Medtech Solutions for Coronary Artery Perforation: The PK Papyrus Covered Stent

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Interventionalists perform approximately 800,000 percutaneous coronary intervention (PCI) procedures annually in the United States. In less than one percent of cases, a coronary artery is perforated during the procedure, causing potentially life-threatening internal bleeding that must be treated immediately, either with a coronary covered stent or via emergency coronary artery bypass graft (CABG) surgery. Overall mortality with coronary artery perforation is about 5 to 10%, and includes risk factors like the patient's age, the need for emergency surgery and the severity of the perforation.[1-3]

Any emergency surgery comes with increased risk for the patient and substantial cost for the hospital. With advances in medical technology, covered coronary stents can quickly and effectively treat perforations and, in many cases, eliminate the need for emergency CABG altogether. One of the first covered stent designs sandwiched a non-porous membrane between two bare-metal stents and could be delivered to the perforation site.[4] Because fewer than 8,000 PCIs in the United States annually require treatment of a perforation with a covered stent, they are classified by the FDA as Humanitarian Use Devices.

For nearly two decades, just one covered stent — the Jostent Graftmaster (Abbott) — had FDA approval for the treatment of coronary artery perforations. Its dual-stent sandwich design—stent-cover-stent — is more rigid and has a larger crossing diameter than a standard bare-metal or drug-eluting stent that physicians are accustomed to using in PCI procedures. This design is able to seal perforations; however, it is only available in select sizes and can only treat a limited range of vessel diameters and perforation lengths.

As the field of interventional cardiology has advanced, bare-metal and drug-eluting stents have become thinner and more agile, and have gained approval for the treatment of more complex disease presentations. Similarly, physician skillsets have continued to evolve in order to treat lesions previously considered untreatable due to inaccessibility or lack of stents approved for such challenging indications.

While bare-metal and drug-eluting stent technology continued to advance, covered stent design moved out of focus. After all, the need for covered stents is very limited comparatively, so this space in the US went 17 years without innovation. But today, with increasingly complex cases, there is potential for perforations that simply cannot be reached with the dual-stent design. The variety of stent lengths and diameters available is too limited and delivery remains relatively cumbersome for physicians during these emergency procedures when every second counts.

Interventional cardiologists now have new single-stent designs available, like PK Papyrus (BIOTRONIK), to seal perforations. PK Papyrus is built on an ultrathin strut stent platform and covered in a durable, elastic, electrospun polyurethane membrane. A single-center, retrospective investigation of 61 patients found it takes just eight minutes to deliver PK Papyrus — 47% less time than the average 15 minutes it takes to deliver the dual-stent design.[2] The more maneuverable PK Papyrus stent is the first ever FDA-approved device for the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter.[5] Recent advancements like the PK Papyrus help physicians in critical care situations minimize complications for patients.

The single-stent design PK Papyrus is the only 5 French-compatible covered coronary stent available in the United States.[6] It is available in 17 sizes, expanding treatment options for physicians, and has the potential to minimize the need for emergency CABG. Because of its thin membrane and ultrathin strut, single-stent design, PK Papyrus has the lowest crossing profile of any covered coronary stent in the United States and exceptional flexibility, with a 23% reduction in diameter and 58% improved flexibility compared to the dual-stent sandwich design.[7,8]

When a perforation occurs, interventional cardiologists need to administer lifesaving treatment. Design innovations have transformed the covered stent from a cumbersome, emergency-use device into a practical and deliverable solution. PK Papyrus is designed to deliver more like a conventional stent, helping physicians to quickly treat an emergency coronary perforation and do so with confidence, as they generally will not have to upsize the radial sheath or gain femoral access, allowing them to keep the wire down the vessel, which potentially reduces the rate of adverse outcomes from this complication while avoiding the costs and risks associated with emergency surgery.

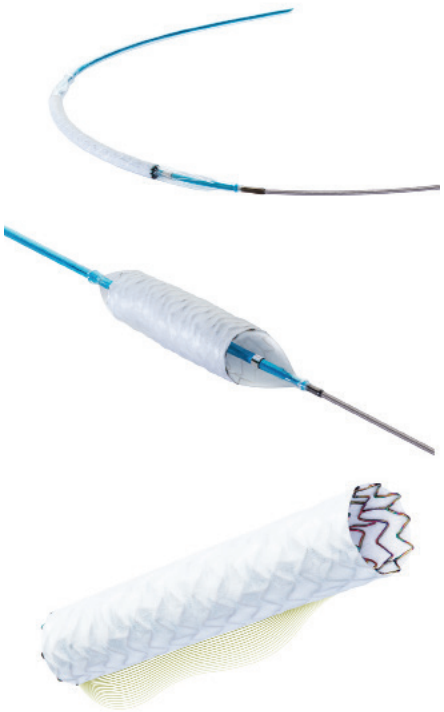

Figure 1A-C. The PK Papyrus Covered Coronary Stent System is the first device approved by the FDA for the treatment of acute coronary artery perforations in 17 years. PK Papyrus is built on BIOTRONIK's ultrathin strut stent platform and features a single-stent design with a unique electrospun polyurethane membrane. *Courtesy BIOTRONIK.*

More information about this meaningful medical technology innovation is available in the FDA's approval announcement.[9] ■

A video featuring David E. Kandzari, MD, Director of Interventional Cardiology and Cardiovascular Research, Piedmont Heart Institute, Atlanta, Georgia, is available with this article online at cathlabdigest.com.

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6. ø 2.5-4.0 mm; 6F compatible for ø 4.5-5.0 mm.
7. Compared to Graftmaster 2.8 /16 (BIOTRONIK data on file).
8. Compared to Jostent Graftmaster 3.0/16 (BIOTRONIK data on file).
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