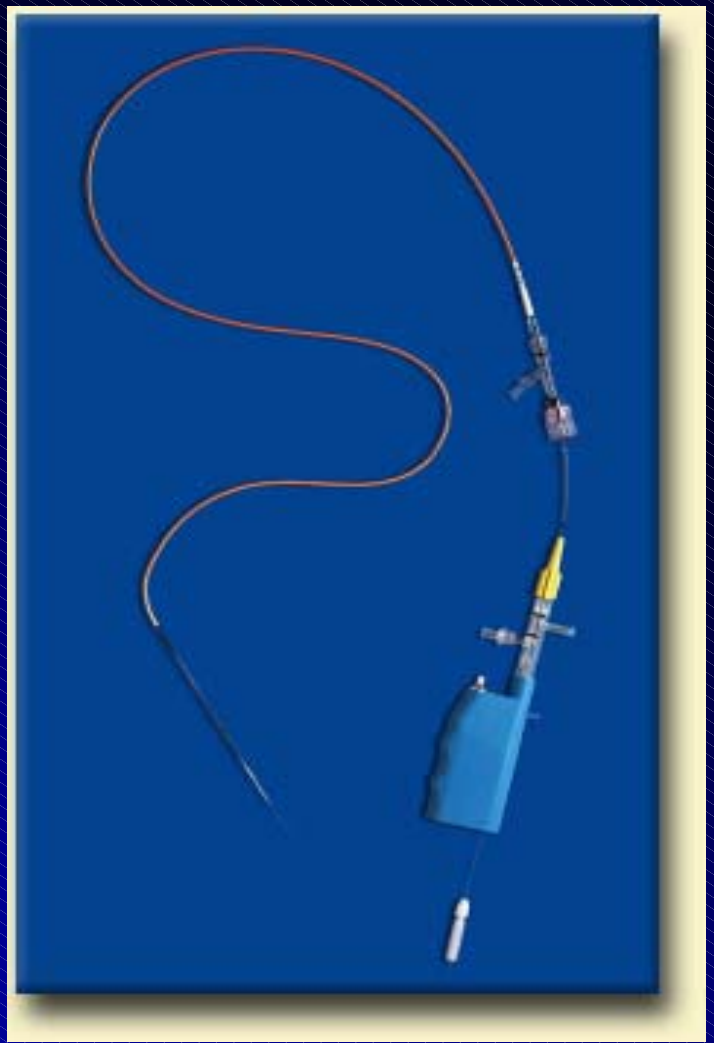
Equipment Overview of DCA Device

Provided from Guidant Company

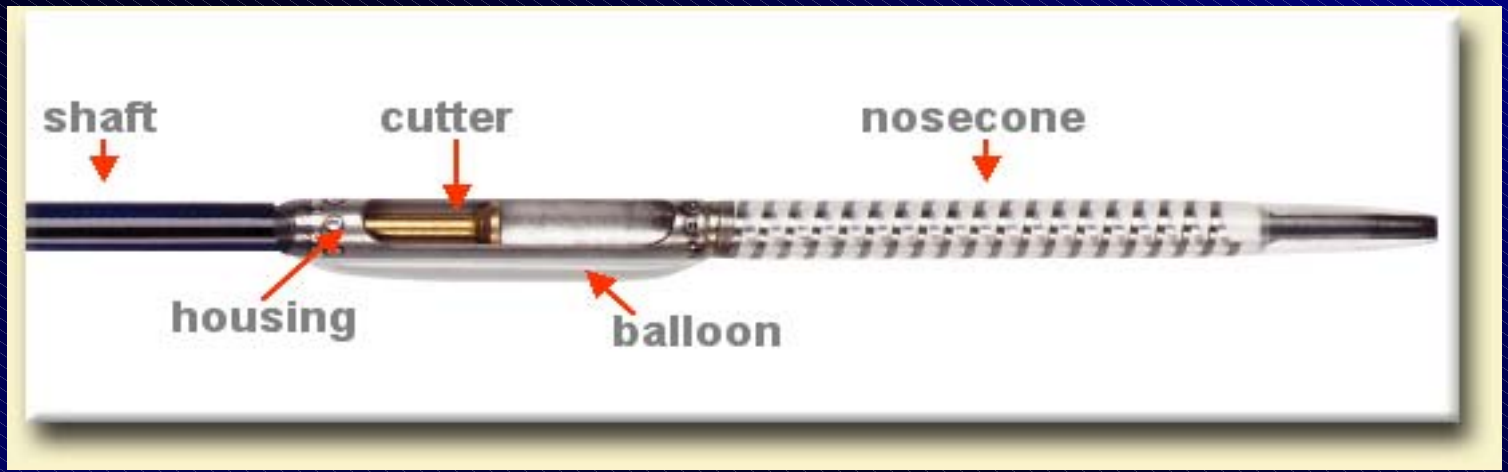
Required Equipment



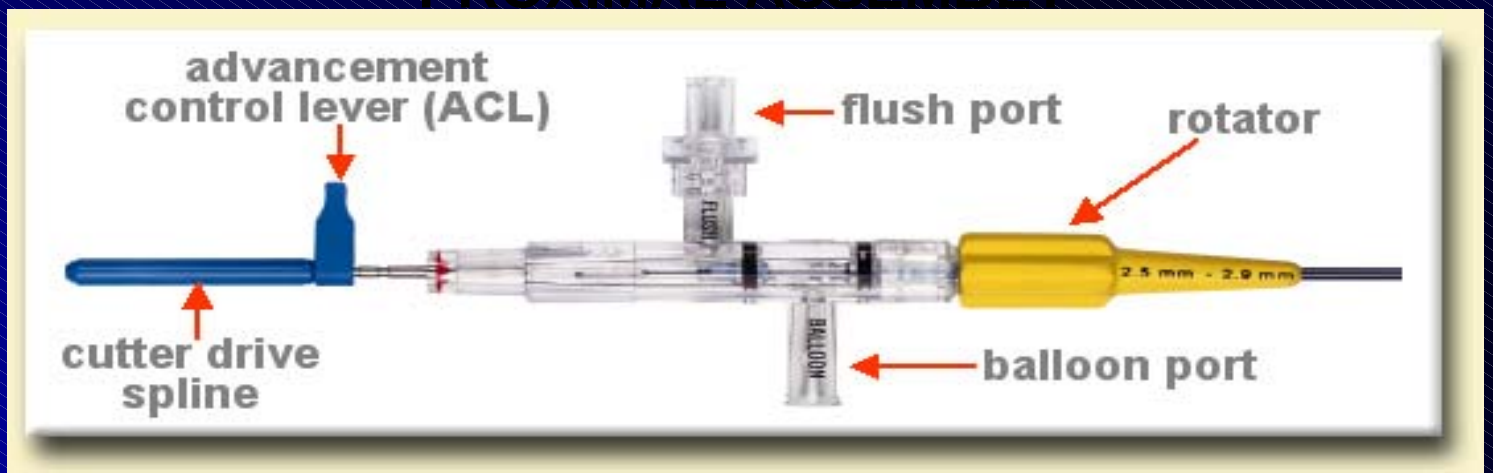
- DCA catheter
- Supportive guiding catheter
- Supportive guide wire
- Motor drive unit (MDU)
- Low pressure inflation device
- Rotating Hemostatic valve (RHV)
- Arterial introducing sheath
- Three-way stopcock
- Guide wire torque device
- Sterile saline solution
- Vials of radiopaque contrast medium
- Syringe (for removing atheroma from the nosecone)

DCA Catheter Overview

DISTAL ASSEMBLY



PROXIMAL ASSEMBLY



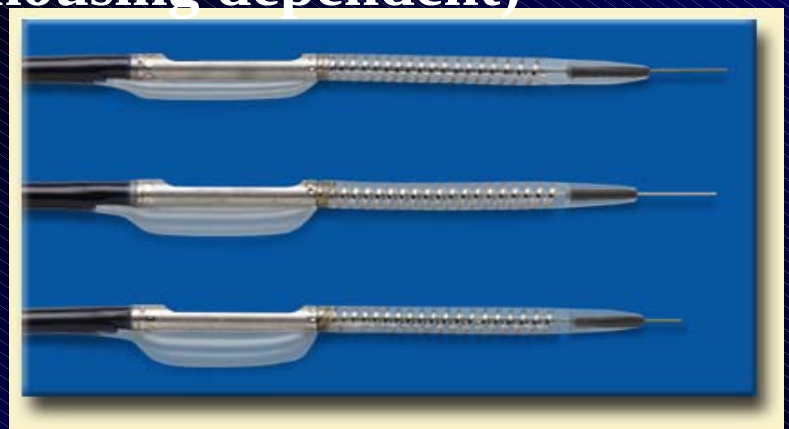
DCA Catheters

- **Four generations of DCA catheters:**
  - **1990 SCA™**
  - **1994 AtheroCath GTO™**
  - **1996 AtheroCath BANTAM™**

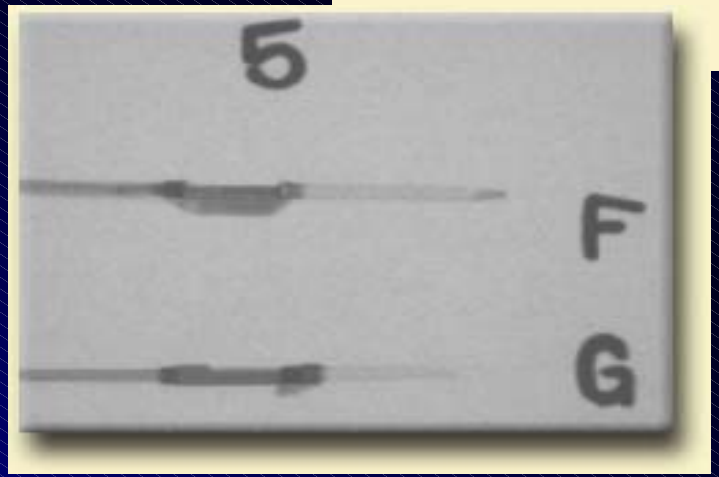
Design Overview

8F Guiding Catheter Compatible

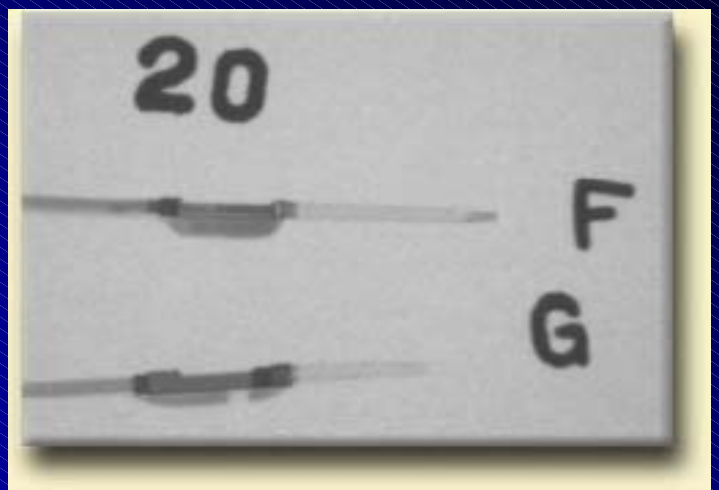
- **Design based on a 6F platform**
  - **.076" maximum diameter of housing and shaft**
  - **Balloon dependent sizing (vs. housing dependent)**
  - **Range of sizes available:**
    - **2.5 mm - 2.9 mm vessels**
    - **3.0 mm - 3.4 mm vessels**
    - **3.5 mm - 4.0 mm vessels**



Improved Balloon Design



5psi: FLEXI-CUT™ & GTO™



20psi: FLEXI-CUT™ & GTO™

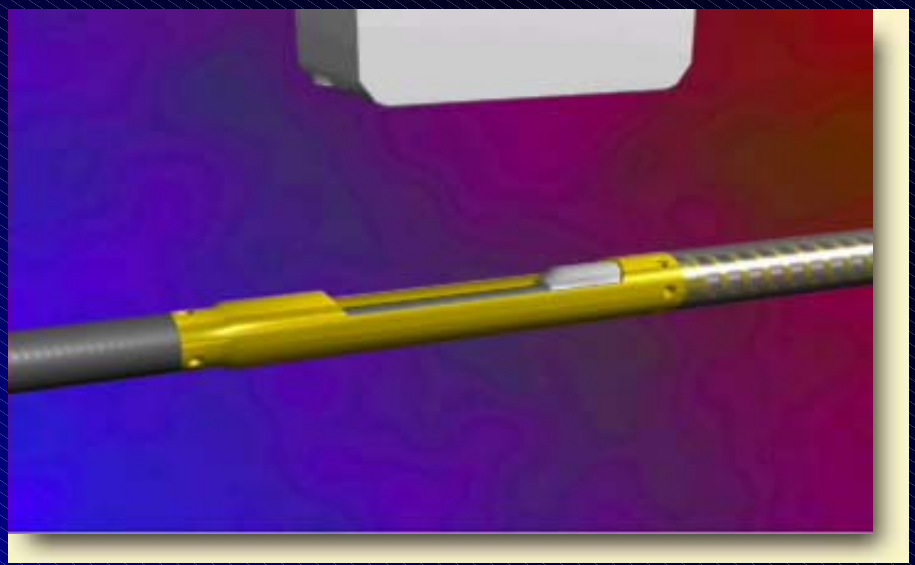
- **Custom-molded PEBAX® balloon**
- **Flat bottom design enhances housing stability within the vessel**
- **Simplified and complete balloon prep**
- **Enhanced visualization**

Improved Device Delivery

- 17% reduction in rigid length of housing
- 11% reduction in shaft diameter
- Variable stiffness, hydrocoat hydrophilic coated shaft
- New nosecone design
  - Lower-profile, 6F
  - Cylindrically shaped
  - Dam prevents material from extruding out of the nosecone
  - Capacity ≥ 7F GTO™

Improved Cutting Efficiency

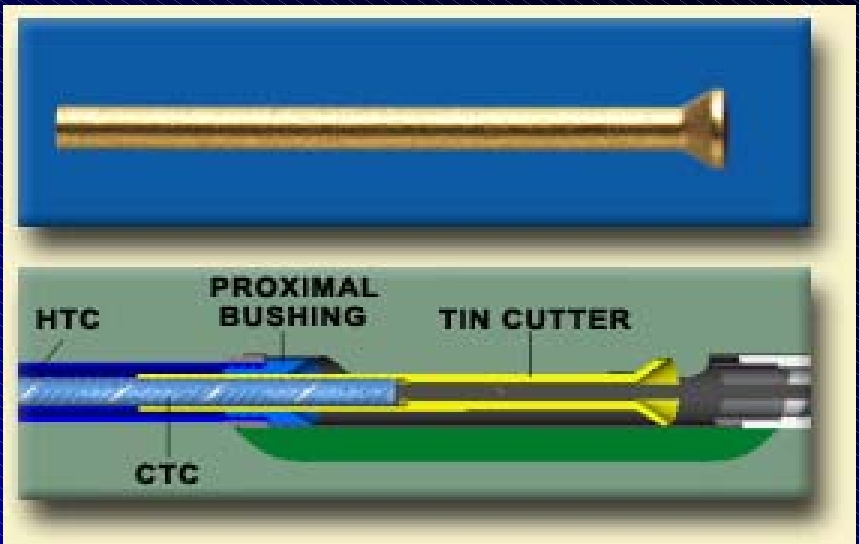
FLEXI-CUT™ vs GTO™



Volumetric comparison of cutting efficiency

- **Cutter Window**
  - **Arc expanded to 127° (vs. 117°)**
  - **9 mm window length**
  - **Improved tissue yield per cut**

Improved Cutting Efficiency



- **Titanium Nitride (TiN) Coated Cutter**
  - **Makes cutting plaque easier and more efficient**
  - **Preserves cutter integrity and minimizes friction**
  - **Held in place by bushing / cutter stem design**

Design Enhancements

- **Excellent torque response**
- **Ergonomic, color-coded rotator hubs**
- **Simplified device prep**
- **Improved MDU/catheter interface**
- **134 cm catheter working length**

Design Summary

- 8F guiding catheter compatible Debulking system
- Treats 2.5-4.0 mm vessels
- Lower profile system
- Enhanced cutting efficiency
- Ultra-hard durable cutting system
- Simplified and complete device prep
- Easier to use system

DCA Catheter Attribute Summary

Attributes	SCA-EX™	AtheroCath GTO™	AtheroCath BANTAM™	FLEXI-CUT™
Guide Compatibility	10F	10F	9F	**8F**
Device Sizing	Housing dependent	Housing dependent	Housing dependent	**Balloon dependent**
Housing Size	5F, 6F, 7F, 7FG	5F, 6F, 7F	5F, 6F, 7F	**6F (with 3 balloon sizes)**
Cutter Window Length	9 mm & 5 mm	9 mm	9 mm	**9 mm**
Cutter Window Arc	117°	117°	117°	**127°**
Cutter Material	Stainless Steel	Stainless Steel	Stainless Steel	**Titanium Nitride (TiN) coated Stainless Steel**
Nosecone Shape	conical	conical	conical	**cylindrical with dam**
Torque Response	1.5 to 1	1 to 1	1.5 to 1	**1 to 1**
Shelf Life	6 months	6 months	2 years	**2 years**
Working Length	125 cm	125 cm	125 cm	**134 cm**

DCA Guiding Catheters

- **Requires supportive, JC shaped guides**
- **Minimum guide ID requirements:**
  - FLEXI-CUT™ *(all sizes)* .087"
  - **5F BANTAM™ .086"**
  - **6F & 7F BANTAM™ .100"**
  - **5F to 7F GTO™ & SCA-EX™ .104"**
- **Recommended guides:**
  - 8F VIKING OPTIMA™ guide for FLEXI-CUT™
  - **9F DVI guide* for AtheroCath BANTAM™**
  - **10F or 9.5F DVI guide* for AtheroCath GTO™, SCA-EX™**

* Guide catheter introducer required for guiding catheters ≥ 9F

Guiding Catheter Compatibility

Cath Size	FLEXI-CUT™ (ALL SIZES)	BANTAM™ 5F	BANTAM™ 6F	BANTAM™ 7F	EX™ 7FG	GTO™ 7F	GTO™ 6F	GTO™ 5F
8F GC ID > .087"	**Yes**	Yes	No*	No	No	No	No	No
9F GC ID > .100"	**Yes**	Yes	Yes	Yes	No	No*	No*	No
9.5F GC ID > .104"	**Yes**	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10F GC ID > .104"	**Yes**	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Yes = AtheroCath will fit in this size GC with the specified minimum I.D. No* = Tight fit inside GC

No* = Tight fit inside GC

Motor Drive Unit

- **Single use, battery-driven Motor Drive Unit (MDU)**
- **Attaches to proximal end of DCA catheter**
  - **Positive snap lock fit onto FLEXI-CUT™**
  - **Wedge fit onto other DCA catheters**
- **Spins cutter at 2,000 RPMs**

Guide Wire

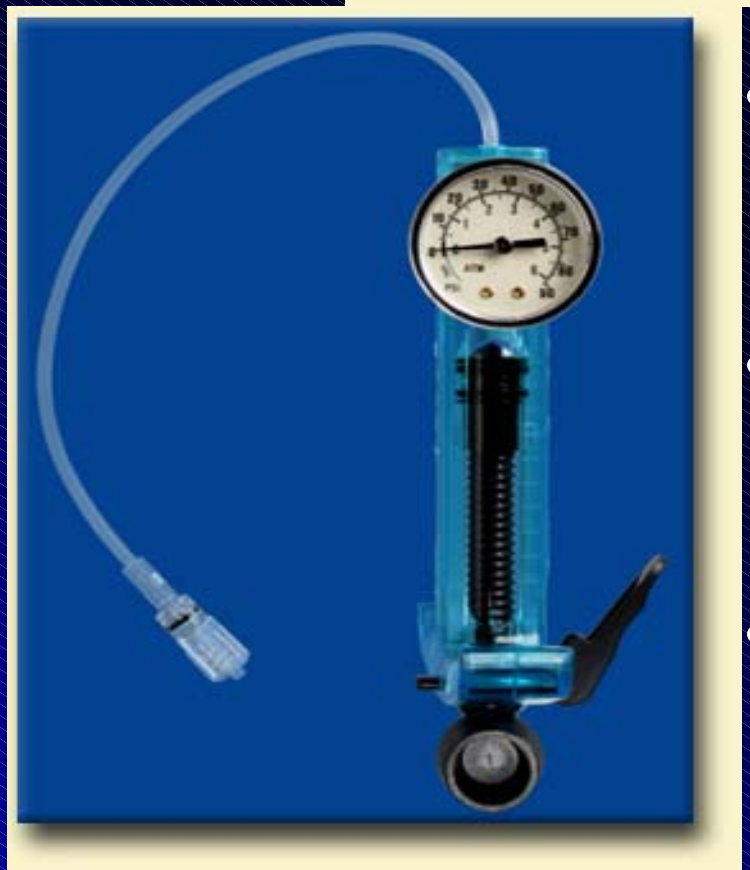
- **Requires supportive .014" wires**
- **Extra support wires stabilize the guiding catheter and aid in device delivery**
- **300 cm length recommended**
- **Plastic coated wires should not be utilized**
- **Recommended guide wire**
  - Flexi-wire™

Guide Wire

- Flexi-wire™

- **Extra support with excellent steerability**
- **Supportive PTFE coated core for smooth device delivery**
- **Hydrocoat hydrophilic coating on distal 8 cm for reduced friction and smooth tracking**
- **Available in 300 and 190 cm lengths**

Inflation Device



- Requires indeflator with low pressure monitoring capabilities
- Balloon inflation pressure should never exceed 60 psi (4 atm)
- Recommended indeflator
  - LP-90™ low pressure inflation device

Hemostatic Value

- Copilot™ **Bleedback control valve**
  - **Reduces blood loss**
  - **Eliminates the need for RHV adjustments**
  - **Clamp seal permits high pressure injections**
  - **Recommended for use with FLEXI-CUT™**
- **Larger ID RHV (<.094" / 7.1F) required for other DCA catheters**

Vascular Sheaths

- **Short sheaths (12 cm) adequate for most procedures**
- **Long sheaths should be used in distal, tortuous anatomy**
- **Venous sheath and temporary pacers are generally not needed**