

Endothelial Progenitor Cell Capture Technology and Beyond



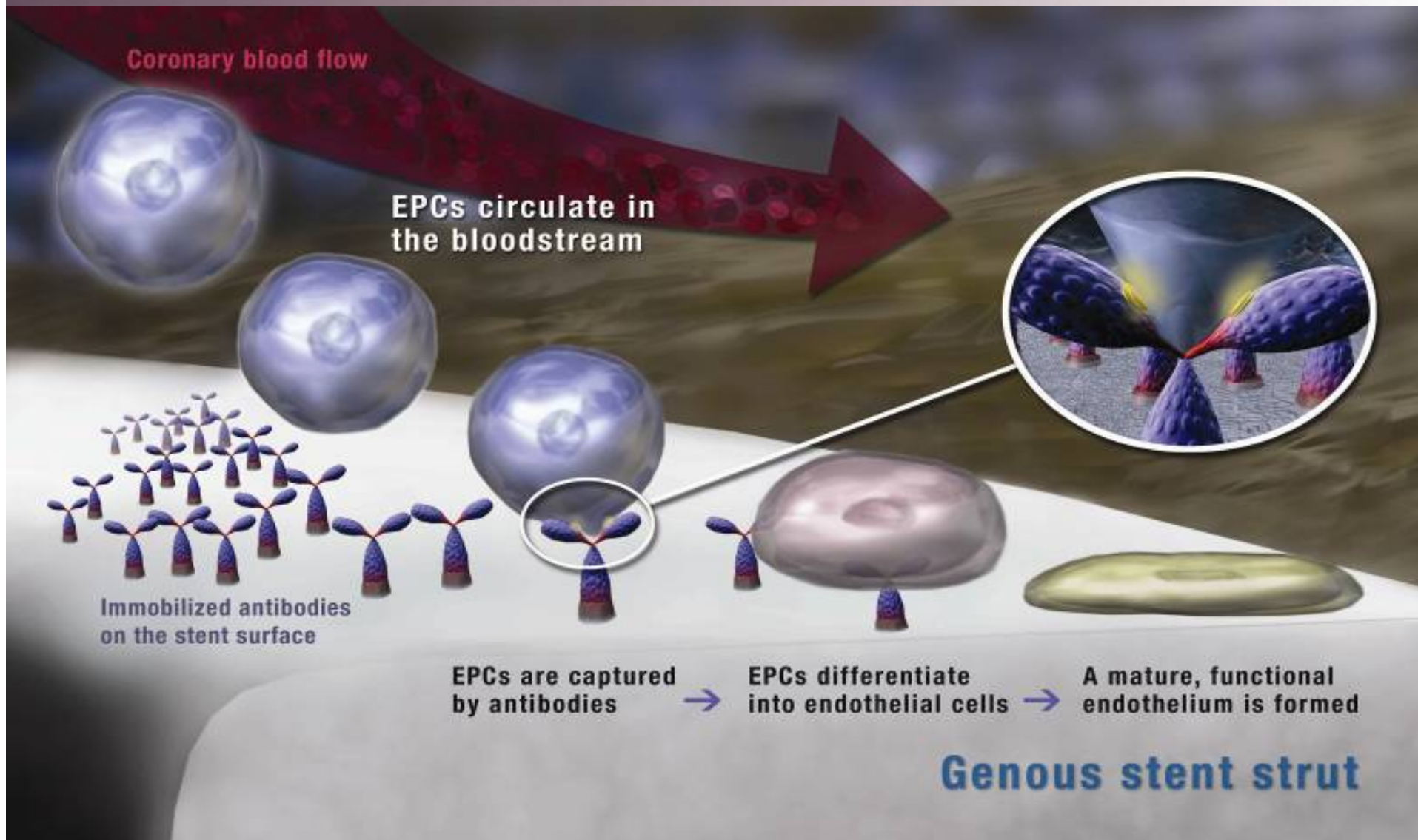
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St. Michael's Hospital, Toronto Canada

April 24, 2008
Summit 2008, TCT Asia Pacific, Seoul

Importance of the endothelium

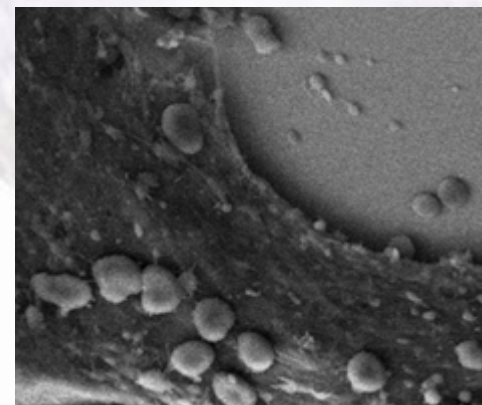
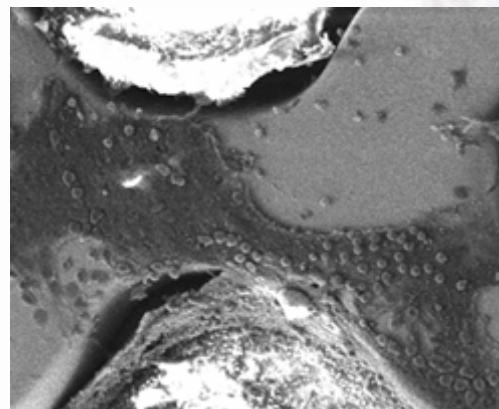
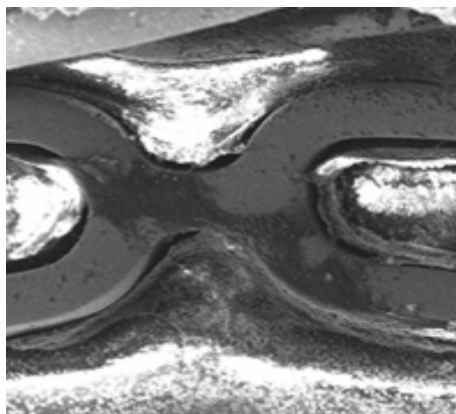
- A confluent endothelium
 - provides a barrier to circulating cytokines
 - produces powerful inhibitors of smooth muscle cell proliferation, migration, and matrix production.
- Proliferation of the neointima after coronary stent implantation is halted by a confluent endothelial layer
- Confluent, healthy endothelial layer prevents thrombus formation

EPC Capture Technology

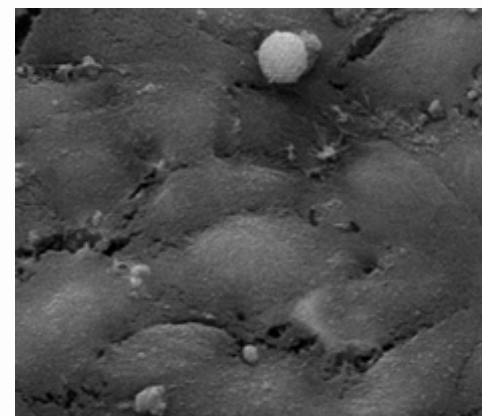
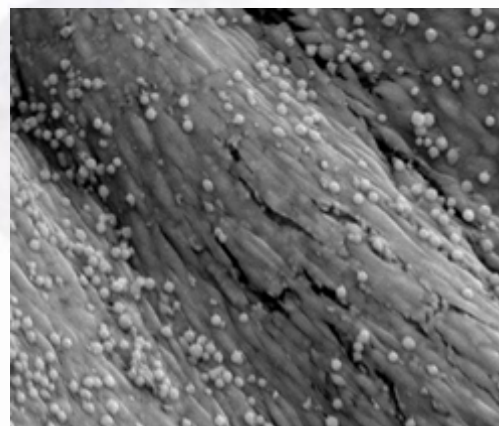
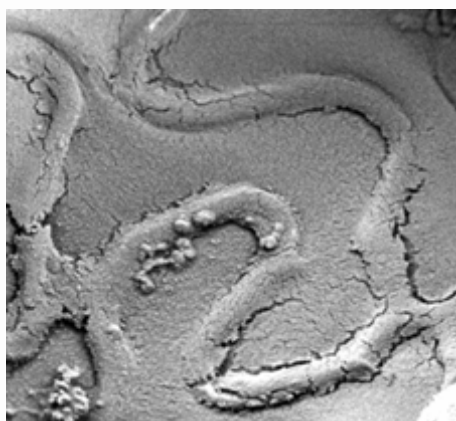


48 Hour Explants

Bare
Metal Stent

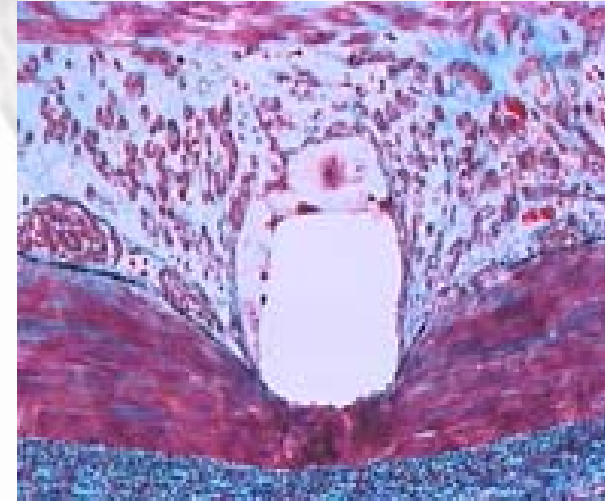
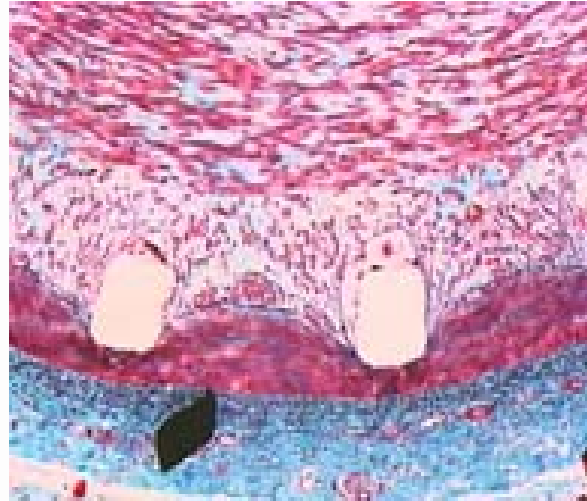


Genous

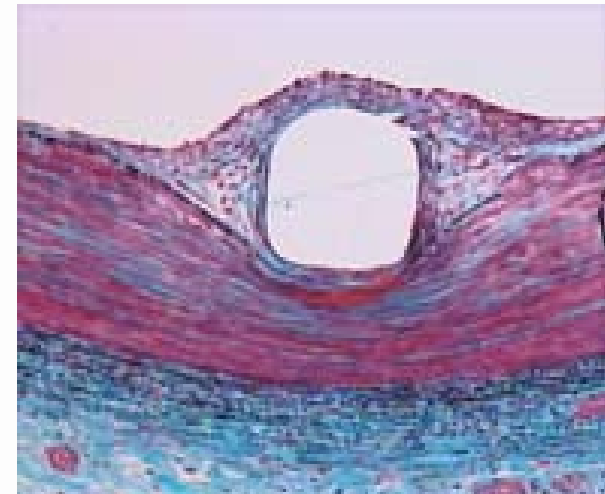
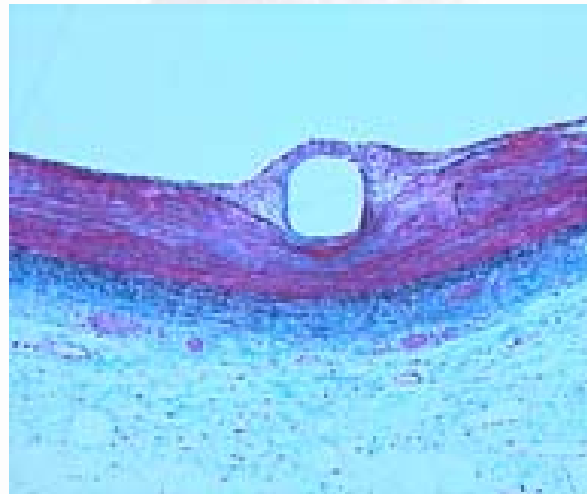


M. Kutryk; porcine coronary implants, unpublished data

Bare Stainless Steel



Antibody Coated



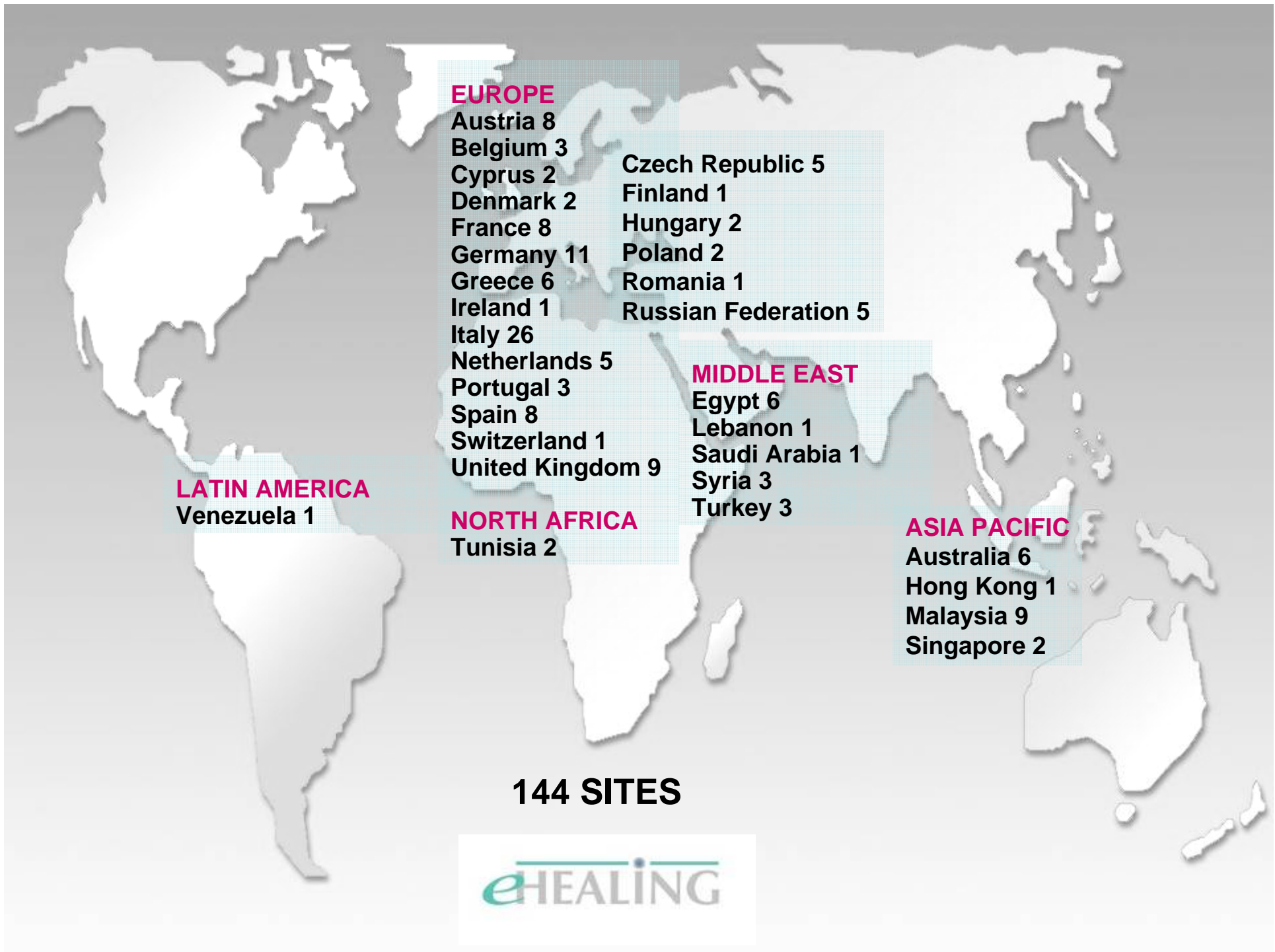
e-HEALING Registry Interim Analysis

Post Marketing Surveillance Registry of the
Genous Bio-engineered R stent

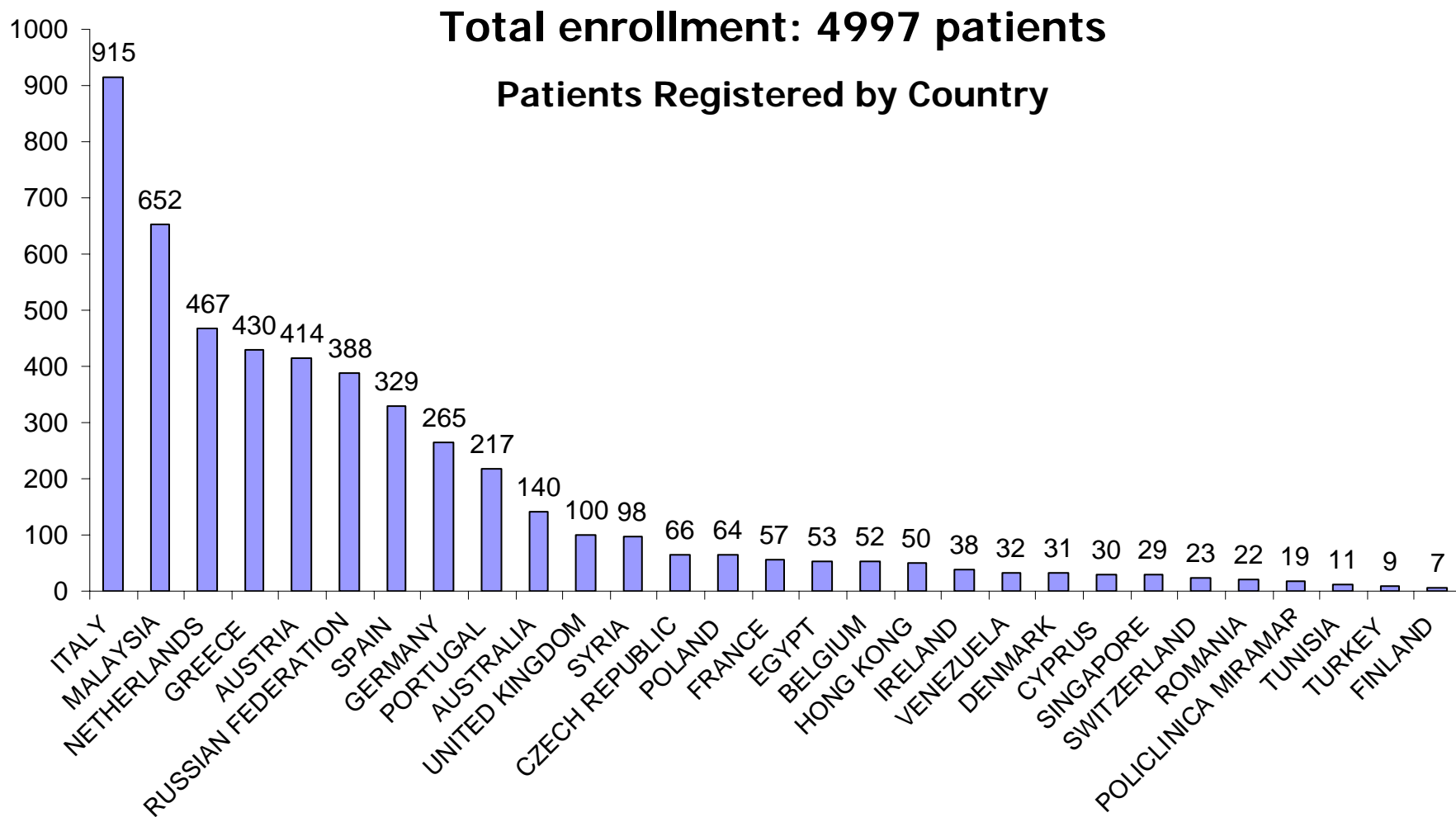
Overview

- Principal Investigators: Prof. Silber and Dr. de Winter
- Multi-center (144 sites), worldwide, prospective registry of patients treated with a Genous Bio-engineered R stent in accordance with the Instructions for Use
- 5000 patients
- Recommendation of at least two weeks statin treatment prior to the procedure and one month clopidogrel post-procedure
- Follow-up: 1, 6, and 12 month clinical follow-up
- Primary outcome: Target Vessel Failure at 12 months

Status - Enrollment complete



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Patient Demographics as of Feb 21, 2008



Age	62.8 years
Males	78.7%
Diabetics	25.0%
Hypertension	68.3%
Hypercholesterolemia	74.5%
Current Smokers	24.8%
Family History	28.1%
Previous MI	36.7%
Previous PCI	19.1%
Previous CABG	6.2%
Previous Stroke	6.0%



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Ischemia Status as of Feb 21, 2008

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Unstable angina	42.3%
Stable angina	43.3%
Silent ischemia	14.4%

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Lesion Characteristics as of Feb 21, 2008

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De novo	97.7%
Restenotic	2.3%

Lesion Classification	
Type A	15.3%
Type B1	35.6%
Type B2	29.6%
Type C	19.5%

Lesion Length (mm)	
Mean ± Std Dev	16.8 ± 8.6

Reference Vessel (mm)	
Mean ± Std Dev	3.0 ± 0.4

Number of stents/patient	1.5
Number of lesions/patient	1.3

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Deviations to Date as of Feb 21, 2008

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Not on statins for at least 2 weeks before procedure	26.8%
Patient with diffuse disease or poor flow distal to lesion	15.3%
Q wave MI \leq 3 days	5.7%
Non Q wave MI \leq 3 days	2.4%
Previous stent implanted is a drug eluting stent	3.6%
Anti-platelet and/or anti-coagulant therapy is contraindicated	2.0%
Saphenous vein grafts or unprotected left main coronary artery	1.8%
Reference diameter < 2.5 or > 3.75	7.2%
Pre procedure thrombus	10.9%
Vessel with excessive tortuosity	1.9%

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Clinical Events in patients with 6 month follow-up

Interim results as of Feb 21, 2008, n=3193

	6 months
Cardiac Death	1.3 %
MI	1.4 %
Q-wave	0.1 %
Non Q-wave	1.3 %
TLR (Clinically Driven)	2.8 %
PCI	2.5 %
CABG	0.3 %
MACE	5.5 %
Acute stent thrombosis	0.2 %
Sub-acute stent thrombosis	0.3 %
Late stent thrombosis	0.3 %

Patients treated before Feb 22, 2007

All events reported before 15 Jan 2008; all events adjudicated by CEC

Worst MACE per patient =cardiac death, MI, CABG, and clinically driven TLR



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Stent thrombosis according to ARC 12 months

Interim results as of Feb 21, 2008

Full population Stent thrombosis (only definite and probable)

Black line: n=1640

Event Free 30 days: 99.4 %

180 days: 99.3%

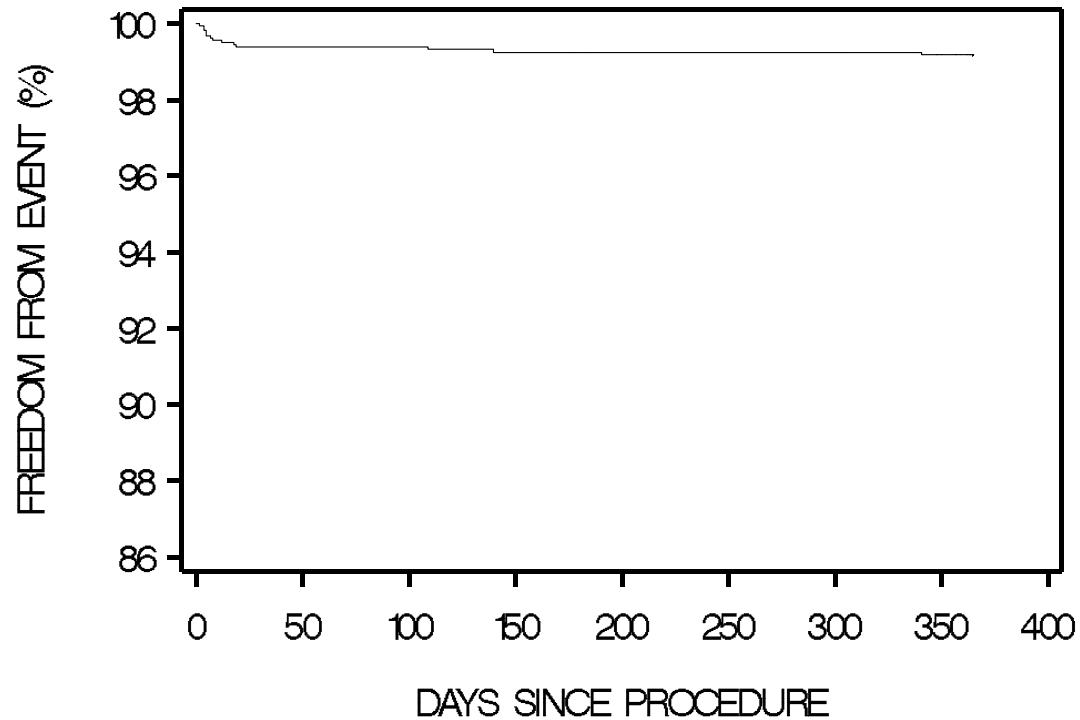
365 days: 99.2%

At risk

30 days: 1617 pt

180 days: 1567 pt

365 days: 1405 pt



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Clinical Events in patients with 12 month follow-up

Interim results as of Feb 21, 2008, n=1640

	30 days	6 months	12 months
Cardiac Death	0.6 %	1.5 %	2.1%
MI	1.2 %	1.6 %	1.8%
Q-wave	0.1 %	0.2 %	0.2%
Non Q-wave	1.0 %	1.4 %	1.5%
TLR (Clinically Driven)	0 %	2.8 %	5.4%
PCI	0.1 %	2.6 %	5.1%
CABG	0.0 %	0.2 %	0.4%
MACE	1.9 %	5.9 %	9.3%
Acute stent thrombosis		0.0 %	
Sub-acute stent thrombosis		0.5 %	
Late stent thrombosis		0.5 %	

Patients treated before Aug 14, 2006

All events reported before Jan 15, 2008; all events adjudicated by CEC



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Clinical Events in DM patients with 6 m fu

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Interim results as of Feb 21, 2008

	6 months
Cardiac Death	2.6 %
MI	1.5 %
Q-wave	0.2 %
Non Q-wave	1.3 %
TLR (Clinically Driven)	2.6 %
PCI	2.4 %
CABG	0.2 %
MACE	6.7 %
Acute stent thrombosis	0.0 %
Sub-acute stent thrombosis	0.4 %
Late stent thrombosis	1.1 %

Patients treated before Aug 14, 2006

All events reported before Jan 15, 2008; all events adjudicated by CEC



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Genous™

Clinical Events in patients w/o statin use with 6 mth fu

Interim results as of Feb 21, 2008

	6 months
Cardiac Death	2.3 %
MI	2.3 %
Q-wave	0.5 %
Non Q-wave	1.9 %
TLR (Clinically Driven)	2.3 %
PCI	2.3 %
CABG	0.0 %
MACE	6.9 %
Acute stent thrombosis	0.0 %
Sub-acute stent thrombosis	0.5 %
Late stent thrombosis	0.0 %

Patients treated before Aug 14, 2006

All events reported before Jan 15, 2008; all events adjudicated by CEC

e-HEALING

Genous™

Clinical Events in TIMI 0/1 patients with 6 mth fu

Interim results as of Feb 21, 2008

	6 months
Cardiac Death	2.1 %
MI	0.9 %
Q-wave	0.3 %
Non Q-wave	0.6 %
TLR (Clinically Driven)	2.1 %
PCI	2.1 %
CABG	0.0 %
MACE	5.0 %
Acute stent thrombosis	0.0 %
Sub-acute stent thrombosis	0.9 %
Late stent thrombosis	0.3 %

Patients treated before Aug 14, 2006

All events reported before Jan 15, 2008; all events adjudicated by CEC

Non-Hierarchical Comparison

Registry	Product	12 Months		
		TLR	MACE	Stent thrombosis
e- HEALING *	Genous	5.4%	9.3%	1.0%
ARRIVE 1 ¹	Taxus	5.4%	8.3%	2.1%
MILESTONE II	Taxus	5.5%	8.7%	2.6%

* Interim results of 1,640 patients treated before Aug 14, 2006 / All events reported before 15 Jan 2008; all events adjudicated by CEC

¹ N= 2,458 12 month follow-up on a total of 2,585 patients / <http://www.bostonscientific.com> (Taxus Express 2 Clinical Programs)

² N= 3,303 12 month follow-up on a total of 3,303 patients / <http://www.bostonscientific.com> (Taxus Express 2 Clinical Programs)

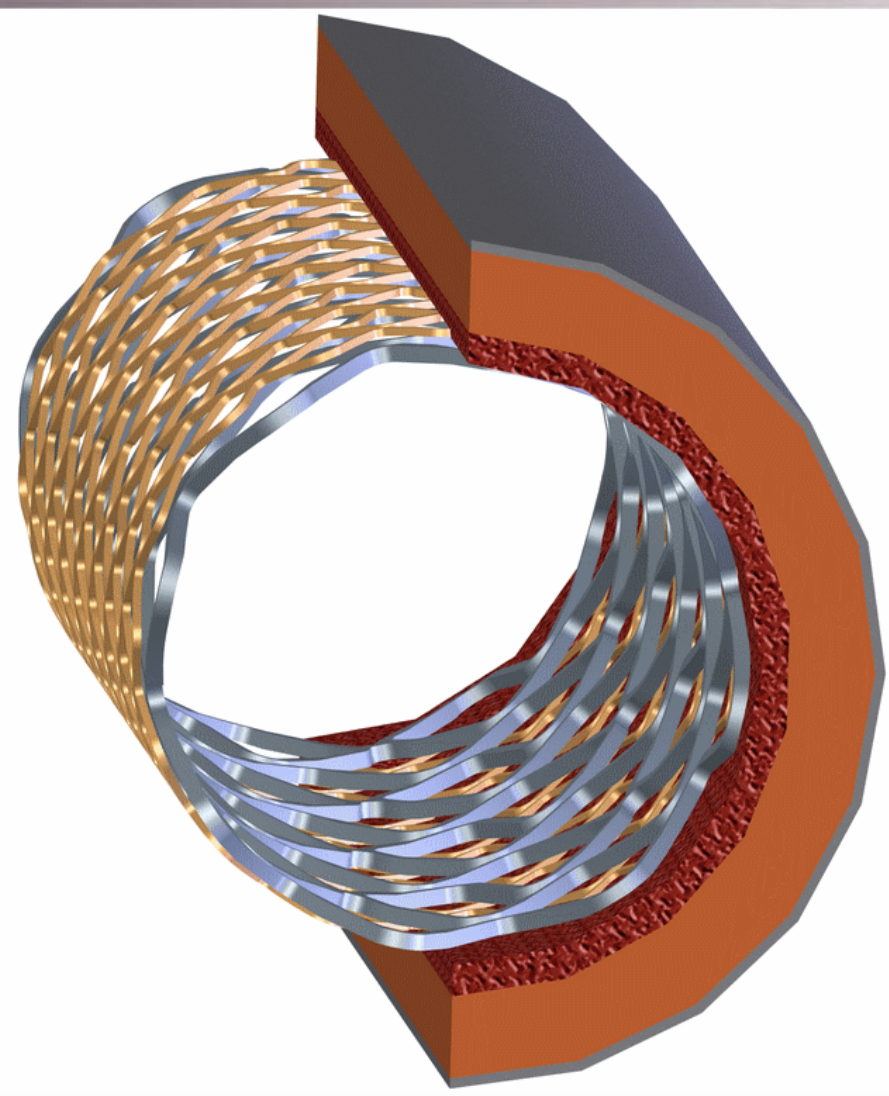
Conclusions

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- The interim data from the e-HEALING Registry demonstrate that the Genous Bio-engineered R stent is safe and effective.
- The 5.5% MACE and 0.8% ST rates at 6 months in 3,193 patients are comparable to Cypher and Taxus registry data.
- The 5.4% TLR and 9.3% MACE rates at 12 months in the first 1,640 patients are low and comparable to Taxus registry data, and the 1.0% thrombosis rate at 1 year is superior to data reported with DES use.

New Designs

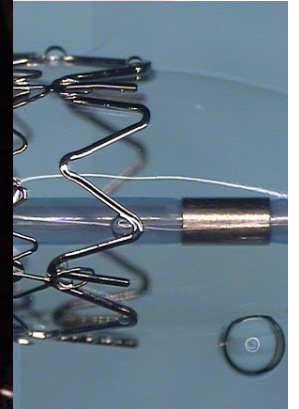
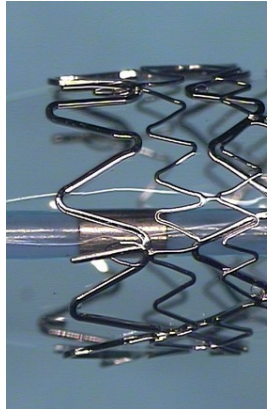
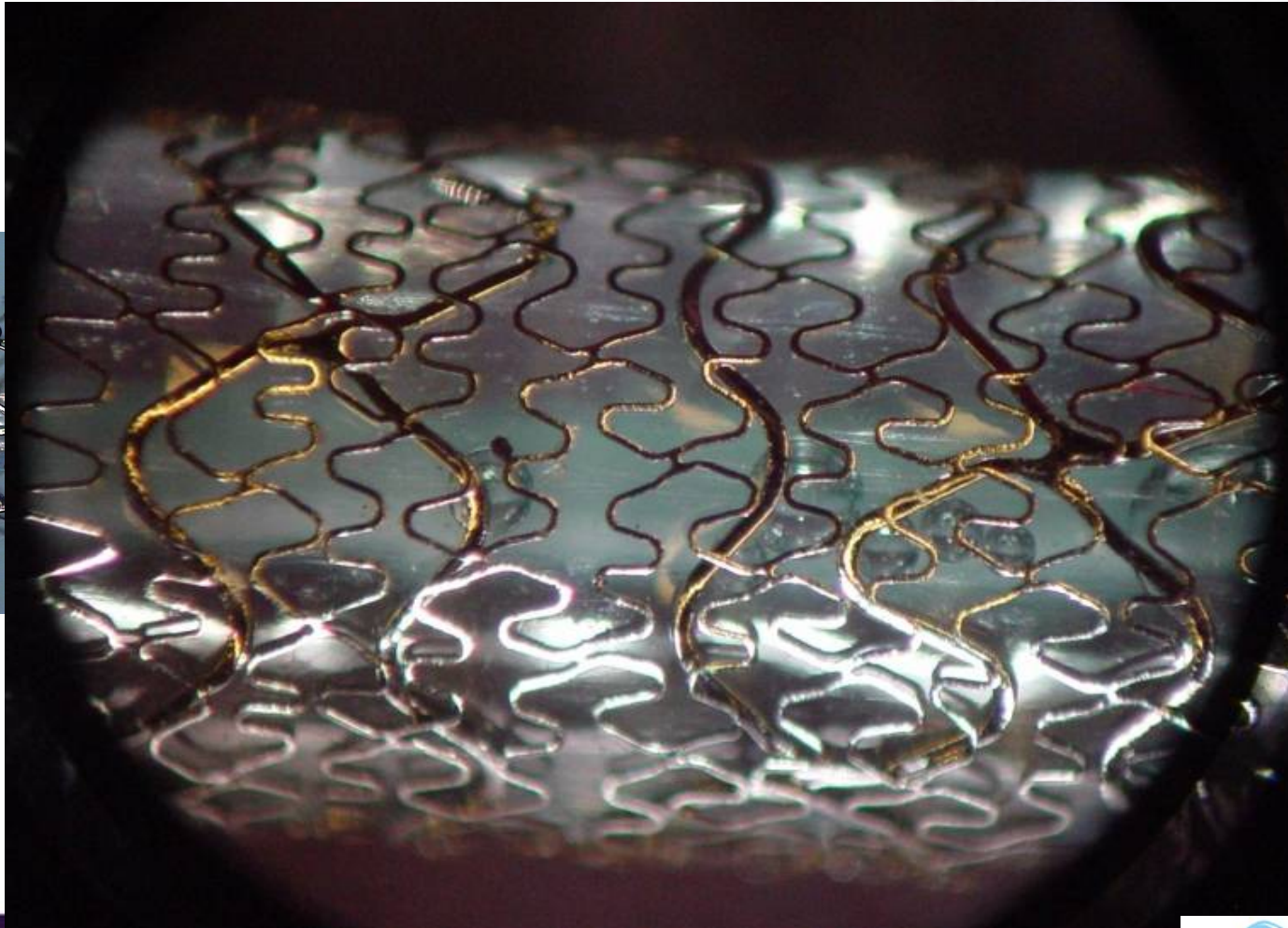
Foil Stent





Foil Stent - Expanded

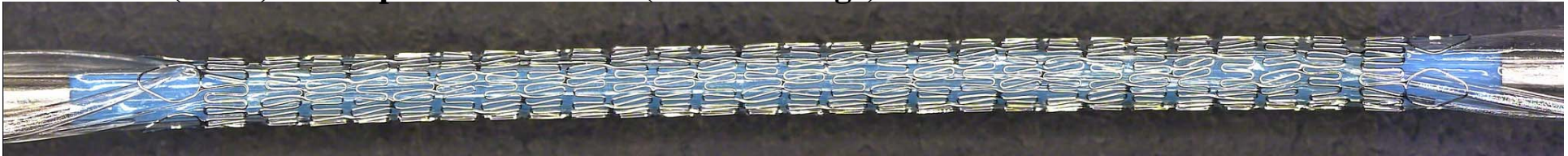
GenOus™



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**CoCr R-stent SDS – profile \leq
1.09mm**

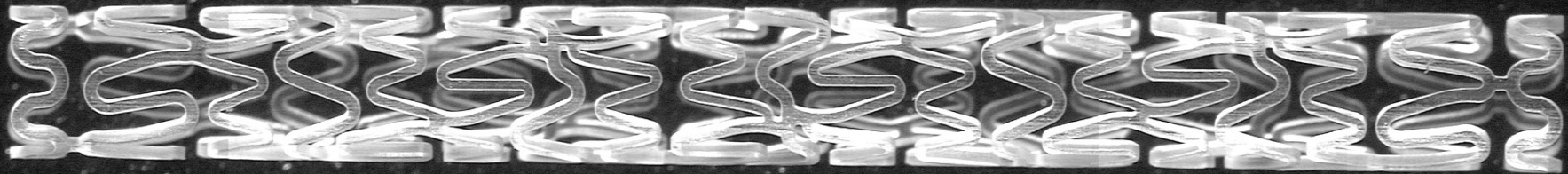
Foil Stent (alone) SDS – profile = 0.99mm (2 SDS average)



Foil Stent (Combo) SDS – profile = 1.13mm (3 SDS average)



- When design is crimped



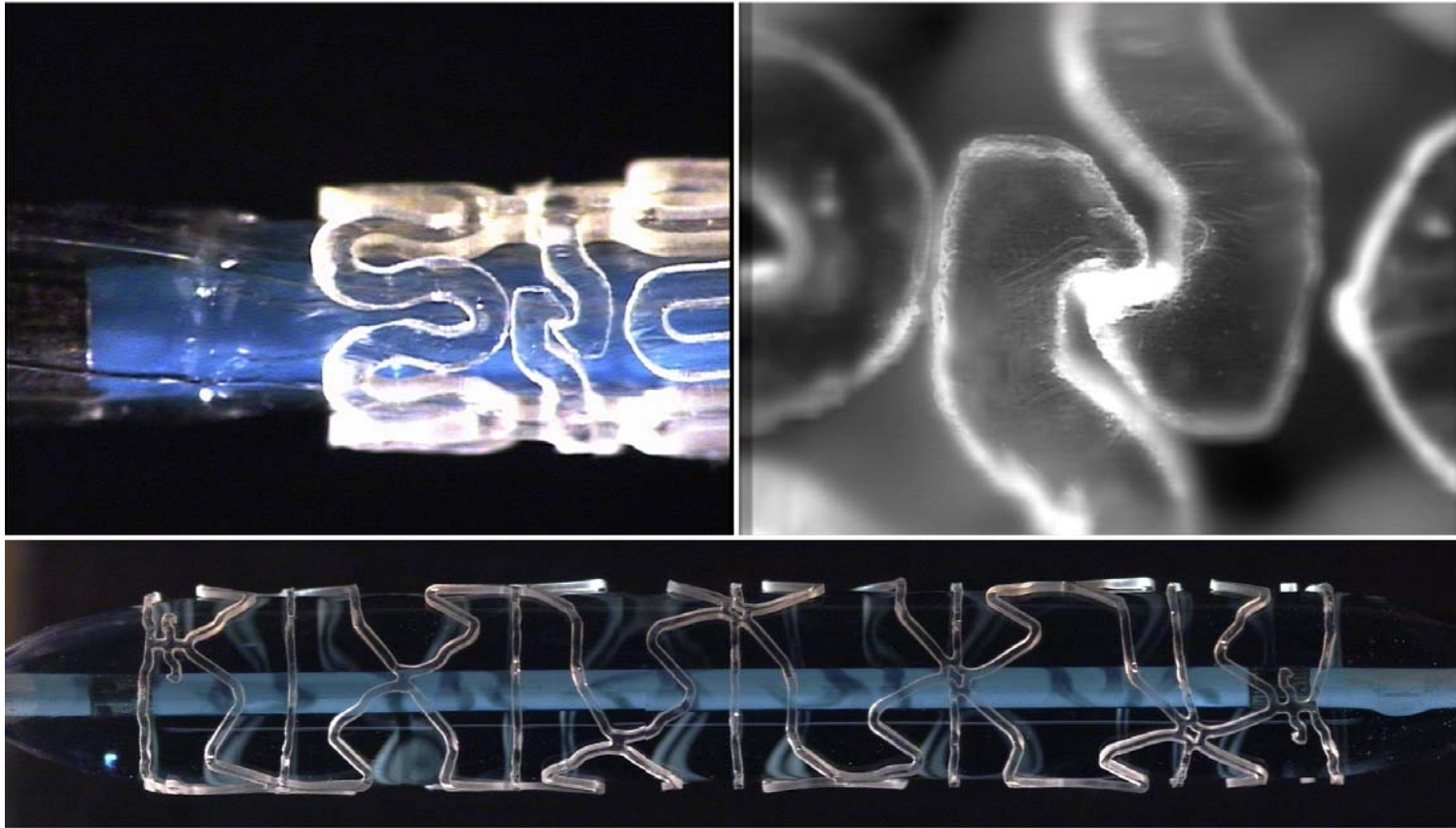
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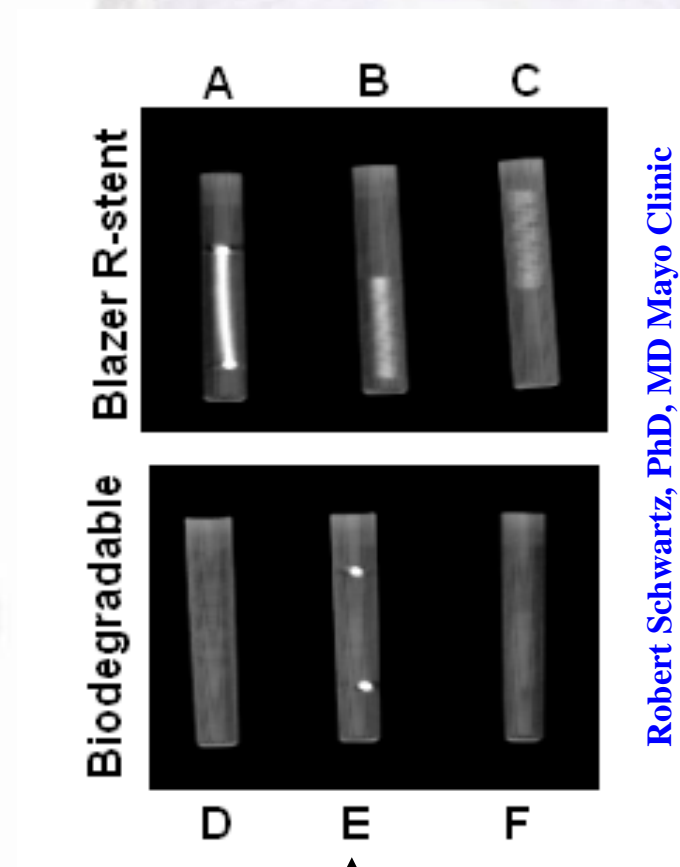
P/N: 176-053 Rev-01 Crimped Profile 1.35mm

Bioabsorbable Genous Stent

Genous™



Radiopaque Markers



Robert Schwartz, PhD, MD Mayo Clinic

Abluminal Drug Coating

