Minima *Pro*™ Stent System

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

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

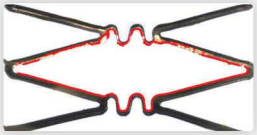
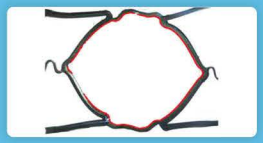
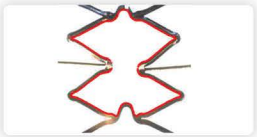
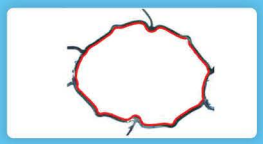
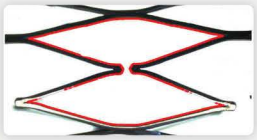
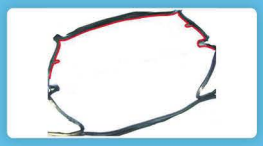
New Hybrid Open Cell Design

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

	Normal Side Cell Shown at 8 mm Outer Diameter		Max Side Cell	
DEVICE	**SHAPE**	**CELL AREA**	**SHAPE**	**CELL AREA**
Minima		6.9 mm²		**19.7 mm²**
Alternative Stent 1		5.6 mm²		**16.5 mm²**
Alternative Stent 2		3.75 mm²		**18.2 mm²**
Minima *Pro*		**8.15 mm²**		**66.4 mm²**

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 *Pro*	**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.

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STENT-RELATED AE

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

RE-DILATION CHARACTERISTICS

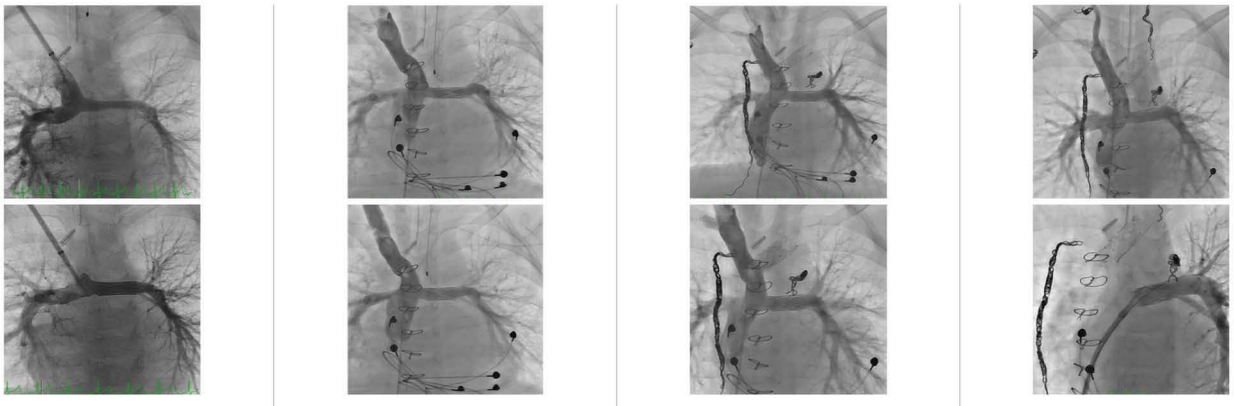
- Median time to re-dilation: **419 d** (1st), 776 d (2nd), 1341 d (3rd)
- Lumen diameter stable between re-dilations at **92%** (56-100%)
- Younger age & lower weight at implant → earlier re-intervention; **no** single - vs biventricular difference

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 *Pro*™
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

* 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).

MKT-0022 Rev. 0

R E N A T A