

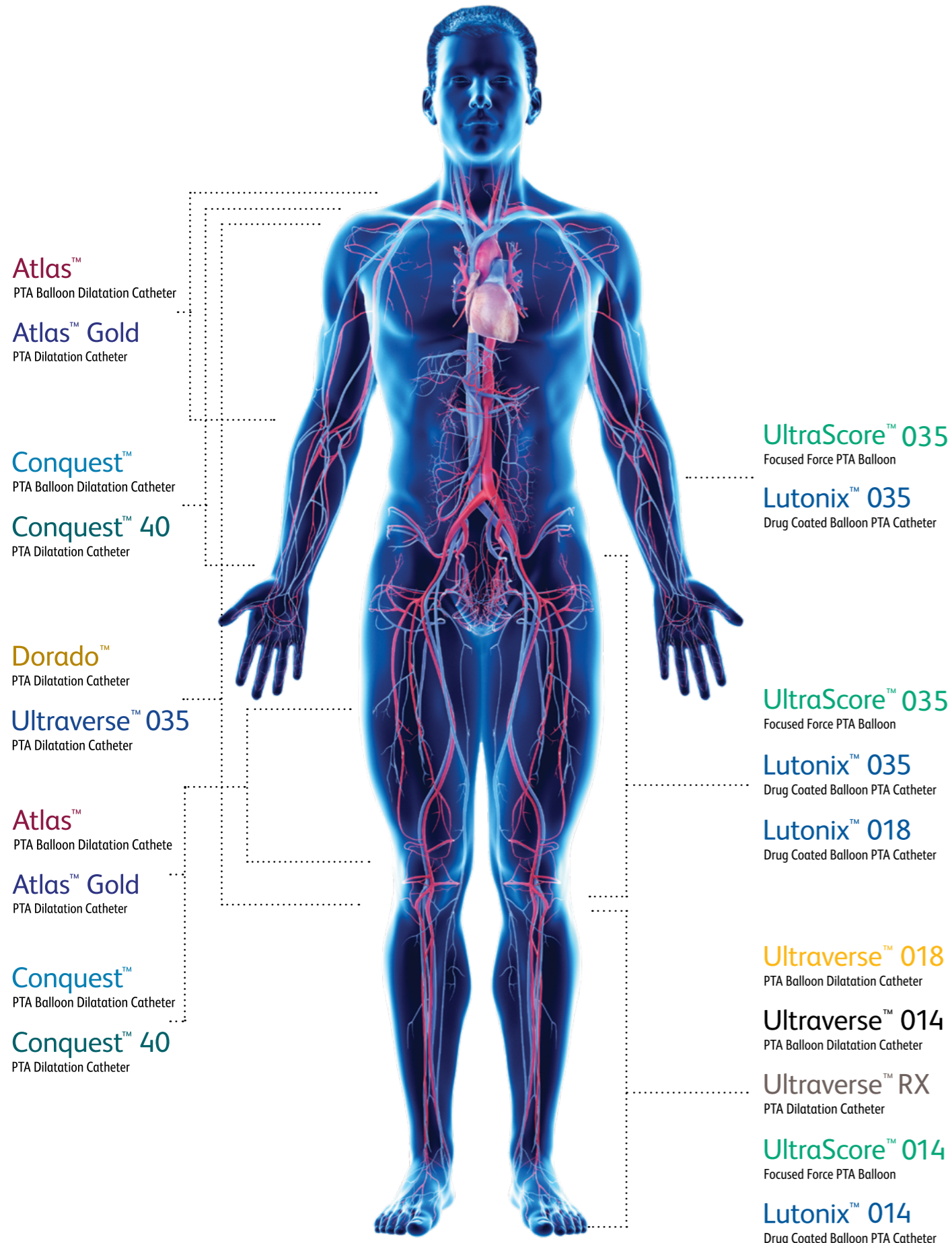
# Leading the Way in PTA

## BD PTA Family of Products



# A Brief History of Anatomical Solutions

As a category leader in the peripheral vascular industry, BD takes pride in fulfilling the clinical needs of our customers and patients through continuous innovation and improvement. We do this by introducing surgical and interventional devices for peripheral vascular patency, while providing exceptional service and support to surgeons, interventionalists and radiologists.



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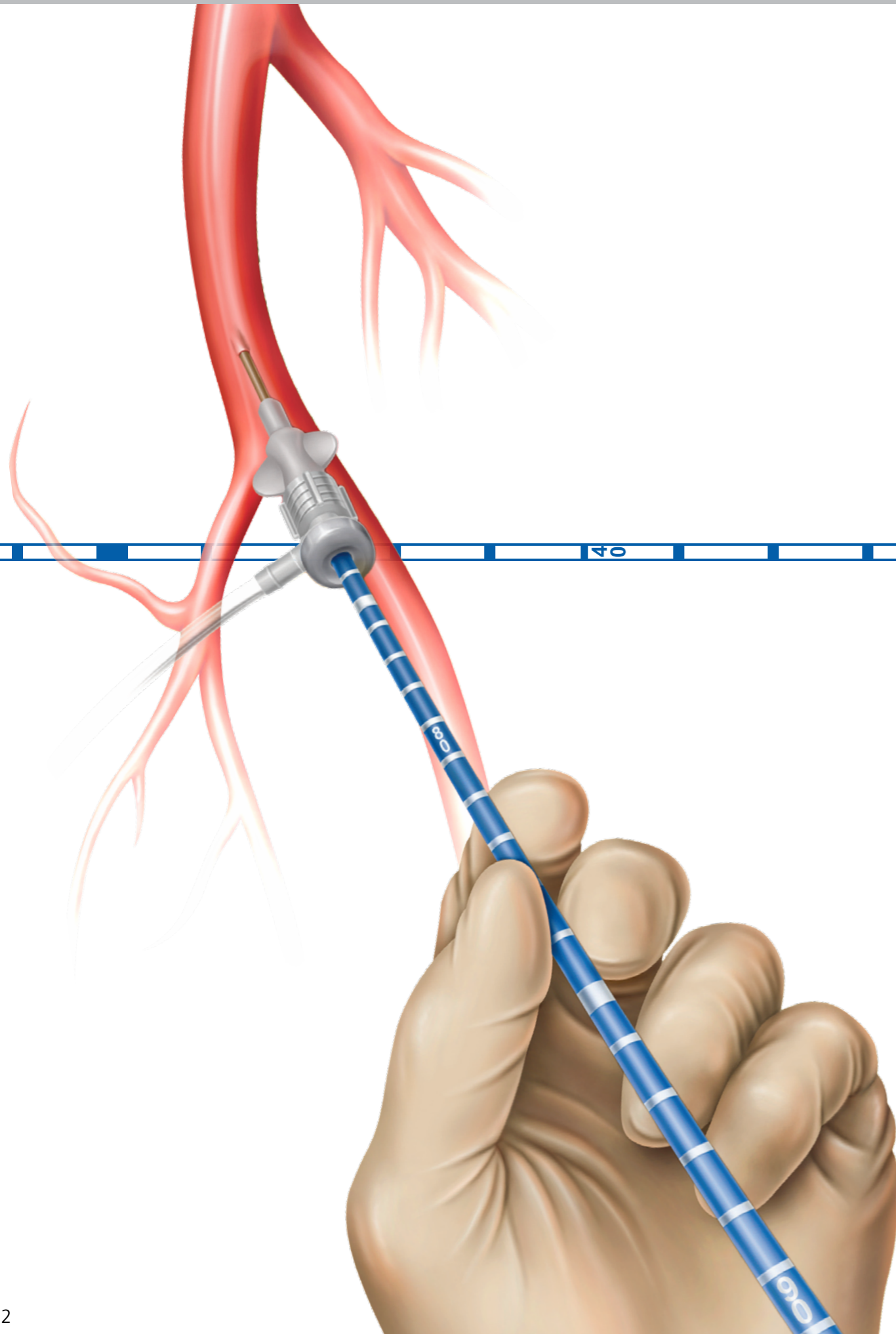
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# GeoAlign™ Marking System

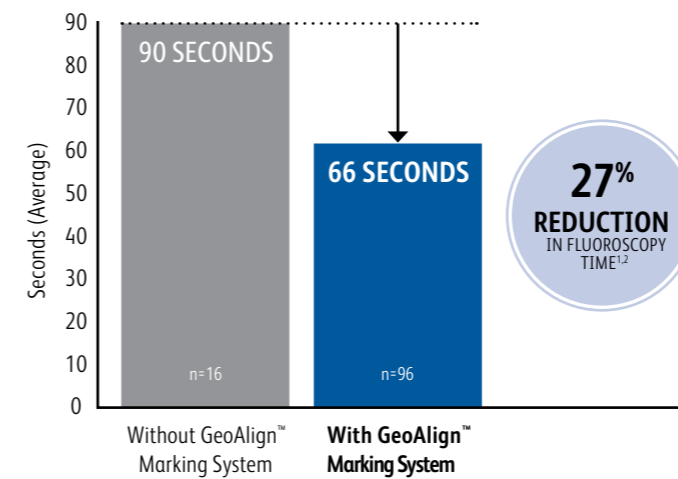
The GeoAlign™ Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. During repeat catheter placement, the GeoAlign™ Marking System is designed to:

- Help increase procedure efficiency and decrease radiation exposure by minimizing fluoroscopy time.
- Facilitate repeatable catheter alignment at the lesion
- Simplify length measurement between two intravascular points

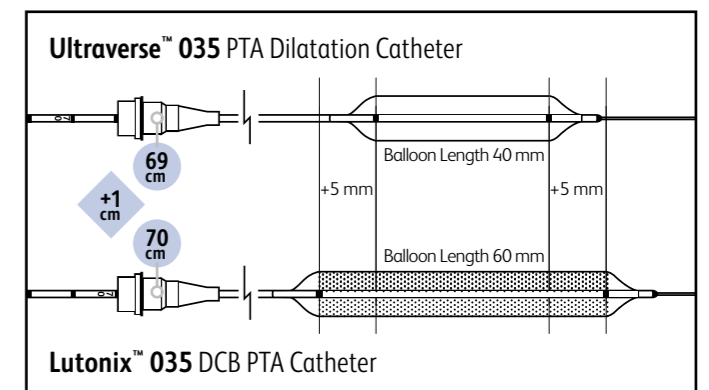
Marker bands are designated in 1 cm increments

Each 10 cm increment is labeled with the distance from the distal end of the balloon

Pre-Clinical Animal Model Arterial PTA Placement<sup>1</sup>



Geographic Alignment

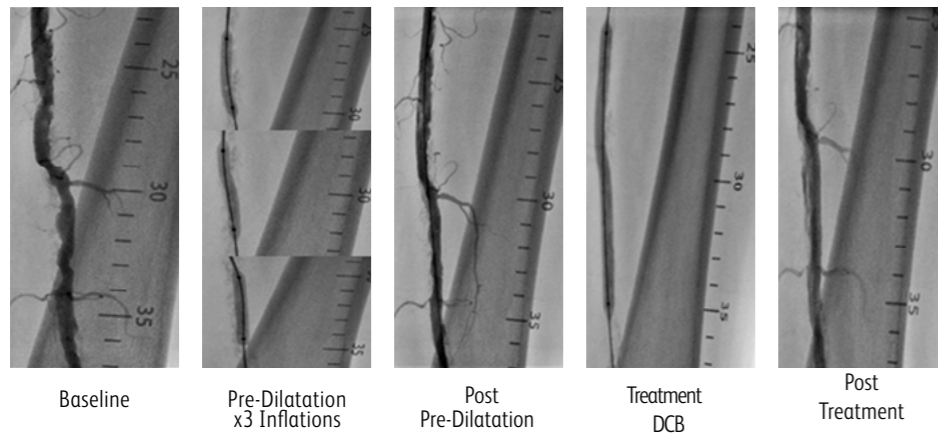


<sup>1</sup> Animal study (repeat PTA in swine artery) performed by 3 physicians who tested the Lutonix™ 035 DCB (no drug) and the Ultraverse™ 035 PTA Catheter, both with GeoAlign™ Markers, to POBA with no GeoAlign™ Markers (n=112, test n = 96, control n = 16). Animal data on file. Bard. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

<sup>2</sup> When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation.

# Maximized Effectiveness Proven Safety

- All sizes 5F sheath profile compatible
- Zero preclinical evidence of downstream necrosis at 90 days\*
- GeoAlign™ Marking System
- Indicated for de novo, restenotic, and in-stent restenotic lesions



Recommended Guidewire .035"	
Balloon Diameters	4 - 7 mm
Balloon Lengths	40 - 150 mm
Shaft Lengths	100, 130 cm
Rated Burst Pressure	10 - 12 atm
Nominal Pressure	6 atm (4, 5 mm), 7 atm (6, 7 mm)
Drug	Paclitaxel (2 µg/mm <sup>2</sup> )
Excipient	Polysorbate and Sorbitol

**Lutonix™ 035**  
Drug Coated Balloon PTA Catheter



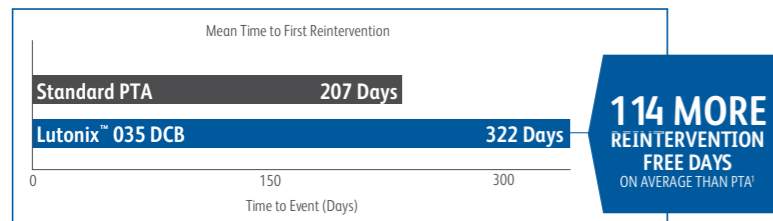
¹ Primary efficacy endpoint is defined as freedom from TLR at 12 months. Total of 648 subjects were evaluable for the primary efficacy endpoint analysis. The 12 month TLR Free rate by subject counts at 12 months was 93.4%. The Kaplan-Meier estimates TLR-Free survival was 94.1% at 12 months and 90.3% at 24 months. TLR-Free survival by lesion location was 94.7% (n=483) for SFA, 92.9% (n=86) for popliteal, and 92.3% (n=121) for patients with lesions in both SFA and popliteal. Data on file, Bard Peripheral Vascular, Inc.

• Comparison of Particulate Embolization after Femoral Artery Treatment with In.Pact- Admiral versus Lutonix- 035 Paclitaxel-Coated Balloons in Healthy Swine. Frank D. Kolodgie, PhD, Erica Pacheco, MS, Kazuyuki Yahagi, MD, Hiroyoshi Mori, MD, Elena Ladich, MD, and Renu Virmani, MD, JVIR September 2016. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

Please refer to the Lutonix-035 IFU for complete data sets and more detailed Lutonix- 035 DCB clinical information, including with regard to the Lutonix- DCB Global SFA Registry and the LEVANT 2 global, prospective, randomized, pivotal study.

# Measurable Clinical Outcomes in AV Access

- At 6 months, the Lutonix™ 035 DCB demonstrated 71.4% TLPP in the Lutonix AV IDE Clinical Trial<sup>1</sup>
- At 24 months, patients who were treated with a Lutonix™ 035 DCB went an average of 322 days before needing a reintervention compared to 207 days when treated with a PTA alone<sup>1</sup>
- In the Lutonix DCB AV Global Registry, the Lutonix™ 035 DCB demonstrated 78.1% TLPP in native fistula, and 73.9% TLPP in native and synthetic (graft) access types, combined, at 6 months<sup>2</sup>



<sup>1</sup> Lutonix™ AV Clinical Trial data on file. N=285. At 6 months, treatment with Lutonix™ 035 DCB resulted in a primary patency rate of 71.4% versus 63.0% with PTA alone. Primary patency defined as ending with a clinically driven re-intervention of the target lesion or access thrombosis. The primary effectiveness analysis for superiority of DCB vs. PTA was not met with a one-sided p-value of p = 0.0562. Mean time to TLPP event for subjects with an event was longer for DCBs (321.8 vs. 207.4 d; p<0.0001). At 30 days, treatment with Lutonix™ 035 resulted in a freedom from primary safety event rate of 95.0% versus 95.8% with PTA alone. Primary safety defined as freedom from localized or systemic serious adverse events through 30 days that reasonably suggests the involvement of the AV access circuit. The primary safety endpoint for non-inferiority for DCB vs. PTA was met with one-sided p-value of p = 0.0019. Percentages reported are derived from Kaplan-Meier analyses.

<sup>2</sup> Lutonix Global AV Registry data on file. N=320. At 6 months, treatment with Lutonix™ 035 DCB resulted in a target lesion primary patency (TLPP) rate of 73.9%. By access type, treatment with Lutonix™ 035 DCB resulted in a TLPP of 78.1% for native fistulas only (240/320) and 61.9% for synthetic (graft) only (80/320). TLPP defined as the interval following index procedure intervention until clinically driven reintervention of the target lesion or access thrombosis. At 30 days, treatment with the Lutonix™ 035 DCB resulted in a freedom from primary safety event rate of 96.1%. Primary safety defined as freedom from any serious adverse event(s) involving the AV access circuit through 30 days. Percentages reported are estimated based on Kaplan-Meier estimates.

<sup>1</sup> Lutonix™ AV Clinical Trial data on file. N=285. At 6 months, treatment with Lutonix™ 035 DCB resulted in a primary patency rate of 71.4% versus 63.0% with PTA alone. Primary patency defined as ending with a clinically driven re-intervention of the target lesion or access thrombosis. The primary effectiveness analysis for superiority of DCB vs. PTA was not met with a one-sided p-value of p = 0.0562. Number of interventions required to maintain TLP at 6 months were 44 in DCB arm versus 64 in the PTA arm. At 30 days, treatment with Lutonix™ 035 resulted in a freedom from primary safety event rate of 95.0% versus 95.8% with PTA alone. Primary safety defined as freedom from localized or systemic serious adverse events through 30 days that reasonably suggests the involvement of the AV access circuit. The primary safety endpoint for noninferiority for DCB vs. PTA was met with one-sided p-value of p = 0.0019. Percentages reported are derived from Kaplan-Meier analyses. Mean time to TLPP event for subjects with an event was longer for DCBs (321.8 vs. 207.4 d; p<.0001)

## Reintervention Free Days

At 24 months, patients treated with a Lutonix™ 035 Drug Coated Balloon PTA Catheter went an average of 322 days before receiving a target lesion reintervention compared to 207 days when treated with PTA alone.<sup>1</sup>

Recommended Guidewire .035"	
Balloon Diameters	4 - 12 mm
Balloon Lengths	40 - 80 mm
Shaft Lengths	75, 100 cm
Rated Burst Pressure	up to 12 atm
Nominal Pressure	6 - 7 atm
Drug	Paclitaxel (2 µg/mm <sup>2</sup> )
Excipient	Polysorbate and Sorbitol

# Lutonix™ 035

## Drug Coated Balloon PTA Catheter

# Delivering More Options with an 018 DCB

- The Lutonix™ 018 DCB is designed to:
- Perform over small guidewires (up to .018")
- Enable alternative access (all sizes 5F or less)
- Utilizes the same proven drug coating formulation as the Lutonix™ 035 DCB, and has a 20% lower crossing profile<sup>1</sup>

Recommended Guidewire .018"	
Balloon Diameters	4 - 7 mm
Balloon Lengths	40 - 220 mm
Shaft Lengths	100, 130 cm
Rated Burst Pressure	10 - 12 atm
Nominal Pressure	6 - 7 atm
Drug	Paclitaxel (2 µg/mm <sup>2</sup> )
Excipient	Polysorbate and Sorbitol

## Lutonix™ 018 Drug Coated Balloon PTA Catheter

<sup>1</sup> Data on file. BD, Tempe, AZ. 4 x 220 mm Lutonix™ 035 DCB N=25, 4 x 220 Lutonix™ 018 DCB N = 30. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results.

# Go Further with Lutonix™ 014 DCB

The LUTONIX™ 014 DCB demonstrated non-inferior safety and 20.7% improved primary patency over PTA\* in a rigorous Level 1, Randomized Clinical Trial.

The LUTONIX™ 014 product line features:

- All 4F sheath compatibility
- Dual distal marker bands
- GEOALIGN™ Marking System

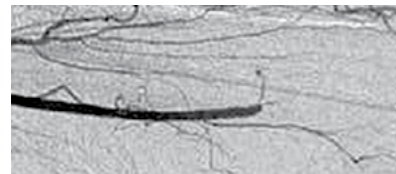
Recommended Guidewire .014"	
Balloon Diameters	2 - 4 mm
Balloon Lengths	40 - 150 mm
Shaft Lengths	150 cm
Rated Burst Pressure	15 atm
Nominal Pressure	6 - 7 atm
Drug	Paclitaxel (2 µg/mm <sup>2</sup> )
Excipient	Polysorbate and Sorbitol

## Lutonix™ 014 Drug Coated Balloon PTA Catheter

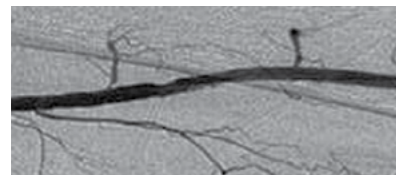
\* Lutonix™ BTK IDE Clinical Data on File. Primary Efficacy is defined as freedom from composite of above-ankle amputation, target lesion occlusion, and clinically-driven target lesion revascularization. As 6 months, treatment with LUTONIX™ 014 DCB resulted in a primary efficacy rate of 73.7% (196/266) versus 63.5% with PTA alone (87/137). The primary effectiveness analysis for superiority of DCB vs. PTA was not met with a p-value of 0.0273. At 30 days, treatment with LUTONIX™ 014 DCB resulted in a freedom from primary safety event rate of 99.3% (283/285) versus 99.4% (154/155) for PTA alone. Primary Safety is defined as freedom from composite of all-cause death, above-ankle (index) amputation or major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/ thrombolysis) of the index limb involving a below-the-knee. The primary safety analysis for non-inferiority for DCB vs. PTA was met with a p-value of <0.001. Percentages reported are derived from Kaplan-Meier analyses.

# Predictable Performance

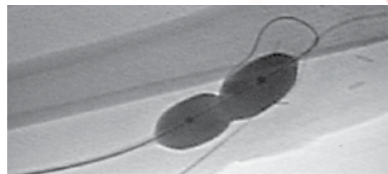
- Ultra non-compliant fiber balloon technology concentrates maximum dilatation force at the lesion
- Checker™ Flex Points provide increased flexibility in tortuous anatomy
- Indicated for post-stent dilatation



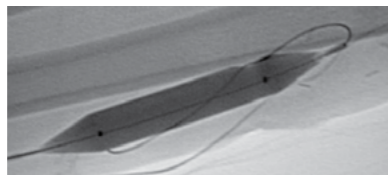
Pre Dorado™ Catheter balloon dilatation



Post Dorado™ Catheter balloon dilatation



Pre AV Access



Post AV Access

Recommended Guidewire .035"	
Balloon Diameters	3 - 10 mm
Balloon Lengths	20 - 200 mm
Shaft Lengths	40, 80, 120, 135 cm
Rated Burst Pressure	up to 24 atm
Nominal Pressure	8 atm
Material	Composite

## Dorado™ PTA Dilatation Catheter

# Performance Meets Precision

- Sheath profile 5F compatible up to 8 x 80 mm\*
- Balloon Diameters: 3 - 12 mm  
Balloon Lengths: 20 - 300 mm
- GeoAlign™ Marking System is designed to help reduce radiation exposure by limiting fluoroscopy time\*\*



Recommended Guidewire .035"	
Balloon Diameters	3 - 12 mm
Balloon Lengths	20 - 300 mm
Shaft Lengths	75, 130 cm
Rated Burst Pressure	up to 21 atm
Nominal Pressure	6 - 8 atm
Material	Nylon

## Ultraverse™ 035 PTA Dilatation Catheter

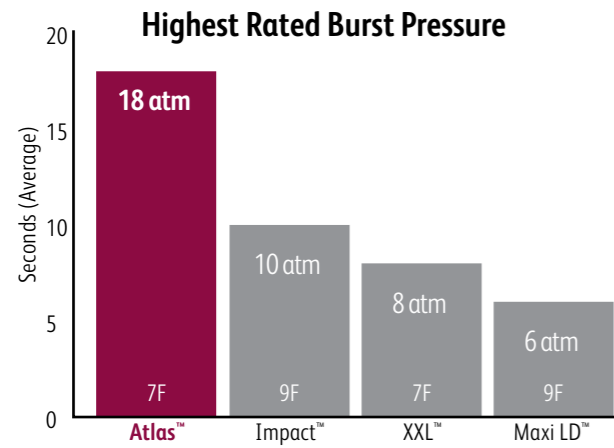
The GeoAlign™ Marking System is not a replacement for fluoroscopy. When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation.

\* 7 x 250 mm and 7 x 300 mm sizes are 6F compatible

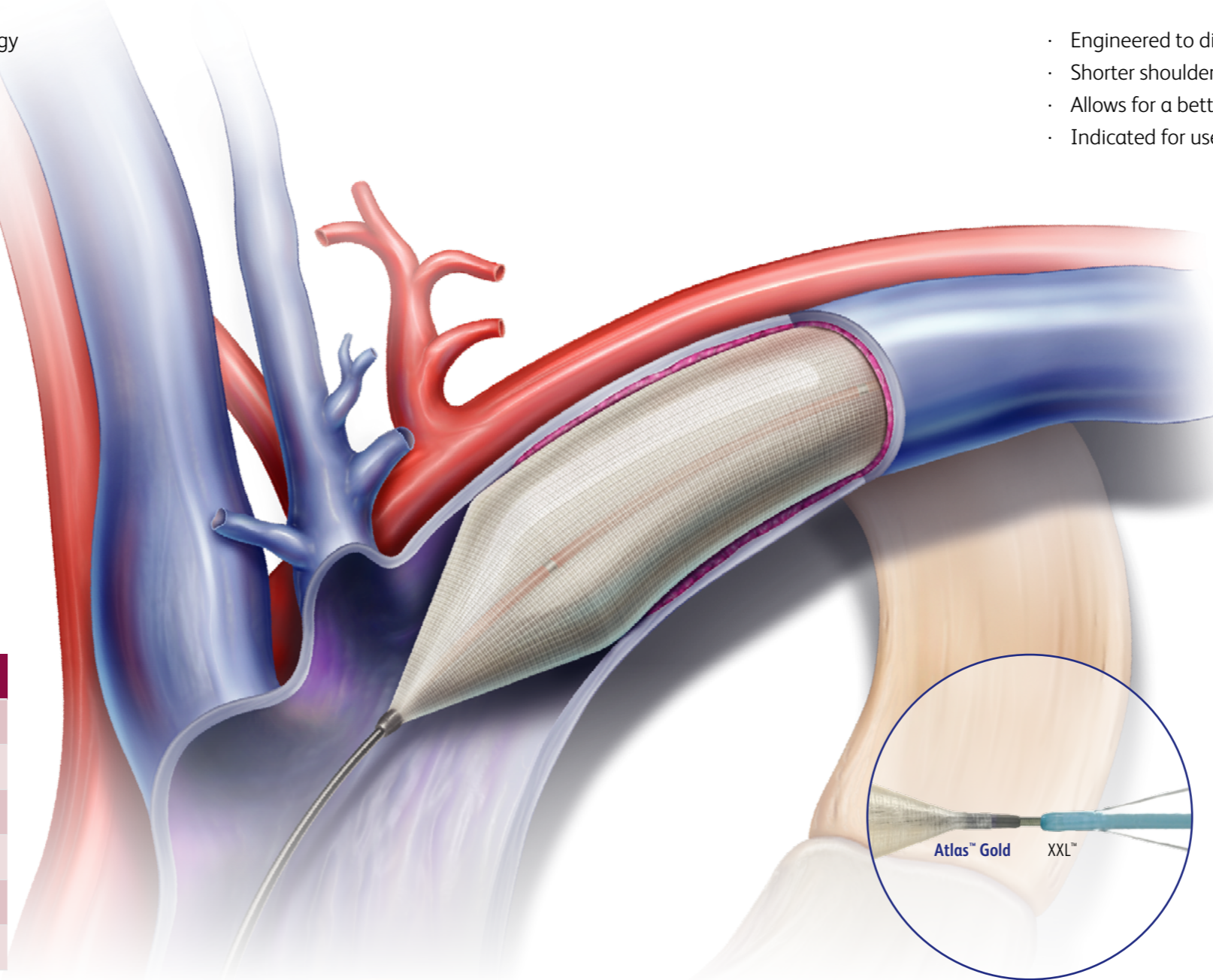
\*\* When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation

# Ultra Non-Compliant Technology

- Large diameter, ultra non-compliant balloon technology
- Delivers maximum dilatation force to resistant lesions
- Large working range for maximum versatility

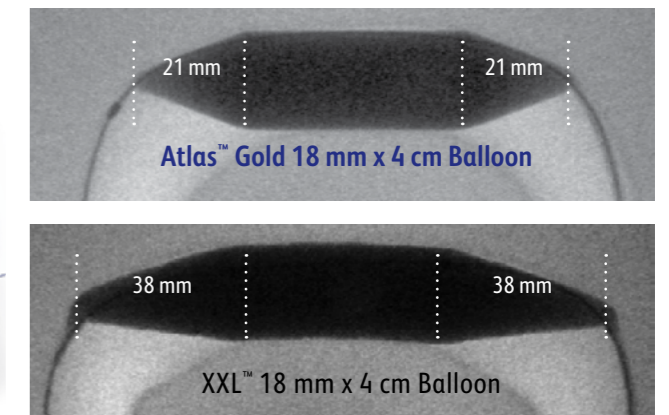


Recommended Guidewire .035"	
Balloon Diameters	12 - 26 mm
Balloon Lengths	20 - 60 mm
Shaft Lengths	75, 120 cm
Rated Burst Pressure	up to 18 atm
Nominal Pressure	4 - 6 atm
Material	Composite



# Enhanced Trackability with Tapered Tip

- Engineered to dilate lesions in curved vessels
- Shorter shoulders designed to minimize vessel straightening
- Allows for a better fit
- Indicated for use in iliac and femoral veins, as well as AV dialysis fistulae



Short shoulders designed to minimize vessel straightening.\*

Images shown are not to scale.

Recommended Guidewire .035"	
Balloon Diameters	12 - 26 mm
Balloon Lengths	20 - 60 mm
Shaft Lengths	80, 120 cm
Rated Burst Pressure	up to 18 atm
Nominal Pressure	4 - 6 atm
Material	Composite

**Atlas™**  
PTA Balloon Dilatation Catheter

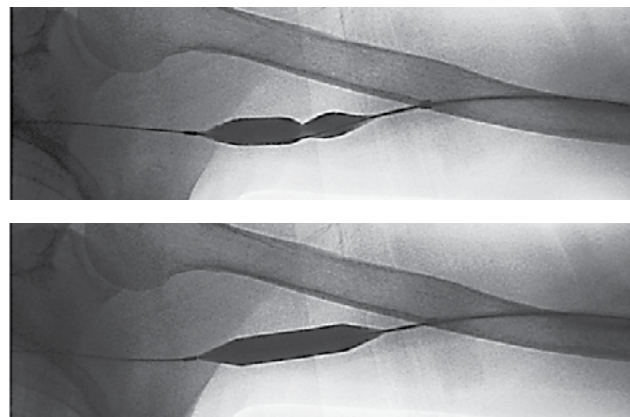
**Atlas™ Gold**  
PTA Dilatation Catheter

\*Information taken directly from each manufacturer's product brochure and IFU. Highest rated burst pressure among competitors listed.



# The Force You Need to Conquer Resistant Lesions

- Allows high pressures without over-expansion
- Predictable balloon diameters
- Virtually no balloon growth beyond stated diameter, even at high pressures
- Delivers maximum forces to areas of most resistance

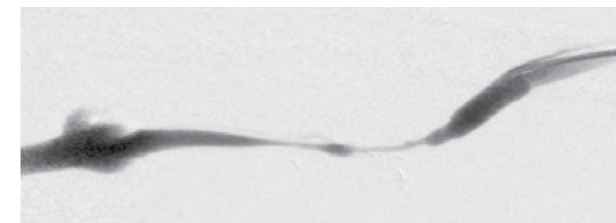
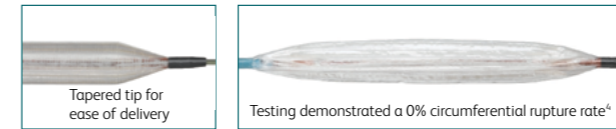


Recommended Guidewire .035"	
Balloon Diameters	5 - 12 mm
Balloon Lengths	20 - 80 mm
Shaft Lengths	50, 75, 120 cm
Rated Burst Pressure	up to 30 atm
Nominal Pressure	8 atm
Material	Composite

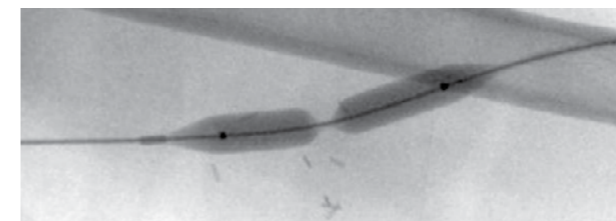
**Conquest™**  
PTA Balloon Dilatation Catheter

## Advancements in Product Features

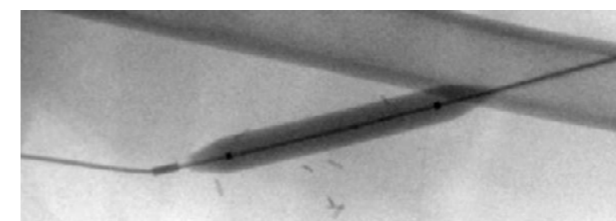
- 40 ATM pressures offered for sizes up to 8 mm 40 mm
- Labeled for syringe inflation



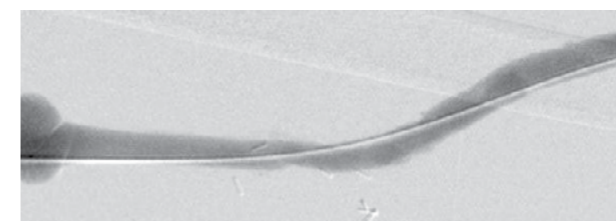
3 cm long high-grade stenosis involving the upper basilic vein



Unable to efface stenosis with standard, non-compliant balloon at 22 atm



Ultra high pressure and ultra non-compliance were needed to efface lesion.



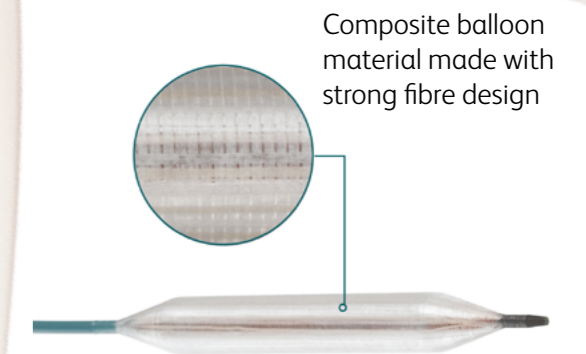
Post angioplasty, the vessel is open and the patient can resume dialysis

Images courtesy of Thomas Vesely, MD. Results from this case may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

\*Foering K, Chittams JL, Trerotola SO, Percutaneous Transluminal Angioplasty Balloon Inflation with Syringes: Who Needs an Inflator? J Vasc Interv Radiol. 2009; 20:629-633. Trerotola SO, et al. Prospective Study of Balloon Inflation Pressures and Other Technical Aspects of Hemodialysis Access Angioplasty J Vasc Interv Radiol. 2005; 16:1613-1618

# Strength that Reaches High Atmospheres

- Enables a single balloon strategy with up to 40 atm
- Tapered tip for ease of delivery
- Literature suggests that 99% of stenoses in hemodialysis access can be treated in the range up to 40 atm\*

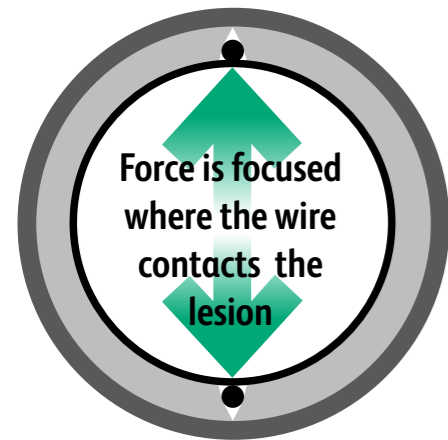


Recommended Guidewire .035"	
Balloon Diameters	4 - 12 mm
Balloon Lengths	20 - 100 mm
Shaft Lengths	50, 75 cm
Rated Burst Pressure	up to 40 atm
Nominal Pressure	8 atm
Material	Composite

**Conquest™ 40**  
PTA Dilatation Catheter

# Engineered for Focused Force

- Designed to fracture plaque longitudinally at lower inflation pressures than a standard PTA balloon of the same size
- 5F and 6F sheath compatibility
- GeoAlign™ Marking System designed to reduce fluoroscopy time\*



Recommended Guidewire .035"	
Balloon Diameters	4 - 8 mm
Balloon Lengths	20 - 300 mm
Shaft Lengths	130 cm
Rated Burst Pressure	10 - 14 atm
Nominal Pressure	6 - 8 atm
Material	Nylon

## UltraScore™ 035 Focused Force PTA Balloon

The GeoAlign™ Marking System is not a replacement for fluoroscopy. When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation.

\* When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.

# Controlled Plaque Modification

- Same focused force design as UltraScore™ 035 Focused Force PTA Balloon, but on an 014 guidewire platform
- 4F and 5F sheath compatibility
- Hydrophilic coating on all 0.14" sizes
- GeoAlign™ Marking System designed to reduce fluoroscopy time\*

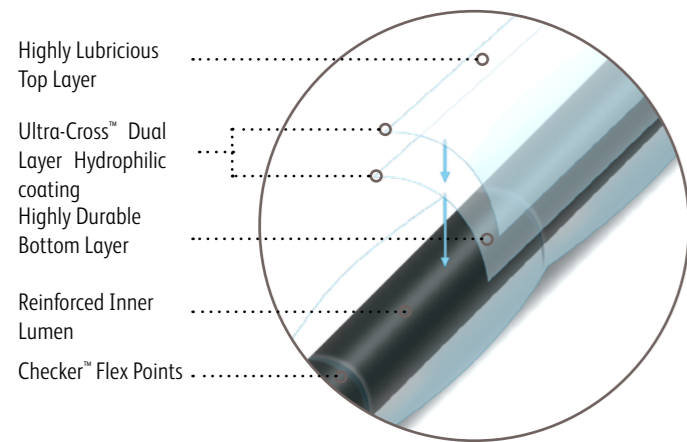
Recommended Guidewire .014"	
Balloon Diameters	2 - 7 mm
Balloon Lengths	20 - 300 mm
Shaft Lengths	150 cm
Rated Burst Pressure	10 - 14 atm
Nominal Pressure	6 atm
Material	Nylon

## UltraScore™ 014 Focused Force PTA Balloon

The GeoAlign™ Marking System is not a replacement for fluoroscopy. When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation.

# Going the Distance

- Exceptional trackability
- Balloon lengths up to 300 mm
- Ultra-Cross™ Dual Layer Hydrophilic coating designed to reduce friction
- Checker™ Flex Points engineered to allow the balloon to flex in tortuous anatomy
- Reinforced inner lumen provides improved axial strength constructed to cross tight lesions

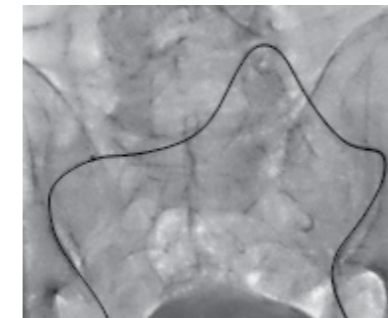


Recommended Guidewire .014"	
Balloon Diameters	1.25 - 7 mm
Balloon Lengths	15 - 300 mm
Shaft Lengths	150, 200 cm
Rated Burst Pressure	up to 16 atm
Nominal Pressure	6 atm
Material	Nylon

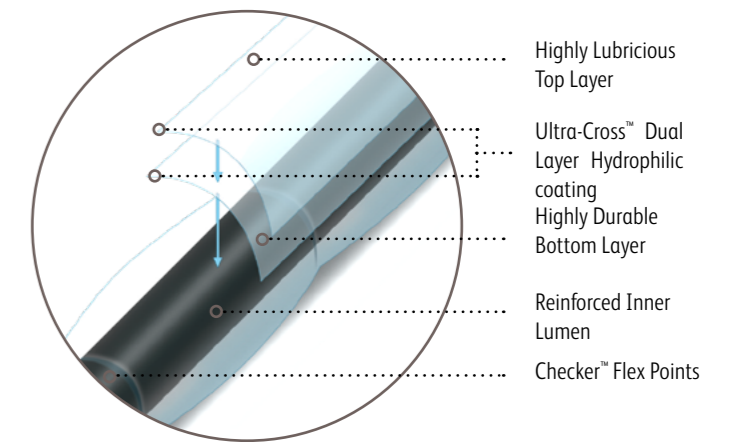
## Ultraverse™ RX PTA Dilatation Catheter

# Navigating the Extremes

- Designed to be delivered below-the-knee
- Excellent trackability
- Balloon lengths up to 300 mm
- Ultra-Cross™ Dual Layer Hydrophilic coating designed to reduce friction
- Checker™ Flex Points engineered to allow the balloon to flex in tortuous anatomy
- Reinforced inner lumen provides improved axial strength constructed to cross tight lesions



Ultraverse™ 014 Catheter navigating a tortuous anatomy



Recommended Guidewire .014"	
Balloon Diameters	1.5 - 5 mm
Balloon Lengths	20 - 300 mm
Shaft Lengths	150 cm
Rated Burst Pressure	13 - 16 atm
Nominal Pressure	6 atm
Material	Nylon

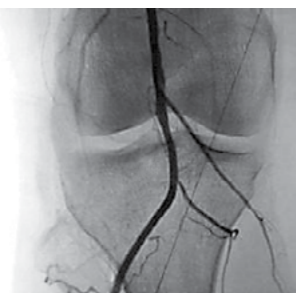
## Ultraverse™ 014 PTA Balloon Dilatation Catheter

# Navigating the Extremes

- Broad size matrix with balloon lengths up to 300 mm · Ultra-Cross™ Dual Layer Hydrophilic coating designed to reduce friction
- Checker™ Flex Points engineered to allow the balloon to flex in tortuous anatomy
- Reinforced inner lumen provides improved axial strength constructed to cross tight lesions



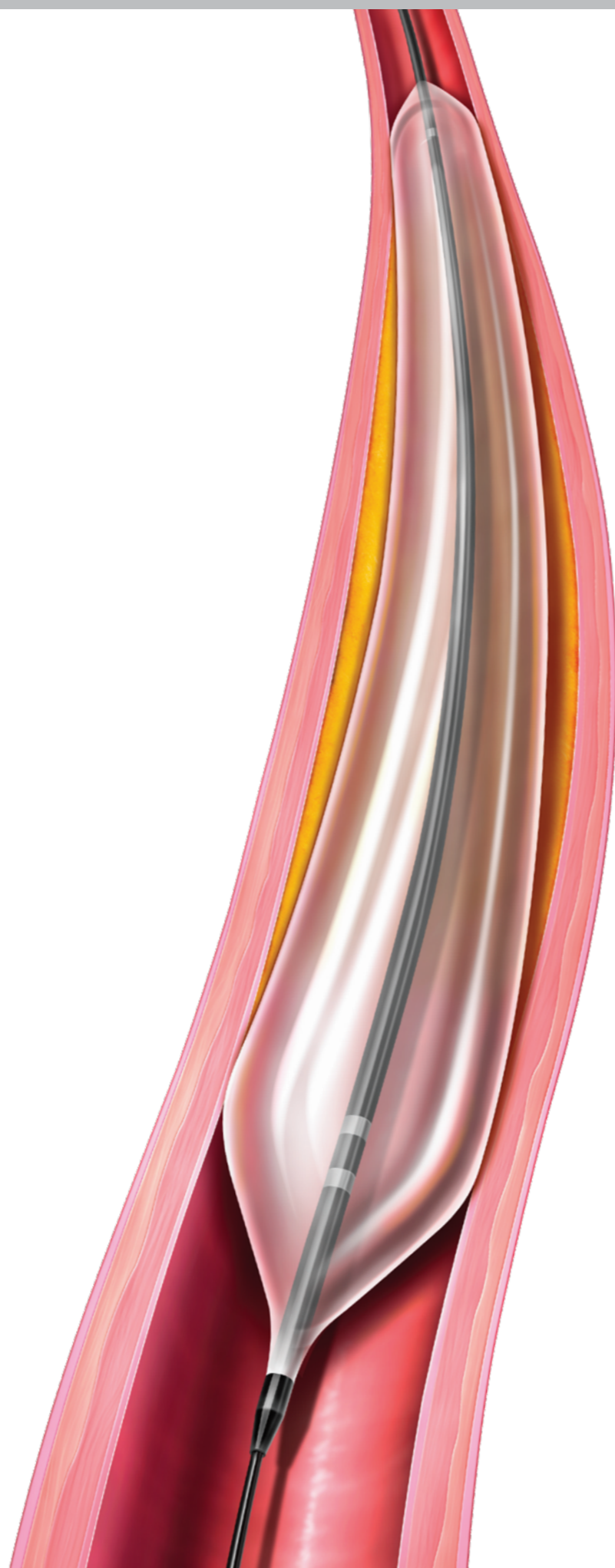
Popliteal CTO pre-intervention



Post crossing and Ultraverse™ 018 Catheter

Recommended Guidewire .018"	
Balloon Diameters	2 - 9 mm
Balloon Lengths	20 - 300 mm
Shaft Lengths	75, 130, 200 cm
Rated Burst Pressure	up to 16 atm
Nominal Pressure	6 atm
Material	Nylon

## Ultraverse™ 018 PTA Balloon Dilatation Catheter



# Inflating to Ultra-High Atmospheres

The Presto™ Inflation Device offers a single solution treatment option.

- Designed to inflate large or small balloons with a single fill of the device
- Large barrel allows for rapid and easy deflation
- Ergonomic design allows for comfortable handling



## Presto™ Inflation Device



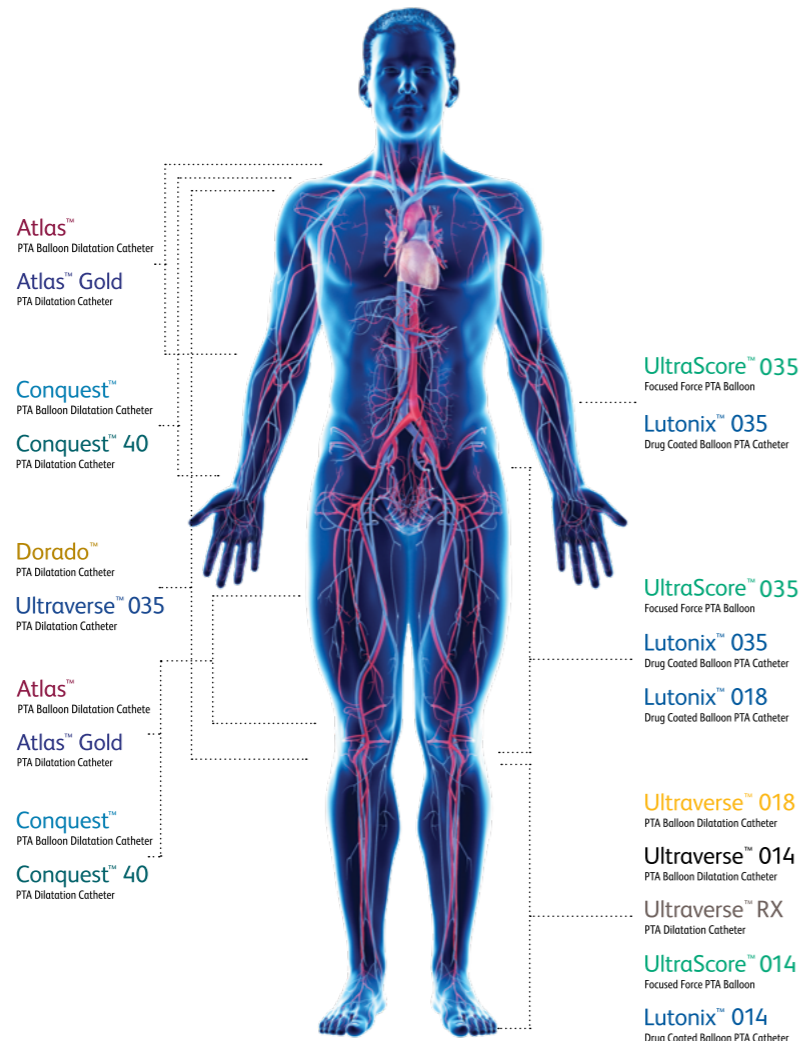








Product	Diameter (mm)	Length (mm)	RBP (atm)	Sheath (F)	Shaft (cm)	Material	Category
Atlas™ Catheter	12 - 26	20 - 60	up to 18	7 - 12	75, 120	Composite	.035" Large Diameter
Atlas™ Gold Catheter	12 - 26	20 - 60	up to 18	7 - 12	80, 120	Composite	.035" Large Diameter
Conquest™ Catheter	5 - 12	20 - 80	up to 30	6 - 8	50, 75, 120	Composite	.035" High Pressure
Conquest™ 40 Catheter	4 - 12	20 - 100	up to 40	6 - 8	50, 75	Composite	.035" High Pressure
Dorado™ Catheter	3 - 10	20 - 200	up to 24	5 - 6	40, 80, 120, 135	Composite	.035" Standard
Lutonix™ 035 Catheter	4 - 12	40 - 150	12	5	75, 100, 130	Drug Coated	.035" Drug Coated
Lutonix™ 014 Catheter	2 - 4	40 - 150	up to 15	4	150	Drug Coated	.014" Drug Coated
Lutonix™ 018 Catheter	4 - 7	40 - 220	up to 12	4 - 5	100, 130	Drug Coated	.018" Drug Coated
UltraScore™ 014 Catheter	2 - 7	20 - 300	up to 14	4 - 5	150	Nylon	.014" Specialty
UltraScore™ 035 Catheter	4 - 8	20 - 300	up to 14	5 - 6	130	Nylon	.035" Specialty
Ultraverse™ 014 Catheter	1.5 - 5	20 - 300	up to 16	4 - 5	150	Nylon	.014" Small Vessel
Ultraverse™ 018 Catheter	2 - 9	20 - 300	up to 16	4 - 6	75, 130, 150	Nylon	.018" Small Vessel
Ultraverse™ 035 Catheter	3 - 12	20 - 300	up to 21	5 - 7	75, 130	Nylon	.035" Standard
Ultraverse™ RX Catheter	1.25 - 7	15 - 300	up to 16	4 - 5	150, 200	Nylon	.014" Small Vessel



**AV (Arterio-Venous):** Products listed with AV indication are for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

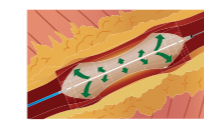
**Nominal (Operating) Pressure:** The pressure at which the balloon reaches its labeled diameter.

**RBP (Rated Burst Pressure):** The pressure at which the manufacturer has 95% confidence that 99.9% of balloons will not burst upon single inflation.

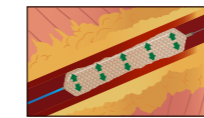
**Compliance:** The amount of diameter growth in the balloon between nominal and rated burst pressure.



A compliant balloon will expand in diameter as atmospheres are increased.



- Compliant balloons may "dogbone or hourglass" around tight calcified lesions.
- Non-compliant balloons maintain fairly constant diameter regardless of pressure and will not stretch or dogbone around a lesion.



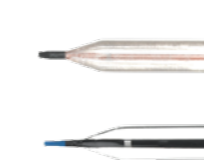
- Ultra non-compliant balloons have the least amount of growth between nominal and RBP, concentrating pressure against the lesion. Compliance charts are not required.

NOTE: Compliance should not be confused with "balloon waist" during inflation, which is normal for all types of balloons.

**Pushability:** Ability to successfully push catheter to the lesion.

**Trackability:** Ease at which catheter tracks over the guidewire in straight or angled anatomy.

**MATERIAL**



- Fiber:** The most non-compliant material due to a strong fiber pattern created from individual strands of material.
- PET / PE blend:** Polyethylene terephthalate.
- Nylon:** More compliant material than PET but more puncture resistant.

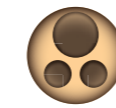
**CATHETER SHAFT**



**Coaxial:** A coaxial shaft has a large inflation lumen and a guidewire lumen. This design allows the balloon to hold greater pressure than a multi-lumen catheter and decreases likelihood of shaft rupture due to high pressures. It also allows for rapid inflation/deflation times while maintaining good pushability.



**Dual Lumen:** A dual lumen shaft has an inflation lumen and a guidewire lumen. Due to the balance between good trackability/ pushability and inflation / deflation times, most standard balloons have a dual lumen.



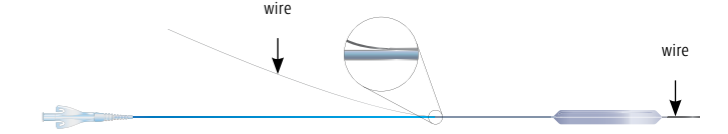
**Triple Lumen:** A triple lumen shaft has two inflation lumens and a guidewire lumen. Triple lumen shafts allow for good track ability/ pushability.

**Inflation/Deflation Times:** Time required to fully inflate and deflate balloon to and from rated burst pressure. Inflation/deflation time is directly related to shaft working length (cm), diameter, and type (e.g., coaxial). Inflation/deflation times will increase with longer shaft working length, smaller shaft diameter and dual/ triple lumen.

**Over-the-Wire (OTW):** Wire enters shaft through proximal y-adapter and exits through the tip of the balloon.



**RX (Rapid Exchange):** Wire enters shaft proximal to balloon and exits through the tip.

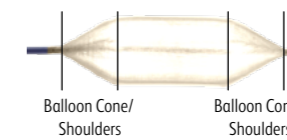


**Working Length:** Shaft length (cm) from bifurcate to tip of balloon.

**Total Length:** Working length plus the additional length outside the sheath.

**Guidewire Length:** Should be twice the total length of the balloon to facilitate loading product without losing access (for OTW; this rule does not apply to RX as the guidewire can be shorter).

**BALLOON CONE / SHOULDERS**



**Balloon Cone Angle:** Angle between the guidewire lumen and the portion of the balloon coming off the shaft and tip (balloon shoulders). A shallow cone angle offers a more gradual taper, smaller sheath compatibility and longer cone.

**Balloon Cone Length:** Horizontal distance from end of balloon to balloon shoulders.

**Balloon Working Length:** Horizontal distance between the shoulders of the balloon.

**PROFILE**

**Crossing Profile:** The diameter of the largest balloon profile along the distal half of the length of the deflated balloon and at the catheter tip (including the inner member or wire).

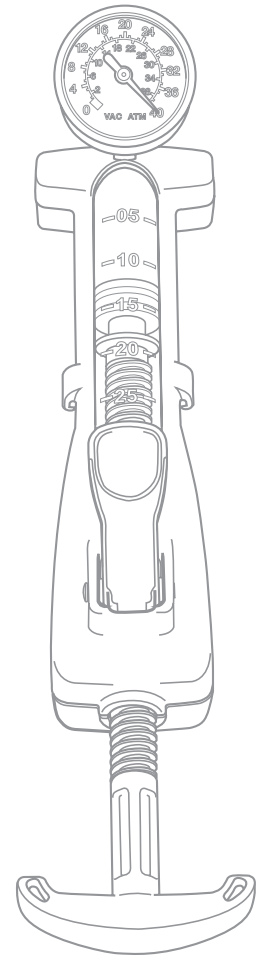
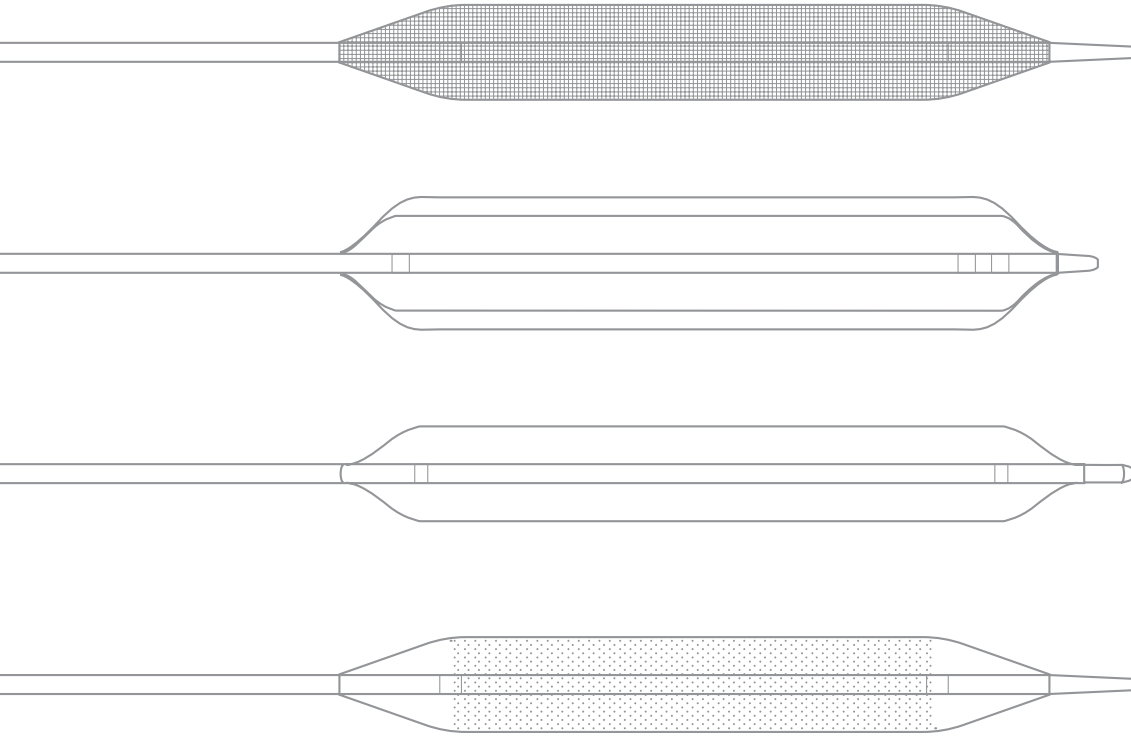
**Introducer Sheath Profile:** The internal diameter of the introducer. It is important to ensure that the catheter shaft outer diameter is less than the Introducer Sheath Profile in order to assure compatibility.

**Tip Entry Profile:** The diameter at the most distal portion of the tip of the balloon.

**Rupture Mode:** The manner in which a balloon bursts.

**Pin Hole Rupture:** Fiber-based balloons may rupture with a small hole in its material. Other materials often do not have this type of rupture because the material is more likely to rip, since it is not supported by fiber.

**Longitudinal Rupture:** A rip that runs lengthwise on the balloon. **Circumferential Rupture:** A rip that encircles the balloon. This is the most catastrophic type of rupture due to its risk of balloon material separation and embolization.



Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions.

For product availability, please consult BD representative in your country

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