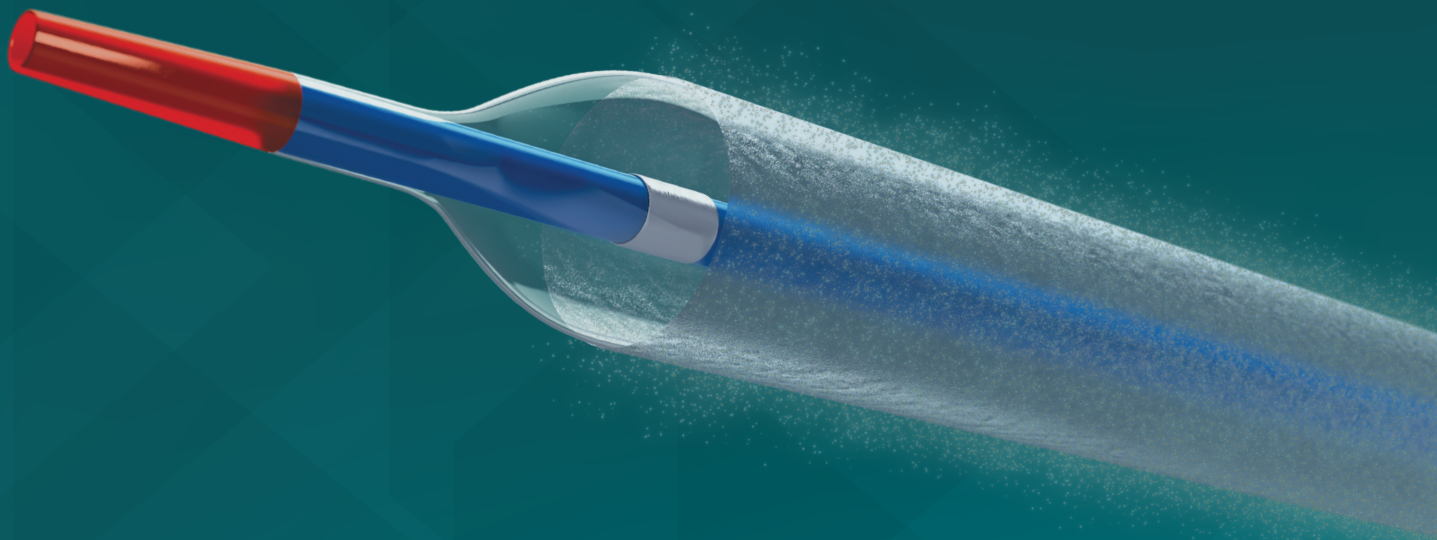


AGENT™

Drug-Coated Balloon



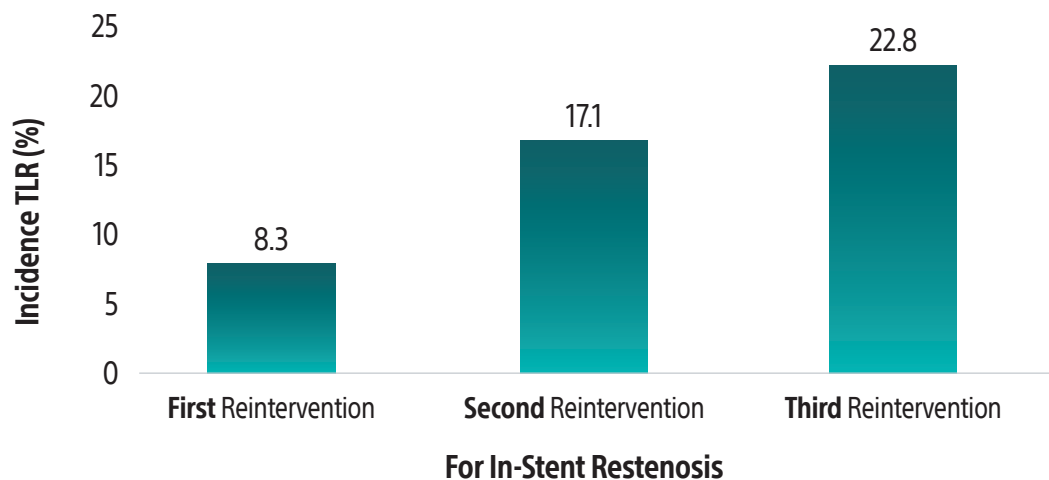
Leave the Right
AGENT Behind

➤ ~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 ISR³



➤ The ISR treatment option you've been waiting for

For patients with ISR, placing additional stents increases risks including thrombosis⁴ 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.⁷

➤ DCB benefits in ISR treatment



Avoid additional layers of metal⁸

Reducing potential stent-related complications



Expand treatment options

Leaving no metal behind for lifetime patient management



Shorten the duration of DAPT^{9*}

Which may result in a reduced rate of medication-related bleeding complications

➤ The European Society of Cardiology (ESC) for myocardial revascularization recommends drug coated balloons (DCBs) for ISR with its highest possible evidence class: 1A¹⁰



*Recommended DAPT for a minimum of 1 month after treatment. The AGENT IDE trial 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.

➤ An AGENT of change for ISR treatment

AGENT Drug-Coated Balloon – 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.



275,000+ patients treated¹¹

16,000+

evaluated or undergoing
evaluation with the AGENT
Drug-Coated Balloon¹¹



FDA Breakthrough Status
Received January 2021¹²

➤ 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.



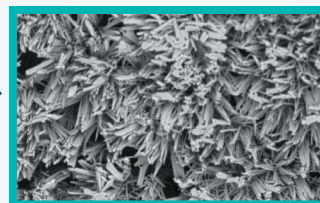
Low balloon
Paclitaxel (PTX)
load at $2\mu\text{g}/\text{mm}^2$



Novel Excipient Acetyl
Tributyl Citrate (ATBC)



Proprietary Coating
Technology



TransPax™

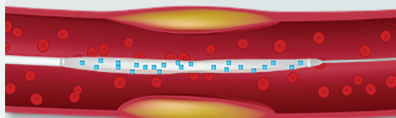
➤ Right Drug. Right Design.

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

1

Targeted Transfer
Balloon to vessel wall



Hydrophobic

Paclitaxel is durable under hydration

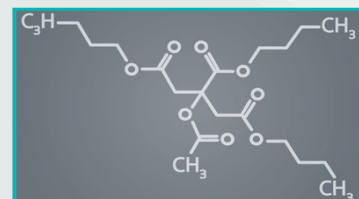


➤ Paclitaxel (PTX) Drug Choice

➤ AGENT Coating Design

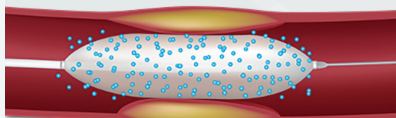
Optimized Excipient

ATBC maximizes balloon-to-vessel wall transfer



2

Rapid Absorption
Vessel wall to tissue



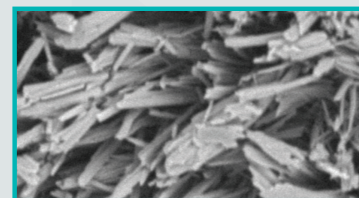
Lipophilic

Paclitaxel has a high affinity for fatty tissue



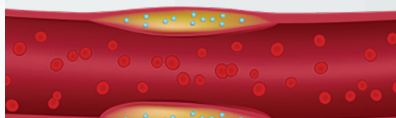
Sharp-Edge Structure

Needlelike coating improves tissue penetration



3

Sustained Retention
Prolonged tissue concentration



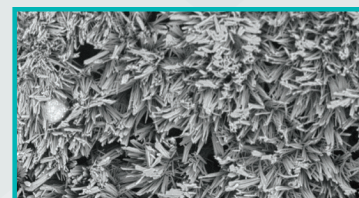
Chemically Stable

Paclitaxel has a long half-life



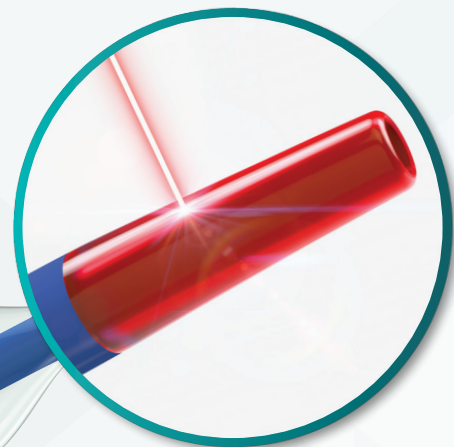
Crystalline Formulation

Crystallized coating maintains therapeutic effect



➤ Exceptional deliverability

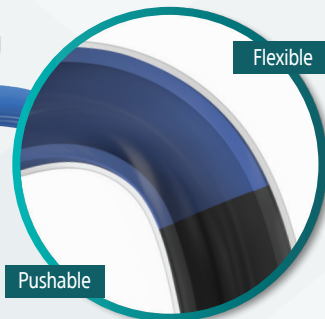
- AGENT Drug-Coated Balloon is designed to reduce time to lesion which maximizes drug tissue concentration and minimizes downstream particulates, reducing the risk of embolization.



- **Laser Bonded Tip**
Improves crossability and reduces tip catch

- **Bi-segment Inner Shaft**
Improves trackability in tortuous distal anatomy

- **Z-Glide™**
Improves tracking with proprietary lubricious coating



MANBA
Medication Assisted
Balloon Angioplasty

➤ Proven clinical performance

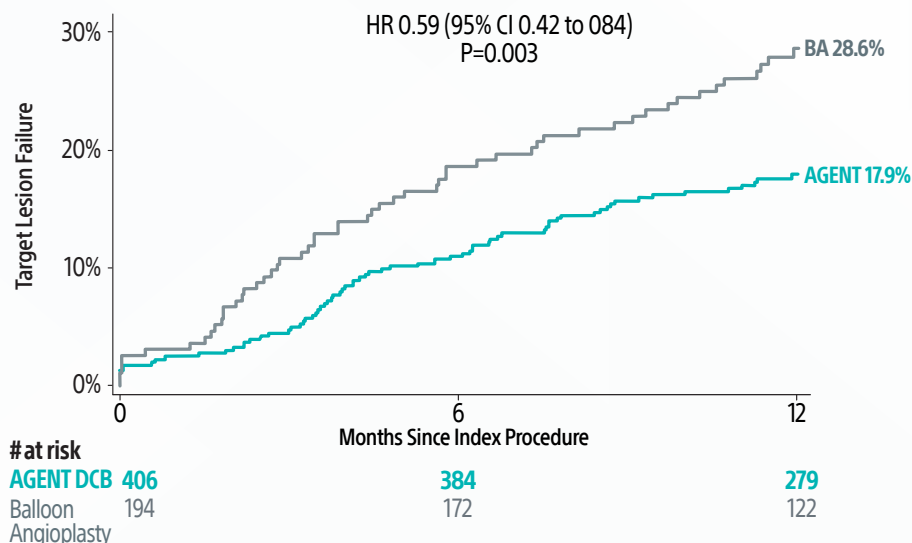
AGENT Drug-Coated Balloon has shown consistently low rates of target lesion revascularization (TLR), stent thrombosis, and late lumen loss.¹³ In the first U.S. clinical trial evaluating the safety and effectiveness of a coronary DCB compared to balloon angioplasty in patients with ISR, AGENT DCB demonstrated statistical superiority.¹⁴

➤ Primary Endpoint: TLF at 1-Year¹⁴

41%

relative risk
reduction
for TLF

NNT=9 Patients*



➤ At one-year, AGENT DCB also demonstrated statistically lower event rates:¹⁴

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

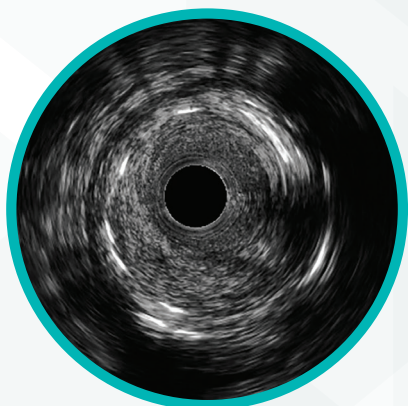
(0.0% vs. 3.2%, P=0.0004)

➤ Effective ISR treatment starts with imaging

While AGENT DCB 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.

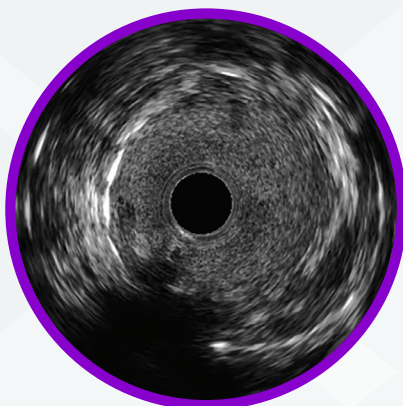
- Modern PCI tools and techniques give you the inside knowledge to improve long-term outcomes in patients' lives.

SEE



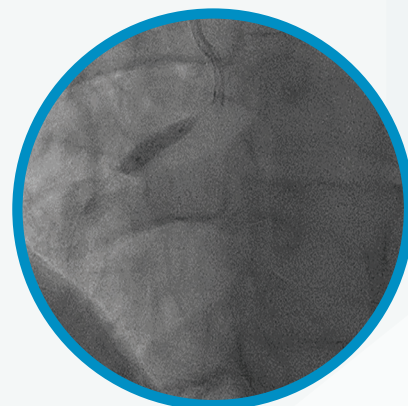
HD-IVUS defines the extent and type of disease

PREP



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

TREAT



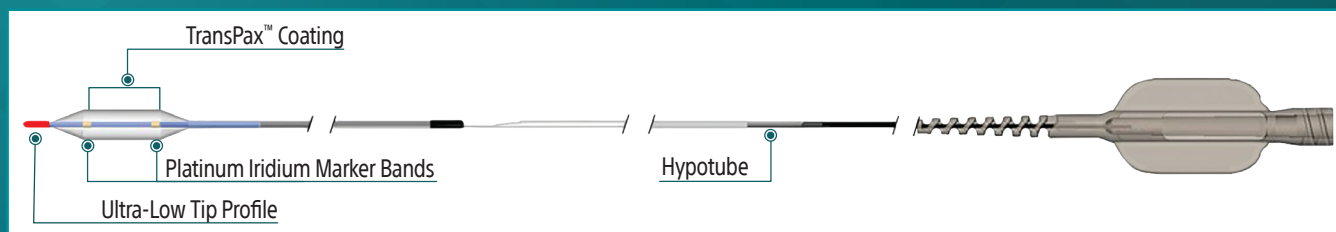
Final Angio confirms final result*

*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 | 0.43 mm or 0.017" | | | |
| Delivery system effective length | 144 cm | | | |
| Delivery system port | Designed for 0.36 mm (0.014") guidewire | | | |
| Balloon material | OptiLEAP™ | | | |
| Shelf life | 24 months | | | |
| Sterilization | Ethylene oxide (EO) | | | |
| Single/multiple use | Single use | | | |
| Guide catheter compatibility | 5Fr or 1.67mm / ID 1.42mm or 0.056 | | | |
| Catheter shaft outer diameter | Distal shaft | Diameter | Balloon length | Outer diameter |
| | | 2.00 mm | 12 mm to 20 mm | 2.3Fr |
| | | 2.00 mm | 30 mm | 2.4Fr |
| | | 2.25, 2.50, 2.75 mm | all lengths | 2.4Fr |
| | | 3.00 mm | 12 mm to 20 mm | 2.4Fr |
| | | 3.00 mm | 30 mm | 2.7Fr |
| | | 3.50 mm and 4.00 mm | all lengths | 2.7Fr |
| | Proximal shaft | Diameter | Balloon length | Outer diameter |
| | | 2.00, 2.25, 2.50, 2.75 mm | all lengths | 1.8Fr |
| | | 3.00 mm | 12 mm to 30 mm | 1.8Fr |
| | | 3.50 mm | 12 mm to 30 mm | 1.8Fr |
| | | 4.00 mm | 12 mm and 15 mm | 1.8Fr |
| | | 3.50 mm | 30 mm | 1.9Fr |
| | | 4.0 mm | 20 mm to 30 mm | 1.9Fr |
| 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

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 | – | – |

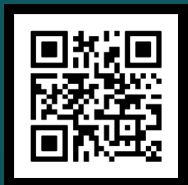
Nominal Pressure

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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AGENT™ Drug-Coated Balloon
Indications, Safety and Warnings

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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