PHILIPS

Complex PCI

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# In-stent restenosis (ISR)

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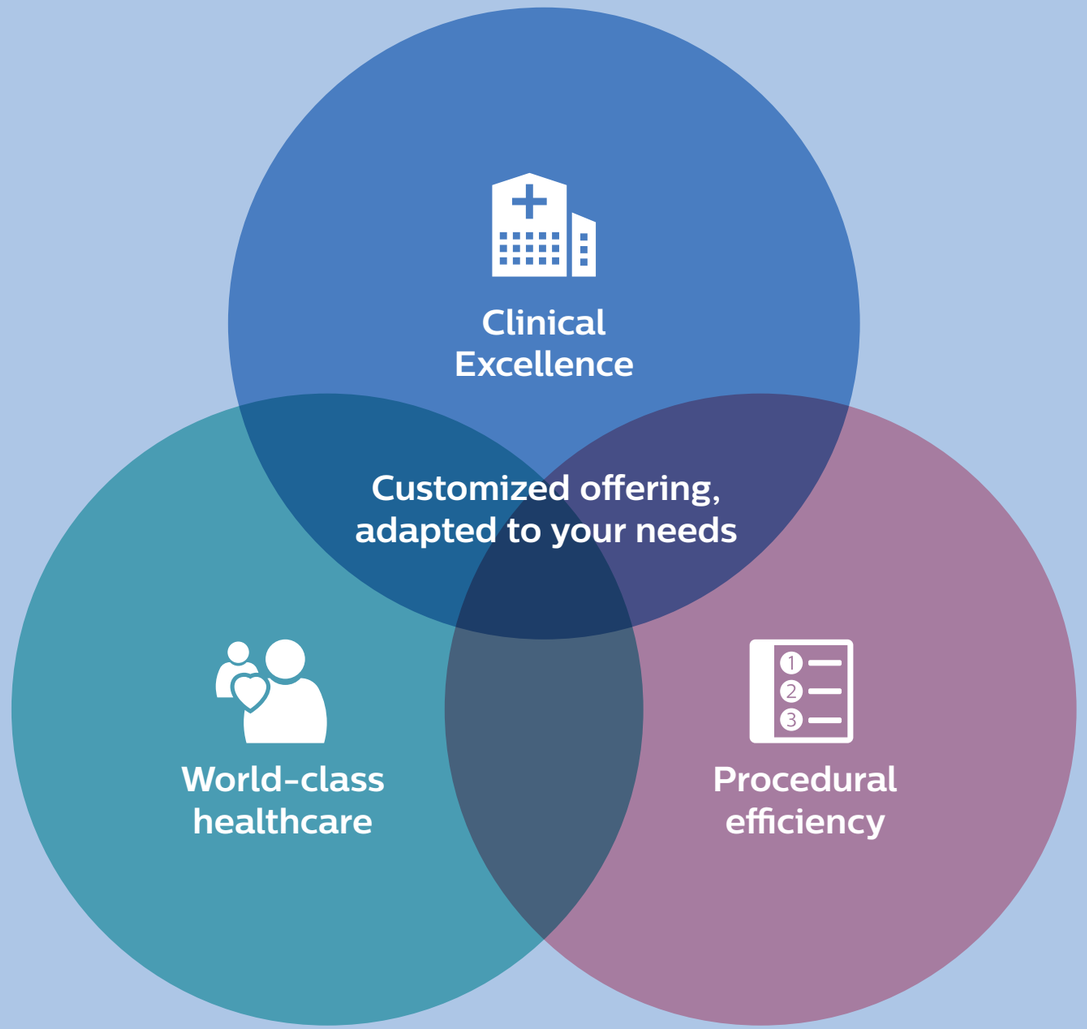
Philips provides a portfolio of specialty coronary diagnostic and therapy devices that enable safe and effective treatment of a wide variety of the most complex coronary lesions types and morphologies, included in-stent restenosis.



**ISR is >50% diameter stenosis at stent's inside or edges,** with different ISR morphologies predicting different TLR rates at 1-year[1,2]

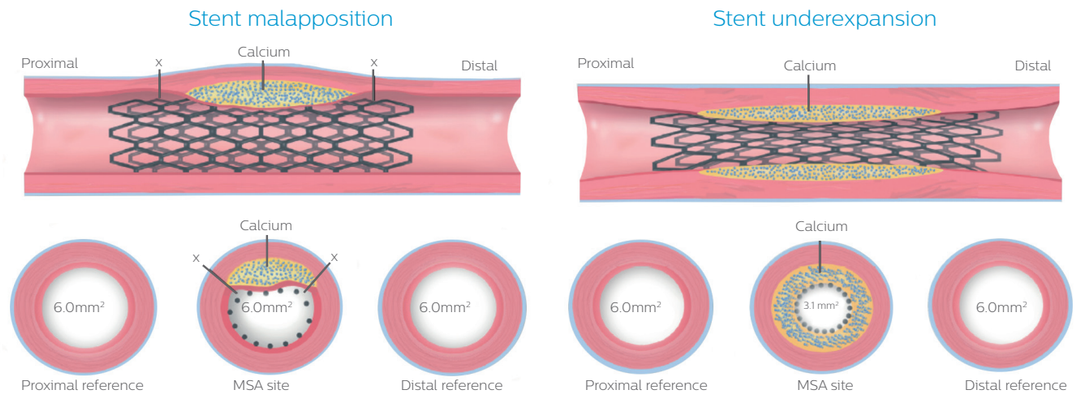
Several factors with both biological and/or procedural causes contribute to the nature of ISR[3]

**Biologic causes**

- Reaction to metal or polymer
- Drug resistance
- Thrombosis

**Procedural causes**

- Stent under-expansion/mal-apposition
- Stent fracture
- Edge trauma
- Geographical miss

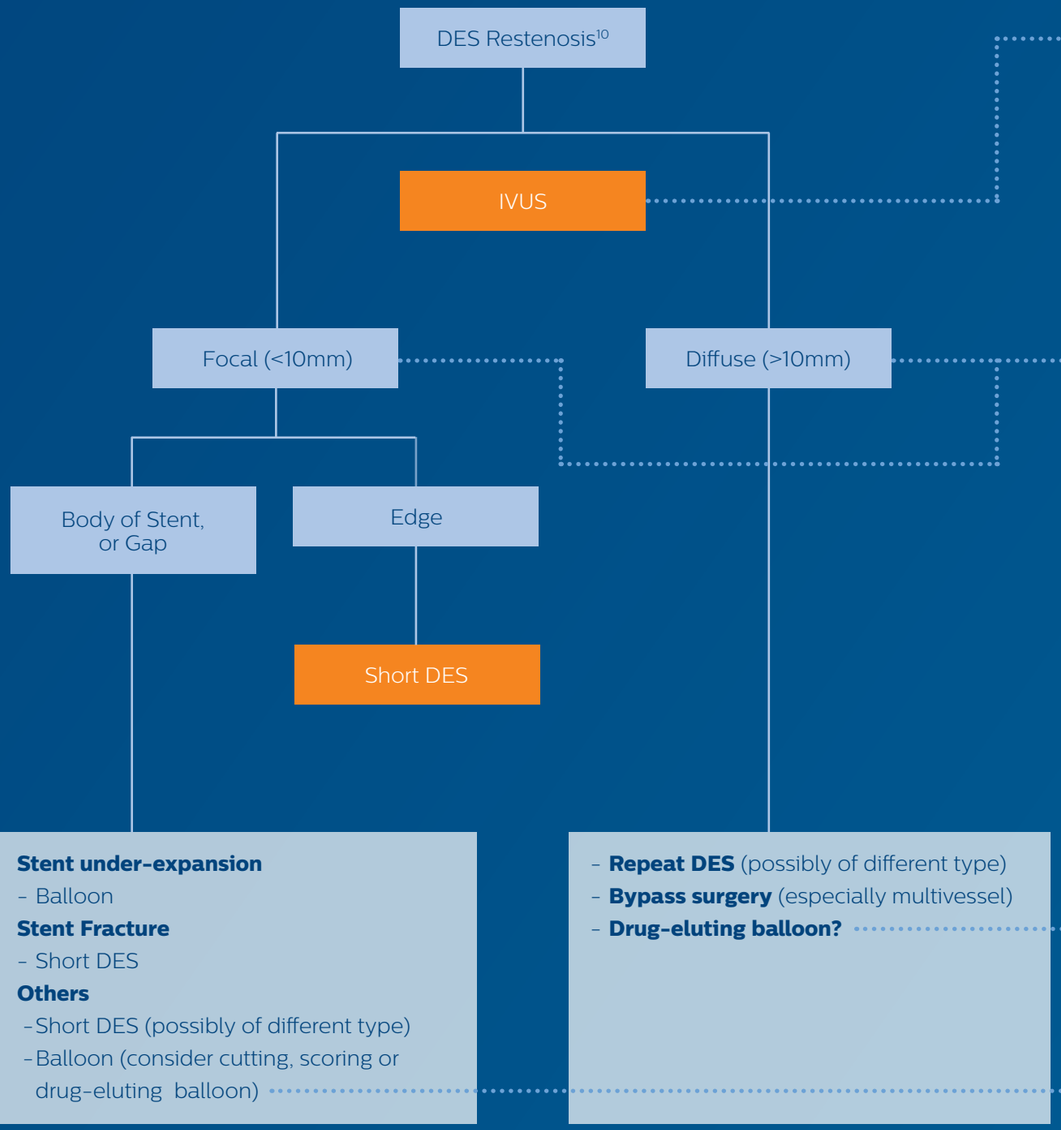



Malapposition (*) occurs at the junction of calcified and noncalcified plaque and in localized areas of reference segment ectasia at the stent edges. However, the stent is fully (albeit not symmetrically) expanded since the MSA of 6.0 mm2 matches the proximal and distal reference segment lumen areas.

**Incidence of ISR (meant PCI for DES restenosis) quite consistent** over either National Registries, All-comers RCTs and Registries, in the range of ≈5%

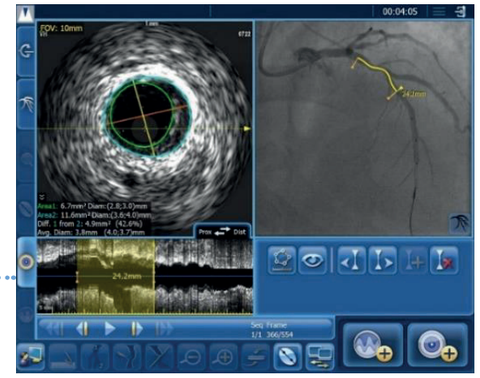
| Source | PCI | Design | Incidence | Notes |
|---|---|---|---|---|
| Cassese et al.[4] | 10.004 | Routine angiographic surveillance after unrestricted use of newer-generation devices | 30,1% BMS<br>14,6% 1st gen DES<br>12,2% 2nd gen DES | Angio-binary restenosis |
| UK BCIS Audit[5] | 96.143 | Registry of the British Cardiovascular Intervention Society | 4,8% | PCI for restenosis, overall incidence (85% DES) |
| Spanish Registry[6] | 67.671 | National Registry of Coronary and Structural Interventions (2010-2015) | 4,7% | PCI for restenosis, could include DES, BMS, multi-layers |
| Norstent Study[7] | 4.504 | Multicentric RCT 1:1 DES Vs. BMS | 4,6% | PCI for DES restenosis |
| RESOLUTE All-Comers[8] | 2.292 | Patients randomly assigned to R-ZES (n = 1,140) or EES (n = 1,152) | 7,0% ZES, 6,5% EES | Clinically driven TLR |
| SCAAR Registry[9] | >25.000 | SCAAR/SWEDHEART records consecutive patients from all centres (n=29) performing PCI in Sweden | 5,6% | PCI treated in-stent restenoses |

# Physiology outperforms angiography in predicting functional significance of ISR, IVUS helps identify location and etiology of ISR to quickly determine and confirm best treatment options

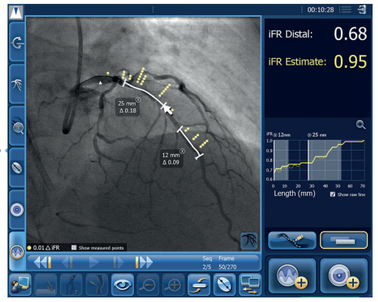



## IVUS helps you verify and optimize your results

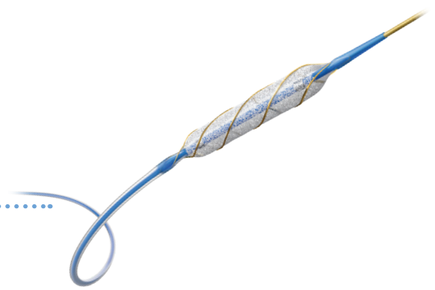
**Eagle Eye Platinum digital IVUS**
**Refinity ST rotational IVUS catheters**



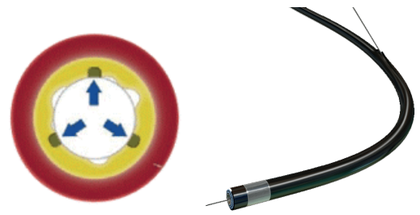
**SyncVision with iFR Co-reg**



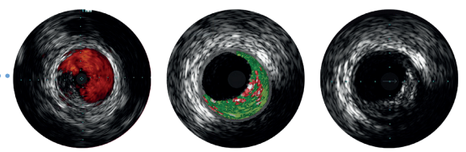

**AngioSculptX drug-coated scoring balloon**



**AngioSculpt PTCA scoring balloon**



**SyncVision with IVUS Co-reg**



**Verrata Plus pressure guide wire**
Plan your procedure using iFR Co-Registration with SyncVision providing physiologic guidance, discriminating focal Vs. diffuse disease.

**Eagle Eye Platinum digital IVUS - Refinity ST rotational IVUS catheters**
With SyncVision with IVUS Co-Registration easily assess for geographic miss and edge complications, confirm stent apposition and optimal expansion for luminal gain.

**AngioSculpt PTCA Scoring Balloon**
Lesion preparation with AngioSculpt outperforms POBA for the treatment of DES-ISR with drug-coated balloons.[11]

**ELCA coronary laser atherectomy**
Effective and safe plaque de-bulking for greater vessel and stent expansion.[12]

By modifying the plaque even behind the struts laser makes it more amendable to further stent expansion.[12]

**AngioSculptX drug-coated scoring balloon**
AngioSculptX is the first and only Treatment Solution combining Plaque Scoring and Drug Delivery in a Single Device[13,14] for a safe and effective treatment of ISR.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