AGENT™
Paclitaxel Drug Coated Balloon

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AGENT™ Drug Coated Balloon

Paclitaxel-Coated Balloon for Percutaneous Coronary Intervention

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Boston Scientific Corporation

Drug Delivery by AGENT™ Drug Coated Balloon

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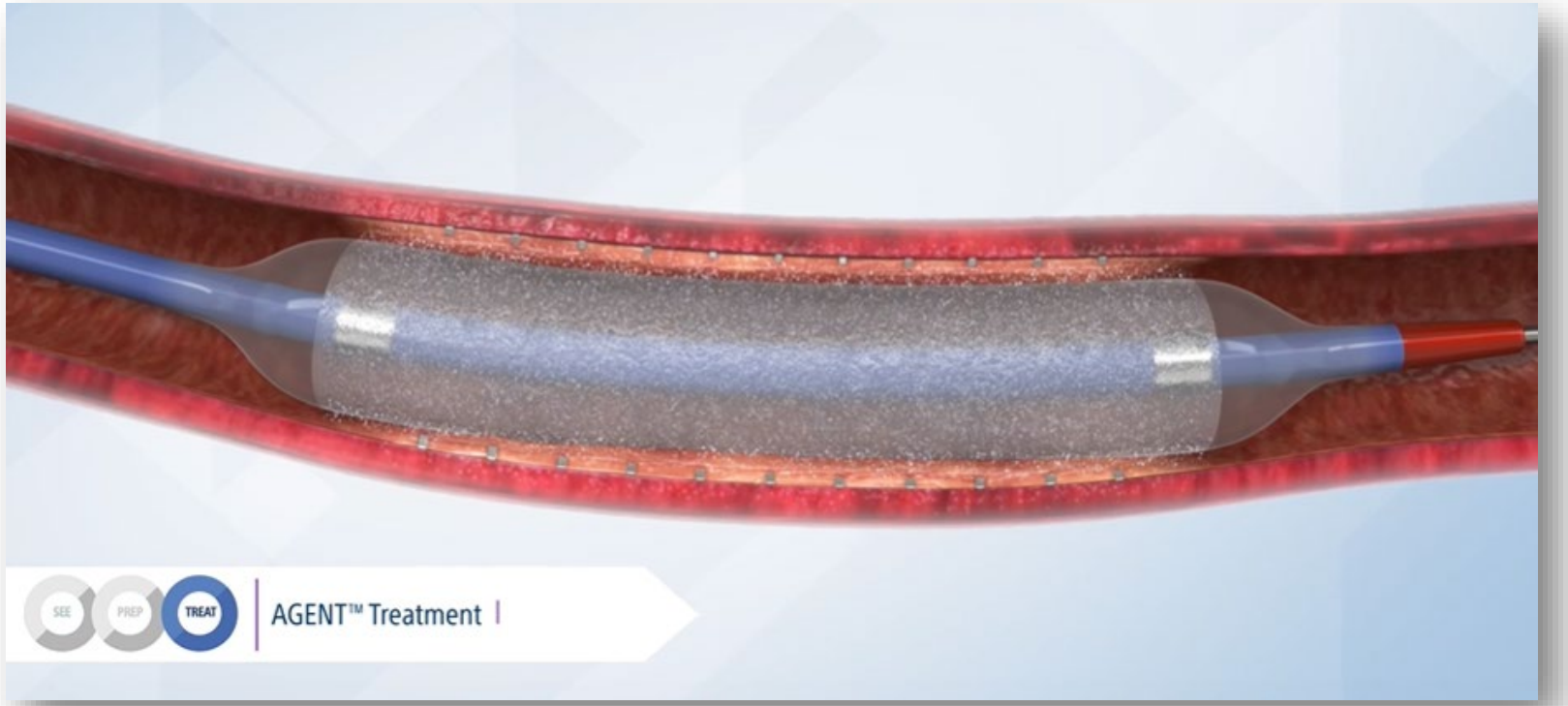
Lesion treatment by localized drug delivery device



Inhibit restenosis by delivering antiproliferative drug directly to the diseased coronary artery tissue

- Fast and homogenous transfer of drug into a prepared vessel wall during single balloon inflation
- Short-term tissue uptake with durable anti-restenotic effect

AGENT™ Drug Coated Balloon (DCB) System

Intraluminal Coronary Implant for Percutaneous Coronary Interventions

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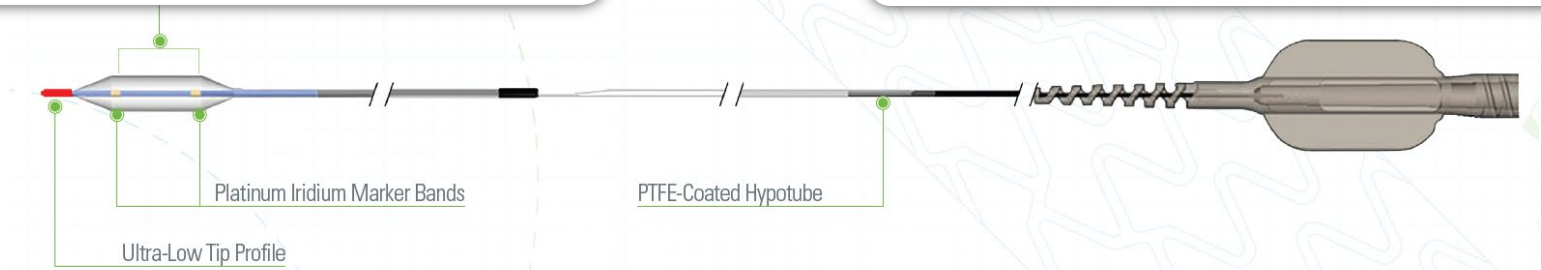
Inserted Transiently Balloon Catheter Component

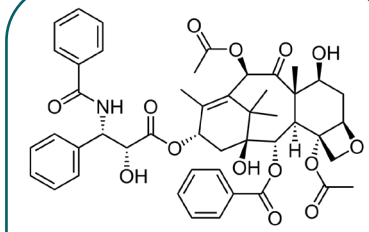
Semi-Compliant Balloon
Delivers anti-restenotic drug

Catheter
Tracks coated balloon to lesion



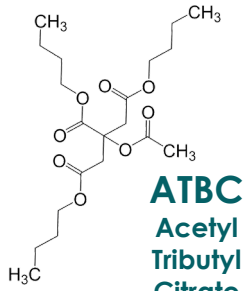
Implanted Permanently Drug Component

Drug
Active Pharmaceutical ingredient



Paclitaxel

Excipient
Maintains coating integrity and facilitates drug transfer



ATBC
Acetyl Tributyl Citrate

Device Name

Product Trade Name: AGENT™ Paclitaxel-Coated Balloon Catheter

Common Names in Device Category:

- Drug-Coated Balloon (DCB)
- Drug-Eluting Balloon (DEB)
- Paclitaxel-Coated Balloon (PCB)
- Sirolimus-Coated Balloon (SCB)

FDA 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)**.

Percutaneous Coronary Intervention (PCI)

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The AGENT™ Drug Coated Balloon (DCB) is an intraluminal device used in the delivery and implantation of drug therapy as part of a percutaneous coronary intervention

DCB PCI procedures are performed in the hospital setting (inpatient & outpatient) by an Interventional Cardiologist with specialized fellowship training, and include the following steps:

- All PCI begin by obtaining arterial access, positioning a guide catheter in the heart, and advancing a guide wire across the coronary artery stenosis
- Using angiographic imaging to visualize the heart and intravascular ultrasound (IVUS) to guide the procedure
- Prepare the vessel for treatment using specialized catheters/devices as needed to open/clear calcified plaque or thrombus
    - Inflation(s) of angioplasty balloon(s) to mechanically dilate the vessel and restore blood flow
- **Using intravascular ultrasound to assess for adequate mechanical lesion preparation**
- **Intraluminal drug delivery and implantation using a drug-coated balloon, to provide durable therapeutic benefit to maintain patency long-term**
    - Additional lesions/vessels may be treated with drug-eluting stent
- Remove the catheter and close the insertion site

Details of PCI procedures including use of drug-coated balloons are documented in the cardiac catheterization report

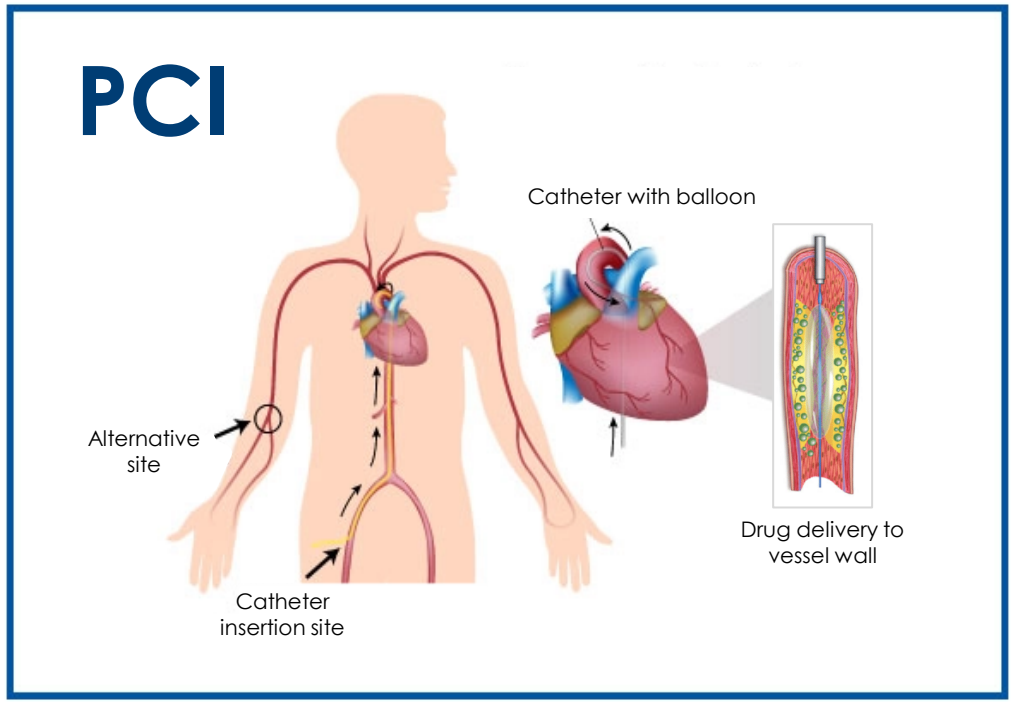

Image from www.medicoverhospitals.in/procedures/coronary-angioplasty-and-stents-insertion

Optimizing Drug-Coated Balloon Clinical Outcomes
Visualization using Intravascular Ultrasound

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Intravascular Ultrasound (IVUS) is used to assess coronary vessel size, stent expansion, and lesion morphology

Optimizing Drug-Coated Balloon Clinical Outcomes
Meticulous Lesion Preparation

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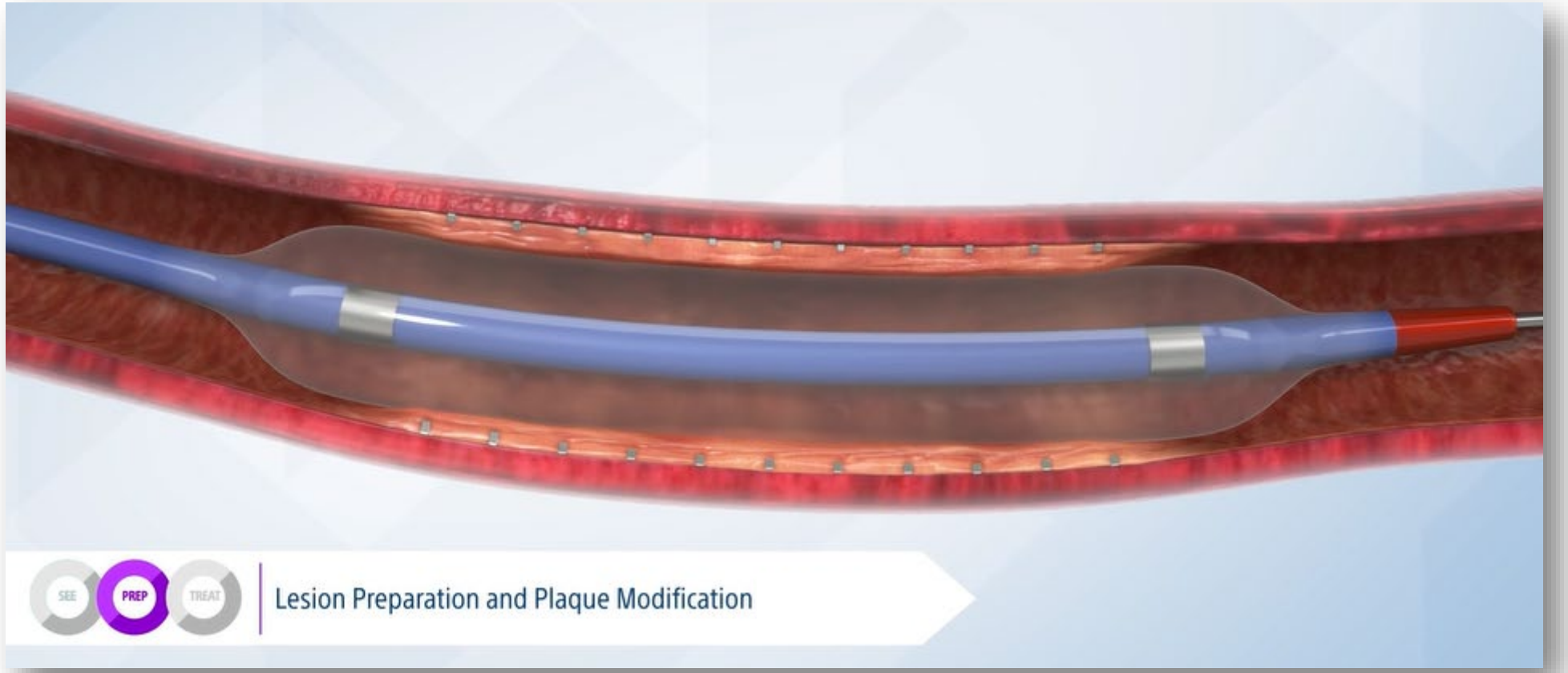
Lesion preparation includes plaque modification as needed (e.g. atherectomy, cutting balloon, intravascular lithotripsy) **and vessel dilation with an angioplasty balloon**



Optimizing Drug-Coated Balloon Clinical Outcomes
Repeat Visualization using Intravascular Ultrasound

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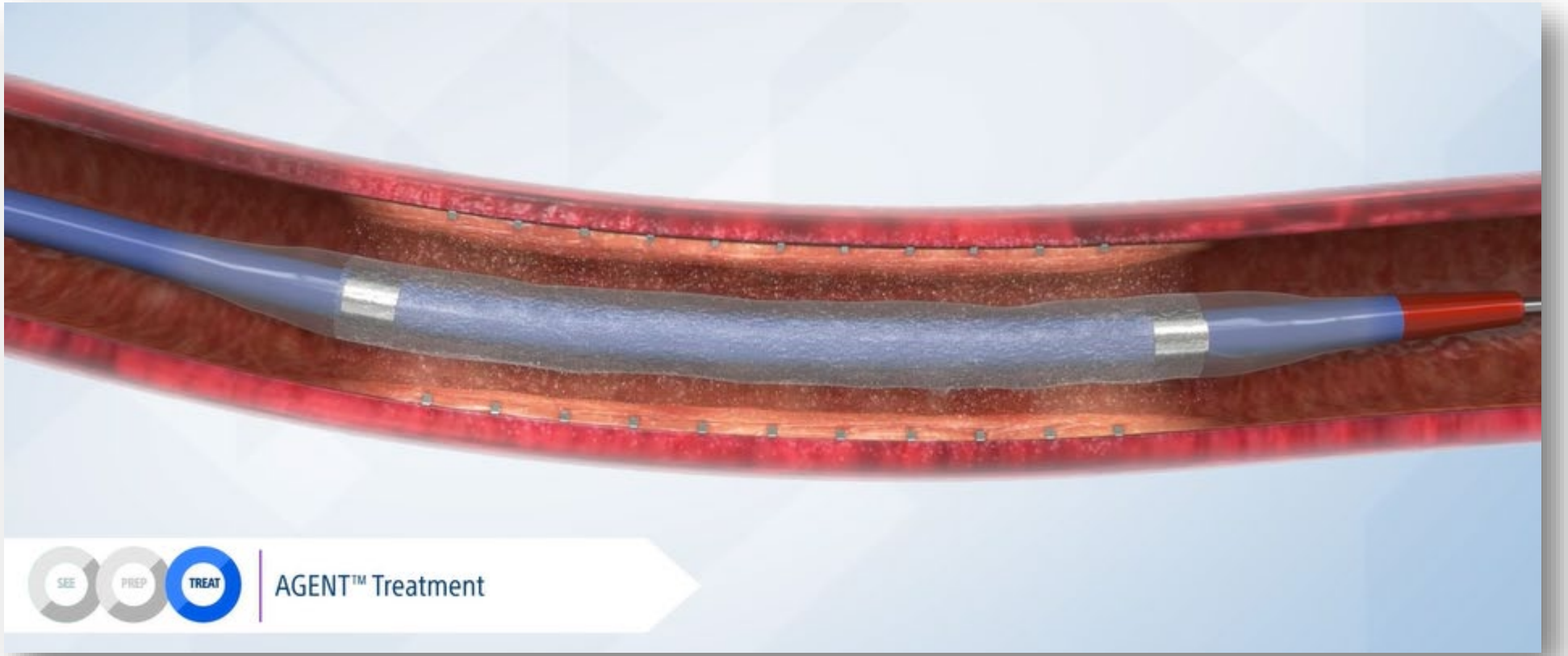
IVUS is used to confirm adequate mechanical lesion preparation, determine proximal/distal DCB landing zones, and size the DCB

Optimizing Drug-Coated Balloon Clinical Outcomes
Drug Implant

Drug-coated balloon is advanced, positioned across the lesion treatment site, and the balloon is expanded to implant the drug

Optimizing Drug-Coated Balloon Clinical Outcomes
Drug Absorption

The fully deflated delivery balloon catheter is withdrawn, and the drug remains in the vessel out to 90 days



Uniquely Identifying Vessels and Devices

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As with other procedures using intraluminal devices, it is necessary to identify both the type and number of vessels treated

- AGENT DCB is indicated for use only in coronary arteries
- Multiple coronary arteries may be treated with AGENT DCB in a single operative episode
  - Multivessel treatment is an indicator of coronary artery disease severity

As with other procedures using single-use intraluminal devices, it is necessary to identify both the type and number of devices used

- AGENT DCB may be used in conjunction with other intraluminal devices
- Patient factors such as lesion length and occurrence of multiple lesions may impact the number of DCBs used
  - Average 1.33 devices per operative episode[1]

1. Iannopollo G, et al. Percutaneous Coronary Intervention With the Agent Paclitaxel-Coated Balloon: A Real-World Multicenter Experience. J Invasive Cardiol. 2020 Mar;32(3):117-122. Epub 2020 Feb 11. PMID: 32045346.

AGENT IDE TRIAL

NCT04647253

Anticipated Publication, estimated 2024

Randomized trial evaluating traditional balloon angioplasty vs. AGENT DCB

AGENT IDE Study Design

Prospective, randomized, multicenter, superiority trial across 40 US Sites (N=600 patients)

- Key Inclusion Criteria: Patients with ISR of a lesion previously treated with BMS or DES; lesion length <26 mm, RVD >2.0 - ≤4.0 mm, and %DS >70 - <100% (asymptomatic) or %DS >50 - <100% (symptomatic)
- Key Exclusion Criteria: Recent STEMI, bifurcation, LM, SVG or arterial graft, thrombus in target vessel

2:1 randomized after successful pre-dilation of target lesion

AGENT DCB	Balloon Angioplasty
n=406	n=194

Primary Endpoint: Target Lesion Failure at 1-year (composite of TLR, TV-MI, or cardiac death)
Clinical follow-up: In-hospital, 30 days, 6 months, 1-year and annually between 2 and 5 years)

1. Yeh, Robert W et al. "Rationale and design of a randomized study comparing the agent drug coated balloon to plain old balloon angioplasty in patients with In-stent restenosis." *American heart journal* vol. 241 (2021): 101-107. doi:10.1016/j.ahj.2021.07.008

AGENT IDE Trial Device Complications

There was a very low occurrence of device deficiencies in the AGENT DCB procedures

3 Reported Device Deficiencies out of **406** Patients in DCB Arm

- One report of **balloon rupture** which occurred during the procedure and led to a serious adverse event of **vessel perforation**. **Bailout stenting was performed** during the same procedure and the event was reported to be resolved
- One report of **failure to cross the lesion** during the procedure. The AGENT DCB was removed, and **pre-dilatation was performed again**. A new AGENT DCB was then used successfully.
  - The device deficiency did not lead to a serious adverse event
- One report of physician decision to **remove an undeployed AGENT DCB** and to **insert a new AGENT DCB** with guidewire for delivery. The second AGENT DCB was used successfully.
  - The device deficiency did not lead to a serious adverse event

Peripheral Artery Drug-Coated Balloons

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Peripheral artery DCB procedures are distinct from coronary DCB procedures

- Drug coated balloons were first introduced in the US for the treatment of peripheral artery disease (PAD) of the femoral and popliteal arteries in 2014
- Peripheral artery DCBs are commonly used for two purposes
    1. Perform mechanical dilation to achieve maximum lumen area
    2. While also delivering drug to maintain durable patency
- Trials of peripheral artery DCBs have repeatedly shown clinically and statistically significant improvement in patency and target lesion revascularization over percutaneous transluminal angioplasty (PTA) with non-drug coated balloon alone
    - There is growing evidence that peripheral artery DCB should be used following PTA with non-drug coated balloon
- Peripheral artery DCBs generally come in very large lengths (up to 180 mm) that allows for the treatment of an entire artery using a single balloon

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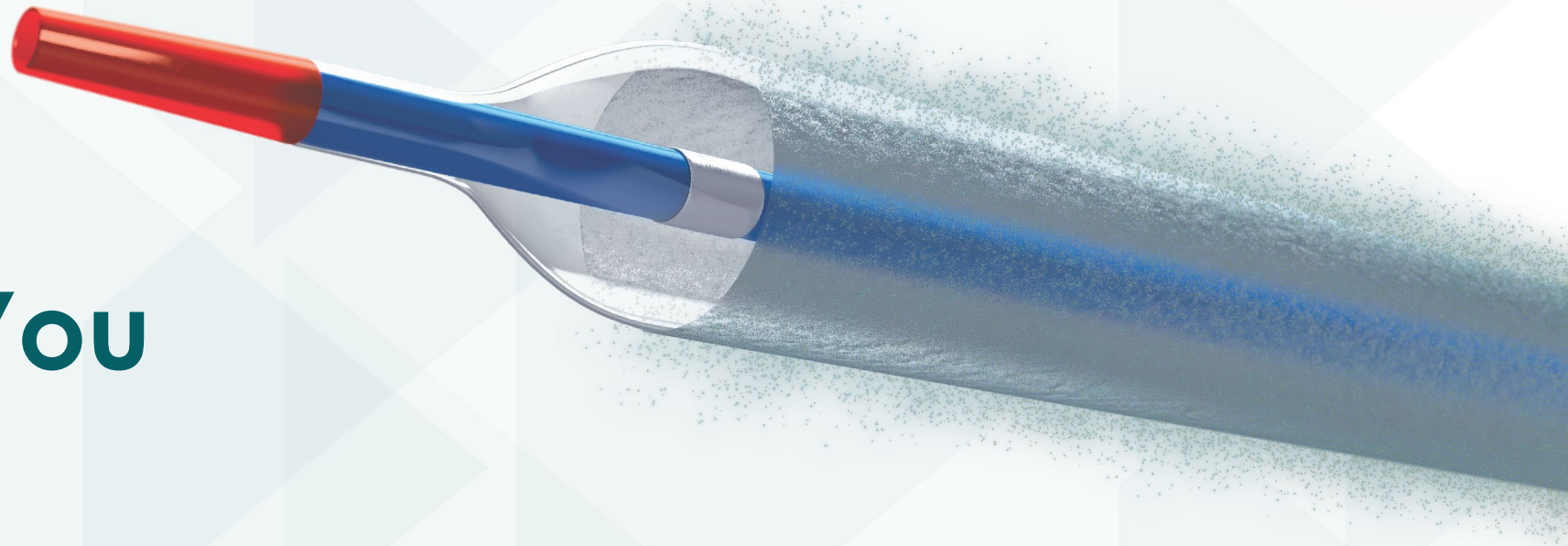

Thank You

Leave the Right
AGENT Behind