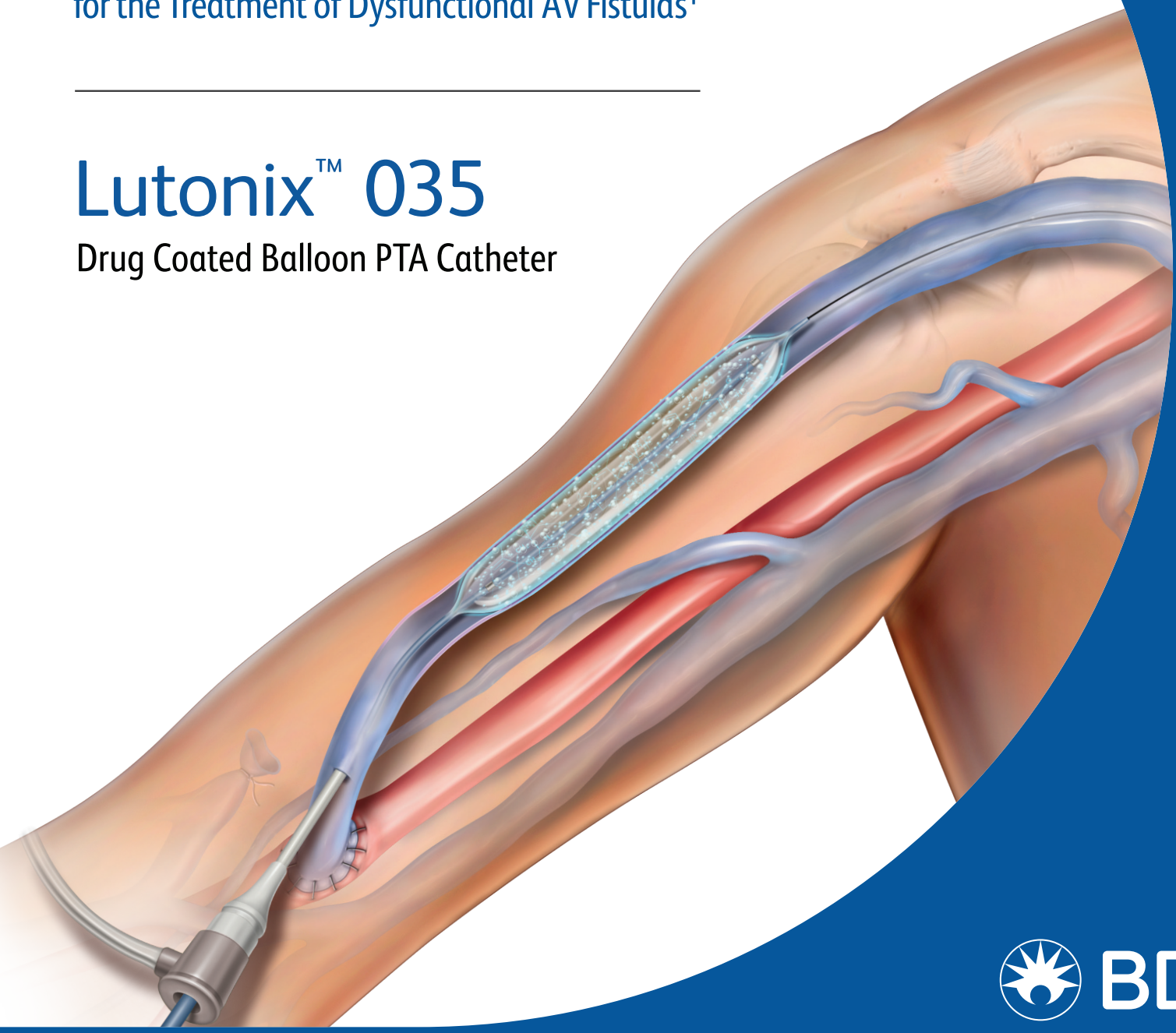
Extended Time to Reintervention

for the Treatment of Dysfunctional AV Fistulas[1]

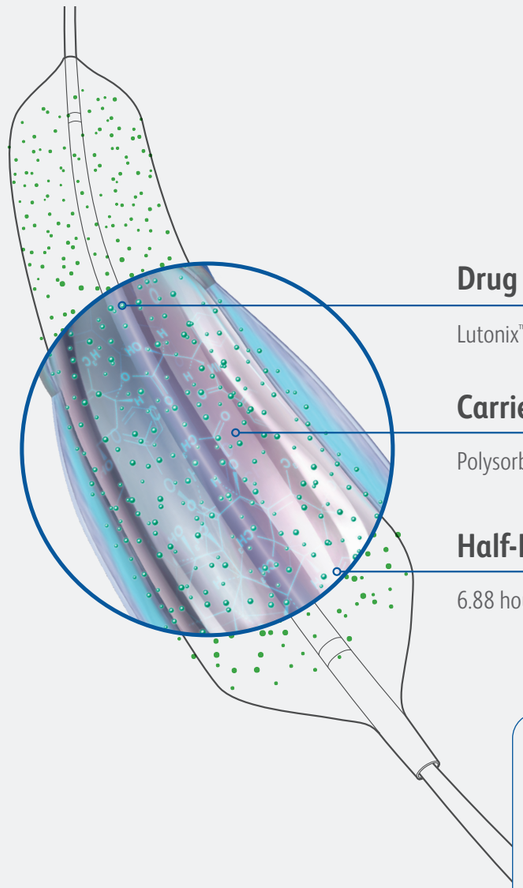
Lutonix™ 035

Drug Coated Balloon PTA Catheter



BD

Optimized DCB Design



Drug

Lutonix™ 035 DCB drug dose of paclitaxel is 2 µg/mm^2

Carriers

Polysorbate and Sorbitol

Half-Life

6.88 hours

Lutonix™ 035 DCB is designed to **inhibit restenosis** in the vessel wall while allowing the lumen to **restore and reendothelialize.**

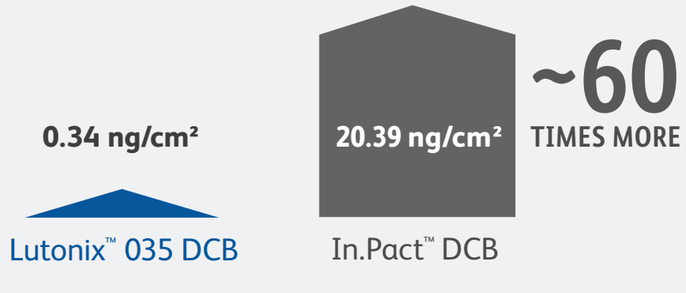
Coating Uniformity + **Drug Retention** + **Drug Release** = **Successful DCB Formulation**

Uniformity & Durability

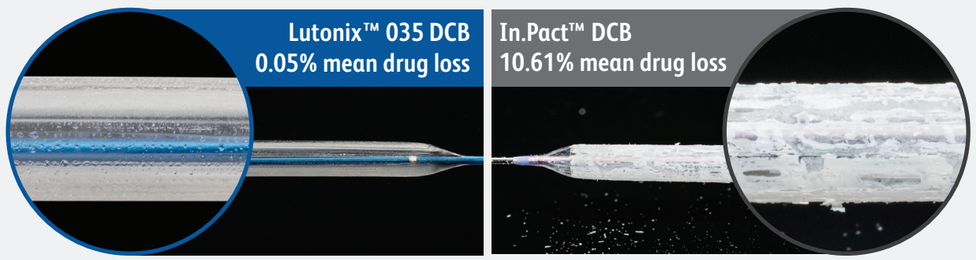
Lutonix™ 035 DCB has a **consistent coating** design that enables 360° paclitaxel treatment at the target vessel.

In simulated use testing, Lutonix™ 035 DCB **limited drug flaking** during preparation and handling, minimizing unnecessary drug exposure to staff and patients.[2]

Average Drug Lost During Simulated Clinical Preparation & Handling[2]



In a dry inflate **"shake test,"** the Lutonix™ 035 DCB showed 0.05% drug loss, on average.[3]



[2] The Simulated Clinical Use test measured average drug loss during simulated preparation and handling by performing a wipe test of the preparation area, using a swab method for quantifying trace amount of drug particles after simulated clinical use. Average drug loss for Lutonix™ 035 DCB was 0.34 ng/cm² or 0.00034 µg/mm² (n=21), whereas average drug loss for In.Pact™ was 20.39 ng/cm² or 0.02039 µg/mm² (n=18). Data on file. BD. Tempe, AZ. Bench test results may not be indicative of clinical performance. Different test methods may yield different results.

[3] The Dry Inflate/Shake test measured the average drug content lost after balloon was inflated, and after lightly knocking each device against the sides of the centrifuge tube, left and right, five times. n=5 for both devices tested. Data on file. BD. Tempe, AZ. Bench test results may not be indicative of actual clinical performance. Different test methods may yield different results.

Lutonix AV IDE Trial[1]

The Lutonix AV IDE Trial was the first U.S. trial to evaluate the use of a DCB for the treatment of dysfunctional AV fistulas.

Clinical Trial Design

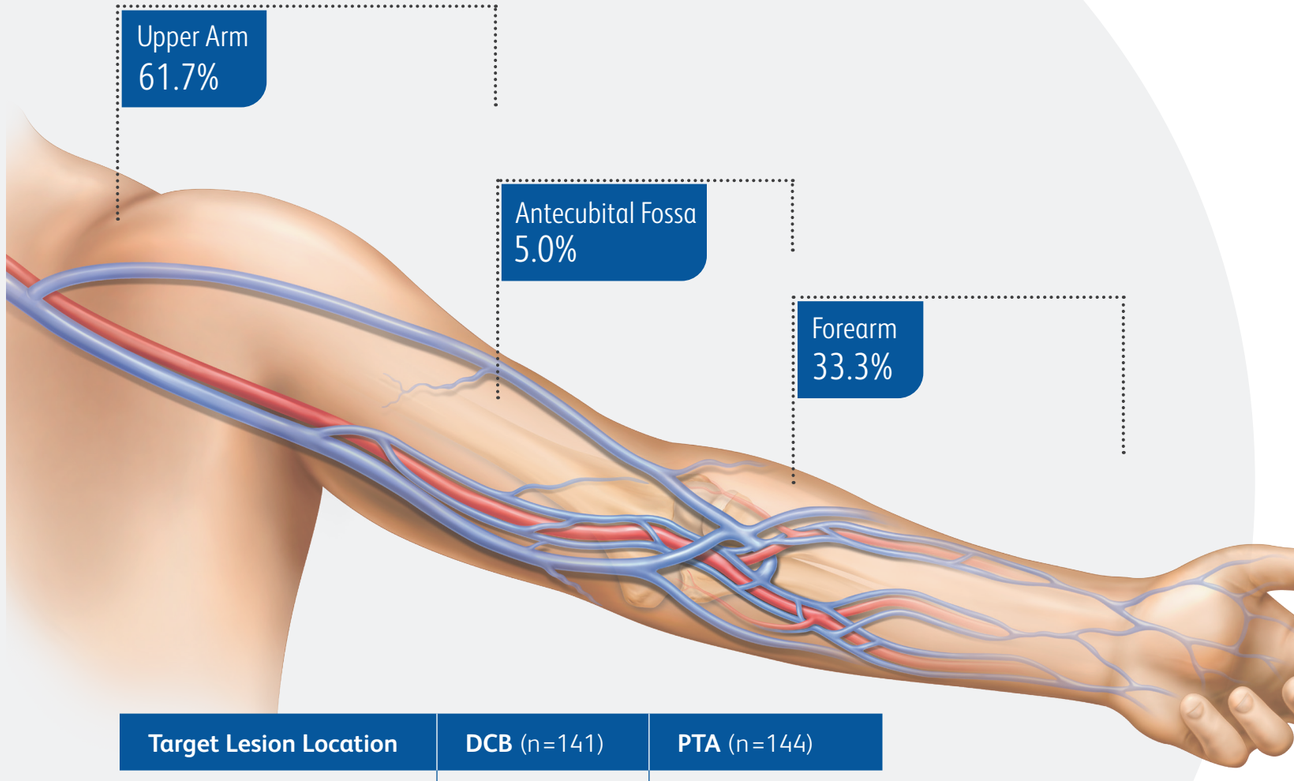
Study Design	Prospective, Global, Multi-Center, Randomized (1:1), Angiography Core Lab Blinded
Number of Patients/Sites	285 randomized subjects at 23 U.S. clinical sites
Primary Effectiveness Endpoint	Target Lesion Primary Patency (TLPP) at 180 days
Primary Safety Endpoint	Freedom from SAE(s) involving the AV access circuit through 30 days

Challenging patient population allowed:[4]

- Treated thrombosed access
- Covered stents in the access circuit
- Secondary non-target lesions

[4] The Lutonix AV IDE Trial allowed patients who underwent treatment of a thrombosed access >30 days prior to the index procedure, patent stents within the access circuit if they were not treated as the target or secondary non-target lesion, and secondary non-target lesions that were not central and could be successfully treated.

Lutonix™ 035 DCB Fistula Locations



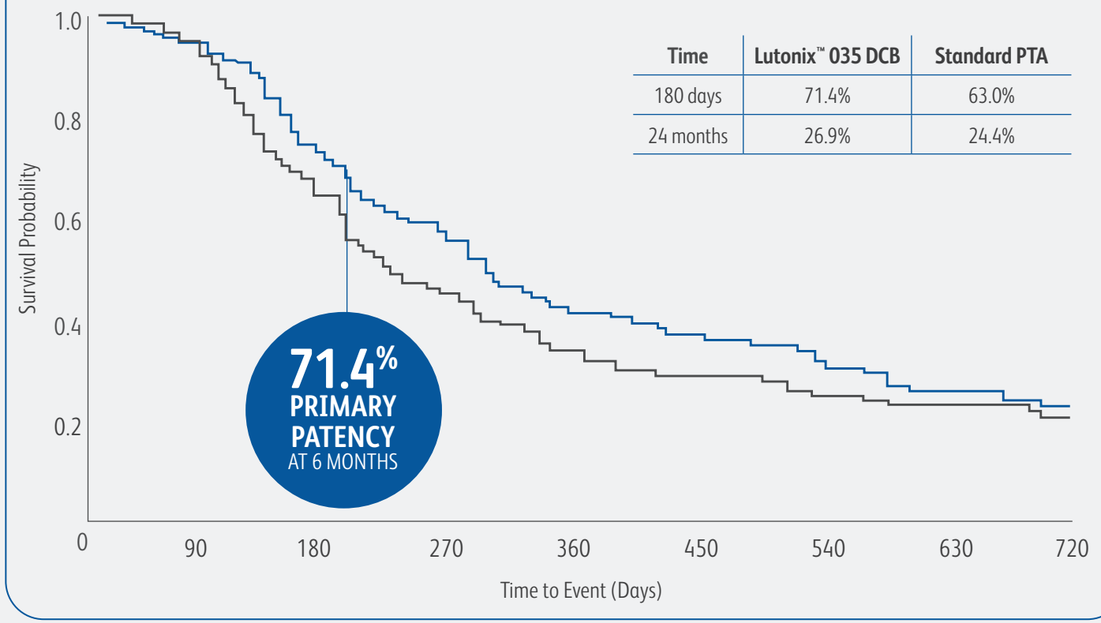
Target Lesion Location	**DCB** (n=141)	**PTA** (n=144)
Inflow	33.8%	29.6%
Outflow	24.5%	22.5%
Cephalic Arch	18.7%	22.5%
Swing Point	14.4%	12.0%
Cannulation Zone	4.3%	9.9%
Anastomotic	4.3%	3.5%

Lutonix AV IDE Trial
Measurable Outcomes[1]

Primary Patency

A trend towards sustained clinical benefit in target lesion primary patency was observed over long term follow-up at 9, 18 and 24 months following Lutonix™ 035 DCB treatment.

Kaplan-Meier Analysis of Target Lesion Primary Patency (TLPP)



Time	Lutonix™ 035 DCB	Standard PTA
180 days	71.4%	63.0%
24 months	26.9%	24.4%

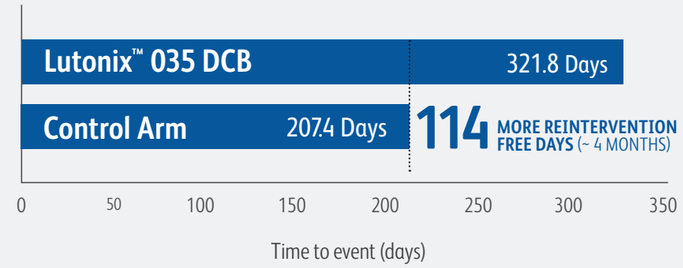
Lutonix™ 035 DCB

Standard PTA

Reinterventions

At 24 months' follow-up, patients treated with a Lutonix™ 035 DCB had gone an average of 321.8 days before first reintervention – 114 more days than patients treated with PTA alone.

Lutonix AV IDE Clinical Trial
Mean Time to First Reintervention



Safety

Lutonix™ 035 DCB met its primary safety endpoint and demonstrated a safety profile that was non-inferior to standard PTA.

95.0%
PRIMARY SAFETY ENDPOINT
AT 30 DAYS

[1] Lutonix AV IDE Trial. Data on file. BD. Tempe, AZ. At 6 months, treatment with Lutonix™ 035 DCB resulted in a target lesion patency rate of 71.4% versus 63.0% with standard PTA alone. Target lesion primary patency defined as freedom from 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. At 30 days, treatment with Lutonix™ 035 DCB was associated with 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. At 24 months' follow-up, the average days before first reintervention was found to be longer for patients treated with a Lutonix™ 035 DCB (321.8 vs. 207.4, p<0.0001).

Lutonix™ 035

Drug Coated Balloon PTA Catheter **Model 9010**

Diameter (mm)	Length (mm)	RBP (atm)	Sheath Profile	Shaft Length	
				75 cm	100 cm
4	40	12	5F	☐ LX3575440V	
	60	12	5F	☐ LX3575460V	
	80	12	5F	☐ LX3575480V	
	100	12	5F	☐ LX35754100V	
5	40	12	5F	☐ LX3575540V	
	60	12	5F	☐ LX3575560V	
	80	12	5F	☐ LX3575580V	
	100	12	5F	☐ LX35755100V	
6	40	12	5F	☐ LX3575640V	
	60	12	5F	☐ LX3575660V	
	80	12	5F	☐ LX3575680V	
	100	12	5F	☐ LX35756100V	
7	40	12	5F	☐ LX3575740V	
	60	12	5F	☐ LX3575760V	
	80	10	5F	☐ LX3575780V	
	100	10	5F	☐ LX35757100V	
8	40	10	6F	☐ LX3575840V	☐ LX35100840V
	60	10	6F	☐ LX3575860V	☐ LX35100860V
	80	10	6F	☐ LX3575880V	☐ LX35100880V
	100	10	6F	☐ LX35758100V	☐ LX351008100V
9	40	11	7F	☐ LX3575940V	☐ LX35100940V
	60	11	7F	☐ LX3575960V	☐ LX35100960V
	80	10	7F	☐ LX3575980V	☐ LX35100980V
10	40	10	7F	☐ LX35751040V	☐ LX351001040V
	60	10	7F	☐ LX35751060V	☐ LX351001060V
12	40	10	7F	☐ LX35751240V	☐ LX351001240V
	60	10	7F	☐ LX35751260V	☐ LX351001260V

Indications for Use: The Lutonix™ Catheter is indicated for percutaneous transluminal angioplasty (PTA), after pre-dilatation, for treatment of stenotic lesions of dysfunctional native arteriovenous dialysis fistulae that are 4 mm to 12 mm in diameter and up to 80 mm in length.

Contraindications: 1) Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children over the next 2 years. It is unknown whether paclitaxel will be excreted in human milk and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. 2) Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.

Warnings: 1) Contents supplied STERILE using ethylene oxide (EO) process. Do not use if sterile barrier is damaged or opened prior to intended use. 2) Do not use after the "Use by" date. 3) Do not use if product damage is evident. 4) The Lutonix™ Catheter is for use in one patient only; do not reuse in another patient, reprocess or resterilize. Risks of reuse in another patient, reprocessing, or resterilization include: · Compromising the structural integrity of the device and/or device failure which, in turn, may result in patient injury, illness or death. · Creating a risk of device contamination and/or patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to patient injury, illness or death. 5) Do not exceed the Rated Burst Pressure (RBP) recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressurization, use of a pressure monitoring device is recommended. 6) Use the recommended balloon inflation medium of contrast and sterile saline (≤50% contrast). Never use air or any gaseous medium to inflate the balloon as this may cause air emboli in case of balloon burst. 7) This product should not be used in patients with known hypersensitivity to paclitaxel or structurally related compounds as this may cause allergic reaction (difficulty in breathing, skin rash, muscle pain).

Potential Adverse Events: Potential adverse events which may be associated with a PTA balloon dilation procedure include, but are not limited to, the following: · Additional intervention · Allergic reaction to drugs or contrast medium · Aneurysm or pseudoaneurysm · Arrhythmias · Embolization · Hematoma · Hemorrhage, including bleeding at the puncture site · Hypotension/hypertension · Inflammation · Loss of permanent access · Occlusion · Pain or tenderness · Sepsis/infection · Shock · Stroke · Steal Syndrome · Thrombosis · Vessel dissection, perforation, rupture, or spasm. Although systemic effects are not anticipated, refer to the Physicians' Desk Reference for more information on the potential adverse events observed with paclitaxel. Potential adverse events, not described in the above source, which may be unique to the paclitaxel drug coating include, but are not limited to, the following: · Allergic/immunologic reaction to the drug coating (paclitaxel) · Alopecia · Anemia · Blood product transfusion · Gastrointestinal symptoms · Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) · Hepatic enzyme changes · Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis · Myalgia/Arthralgia · Myelosuppression · Peripheral neuropathy

The products referenced herein do not have the exact same indications for use. Please consult respective product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions. ℞ only

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