Appendix A -- Patient Information Guide text (in English)

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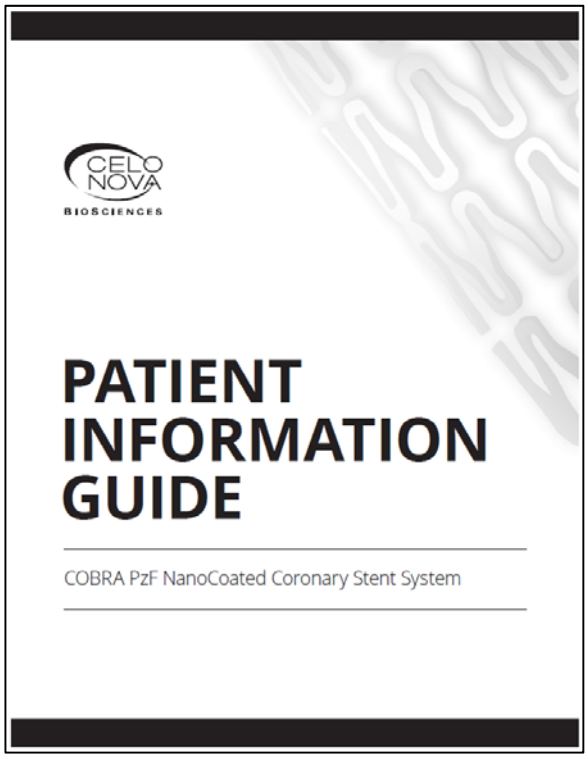
Front Cover



Back Cover

COBRA PzF NanoCoated Coronary Stent System

Patient Information Guide

Caution: Federal law restricts this device to sale by or on the order of a physician.

Note: Instructions, indications, contraindications, warnings, and precautions can be found in the instructions for use supplied with each product.

1. Introduction

You have recently had a COBRA PzF NanoCoated stent implanted in the coronary arteries of your heart. The information in this booklet is not only intended to describe the stent in more detail, but also answers some of the common questions around the use of stents to treat Coronary Artery Disease (CAD). After you read this booklet, if you have any questions about the COBRA PzF NanoCoated stent or the stenting procedure, be sure to ask your cardiologist. If you need additional information about the COBRA PzF NanoCoated stent, please refer to www.celonova.com or call CeloNova BioSciences Customer Service at +1.888.388.3888.

2. What is CAD?

CAD affects the arteries that surround the heart. These coronary arteries supply blood with oxygen to the heart muscle to allow it to function properly. CAD occurs when the inner walls of the coronary arteries thicken due to

plaque, a buildup of cholesterol, fatty deposits, calcium, and other elements carried in the blood. As the plaque develops, the inside of the artery narrows. When the artery narrows, blood flow, is restricted, so less oxygen and other nutrients reach the heart muscle. This condition, known as atherosclerosis, may lead to chest pain (angina pectoris) or a heart attack (myocardial infarction).

3. COBRA PzF NanoCoated Stent

The COBRA PzF NanoCoated stent is a made of a cobalt chromium (CoCr) alloy. By design, this stent acts as a miniature, circular scaffolding that flexes to fit the shape of your artery, helping it maintain structure and strength.

4. PzF NanoCoating

PzF NanoCoating, which has been applied to the stent's surface, is a proprietary material developed by CeloNova BioSciences. The PzF NanoCoating was designed to be flexible, durable, and biocompatible.

5. Clinical Summary

The principal safety and effectiveness for the COBRA PzF NanoCoated stent is from the global PzF SHIELD clinical trial. The PzF SHIELD trial included 296 patients with planned follow-up at 30 days, 6, 9 and 12 months post index procedure. Additional follow-up is planned annually through 5 years post index procedure. The combined occurrence of death, heart attack and repeat revascularization was 4.6% for the COBRA PzF stent at 9 months. The study results showed that the COBRA PzF stent was as safe and effective as other approved bare metal coronary stents.

6. Potential Adverse Events

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

- Abrupt closure
- Access site pain, hematoma, or hemorrhage
- Allergic/reactions (including to contrast media, stent materials or medication)
- Angina
- Aneurysm (Coronary)
- Arteriovenous fistula
- Arrhythmias, including ventricular tachycardia or fibrillation
- Bleeding
- Cardiac tamponade
- Cardiogenic shock
- Cardiomyopathy
- Death
- Emboli (including air, tissue, plaque, thrombus or device materials)
- Failure to deliver stent to intended site
- Heart failure
- Hematoma
- Hypotension and/or hypertension
- Infection, local and/ or systemic
- ischemia, myocardial
- Myocardial infarction
- Pericardial effusion
- Pseudoaneurysm
- Pulmonary edema
- Renal insufficiency or failure
- Respiratory failure

- Restenosis of the stented segment
- Shock
- Stent fracture or deformation
- Stent migration
- Stent thrombosis
- Stroke or transient ischemic attack (TIA)
- Total vessel occlusion
- Vessel spasm
- Vessel injury (including dissection, perforation, rupture or trauma)

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

7. Recovery

Following the procedure, you will be monitored closely during rest and recovery. Discharge from the hospital generally occurs one to three days after the procedure.

Steps for Success

1. Follow your cardiologist's guidelines and communicate regularly, and/or as needed:
   - Medication regimen—Do not discontinue treatment without consulting your cardiologist. Side effects (including headaches, nausea, vomiting, rash) should be reported immediately.
   - Physical activities—Return to normal activities gradually, pacing your return to activity as you feel better. Check with your cardiologist about strenuous activities.
   - Changes in lifestyle—Discuss any changes in lifestyle you make during your recovery period.
2. Attend all scheduled follow-up appointments, including laboratory blood testing.
3. 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.

8. Medications

Your cardiologist will prescribe blood thinning medications. Usually the medications include aspirin and a drug known as an antiplatelet. These medications help to prevent blood clots from forming on your stent. It is extremely important you take these drugs as directed by your cardiologist. If you are asked to stop these medications by another doctor or a dentist for any reason, you must check with your cardiologist first.

9. Frequently Asked Questions

Q: Once positioned in the artery, is the stent designed to move?

A: No. The stent is designed to remain in the targeted artery position.

Q: Will the stent rust?

A: No. Manufacturing processing and materials prevent the stent from rusting.

Q: Will a stent implant set-off a metal detector?

A: No. The stent will remain unnoticeable to standard metal detectors.

Q: How soon can I go back to work?

A: Consult your cardiologist. The majority of people return back to work within a few days following the procedure.

Q: What if I still have pain?

A: Consult your cardiologist immediately if you experience pain following the procedure.

Q: Can I undergo MRI or scanner testing with a COBRA PzF stent?

A: Yes. A patient implanted with a COBRA PzF NanoCoated stent can safely undergo an MRI scan under certain conditions. These conditions are described on the Stent Implant Card (see Figure 1).

Prior to undergoing an MRI scan, inform your doctor or MR technologist that you have a COBRA PzF NanoCoated stent.

Q: Can I play sports?

A: Consult your cardiologist, who will tell you what sports you can play and when you can start them.

Q: Should I change my diet?

A: Follow your doctor's recommendations for changes to diet.

10. More Information

For more information on the COBRA PzF NanoCoated Coronary Stent System, please refer to www.celonova.com or call customer service at +1 888.388.3888.

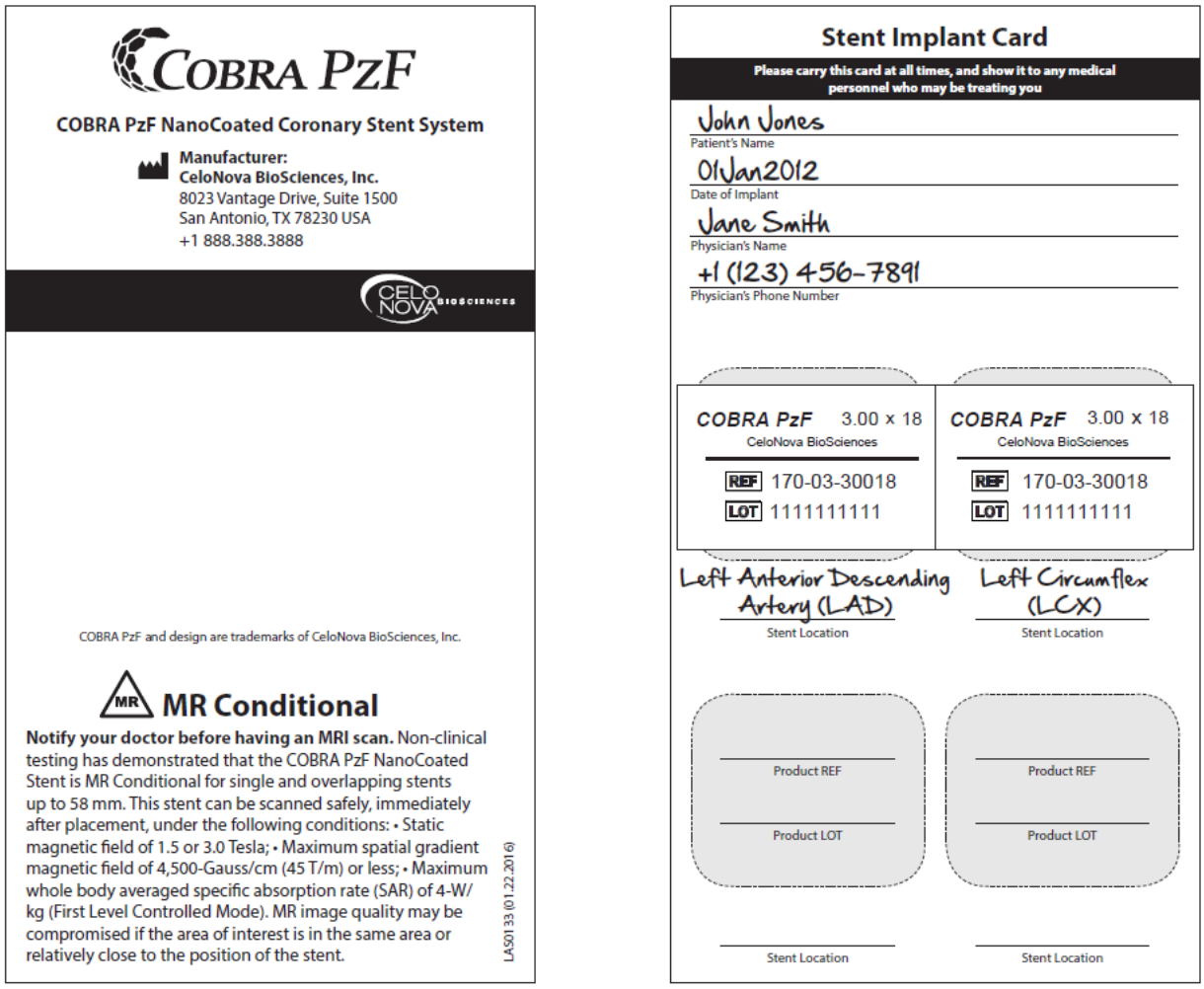
Manufacturer:

CeloNova BioSciences, Inc.
8023 Vantage Drive, Suite 1500
San Antonio, TX 78230 USA
+1 888.388.3888

Stent Implant Card

Information on this card describes the MRI conditions appropriate for Patients with Cobra PzF NanoCoated stent implant(s). This card must be carried with you at all times.

Figure 1 Sample Image



(Names in sample image are provided for illustration purposes, only)