

PK Papyrus

Covered Coronary Stent

Patient Information Guide



PATIENT INFORMATION GUIDE

This guide explains the probable benefits and potential risks associated with having a PK Papyrus covered stent implanted along with medication recommendations and answers to questions you may have about coronary stents.

Coronary Artery Disease

Coronary arteries are blood vessels that carry oxygen and nutrient-rich blood to the heart muscle. Arteries can become narrowed or blocked if plaque (composed of cholesterol deposits and scar tissue) builds up in the arterial walls. This process is called atherosclerosis or coronary artery disease. When this happens, your heart may not receive the oxygen it needs due to blood flow reduction. The lack of blood flow can result in chest pain, shortness of breath, and possibly a heart attack.

Treatment with a Covered Coronary Stent

Your physician may have informed you that one or more of your coronary arteries have significantly narrowed, and that you may require treatment with a Percutaneous Coronary Intervention (PCI) procedure. Typically, the physician performing the PCI procedure will inflate a balloon within the narrowed part of the coronary artery and then implant a stent, which is a metallic tube that helps keep the artery open.

A coronary artery perforation caused by a tear in the artery wall is a rare but serious complication that can occur during a PCI procedure. When a coronary artery perforation is severe, blood leaks out of the artery into the sac surrounding the heart (pericardial sac). If not successfully treated, blood collecting in the pericardial sac can interfere with heart function and cause a life-threatening condition called pericardial tamponade.

A covered stent is a tiny metal mesh-like tube with a covering. The metallic tube holds the coronary artery open, and the coverings seals the site of the arterial perforation. Implantation of a covered stent allows blood flow within the coronary artery to the heart muscle and prevents further blood accumulation in the pericardial sac.

A covered stent is delivered to the site of the coronary artery perforation on a balloon catheter delivery system. Once it is positioned in place, the covered stent is expanded and implanted in your artery by inflating the balloon. The covered stent maintains the opening of the artery while sealing the perforated vessel wall. The covered stent is left in the artery permanently, and over time, tissue from the coronary artery wall covers the device.

The PK Papyrus Covered Coronary Stent

The PK Papyrus covered stent is intended as a permanent coronary artery implant. It is made from a cobalt chromium (CoCr) metal alloy and is covered with a polyurethane membrane. Cobalt chromium is a metal commonly used for coronary stents. The polymer cover on the stent acts to seal the perforated vessel. The PK Papyrus covered stent is designed to be strong enough to keep the vessel open but also flexible to fit the shape of your artery.

The PK Papyrus covered stent is delivered to the coronary artery using a PK Papyrus balloon catheter delivery system. Together, the PK Papyrus covered stent and the delivery system make up the PK Papyrus Covered Coronary Stent System.

Potential Risks and Adverse Events

Potential risks and adverse events that may be associated with the use of a covered coronary stent in the native coronary arteries include, but are not limited to:

- Allergic reaction to the contrast media, stent materials, or antiplatelet medications or anticoagulants (blood thinning drugs).

- Abnormal heart rates or rhythms such as a rapid heart rate, slow heart rate, or an irregular heart rate that can cause a quivering sensation in your chest, shortness of breath, dizziness, fatigue or weakness. Some abnormal heart rates or rhythms may be serious and require specific treatments.
- Bleeding events such as bleeding from the site where the stent system was inserted into your blood vessels, requiring special medication, blood transfusions (for severe bleeding), or surgical repair of injured blood vessels.
- Heart events such as heart attack or reduced blood flow to your heart muscle; abrupt closure of the treated coronary artery; re-narrowing of the treated artery due to the growth of scar tissue with the PK Papyrus covered stent; cardiogenic shock (severe damage to your heart where it cannot supply enough blood to the rest of your body); chest pain, fluid build-up in the sac around the heart resulting in reduced heart function (pericardial tamponade); persistent coronary artery perforation or a new coronary artery tear; need for emergency heart surgery.
- Death.
- Infection and sepsis.
- Nervous system events such as stroke, transient ischemic attack (TIA), nerve damage or pain.
- Breathing or lung events such as heart failure, build-up of fluid in your lungs, difficulty breathing, or inability to breathe.
- PK Papyrus covered coronary stent system events such as stent placed in an unintended or unplanned location; stent falling off the balloon catheter(dislodgement); stent deformation (bending or twisting); stent migrating to an unintended location (embolization); stent thrombosis (blood clot within the stent) or artery occlusion; stent fracture (break); stent movement; stent not fully in contact with the vessel wall; delivery system balloon inflation difficulties, rupture or pinhole of the balloon; balloon deflation difficulties; difficulty removing the balloon catheter from blood vessels, release of balloon catheter material into the blood stream (embolization) that may cause blood clots or organ damage.
- Blood vessel system events such as hypotension (low blood pressure); hypertension (high blood pressure); access site bruising and/or a blood collection under the skin (hematoma); access site blood vessel injury such as an arterial perforation or tear in the vessel wall (dissection); arteriovenous fistula (an abnormal connection between an artery and a vein); intra-abdominal (retroperitoneal) bleeding; re-narrowing of blood vessels; blood clot formation or vessel obstruction; vessel spasm; reduced blood flow to the tissues supplied by a blood vessel; due to vessel blockage by blood clots, plaque, or foreign material (embolization).

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

Clinical Data Summary

The safety and probable benefit of the PK Papyrus Covered Coronary Stent System is based on a survey of device use in Europe and Asia. The objective of the survey was to evaluate the success and safety of the PK Papyrus covered stent as a life-saving treatment for coronary perforations. The survey included responses for 80 patients treated for coronary perforations. In 91.3% (73 of 80) of the cases, the perforation was successfully sealed with the implantation of one or more PK Papyrus covered stents.

Of the 80 patients in which PK Papyrus covered stent implantation was attempted to save the patient's life in an emergency situation, 77 (96.3%) survived the procedure, and two patients died during the procedure. In the surveys completed, in-hospital complications were reported in 17.5% (14 of 80) patients. Eight patients (10%, 8 of 80) experienced cardiac death, either during the procedure (2) or prior to hospital discharge (6). Seven patients (8.8%, 7 of 80) had pericardial tamponade (life-threatening blood collection within the heart sac) that required pericardiocentesis (a procedure to drain the blood collection around the heart).

In-hospital complications that were related to the PK Papyrus Covered Coronary Stent System were reported in 8 patients (10%, 8 of 80). Stent dislodgement was reported in 7.5% (6 of 80) patients, and stent

thrombosis (blood clot or possible clot in the stent) was reported in 2.5% (2 of 80) patients.

Follow-up surveys for 22 patients after PK Papyrus implantation and hospital discharge reported three (13.6%, 3 of 22) patients with an adverse event. Of these three, one patient experienced a non-cardiac death, one patient had a heart attack, and one patient had a blockage of the vessel within the PK Papyrus covered stent requiring a procedure to treat the blockage within the vessel with a balloon or stent.

The survey results support the safety and adequate sealing performance of the PK Papyrus covered stent for coronary artery perforations.

Medications

Your doctor may prescribe blood thinning medications to prevent blood clots from forming within the PK Papyrus covered stent. These medications include aspirin in addition to clopidogrel (Plavix®), ticlopidine (Ticlid®), prasugrel (Effient®) or ticagrelor (Brilinta®). It is extremely important to follow your doctor's medication recommendations. These blood thinning medications lower the risk of blood clot formation within your PK Papyrus Covered Stent, which could cause a heart attack or death.

You should report potential side effects from medications immediately. These may include bleeding, headaches, nausea, vomiting or rash.

Do not stop taking your medications unless you are asked to stop by the doctor who implanted your stent. If surgery or dental work is recommended that would require you to stop taking blood thinning medications prematurely, you and your doctors should carefully consider the risks and benefits of surgery or dental work versus the possible risks from early discontinuation of these medications.

If you do require premature discontinuation of blood thinning medications because of significant bleeding, your doctor will carefully monitor you for possible complications. Once your condition stabilizes, your doctor will decide when to restart blood thinning medications.

After the Procedure

After the PK Papyrus covered stent implantation procedure, you will rest in a unit where nurses and doctors can monitor you closely during your recovery. You may be asked to stay in bed for several hours. It may be one or more days before you are discharged from the hospital, during which time you will be monitored to make sure that the coronary perforation remains effectively sealed. It is recommended that one or more soundwave tests of your heart (echocardiograms) will be performed before hospital discharge. Your physician will schedule a follow-up visit after hospital discharge to check for signs of recurrent perforation or re-narrowing in your coronary arteries.

Activity

- Follow your doctor's guidelines.
- Return to normal activities gradually. Pace yourself with resuming activities as you feel better. Ask your doctor about specific exercise or strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Keep up with all follow-up appointments, including any laboratory blood tests.
- Carry your Patient Implant Card at all times and show it to any medical professional who treats you (for example, for dental work, medical care, or emergency room visits).

Frequently Asked Questions

Can the stent move?

No. Once implanted as directed, the PK Papyrus covered stent cannot move because it is in firm contact with the coronary artery wall. Over time, the stent becomes covered with vessel wall tissue.

Can the stent rust?

No. The stent is made of a rust-proof material, meaning it will not rust inside your body.

Can I walk through metal detectors or security with a stent?

Yes. You may walk through metal detectors or security scan with a PK Papyrus Covered Stent.

How soon can I go back to work?

Ask your doctor about when you can return to work. The majority of people return to work within a few days following the procedure. Most people are back to their earlier lifestyle within weeks or a month or so, depending on the damage done to the heart by coronary artery disease, the PCI procedure, and the coronary artery perforation.

What if I still have pain?

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

Can I undergo an X-ray, MRI or scanner tests with a stent?

An X-Ray or CT Scan can be performed at any time. For an MRI scan, inform your doctor or MR technician that you have a PK Papyrus covered stent prior to undergoing an MRI scan and show your Patient Implant Card for the scanning conditions. MRI safety tests have demonstrated that the PK Papyrus covered stent is "MR conditional." The conditions under which an MRI scan can be safely performed are listed on your Patient Implant Card and may be found at <https://manuals.biotronik.com>.

Can I exercise or play sports?

Your doctor will tell you what types of exercise and 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 cholesterol in your blood and reduce your heart disease risk. Ask your doctor if you have questions about your diet.

More Information

For more information about the PK Papyrus covered stent, please visit our website (www.biotronik.com) or call our 24-hour Support at (800) 547-0394.

Indications, contraindications, warnings and the directions for use can be found in the product's Instructions For Use manual.

HUMANITARIAN DEVICE. Authorized by Federal law for use in the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter. The effectiveness of this device for this use has not been demonstrated.

CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a physician.

PK Papyrus Covered Coronary Stent System is a product of BIOTRONIK.

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