

100 pirkimo dalis

Ultimaster[®]

Drug Eluting Stent

Ultimate design
for **mastering** complexity

SOLUTIONS FOR



ACUTE MYOCARDIAL INFARCTION

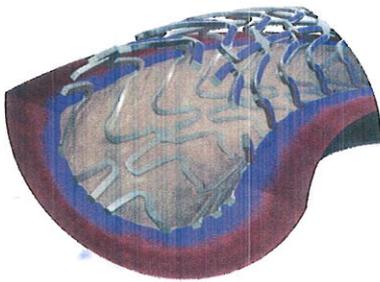
TERUM



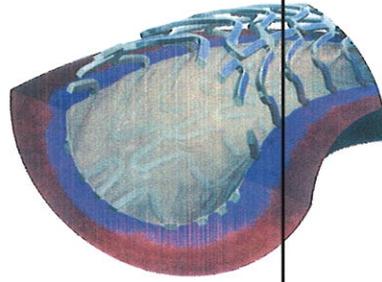
Optimized drug release technology targeting long-term safety

Bioresorbable PDLLA-PCL polymer to eliminate long-term polymer exposure

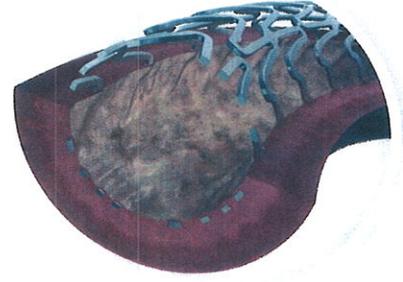
Post-implantation



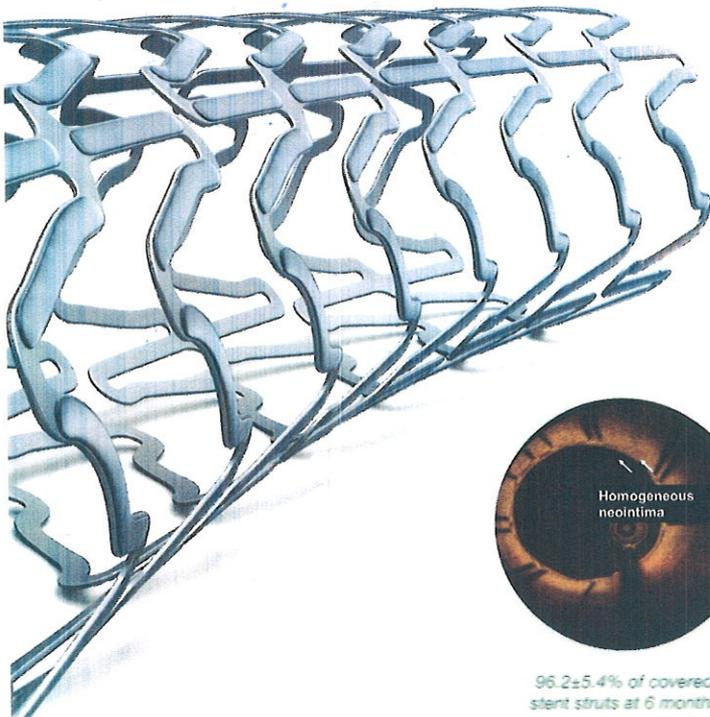
1 month after



3-4 months after



The polymer and the drug are released simultaneously and absorbed within 3-4 months, matching biological responses. The coating is tailored to facilitate vascular healing.

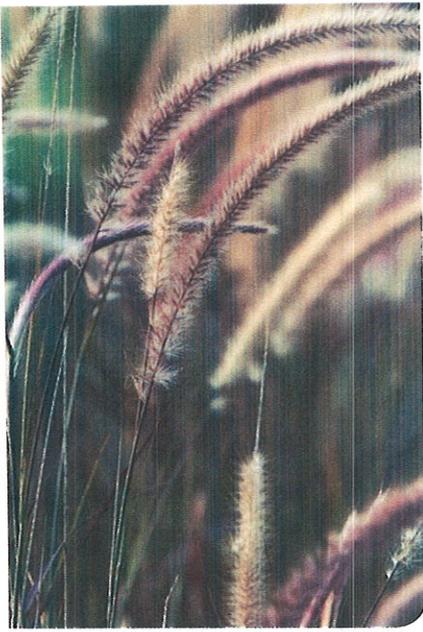


96.2±5.4% of covered stent struts at 6 months

Abluminal and gradient coating ensure fast and functional endothelialization

Coating layer only on abluminal side for targeted drug delivery. Unique gradient coating: no polymer on the stent parts with highest physical stress.

Such technology reduces the risk of the polymer cracking and lamination, assuring homogeneous drug distribution.

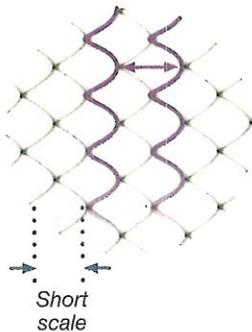


Enhanced conformability aims for long-term vessel patency

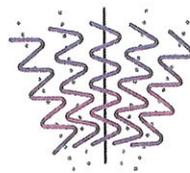
New vessel friendly platform with bio-inspired stent design

Strut structure comprised of small, snake scale-like curvatures.

In-phase alignment

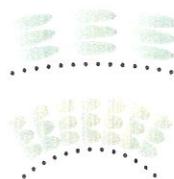


Excellent flexibility



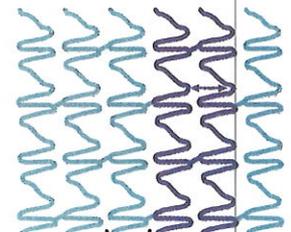
No interference between adjacent strut leads for smooth curve

Enhanced conformability



Small scales adapt to tortuous anatomies

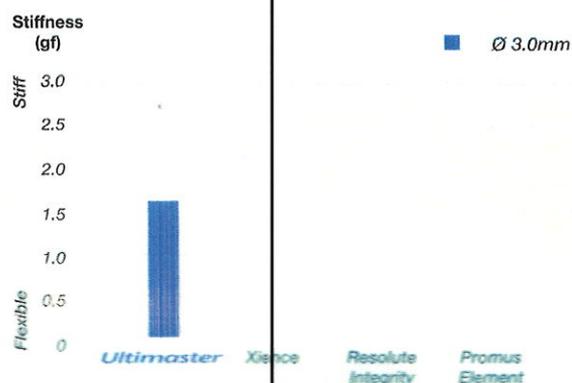
In-phase design



Short segment length

CoCr L605 80µm stent struts for optimal balance between radial force, visibility and flexibility

Stent Flexibility (conformability)



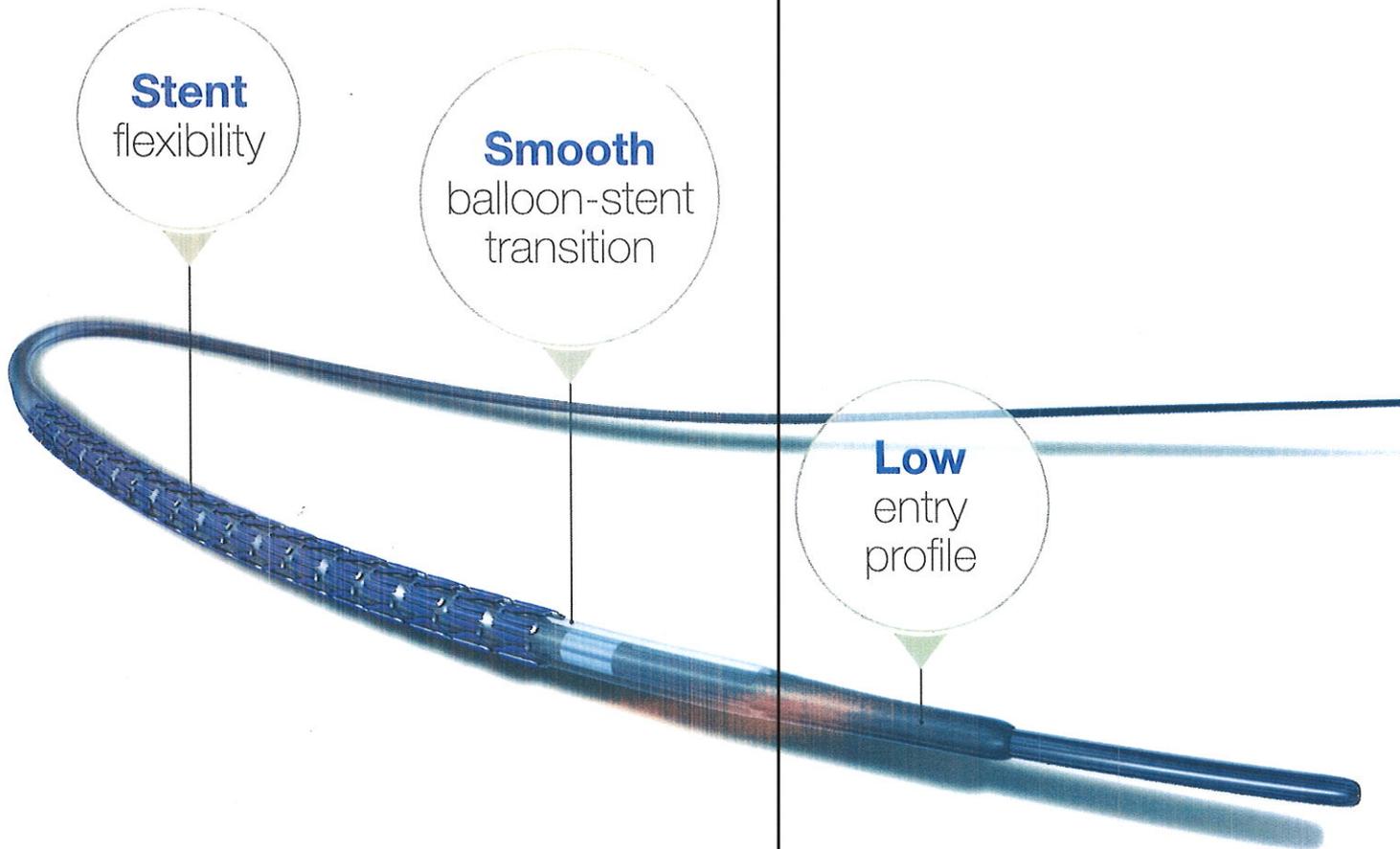
Method: measure the force required to push the stent 1 mm down



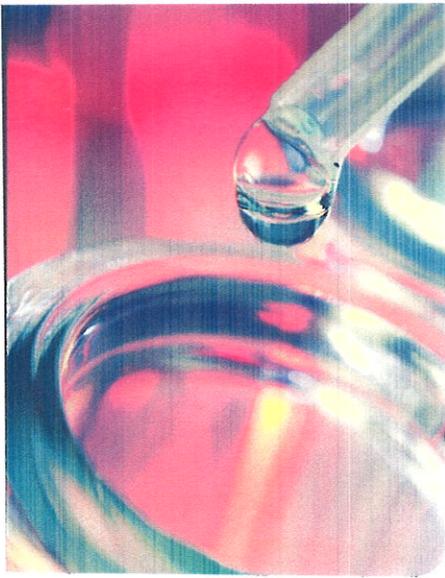


Reliable deliverability for consistent excellent performance

Low entry profile eliminates the gap between the tip and the guide wire for outstanding trackability



Famous Terumo hydrophilic coating, enhanced stent flexibility and smooth stent-balloon transition enable ultimate stent crossability



Design hypothesis supported by a comprehensive clinical program

More than **20 000 patients** in the clinical program

On-going studies

MASTER	500 pts	Randomised 3:1 vs BMS	STEMI
DISCOVERY 1T03	60 pts	Single arm	Multivessel disease OFDI strut coverage
GLOBAL REGISTRY	20 000 pts	Single arm	All-comers
SMALL VESSELS	80 pts	Single arm	Stents 2.25 mm

CENTURY II¹

Large, randomized, prospective, intercontinental trial:

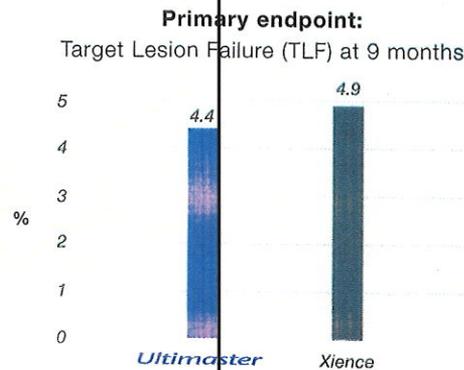
1 123 patients, 58 hospitals, 13 countries worldwide

CENTURY²

- Primary endpoint Late Loss (LL) at 6 months LL at 6 months: 0.04 mm
- OCT strut coverage at 6 months: 96.2±5.4%
- Target Lesion Failure (TLF) at 2 years: 5.7%
- Late and Very Late Stent Thrombosis: 0.0%

TCD-10023PK³

- Sirolimus concentration in whole blood non-measurable after 28 days
- LL at 6 months: 0.10 mm



Target Lesion Failure: composite of cardiac death, target vessel MI, clinically indicated TLR

Ultimaster DES matches Xience DES in primary endpoint.

**Low rate of adverse events up to 2 years
No late and very late stent thrombosis**

Preserved endothelial function

Ultimaster®

Ultimate design for mastering complexity

- ▶ Excellent acute performance
- ▶ Targeting favorable long-term clinical outcomes

Delivery System Specifications

Guide wire compatibility: 0.014" / 0.36 mm
Balloon material: Nylon 12
Nominal pressure: 9 atm
Rated Burst Pressure: 16 atm - 2.5 to 3.0 mm
14 atm - 3.5 to 4.0 mm
Entry profile: 0.017" / 0.43 mm
Crossing profile: 0.044" (1.12 mm) for 3.0 mm
Shaft: max size - 2.6 Fr / 0.88 mm
min size - 2.0 Fr / 0.67 mm
Coating: hydrophilic - distal shaft
silicone - proximal shaft
Minimum guide catheter: 5.0 Fr (0.056" / 1.42 mm)
Usable length: 144 cm

Stent Specifications

Stent design: open cell
Stent material: Cobalt Chromium L605
Strut thickness: 80 µm
Drug: sirolimus
Drug dose: 3.9 µg/mm stent length
Polymer: Poly (DL-lactide-co-caprolactone)
Coating: abluminal & gradient
Polymer degradation time and drug release: 3-4 months

Ordering Information

Diameter (mm)	Length (mm)							
	9	12	15	18	24	28	33	38
2.25	DE-RD2209KSM	DE-RD2212KSM	DE-RD2215KSM	DE-RD2218KSM	DE-RD2224KSM	DE-RD2228KSM	DE-RD2233KSM	DE-RD2238KSM
2.50	DE-RD2509KSM	DE-RD2512KSM	DE-RD2515KSM	DE-RD2518KSM	DE-RD2524KSM	DE-RD2528KSM	DE-RD2533KSM	DE-RD2538KSM
2.75	DE-RD2709KSM	DE-RD2712KSM	DE-RD2715KSM	DE-RD2718KSM	DE-RD2724KSM	DE-RD2728KSM	DE-RD2733KSM	DE-RD2738KSM
3.00	DE-RD3009KSM	DE-RD3012KSM	DE-RD3015KSM	DE-RD3018KSM	DE-RD3024KSM	DE-RD3028KSM	DE-RD3033KSM	DE-RD3038KSM
3.50	DE-RD3509KSM	DE-RD3512KSM	DE-RD3515KSM	DE-RD3518KSM	DE-RD3524KSM	DE-RD3528KSM	DE-RD3533KSM	DE-RD3538KSM
4.00	DE-RD4009KSM	DE-RD4012KSM	DE-RD4015KSM	DE-RD4018KSM	DE-RD4024KSM	DE-RD4028KSM	DE-RD4033KSM	DE-RD4038KSM



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