



Minima *Pro*TM Stent System

Built to **Perform.**
Built to **Reach Further.**
Built for **Life.**

A detailed image of the Minima Pro catheter. The device consists of a dark blue ergonomic handle with the brand name 'Minima Pro' in white script. A clear plastic tube with a connector is attached to the top of the handle. A long, thin, braided metal shaft extends from the bottom of the handle. At the end of the shaft is a catheter assembly with a balloon and a side port. A callout line points from the 'Integrated Contrast Port' text to the side port. Another callout line points from the 'Removable Balloon Catheter' text to the catheter assembly. A third callout line points from the 'Redesigned Ergonomic Handle' text to the handle. A fourth callout line points from the '70 cm Working Length' text to the shaft.

Integrated Contrast Port

Provides the **option for spot angiograms** via the integrated sheath

Removable Balloon Catheter

Ability to remove the balloon shaft post-deployment, minimizing the need for multiple sheath exchanges

Redesigned Ergonomic Handle

Designed with ease of use in mind, including a **new binary locking mechanism**

70 cm Working Length

Compatible with ≤ 65 cm long sheaths

Now Available in 10 mm Balloon

Implantable from **5.1 mm** to
10.4 mm across all 3 balloon sizes

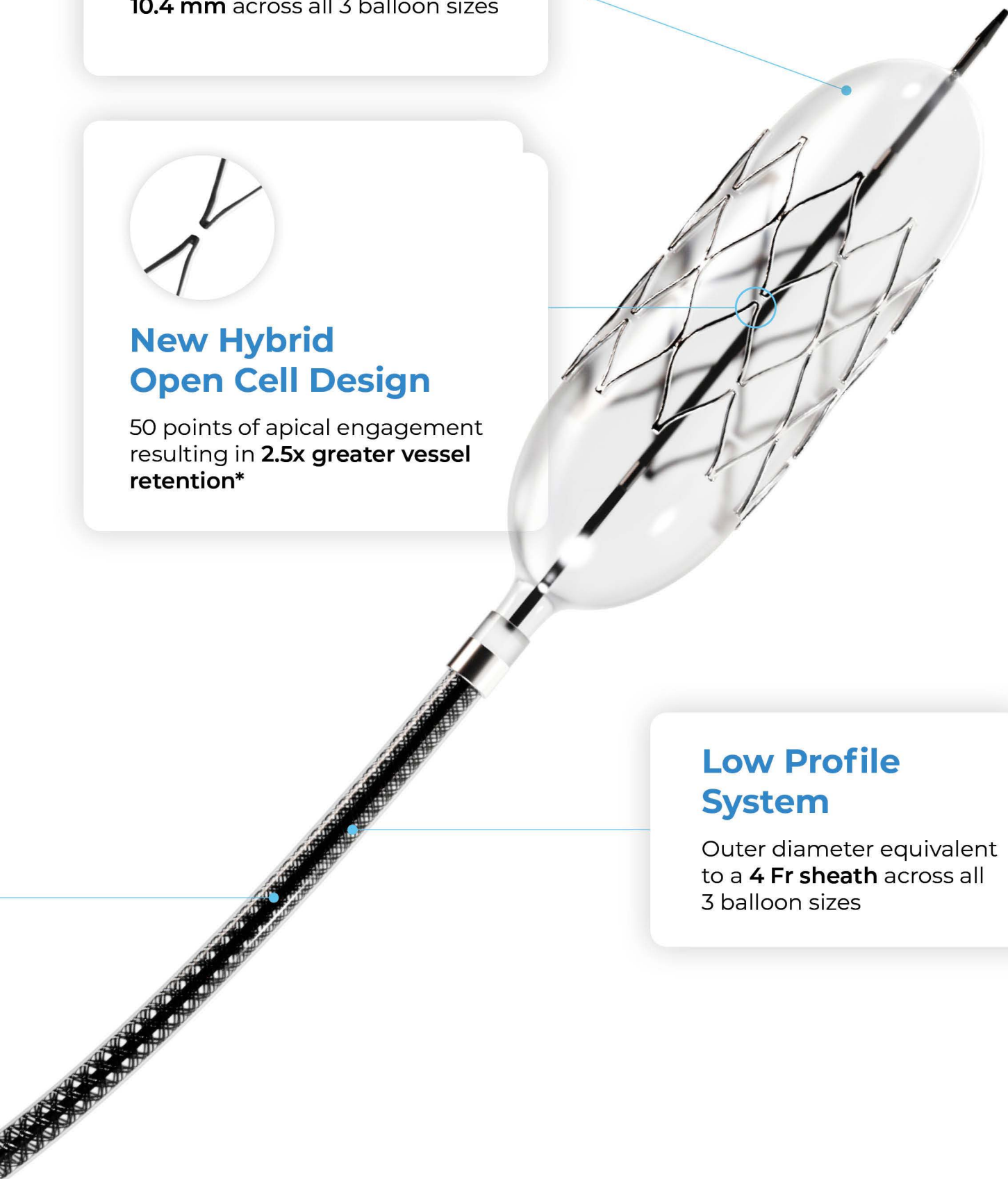


New Hybrid Open Cell Design

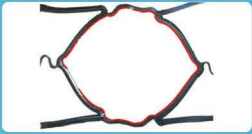
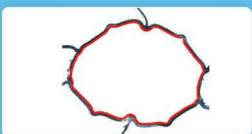
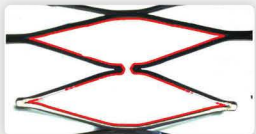
50 points of apical engagement
resulting in **2.5x greater vessel
retention***

Low Profile System

Outer diameter equivalent
to a **4 Fr sheath** across all
3 balloon sizes



Cross Side Branches with More Confidence

DEVICE	Normal Side Cell Shown at 8 mm Outer Diameter		Max Side Cell	
	SHAPE	CELL AREA	SHAPE	CELL AREA
Minima		6.9 mm ²		19.7 mm ²
Alternative Stent 1		5.6 mm ²		16.5 mm ²
Alternative Stent 2		3.75 mm ²		18.2 mm ²
Minima <i>Pro</i>		8.15 mm ²		66.4 mm ²

MAX SIDE CELL AREA
3.3x Larger[†]

Improved Spot Angiogram Performance

Device	Max Flow Rate w/ Balloon Unsheathed — (Pre-Deployment)	Max Flow Rate w/ Balloon Removed — (Post-Deployment)
Minima	5 mL/s	17 mL/s
Minima <i>Pro</i>	13 mL/s	51 mL/s

ANGIOGRAPHY FLOW RATE
3x Maximum Flow Rate vs. Minima[†]

U.S. Pivotal GROWTH Trial Midterm Results[†]

Due to the similarities in the Minima Stent and Delivery System and Minima *Pro* Stent and Delivery System designs, the results of the GROWTH study are applicable to the Minima *Pro* Stent and Delivery System.[≈]

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PATIENTS UNDERWENT RE-DILATION

32 re-dilations total —
10 had a second, 1 a third.
Median 3.4-year follow-up
across all 42 implants.

50%

NO REPEAT RE-DILATION

Half the cohort needed no
further re-dilation over a
median 3.4 years — despite
young age and small size at
implant.

1

STENT-RELATED AE

Across 32 re-dilations: one
small pseudoaneurysm, no
intervention. Of 5 total AEs, two
were vascular access.

RE-DILATION CHARACTERISTICS

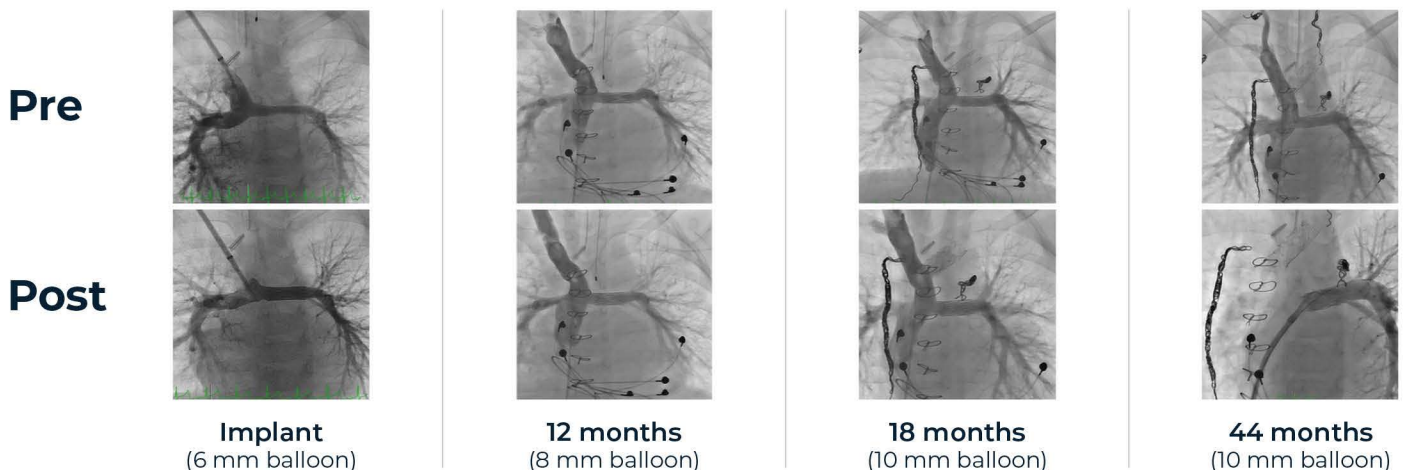
- Median time to re-dilation: **419 d** (1st), 776 d (2nd), 1341 d (3rd)
- Lumen diameter stable between re-dilations at **92%** (56-100%)
- Younger age & lower weight at implant → earlier re-intervention; **no** single - vs biventricular difference

CASE IN POINT • SERIAL RE-DILATION

4.2 → 8.9 mm at the LPA hilum

A 6-month-old with hypoplastic left heart, re-dilated to match the growing vessel

A 6-month-old female with hypoplastic left heart syndrome, palliated through a bidirectional Glenn and complicated by left pulmonary artery (LPA) hypoplasia. The LPA was stented with the Minima Stent System on a 6 mm balloon, then re-dilated in 2mm increments at 12, 18, and 44 months — the most recent with an ultra-high-pressure balloon to match the native vessel. **Distal LPA-hilum diameter grew from 4.2 mm at implant to 8.9 mm**, alongside marked gains in stent caliber.



Minima vs. Minima *Pro*[™] Specifications

Specification	Minima	Minima <i>Pro</i> [™]
Catheter effective length	63 cm	70 cm
Stent design	Closed-cell	Hybrid open-cell
Balloon options	6 mm, 8 mm	6 mm, 8 mm, 10 mm
Vessel contact points	~20	~50
Delivery handle	Twist Lock	Binary locking system
Packaging	Coiled	Straight
Profile	4 Fr	4 Fr
Initial implant range	5.1 – 8.5 mm	5.1 – 10.4 mm
Re-expansion to adult size	≤ 24 mm	≤ 24 mm
Guidewire Compatibility	.014" and .018"	.014" and .018"
FDA approved indication	CoA & BPAS	CoA & BPAS

Ordering Information

Part Number	FG-0009	FG-0010	FG-0011
Stent Diameter x Length	6 mm x 16 mm	8 mm x 16 mm	10 mm x 16 mm
Nominal Pressure	8 atm	10 atm	8 atm
Rated Burst Pressure	14 atm	14 atm	10 atm

Important Information:

Indications, contraindications, warnings, and instructions for use can be found with the product labeling and packaging materials supplied with each device or at renatamedical.com/manuals. Federal law restricts this product for sale by or on the order of a physician. This product is intended only for use by or under the direction of a physician and approved for U.S. use only.

Illustrations are artistic renderings only and should not be considered as engineering drawings or photographs. Photos are on file at Renata Medical, Inc., 4675 MacArthur Court, Suite 1150, Newport Beach, CA 92660.

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* Data on File (TS-0018 Rev. 0).

† Data on File (TS-0024 Rev. 0).

≈ Data on File (TS-0025 Rev. 0).

¶ Data on File (RPT-0009 Rev. 11).



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