

Easy Single-Step Deployment & Removal



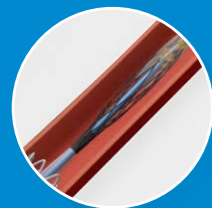
Open Filter
No Filter Prep



Post Dilate Stent



Capture Emboli



Close & Remove Filter
No Retrieval Catheter

Paladin® Carotid Post-Dilation Balloon with Integrated Embolic Protection

PRODUCT NUMBER	UNITS	COMPONENT			GUIDEWIRE		SHEATH/ GUIDE CATHETER	
		FILTER SIZE (mm)	BALLOON DIAMETER (mm)	BALLOON LENGTH (mm)	WIRE LENGTH (cm)	WIRE DIAMETER (in/mm)	MINIMUM ID (in)	COMPATIBILITY (F)
PLD-10083-1	1	Up to 7	5	20	190	0.014/0.36	0.066	6 (SHEATH)/ 7 (GC)
PLD-10083-5	5	Up to 7	5	20	190	0.014/0.36	0.066	6 (SHEATH)/ 7 (GC)

Indications for Use

The Paladin device is indicated for post-dilation of a deployed self-expanding stent in the carotid artery. The Paladin device incorporates a distal filter-based embolic protection device. The crossing profile of the Paladin system is 0.054". The device is advanced as a post-dilation system over a 0.014" guidewire. The filter can be expanded to maximum of 7 mm.

Contraindications

- The integrated filter should not be deployed within a carotid stent.
- The Paladin device is contraindicated for use in coronary arteries.
- Contraindicated for use in patients who cannot tolerate anticoagulant or anti-platelet therapy.
- Contraindicated for use in patients with known hypersensitivity to nitinol.
- Contraindicated for use in patients with unresolved bleeding disorders.

References

1. Carotid Artery Stenting in Octogenarians. Periprocedural Stroke Risk Predictor Analysis From the Multicenter Carotid ACCULINK/ ACCUNET Post Approval Trial to Uncover Rare Events (CAPTURE 2) Clinical Trial. *Stroke*. 2010; 41: 757-764 doi: 10.1161/STROKEAHA.109.569426; *Stroke*. 2007; 38: 707-714 doi: 10.1161/01.STR.0000250047.01624.fd
2. Contego Medical - Clinical Evaluation Report, December 2014
3. Siewiorek GM, Wholey MH, Finol EA. A comparative analysis of bench-top performance assessment of distal protection filters in transient flow conditions. *Journal of Endovascular Therapy* 2012;19(2):249-260.
4. Bench top testing data on file at Contego Medical

Contego Medical
INTEGRATED EMBOLIC PROTECTION

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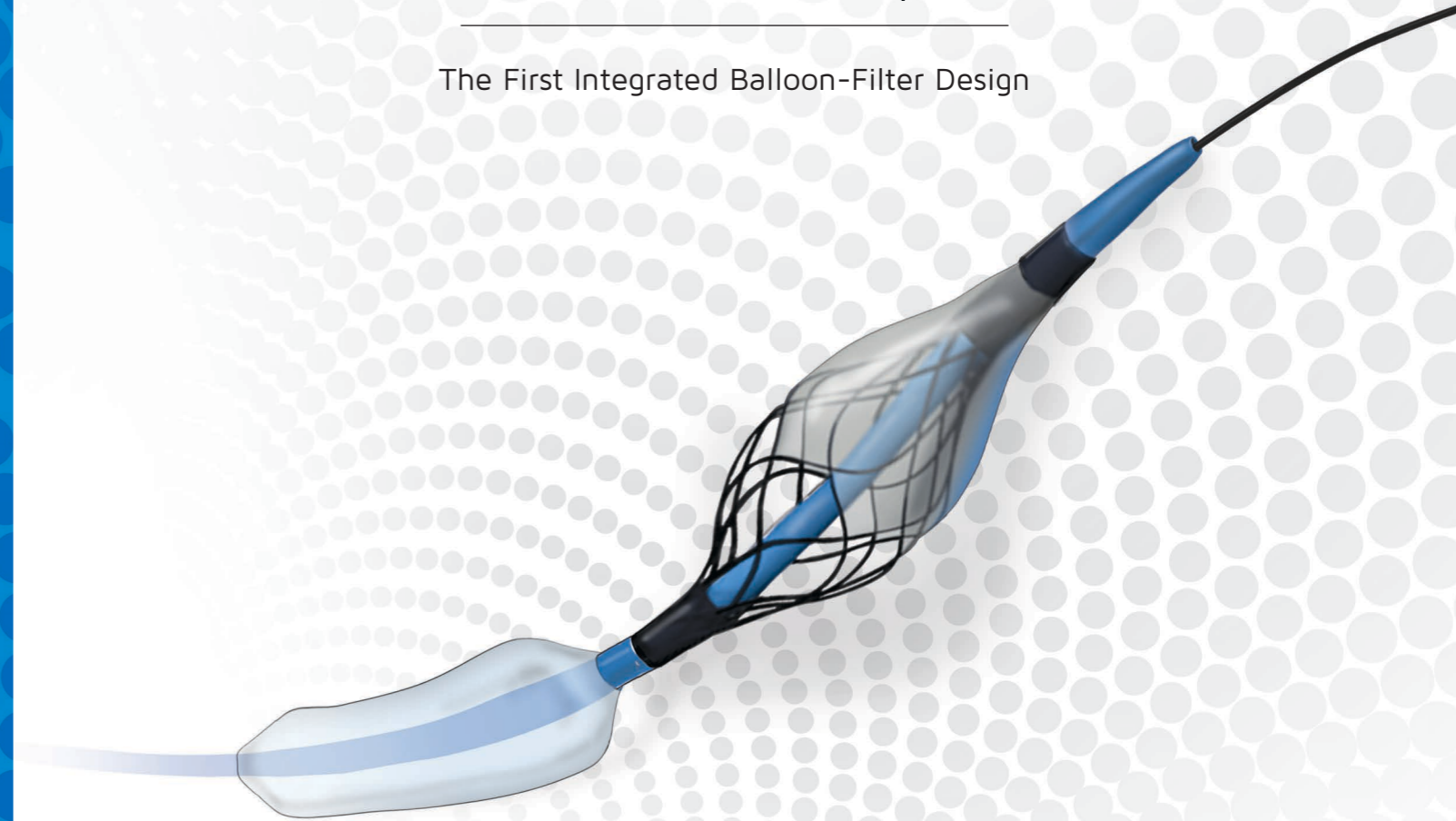
Paladin® is a registration of Contego Medical, LLC.

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ContegoMedical.com

Extra Protection Without Extra Steps

The First Integrated Balloon-Filter Design



Paladin®

CAROTID POST-DILATION BALLOON
WITH INTEGRATED EMBOLIC PROTECTION

Contego Medical
INTEGRATED EMBOLIC PROTECTION

“The highest risk of embolization during CAS is in post-dilation. Therefore, the biggest opportunity to reduce risk is during this phase.”

DR. WILLIAM GRAY

Improves Protection in the Most Critical Phase

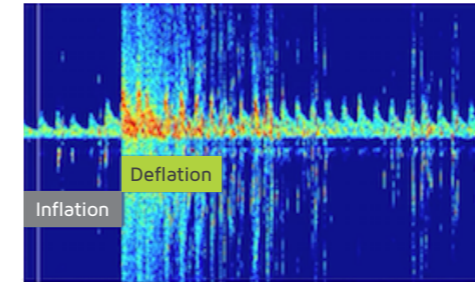
The Paladin® Carotid Post-Dilation Balloon with Integrated Embolic Protection is designed to reduce the risk of stroke by providing extra protection during post-dilation. The Paladin® EPS is the first device to incorporate a distal filter into a balloon dilation catheter to easily protect the brain from emboli without adding any extra procedure steps or catheter exchanges.



Stroke Protection When it Matters Most

Ischemic stroke risk remains unacceptably high in carotid stent procedures, even with the use of conventional embolic protection devices. Some groups such as symptomatic patients and octogenarians are at higher risk than others.¹

Neurovascular embolization occurs during post-dilation even with the use of distal filters

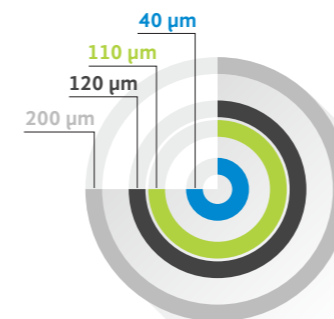


Size Matters

Paladin® Captures What Others Miss^{2,3}

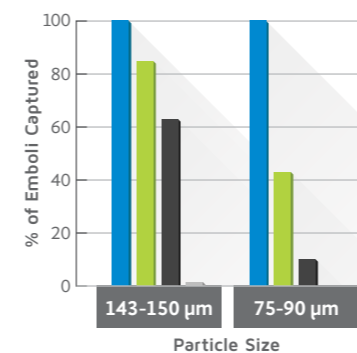
- The Paladin® EPS captures smaller emboli. Paladin® EPS pore sizes $\approx 40 \mu\text{m}$ while commercially available filters are all $\geq 100 \mu\text{m}$.
- Better wall apposition (capture efficiency) by being able to adjust the filter diameter to suit the patient's anatomy.

Filter Pore Sizes (Max.)



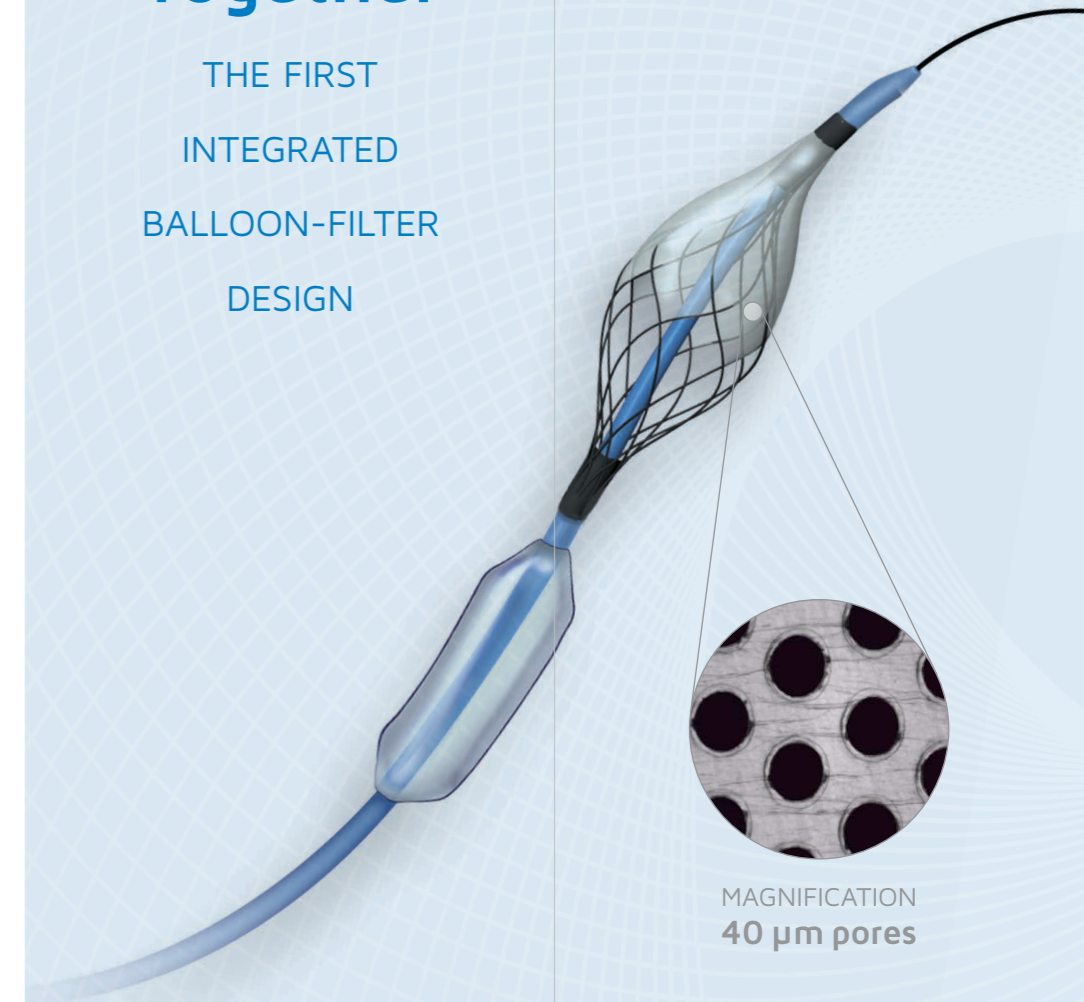
■ Paladin® EPS ■ Filter A ■ Filter B ■ Filter C

Capture Efficiency^{3,4}



Better Together

THE FIRST INTEGRATED BALLOON-FILTER DESIGN



MAGNIFICATION 40 μm pores

Paladin® Balloon

- Low profile design for high deliverability
- Durable nylon multi-compliant material
- 6F sheath/7F GC compatibility
- Nominal/Rated Burst Pressure = 8 atm/14 atm (810 kPa/1419 kPa)

Paladin® Filter

- Adjustable in-vivo up to 7 mm
- 40 μm pores for capturing critical emboli
- Superior wall apposition via concentric braided nitinol design
- Minimal landing zone due to fixed, 4 mm balloon-filter transition
- Easy single-step deployment
- No delivery or recovery sheaths