

RELIABLE SAFETY

Reliable safety to soft tissue by safely selecting and fracturing intimal and medial calcifications

ENHANCE EFFICIENCY

Minimize complications and effectively manage costs to improve patient care

SIMPLIFY PROCEDURES

Simple and intuitive system that makes complex calcified procedures more predictable

SHUNMEI AND ITS SUBSIDIARIES

SHUNMEI MEDICAL CO.,LTD

Add: No.8 jinlong 1st street, Baolong Industrial Zone,
Longgang District, Shenzhen, China.
Branch Office: Yifa Industrial Zone, Dushi Village,
Pingtan Town, Huiyang District, Huizhou, China.
Mobile/Whatsapp: 86-183-4436 9007 86-135-1076 5957
E-mail: nora@shunmed.com nora1@shunmed.com
Website: www.shunmed.com



Youtube:
<https://youtu.be/SVI2LCgCGeo>



Twitter:
<https://twitter.com/Shunmei73902015>



Tiktok:
www.tiktok.com/@shunmei2022



Facebook:
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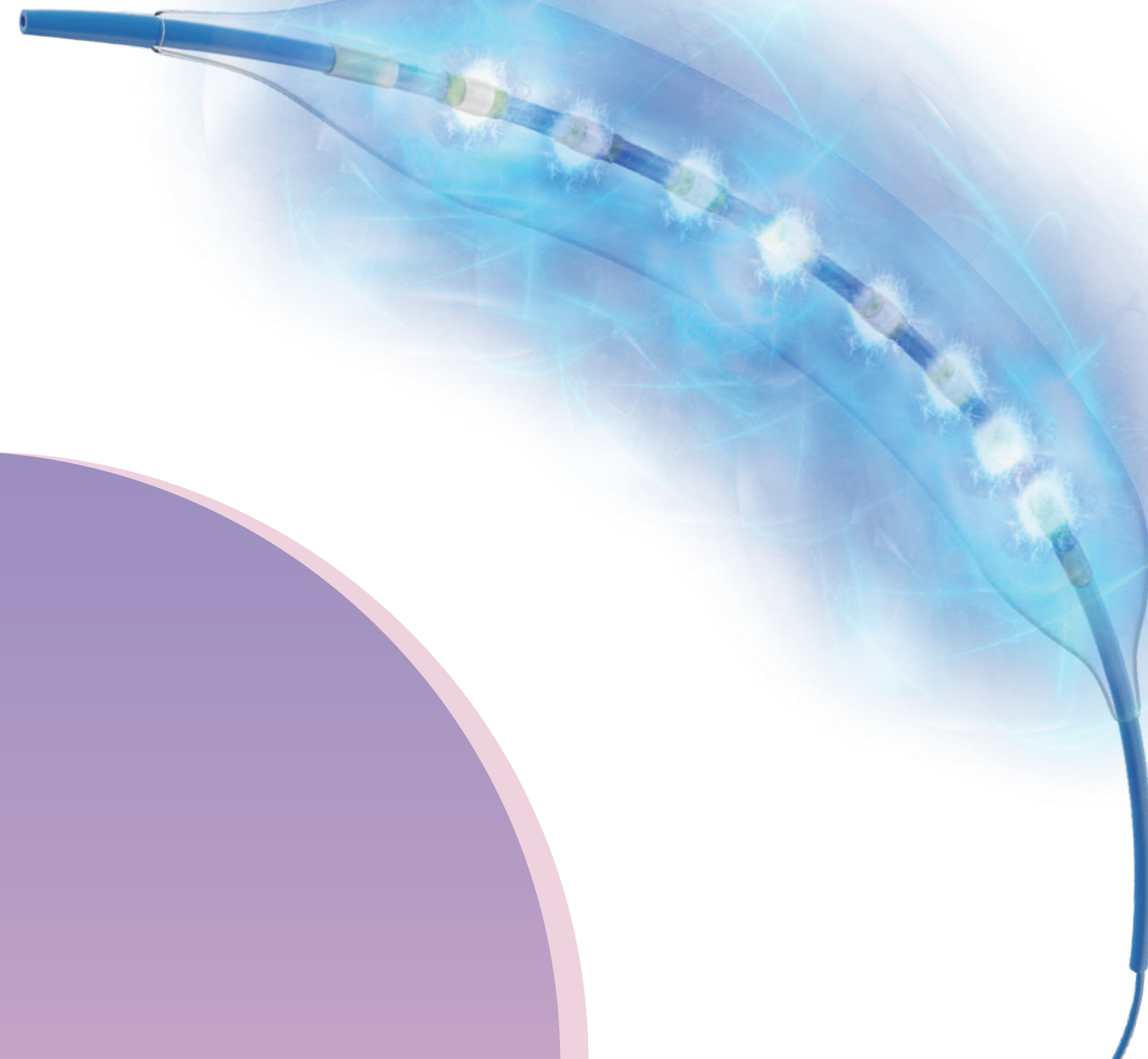


APP

SHUNMEI SP. Z O.O.

SHUNMEI MEDİKAL VE TIBBİ CİHAZLAR TİCARET ANONİM ŞİRKETİ

Shunmei®



ShockFast™

Intravascular Lithotripsy -IVL

P-IVL



2 PCS

Radiopaque Markers



4-8 PCS

Electrodes



UP to 400

Pulses



OTW

Design



Intravascular Lithotripsy Catheter-Coronary (P-IVL)

Ordering Information

Code	Catalog Number	Emitters	Pulses (Max)	Pulses per Cycle	Diameter (mm)	Length (mm)	Guidewire Compat.	Compatible Introducer Sheath	Working Length (cm)	Crossing Profile Range(in)
629964	PIVL14-25400	4	160	20	2.50	40	0.014"	6Fr	135	0.052 max
631143	PIVL14-25600	6	240	30	2.50	60	0.014"	6Fr	135	0.052 max
629965	PIVL14-30400	4	160	20	3.00	40	0.014"	6Fr	135	0.052 max
631144	PIVL14-30600	6	240	30	3.00	60	0.014"	6Fr	135	0.052 max
629966	PIVL14-35400	4	200	20	3.50	40	0.014"	6Fr	135	0.052 max
629956	PIVL14-35600	6	300	30	3.50	60	0.014"	6Fr	135	0.055 max
631145	PIVL14-35800	8	400	40	3.50	80	0.014"	6Fr	135	0.055 max
629967	PIVL14-40400	4	200	20	4.00	40	0.014"	6Fr	135	0.055 max
629957	PIVL14-40600	6	300	30	4.00	60	0.014"	6Fr	135	0.055 max
631146	PIVL14-40800	8	400	40	4.00	80	0.014"	6Fr	135	0.055 max
631174	PIVL18-45600*	6	300	30	4.50	60	0.014/0.018"	6Fr	135	0.057 max
631175	PIVL18-45800*	8	400	40	4.50	80	0.014/0.018"	6Fr	135	0.057 max
631176	PIVL18-50600*	6	300	30	5.00	60	0.014/0.018"	6Fr	135	0.059 max
631177	PIVL18-50800*	8	400	40	5.00	80	0.014/0.018"	6Fr	135	0.059 max
631178	PIVL18-55600*	6	300	30	5.50	60	0.014/0.018"	6Fr	135	0.065 max
631179	PIVL18-55800*	8	400	40	5.50	80	0.014/0.018"	6Fr	135	0.065 max
631180	PIVL18-60600*	6	300	30	6.00	60	0.014/0.018"	6Fr	135	0.065 max
631181	PIVL18-60800*	8	400	40	6.00	80	0.014/0.018"	6Fr	135	0.065 max
631182	PIVL18-65600	6	300	30	6.50	60	0.014/0.018"	7Fr	135	0.070 max
631183	PIVL18-65800	8	400	40	6.50	80	0.014/0.018"	7Fr	135	0.070 max
631184	PIVL18-70600	6	300	30	7.00	60	0.014/0.018"	7Fr	135	0.073 max
631185	PIVL18-70800	8	400	40	7.00	80	0.014/0.018"	7Fr	135	0.073 max
631186	PIVL18-80600	6	300	30	8.00	60	0.014/0.018"	7Fr	135	0.075 max
631187	PIVL18-80800	8	400	40	8.00	80	0.014/0.018"	7Fr	135	0.075 max

*Common specifications

General Parameters: Balloon Treatment Pressure (atm): 4; Nominal Pressure (atm): 6; Rated Burst Pressure (atm): 10.



Intravascular Lithotripsy Generator + Connector Cable Ordering Information



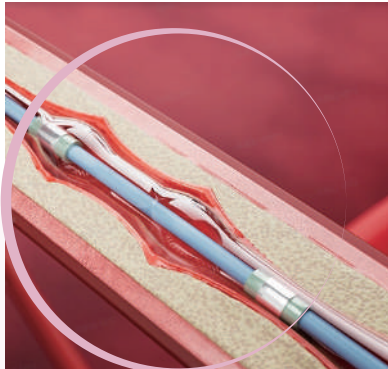
Generator
634492



Connector Cable
634493

Power	100-240VAC; 50/60Hz; 1.3A Service
Battery	6600mAh; To prevent battery depletion, it is recommended to fully charge the battery at least once a month.
Output	Output voltage 3.0kv peak, RMS value 2.5kv, pulse frequency 1.5Hz
Size	200mm(H)*296mm(L)* 84mm(W)
Installation	IV Pole or Table
Weight	2534g
Length	195cm
Compatibility	Exclusively for the connection of Shunmei IVL generator and balloon
Operation	Lithotripsy pusling is activated by long-pressing or double-clicking the button on the handle
Use	Re-usable

Effective Mechanism for Calcium Disruption

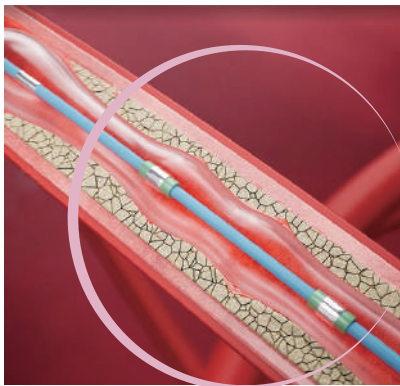
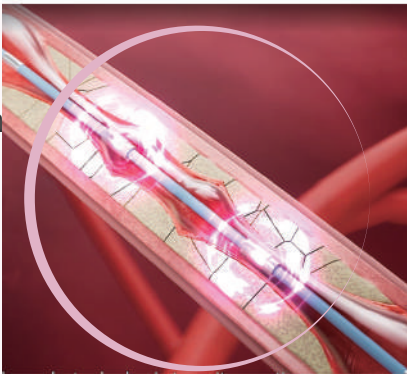


Positioning the Catheter: The P-IVL catheter is navigated across the calcified lesion along a 0.014/0.018" guidewire. Once properly positioned, the integrated balloon is inflated to 4 atm to ensure optimal energy transfer for the procedure.

01

02

Energy Activation: Upon electrical discharge from the emitters, the fluid inside the balloon vaporizes rapidly, creating expanding and collapsing bubbles that generate sonic pressure waves.



Targeted Effect: The sonic waves produce a localized field effect, allowing the waves to pass through the soft vascular tissue and selectively crack the intimal and medial calcium deposits within the vessel wall.

03

04

Lesion Dilatation: After the calcium has been modified, the same integrated balloon is gently inflated at low pressure to dilate the lesion, thus maximizing luminal gain without damaging healthy tissue.

