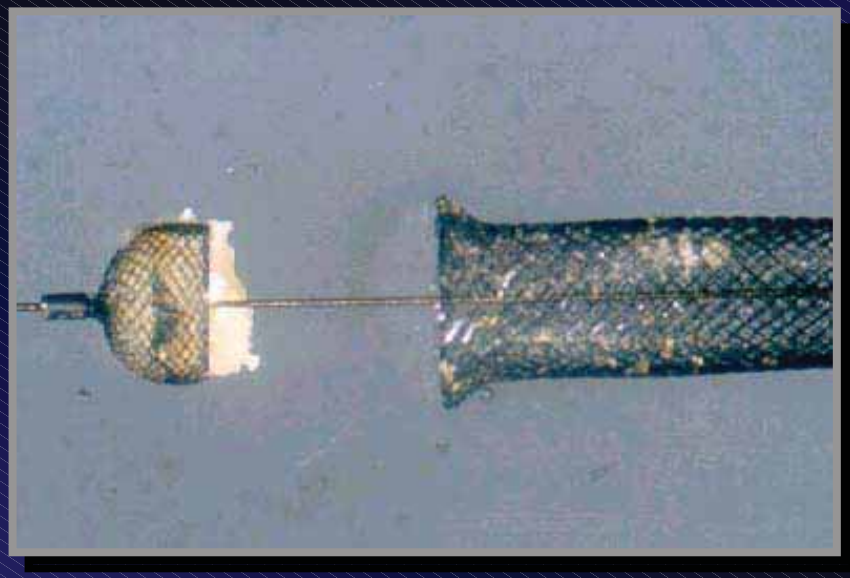


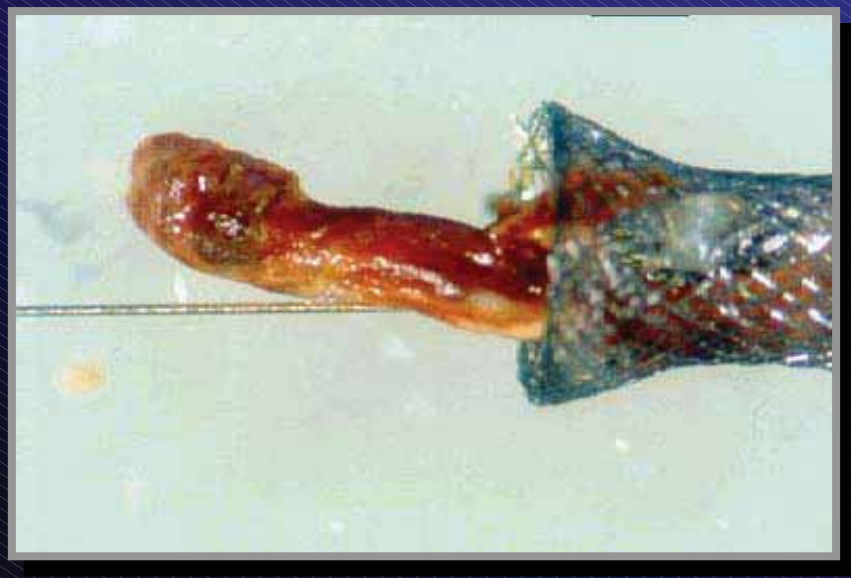


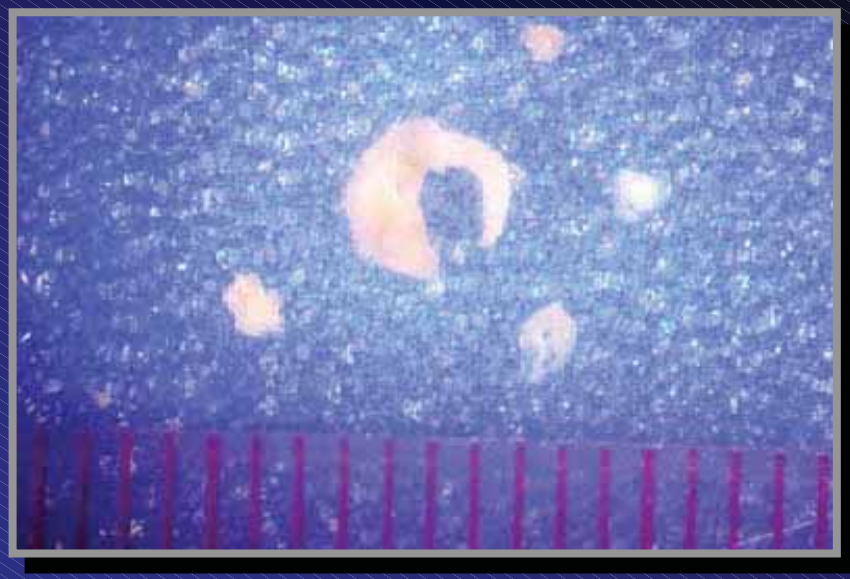


Extraction Using Filter Wire

Extraction Using Trap Device

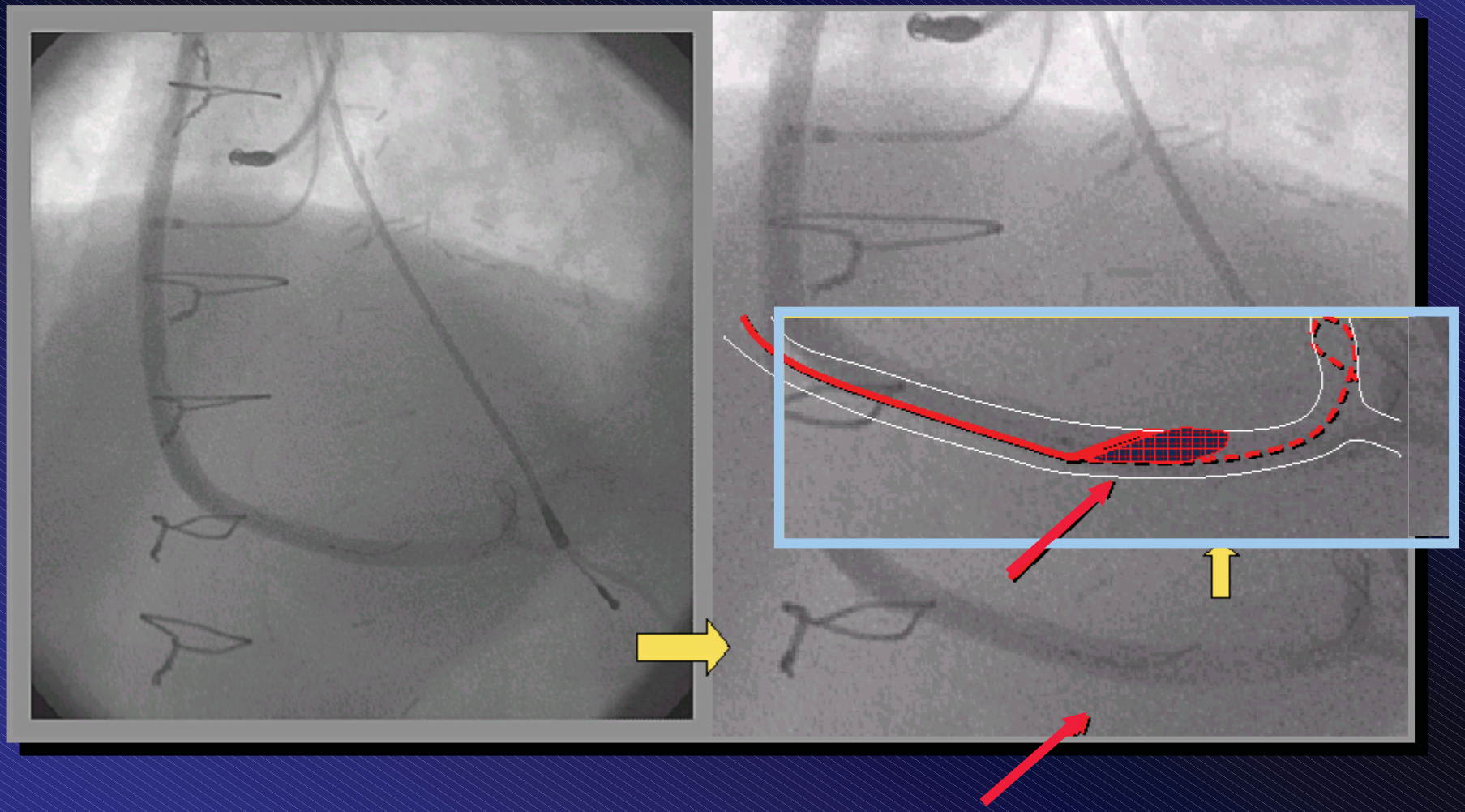






Problems of FilterWire

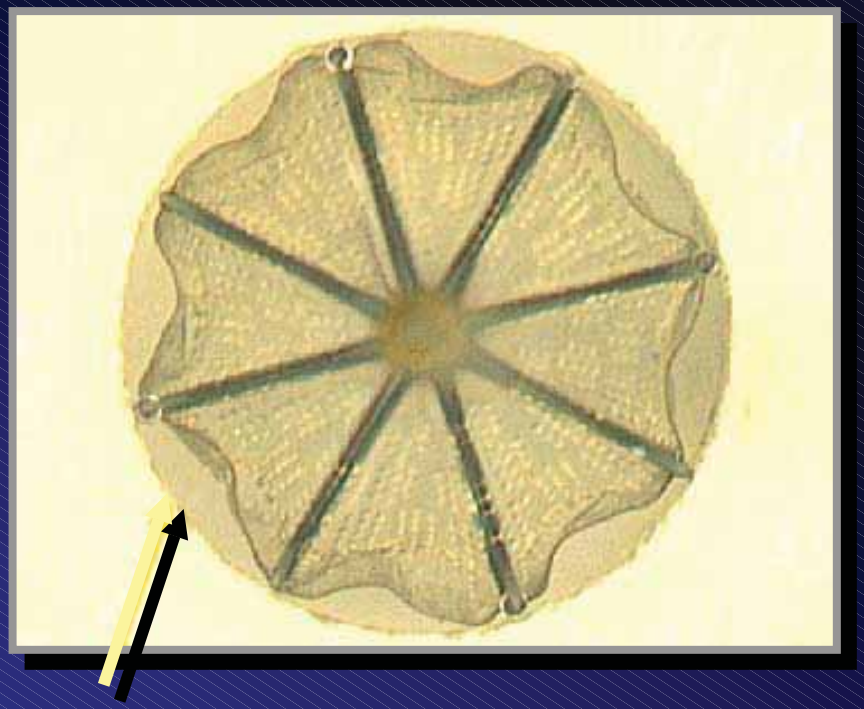
Poor Apposition



Problems of FilterWire

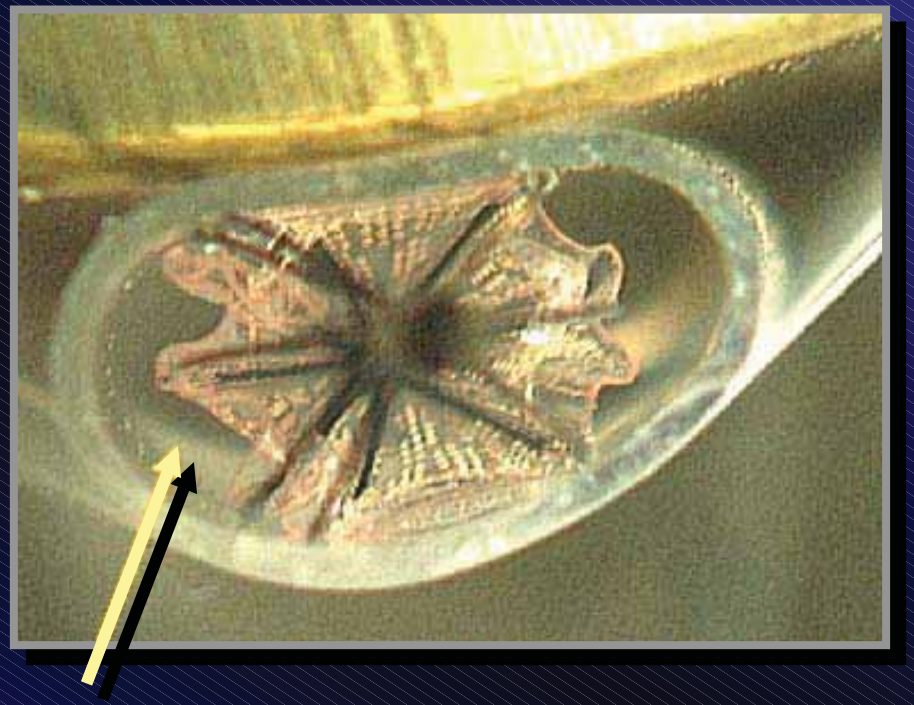
Lack of Apposition

6.0 mm Angioguard
in 5.5 mm round tube



Lack of circumferential wall apposition between struts

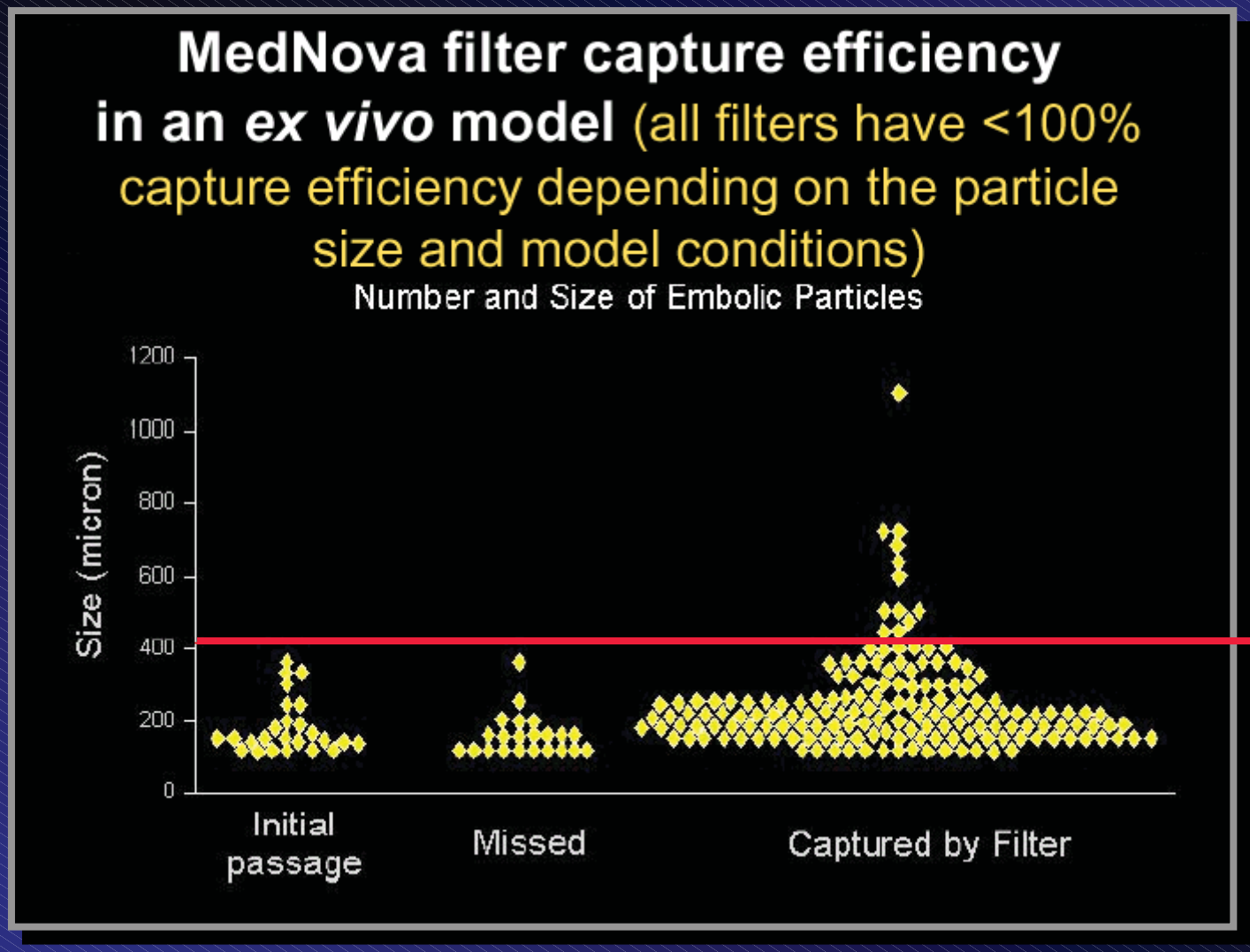
6.0 mm Angioguard in a
5.0 mm asymmetrical tube



The asymmetrical shape causes struts to pull farther away from wall

Problems of FilterWire

Capture Efficacy



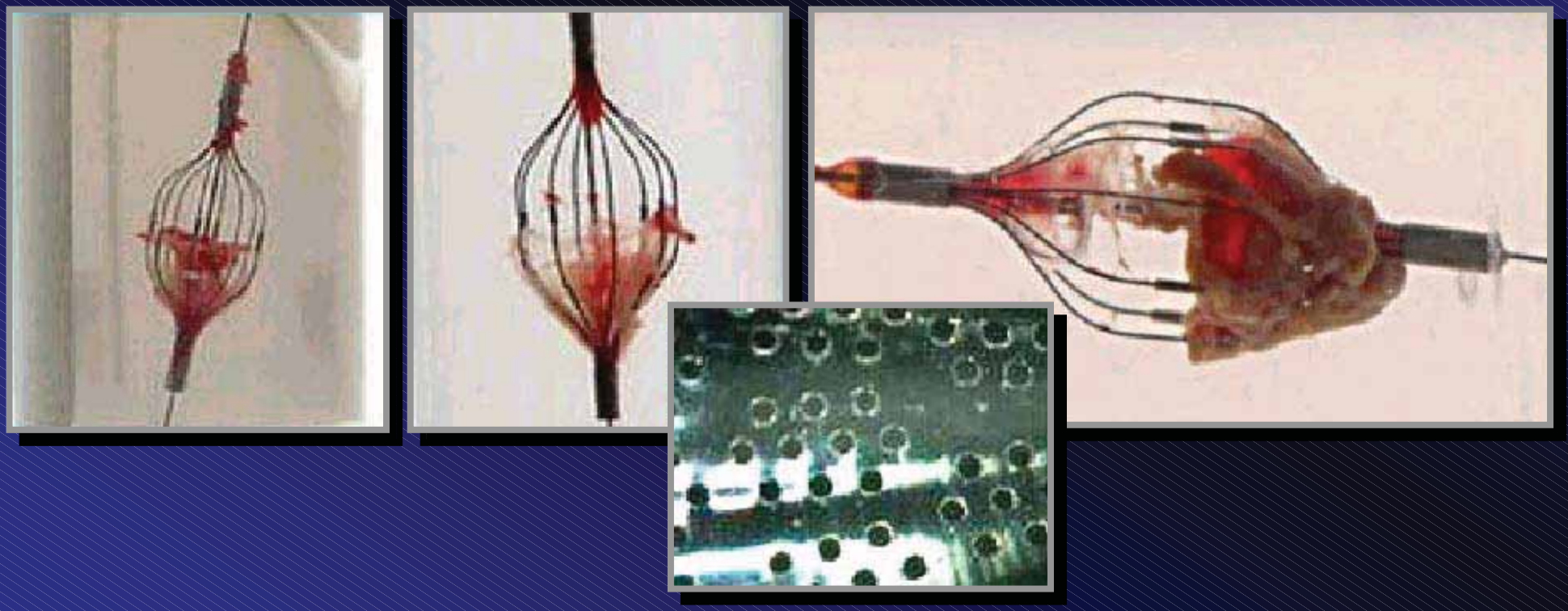
Ohki T et al. J Vasc Surg 1999;30:1034-44

Problems of FilterWire

Extruded Debris

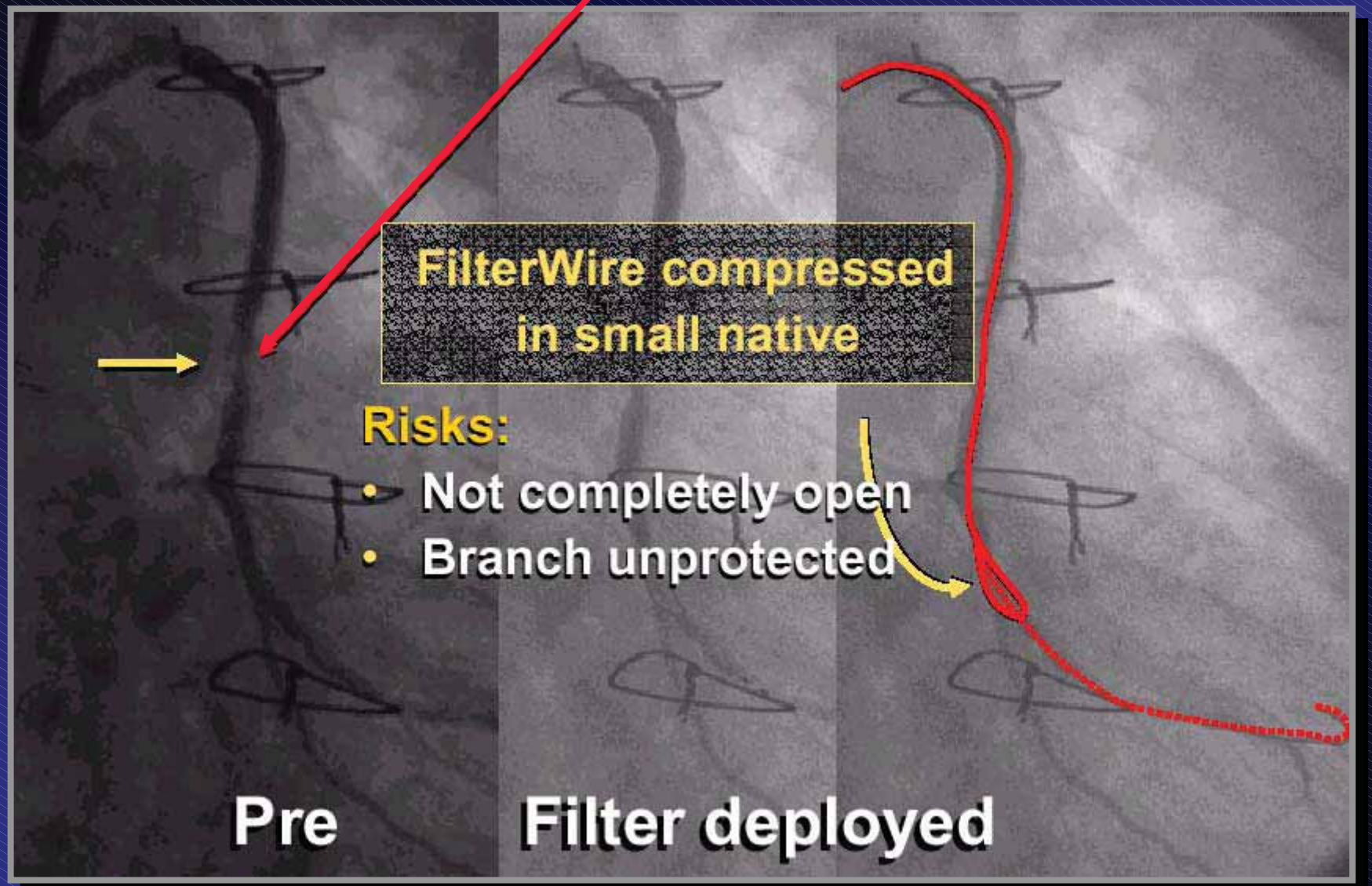
Cordis AngioGuard Cases

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



Problems of FilterWire

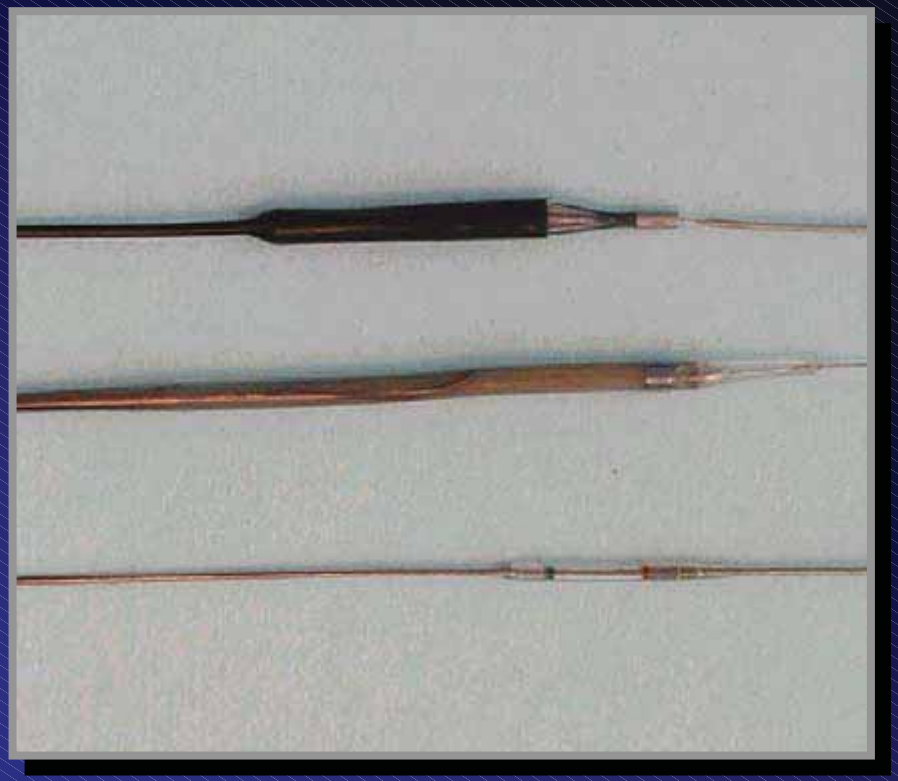
Too Distal Lesion



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

Medtronic AVE

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

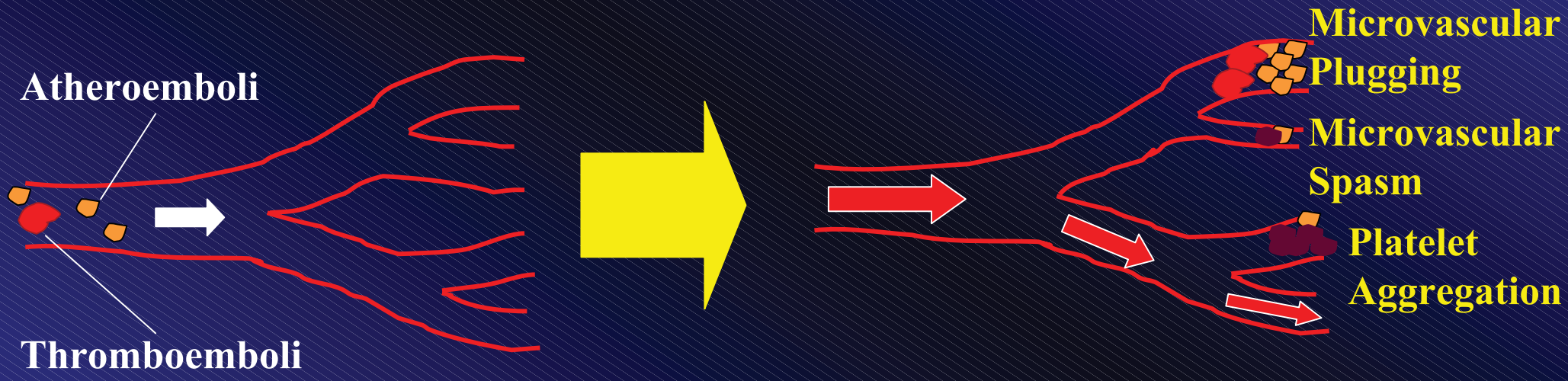
Definition

Microembolization occurs when particles from atherosclerotic lesions or other sources pass into the distal capillary beds possibly causing microvascular obstruction.

Microembolism

Microvascular Obstruction

Hori M, et.al. *Am J Physiol* 1986; 250:H509-18.



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

Microembolization

Pharmacotherapy

Red Thrombus → **Fibrinolysis**

Platelet Aggregation (White Thrombus) → **GP IIb/IIIa Antagonists**

Fibrinolysis + **GP IIb/IIIa Antagonists** = **Combination Therapy**

Microvascular Spasm → **Calcium Channel Blockers, Nipride, Adenosine**

Atheroemboli → **???**

There is an atheroma component to embolization that cannot be managed with pharmocologic agents.

Adjunctive distal protection will likely prove beneficial.

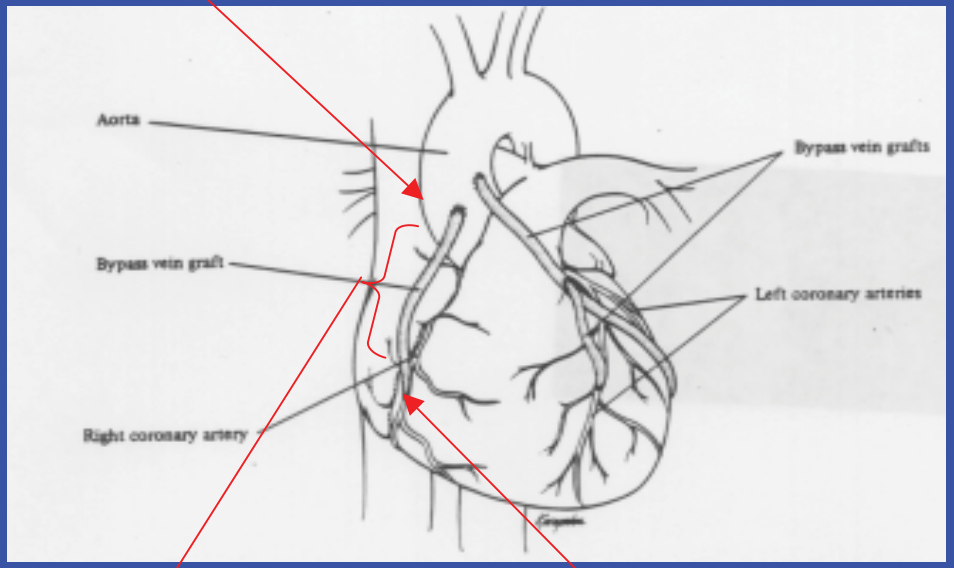
Microembolization

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

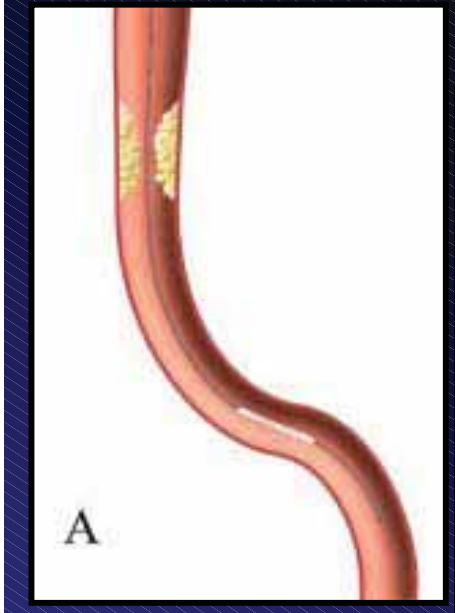
- The average longevity of an SVG graft is 8-10 years
  - 40% occlude and 75% develop severe narrowing

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

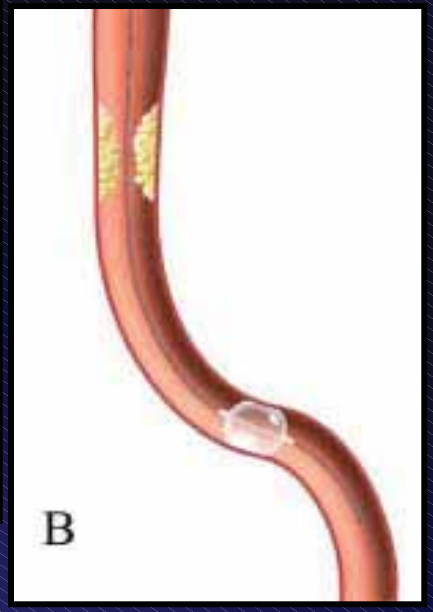
- SVG adverse events:
  - AHA - November 1998. Kalon Ho, MD
  - 415 stented SVGs at Beth Israel and Washington Hospital Center
  - 17.8% MACE: Q-MI, non-Q MI, Death, E-CABG
  - CKMB >3x normal: 30 day mortality increase from 0.9% to 14%

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



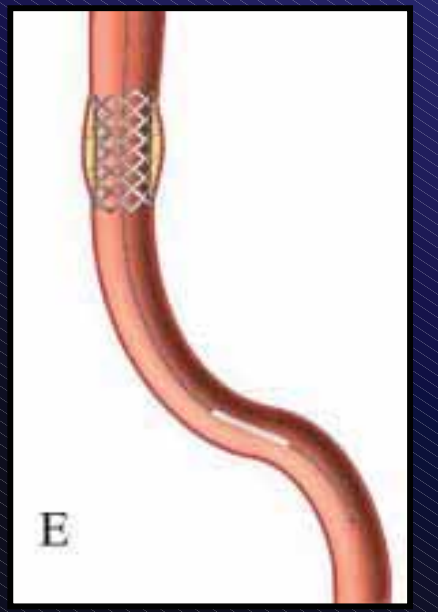
A. Cross the lesion with the GuardWire Plus.



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.

SVG Clinical Data

- **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…..

SVG Clinical Data

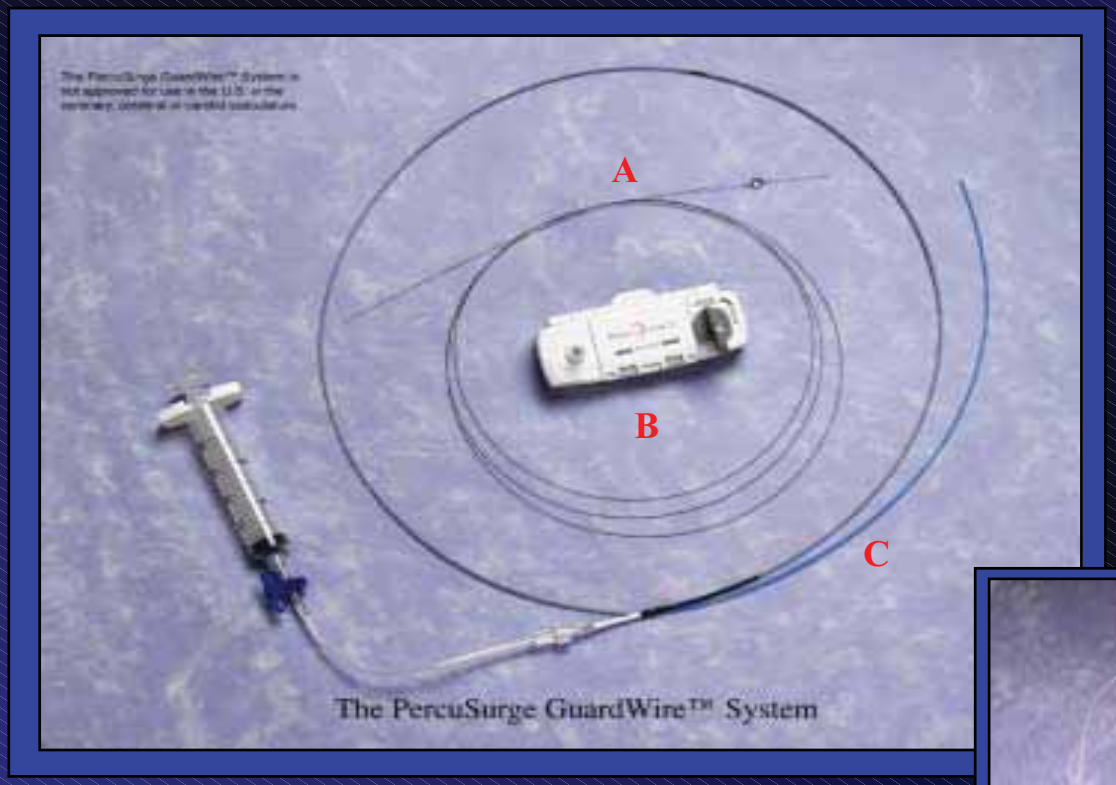
- **SAFE – European Multi-Center Study**
  Saphenous Vein Graft Angioplasty Free of Emboli
  - **103 patients, 8 sites, non-randomized**
  - **MACE = 4.9% vs. 17.8% (historical control)**
  - **73% reduction in adverse events (death, MI, CABG, repeat revascularization)**

The SAFE data provided the framework for a large multicenter, randomized trial in the US called SAFER…

SVG Clinical Data

- **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



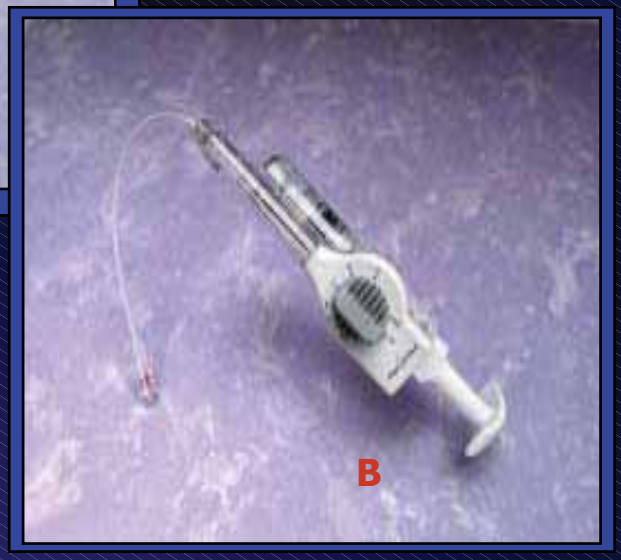
System Components

A. The GuardWire Plus Temporary Occlusion Balloon

B. The MicroSeal® Adapter and EZ Flator™

Inflation/ Deflation System

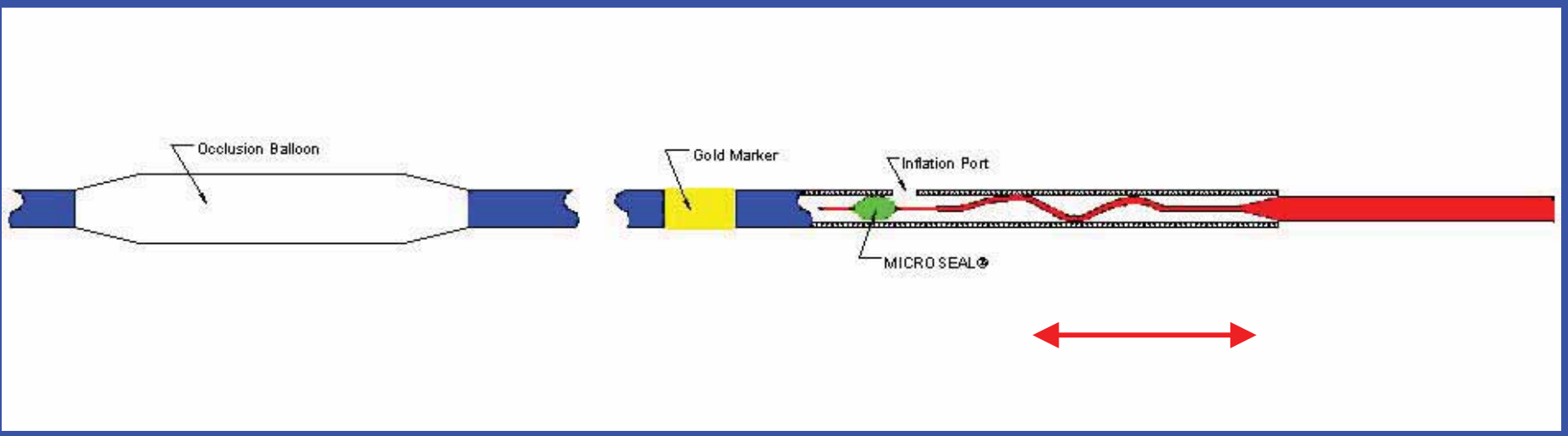
C. The Export Aspiration Catheter



The Distal Occlusion Balloon Concept

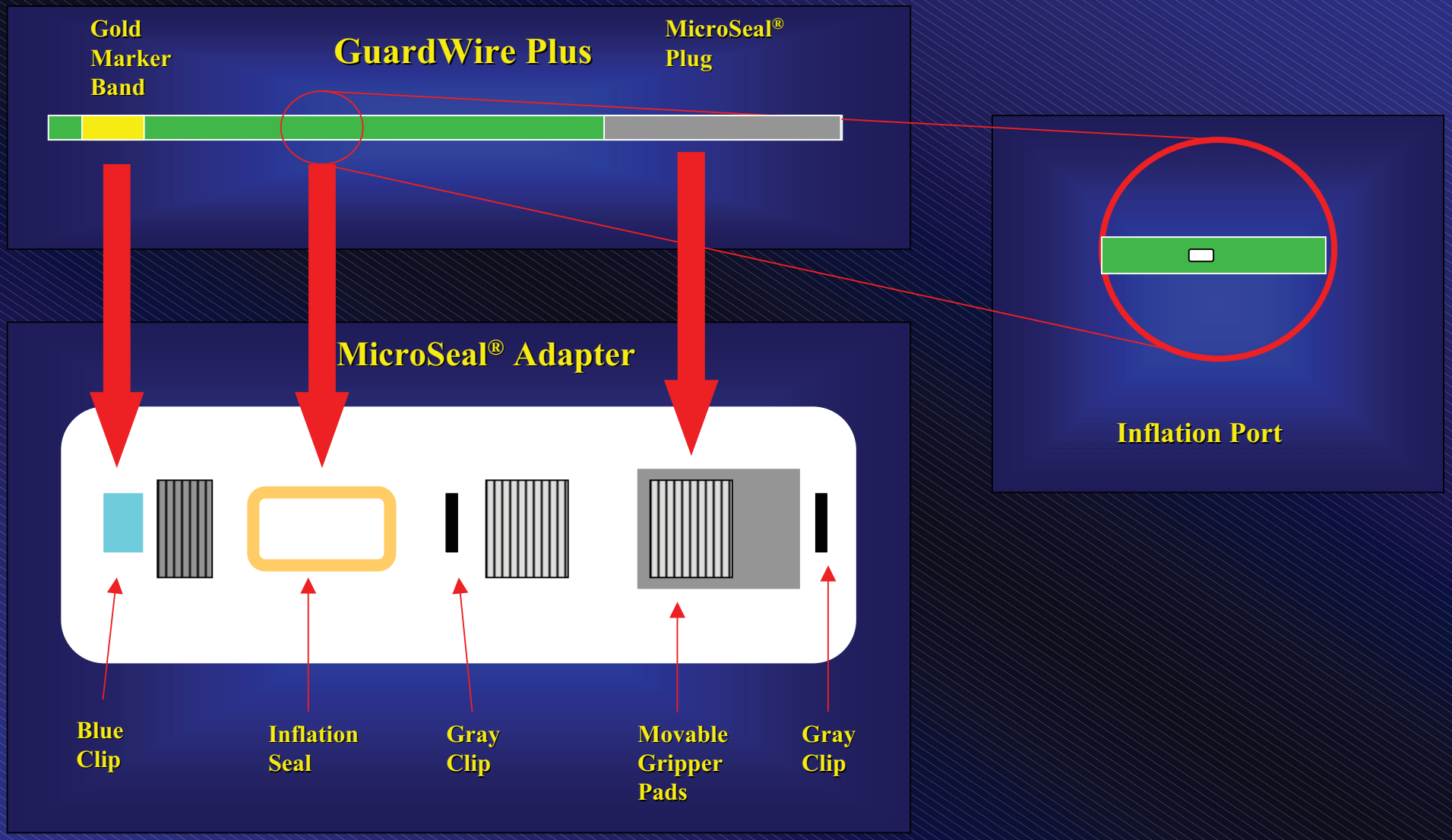
- **Dual Role of the GuardWire**
  - Primary PTCA wire
  - Temporary occlusion balloon for distal protection
- **Unique Requirement**
  - Inflate distal occlusion balloon
  - Remove the inflation device
  - Balloon must remain inflated
- **Design elements that permits the device to function this way**
  - MicroSeal plug seals & unseals the inflation lumen
  - The MicroSeal Adapter simply opens & closes the MicroSeal plug

MicroSeal® Technology



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.

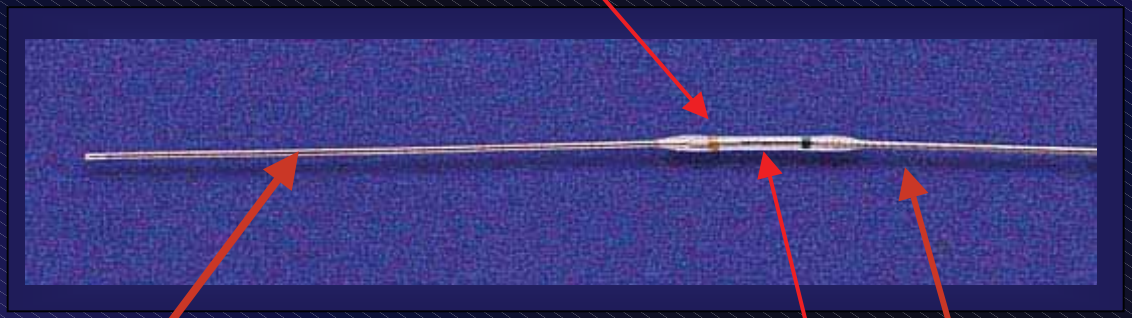
The MicroSeal® Adapter



The GuardWire Plus

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

Lengths: 200 & 300 cm



2.5 cm shapeable tip

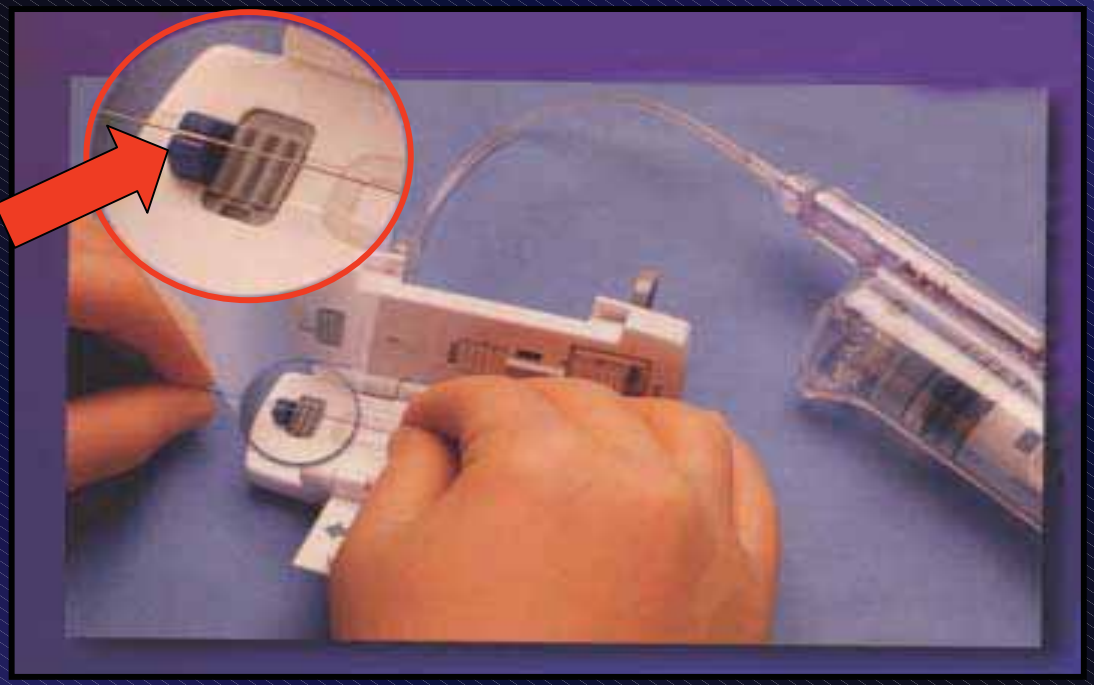
Occlusion Balloon:
- **3.0-6.0 occlusion diameter range**
- **Proximal balloon marker**

The Export® Aspiration Catheter

Length: 145 cm
Design: Rapid Exchange
- **35cm GW exit**

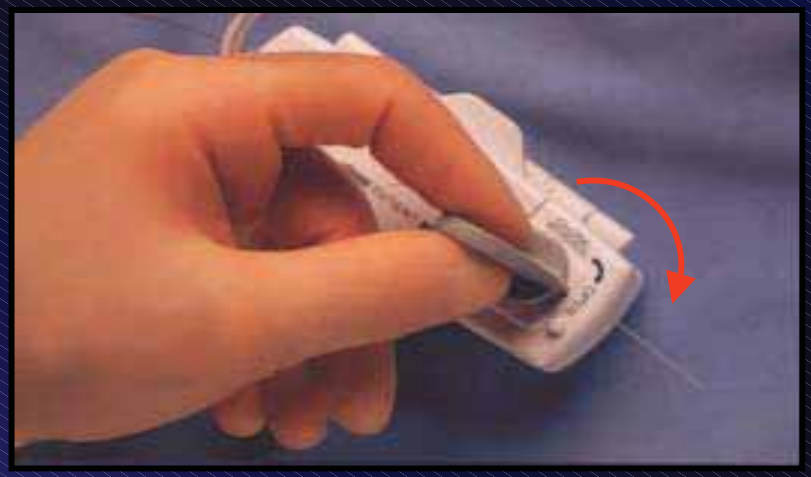
Aspiration Lumen: 1mm

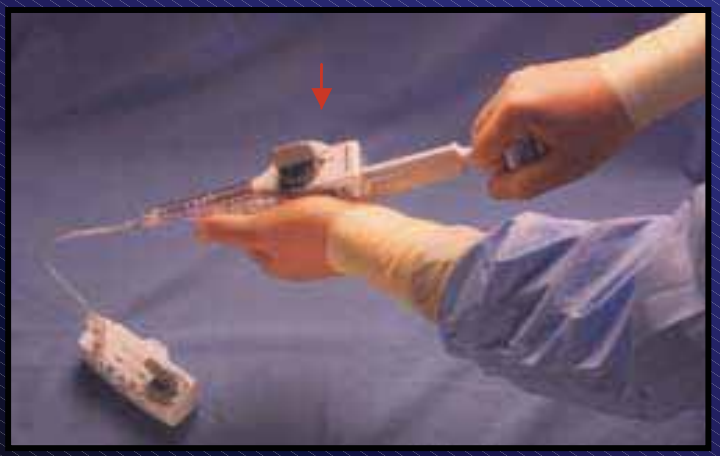
Prepping the GuardWire Plus



- 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





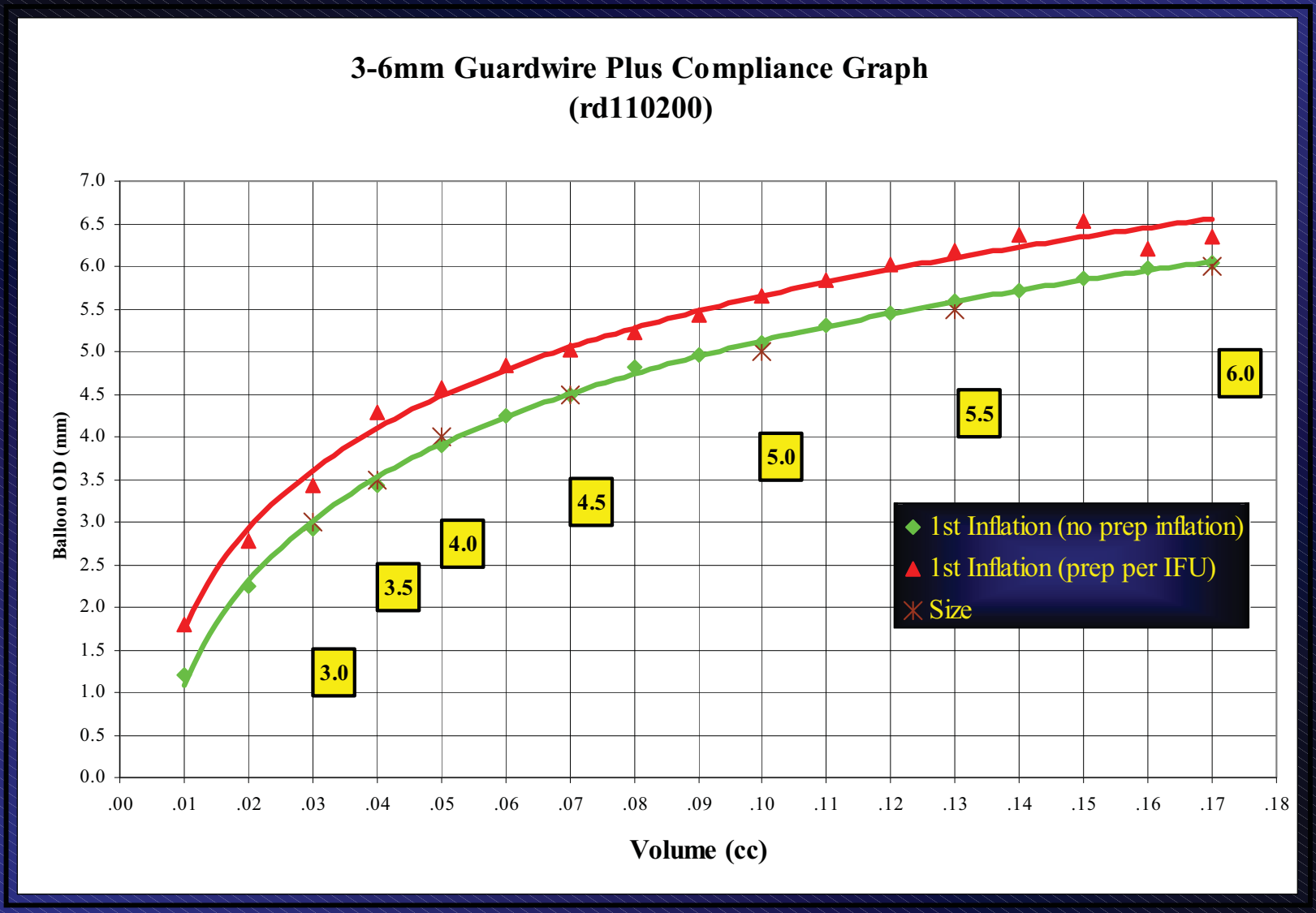
- Turn the gray knob on the Adapter to ‘OPEN’
- Pull negative with EZ Flator x 30 seconds
- Return the handle to ambient (neutral position)

Prepping the GuardWire Plus

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

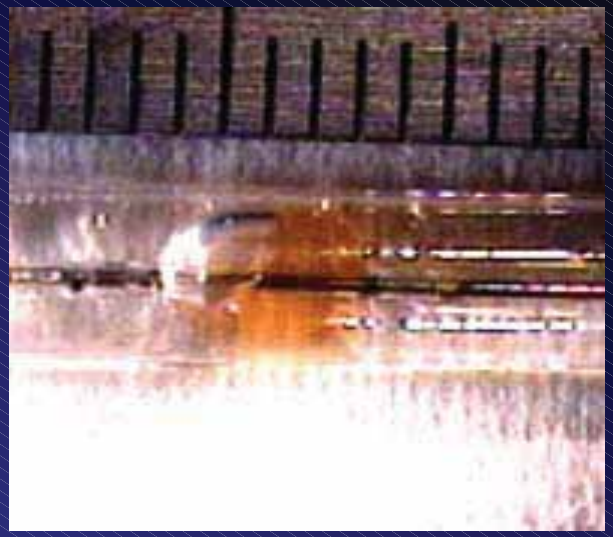
*Note that the balloon will NOT reach its stated size
on this test inflation, but WILL upon second inflation

The GuardWire Plus

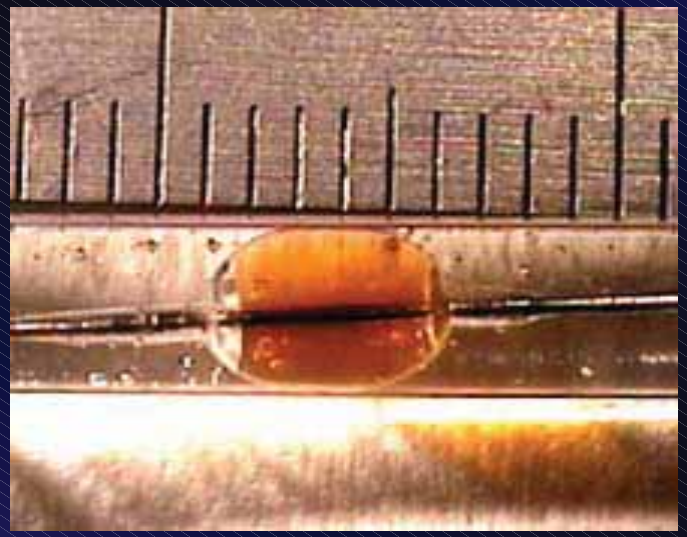


The GuardWire Plus

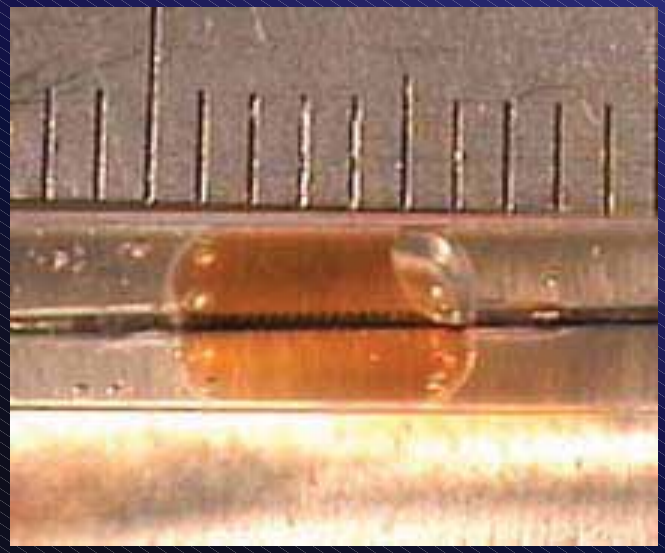
Inflation in a 3.0mm glass tube



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

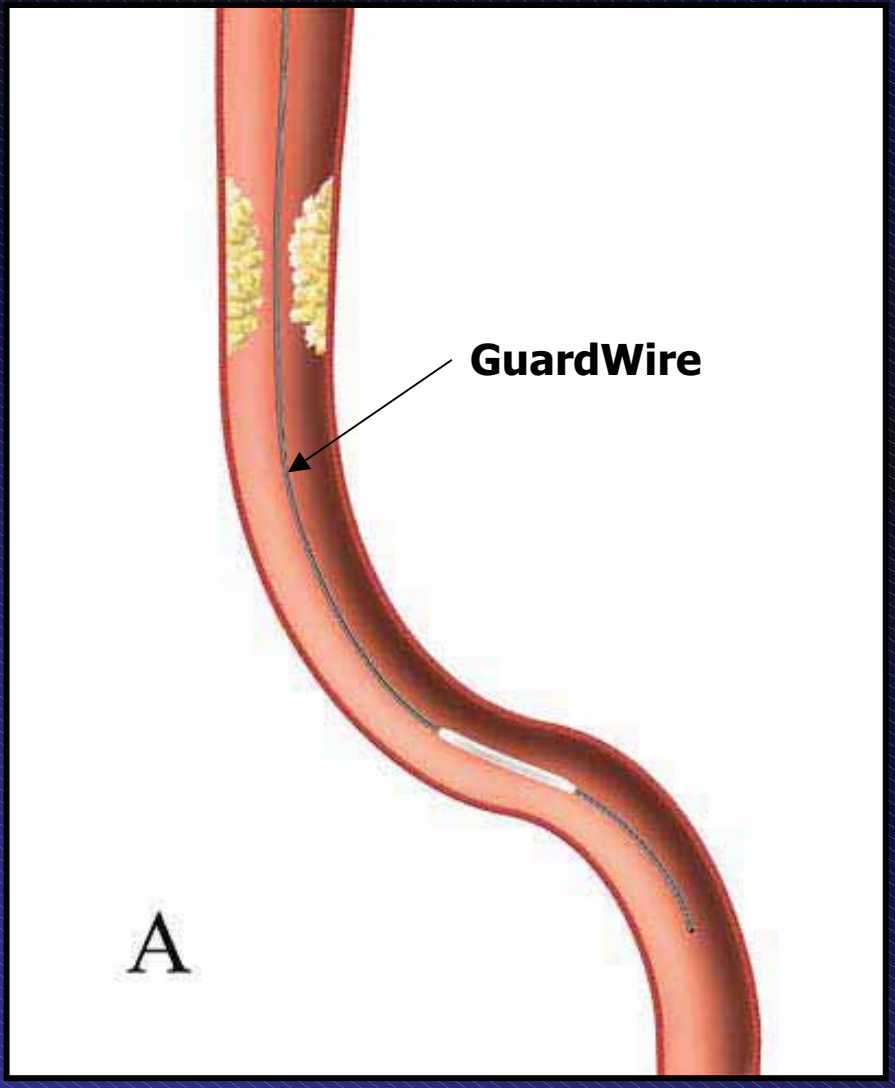
- Turn the gray knob to ‘CLOSE MICROSEAL’
  - This pushes the MicroSeal plug back into the hypotube, sealing the inflation/deflation lumen closed
- Unlatch and open the Adapter - remove the wire from the blue clip first
- Prep is complete

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

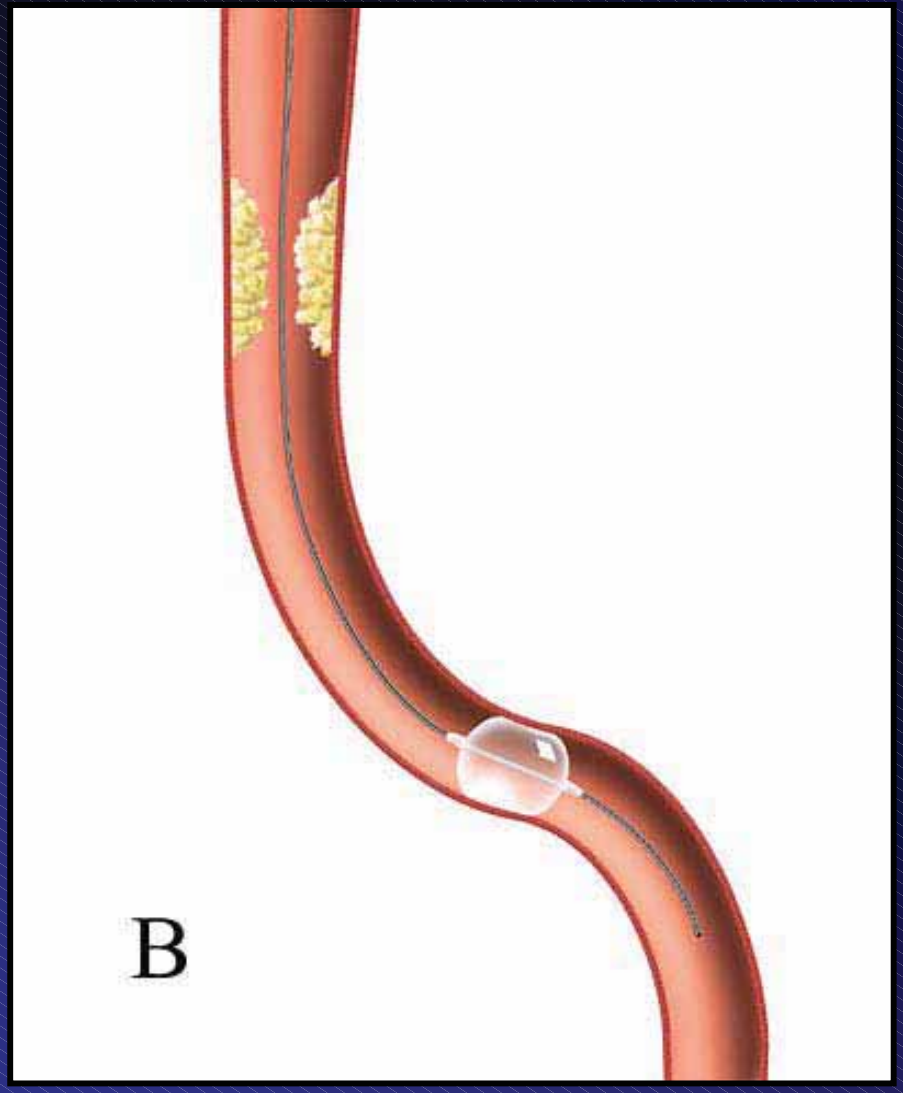
Distal Protection Procedure

Crossing the Lesion



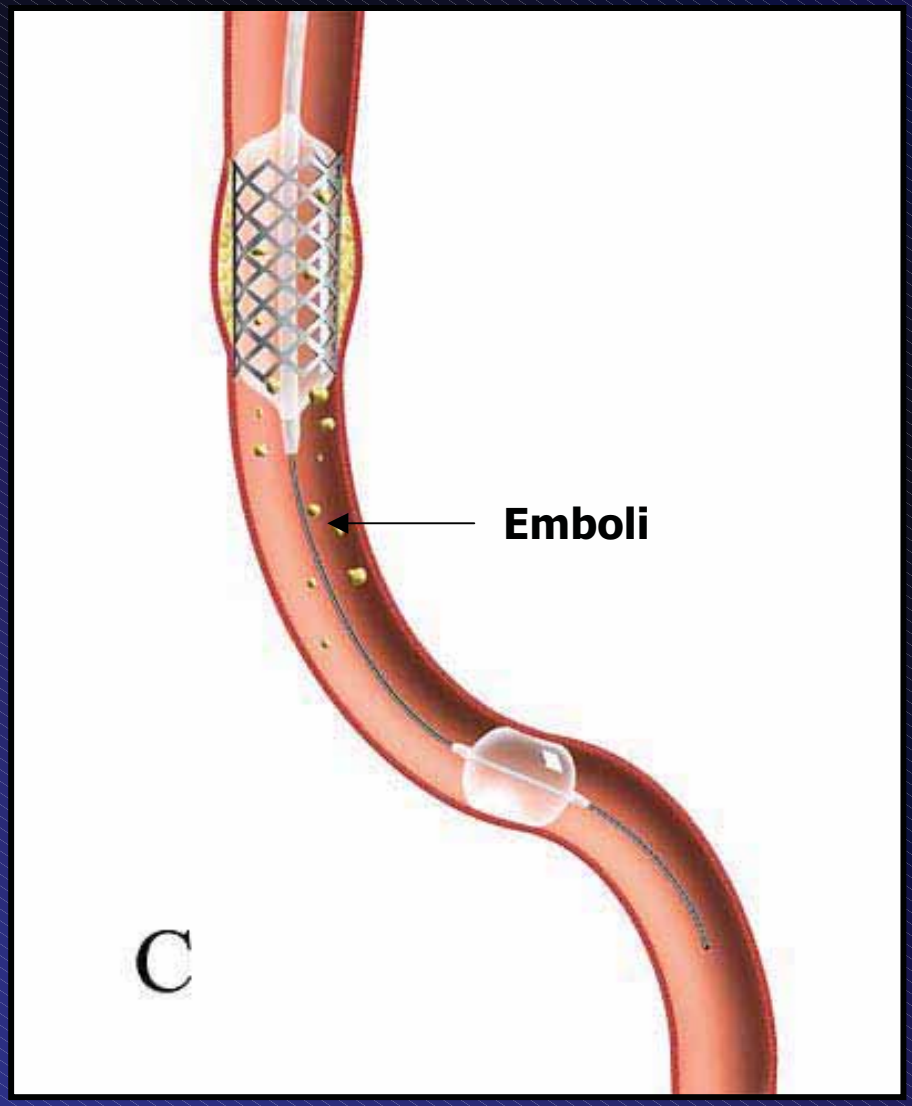
- Cross lesion with GuardWire Plus
- Position distal occlusion balloon proximal to anastomosis
- Advance stent/balloon to tip of guide
- Insert proximal wire into Adapter

Occluding the Vessel



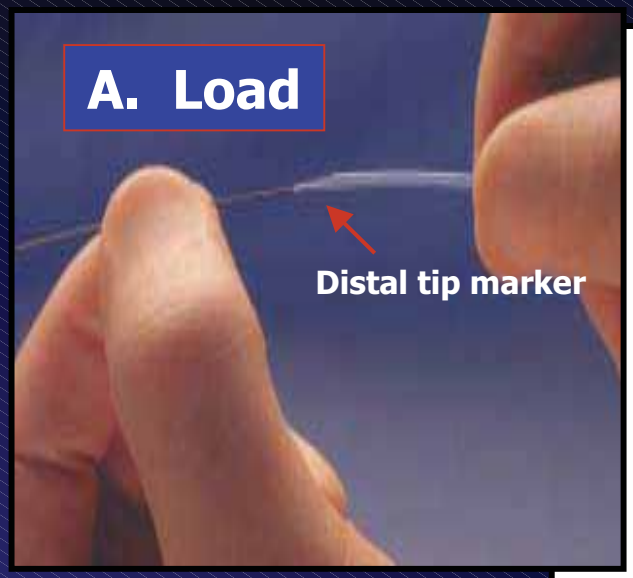
- Inflate distal occlusion balloon until vessel is occluded (may require 0.5mm greater than reference)
- Confirm occlusion

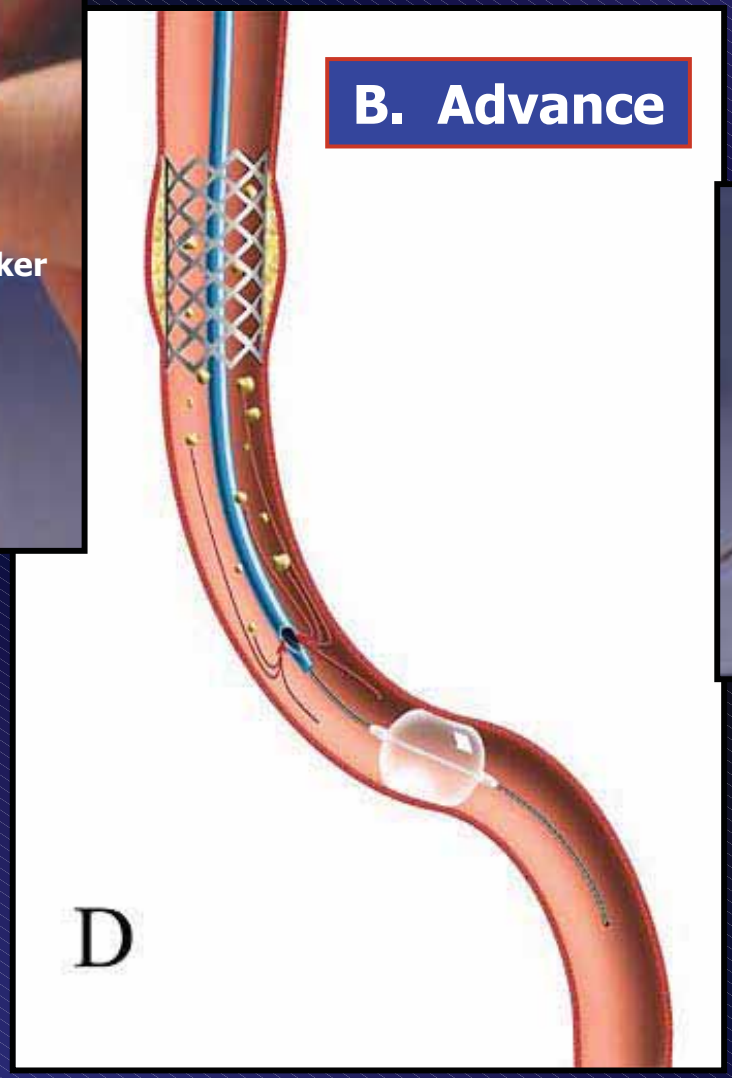
Treating the Lesion



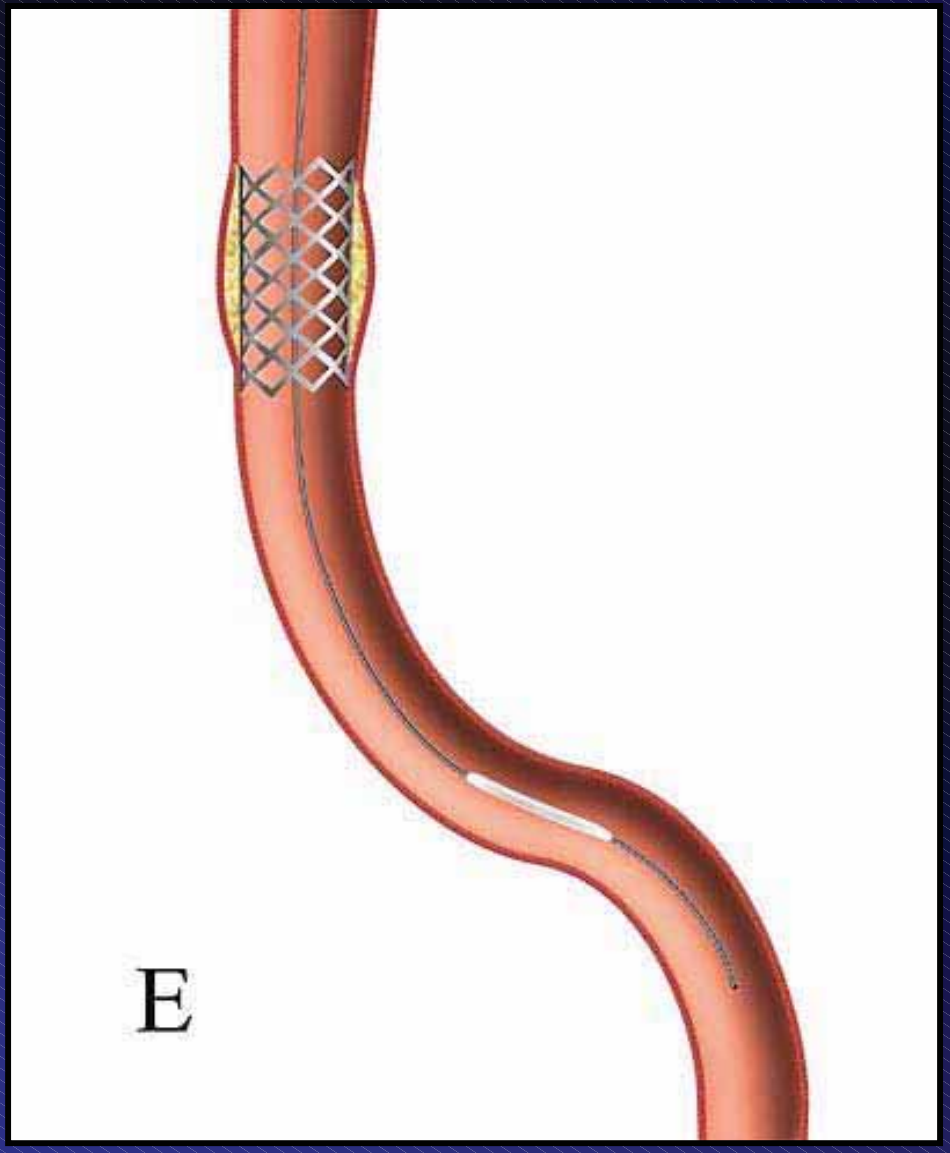
- Close the MicroSeal plug
- Unlatch the Adapter and remove the wire
- Advance the interventional catheter and treat the lesion

Aspirating Particulate Debris





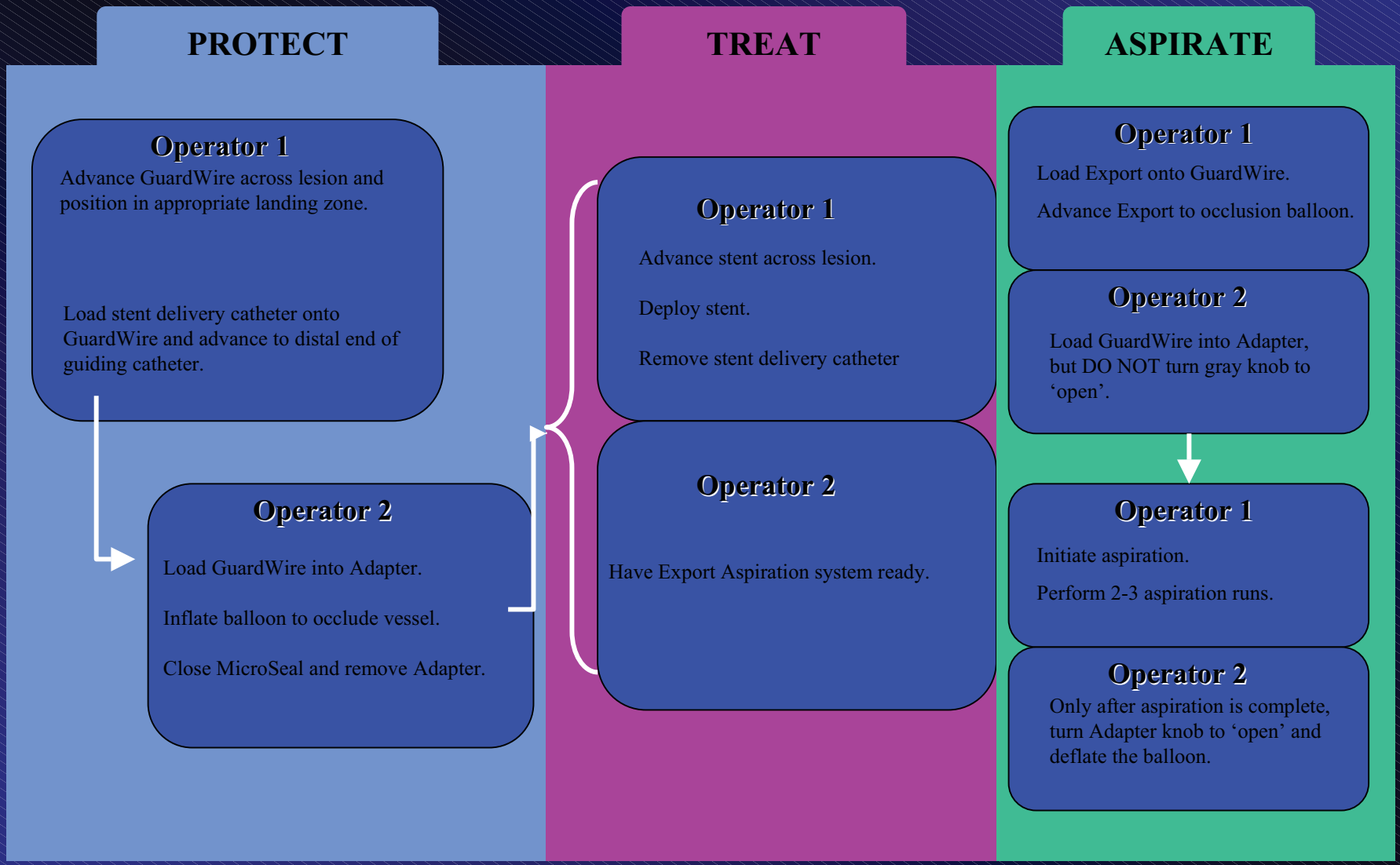
Deflating the Balloon



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



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.

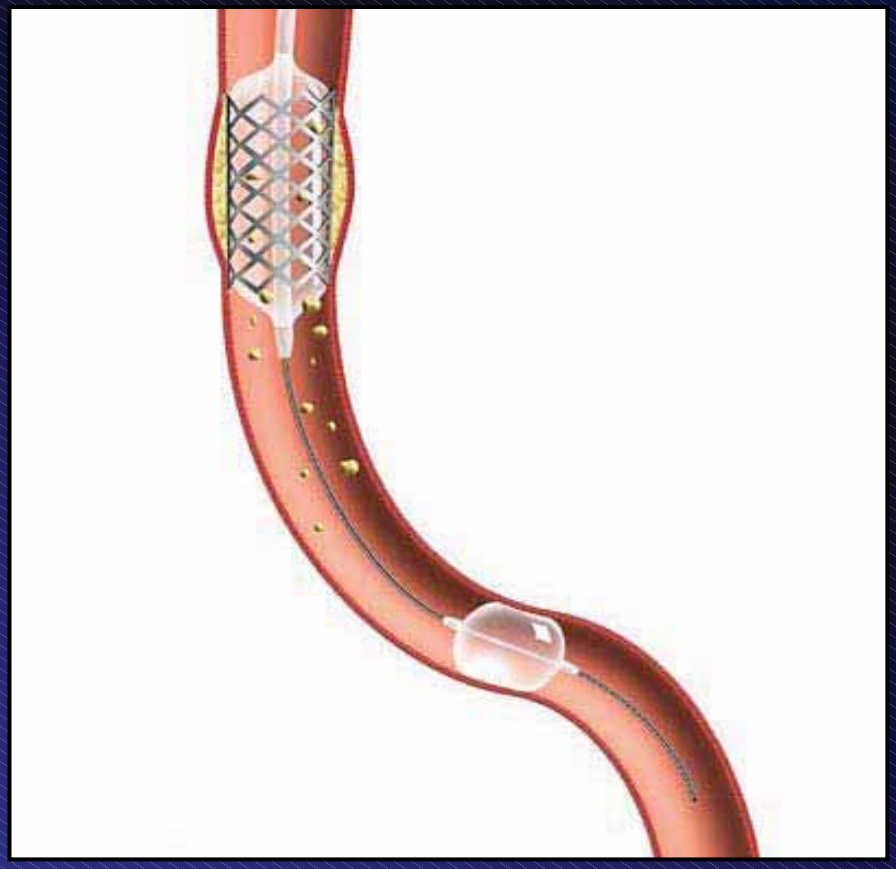
- Consider selecting a stent length that will comfortably and completely cover the entire lesion length – slightly longer stents will facilitate stent positioning.

Troubleshooting
Defining the Balloon Landing Zone

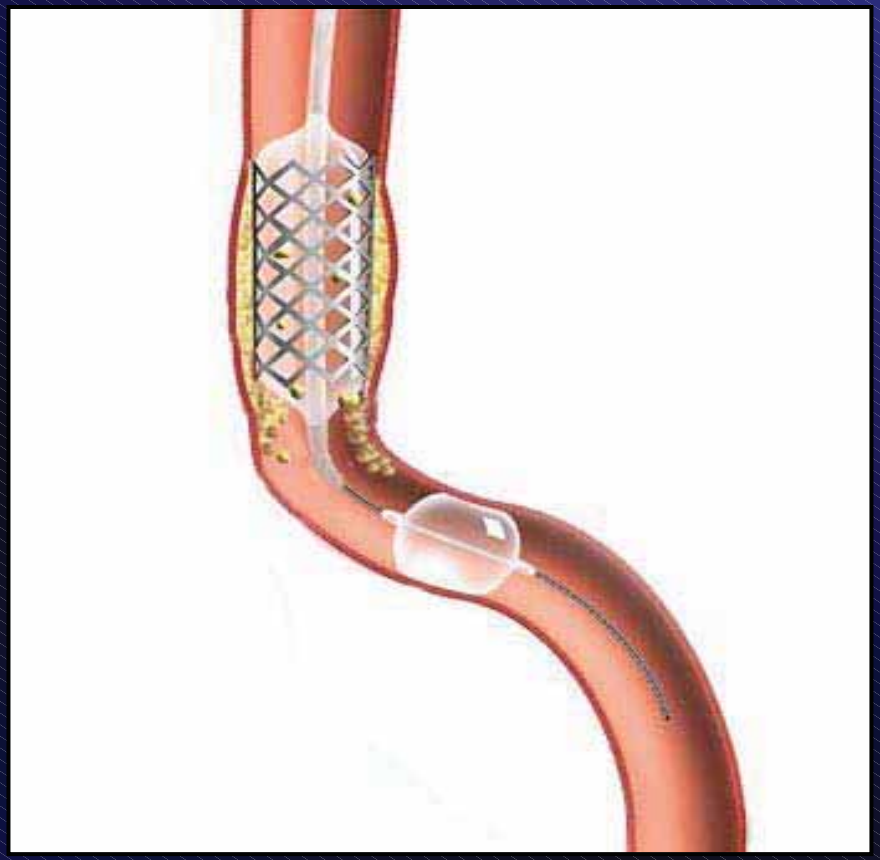
- **Inflate the GuardWire Plus balloon in an angiographically non-disease vessel segment.**
- **Position the GuardWire Plus marker band at least 3cm beyond the distal margin of the lesion.**
- **The inflated GuardWire Plus is NOT intended to act as an anchor in the vessel. Stabilize the wire by holding 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.

Troubleshooting
GuardWire Kinking

- 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.**