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ION™

*Paclitaxel-Eluting Platinum Chromium
Coronary Stent System*

Patient Information Guide

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PATIENT INFORMATION GUIDE

You have recently had an ION drug-coated stent implanted in the coronary arteries of your heart. The following information is important for you to know, including the possible risks associated with having a stent implant along with medication recommendations and questions you may have about your stent.

ION Drug Eluting Stent

The ION stent is a bare-metal stent with a special drug coating added to help reduce the chance of the artery becoming blocked again. The drug is released from the stent over the period of time during which re-blockage is most likely to occur. The stent was designed to be very flexible, allowing it to fit the shape of your artery.

Polymer Coating

The stent is coated with a proprietary polymer, which was developed specifically for drug-eluting stents. The polymer carries and protects the drug before and during the procedure. Once the stent is implanted, it helps control drug release into the coronary arterial wall. This contributes to even and consistent distribution of the drug from the stent.

Drug Release

The ION drug-eluting stent is coated with a drug and polymer and has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls. Both the amount of drug and release rate have been determined so that healing can occur while allowing the processes leading to restenosis to be minimized, thus reducing the need for additional treatment in the stented area.

Potential adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries include but are not limited to:

- Abrupt stent closure
- Acute myocardial infarction
- Allergic reaction to anti-coagulant and/or antiplatelet therapy, contrast medium, or stent materials
- Angina
- Arrhythmias, including ventricular fibrillation and ventricular tachycardia
- Arteriovenous fistula
- Cardiac tamponade
- Cardiogenic shock/pulmonary edema
- Coronary aneurysm
- Death
- Dissection
- Emboli, distal (air, tissue or thrombotic material or material from devices(s) used in the procedure)

- Heart failure
 - Hematoma
 - Hemorrhage, required transfusion
 - Hypotension/hypertension
 - Infection, local or systemic
 - Ischemia, myocardial
 - Pain, access site
 - Perforation or rupture of coronary artery
 - Pericardial effusion
 - Pseudoaneurysm, femoral
 - Renal failure
 - Respiratory failure
 - Restenosis of stented segment
 - Stent embolization or migration
 - Stent thrombosis/occlusion
 - Stroke/cerebrovascular accident/TIA
 - Total occlusion of coronary artery
 - Vessel spasm
 - Vessel trauma requiring surgical repair or reintervention
- Potential adverse events related to the drug paclitaxel or the stent polymer include:**
- Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or the polymer stent coating (or its individual components)
 - Alopecia
 - Anemia
 - Blood product transfusion
 - Gastrointestinal symptoms
 - Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia)
 - Hepatic enzyme changes
 - Histologic changes in vessel wall, including inflammation, cellular damage or necrosis
 - Myalgia/arthralgia
 - Peripheral neuropathy

Exposure to paclitaxel and the polymer coating is directly related to the number of implanted stents. Use of more than one ION stent has not been adequately evaluated. Use of multiple stents will result in your exposure to a larger amount of paclitaxel and polymer coating than experienced in the clinical studies. There is no clinical experience on the performance of the ION stent when used with other types of coated or drug-eluting stents.

There may be other potential adverse events that are unforeseen at this time.

Medications

Your cardiologist may prescribe a number of medications to thin the blood and prevent blood clots from forming and adhering to the surface of the stent. These medications will include aspirin and blood thinning drugs such as Plavix®, Ticlid® or Effient® (Prasugrel). It is extremely important that you follow your doctor's instructions on what medications to take. If you stop taking these medications

before being instructed to do so by your cardiologist, the chances of blood clot formation on the stent, subsequent heart attack or even death are increased.

If you plan to have any type of surgery or dental work which may require you to stop taking these medications prematurely, you and your cardiologist should discuss whether or not placement of a stent is the right treatment for you.

If surgery or dental work is recommended which would require you to stop taking these medications prematurely after you've received the stent, you and your doctor should carefully consider the risks and benefits of this additional surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require premature discontinuation of these medications because of significant bleeding, then your cardiologist will be carefully monitoring you for possible complications. Once your condition has stabilized, your cardiologist will probably put you back on these medications.

Clinical Data Summary

The safety and effectiveness of the ION Stent were compared to the TAXUS Express Stent, in the PERSEUS Workhorse clinical trial that included 1262 patients with a planned five-year clinical follow-up. The study results showed that patients who received an ION Stent had a similar incidence of bypass surgery or repeat angioplasty in the lesion where the stent was placed when compared to patients who received a TAXUS Express Stent (3.8% ION vs. 4.5% TAXUS Express) at 12 months. The combined occurrence of Major Adverse Cardiac Events, which is comprised of cardiac death, heart attacks, bypass surgery and repeat angioplasty, was 7.4% (ION) vs. 7.7% (TAXUS Express) at 12 months.

Full study results are provided in the ION Directions for Use, found on www.bostonscientific.com.

AFTER THE PROCEDURE

After the stent is implanted, you will be moved to a cardiology ward for a short period where you can be monitored closely as you begin to recover. On average, your hospital stay may last one to three days before you are discharged.

ACTIVITY

- Follow your doctor's guidelines.
- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from medications immediately. These may include headaches, nausea, vomiting or rash.
- Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent.
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your Stent Implant Card at all times. If you receive dental or medical care or report to an emergency room/center, show your Stent Implant Card.

FREQUENTLY ASKED QUESTIONS

Can the stent move or rust?

Once positioned by your physician, the stent does not move on its own. It is manufactured so it will not rust.

Can I walk through metal detectors with a stent?

Yes, without any fear of setting them off.

How soon can I go back to work?

The majority of people return to work within a few days following the procedure.

What if I still get pains?

If you experience pain, immediately inform your cardiologist or the center where the procedure was performed.

Can I undergo MRI or scanner testing with a stent?

MRI safety testing has shown that the stent should not migrate in the MRI environment typically used in a clinical setting ($\leq 3T$), and that MRI may be performed immediately following stent implantation. Testing also demonstrated that stent heating due to the MRI is less than 2.6 degrees Celsius and should not affect performance of the implanted stent or the drug coating.

Can I play sports?

Your doctor will tell you what sports you can play and when you can start them.

What should I change in my diet?

Your doctor may prescribe a low-fat, low-cholesterol diet to help reduce the levels of fat in your blood and reduce your risk.

Does paclitaxel have any drug interactions that I should be concerned about?

Formal drug interaction studies with paclitaxel-based stents have not been conducted. Since some paclitaxel will remain on the stent, interactions at the location of the stent itself affecting the performance of the drug cannot be ruled out. Be sure to discuss with your doctor any drugs you are taking or planning to take.

What if I have taken paclitaxel before and had a reaction to it?

Be sure to let your doctor know if you have had a previous reaction to paclitaxel.



Stent Implant Location

**Boston
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Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
1.888.272.1001
www.bostonscientific.com
www.stent.com

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If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician/technologist that you have a stent implant. Test results indicate that the ION Stent is MR Conditional. Patients with single or overlapped ION Stents up to 74 mm in total length can undergo MRI scans safely under the following conditions:

- Field strengths of 1.5 Tesla and 3 Tesla
- Static magnetic field gradient < 9 T/m (extrapolated)
- Normal operating mode (maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg) for a total active MR scan time (with RF exposure) of 15 minutes or less

The stent(s) should not migrate in this MRI environment and MRI may be performed immediately following the implantation of an ION Stent(s). Prior to undergoing an MRI scan, inform your doctor that you have an ION Stent.

MR image quality will be compromised if the area of interest is in the same area or relatively close to the position of the stent. Please contact 1.888.272.1001 for more information about MR image artifact.

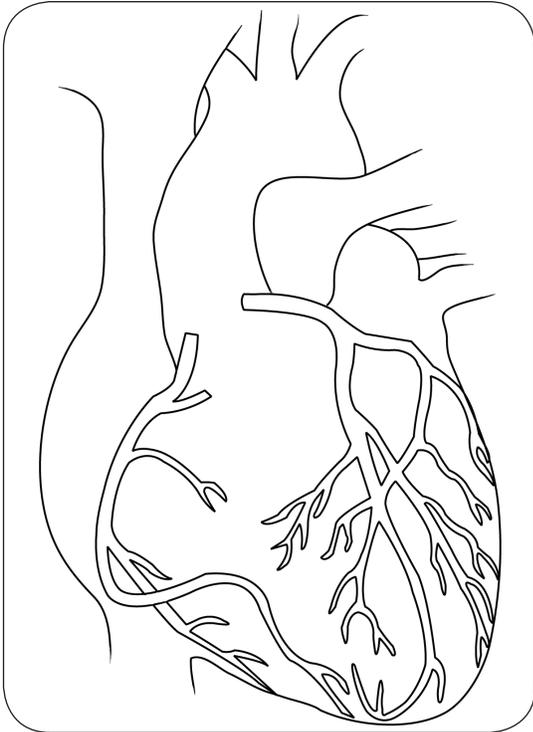
PLEASE CARRY YOUR CARD AT ALL TIMES

Your cardiologist has prescribed a number of medications to thin the blood and prevent blood clots after your implant. It is extremely important to follow the medication regimen as prescribed by your cardiologist. Before considering any surgery or dental work which would require you to stop taking these medicines early, you and your doctors should consider the risks from premature discontinuation of these medications. **For questions regarding your Coronary Stent System or other procedures (e.g., MRI), please contact your implanting cardiologist.**

Stent Identification Information

Patient Name	Patient Phone Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant
Product Name	Product Name
Product Lot Number	Product Lot Number
Stent Location	Stent Location

Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law and governing law outside the U.S.A. restricts these products to sale by or on the order of a physician. ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System is a product of Boston Scientific Corporation.



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