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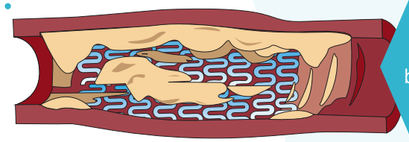
Patient Guide

Understanding Treatment Options for In-Stent Restenosis (ISR)

What is In-Stent Restenosis (ISR)?

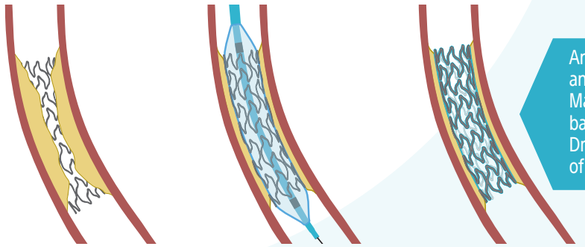
If you have been previously diagnosed with coronary artery disease, a narrowing ("stenosis") of one or more blood vessels (coronary arteries) that supply blood and oxygen to the heart, then you may have been treated with a stent. A stent helps keep the artery open. When a part of the artery with a stent gets blocked or re-narrowed, it's called in-stent restenosis (ISR).



The re-narrowing can be caused by a combination of factors including the blockage reforming or new tissue growth within the treated area.

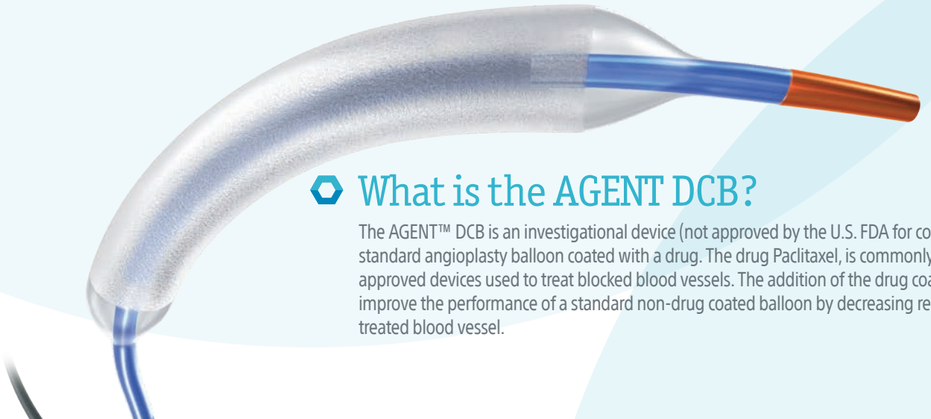
What are the Treatment Options for ISR?

The re-narrowing can be treated by performing a balloon angioplasty, also known as Percutaneous Transluminal Coronary Angioplasty (PTCA). This is a minimally invasive surgical procedure used to restore blood flow through the vessel using a small inflatable balloon that is inserted and directed to your re-narrowed blood vessel using a thin tube. The balloon is expanded against the blockage to re-open the blood vessel and restore blood flow. The balloon is then deflated, and both the tube and the balloon are removed from the body. Other treatment options for ISR are medication, stent placement, brachytherapy or coronary artery bypass graft surgery (CABG).



ISR Before Treatment | AGENT DCB Procedure | Result after AGENT DCB Procedure

Another treatment option for ISR is angioplasty with a drug-coated balloon (DCB). Many standard (non-coated) angioplasty balloons are approved by the U.S Food and Drug Administration (FDA) for the treatment of ISR, but drug-coated balloons are not.



What is the AGENT DCB?

The AGENT™ DCB is an investigational device (not approved by the U.S. FDA for commercial sale or use). It is a standard angioplasty balloon coated with a drug. The drug Paclitaxel, is commonly used in other commercially approved devices used to treat blocked blood vessels. The addition of the drug coating on the balloon could improve the performance of a standard non-drug coated balloon by decreasing repeat re-narrowing of the treated blood vessel.

What is the AGENT IDE Trial?

Management of in-stent restenosis (ISR) following implantation of a coronary stent is clinically challenging. Drug-coated balloons (DCBs) may fill an unmet need for patients with ISR. The AGENT IDE clinical trial will compare AGENT DCB to standard balloon angioplasty for the treatment of patients with re-narrowed blood vessel(s).

AGENT IDE Trial

Who May Qualify for the AGENT IDE Trial?

The AGENT IDE Trial may be appropriate for patients who have been treated previously with a coronary stent and have been diagnosed with ISR.

What is Required of Me in the Trial?

By joining this study:

- Information will be recorded before and during your procedure, and at the time of your discharge from the hospital.
- This is a randomized study. If you are eligible to participate, you will be randomly assigned to treatment with either the AGENT drug-coated balloon or a standard non-drug coated balloon. You will not know which balloon you were treated with for the duration of the study.
- You will be required to attend follow-up visits at 30 days, 6 months, 12 months, and then once every year for a total of 5 years after your balloon angioplasty procedure. Some follow-up appointments will be done at your doctor's office and some may be done by telephone. Your participation in the study will be complete after your five-year follow-up visit.
- You will receive medication that will help to decrease the chance of blood clots forming during and after the procedure. These medications are routinely used in patients who undergo angioplasty procedures and are not considered investigational. Your doctor will tell you which medications to take and for how long.
- You will be expected to tell your study doctor about any changes to your medications, any other medical treatments and/or medical problems or concerns that you may have, including any hospital admissions, even if they are not related to the study.

Talk to Your Doctor

If you have been diagnosed with ISR and you are interested in learning more about the AGENT IDE clinical trial, discuss with your doctor.

www.bostonscientific.com/agentIDE

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