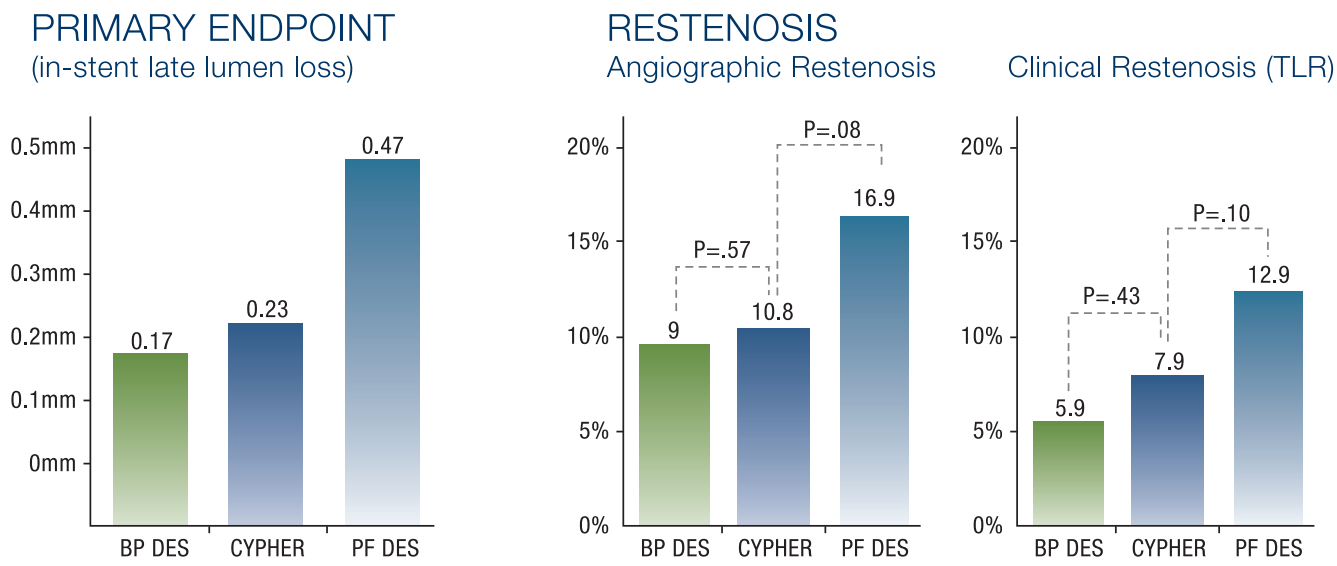
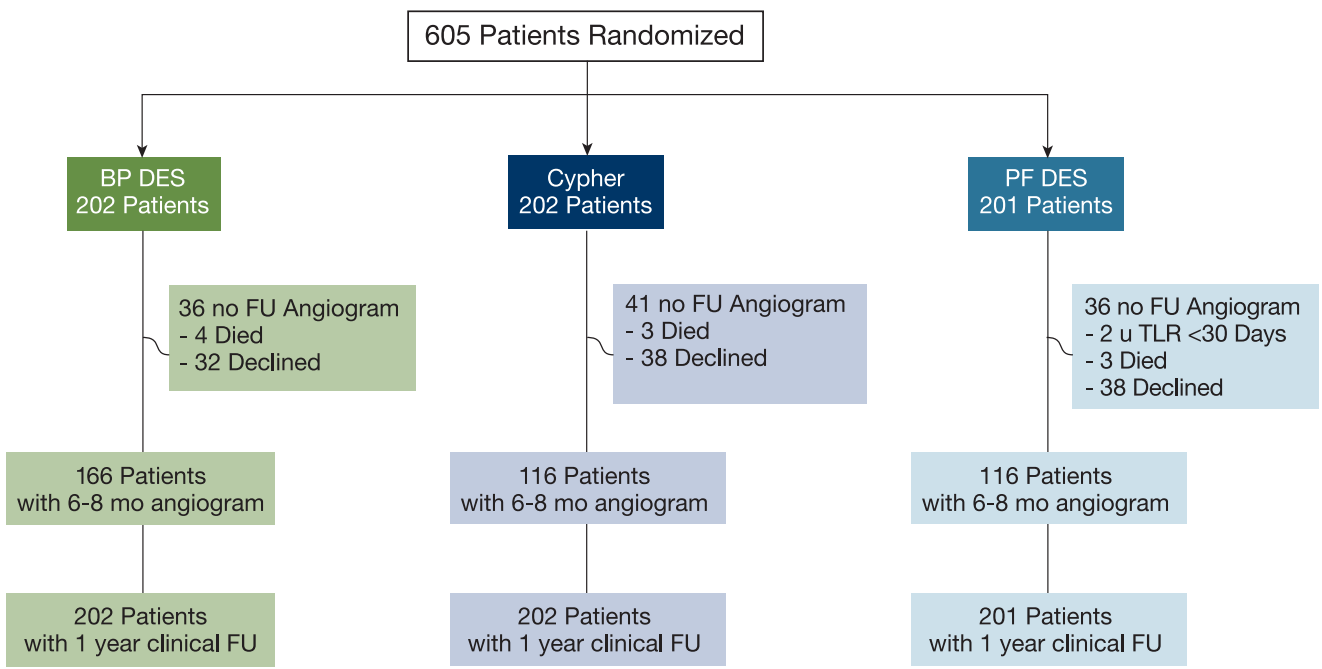


ISAR TEST 3

Study Hypothesis: Both PF (Polymer-free) and BP (Biodegradable Polymer) Sirolimus eluting stents are non-inferior to the Cypher stent in terms of late lumen loss.

Assumptions: Margin of non-inferiority for in-stent late lumen loss of 0.16mm, power of 80%.

605 patients enrolled to accommodate for possible missing follow-up angiograms.



Results: BP (Biodegradable Polymer with Sirolimus) shows the lowest late lumen loss and restenosis when compared to Cypher and Polymer Free Sirolimus Stents.

Study conducted at Deutsches Herzzentrum and 1st Med. Klinik rechts der Isar, Technische Universitat, Munich, Germany comparing PF (Polymer Free stent with Sirolimus), BP (Biodegradable polymer with Sirolimus) and Cypher (Biostable polymer with Sirolimus).

The ProNOVA XR Stent contains the same biodegradable polymer as in the above study.

ProNovaXR Technical Data

PRESSURE [MPa/bar]	DIAMETER [mm]					
	2.25	2.50	2.75	3.00	3.50	4.00
BALLOON [mm]	2.25	2.50	2.75	3.00	3.50	4.00
08/8	2.25	2.50	2.75	3.00	3.50	4.00
0.9/9	2.28	2.53	2.78	3.03	3.55	4.04
1.0/10	2.30	2.56	2.81	3.06	3.59	4.09
1.1/11	2.33	2.59	2.84	3.09	3.62	4.12
1.2/12	2.36	2.62	2.86	3.12	3.65	4.15
1.3/13	2.39	2.65	2.89	3.14	3.69	4.19
1.4/14	2.42	2.68	2.91	3.17	3.72	4.23
1.5/15	2.46	2.71	2.94	3.20	3.76	4.27
1.6/16	2.50	2.74	2.97	3.22	3.80	4.31
1.7/17	2.54	2.78	3.00	3.25		
1.8/18	2.60	2.82	3.03			
1.9/19	2.66					

Nominal pressure at 8 Bar [0.8 MPa] RATED BURST PRESSURE

ProNovaXR Ordering Information

STENT LENGTH (mm)	DIAMETER (mm)					
	2.25	2.50	2.75	3.00	3.50	4.00
13	PNXR22513	PNXR2513	PNXR27513	PNXR3013	PNXR3513	PNXR4013
18	PNXR22518	PNXR2518	PNXR27518	PNXR3018	PNXR3518	PNXR4018
23	PNXR22523	PNXR2523	PNXR27523	PNXR3023	PNXR3523	PNXR4023
28	PNXR22528	PNXR2528	PNXR27528	PNXR3028	PNXR3528	PNXR4028
33	PNXR22533	PNXR2533	PNXR27533	PNXR3033	PNXR3533	PNXR4033
38	PNXR22538	PNXR2538	PNXR27538	PNXR3038	PNXR3538	PNXR4038
43	PNXR22543	PNXR2543	PNXR27543	PNXR3043	PNXR3543	PNXR4043
48	PNXR22548	PNXR2548	PNXR27548	PNXR3048	PNXR3548	PNXR4048



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DEFINING THE NEXT GENERATION
IN DRUG ELUTING STENT TECHNOLOGY



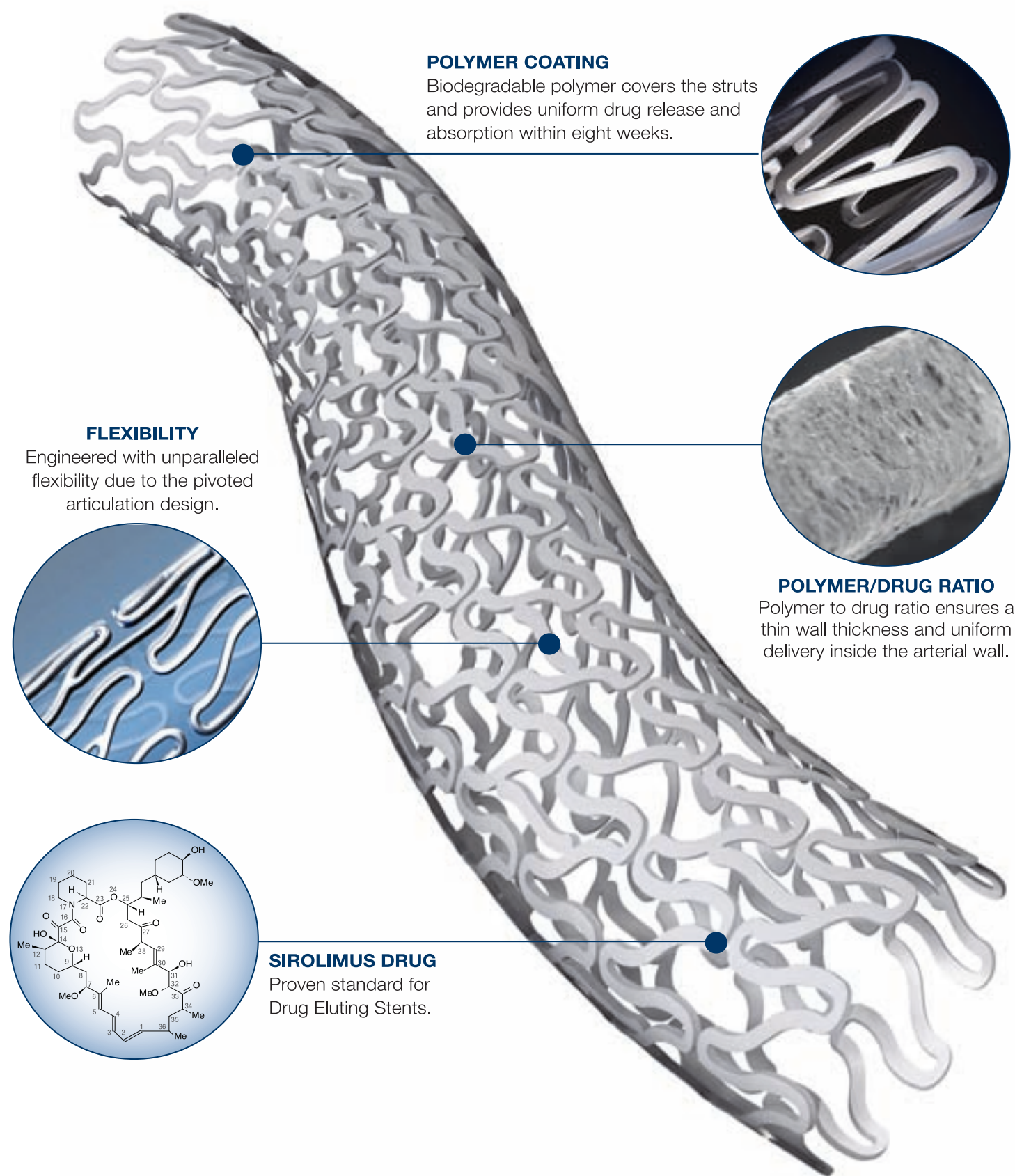
COBALT CHROMIUM STENT PLATFORM

SIROLIMUS DRUG

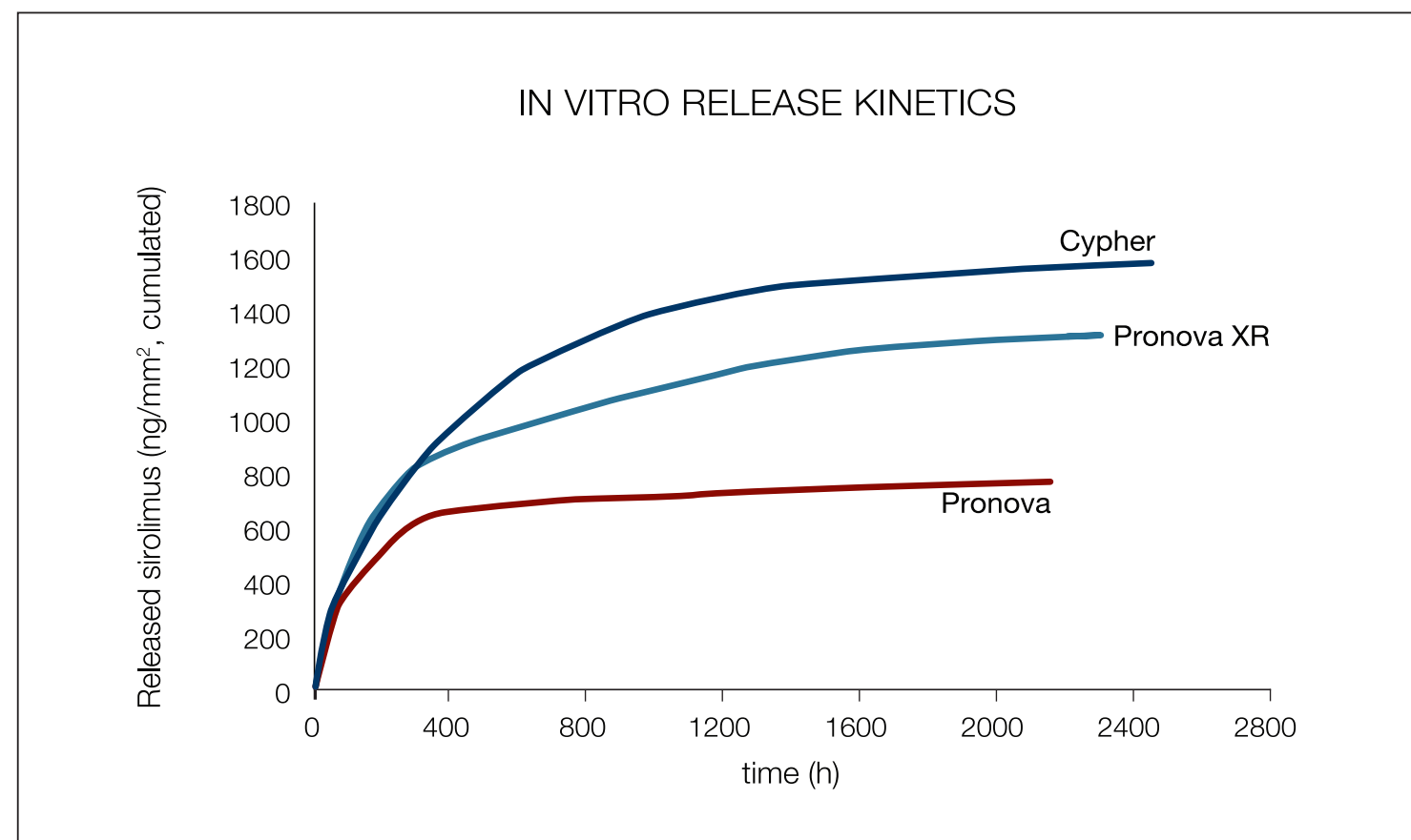
BIODEGRADABLE RELEASE TECHNOLOGY



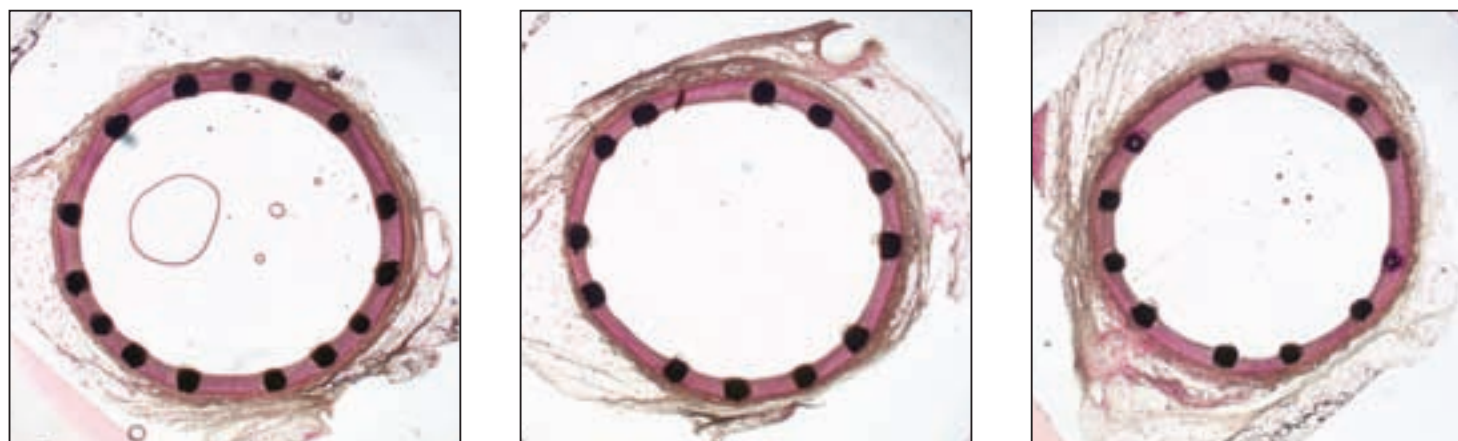
ProNOVA XR: Sirolimus Eluting Stent



RELEASE KINETICS



PRECLINICAL STUDIES

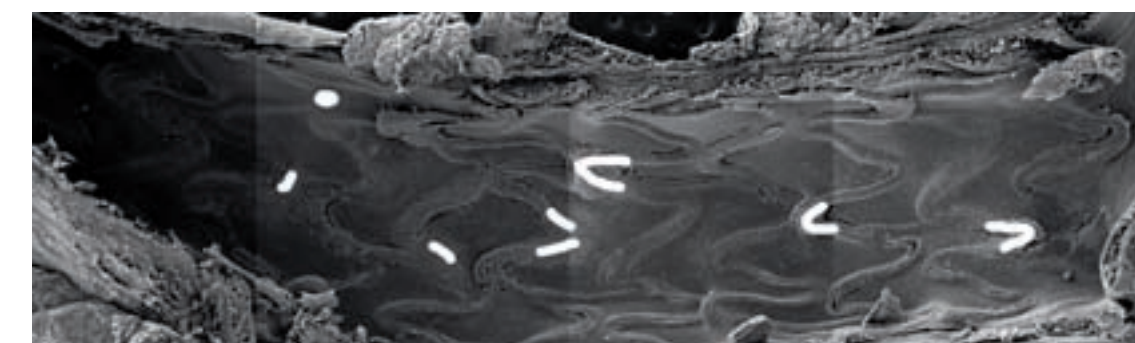


Preclinical studies confirm the thin neointima formation after 90 days in a pig coronary artery demonstrating excellent healing characteristics of the XR Stent.

ENDOTHELIALIZATION STUDIES

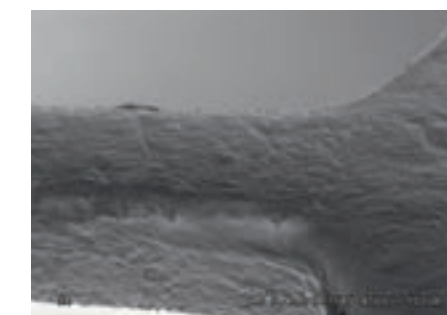


7 Days: Partial endothelial coverage of the stent struts (< 50%)

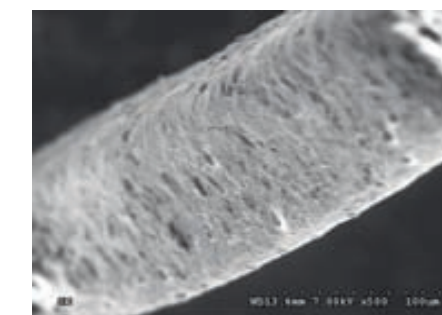


14 Days: Total endothelial coverage of the stent struts (> 95%)

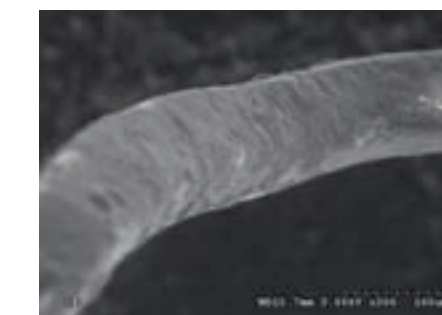
BIOABSORPTION STUDIES



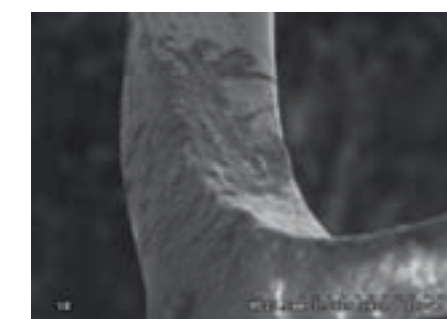
2 DAYS



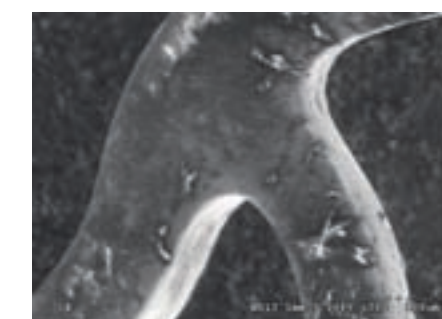
7 DAYS



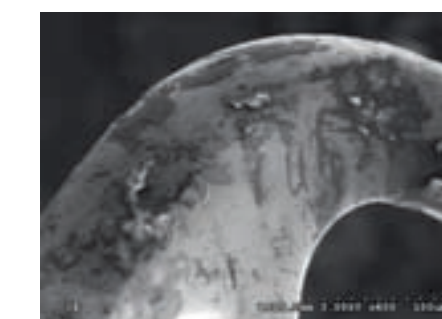
14 DAYS



28 DAYS



42 DAYS



84 DAYS

Stents explanted from pig coronary vessels demonstrate that after 42 days the stent surface is similar to a bare metal stent showing complete absorption of the polymer from the struts.