PK Papyrus

Covered Coronary Stent System

English

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 (USA) law restricts this device to sale by or on the order of a physician.

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Description

The PK Papyrus Covered Coronary Stent System (hereinafter PK Papyrus) is a balloon-expandable covered stent (hereinafter PK Papyrus stent) that is pre-mounted on a fast-exchange delivery system. The stent is intended for permanent intraluminal placement in the coronary arteries to treat acute coronary artery perforations.

The stent is made from a silicon carbide (proBIO) coated cobalt chromium alloy (L-605) and covered by a polyurethane membrane on its external surface. The stent is centered between two radiopaque markers to facilitate fluoroscopic visualization and positioning.

The proximal shaft of the delivery system is a hypotube and has a single Luer port for connecting an inflation/deflation device to inflate/deflate the balloon. The catheter has a hydrophobic coating on the outer surface of the proximal shaft and a hydrophilic coating on the outer surface of the distal shaft. The guide wire lumen starts at the delivery system tip and ends at the guide wire exit point 29 cm from the distal end.

PK Papyrus is compatible with guide wires with a diameter of 0.014“ (0.36 mm) and guiding catheters with an inner diameter of ≥ 0.056“ (1.42 mm; 5F) for 2.5-4.0 mm stents and inner diameter of ≥ 0.070” (1.78 mm; 6F) for 4.5-5.0 mm stents.

To indicate when the delivery system tip exits from the guiding catheter, markers are located on the hypotube 92 cm (brachial technique) and 102 cm (femoral technique) from the distal end of the delivery system.

The click-in hypotube fastener on the hub is designed to facilitate the handling of the stent system when it is stored on the preparation table.

Caution: This fastener is intended to hold only the hypotube section of the delivery system; the distal shaft should not be held by the click-in fastener.

A summary of the PK Papyrus is shown in Table 1.

Table 1. PK Papyrus Stent System Features

	PK Papyrus Covered Coronary Stent System
Available Stent Lengths (mm)	15, 20, 26
Available Stent Diameter (mm)	2.5, 3.0, 3.5, 4.0, 4.5, 5.0
Stent Material	silicon carbide (proBIO) coated cobalt chromium alloy (L-605)
Stent Cover	polyurethane
Delivery System Working Length (cm)	140
Delivery System Design	Fast-Exchange: Single Luer port for inflation/deflation; guide wire exit port is 29 cm from the distal end
Stent Delivery System Balloon	Two radiopaque markers to facilitate fluoroscopic visualization and positioning
Balloon Inflation Pressure	Nominal Pressure: 7 atm (Ø4.0-5.0 mm); 8 atm (Ø2.5-3.5 mm) Rated Burst Pressure: 14 atm (Ø4.5-5.0 mm); 16 atm (Ø2.5-4.0 mm)
Minimum Guiding Catheter Inner Diameter	5F (≥ 0.056“ / 1.42 mm): Ø2.5-4.0 mm 6F (≥ 0.070” / 1.78 mm): Ø4.5-5.0 mm

How Supplied

Sterile. Non-pyrogenic. Device is sterilized with ethylene oxide.

Note: Visual aid (SOS) is placed on the labels for easy recognition.

Contents

- One (1) stent system and one (1) compliance chart in a sealed, peel-open pouch.
- One (1) patient implant card.

Storage

Store in a dark, dry location between 10°C / 50°F and 25°C / 77°F.

Indications

The PK Papyrus is indicated for the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter.

Contraindications

Contraindications for PK Papyrus and stenting in general are:

- Patients in whom antiplatelet agents or anticoagulation therapy is contraindicated.
- Patients with a known allergy or hypersensitivity to amorphous silicon carbide or any other compound of the system (siloxane-based polyurethane, L-605 cobalt chromium alloy including tungsten and nickel).
- Lesions that cannot be reached or treated with the system.
- Lesions with threatened or abrupt closure during attempted pre-dilation prior to stent implantation.
- Risk of treatment-related occlusion of vital coronary artery side branches.
- Uncorrected bleeding disorders.
- Allergy to contrast media.

Warnings

- This device is designed and intended for single use only. DO NOT resterilize and/ or reuse. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection, and sterilization may compromise essential material and design characteristics leading to device failure.
- DO NOT use the stent system if the outer or the inner package is damaged or opened, or any information provided is obscured or damaged.
- DO NOT use device after the “Use by” date indicated on the label.
- DO NOT rotate the stent system if the tip is constrained.
- DO NOT expose the stent system to organic solvents e.g. alcohol.
- DO NOT apply vacuum prior to introduction of the stent system. This may cause premature dislodgement of the stent.
- Manipulate the stent system under angiographic guidance when it is in the body.
- Use only an appropriate balloon inflation medium (e.g. 50:50 mixture by volume of contrast medium and saline). NEVER use air or any gaseous medium to inflate the balloon.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should not exceed the original diameter of the vessel proximal and distal to the lesion.
- Balloon pressure must not exceed the rated burst pressure (RBP). Use of a pressure-monitoring device is mandatory to prevent over-pressurization.
- Patients with renal insufficiency receiving a PK Papyrus Stent may be at an increased risk of worsening renal function or renal failure due to the need for an increased volume of contrast.
- Caution should be taken if a PK Papyrus Stent is inserted in thrombus-containing lesions, as this may increase the risk of complications, including myocardial infarction and death.
- Covered stents used to treat coronary ruptures can be associated with high rates of restenosis. Restenosis of a PK Papyrus Covered Coronary Stent may require revascularization of the arterial segment. The safety and effectiveness of re-dilation of a PK Papyrus Stent to treat restenosis have not been established.

Precautions

- Only physicians thoroughly trained and experienced in the performance of percutaneous transluminal coronary angioplasty (PTCA) and stent implantation should use this device.
- Narrow, calcified and tortuous lesions or other lesions that could impede the delivery of the PK Papyrus Stent must be pre-dilated with an appropriately-sized angioplasty balloon or another arterial dilatation method before using the PK Papyrus Covered Coronary Stent System.
- Exercise care during device handling to reduce the possibility of disrupting the placement of the stent on the balloon and accidental breakage, bending or kinking of the stent system shaft and damaging its cover.
- Forceful movements may dislodge the protector and the stent.
- The click-in hypotube fastener is intended to hold only the hypotube section of the delivery system; the distal shaft should not be held by the click-in fastener.
- When removing the stent protector, always pull at the very distal end of the protector to avoid dislodging the stent.
- Prior to the procedure, the stent system should be visually examined to verify functionality; the stent must be visually checked for uniformity, no protruding struts, centering on the balloon, and cover integrity and ensure that its size is suitable for the specific procedure for which it is to be used.
- Avoid excessive manipulation of the stent during flushing of the guide wire lumen.
- Use guiding catheters with a minimum inner diameter of ≥ 0.056” (1.42 mm; 5F) for 2.5-4.0 mm stents and a minimum of ≥ 0.070” (1.78 mm; 6F) for 4.5-5.0 mm stents.
- Use only guide wires with a diameter of 0.014” (0.36 mm).
- When inserting and positioning the stent system, ensure that the hemostatic valve of the guiding catheter is fully open. A partially opened hemostatic valve may damage the stent, the cover integrity or dislodge the stent from the centered location on the balloon.
- Ensure that the guide wire exit port remains inside the guiding catheter at all times. The guide wire exit port is indicated on the label.
- DO NOT apply excessive force while accessing or crossing the lesion. This may damage the stent, stent cover and/or dislodge the stent from the balloon. If resistance is felt at any time, stop the procedure and determine the cause of resistance before proceeding. If the stent system is unable to reach or cross the lesion easily, the procedure should be aborted. Refer to the section “Removal of an Unexpanded Stent.”
- DO NOT inflate the balloon if a vacuum cannot be held as this indicates a leak in the delivery system. If a vacuum cannot be held, refer to section “Removal of an Unexpanded Stent.”
- Inflate to at least the nominal pressure (NP) indicated on the label and in the “Compliance Chart” table. DO NOT exceed the rated burst pressure (RBP).
- Avoid barotrauma outside the stent margins during post-dilation.
- DO NOT post-dilate the stent to more than the maximum expandable diameter recommended in the “Sizes” table.
- The use of mechanical atherectomy or laser catheters is not recommended in the stented area.
- Exercise care during crossing the deployed stent with guide wires, accessory devices, or adjunct devices to avoid disruption of the stent cover, disruption of the stent geometry, or stent migration.
- If resistance is encountered during removal of the delivery system, remove the delivery system and the guiding catheter as a single unit. Refer to section “Removal of the Delivery System/Stent System and the Guiding Catheter as a Single Unit.”
- DO NOT re-insert the stent system as the stent and/or the delivery system may have been damaged during the initial attempt to cross the lesion or during withdrawal.
- Failure to follow correct removal steps for an unexpanded stent system and/or applying excessive force to the stent system can potentially result in loss or damage to the stent and/or delivery system components.

Potential Adverse Events/Complications

Possible adverse events associated with the use of the PK Papyrus when used as intended are:

- Cardiac events: myocardial infarction or ischemia; abrupt closure of treated artery or side branch; restenosis of the treated artery; cardiogenic shock; angina; coronary dissection; perforation or other coronary or aortic injury; residual coronary perforation; cardiac perforation; pericardial effusion; pericardial tamponade; coronary aneurysm formation; need for emergency cardiac surgery.
- Arrhythmic events: ventricular tachycardia, ventricular fibrillation, atrial fibrillation, sinus bradycardia.

- Stent system events: failure to deliver the stent to the intended site, stent dislodgement from the delivery system, failure to deliver stent to the intended site, stent deformation, stent embolization, stent thrombosis or occlusion, stent fracture, stent migration, stent loss, mal-apposition of the stent to the arterial wall, delivery system balloon inflation or deflation difficulties, delivery system balloon rupture, delivery system withdrawal difficulties, embolization of catheter material.
- Respiratory events: acute pulmonary edema, congestive heart failure, respiratory insufficiency or failure.
- Vascular events: pseudoaneurysm; arteriovenous fistula; retroperitoneal hemorrhage or hematoma; vessel dissection, perforation, rupture or other injury; restenosis, thrombosis or occlusion; compromise of side branch patency; occlusion of side branches; vasospasm; peripheral ischemia; embolization of air, thrombotic, atherosclerotic or catheter material.
- Hemodynamic events: hypotension or hypertension.
- Neurologic events: stroke, TIA, peripheral nerve injury.
- Bleeding events: access site hemorrhage, access site hematoma.
- Local or systemic infection.
- Allergic reactions to contrast media, antiplatelet agents, anticoagulants, amorphous silicon carbide or any other system components (e.g., siloxane-based polyurethane, L-605 cobalt chromium alloy including tungsten and nickel).
- Death.

Directions for Use

Patient Preparation and Stent System Selection

1. Prepare the patient for a PCI procedure according to the institution's standard clinical practice.

Caution: Narrow, calcified and tortuous lesions or other lesions that could impede the delivery of the PK Papyrus Stent must be pre-dilated with an appropriately-sized angioplasty balloon or pre-treated with another arterial dilatation method before using the PK Papyrus Covered Coronary Stent System.

2. Select the stent size to match the diameter of the vessel to achieve a final stent diameter to vessel ratio of 1:1 and a full coverage of the lesion over its entire length with a single stent. Wherever possible, choose the stent length to avoid side branch occlusion and use of overlapping stents.

Stent System Preparation

Caution: Exercise care during device handling to reduce the possibility of disrupting the placement of the stent on the balloon and accidental breakage, bending or kinking of the stent system shaft and damaging its cover.

3. Remove the protection ring containing the stent system from the sterile package and place it onto a sterile field.
4. Gently pull out the stent system from the protection ring.

Caution: Forceful movements may dislodge the protector and the stent.

Caution: The click-in hypotube fastener is intended to hold only the hypotube section of the delivery system; the distal shaft should not be held by the click-in fastener.

5. Carefully remove the balloon/stent protector and discard.

Caution: When removing the stent protector, always pull at the very distal end of the protector to avoid dislodging the stent.

6. Check for visual integrity of the stent and cover and centering of the stent on the balloon.

Caution: Prior to the procedure, the stent system must be visually examined to verify its functionality, uniformity, centering of the balloon on the stent, and integrity of the cover. Confirm that there are no protruding struts and the stent size is suitable for the target vessel.

Flushing of the Guide Wire Lumen

7. Connect a syringe (10 – 20 mL) containing sterile saline to an appropriately-sized flushing needle. Carefully insert the needle into the distal tip of the delivery system and flush the guide wire lumen.

Warning: DO NOT apply a vacuum prior to the introduction of the stent system. This may cause premature dislodgement of the stent.

Caution: Avoid excessive manipulation of the stent during guide wire lumen flushing.

8. Remove the syringe and the flushing needle.
9. Leave the prepared stent system at ambient pressure.

Insertion and Stent Positioning

10. Attach a hemostatic valve to the Luer port of the guiding catheter positioned within the vasculature.
11. Position the guide wire under fluoroscopy in accordance with PCI techniques.
12. Back-load the proximal end of the guide wire into the distal tip of the delivery system until it exits at the guide wire exit port.
13. Open the hemostatic valve completely.
14. Carefully insert the stent system through the hemostatic valve.

Caution: When inserting and positioning the stent system, ensure that the hemostatic valve of the guiding catheter is fully open. A partially opened hemostatic valve may damage the stent and the cover integrity or dislodge the stent from its centered location on the balloon.

15. Advance the stent system through the guiding catheter using fluoroscopic guidance to determine when the delivery system tip approaches the distal tip of the guiding catheter.

Note: The shaft exit markers on the hypotube may be used to approximate when the stent system has reached the distal end of the guiding catheter.

16. Carefully advance the stent system into the coronary artery over the guide wire while maintaining stable guiding catheter position and stable guide wire placement across the target lesion.
17. Position the stent within the lesion using the balloon radiopaque markers as reference points.

Caution: DO NOT apply excessive force while accessing or crossing the lesion. This may damage the stent and stent cover and/or dislodge the stent from the balloon. If resistance is felt at any time, stop the procedure and determine the cause of resistance before proceeding. If the stent system is unable to reach or cross the lesion easily, the procedure should be aborted. Refer to the section "Removal of an Unexpanded Stent."

18. Verify the stent position using angiographic guidance to assure adequate coverage of the lesion including the proximal and distal margins.

Remove Air from the Delivery System

19. Connect a three-way stopcock to the Luer port according to hospital procedure.
20. Prepare and remove air from a 20-ml capacity inflation/deflation device according to the manufacturer's instructions.
21. Attach the inflation/deflation device containing 3 ml of balloon inflation medium to the stopcock.

Warning: Use only an appropriate balloon inflation medium (e.g., 50:50 mixture by volume of contrast medium and saline). NEVER use air or any gaseous medium to inflate the balloon.

22. Open the stopcock so that an open fluid path between the delivery system and the inflation/deflation device is established.
23. Pull back on the plunger of the inflation/deflation device and aspirate air from the catheter for at least 30 seconds.

Caution: DO NOT inflate the balloon if a vacuum cannot be held, as this indicates a leak in the delivery system. If a vacuum cannot be held, refer to section "Removal of an Unexpanded Stent."

24. Close the stopcock so that the fluid path to the catheter is closed and evacuate all air from the inflation/deflation device through the stopcock.
25. Repeat steps 22-24 if necessary to ensure air contained in the stent system is removed. Release the inflation/deflation barrel to ambient pressure.

Stent Deployment

26. Inflate the balloon gradually to expand the stent to the target diameter in accordance with the "Compliance Chart" table. Hold that pressure for 15-30 seconds.

Caution: Inflate to at least the nominal pressure (NP) indicated in the "Compliance Chart" table. DO NOT exceed the balloon rated burst pressure (RBP).

Note: Use multiple fluoroscopy views to verify the stent position and to ensure that the stent has been completely expanded.

27. If necessary, the delivery system balloon may be redilated to achieve optimum apposition of the implanted stent to the vessel wall. Deployed stents should not be left under-dilated. Stent wall apposition should be verified through routine angiography or intravascular ultrasound.
28. If the angiographic result is still suboptimal and the extravasation of blood persists (i.e., in adequate perforation sealing), the stent may be further expanded with other standard angioplasty techniques.

Caution: Avoid barotrauma outside the stent margins during post-dilation.

Caution: DO NOT post-dilate the stent to more than the maximum expandable diameter recommended in the "Sizes" table.

Caution: Exercise care during crossing the deployed stent with guide wires, accessory devices, or adjunct devices to avoid disrupting the stent cover, disrupting the stent geometry, or stent migration.

Balloon Deflation and Delivery System Removal

29. Deflate the balloon in accordance with standard PCI procedures. Apply negative pressure to the balloon for at least 40 seconds before carefully withdrawing the delivery system from the vessel.
30. If the balloon cannot be withdrawn from the stent easily, very carefully advance and retract the delivery system slightly until it is possible to withdraw the balloon.
31. Under fluoroscopic control, withdraw the delivery system carefully into the guiding catheter.

Caution: If resistance is encountered during removal of the delivery system, remove the delivery system and the guiding catheter as a single unit. Refer to section "Removal of the Delivery System/Stent System and the Guiding Catheter as a Single Unit."

32. Inspect the device immediately upon removal from the patient for any signs of catheter breakage or fragmentation.
33. After use, dispose the product and packaging in accordance with the hospital procedure and/or normal industrial/local standards.

Special Retrieval Techniques

Removal of an Unexpanded Stent

1. Make sure that the guiding catheter tip and the guide wire are aligned to avoid any acute angle between the guide wire and guiding catheter tip.
2. Slowly pull back the stent system. The entry of the stent into the guiding catheter must be performed slowly under fluoroscopic control to avoid dislodgement of the stent from its position on the delivery system balloon.

Caution: If resistance is encountered during removal of the delivery system, remove the delivery system and the guiding catheter as a single unit. Refer to section "Removal of the Delivery System/Stent System and the Guiding Catheter as a Single Unit."

Caution: DO NOT re-insert the stent system as the stent and/or the delivery system may have been damaged during the initial attempt to cross the lesion or during withdrawal.

Removal of the Delivery System/Stent System and the Guiding Catheter as a Single Unit

1. Position the proximal balloon marker just distal to the tip of the guiding catheter.
2. Advance the guide wire into the artery as distally and safely as possible.
3. Tighten the hemostatic valve to secure the delivery system to the guiding catheter.
4. Remove the guiding catheter and the delivery system as a single unit.

Caution: Failure to follow correct removal steps for an unexpanded stent system and/or applying excessive force to the stent system can potentially result in loss or damage to the stent and/or delivery system components.

Post-procedural Follow-up

- Angiographic evaluation should be performed periodically during the 15 minutes after stent implantation.
- Serial echocardiography should be performed with subsequent echocardiograms obtained at regular intervals for approximately 12-48 hours.
- The patient should be monitored for persistent or recurrent signs of coronary perforation after PK Papyrus Stent implantation.
- Covered stents used to treat coronary ruptures can be associated with high rates of restenosis. Therefore, physicians should follow these patients closely for clinical evidence of restenosis.
- Antiplatelet/anticoagulation therapy is recommended to be used after PK Papyrus Stent implantation. Currently, there are no professional society guideline recommendations for the duration of dual antiplatelet therapy (DAPT) after covered coronary stent implantation. In the absence of evidence-based guidance, DAPT administration is generally recommended for at least 6 months after PK Papyrus Stent implantation. The treating physician should tailor the selection of antiplatelet agents and DAPT duration based on the patient's condition.
- Patients should be advised to:
  - Always carry the Patient Implant Card.
  - Read the Patient Information Guide available online (manuals.biotronik.com).

MRI Safety Information

Non-clinical tests have demonstrated that the PK Papyrus Stent is MR conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3 T.
- Maximum spatial field gradient of 3000 gauss/cm (30 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the PK Papyrus Stent is expected to produce a maximum temperature rise of less than 5.7 ºC after 15 minutes of continuous scanning.

In non-clinical tests, the image artifact caused by the device extended approximately 7 mm from the PK Papyrus Stent when imaged with a gradient echo pulse sequence and a 3.0 T MR system. The artifact may obscure the device lumen.

Summary of Clinical Experience

Clinical information was obtained from voluntary responses as a part of a non-US post-market clinical survey system and was combined with consumer product reporting information. BIOTRONIK received in-hospital PK Papyrus Stent data on 80 treated coronary perforation patients (surveys only in 69 cases, complaints only in 6 cases, or both in 5 cases) from 16 European and Asian countries. An additional 22 post-hospital discharge surveys were received with follow-up durations ranging from 8 to 832 days.

Results

Demographic information was limited to patient age ranges (Table 1) due to national data collection and privacy laws. Information regarding the Ellis Classification for perforation, procedural characteristics, device and procedure success, and complications was collected (Tables 2 – Table 7).

Table 1: Patient Age Ranges

Age (n = 80)	Number (%)
Under 40	0 (0.0%)
40 to 49	1 (1.3%)
50 to 59	4 (5.0%)
60 to 69	22 (27.5%)
70 to 79	27 (33.8%)
80 to 89	18 (22.5%)
Over 90	2 (2.5%)
Answer not provided	6 (7.5%)

Table 2 shows the Ellis Classification for Perforation and other anatomic and procedural elements.

Table 2: Coronary Perforation and Stent Characteristics

Variable	Category	Number (%)
Ellis Classification for Perforation* (n=80 patients)	Class I	8 (10.0%)
	Class II	12 (15.0%)
	Class III	40 (50.0%)
	Class IV	14 (17.5%)
	Answer not provided	6 (7.5%)
Implant location (n=80 patients)	LAD	39 (48.8%)
	RCA	19 (23.8%)
	LCX	17 (21.3%)
	Bypass Graft	3 (3.8%)
	LMCA	2 (2.5%)
Reference vessel diameter (mm) (n=60 patients)	mean ± SD	3.13 ± 0.64
Perforation length (mm) (n=53 patients)	mean ± SD	6.21 ± 6.71
Number of PK Papyrus Stents implanted per patient (n=80 patients)	mean ± SD	1.11 ± 0.48
Procedures performed in attempts to stop bleeding from perforation site prior to PK Papyrus Stent implantation (n=80 patients)	Any attempt†	50 (62.5%)
	Balloon	46 (57.5%)
	Stenting	7 (8.8%)
	Coil	2 (2.5%)
	Use of a different covered stent	2 (2.5%)
	Protamine injection	1 (1.3%)

* Ellis Classification for Perforation[1] definitions: Class I (extraluminal crater without extravasation), Class II (pericardial or myocardial blush without contrast jet extravasation), Class III (extravasation through frank (>1 mm) perforation), Class IV (cavity perforation into an anatomic cavity chamber, spilling coronary sinus, etc.).

† More than one prior attempt may be recorded per case.

Procedure success was evaluated on a patient-level basis. In the 80 perforation cases; a PK Papyrus Stent was successfully delivered in 95.0% (76), with 91.3% (73) of perforations successfully sealed (Table 3).

Table 3: Procedure Success

Procedure Success (Patient-level Evaluation)	Number (%)
PK Papyrus Stent successfully delivered to perforation* (n=80)	76 (95.0%)
Perforation sealed successfully† (n=80)	73 (91.3%)

* Patient-level delivery success was defined as the successful delivery of at least one PK Papyrus stent to the target perforation, such that the stent was able to be positioned properly in the area of perforation.

† Patient-level perforation sealing success was defined as successful sealing of a coronary perforation per operator assessment with use of one or more PK Papyrus stents as assessed after the procedure.

Reasons for unsuccessful delivery included one case in which the PK Papyrus Stent dislodged from the delivery system when passed through a previously implanted stent, one case in which two PK Papyrus Stents were attempted for use but could not advance through a proximal lesion, one case in which the PK Papyrus Stent could not reach the perforation site, and one case in which the PK Papyrus Stent could not pass through a previously implanted stent. These four cases were all considered both unsuccessful in delivery and perforation sealing. There were three patients in whom a PK Papyrus Stent was successfully delivered to the perforation site, but the perforation was not sealed by the stent(s).

Immediate procedure patient survival is defined as the patient status at the close of the procedure. Of the 80 patients who underwent attempted PK Papyrus Stent implantation, 77 (96.3%) survived the procedure, with two deaths occurring in patients with Class IV perforations (Table 4). There was no information regarding procedural survival of one patient with a Class IV perforation.

Table 4: Immediate Procedural Patient Survival Stratified by Ellis Perforation Classification

Ellis Perforation Classification	Survival	Death	Answer not provided
Class I (n=8)	8 (100.0%)	0 (0.0%)	0 (0.0%)
Class II (n=12)	12 (100.0%)	0 (0.0%)	0 (0.0%)
Class III (n=40)	40 (100.0%)	0 (0.0%)	0 (0.0%)
Class IV (n=14)	11 (78.6%)	2 (14.3%)	1 (7.1%)
Class not provided (n=6)	6 (100.0%)	0 (0.0%)	0 (0.0%)
Overall (n=80)	77 (96.3%)	2 (2.5%)	1 (1.3%)

In-hospital complications are shown in Table 5.

Table 5: In-Hospital Complications

Category	Number of Complications	Number of Patients with Complication	Percentage of Patients (n = 80)
Death	8	8	10.0%
Timing			
Post-procedural death	6	6	7.5%
Procedural death	2	2	2.5%
Mode			
Sudden cardiac death	1	1	1.3%
Cardiac death	7	7	8.8%
Non-cardiac death	0	0	0.0%
Pericardiocentesis due to tamponade	7	7	8.8%
Other urgent cardiac surgery	0	0	0.0%
Post-procedural MI	0	0	0.0%
Overall Hospital Outcome Events Total	15	14*	17.5%

* Patients may have had more than one category of complication; therefore, the number of unique patients with any complication is not the sum of the individual components.

In the surveys completed, there were no reported cases of post-procedural MI or other urgent cardiac surgery following implantation of the PK Papyrus Stent. A total of six patients died after the procedure and prior to discharge from the hospital. Five of these six patients had Class III perforations; the Ellis Classification was not reported in the sixth patient. Mortality rates within the Class III perforation group were 12.5% (5 out of 40).

Seven patients (out of 80, 8.8%) were reported to have required pericardiocentesis due to pericardial tamponade following implantation of a PK Papyrus Stent. Among 40 patients with Ellis Class III coronary artery perforations, pericardiocentesis due tamponade was reported in 6 patients (15.0%).

Table 6 shows in-hospital complication events that had at least a possible relationship to the PK Papyrus Stent.

Table 6: In-Hospital Device-Related Complications

Complication	Number of Occurrences	Number of Patients with Occurrence	Percentage of Patients (n = 80)
Stent Dislodgement	9	6	7.5%
Dislodgement during retrieval	3	2	2.5%
Dislodgement in catheter extension	3	1	1.3%
Dislodgement during delivery	2	2	2.5%
Dislodgement during lesion or stent passage	1	1	1.3%
Stent Thrombosis	2	2	2.5%
Definite	1	1	1.3%
Probable	1	1	1.3%
Possible	0	0	0.0%
Overall Any In-Hospital Device	11	8	10.0%

Of the two stent thrombosis cases, definite stent thrombosis was reported in a case in which acute thrombosis was noted in the procedure notes. In the second stent thrombosis case, the patient died the day after PK Papyrus Stent implantation due to sudden cardiac arrest; therefore, the event is reported as a case of probable stent thrombosis per the ARC stent thrombosis definitions.

Post-hospital discharge follow-up surveys were received for 22 patients. Table 7 shows the Major Adverse Cardiac Events (MACE) that may have had at least a possible relationship to the procedure or the PK Papyrus Stent.

Table 7: Follow-up MACE Complications

Complication Category	Number of Complications	Number of Patients	Percentage of Patients (n = 22)
All-cause death	1	1	4.5%
Sudden cardiac death	0	0	0.0%
Non-cardiac death	1	1	4.5%
Myocardial infarction	1	1	4.5%
Stent thrombosis	0	0	0.0%
Target lesion revascularization	1	1	4.5%
Target vessel non-target lesion revascularization	0	0	0.0%
Overall Follow-up MACE Complications Total	3	3	13.6%

One patient experienced non-cardiac death due to cancer 630 days after the PK Papyrus Stent implantation. No complications were reported after discharge in 72.7% (16/ 22) of patients for which a follow-up survey was received. Three patients experienced clinical events that were determined to not meet the MACE categories and were unrelated to the procedure or the stent as assessed by the physician (one patient was hospitalized for pericarditis two weeks post-implant, one patient was hospitalized for cardiac decompensation with left bundle branch block and a repolarization abnormality, and one patient experienced intermittent non-exertional chest pain).

Conclusions

The results from this dataset consisting of a retrospective evaluation of voluntary post-market clinical surveys and product complaints support the safety and probable benefit of the PK Papyrus covered stent to seal coronary artery perforations in coronary vessels.

Reference

1. Ellis S, Ajluni S, Arnold A et al. Increased coronary perforation in the new device era. Incidence, classification, management, and outcome. Circulation 1994;90(6):2725-30.

Applicability to Pediatric Population

Coronary artery disease is not typically found in pediatric populations. Accordingly, the safety and performance of the PK Papyrus covered stent system in pediatric populations have not been established.

Warranty/Liability

The product and each component of its system (hereinafter the product) have been designed, manufactured, tested and packaged with all reasonable care. However, BIOTRONIK has no control over the conditions under which the product is used and a disturbance of the intended function of the product may occur for various reasons. BIOTRONIK disclaims all warranties, expressed or implied regarding the product, including but not limited to, any warranty of merchantability or fitness for a particular purpose of the product. Product descriptions or user guidelines in publications do not constitute any expressed representation or any expressed or implied warranty. BIOTRONIK is not liable for any direct, incidental or consequential damages or medical expenses caused by any use, defect, failure or malfunction of the product whether the claim is based on contract, warranty, tort or otherwise. These limitations of liability and warranty are not intended to contravene any mandatory provisions of applicable law. If any clause of the disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects BIOTRONIK's legitimate interest in limiting its liability or warranty without infringing any mandatory provisions of applicable law. No person has any authority to bind BIOTRONIK to any warranty or liability regarding the product.

Symbol Legend

STERILE EO	Sterilized using ethylene oxide		Do not use if package is damaged
	Do not reuse	LOT	Batch code
	Caution	REF	Catalogue number
	Keep dry		Use by
	Keep away from sunlight		Consult instructions for use
	Do not resterilize	MR	MR conditional
	Date of manufacture		Manufacturer
NP	Nominal pressure	RBP	Rated burst pressure
	Temperature limitation		

Sizes

Stent Design	SMALL		MEDIUM		LARGE	
Stent Length (mm)	2.5	3.0 3.5	4.0	4.5	5.0	
15	X	X	X	X	X	X
20	X	X	X	X	X	X
26	-	X	X	X	X	X
Maximum Diameter for Post-dilation	3.5 mm		4.65 mm		5.63 mm	

Stent Inner Diameter (mm)

Caution: If post-dilation is required, DO NOT post-dilate the stent more than the maximum expandable diameter.

Compliance Chart

Inflation Pressure			Stent Inner Diameter (mm)					
	atm	(kPa)	2.5	3.0	3.5	4.0	4.5	5.0
NP	7	(709)	-	-	-			
						4.13	4.62	5.06
	9	(912)	2.56	3.08	3.56	4.25	4.74	5.19
	10	(1013)	2.62	3.15	3.63	4.34	4.83	5.30
	11	(1115)	2.67	3.21	3.69	4.41	4.91	5.39
	12	(1216)	2.71	3.26	3.75	4.47	4.98	5.46
	13	(1317)	2.74	3.30	3.79	4.52	5.03	5.52
RBP	14	(1419)	2.77	3.33	3.82	4.56	5.08	5.57
	15	(1520)	2.79	3.36	3.86	4.60	-	- RBP
16	(1621)		2.82	3.39	3.89	4.64	-	- In

In vitro tests have shown that all balloons reached their nominal size at given nominal pressure.

RBP: In vitro tests have shown that with 95% confidence, 99.9% of the balloons will not burst at or below the given rated burst pressure. DO NOT exceed RBP.

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