

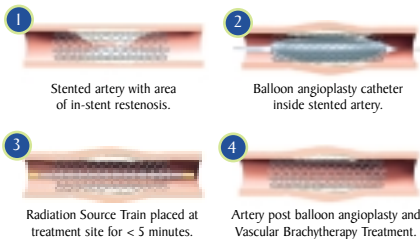


Introduction

Peripheral Vascular Disease (PVD) is a disease where the arteries that supply blood to the arms or legs become narrowed or blocked. This narrowing or blockage is called stenosis and is commonly treated with angioplasty and/or placement of a stent. In-stent restenosis is the re-narrowing of the artery within a previously placed stent requiring additional treatment to keep the artery open. This patient guide will introduce you to Vascular Brachytherapy with the Corona™ System, which is designed to reduce the need for repeat interventions due to in-stent restenosis.

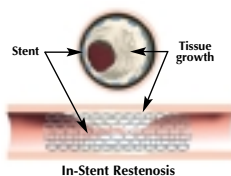
What are Angioplasty and Stent Placement?

Angioplasty involves the inflation of a balloon in a narrowed area of the artery. The balloon compresses the plaque (material causing the narrowing) against the wall of the artery. A successful angioplasty procedure opens the narrowing in the artery and improves blood flow. Stents, which are small wire mesh-like tubes, may be placed at the time of the angioplasty to help keep the artery open. Both angioplasty and stenting cause a small injury to the wall of the artery that usually heals within 3 to 9 months.



What Causes In-Stent Restenosis?

In-stent restenosis is the re-narrowing of the artery following stent placement and is due to the overgrowth of scar tissue on the artery wall during the healing process. In-stent restenosis requires angioplasty and possibly an additional intervention to re-open the artery.



What is Vascular Brachytherapy (VBT)?

Vascular Brachytherapy (VBT) is a procedure designed to reduce the reoccurrence of in-stent restenosis in arteries. In VBT, a known therapeutic dose of radiation is delivered within the narrowed area of the stent for a specified amount of time in order to reduce scar tissue formation during the healing process.

What is the Corona™ System?

The Corona™ System is a VBT device designed to deliver beta radiation using low penetrating Strontium 90 to the wall of the artery following angioplasty and/or additional intervention for in-stent restenosis. It is currently being studied for safety and effectiveness in the MOBILE Trial.

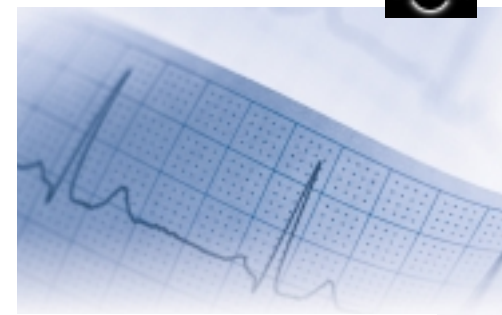
How is Treatment with the Corona™ System Performed?

You will be taken to the interventional laboratory where the procedure to re-open the narrowed stent in the artery of your leg is performed. Following this procedure, if you are part of the roll-in phase, or randomized to receive treatment with the Corona™ System, a catheter with a balloon on the end of it is positioned in the previously narrowed portion of the artery. The balloon is then inflated to a very low pressure to maximize the treatment of

the beta radiation. The Strontium 90 beta radiation sources are then hydraulically delivered through this catheter to the treatment site where they will remain in place for a prescribed length of time, typically 3 to 4 minutes. Because blockages in the leg can be quite long, up to 6 radiation treatments may need to be performed within the artery. When each radiation treatment is completed, the Strontium 90 beta radiation sources are removed. **No radiation remains in the body.**

What is the MOBILE Trial?

VBT is currently approved by the FDA for treating in-stent restenosis in the coronary (heart) arteries based on the results of several clinical trials. These trials have demonstrated a significant reduction in the need for additional interventional procedures when VBT is used following angioplasty or other procedure to re-open the area of in-stent restenosis. In addition, several studies using VBT to treat narrowing of the arteries in the leg suggest reduction in the occurrence of restenosis, but further clinical trials are necessary in order to obtain FDA approval to use VBT in the peripheral arteries. The MOBILE Trial is being performed to evaluate the newly designed Corona™ System and its effectiveness in reducing in-stent



restenosis in the arteries of the leg. There are two phases to the MOBILE Trial: the Roll-in phase and the Randomized Phase. Up to 150 patients will be part of the Roll-in phase, which means that they will not be randomized, but will all receive treatment with the Corona™ System. If you are selected for the Randomized phase, you will be assigned by chance to receive VBT with the Corona™ System, or no further treatment beyond the standard of care prescribed by your physician. Roughly one-half of the patients enrolled will be randomly selected to receive treatment with the Corona™ System. The other half will receive the current medical standard of care only.



Frequently Asked Questions (FAQ)

What will the Corona™ System treatment feel like?

As with any interventional procedure involving placement of a catheter, you may feel some discomfort in your groin and/or leg as the Corona™ catheter is positioned within the artery. This discomfort is temporary and is relieved when the catheter is removed. There should be no additional sensation during the treatment with the Strontium 90 beta radiation sources.

What are the risks of treatment with the Corona™ System?

There are risks associated with any interventional procedure that will be explained by your physician. Potential risks associated with radiation of the leg include arterial damage, re-narrowing of the treated artery, emergency surgery, radiation-induced diseases, amputation and death. The dose of radiation is limited to the artery being treated and the risk of the complications mentioned is felt to be very small. The long-term adverse effects of radiation are unknown at this time, however there is data on patients treated with Strontium 90 for in-stent restenosis in the coronary arteries 2 years out. This data shows that the group treated with the Strontium 90 radiation has fewer adverse events and less need for additional interventions compared to the group that did not receive radiation.

What are the treatment alternatives to VBT?

You should discuss with your physician alternative treatments including angioplasty, additional stent placement, medical therapy and/or bypass graft surgery.

What are the contraindications and precautions?

The contraindications and precautions that apply to angioplasty or other interventional procedures also

apply to Vascular Brachytherapy. In addition, the inability to tolerate anti-platelet therapy or anticoagulant medications will exclude you from the MOBILE Trial. Women who are pregnant, or who suspect pregnancy, will also be excluded from participating in the MOBILE Trial.

How long is the hospital stay?

Treatment with the Corona™ System will add approximately 10 to 30 minutes to your procedure time in the interventional lab. Your hospital stay should be the same as for an angioplasty or stent procedure.

Will additional medication be prescribed?

Anti-platelet therapy will be prescribed by your physician for a minimum of 6 months after the procedure. It is important to advise your physician of the inability to tolerate this type of medication.

What patient follow-up is required?

To follow your progress, you will be contacted at certain intervals after your procedure. You will be required to undergo a clinical follow-up examination (office visit, telephone call and/or mail-in questionnaire) at 3 months, 9 months and 2 years to assess your condition. At 9 months following your procedure, you may be required to have an angiogram to assess the opening of your vessel. You may also be contacted at additional time points to follow your progress by telephone or mail-in questionnaire.

Will health insurance cover the cost of the procedure?

The routine cost for the angioplasty procedure, or other procedure to open the narrowing in your artery, will be billed to your health insurance carrier. The cost of follow-up studies performed on the sponsor's behalf and considered to be more than standard medical practice, will be paid for by the sponsor.



Novoste™

Patient Guide
and Information Card

CORONA
System

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MOBILE TRIAL PATIENT INFORMATION CARD

Patient Name: _____

Hospital Name: _____ Phone #: _____

Cardiologist Name: _____ Phone #: _____

Date of Procedure: _____ New Stent Placed: Yes ___ No ___

Was Patient involved in the Roll-in or Randomized Phase of the MOBILE Trial?
 Roll-in Randomized

Anti-platelet Therapy:
 Drug / Dose prescribed: _____ Date of prescription: _____

Please take your Anti-Platelet Therapy as prescribed from _____ to _____
(Date of Procedure) (6 Months After Procedure)

It is very important to follow your physicians instructions regarding anti-platelet therapy.

Follow-Up Schedule:
 Date of 3-month follow-up: _____ Date of 3-month angiogram: _____
 Not Applicable Not Applicable

Date of 9-month follow-up: _____ Date of 9-month angiogram: _____
*Applicable for All Participants Not Applicable

Month to expect 2-year follow-up telephone call: _____

Additional follow-up appointments: _____
(Date) (Reason)

