Vascular Intervention // Coronary Covered Coronary Stent System

PK Papyrus

Exceptional deliverability^{1,2}

Covered single stent design

Designed to save lives when seconds count³

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.



PK Papyrus

Designed to deliver more like a conventional stent^{1, 2}

Superior design for exceptional deliverability^{1,2}

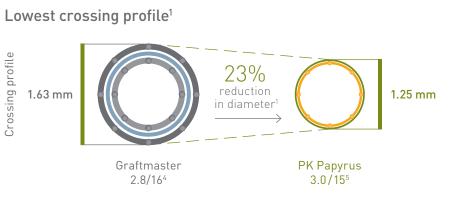
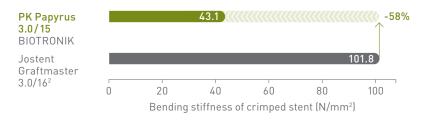


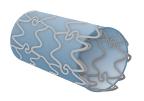
Illustration depicts crimped devices prior to inflation

Superior flexibility²



Covered single stent design

- BIOTRONIK's ultrathin strut stent platform (Cobalt Chromium).
- Highly elastic membrane capable of sealing coronary artery perforations.⁶

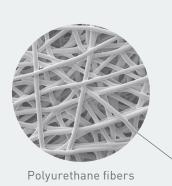


Jostent Graftmaster Traditional sandwich stent design



PK Papyrus Covered single stent design





(2000x) → 10 µm

The only 5F compatibility*

Time to expand your options with **PK Papyrus**

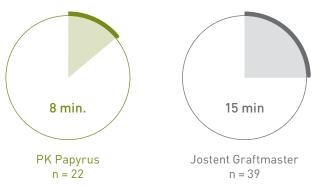
Broadest range of sizes on the US market⁷

- The only 5F compatible* coronary covered stent with the broadest range of sizes.⁷ For main sizes no need for guide catheter upgrade.*
- First FDA approved 2.5 mm diameter.

Designed to save lives when seconds count³

Shorter time to deliver⁶

Single center, retrospective investigation of 61 patients treated with covered coronary stents.⁸



Median time to deliver (p=0.001)



PK Papyrus

Vascular Intervention Coronary

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*



Technical Data Stent Stent cover material Non-woven, electrospun polyurethane Cobalt chromium (L-605) with proBIO (amorphous silicon Stent material carbide) coating Maximum stent expansion diameter ø 2.5 - 3.0 mm: 3.50 mm; ø 3.5 - 4.0 mm: 4.65 mm; ø 4.5 - 5.0 mm: 5.63 mm **Delivery system** Guide wire diameter 0.014" 140 cm Usable catheter length ø 2.5 - 4.0 mm: 5F (min. l.D.** 0.056"); ø 4.5 - 5.0 mm: 6F (min. l.D.** 0.070") Recommended guide catheter Nominal pressure (NP) ø 2.5 - 3.5 mm: 8 atm; ø 4.0 - 5.0 mm: 7 atm ø 2.5 - 4.0 mm: 16 atm; ø 4.5 - 5.0 mm: 14 atm Rated burst pressure (RBP) **I.D. = Inner Diameter

Compliance Chart	Inflation pressure atm	Stent inner diameter (mm)							
		2.5	3.0	3.5	4.0	4.5	5.0		
Nominal pressure (NP)	7	-	-	-	4.01	4.55	4.93		
Nominal pressure (NP)	8	2.52	2.99	3.53	4.14	4.69	5.09		
	9	2.59	3.07	3.63	4.26	4.82	5.23		
	10	2.65	3.15	3.71	4.35	4.91	5.34		
	11	2.70	3.21	3.77	4.43	4.99	5.43		
	12	2.74	3.26	3.82	4.49	5.06	5.50		
	13	2.77	3.30	3.86	4.54	5.11	5.56		
Rated burst pressure (RBP)	14	2.80	3.34	3.90	4.59	5.16	5.61		
	15	2.83	3.37	3.93	4.63	-	-		
Rated burst pressure (RBP)	16	2.86	3.40	3.96	4.67	-	-		

Ordering Information	Stent ø (mm)	Catheter len Stent length			
		15	20	26	
	2.5	434887	434893	-	
5F	3.0	434888	434894	434899	
•	3.5	434889	434895	434900	
	4.0	434890	434896	434901	
6F	4.5	434891	434897	434902	
•	5.0	434892	434898	434903	

1. Compared to Graftmaster 2.8 /16 [BIOTRONIK data on file]; 2. Compared to Jostent Graftmaster 3.0/16 [BIOTRONIK data on file]; 3. Broad range of sizes available on the US market; 4. Data obtained from Graftmaster Coronary Stent Graft System Brochure 11/13/12; 5. PK Papyrus 3.0/15; [BIOTRONIK data on file]; 6. Hernandez-Enriquez M, et al. Outcomes after use of covered stents to treat coronary artery perforations. Comparison of old and new-generation covered stents. J Interv Cardiol. 2018; 1-7; 7. Compared to Graftmaster based on the broader range of sizes available on the US market; 8. Population is representative of real world interventional practice and was not a randomized prospective clinical trial.

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*Indication as per IFU.

Information on devices manufactured at companies other than BIOTRONIK was gathered from multiple sources. However, it has not been verified by the vendors and we cannot guarantee its accuracy.

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