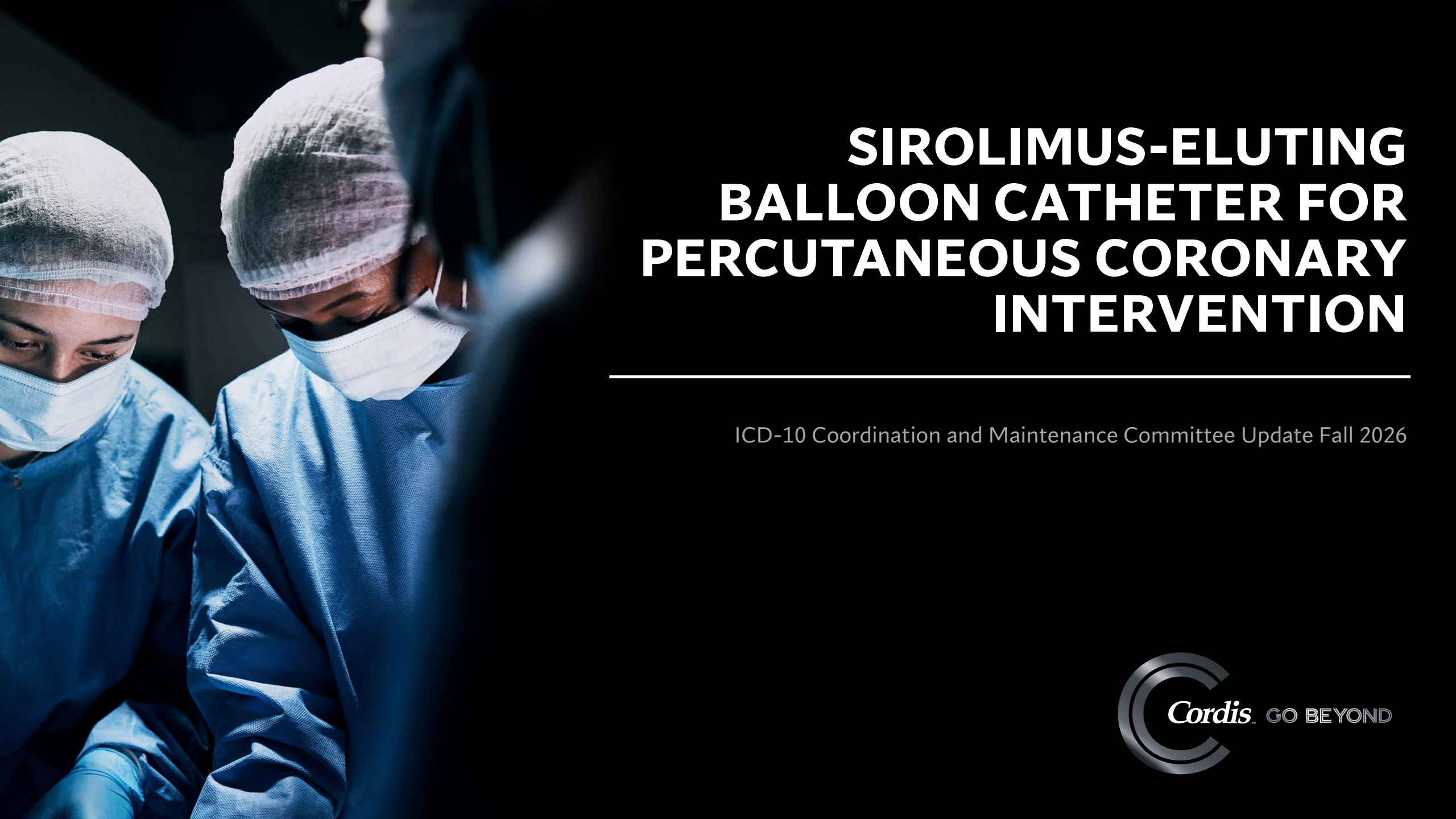




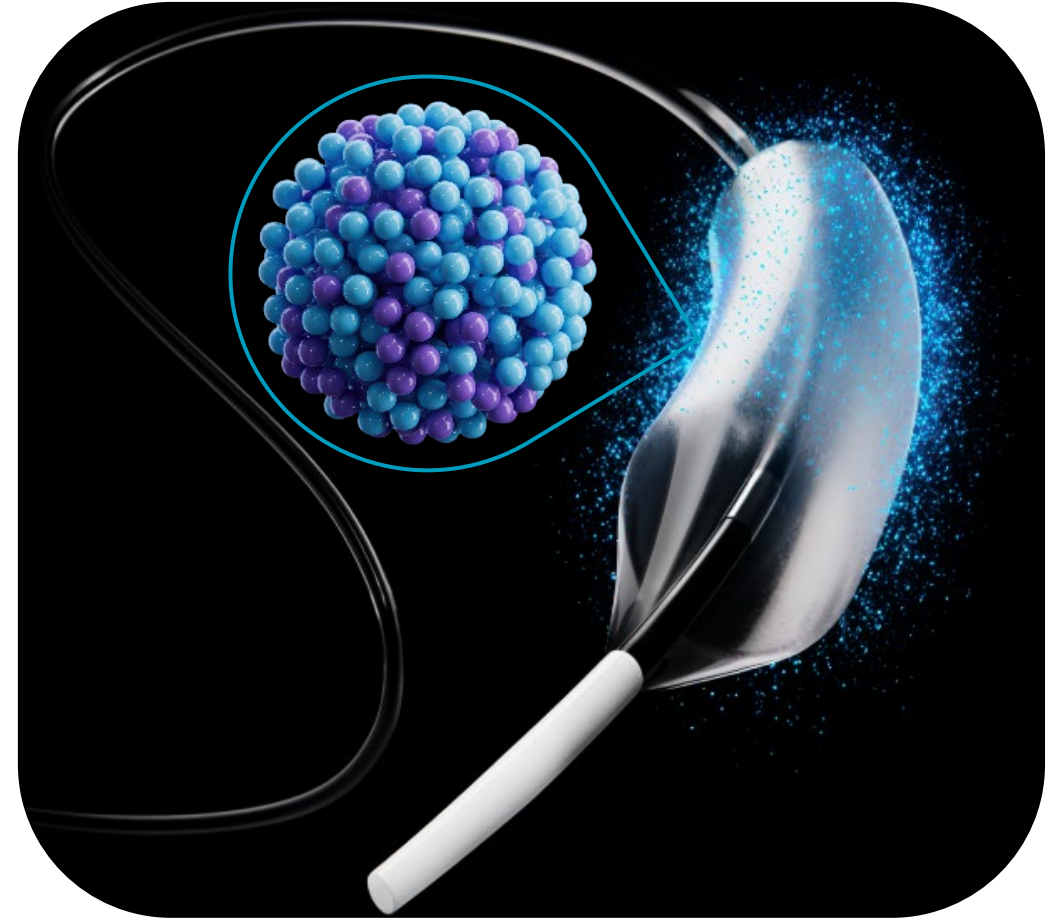
SIROLIMUS-ELUTING BALLOON CATHETER FOR PERCUTANEOUS CORONARY INTERVENTION

ICD-10 Coordination and Maintenance Committee Update Fall 2026



AGENDA

1. Coronary In-Stent Restenosis Disease State
2. SELUTION SLR™ PTCA Drug-Eluting Balloon Technology
3. Drug-Eluting Balloon Procedure Steps
4. Medical Records and Coding



SELUTION SLR™ PTCA Drug-Eluting Balloon

Coronary In-stent Restenosis (ISR)

- Per the CDC, “coronary artery disease (CAD) is the most common type of heart disease, killing 382,820 people in 2020”. Approximately 7.2% of adults have CAD with increase penetration of common risk factors such as diabetes and hypertension.
- Per the Diagnostic Catheterization and Percutaneous Coronary Intervention registry of the National Cardiovascular Data Registry, ISR represents approximately 10% of all percutaneous coronary interventions (PCI) with approximately 25% of patients presenting with acute myocardial infarction.
- Existing treatments for coronary ISR include PCI such as repeat stenting with either a drug-eluting or bare-metal stent, repeated balloon dilation and coronary brachytherapy. The majority of ISR procedures in the United States are currently treated by implantation of an additional stent.
- Repeated DES implantation has historically shown superior results for treating ISR compared with balloon dilation alone. However, use of a metallic scaffold further narrows the luminal diameter, and multiple stent layers are associated with a progressively higher risk of recurrent ISR and negative clinical outcomes.
- The SELUTION SLR™ PTCA DEB (SELUTION SLR™) provides superior outcomes for ISR treatment as compared to balloon dilation with a non-drug treated balloon alone, providing sustained therapeutic drug delivery without requiring the implant of a metallic stent.

Selution SLR™ Drug-Eluting Balloon Technology Overview

- The SELUTION SLR™ is a single-use sirolimus coated intraluminal device used for the purpose of improving myocardial perfusion when treating ISR.
- Two unique technologies enable the SELUTION SLR™ to deliver sirolimus that overcome the historical challenges of using sirolimus on an angioplasty balloon platform:
 - MicroReservoir Technology: 4 um reservoirs that combine PLGA and the preferred Sirolimus drug providing sustained release through 90 days.
 - Phospholipid Blend Coating: Protects during insertion and tracking to the lesion, and facilitates transfer of the microreservoir from the balloon to the vessel wall.
- SELUTION SLR™ is designed to provide an inflatable segment of known diameter and length at recommended pressures. The balloon has two radiopaque markers that indicate the balloon's working length and aid in the positioning of the balloon relative to the stenosis. The catheter tip is tapered to facilitate advancement of the catheter to the treatment area and through the stenosis.

SELUTION SLR™ Drug-Eluting Balloon Procedure Steps (page 1 of 2)

1. Vascular Access

The common femoral artery or radial artery are accessed under ultrasound and/or fluoroscopic guidance to ensure safe anterior wall puncture of a relatively disease-free vessel segment. Typically, a 6 Fr introducer sheath is then placed. An 0.014” guidewire and shaped guiding catheter are inserted to facilitate the passage to the different coronary arteries.

2. Lesion Crossing

Depending on the grade and location of the stenosis, an appropriate guide catheter is selected to facilitate access and lesion crossing. Additionally, the guide catheter offers support during the procedure when advancing different devices through the lumen to access the artery and be able to reach the lesion. This is followed by crossing the lesion with an 0.014” wire to facilitate intravascular imaging, prepping and treatment of the lesion.

3. Pre-Dilatation

Intravascular imaging may be used to define the characteristics of the plaque and size of the vessel to personalize treatment. Pre-dilatation is performed using a standard (uncoated) PTCA balloon same diameter as the artery and a length corresponding to the length of the stenosis. Pre-dilatation is performed at the respective pressure to reach the required diameter based on the compliance chart for approximately 30 seconds. Based on the lesion characteristics, other vessel preparation devices can include specialty balloons (cutting/scoring) and/or atherectomy, and/or intravascular lithotripsy.

SELUTION SLR™ Drug-Eluting Balloon Procedure Steps (page 2 of 2)

4. DEB Treatment

The size and length of the DEB may be chosen based upon the balloon used for the pre-dilatation and/or intravascular imaging. Inflation of the DEB per the compliance card guidance to achieve the targeted diameter. Minimal inflation times of 30 seconds and up to 60 seconds based on the patient tolerance of symptoms created during balloon inflation. After drug eluting balloon treatment, if there is elastic recoil or a flow limiting dissection, then bailout stent placement is recommended.

5. Vascular Closure

Upon completion of the PCI procedure, hemostasis is obtained with manual compression. Vascular closure devices may be used to accelerate hemostasis and patient ambulation based on individual hospital standards.

Medical Records and Coding

Documentation of the use of the SELUTION SLR™ PTCA DEB will be included in the operative report and may contain the following terms:

- SELUTION SLR™ Drug Eluting Balloon Catheter
- SELUTION SLR™ Balloon Catheter
- SELUTION SLR™ DEB Catheter
- SELUTION SLR™ Catheter
- SELUTION™ DEB Catheter
- Drug Eluting Balloon
- DEB Catheter
- SELUTION SLR™
- SELUTION™