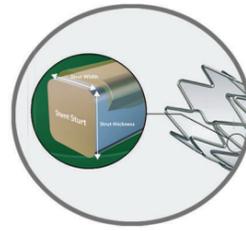
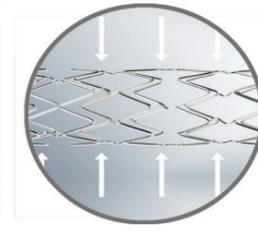




Hybrid Cell Design
Balancing Flexibility & Support



70 µm Ultra - Thin Struts
Designed for Minimal Vascular Impact



L605 CoCr Platform
High Radial Strength (0.8 N/mm) & Minimal Recoil



Fully Bioreabsorbable Polymer
Controlled Sirolimus Elution (80% in 4-6 Weeks)

Specification

Balloon Type	: Rapid Exchange (RX)
Balloon Compliance	: Semi-Compliant
Balloon Folding	: Tri-Fold
Total Working Length	: 142cm
Stent Length (mm)	: 8mm to 38 mm (8,13,18,23,28,33,38)
Stent Diameter (mm)	: 2.50 mm to 4.00 mm (2.50,2.75,3.00,3.25,3.50,3.75 & 4.00 mm)
Distal Shaft Diameter	: 2.6 Fr
Proximal Shaft	: 1.9 Fr
Nominal Pressure	: 8 atm
Rated Burst Pressure	: 16 atm
Crossing Profile	:
Vessel Size (mm)	Profile (mm)
2.50/2.75/3.00	< 1.10
3.25/ 3.50/4.00	< 1.15
Balloon Material	: Nylon
Marker Material	: Platinum and Iridium
Radio Opaque Markers	: 2
Tip Length	: 4 mm
Tip Entry Profile	: 0.019"
Distal Shaft Coating	: Hydrophilic
Minimum Guide Catheter ID	: 5 Fr
Max. Guidewire Compatibility	: 0.014"
Inflation Time	: ≤10 sec
Deflation Time	: ≤ 25 sec
Shelf Life	: 18 Months

Stent Specifications

Design	: Hybrid
Material	: L 605 Cobalt Chromium Alloy
Strut Thickness	: 70 µm (0.070 mm)
Strut Width	: 100 µm (0.10 mm)
Radial Strength	: 0.8 N/mm
Maximum Expansion Profile	: ≤ 4 atm beyond RBP pressure 0.1 – 0.2 mm
Drug	: Sirolimus
Drug Dose	: 1.4µg/mm ² (Sirolimus per square mm of stent surface area)
Drug Elution Profile	
Day 1	: 25% - 45% of label claim
Day 7	: 50% - 80% of label claim
Total Drug on Stent	
Polymer	: PLLA-PLGA
Polymer Degradation	: 6 months (from time of implantation)
Mean Recoil	: < 5%
Mean Foreshortening	: < 3%

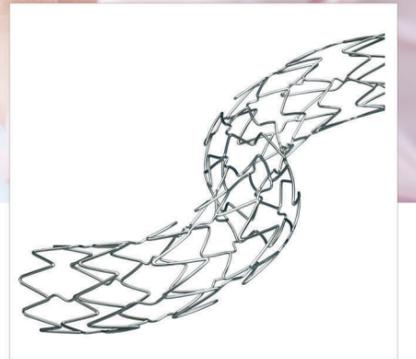
Compliance Chart
Stent Compliance

Stent Diameter (mm)	Inflation Pressure (atm)									
	4 atm	6 atm	8 atm	10 atm	12 atm	14 atm	16 atm	18 atm	20 atm	
2.50	2.11	2.42	2.50	2.65	2.72	2.79	2.88	2.98	3.06	
2.75	2.42	2.60	2.75	2.84	2.92	2.97	3.02	3.07	3.12	
3.00	2.66	2.84	3.00	3.12	3.20	3.29	3.37	3.46	3.53	
3.25	2.87	3.07	3.25	3.36	3.45	3.54	3.62	3.69	3.76	
3.50	2.98	3.20	3.50	3.56	3.67	3.78	3.88	3.98	4.08	
3.75	3.29	3.49	3.75	3.83	3.90	3.98	4.04	4.10	4.19	
4.00	3.38	3.74	4.00	4.05	4.16	4.22	4.28	4.36	4.47	
			N/P						RBP	

SCAN THE QR CODE FOR ORDERING INFORMATION



**Engineered for Optimal Outcomes:
Precision, Performance, & Safety**



RAPSTROM™ ELITE
Sirolimus-Eluting Coronary Stent System

A Synergistic Approach to Coronary Artery Disease Treatment

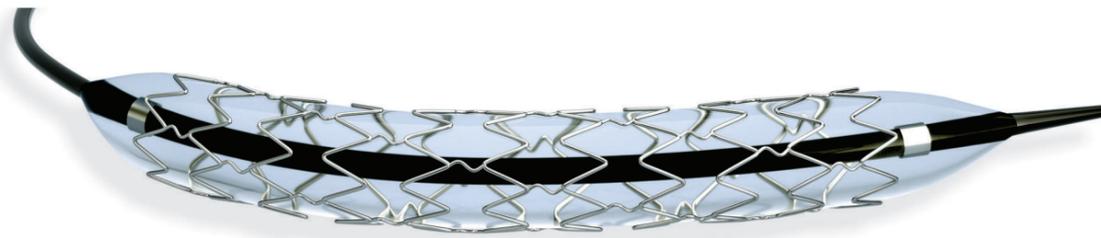
Advancing Percutaneous Coronary Intervention through Optimized Design and Controlled Drug Delivery

The Rapstrom™ Elite represents an advanced generation sirolimus-eluting coronary stent system engineered for optimal performance in the treatment of coronary artery disease. It integrates a proven L605 cobalt chromium (CoCr) alloy platform with the established anti-proliferative efficacy of sirolimus, delivered via a fully bioresorbable polymer coating.

Designed specifically for the treatment of de novo lesions ($\leq 38\text{mm}$) in native coronary arteries with reference vessel diameters ranging from $\geq 2.5\text{mm}$ to $\leq 4.0\text{mm}$, Rapstrom™ Elite aims to restore and maintain coronary luminal diameter while minimizing the potential for restenosis and thrombosis.

Core Technological Pillars

-  **Platform Material**
High-strength L605 Cobalt Chromium Alloy
-  **Polymer**
Fully Bioreabsorbable Poly (L-lactide-co-glycolide) [PLLA-PLGA] based polymer
-  **Drug**
Sirolimus (targeted anti-restenosis agent)
-  **Design**
Hybrid cell architecture (open and closed cells)



Engineered for Clinical Performance

1 Advanced Stent Architecture

Hybrid Cell Design

A sophisticated combination of open and closed cells provide an optimized balance between conformability and scaffolding integrity. Facilitates excellent side branch access (open cells)

- Enhances flexibility and trackability for navigating tortuous vessel segments (open cells)
- Ensures uniform vessel support (closed cells)

Ultra-Thin Strut Profile

- Strut thickness maintained at **70µm (0.07 mm)**
- Strut width optimized at **100 µm (0.10 mm)**
- This design minimizes vessel wall injury during deployment, potentially promoting faster endothelialization and reducing thrombogenicity.
- Contributes to a minimal metal-to-artery surface area ratio.

2 Robust L605 Cobalt Chromium Platform

- Provides superior radial strength (approx. **0.8 N/mm**) compared to traditional stainless steel platforms, ensuring effective lesion scaffolding and resistance to compression
- Engineered for **minimal elastic recoil**, maintaining achieved luminal gain post-procedure.
- Offers enhanced radiopacity for improved visualization under fluoroscopy during placement.

3 Bioresorbable Polymer and Controlled Drug Elution

- Features a **fully absorbable PLLA-PLGA based polymer coating**, minimizing long-term polymer exposure and associated inflammatory responses.
- The polymer matrix, combined with crystalline sirolimus, ensures strong coating integrity and **controlled drug release kinetics**.
- Approximately **80% of the sirolimus dose is eluted within the initial 4-6 weeks**, aligning with the critical period for inhibiting neointimal hyperplasia.
- Designed for a **higher drug load relative to polymer thickness**, optimizing therapeutic delivery.

Proven Clinical Efficacy

Patients with de novo coronary artery disease and high clinical risk profile, treated with implantation of one or more Rapstrom stents between 2.5 to 4 mm in diameter and between 13 and 38 mm in length, in ACC/AHA type B lesions, carried a higher drug load to polymer thickness ratio.

Patient Clinical Profile

Diabetes - 35%
Acute Coronary Syndrome - 82%

Table 2
Baseline clinical characteristics

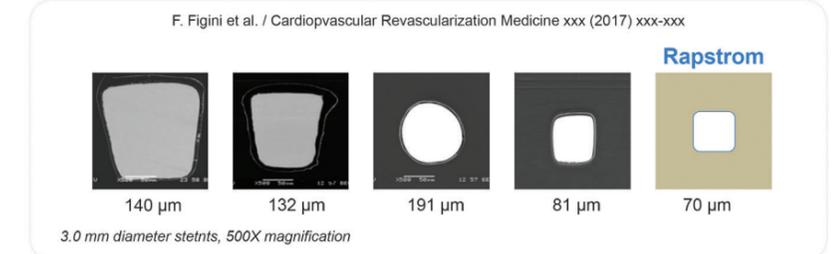
Patient n	1073
Male sex	819 (76)
Age	53 ± 14
BMI	25.8 ± 2.1
Diabetes	376 (35)
Current smoke	401 (37)
Hypercholesterolemia	309 (29)
Family history of CAD	478 (45)
Hypertension	507 (47)
Previous MI	285 (27)
Previous CABG	87 (8)
Prior PCI	76 (4)
Clinical Presentation	
Acute MI	497 (46)
Unstable angina	384 (36)
Stable angina	128 (12)
Silent ischemia	64 (6)

BMI: Body Mass Index; CAD: Coronary Artery Disease; MI: Myocardial Infarction; CABG: Coronary Artery Bypass Grafting; PCI: Percutaneous Coronary Intervention

Indications for Use

The Rapstrom™ Elite Sirolimus-Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to de novo lesions in native coronary arteries.

Drug Load to Polymer Thickness Ratio



Product	Strut Thickness (µm)	Polymer Thickness (µm)	Total Drug Load (µm/mm ²) *per mm
Product 1	140	12.6	1.4
Product 2	132	16	1.0
Product 3	91	5.3	*10
Product 4	81	7.6	1.0
Rapstrom	70	4.5	1.4

Fig. 1. Comparison of strut cross-section, polymer thickness and drug load of Cypher, Taxus, Endeavor, Xience V and Rapstrom stents.

Clinical Outcomes: MACE Rate Follow-up: 36 Months

Major Adverse Cardiac Events (MACE) were tracked over a 3-year period in the evaluated cohort (Figini et al., 2017), with the following cumulative rates observed:

- Early Phase (3 Months): 0.8%
- 12 Months (1 Year): 11.2%
- 36 Months (3 Years): 14.8%

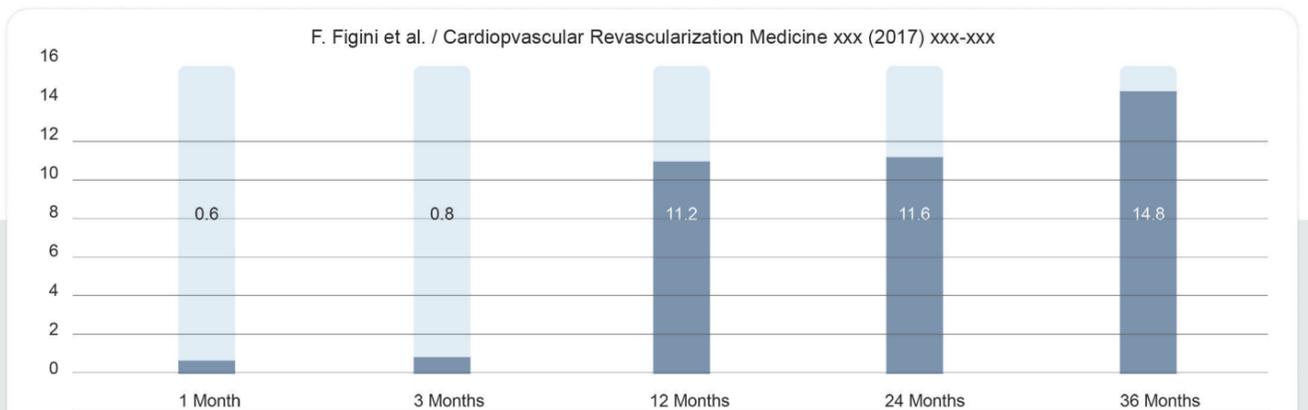


Fig. 2. MACE rate over follow-up period.

Figini F, et al, Long-term results of a sirolimus-eluting stent with biodegradable polymer (RAPSTROM™) in de novo coronary stenoses, Cardiovasc Revasc Med (2017), <https://doi.org/10.1016/j.carrev.2017.10.003>(2017)