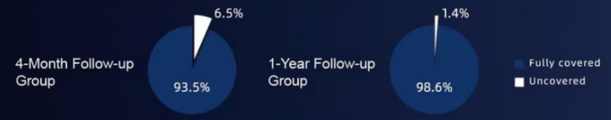
CREDIT Study

Ideal Endothelialization (CREDIT I)

0 restenosis with the EXCROSSAL stent over time up to 1 year

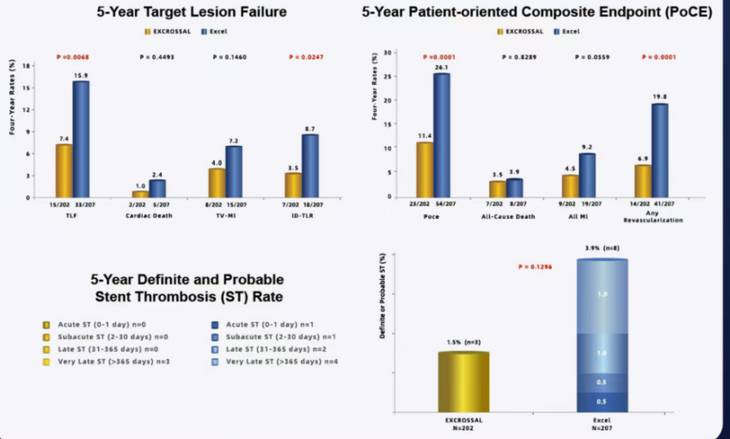
	4-month follow-up group	12-month follow-up group
Late loss, mm	0.08±0.14	0.07±0.13
Restenosis rate, %	0	0

Quick endothelialization after EXCROSSAL stent's implantation, and ideal endothelialization within 12 months.



Long-term follow-up observations have shown more clinical benefits to patients (CREDIT II)

CREDIT II Randomized Controlled Study



COMPLIANCE TABLE

Pressure (mm)	8 NP	10	12	14 RBP	16 RBP
Nominal balloon diameter (mm)	For stent lengths 9 to 29 mm				
2.25	2.25	2.31	2.37	2.43	2.49
2.50	2.50	2.56	2.62	2.68	2.74
2.75	2.75	2.81	2.87	2.93	2.99
3.00	3.00	3.06	3.12	3.18	3.24
3.50	3.50	3.56	3.62	3.68	-
4.00	4.00	4.06	4.12	4.18	-
Nominal balloon diameter (mm)	For stent lengths 33 and 36 mm				
2.50	2.50	2.56	2.62	2.68	2.74
2.75	2.75	2.81	2.87	2.93	2.99
3.00	3.00	3.08	3.16	3.24	3.32
3.50	3.50	3.60	3.70	3.80	-

Specifications

Length	Diameter					
	Ø2.25 mm	Ø2.50 mm	Ø2.75 mm	Ø3.00 mm	Ø3.50mm	Ø4.00 mm
9mm	RDES II-2209	RDES II-2509	RDES II-2709	RDES II-3009	RDES II-3509	RDES II-4009
14mm	RDES II-2214	RDES II-2514	RDES II-2714	RDES II-3014	RDES II-3514	RDES II-4014
19mm	RDES II-2219	RDES II-2519	RDES II-2719	RDES II-3019	RDES II-3519	RDES II-4019
24mm	RDES II-2224	RDES II-2524	RDES II-2724	RDES II-3024	RDES II-3524	RDES II-4024
29mm	RDES II-2229	RDES II-2529	RDES II-2729	RDES II-3029	RDES II-3529	RDES II-4029
33mm		RDES II-2533	RDES II-2733	RDES II-3033	RDES II-3533	
36mm		RDES II-2536	RDES II-2736	RDES II-3036	RDES II-3536	

- Indications: The EXCROSSAL stent is indicated for the treatment of myocardial ischemia or angina pectoris caused by de novo coronary artery stenosis or occlusion; the diameter of diseased vessel should be between 2.25 mm and 4.0 mm, and the length of lesion should be 36 mm or less. See the IFU for contraindications and precautions.
- Registration Certificate No.: CFDA20173461407 • The device images are for illustrative purpose. Please refer to the actual product.
• Internal data for clinical reference only

EXCROSSAL 心跃™
New generation of drug-coated stent system

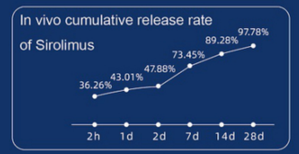
bluesail+
蓝帆医疗
JWMS 吉威医疗

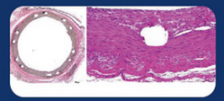
EXCROSSAL 心跃™

A New generation of Sirolimus drug-eluting stent system

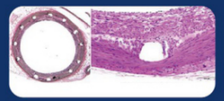
Abluminal PLA coating + optimized 1/3 drug loading

– Significantly shorten DAPT time and reduce long-term postoperative risk in patients





28 days



180 days

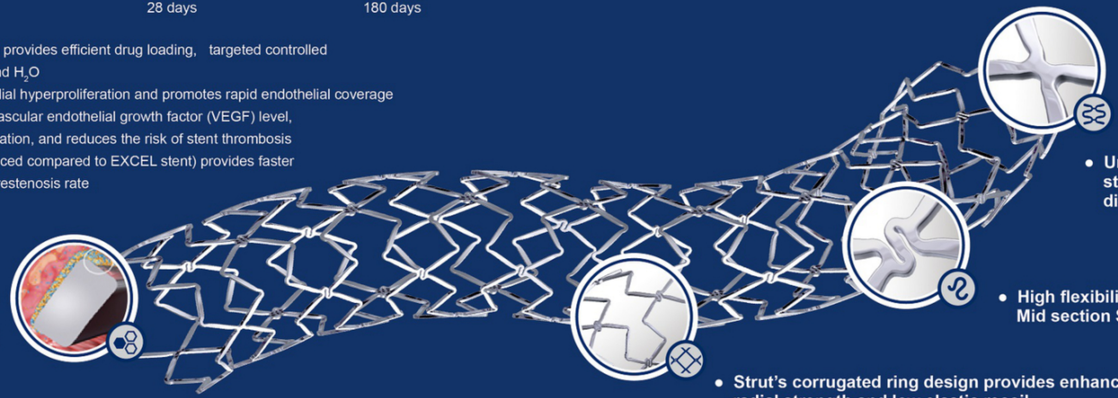
- 4 μm polylactic acid (PLA) integrated coating provides efficient drug loading, targeted controlled release, and complete degradation to CO_2 and H_2O
- Abluminal coating technique inhibits endothelial hyperproliferation and promotes rapid endothelial coverage
- PLA degradation product-lactate increases vascular endothelial growth factor (VEGF) level, increases endothelial cell proliferation & migration, and reduces the risk of stent thrombosis
- An optimized drug dose (2/3 lower dose reduced compared to EXCEL stent) provides faster endothelial repair without compromising the restenosis rate

Gladden LB. J Physiol. 2004; 558(1):5-30
Ghani, QP. et al. Methods in Enzymology. 2004; 381(36):565-75

Innovative platform with high performance

– Easy to operate and quick completion of the procedure

- Innovative CHROMA™ global platform, with both Chinese and American patents
- Cobalt-chromium platform, coupled with unique Hybrid stent design, thin strut thickness: 84 μm
- Dual platform design to better fit the vessel diameter: SV-6 ring configuration (2.25-3.0 mm); MV-9 ring configuration (3.50-4.0 mm)
- Advanced stent delivery system (SDS): Hypotube design of proximal tube, PTFE hydrophilic coating, Profile 2.1F (0.70 mm), embedded platinum-iridium markers, clear visibility, fast positioning



- **The world's first Abluminal degradable coating drug eluting technology**
- **Unmatched longitudinal strength proximal and distal straight links**
- **High flexibility Mid section S-shape links**
- **Strut's corrugated ring design provides enhanced radial strength and low elastic recoil**

Low Profile and Large Cell Opening

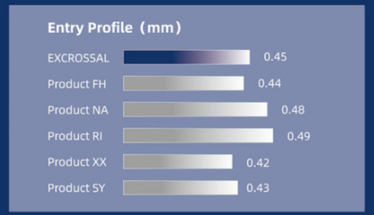
– More advantages for complex lesion operation and extreme operation

- 2.25 mm diameter, coupled with a unique 9 mm length, provide multiple options for small vessel lesions
- Larger cell opening diameter granted easier side branch access , and improved efficiency for bifurcation lesions
- Effectively verified over-expanded data to ensure the safe use of stent under ultimate conditions
  - Flexible option for large vessels over 4 mm diameter
  - Better stent apposition and lower incidence of late thrombosis under circumstances of difference in proximal and distal lumen diameter

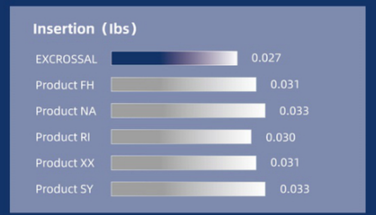
EXCROSSAL 3019	EXCROSSAL 4019
6-Cell Configuration (2.25-3.0 mm) (post-expansion with 5.0 mm balloon)	9-Cell Configuration (3.50-4.0mm) (Post-expansion with 6.0mm balloon)
 Outer Diameter 4.474 mm  Over-expanded Cell Diameter 2.585 mm	 Outer Diameter 5.683 mm  Over-expanded Cell Diameter 2.658 mm
Average elastic recoil of over-expanded stent: 1.70%	Average elastic recoil of over-expanded stent: 1.88%
Average Radial Strength of over-expanded stent: 0.13 N/mm	Average Radial Strength of over-expanded stent: 0.11 N/mm

The elastic recoil performance of the stent met the quality control requirements, and the radial support performance of the stent met the quality control requirements: ≥0.1 N/mm

Laboratory test data for reference only

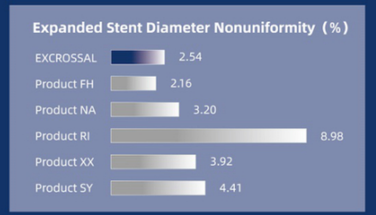


For delivery system catheters, the tapered tip configuration, smaller tip OD and appropriate tip length provide less chance of tip damage, easier passing through the lesions, and less damage to the vessel when crossing complex lesions.

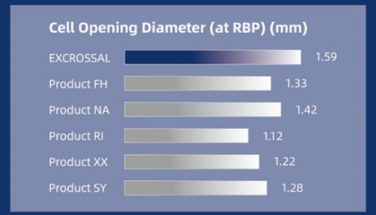


The insertion force is the push force at the distal portion of the stent when entering the vascular model from the guiding catheter, it simulates the push force of the device entering the human vascular from the guiding catheter; the smaller its value, the better.

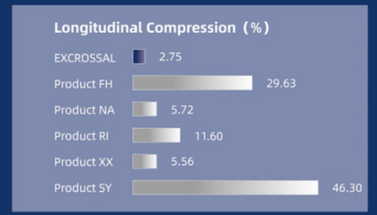
Traceability refers to the ability of the SDS to advance along the guidewire through the vascular path, including narrow and/or tortuous vascular structure. Theoretically, a smaller peak force yields better passing performance of the stent in human body.



The expanded stent diameter non-uniformity reflects the degree of "dog-bone effect" that occurs during stent deployment. A smaller non-uniformity reflects better performance of the stent.



After opening the stent cell, the larger diameter of the cell, the better performance of side branch crossing in bifurcation lesions treatment.



A smaller longitudinal anti-extrusion is better, so that the stent is not easy to deform and damage, avoiding the "accordion effect".