Teleflex™
Empowering the future of healthcare

PK Papyrus™

Covered coronary stent system

Designed to save lives when seconds count.

PK Papyrus™

Designed to save lives when seconds count.[1,2]

Clinically proven[a,3–15]

>1,500
patients with PK Papyrus™ studied in clinical studies[16]

10
Number of publications available[3-12]

93.7 %
Patients were not referred to emergency cardiac surgery.[b,7] PK Papyrus™ is safe and effective as confirmed by one of the largest patient datasets for covered stents.[c,7]

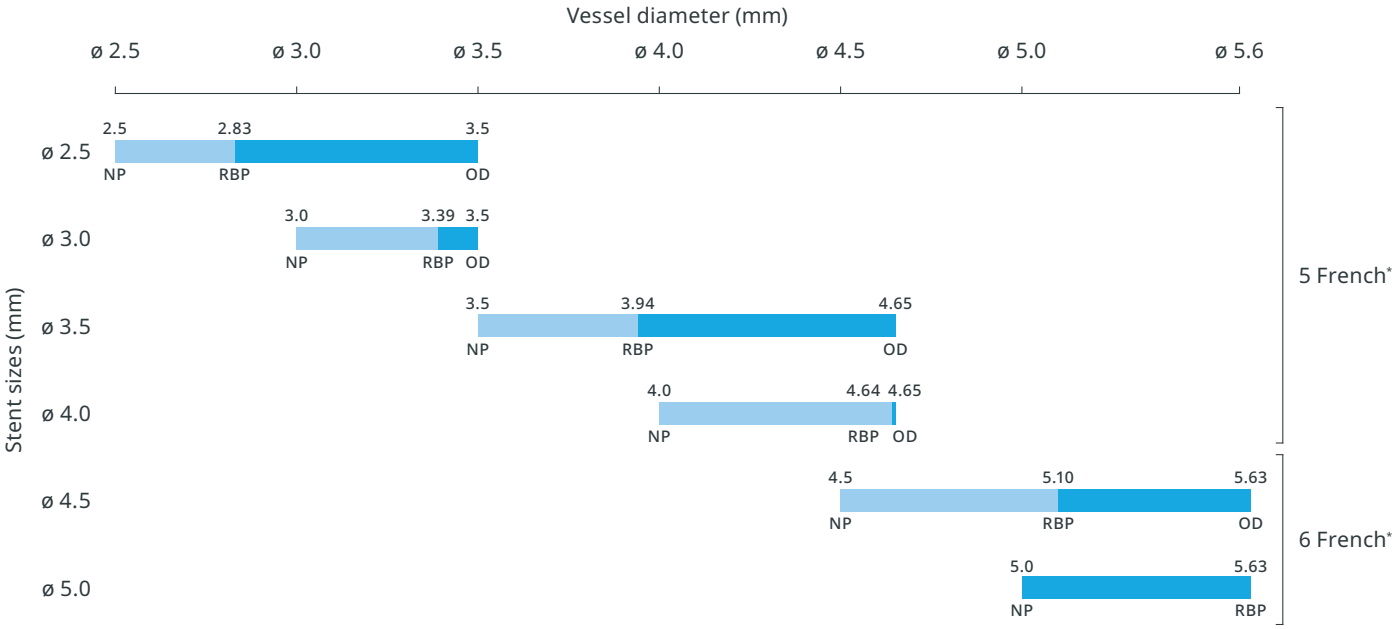
PK Papyrus™ bears the CE mark and is fully certified in accordance with the MDR, FDA[d], and PMDA.

Covered single stent design

Unique manufacturing method allows for an ultra thin membrane capable of sealing vessel perforations[1] and achieve a true covered single stent design[1]. Expect a high performing platform with an ultra thin membrane to deliver like a conventional stent.[1]

PK Papyrus™
Single stent design

Overexpansion diameters



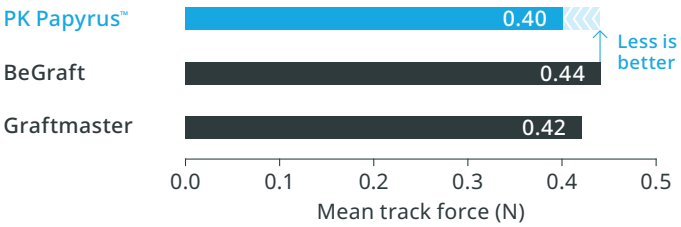
NP: Nominal Pressure; RBP: Rated Burst Pressure; OD: Overexpansion Diameter. Balloon exchange required.
**Guide Catheter Compatibility*

The elastic membrane does not impair stent expansion.[1]

Exceptional deliverability[e,1,3]

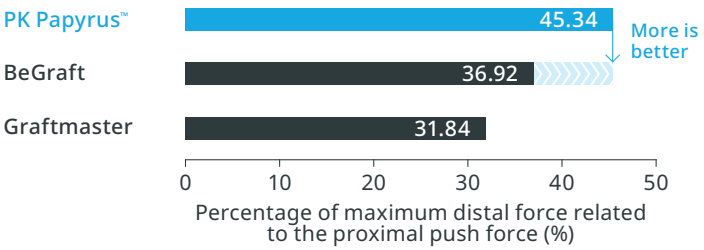
Consistently high stent delivery success[f,3-7]
PK Papyrus™ is associated with reliable delivery (97.7 % stent delivery success) and successful sealing (92.1 %), favored by its unique design.[7]

Trackability



Enhanced Track[17]

Pushability

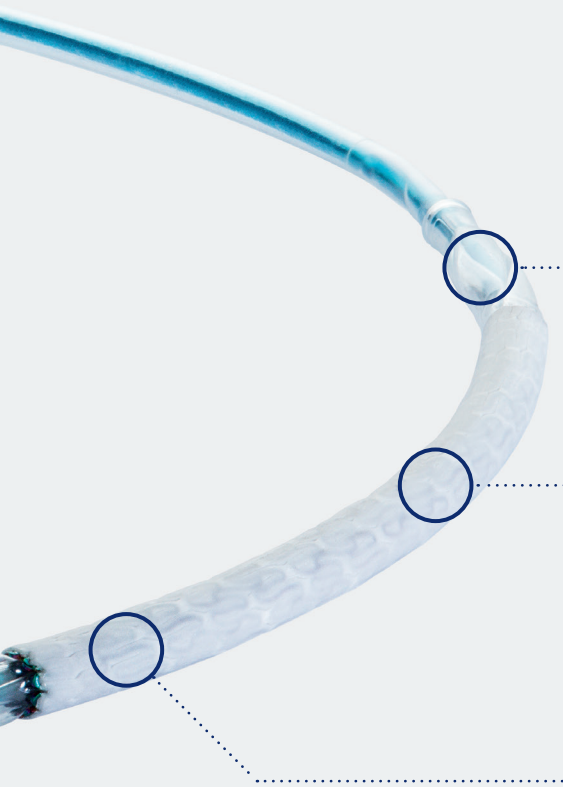


Better Push[17]

Flexibility in crimped state

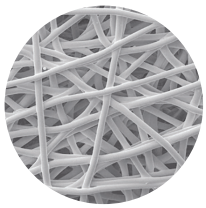
Higher Flexibility[g,17]

Device technology



PK Papyrus™ features a design with exceptional deliverability[e,1], built on the same Orsiro™ Mission™ stent platform[h,1], one of the most studied drug-eluting stents[18].

Cover material
Highly elastic polyurethane (PU) membrane.[1]



Polyurethane fibers (2000×)

Low crossing profile[1]
23 % reduction in crossing profile compared to the traditional sandwich design stent.[19]

5F Compatibility

5F

For main sizes – no need for guide catheter upgrade (ø 2.5–4.0 mm).

PK Papyrus™

Vascular Intervention Coronary

Indicated for acute coronary artery perforations.[i]

Technical data

STENT	
Stent cover material	Non-woven, electrospun polyurethane
Stent strut thickness	ø 2.5–3.0 mm: 60 µm (0.0024”); ø 3.5–4.0 mm: 80 µm (0.0031”); ø 4.5–5.0 mm: 120 µm (0.0047”)
Stent material	Cobalt chromium (L-605) with proBIO™ (Amorphous Silicon 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”
Usable catheter length	140 cm
Recommended guide catheter	ø 2.5–4.0 mm: 5F (min. I.D.** 0.056”); ø 4.5–5.0 mm: 6F (min. I.D.** 0.070”)
Nominal pressure (NP)	ø 2.5–3.5 mm: 8 atm; ø 4.0–5.0 mm: 7 atm
Rated burst pressure (RBP)	ø 2.5–4.0 mm: 16 atm; ø 4.5–5.0 mm: 14 atm

***I.D. = Inner Diameter*

Ordering Information

	STENT Ø	CATHETER LENGTH 140 CM; STENT LENGTH		
		15 mm	**20 mm**	**26 mm**
5F	**2.5 mm**	369380	369386	–
	3.0 mm	369381	369387	381789
	3.5 mm	369382	369388	381790
	4.0 mm	369383	369389	381791
6F	**4.5 mm**	369384	369390	369392
	5.0 mm	369385	369391	369393

References

1 Data on file.
2 Al-Lamee R, et al. Incidence, Predictors, Management, Immediate and Long-Term Outcomes Following Grade III Coronary Perforation. JACC: Cardiovasc Interv. 2011 Jan; 4(1):87-95.
3 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.
4 Harnek J, James SK, Lagerqvist BO. et al. Very long-term outcome of coronary covered stents: a report from the SCAAR registry. EuroIntervention. 2019; 14: 1660-1667. doi: 10.4244/ EIJ-D-18-00855.
5 Birkemeyer R , Olivecrona G.K, Hellig F et al. Sealing of coronary perforations with a second-generation covered stent graft - Results from the PAST-PERF registry. Cardiovascular Revascularization Medicine. 2020; doi: 10.1016/j. carrev.2020.10.012.
6 Kandzari DE, Birkemeyer R. PK Papyrus covered stent: Device description and early experience for the treatment of coronary artery perforations. Caheter Cardiovasc Interv. 2019;1–5. doi.org/10.1002/ccd.28306.
7 Kandzari D.E, Sarao R.C. and Waksman R. Clinical experience of the PK Papyrus covered stent in patients with coronary artery perforations: Results from a multi-center humani-tarian device exemption survey, Cardiovascular Revascularization Medicine. 2022. doi: 10.1016/j.carrev.2022.04.009.
8 Nagaraja V , Schwarz K et al. Outcomes of patients who undergo percutaneous coronary intervention with covered stents for coronary perforation: A systematic review and pooled analysis of data. Catheter Cardiovasc Interv. 2019; 1–7. DOI: 10.1002/ccd.28646.
9 Hernandez-Enriquez et al. Use and outcomes of the PK Papyrus covered stent in France: SOS PK Papyrus registry. Catheter Cardiovasc Interv. 2020; doi: 10.1002/ccd.29328.
10 Wańha W, Januszek R, Kołodziejczak M, Kuźma Ł, Tajstra M, Figatowski T et al. Procedural and 1-year outcomes following large vessel coronary artery perforation treated by covered stents implantation: Multicentre CRACK registry. PLoS ONE. 2021; 16(5): e0249698. doi: 10.1371/journal. pone.0249698.
11 Bossard, M., Maria Cioffi G., et al. “Burying” covered coronary stents under drug-eluting stents: A novel approach to ensure long-term stent patency. Cardiology Journal, 2023, 30(2), 196-198. https://doi. org/10.5603/CJ.a2022.0116.
12 Jurado-Roman A et al. Clinical outcomes after implantation of polyurethane-covered cobalt-chromium stents. Insights from the Pa-pyrus-Spain registry. Cardiovascular Revascularization Medicine 2020 Aug; S1553-8389(20)30486-3. doi: 10.1016/j.carrev.2020.08.017. Online ahead of print.
13 Kufner S et al. Outcome after new generation single-layer polytetrafluoroethylene-covered stent implantation for the treatment of coronary artery perforation. Catheter Cardiovasc Interv. 2018; 1-9. DOI: 10.1002/ccd.27979.
14 Voll F, Koch T, Tölg R, Lenz T, Schroeter M, Lenders G, Hokken R, Cassese S, Xhepa E, Schunkert H, Kastrati A, Kufner S. Clinical safety and efficacy of new-generation single-layer polytetrafluorethylene covered coronary stents. Cardiovasc Revasc Med.2023:1–7.
15 Azzalini, L., Poletti, E., Ayoub, M., Ojeda, S., Zivelonghi, C., La Manna, A., Bellini, B., Lostalo, A., Luque, A., Venuti, G., Montorfano, M., Agostoni, P., Pan, M., Carlino, M., & Mashayekhi, K. Coronary artery perforation during chronic total occlusion percutaneous coronary intervention: Epidemiology, mechanisms, management, and outcomes. EuroIntervention. 2019. https://doi.org/10.4244/ EIJ-D-19-00282.
16 Overview of clinical trials based on an intensive literature research including sponsored and IITs for CAP patient number treated with PK Papyrus covered coronary stent system, Data as of July 2022 – Data on file.
17 Data on file, IIB data 2020, PK Papyrus Ø 3.0, 15 mm vs. BeGraft Coronary Stent Graft System Ø 3.0, 16 mm.
18 In large RCTs, based on Taglieri N et al. Target lesion failure with current drug-eluting stents evidence from a comprehensive network meta-analysis. JACC 2020.
19 Compared to Graftmaster 2.8/16, (Data on file).

Refer to IFU

Refer to QR code for a copy of the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

About Teleflex

As a global provider of medical technologies, Teleflex is driven by our purpose to improve the health and quality of people's lives. Through our vision to become the most trusted partner in healthcare, we offer a diverse portfolio with solutions in the therapy areas of anesthesia, emergency medicine, interventional cardiology and radiology, surgical, vascular access, and urology. We believe that the potential of great people, purpose driven innovation, and world-class products can shape the future direction of healthcare.

Teleflex is the home of Arrow™, Barrigel™, Deknatel™, LMA™, Pilling™, QuikClot™, Rüsch™, UroLift™ and Weck™ – trusted brands united by a common sense of purpose.

At Teleflex, we are empowering the future of healthcare. For more information, please visit teleflex.com.

Corporate Office

Phone +1 610 225 6800, 550 E. Swedesford Road, Suite 400, Wayne, PA 19087, USA

Regional Offices

United States: Phone +1 919 544 8000, Toll Free 866 246 6990, cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

Latin America: Phone +1 919 433 4999, la.cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

International: Phone +353 (0)9 06 46 08 00, orders.intl@teleflex.com, Teleflex Medical Europe Ltd., IDA Business and Technology Park, Dublin Road, Athlone, Co Westmeath, Ireland

[a]More clinical studies including larger number of patients reporting clinical outcomes with longer follow-up time than BeGraft Coronary Stent Graft System; [b]In 93.7 % of coronary artery perforation cases; [c]Based on the clinical experience of the PK Papyrus covered stent in patients with coronary artery perforations: results from the multi-center humanitarian device exemption survey. Cardiovascular Revascularization Medicine. 2021; [d]Humanitarian Device Exemption; [e]Compared to Jostent Graftmaster; [f]Based on over a 1,000 patients treated with PK Papyrus covered coronary stent system, Clinical program as of July 2022 Data on file; [g]In crimped state; [h]Based on up to 4.0 diameter; [i]Indication as per IFU.

394771-EN · REV J · 11 25 PDF

Teleflex™
Empowering the future of healthcare