

Elixir<sup>®</sup>

MEDICAL CORPORATION

---

**INNOVATION FOR LIFE<sup>®</sup>**

# DESyne®

NOVOLIMUS ELUTING CORONARY STENT SYSTEM

**INNOVATING VASCULAR RESTORATION™**  
LEADING THE WAY TO NEXT GENERATION DES PLATFORMS



**Elixir**  
MEDICAL CORPORATION  
INNOVATION FOR LIFE®

# ENGINEERED TO MAXIMIZE DELIVERABILITY & CLINICAL PERFORMANCE

---

**DESyne<sup>®</sup>** maximizes deliverability  
and is able to deliver superior  
performance with **the lowest  
published late lumen loss<sup>4</sup>**.

# FORMULA X™ Coating Technology

## Advanced Drug/Polymer Coating Technology

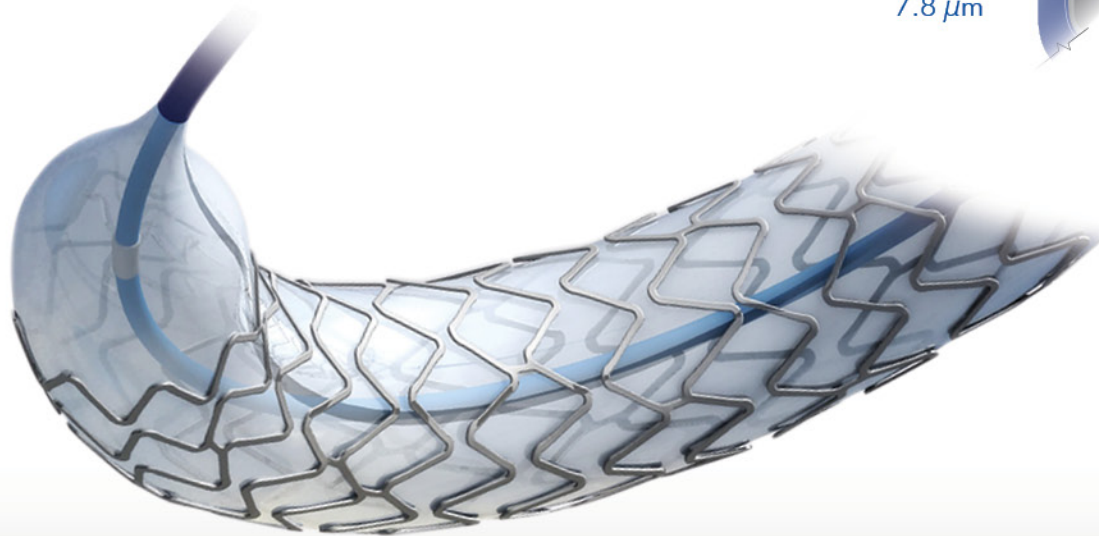
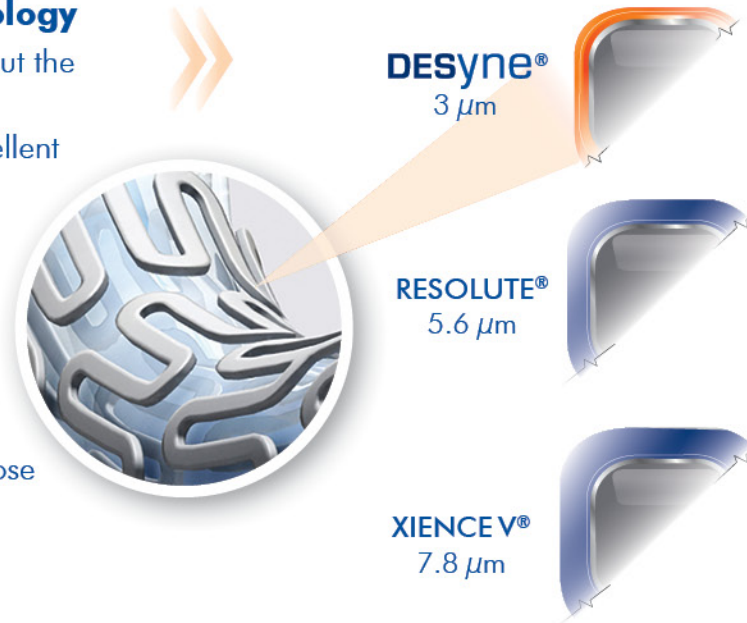
- » Thin polymer and drug matrix coating without the need for a primer coating
- » Superior DES clinical performance with excellent safety profile<sup>1</sup>

## Lowest Polymer Coating Load<sup>2</sup>

- » Reduced risk of adverse clinical events<sup>1</sup>
- » Improved polymer biocompatibility<sup>3</sup>

## Low Drug Dose

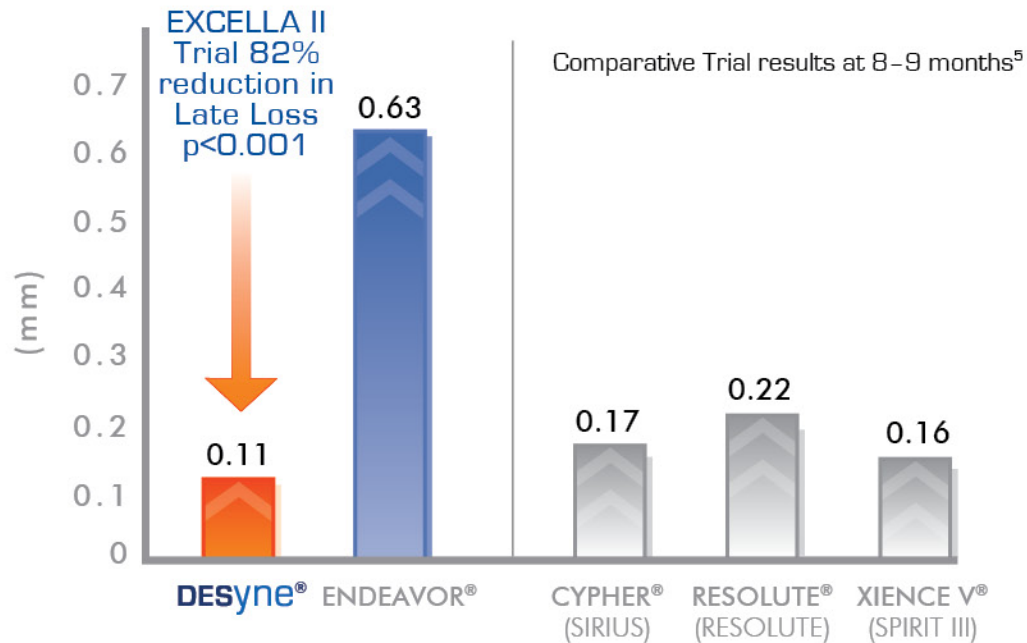
- » Sustainable performance with lower drug dose



# CLINICAL Performance Sets New Standards

## EXCELLA II RCT (n = 210)

### Late Lumen Loss at 9 Months

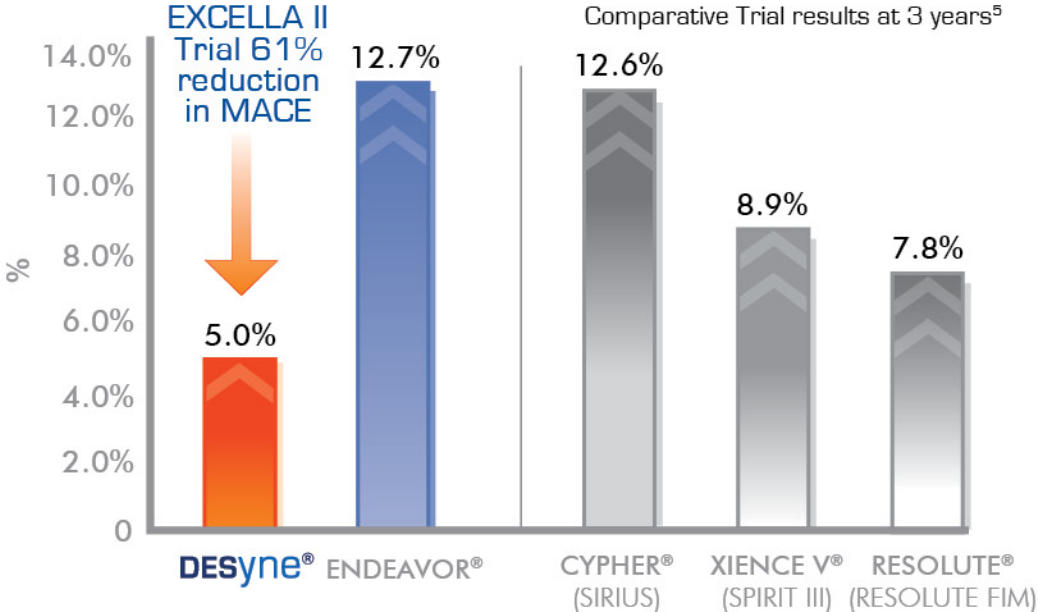


- » Significant reduction in late lumen loss,  $p = 0.001$
- » Lowest published late lumen loss <sup>4</sup>

# CLINICAL Performance Sets New Standards

## EXCELLA II RCT (n = 210)

### Major Adverse Cardiac Events (MACE) at 3 Years Clinical Follow-up

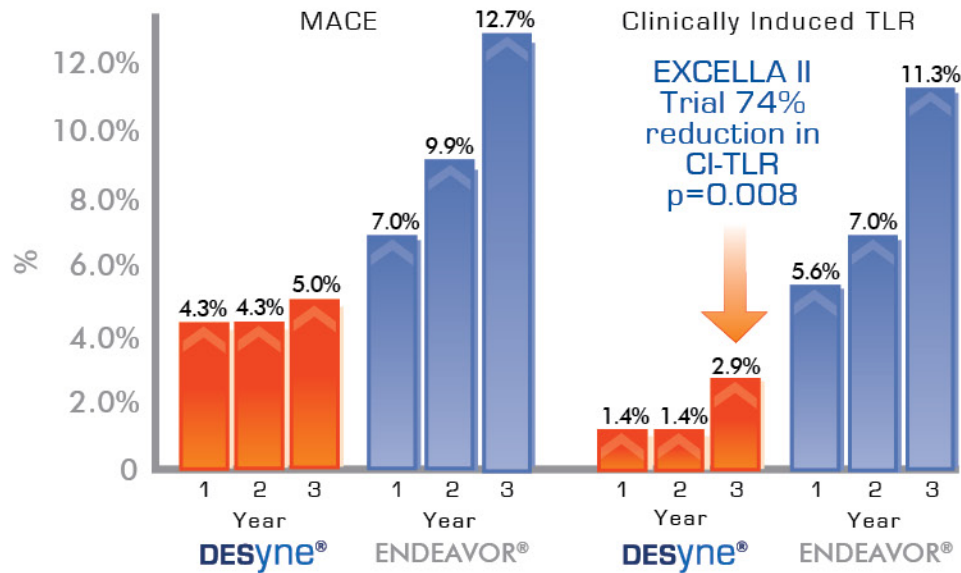


» MACE defined as Target Lesion Revascularization, Cardiac Death and Myocardial Infarction

# CLINICAL Performance Sets New Standards

## EXCELLA II RCT (n = 210)

### Clinical Follow-up year 1, 2 and 3

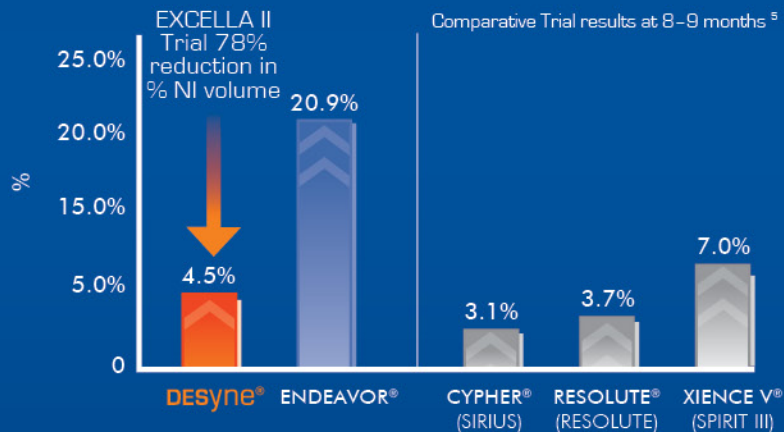


» Sustained clinical performance over time

# CLINICAL Performance Sets New Standards

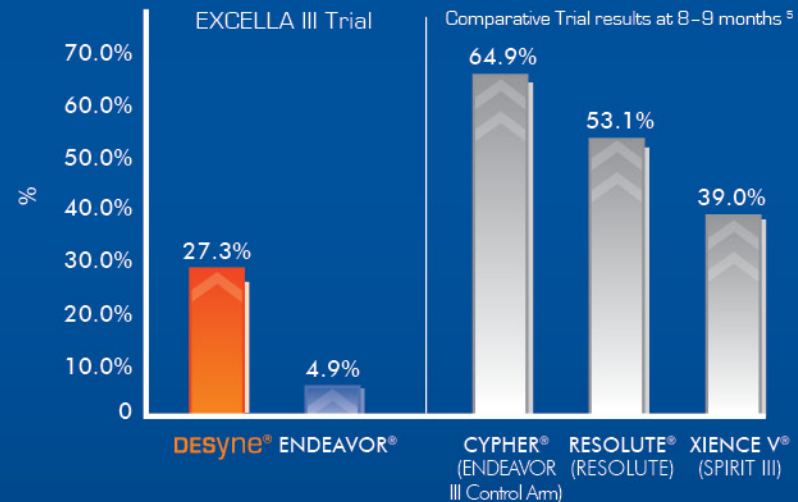
## EXCELLA II RCT (n = 210)

### Neointimal Volume Obstruction by IVUS at 9 Months



» Low neointimal volume obstruction

### Neointima-free Frame Ratio (% cross-sections without neointima coverage)



» Optimal neointimal coverage with low neointimal volume obstruction



# SIZE AVAILABILITY

---

Stent Diameter (mm)	Stent Length (mm)					
	14	18	NEW! 23	28	NEW! 32	NEW! 38
2.5	✓	✓	✓	✓	✓	✓
3.0	✓	✓	✓	✓	✓	✓
3.5	✓	✓	✓	✓	✓	✓

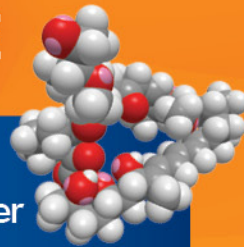
## INTERNATIONAL (OUS) USE ONLY

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

# EXCELLA BD

## SUPERIOR CLINICAL PERFORMANCE

Proven Novolimus drug in a degradable polylactide-based polymer



Advanced drug coating on proven stent design

Superior clinical performance through 6 months\*

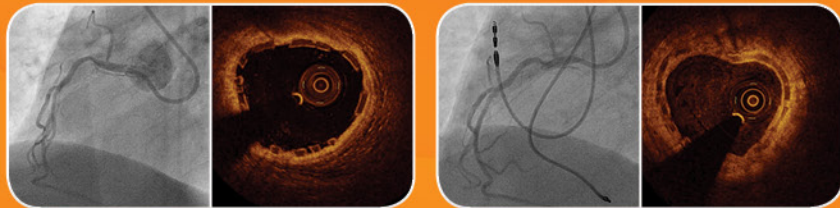
## Angiographic and IVUS Results through 6 months

In-Stent Analysis	Novolimus	Zotarolimus	P value
<b>RVD. mm</b>	N <sub>(n)</sub> = 154	N <sub>(n)</sub> = 75	
Post-procedure	2.84±0.43	2.91±0.38	0.20
At 9-months	2.82±0.44	2.70±0.42	0.06
<b>MLD / Late Lumen loss (LLL), (mm)</b>			
Acute gain	1.36±0.40	1.47±0.36	0.047
Acute gain (%)	46.48±11.65	47.51±11.13	0.53
MLD post-procedure	2.48±0.39	2.57±0.37	0.10
MLD at 9-months	2.36±0.48	1.95±0.48	< 0.001
<b>LLL at 9-months</b>	<b>0.11±0.32</b>	<b>0.63±0.42</b>	<b>&lt; 0.001</b>
Loss index	0.08±0.28	0.42±0.27	< 0.001
<b>Diameter Stenosis (%)</b>			
Post-procedure	12±5	11±5	0.34
At 9-months	16±12	28±14	< 0.001
<b>Binary Restenosis (%)</b>			
<b>At 9-months</b>	<b>1.4% (2/138)</b>	<b>7.6% (5/66)</b>	<b>0.037</b>
<b>Volumetric Analysis</b>	N <sub>(n)</sub> = 34	N <sub>(n)</sub> = 15	
<b>%Neointimal volume obstruction (%)</b>	<b>4.5±5.1</b>	<b>20.9±11.3</b>	<b>&lt;0.001</b>

# THE NEXT ADVANCEMENT IN VASCULAR RESTORATION

## DESOLVE FIM

Proving Performance  
with a First-in Man Trial



POST-STENTING  
(BASELINE)

6 MONTH  
FOLLOW-UP

## DESOLVE NX TRIAL

(ENROLLMENT INITIATED)

- DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System
- Available scaffold sizes: 3.0 x 14mm, 3.0 x 18mm, 3.25 x 14mm, 3.25 x 18mm, 3.5 x 14 mm and 3.5 x 18 mm

## DESolve Nx Clinical Trial Design

Single De Novo Coronary Artery Lesion  
Reference vessel diameter: 2.75 – 3.5mm  
Lesion length: <14 mm, DAPT 12 months

DESolve Nx Novolimus Eluting Bioresorbable  
Coronary Scaffold System

15 sites worldwide  
Belgium, Germany, Poland, Brazil and New Zealand  
120 patients

Clinical MACE

30d 6mo 1yr 2yr 3yr 4yr 5yr

Angiographic  
IVUS, OCT and MSCT

**Principal Imaging Endpoint:** in-scaffold late lumen loss by QCA at 6 months

**Safety Endpoints:**

- Clinical: Major Adverse Cardiac Events (cardiac death, target vessel MI, and clinically-indicated TLR), and scaffold thrombosis at 1, 6, and 12 months, 2 – 5 years
- QCA: In-segment late lumen loss, binary restenosis, and percent diameter stenosis at 6 months
- IVUS: In-scaffold percent volume obstruction at 6 months (sub-set)
- OCT: Scaffold and vessel assessment at 6 and 24 months (sub-set)
- MSCT: Vessel assessment at 1 year (sub-set)