

SELUTION SLR™ PTCA
DRUG-ELUTING BALLOON

PATIENT BROCHURE





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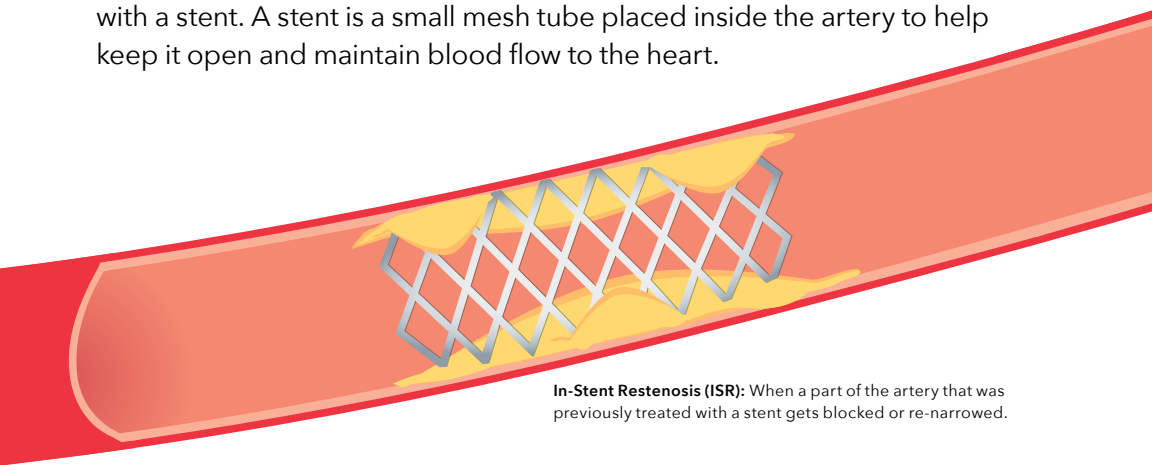
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WHAT IS CORONARY ARTERY DISEASE (CAD)?

Coronary artery disease (CAD) is a narrowing of the arteries, resulting in reduced blood flow to the heart. Coronary arteries become narrowed by a build-up of plaque, including cholesterol, fatty deposits, calcium and other substances.

People at higher risk of developing CAD include those who smoke or those who have high cholesterol, diabetes, high blood pressure, obesity, or family history of heart disease.

If you have been previously diagnosed with CAD, you may have been treated with a stent. A stent is a small mesh tube placed inside the artery to help keep it open and maintain blood flow to the heart.



In-Stent Restenosis (ISR): When a part of the artery that was previously treated with a stent gets blocked or re-narrowed.

WHAT IS IN-STENT RESTENOSIS (ISR)?

When a part of the artery that was previously treated with a stent gets blocked or re-narrowed, it's called In-Stent Restenosis (ISR). This re-narrowing is caused by blockage that has reoccurred or by new tissue growing inside the stent, which can reduce blood flow to the heart.

ALTERNATIVE TREATMENT OPTIONS FOR ISR

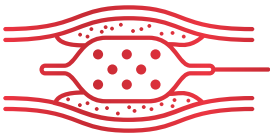
Management of In-Stent Restenosis (ISR) after a coronary stent has been implanted is clinically challenging. The treatment options for ISR include:



Medical management



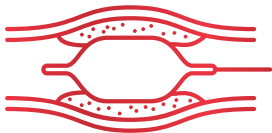
Risk factor modification such as diet, exercise, and smoking cessation



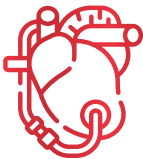
Drug coated balloon (DCB)



Repeat stent placement (bare metal stent (BMS) or drug-eluting stent (DES))



Percutaneous Transluminal Coronary Angioplasty (PTCA) (also referred to as "plain old balloon angioplasty" (POBA))



Coronary Artery Bypass Grafting (CABG) Surgery



Radiation therapy

WHAT IS THE SELUTION SLR™ PTCA DRUG-ELUTING BALLOON (DEB)?

The SELUTION SLR™ PTCA DEB is a balloon catheter that has the drug sirolimus applied to the surface of the balloon. The drug-eluting balloon is inflated inside the blood vessel to allow drug transfer into the vessel wall and prevent re-narrowing of the artery.

WHAT IS SIROLIMUS?

Sirolimus is a drug that helps the blood vessels remain open after a procedure to treat narrowed or blocked arteries. The surface of SELUTION SLR™ PTCA DEB is coated with a small amount of sirolimus which is delivered directly to the vessel wall during balloon inflation.

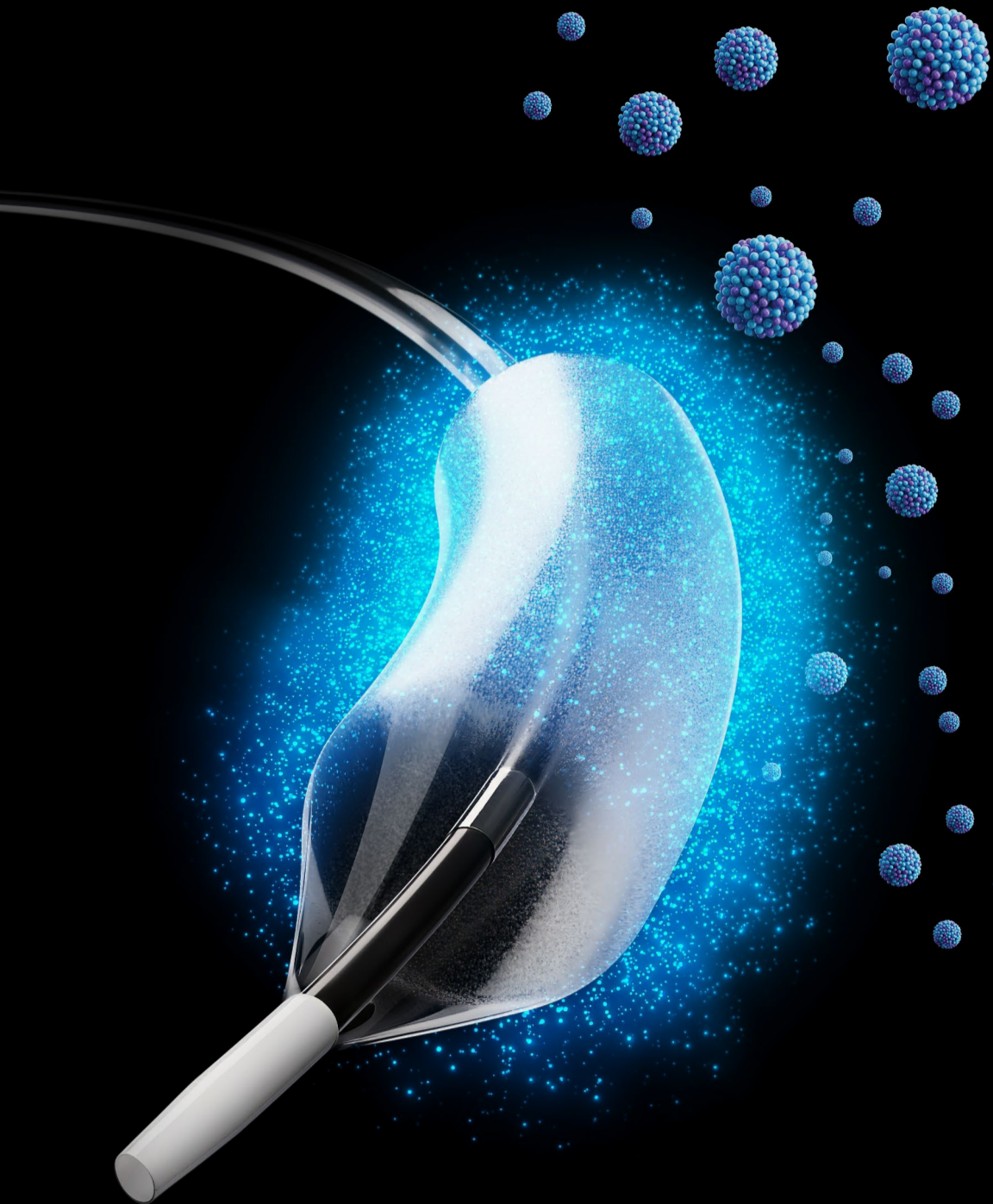
USE OF THE SELUTION SLR™ PTCA DEB

The SELUTION SLR™ PTCA DEB is intended to improve blood flow to the vessels of the heart and reduce the chance of the artery narrowing again. The SELUTION SLR™ PTCA DEB delivers drug directly to the vessel wall without placing any new metal inside your body. Your doctor can help you determine if you may be a good candidate for treatment with a drug-eluting balloon.

CONTRAINDICATIONS

The SELUTION SLR™ PTCA DEB should not be used if:

- You have known allergies or reactions to sirolimus
- You are unable to take recommended medications prescribed before, during, or after the procedure
- Your narrowed artery is in the head or neck
- Your narrowed artery is in the left main artery that supplies blood to the heart, which has not been treated or protected
- You have blood vessel spasms (sudden narrowing of the artery) without a significant blockage
- You are pregnant, breastfeeding, planning to become pregnant, or father a child



RISKS

Potential adverse events that may be associated with the use of SELUTION SLR™ PTCA DEB include, but are not limited to:

- Abnormal heart beats
- Additional procedures that may include surgery
- Allergic reaction to the device or medicines used during the procedure
- Bleeding, bruising, or swelling
- Blockage of an artery
- Chest pain from your heart
- Damage to the treated blood vessel
- Death
- Fever
- Heart Attack
- Fluid build-up around the heart that prevents it from pumping
- Infection, including in the blood
- Inflammation
- Kidney failure
- Life threatening condition where the body is not getting enough blood flow
- Low blood cell count (white, red, platelets)
- Low/high blood pressure
- Organ failure
- Pain where the device was inserted
- Reduced blood flow to the brain
- Slower blood flow in the treated vessel

Potential adverse events related to the drug (sirolimus) include, but are not limited to:

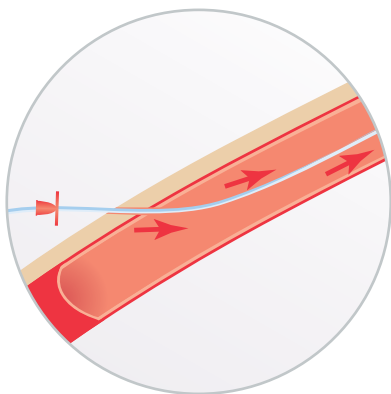
- Abnormal liver function
- Cancers
- Diarrhea
- High fat levels in the blood
- Immune, allergic, or systemic reactions
- Infection
- Joint pain
- Low salt levels in the blood
- Scarring of lung tissue

BENEFITS

- The SELUTION SLR™ PTCA DEB is designed to open blocked arteries in the heart and to keep them open.
- The SELUTION SLR™ PTCA DEB also provides a benefit of not implanting another stent, which may allow for more options for future treatments, if needed.



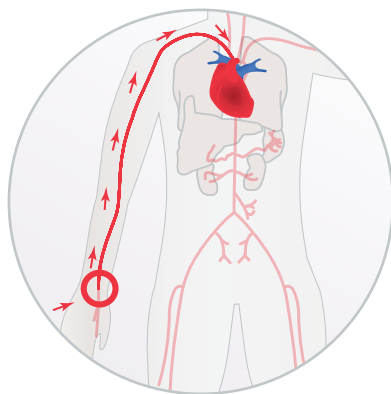
WHAT HAPPENS DURING A TYPICAL DRUG-ELUTING BALLOON PROCEDURE?



1. You will be given medication to help you relax.

The device insertion site (usually the wrist or groin) will be cleaned and numbed with local anaesthesia.

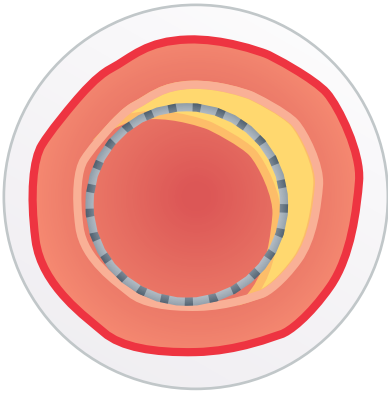
Your doctor will make a small opening with a needle in your skin to gain access to the artery.



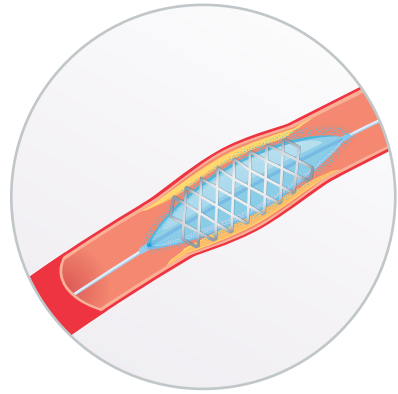
2. A guidewire and catheter are inserted and guided through your blood vessels to the narrowed section of the artery.

The doctor will inject a dye into the narrowed section of the previously placed stent. Your doctor may choose not to use this product if you have sensitivity to this dye or have other risks based on this procedure.

Your doctor will then use devices to prepare the diseased vessel within previously placed stent.



- 3.** When the doctor is satisfied that the vessel is properly prepared and blood flow is adequate, the drug-eluting balloon will be inserted.



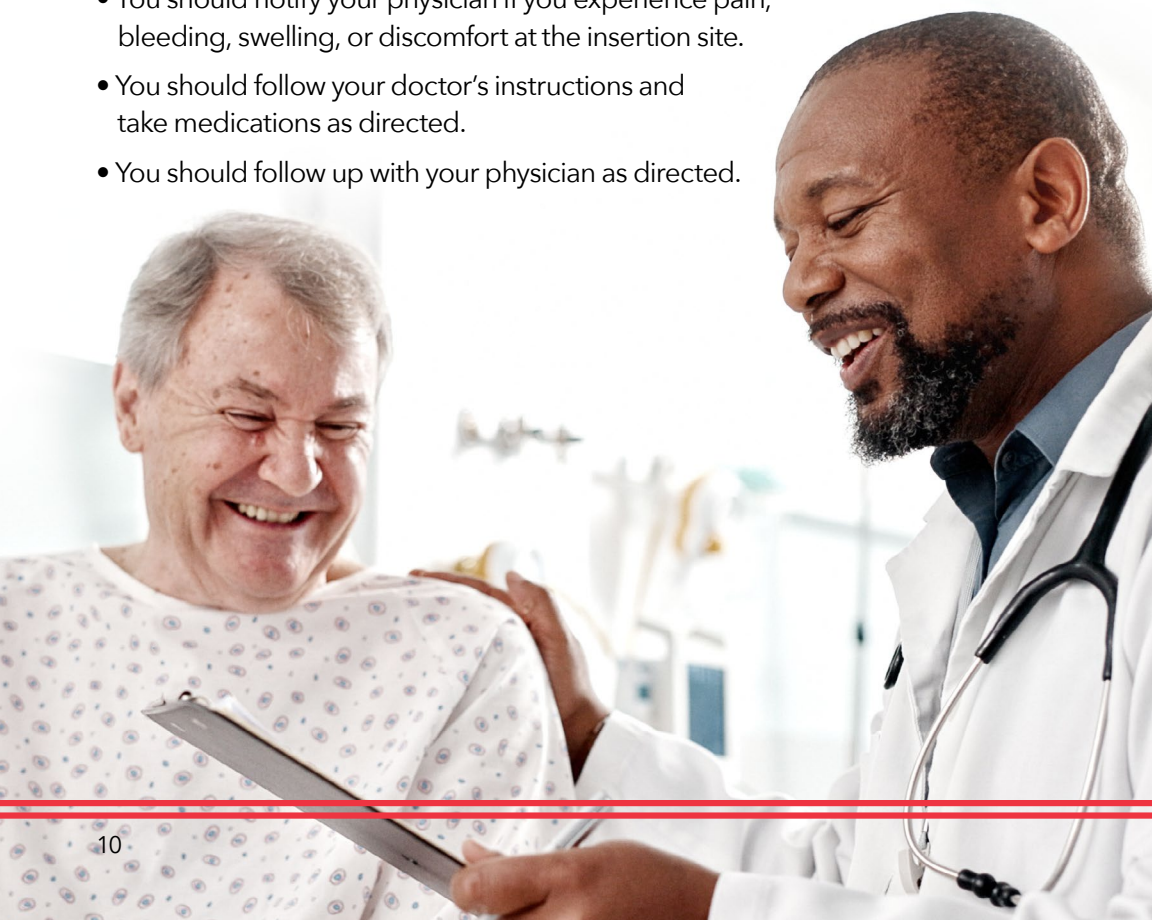
- 4.** After the drug-eluting balloon is inserted, the balloon is inflated to make contact with the artery wall, allowing the drug to be released.

Once the drug is delivered, the balloon will be deflated and removed and the insertion site will be closed.

The drug will be absorbed into the artery and is designed to keep the artery open and prevent future narrowing of the artery.

WHAT TO EXPECT AFTER THE PROCEDURE

- You will be moved to a recovery area within the hospital and will be monitored for several hours or overnight.
- You may feel drowsy from the sedative given during the procedure. This is normal and the effect will wear off in few hours.
- Your vital signs (blood pressure and heart rate) and the puncture site will be monitored closely.
- You may be asked to drink plenty of liquids to flush the dye out of your system.
- You may be asked to lie flat for several hours, so the insertion site can heal quickly.
- You should notify your physician if you experience pain, bleeding, swelling, or discomfort at the insertion site.
- You should follow your doctor's instructions and take medications as directed.
- You should follow up with your physician as directed.



LIVING WITH CORONARY ARTERY DISEASE

Coronary Artery Disease is a long-term condition that cannot be cured, but can be managed effectively. Treatment for Coronary Artery Disease includes managing risk factors that may contribute to the recurrence of symptoms.

The American Heart Association* suggests, at a minimum, following healthy lifestyle changes:

- Stop smoking and avoid tobacco use
- Keep your blood pressure and blood sugar within the normal range
- Lose excess weight
- Exercise regularly
- Control stress
- Reduce fat in your diet
- Eat healthy food

Maintaining a healthy lifestyle can have a positive impact on the long term management of your coronary artery disease. Talk to your health care provider about steps you can take to improve your lifestyle for a healthier outcome and enhanced quality of life.

* For more about American Heart Association healthy lifestyle changes, please visit bit.ly/AHA-lifestyle

CLINICAL DATA SUMMARY

The SELUTION SLR™ PTCA DEB was evaluated in the clinical study called SELUTION4ISR. The study enrolled 418 patients to determine if SELUTION SLR™ PTCA DEB showed acceptable performance for long-term (12-month) safety and effectiveness.

The SELUTION4ISR study demonstrated that the SELUTION SLR™ PTCA DEB showed similar clinical benefits when compared to the current standard of care, including drug-eluting stents and balloon angioplasty.

The results of this study confirmed that the SELUTION SLR™ PTCA DEB is safe and effective in treating in-stent restenosis in coronary arteries.

GLOSSARY

Diabetes

A chronic (long-term) condition where the body is unable to produce a hormone called insulin and cannot properly break down sugar in the blood. Diabetes is a risk factor for CAD.

Obesity

A condition where a person has too much body fat, which can affect their health. It happens when you take in more calories than your body uses, often over a long period of time. Obesity is a risk factor for CAD.

Coronary Artery

A blood vessel that carries oxygen-rich blood to the heart muscle.

Balloon Catheter

A thin, flexible tube with a balloon attached to the tip that can be inflated inside the blood vessel.

Sirolimus

A drug that prevents blood vessels from re-narrowing by reducing the scar tissue forming and slowing down the growth of cells inside the blood vessels.

Percutaneous Transluminal Coronary Angioplasty (PTCA)

A minimally invasive procedure that can open blocked or narrowed coronary arteries using a thin, flexible tube or a catheter with a balloon at the end of it. When the tube is in place, the balloon is inflated to open the blood vessel or artery to restore the normal blood flow.

Drug-Coated Balloon or Drug-Eluting Balloon

A balloon that delivers the therapeutic drug directly to the blood vessel wall.

Bare Metal Stent or Drug-Eluting Stent

A small mesh tube made of metal or special material that is used to keep the blood vessel open.

Coronary Artery Bypass Grafting (CABG)

A surgical procedure (also known as open heart surgery) used to create an alternate route for blood to flow to the heart when one or more coronary arteries are blocked or narrowed. CABG is an alternate procedure available to treat CAD.

For more information on product labeling please visit www.cordislabeling.com

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Prior to use, refer to the instructions for use supplied with this device or available at www.cordislabeling.com for indications, contraindications, suggested procedure, warnings and precautions.

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