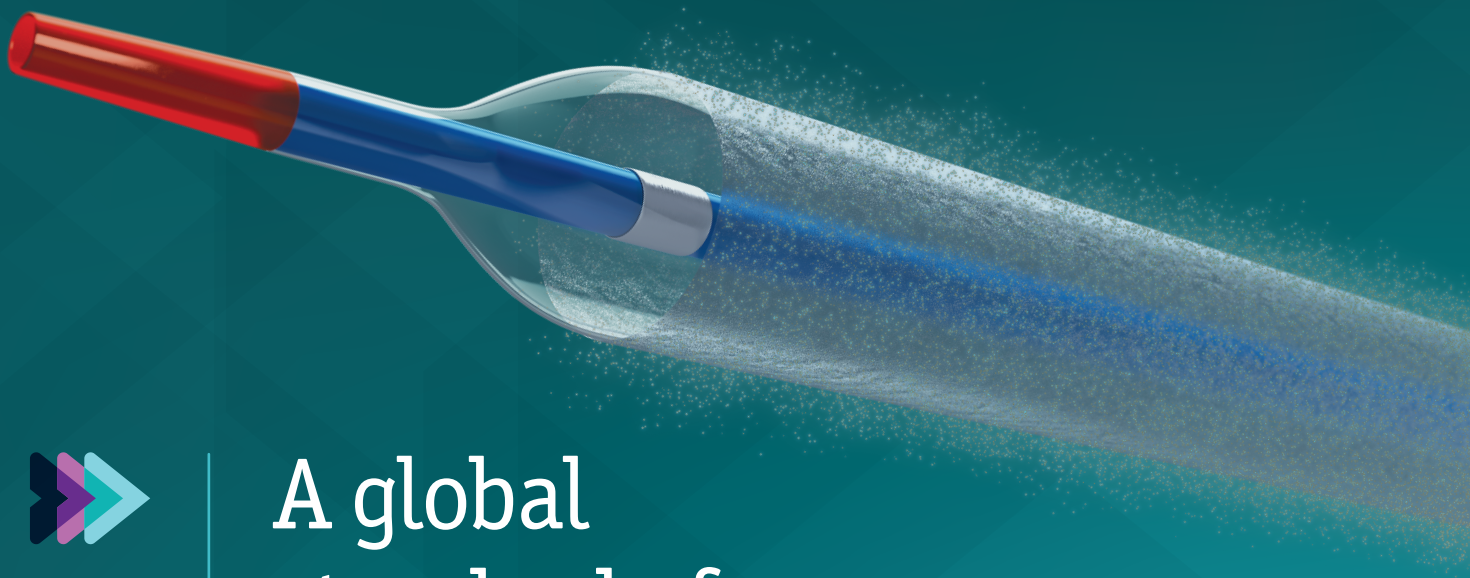
Boston Scientific
Advancing science for life™

AGENT™
Drug-Coated Balloon

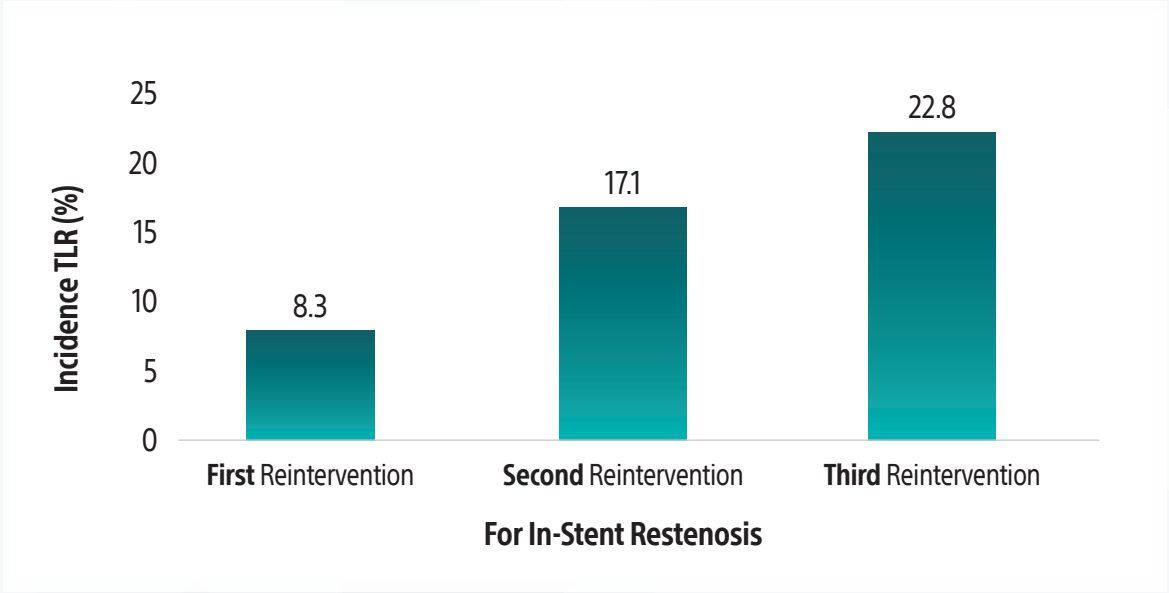


A global
standard of care.
Now in the U.S.

~10% of PCIs are complicated by in-stent restenosis (ISR)[1]

Currently, **82% of patients with ISR** receive another stent,[2] which is associated with a higher risk of target lesion revascularization.[3]

Repeat intervention associated with higher risk of target lesion revascularization for ISR[3]



The ISR treatment option you've been waiting for

For patients with ISR, placing additional stents increases risks including thrombosis[4] and future ISR.[5,6] Coronary drug-coated balloons (DCBs) provide a proven alternative and have been used to treat more than 1 million patients worldwide[10].

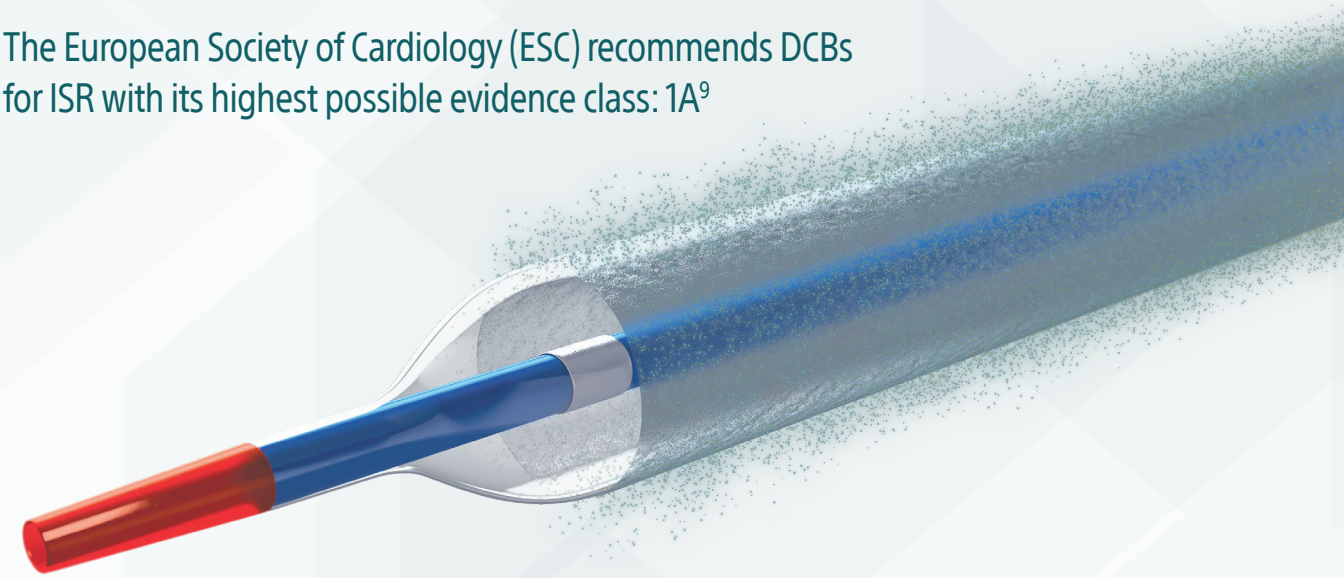
DCB benefits in ISR treatment

Avoid additional layers of metal
Reducing potential stent-related complications

Expand treatment options
Leaving no metal behind for lifetime patient management

Shorten the duration of DAPT[7]
Which may result in a reduced rate of medication-related bleeding complications[8]

The European Society of Cardiology (ESC) recommends DCBs for ISR with its highest possible evidence class: 1A[9]



An AGENT of change for ISR treatment

AGENT DCB – the first and only coronary DCB approved for use in the U.S. – expands treatment options for physicians and their patients by delivering a targeted anti-proliferative drug dose, without introducing an extra layer of metal.

100,000+ patients treated[10]

4,400+
evaluated or undergoing evaluation with the AGENT Drug-Coated Balloon[10]

FDA Breakthrough Status
Received January 2021[11]

TransPax™ Coating Technology

With the right balance of hydrophilic and hydrophobic characteristics, the proprietary TransPax Coating Technology maximizes drug transfer to the target vessel wall and delivers the right amount of treatment exactly where it's needed.

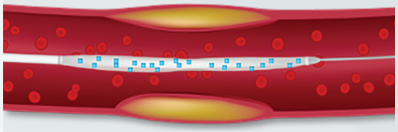
Low balloon Paclitaxel (PTX) load at 2µg/mm^2 + Novel Excipient Acetyl Tributyl Citrate (ATBC) + Proprietary Coating Technology →

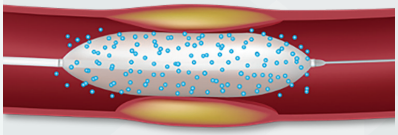
TransPax™

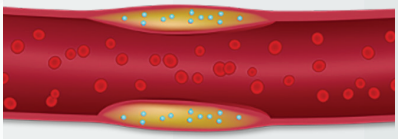
Right Drug. Right Design.

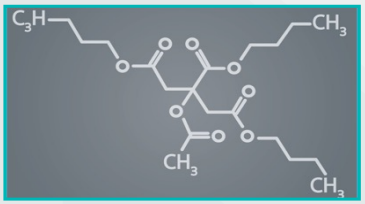
AGENT Drug-Coated Balloon uses paclitaxel, the drug used in the majority of DCBs worldwide. AGENT DCB is designed with a novel excipient, sharp-edge structure, and uniform crystalline formulation. As a result, AGENT transfers more drug to the tissue and less of it downstream.

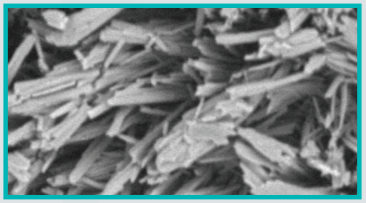
Design Requirement	Paclitaxel (PTX) Drug Choice	AGENT Coating Design
1 **Targeted Transfer** Balloon to vessel wall	**Hydrophobic** Paclitaxel is durable under hydration	**Optimized Excipient** ATBC maximizes balloon-to-vessel wall transfer
2 **Rapid Absorption** Vessel wall to tissue	**Lipophilic** Paclitaxel has a high affinity for fatty tissue	**Sharp-Edge Structure** Needlelike coating improves tissue penetration
3 **Sustained Retention** Prolonged tissue concentration	**Chemically Stable** Paclitaxel has a long half-life	**Crystalline Formulation** Crystallized coating maintains therapeutic effect

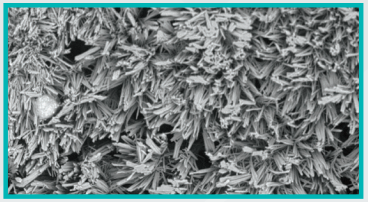






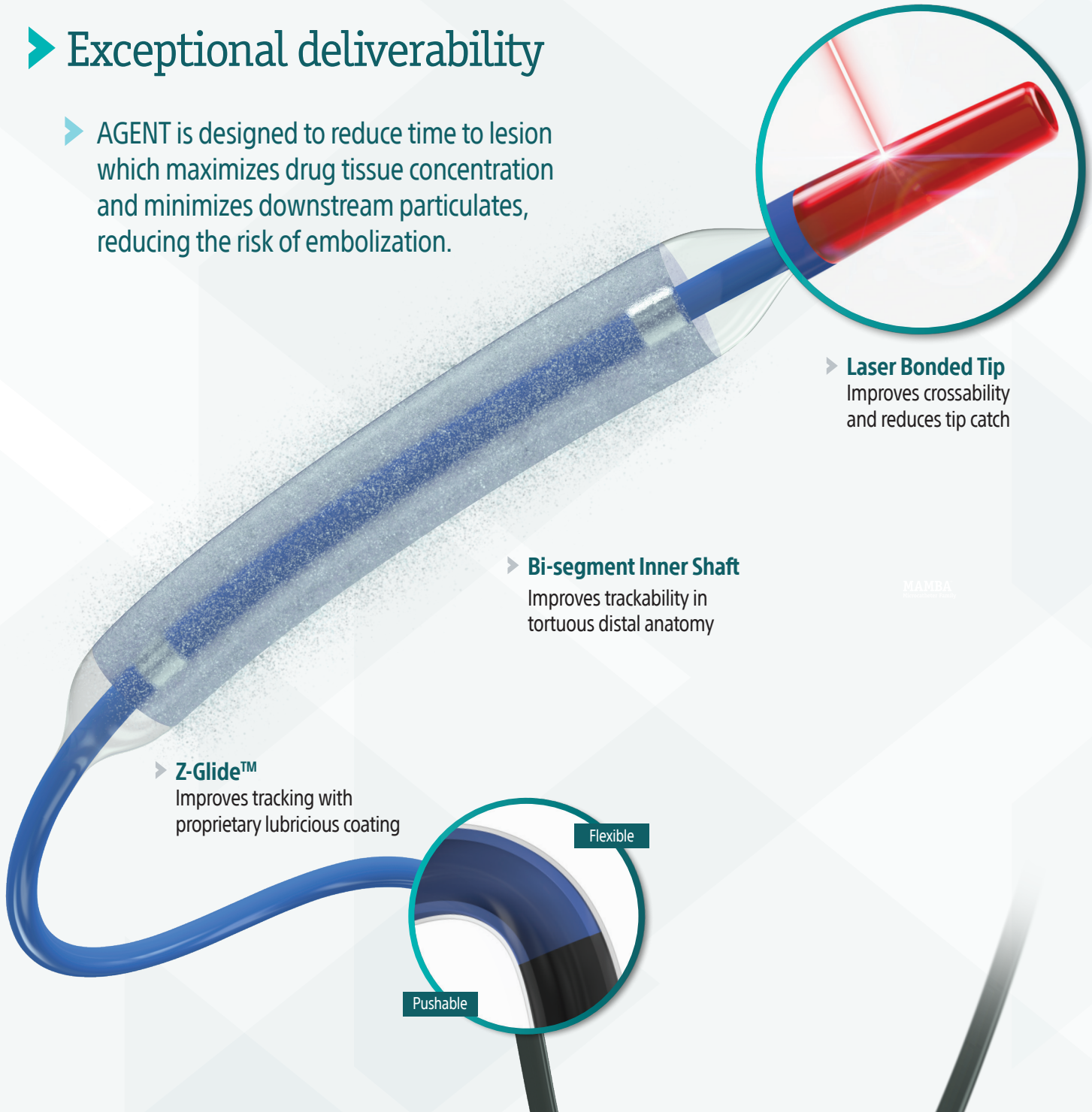






Exceptional deliverability

AGENT is designed to reduce time to lesion which maximizes drug tissue concentration and minimizes downstream particulates, reducing the risk of embolization.



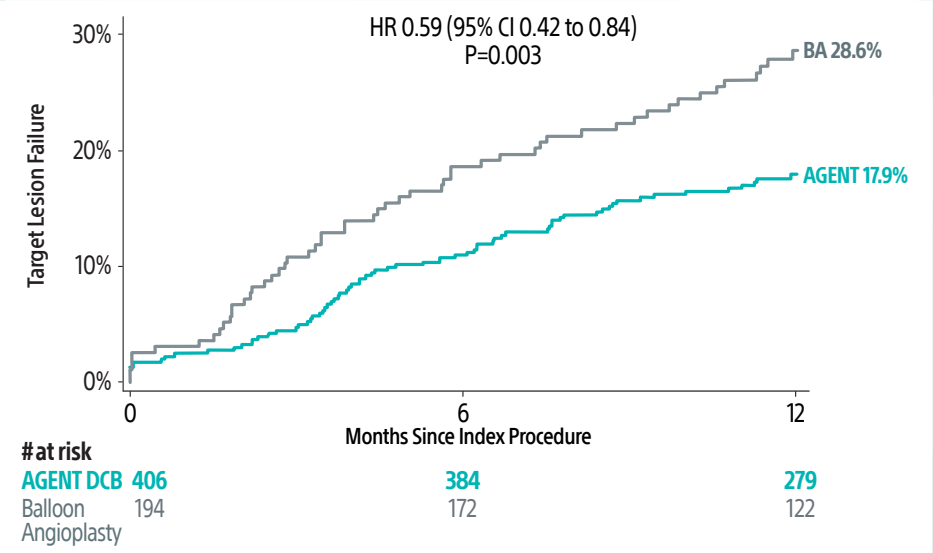
Proven clinical performance

AGENT Drug-Coated Balloon has shown consistently low rates of target lesion revascularization (TLR), stent thrombosis, and late lumen loss[19]. In the first U.S. clinical trial evaluating the safety and effectiveness of a coronary DCB compared to balloon angioplasty in patients with ISR, AGENT demonstrated statistical superiority.[20]

Primary Endpoint: TLF at 1-Year

41%
relative risk reduction for **TLF**

NNT=9 Patients*



At one-year, AGENT DCB also demonstrated statistically lower event rates[20]:

50%
risk reduction for **TLR**
(13.0% vs. 24.7%, P=0.0005)

49%
risk reduction for **TV-MI**
(5.8% vs. 11.1%, P=0.023)

0%
ZERO def/prob ST
(0.0% vs. 3.2%, P=0.0004)

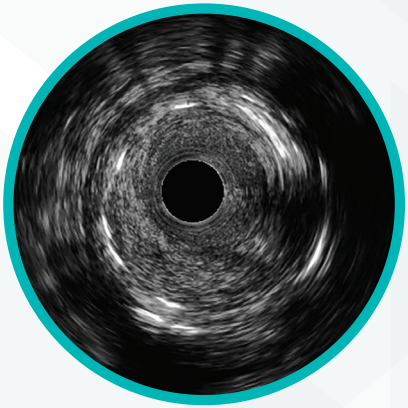
*Number Needed to Treat to prevent 1 TLF

Effective ISR treatment starts with imaging

While AGENT Drug-Coated Balloon provides you with another option for ISR treatment, determining the right treatment for your patients starts with imaging. With the most comprehensive Modern PCI portfolio on the market, Boston Scientific has the tools needed to See, Prep, and Treat ISR.

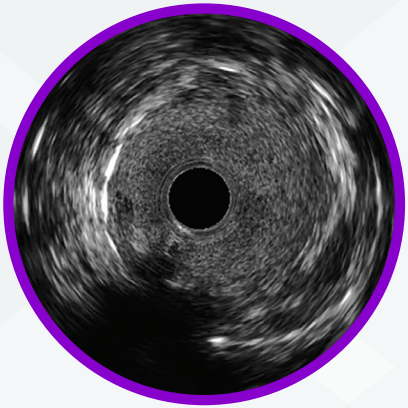
Modern PCI tools and techniques give you the inside knowledge to improve long-term outcomes in patients' lives.

SEE



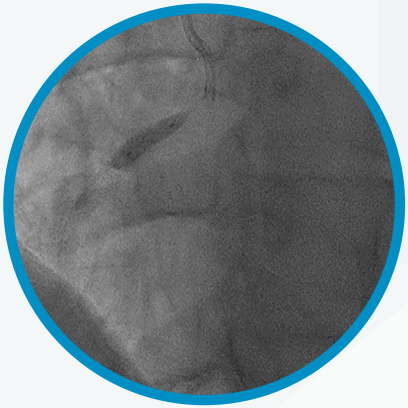
HD-IVUS defines the extent and type of disease

PREP



HD-IVUS confirms lesion modification and helps determine the most appropriate treatment

TREAT



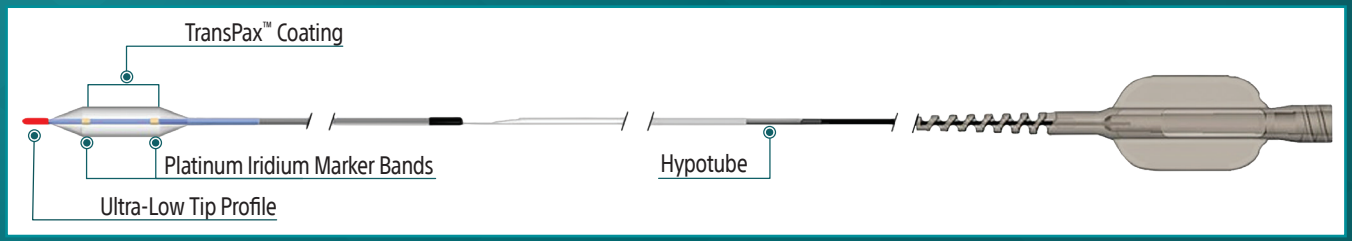
Final Angio confirms final result*

*Optional intravascular imaging to confirm final results and ensure no flow-limiting dissection

Product Details

Indications for use	The AGENT Paclitaxel-Coated Balloon Catheter is intended to be used after appropriate vessel preparation in adult patients undergoing percutaneous coronary intervention (PCI) in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR).			
Drug coating	The TransPax™ drug coating is a proprietary formulation of paclitaxel and a citrate ester excipient (acetyl tributyl citrate—ATBC). The AGENT balloon catheter is designed to prevent hyperplasia of smooth muscle cells at the treated lesion site.			
Drug dose	2.0 µg per mm^2 of the balloon surface			
Recommended inflation time	At least 30 seconds			
Antiplatelet regimen	Recommended for a minimum of 1 month after treatment*			
Available balloon lengths	In mm: 12, 15, 20, 30			
Available balloon diameters	In mm: 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00			
Lesion entry profile	0.017 in (0.43 mm)			
Delivery system effective length	144 cm			
Delivery system port	Designed for 0.014 in (0.36 mm) guidewire			
Balloon material	OptiLEAP™			
Shelf life	24 months			
Sterilization	Ethylene Oxide (EO)			
Single/multiple use	Single use			
Guide catheter compatibility	5 F (1.67 mm) / ID 0.056 in (1.42 mm)			
Catheter shaft outer diameter	**Distal shaft**	Diameter	Balloon length	Outer diameter
		2.00 mm	12 mm to 20 mm	2.3 F
		2.00 mm	30 mm	2.4 F
		2.25, 2.50, 2.75 mm	all lengths	2.4 F
		3.00 mm	12 mm to 20 mm	2.4 F
		3.00 mm	30 mm	2.7 F
		3.50 mm and 4.00 mm	all lengths	2.7 F
	Proximal shaft	Diameter	Balloon length	Outer diameter
		2.00, 2.25, 2.50, 2.75 mm	all lengths	1.8 F
		3.00 mm	12 mm to 30 mm	1.8 F
		3.50 mm	12 mm to 20 mm	1.8 F
		4.00 mm	12 mm and 15 mm	1.8 F
		3.50 mm	30 mm	1.9 F
		4.0 mm	20 mm to 30 mm	1.9 F
Marker band material	Platinum Iridium			
Marker band placement	The outside edges of the marker bands indicate the balloon's shoulders and coated region			

* The AGENT DCB IDE required that enrolled subjects receive a minimum of 1-month of DAPT followed by antiplatelet monotherapy for the duration of the study. In accordance with this information and expert consensus, physicians should use their clinical judgement with each patient in deciding on the duration of DAPT following use of AGENT DCB.



Compliance Chart

Drug-Coated Balloon Size (mm)

Pressure atm (kPa)	2.00	2.25	2.50	2.75	3.00	3.50	4.00
3.0 (304)	1.86	2.06	2.28	2.53	2.76	3.19	3.66
4.0 (405)	1.93	2.14	2.37	2.61	2.85	3.30	3.80
5.0 (507)	1.99	2.20	2.44	2.68	2.93	3.39	3.88
6.0 (608)	2.03	2.26	2.50	2.75	3.00	3.46	3.96
7.0 (709)	2.07	2.31	2.55	2.81	3.06	3.52	4.04
8.0 (811)	2.10	2.34	2.59	2.85	3.11	3.57	4.09
9.0 (912)	2.13	2.38	2.62	2.88	3.15	3.61	4.14
10.0 (1013)	2.15	2.40	2.65	2.91	3.18	3.64	4.18
11.0 (1115)	2.18	2.42	2.67	2.94	3.21	3.68	4.22
12.0 (1216)	2.19	2.44	2.69	2.96	3.23	3.72	4.25
13.0 (1317)	2.21	2.46	2.72	2.99	3.26	–	–
14.0 (1419)	2.23	2.48	2.74	3.02	3.28	–	–

Nominal Pressure Rated Burst Pressure. Do Not Exceed.

Ordering Information

Ø (mm)	12mm	15mm	20mm	30mm
2.00	H749 396081220 0	H749 396081520 0	H749 396082020 0	H749 396083020 0
2.25	H749 396081222 0	H749 396081522 0	H749 396082022 0	H749 396083022 0
2.50	H749 396081225 0	H749 396081525 0	H749 396082025 0	H749 396083025 0
2.75	H749 396081227 0	H749 396081527 0	H749 396082027 0	H749 396083027 0
3.00	H749 396081230 0	H749 396081530 0	H749 396082030 0	H749 396083030 0
3.50	H749 396081235 0	H749 396081535 0	H749 396082035 0	H749 396083035 0
4.00	H749 396081240 0	H749 396081540 0	H749 396082040 0	H749 396083040 0

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℞ ONLY

AGENT™ MONORAIL™ Paclitaxel-Coated Balloon Catheter

INTENDED USE / INDICATIONS FOR USE The AGENT Paclitaxel-Coated Balloon Catheter is intended to be used after appropriate vessel preparation in adult patients undergoing percutaneous coronary intervention (PCI) in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR). **CONTRAINDICATION** Use of the AGENT Drug-Coated Balloon Catheter is contraindicated in the following: • Use in the supra-aortic/cerebrovascular arteries. • Unprotected native left main coronary artery disease. • Coronary artery spasm in the absence of a significant stenosis. • Patients with known hypersensitivity to paclitaxel (or structurally-related compounds). • Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy. • Pregnant or breast-feeding women or women who are intending to become pregnant, or men intending to father children. **WARNINGS** • The drug-coated balloon catheter should only be used by physicians experienced in percutaneous coronary intervention. • As for all PCI procedures, the need for on-site surgical backup should be considered per the 2023 SCAI Expert Consensus Statement on Percutaneous Coronary Interventions Without On-Site Surgical Backup. • As for all PCI procedures, use in patients who are not acceptable candidates for open heart surgery requires careful consideration, including possible hemodynamic support during the procedure, as treatment of this patient population carries special risk. • Use extreme caution and careful judgment in patients who have severe reaction to contrast agents that cannot be adequately pre-medicated. • Use only the recommended balloon inflation medium (50:50 mixture of contrast medium and sterile saline solution). Never use air or any gaseous medium to inflate the balloon. • When the balloon catheter is exposed to the vascular system, it should be manipulated using high-quality fluoroscopic observation. • Do not advance or withdraw the catheter unless the drug-coated balloon is fully deflated under vacuum. If unusual resistance is felt during manipulation, determine the cause of the resistance before proceeding. If the source of resistance cannot be determined, it is recommended to extract the entire system (as a unit) with the guide catheter. • If difficulty is experienced during drug-coated balloon treatment, do not continue. Deflate the device and remove the catheter. • To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel just proximal and distal to the stenosis. • Do not exceed the rated burst pressure indicated on the compliance chart. Use of an inflation device is recommended to assure accurate pressurization. • If difficulty is experienced removing the device, other retrieval methods (additional wires, snares and/or forceps) may cause vessel trauma. Complications can include but are not limited to bleeding, hematoma, or pseudoaneurysm. • The safety and effectiveness of using more than one AGENT DCB to treat a single lesion or multiple lesions/vessels per procedure has not been established. Preclinical studies suggest that use of multiple DCBs within a single coronary vessel may be associated with downstream perivascular inflammatory injury as a consequence of microvascular obstruction **PRECAUTIONS** • Any use for procedures other than those indicated in these instructions is not recommended. • Use the drug-coated balloon catheter prior to the "Use By" date specified on the package. • The treatment site should be adequately prepared (intravascular imaging guidance recommended) to achieve the maximum lumen diameter prior to treatment with AGENT Drug-Coated Balloon. **Note:** Current US and European PCI guidelines recommend intravascular imaging (IVUS) to identify the mechanism of stent failure. • Drug-coated balloon PCI should be used with caution during procedures involving calcified vessels due to the abrasive nature of these lesions. • Significant stenosis (> 50 %) proximal to the treatment site must be pretreated to prevent abrasion and delamination of the balloon's drug coating while crossing the lesion. • Precautions to prevent or reduce thrombosis should be taken during any PCI procedure: ○ The patient should be treated with heparin or similar agent during the procedure. ○ Flush all products entering the vascular system with heparinized sterile isotonic saline or a similar solution prior to use. • Carefully inspect the drug-coated balloon catheter prior to use to verify it has not been damaged during shipment or preparation; confirm that its size, shape, and condition are suitable for the procedure **Note:** After removing the balloon protector, a white powdery substance may be observed inside the balloon protector and will not impact the delivered drug dose. • If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the AGENT device and replace with another. • Do not expose the drug-coated balloon catheter to organic solvents such as alcohol or detergents. • When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire with heparinized saline to improve catheter movement on the guidewire. • Do not touch, wipe, bend, or squeeze the drug-coated balloon, or allow it to come into contact with any liquids prior to insertion as damage to the device's drug coating or premature release of the drug may occur. • If using a Tuohy-Borst type adapter, take care to not over-tighten the hemostatic valve around the catheter shaft as lumen constriction may occur, affecting inflation/deflation or damaging the device's drug coating. • Never advance the drug-coated balloon catheter without the guidewire extending from the tip. Do not use the AGENT DCB if the lesion is unable to be crossed with a guidewire. • The AGENT DCB is indicated for lesions up to 26 mm using one balloon. The safety and effectiveness of treating lesions longer than 26 mm has not been established. When clinically warranted, observe the following precautions to prevent local drug overdosing: ○ If treating a long lesion (longer than the maximum balloon length available), each individual segment should be treated only once with a drug-coated balloon. Treat each segment with a new balloon and try to minimize overlapping the treated segments. ○ Do not use a second drug-coated balloon at the same treatment site. • The AGENT DCB was not studied clinically with use of bail out stenting, including drug-eluting stent (DES). Implanting a drug-eluting stent at the same treatment site may have added risks, including overdosage or interaction between the active agents. • Published literature has reported paclitaxel caused cell aneuploidy at tissue concentrations similar to tissue concentrations recorded after treatment with an AGENT Drug-Coated Balloon in preclinical studies. The aneugenic effect is due to paclitaxel's pharmacodynamic action of interfering with microtubule disassembly, which is also the basis for the pharmacodynamic action preventing restenosis in vascular tissue following treatment with an AGENT Drug-Coated Balloon. The relevance of both this observation and the aneugenic mechanism of genotoxicity for human carcinogenicity is currently not known. • The AGENT Drug-Coated Balloon has not been tested in pregnant women or in men intending to father children; effects on the developing fetus have not been studied. The risks and reproductive effects of paclitaxel administered through the coronary vasculature remain unknown. The AGENT Drug-Coated Balloon is contraindicated for use in women who are pregnant or attempting to conceive, or men intending to father children. It is not known whether paclitaxel is distributed in human milk. In lactating rats given paclitaxel, milk concentrations appeared to be higher than maternal plasma levels and declined in parallel with the maternal levels. • Possible interactions between paclitaxel and concomitantly administered medications have not been formally investigated. Drug interactions of systemic chemotherapeutic levels of paclitaxel with possible concomitant medications are outlined in the labeling for finished pharmaceuticals containing paclitaxel, such as TAXOL. • The optimal duration of dual anti-platelet therapy (DAPT) post PCI for ISR is currently unknown. Published expert consensus opinion has suggested that DAPT should be used for a minimum of one month post ISR PCI. While the AGENT DCB IDE required that enrolled subjects receive a minimum of 1-month of DAPT followed by antiplatelet monotherapy for the duration of the study, more than 70 % of enrolled patients remained on DAPT for at least 1 year. In conjunction with this information, operators should use clinical judgment in deciding on the duration of DAPT following use of AGENT DCB. **ADVERSE EVENTS** Potential adverse events which may be associated with the use of a drug-coated balloon (DCB) or DCB procedure include, but are not limited to, the following: • Additional, possibly surgical, intervention • Allergy (drug coating and its components, device, medications, contrast) • Arrhythmia including conduction system disorder. • Bleeding (including hemorrhage or hematoma possibly requiring transfusion or additional intervention) • Cerebrovascular accident (stroke)/transient ischemic attack (TIA) • Death • Embolism (tissue, plaque, thrombus, device, drug coating) • Fever/inflammation • Hemodynamic instability • Hypotension/hypertension (shock) • Kidney injury/failure • Myocardial ischemia/infarction • Organ insufficiency/failure (heart, liver, lungs • Pain (anginal, non-anginal) • Pericardial effusion/cardiac tamponade • Radiation injury • Sepsis/infection • Slow flow/no reflow • Vessel injury (spasm, dissection, perforation, rupture, arteriovenous fistula, aneurysm) • Vessel occlusion (abrupt closure, slow flow/no reflow, thrombosis, restenosis) Potential adverse events not captured above that have been associated with administration of paclitaxel at systemic doses, include, but are not limited to, the following: • Abnormal liver enzymes • Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) • Alopecia • Anemi • 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 • Peripheral neuropathy IC-1821709-AA

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. The material not intended for use in France.

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