

SafeCut™

Coronary
Cutting Balloon
Dilatation Catheter



Precise
Cutting
Smooth
Flow



APP



APP

SHUNMEI AND ITS SUBSIDIARIES

SHUNMEI MEDICAL CO., LTD.

Add: R301 and R401, Building B, Shenchanggang Investment Co., Ltd.,
No. 8, Jinlong First Road, Baolong Community, Baolong Street,
Longgang District, Shenzhen, 518116 Guangdong, P.R. China

Branch Office: Yifa 3rd road, Yifa Industrial Zone,
Pingtan Town, Huiyang District, Huizhou,
516259, Guangdong, P.R. China

Mobile/Whatsapp: +86 18344359973 +86 18344369007
E-mail: nora@shunmed.com nora1@shunmed.com
Website: www.shunmed.com

SHUNMEI SP. Z O.O.

SHUNMEI MEDİKAL VE TIBBİ CİHAZLAR
TİCARET ANONİM ŞİRKETİ

Shunmei Search



Medical technology creates future

Shunmei®

SUMMARY REPORT OF CLINICAL TRIALS OF CORONARY ARTERY CUTTING BALLOON DILATION CATHETER

Version number/date:V1.0/November 2, 2025

Basic Information

Applicant:	SHUNMEIMEDICALCO..LTD
Test Name:	Prospective, multicenter, randomized controlled clinical trial evaluating the safety and efficacy of coronary artery cutting balloon dilation catheter in the treatment of coronary artery disease
Team leader unit:	TEDA International Cardiovascular Hospital./Dr. Rui Jing
Test time:	June 12th, 2025- August 20th, 2025
Sample size:	168 cases (84 in the experimental group and 84 in the control group)

Experimental Design

Experimental Group	Coronary artery cutting balloon dilation catheter (SHUNMEIMEDICALCO..LTD)
Control Group	Wolverine Coronary Cutting Balloon, Boston Scientific Company
Primary Endpoint	Success rate of device use (non inferiority design, non inferiority threshold -10%)

main results

Primary efficacy endpoint - success rate of device use	Experimental Group	Control Group	95% CI
	97.62%	96.39%	[-3.94%, 6.41%]
✔ Non inferiority established (CI lower limit>-10%)			

Safety results

AE incidence rate in the experimental group	Control group AE incidence rate	Equipment related AE (experimental group)
32.14%	34.52%	1 case
There was no statistical difference in safety indicators between the two groups, and no device defects occurred		

Conclusion

The coronary cutting balloon dilation catheter from Shenzhen Shunmei Medical Co., Ltd. is as safe as Boston Scientific's cutting balloon catheter in the treatment of coronary artery disease, and its effectiveness is not inferior to the control product. There is no significant difference in clinical prognosis between the two devices.

01 Outstanding Crossability

The balloon features a **dual-layer design**. The inner layer provides strong support and burst performance, ensuring effective balloon dilation. The outer layer is soft and significantly enhances the ability to navigate through narrow and complex vessels.

02 Non-compliant Balloon

The non-compliant balloon is high-tolerance and not easy to break.

03 Excellent Deliverability

The combination of a high-pushability shaft and a low-friction hydrophilic coating ensures smooth delivery and easy navigation through complex lesion areas.

04 Precise Cutting

The sharp-edged blade effectively performs directional cutting on the lesion.

High-pressure resistance:20 atm (non-compliant balloon design)



Technical specification	
Guide Wire Size (in)	0.014"
Effective Catheter Length (cm)	145
Entry Profile (in)	0.0162
Tip Crossing Profile (in)	0.0220
Nominal Pressure of Balloon (kPa(atm)):	1013(10)
Rated Burst Pressure of Balloon (kPa(atm)):	2026(20)

Models and Sizes :

Code	Model Number	Balloon Diameter (mm)	Effective Balloon Length (mm)	Effective Catheter Length (cm)	Total Number Of Blades	Number of Blade Rows	Crossing Profile (in)
635519	2.00×5	2	5	145	3	3	0.0460
635520	2.00×10		10		6		
635521	2.00×15		15		9		
635762	2.00×20		20		12		
635522	2.25×5	2.25	5		3		0.0460
635523	2.25×10		10		6		
635524	2.25×15		15		9		
635763	2.25×20		20		12		
635525	2.50×5	2.5	5		3		0.0490
635526	2.50×10		10		6		
635527	2.50×15		15		9		
635764	2.50×20		20		12		
635528	2.75×5	2.75	5		3	3	0.0490
635529	2.75×10		10		6		
635530	2.75×15		15		9		
635765	2.75×20		20		12		
635531	3.00×5	3	5		3		0.0520
635532	3.00×10		10		6		
635533	3.00×15		15		9		
635766	3.00×20		20		12		
635534	3.25×5	3.25	5		3	4	0.0520
635535	3.25×10		10		6		
635536	3.25×15		15		9		
635767	3.25×20		20		12		
635537	3.50×5	3.5	5		4		0.0570
635538	3.50×10		10		8		
635539	3.50×15		15		12		
635768	3.50×20		20		16		
635549	3.75×5	3.75	5		4		0.0570
635550	3.75×10		10		8		
635551	3.75×15		15		12		
635769	3.75×20		20		16		
635552	4.00×5	4	5		4	4	0.0580
635553	4.00×10		10		8		
635554	4.00×15		15		12		
635770	4.00×20		20		16		