

First-in-Man Study

ANGIOGRAPHIC RESULTS

Irist achieves 4,5% binary restenosis.

	9 months		
	Irist n=66	Apolo 3 n=31	
MLD (mm)	2,27	1,98	
Stenosis diameter (%)	25,00	34,00	
Late Loss (mm) (*)	0,63	0,91	(*) Primary endpoint: p= 0,012
Binary restenosis (%) (**)	4,50	17,40	(**) Secondary endpoint: p= 0,027

CLINICAL RESULTS

	9 months		2 years	
	Irist n=70	Apolo 3 n=35	Irist n=70	Apolo 3 n=35
Death (Cardiac) (%)	1,4	0	1,4	0
Myocardial infarction (%)	1,4	0	2,8	0
CABG (%)	0	0	0	0
TLR (%)	4,3	11,4	5,7	14,3
MACE (%)	7,1	11,4	9,9	14,3

Death: Sudden death at four months. Possible cardiac death. **Myocardial infarction:** 1) Iatrogenic coronary dissection during follow-up angiography. 2) Non related with the target artery. AMI caused by occlusion of an artery treated after with another stent, and after the discontinuation of the antiplatelet therapy. The Irist stents were not occluded.

Irist showed at 24 months:

- No late catch-up
- No significant increase on TLR
- No late thrombosis

These results might indicate a safety trend of the IRIST stent.

Irist Small

Diameter (mm)	Length (mm)	Profile (inches)	Reference
2,50	9	0,037	56259
2,50	14	0,037	56254
2,50	19	0,037	56250
2,50	23	0,037	56253
2,50	28	0,037	56258
2,50	36	0,037	56256
2,75	9	0,038	56279
2,75	14	0,038	56274
2,75	19	0,038	56270
2,75	23	0,038	56273
2,75	28	0,038	56278
2,75	36	0,038	56276

Irist

Diameter (mm)	Length (mm)	Profile (inches)	Reference
3,00	9	0,038	56309
3,00	14	0,038	56314
3,00	18	0,038	56318
3,00	23	0,038	56323
3,00	28	0,038	56328
3,00	36	0,038	56336
3,50	9	0,039	56359
3,50	14	0,039	56354
3,50	18	0,039	56358
3,50	23	0,039	56353
3,50	28	0,039	56350
3,50	36	0,039	56356
4,00	9	0,040	56409
4,00	14	0,040	56414
4,00	18	0,040	56418
4,00	23	0,040	56423
4,00	28	0,040	56428
4,00	36	0,040	56436
4,50	14	0,041	56454
4,50	18	0,041	56458
4,50	23	0,041	56453
4,50	28	0,041	56450
4,50	36	0,041	56456

Rated burst: 16 atm.
Average burst pressure: 22 atm.

Device restricted for use by a Doctor or on the order of a physician.
Prior to use, please read all precautionary statements and possible complications specified in attached instructions for use.

Irist®

Simvastatin DES

Providing DES efficacy
and BMS safety



Low crossing profile and
EXCELLENT TRACKABILITY

Irist® Simvastatin DES



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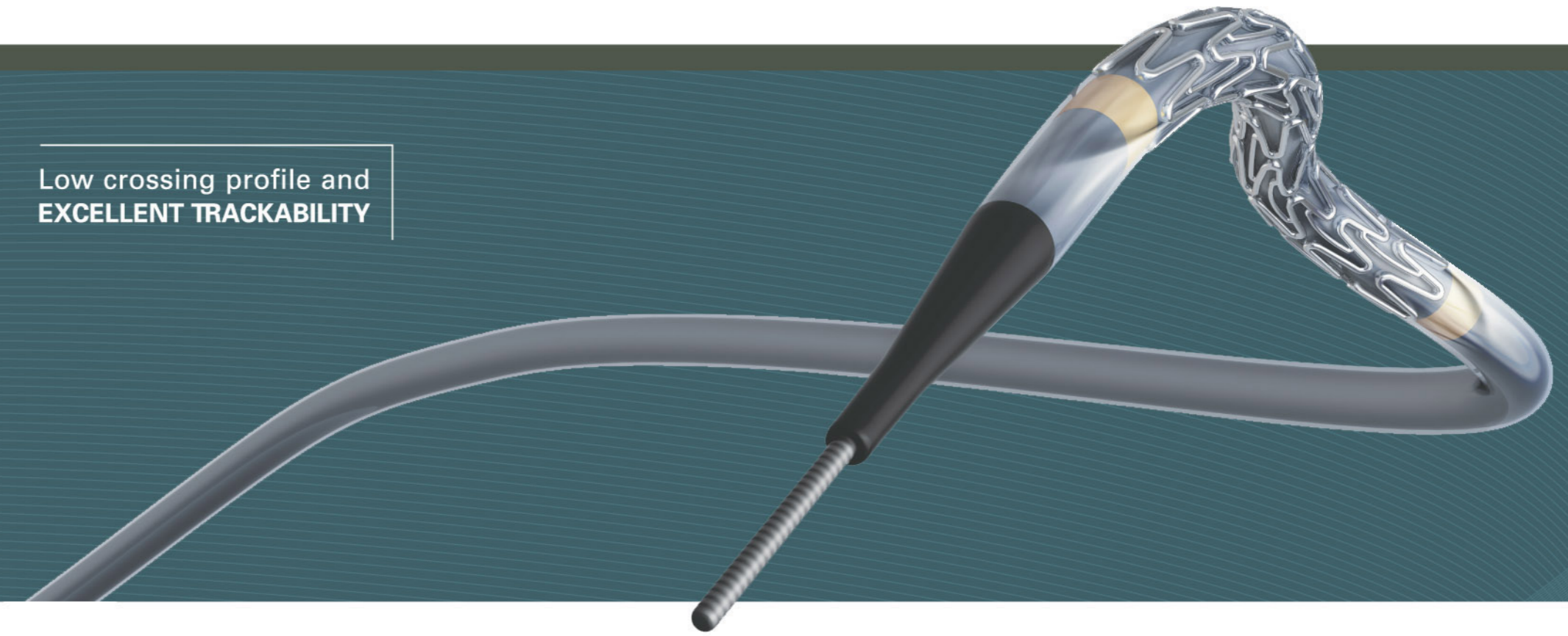
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Irist[®]
Simvastatin DES

Irist is a simvastatin drug eluting stent indicated in patients with acute coronary syndrome and coronary vessel lesions with moderate risk of restenosis.

Low crossing profile and
EXCELLENT TRACKABILITY



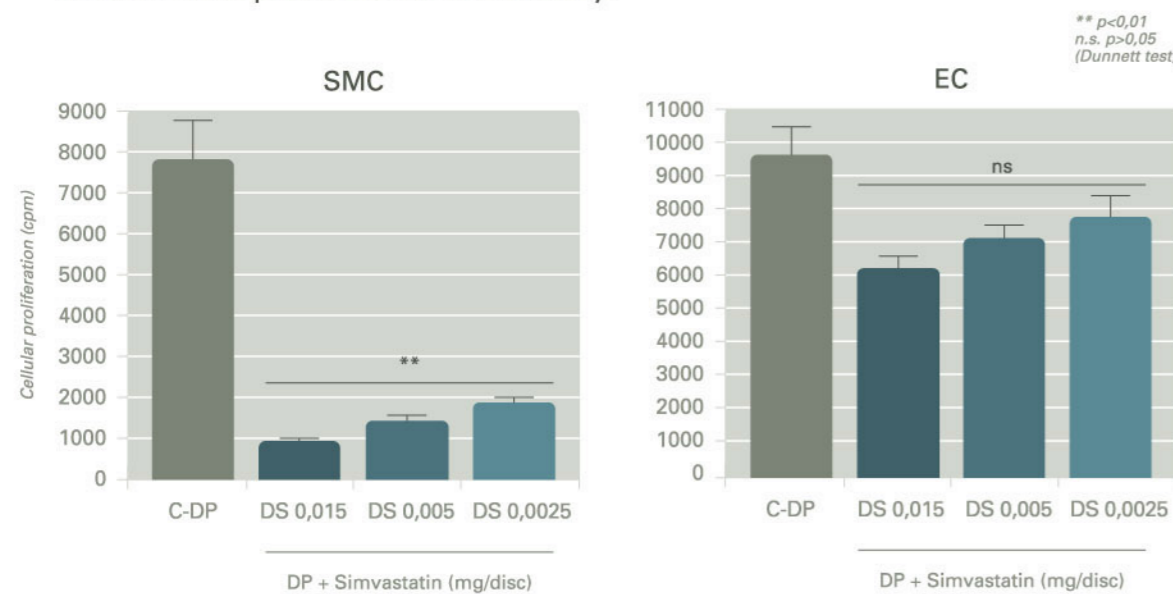
Simvastatin: Safe & Effective

Simvastatin is an HMG-CoA reductase inhibitor with demonstrated pleiotropic effects that provide it with antirestenotic properties:

- Improvement of endothelial function.
- Increases NO synthesis.
- Anti-oxidative properties.
- Inhibits inflammatory responses.
- Stabilizes atheroma plaque.
- More selective of Smooth Muscle Cells than Endothelial Cells thus theoretically fostering a higher degree of reendothelization and reducing risk of late thrombosis.

ANTI-PROLIFERATIVE

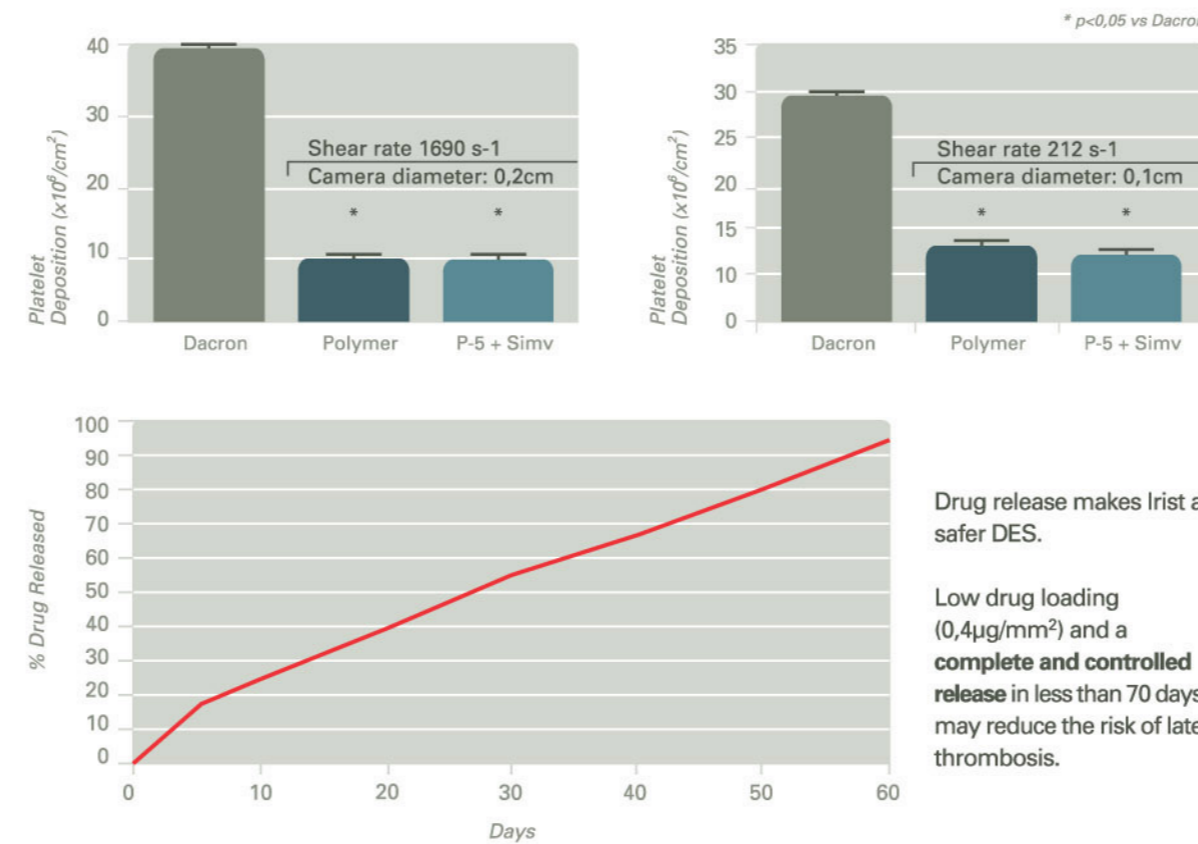
In-Vitro cellular proliferation inhibition study.



Unique drug delivery technology

- P-5 is a specifically designed polymer for use in DES devices that ensures an homogeneous drug release.
- P-5 is a Triflusal based polymer with antiaggregant and anti-inflammatory properties.

ANTIAGGREGANT PROPERTIES



A perfect fit for every vessel

Irist and Irist Small use highly flexible stent platforms (Apolo 3 / Apolo Small) with a low crossing profile, easing navigation through most complex vessel profiles.

Irist (6 crowns - 3 connectors)



Irist Small (5 crowns - 2 connectors)



Irist and Irist Small's radial force combined with their flexibility provide strong support in straight and curved vessels.

Irist and Irist Small's designs, with their wide range of sizes, allow daily PTCA practice to reach big and small vessels with same excellent performance.

AVAILABLE SIZES

Diameter	Length						
	9	14	19	23	28	36	
2,50	✓	✓	✓	✓	✓	✓	Irist Small
2,75	✓	✓	✓	✓	✓	✓	
3,00	✓	✓	✓	✓	✓	✓	Irist
3,50	✓	✓	✓	✓	✓	✓	
4,00	✓	✓	✓	✓	✓	✓	
4,50	-	✓	✓	✓	✓	✓	

