# The Illumina FIH study with a next generation DES – 12-months results

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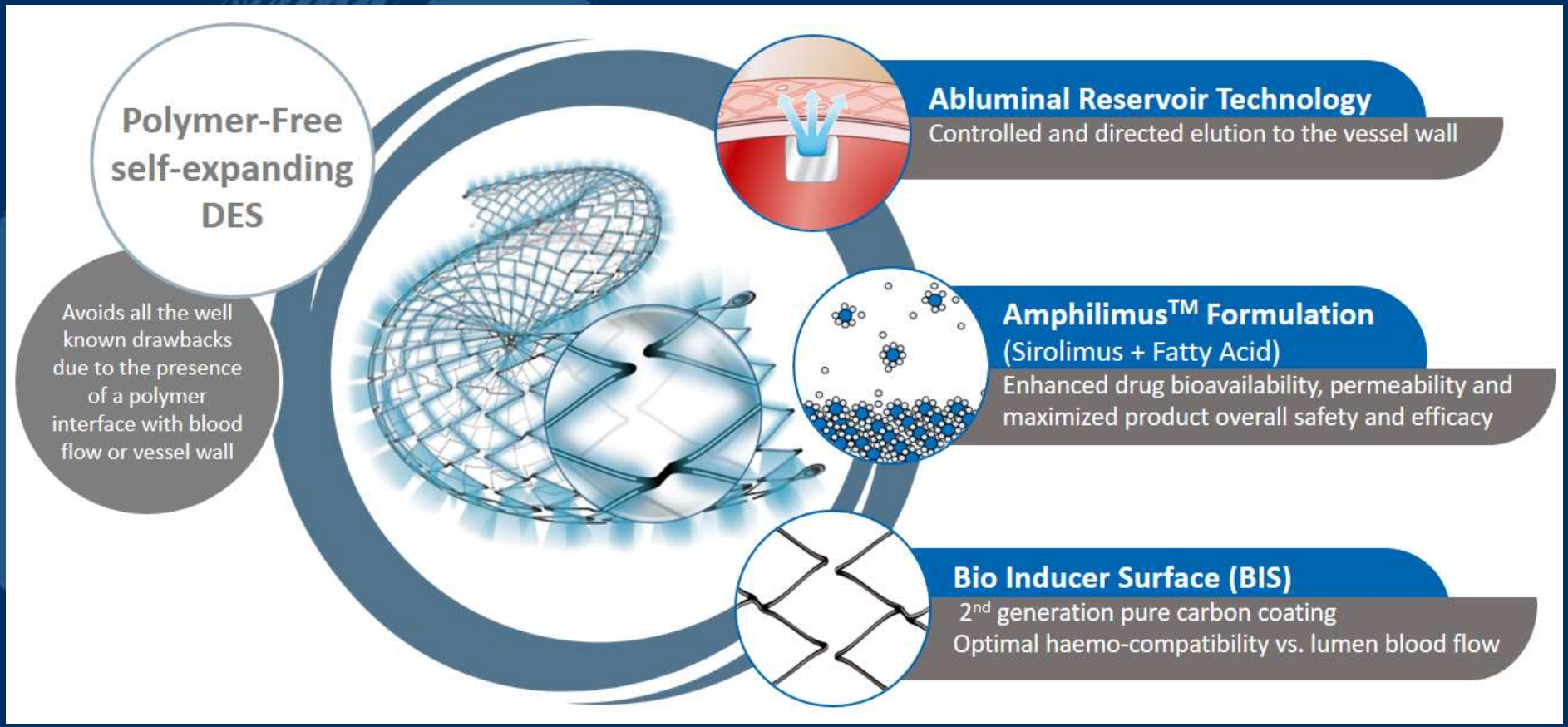
# Disclosure

Dierk Scheinert, MD

Advisory Board /Consultant:

Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies

# NiTiDES features description



# ILLUMINA study design

## Innovative siroLimus seLf expanding drUg-eluting stent for the treatMent of perIpheral disease: evaluation of safety aNd efficAcy

**Prospective, Single arm ; 10 centers in Europe (n= 100 pts)**
**Prof. Dierk Scheinert (Coordinating Clinical Investigator, Leipzig-Germany)**
**eCRFs; Core Lab; CEC**

**Primary Endpoint:**

- **SAFETY: Composite of Major Adverse Events – MAE** (death, target limb amputation, target limb ischemia requiring surgical intervention or surgical repair of target vessel or clinically-driven target lesion revascularization and freedom from worsening of the Rutherford score by 2 classes, or to class 5 or 6)
- **EFFICACY: Primary patency at 12 months.** Primary patency is defined as absence of clinically-driven target lesion revascularization or binary restenosis (PSVR >2.4 - duplex evaluation)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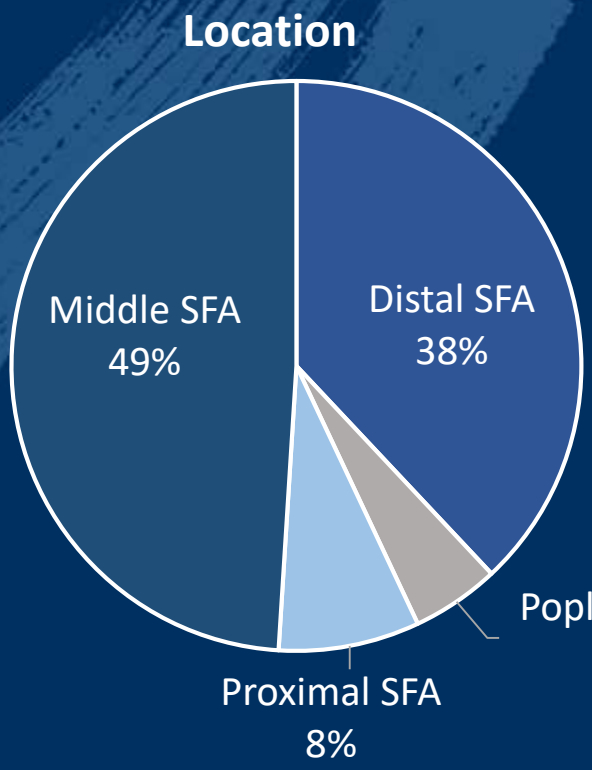
# ILLUMINA study
# centers and enrolled pts.

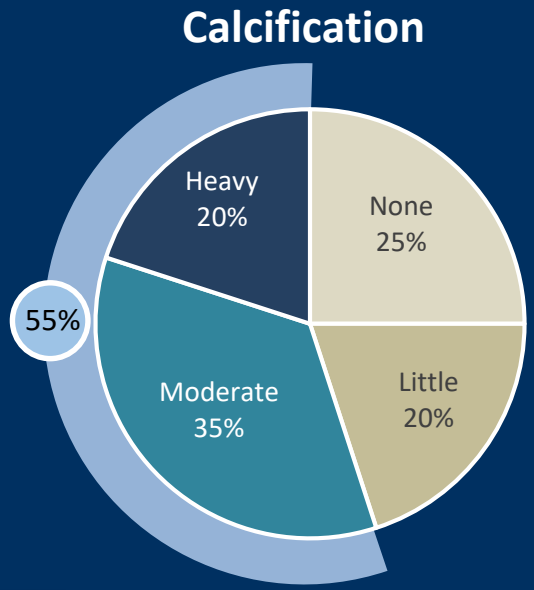
| Sites | | N |
|---|---|---|
| • Universitätsklinikum Leipzig | Scheinert | 3 |
| • Universitäts-Herzzentrum Freiburg Bad Krozingen | Zeller | 13 |
| • Regiomed GefäBzentrum Sonneberg | Thieme | 13 |
| • St. Gertrauden Krankenhaus GmbH - Berlin | Langhoff | 17 |
| **Total Germany** | | **46** |
| • San Raffaele Hospital - Milan | Chiesa/Kahlberg | 15 |
| • Maria Cecilia Hospital - Cotignola | Cremonesi | 2 |
| • Fondazione IRCCS Policlinico San Matteo - Pavia | Marone | 2 |
| **Total Italy** | | **19** |
| • Clinique Pasteur - Toulouse | Sauguet | 24 |
| • Polyclinique Les Fleurs - Ollioules | Commeau | 3 |
| • Centre Prive Claude Galien - Quincy | Garot | 8 |
| **Total France** | | **35** |
| **Patients GRAND TOTAL** | | **100** |

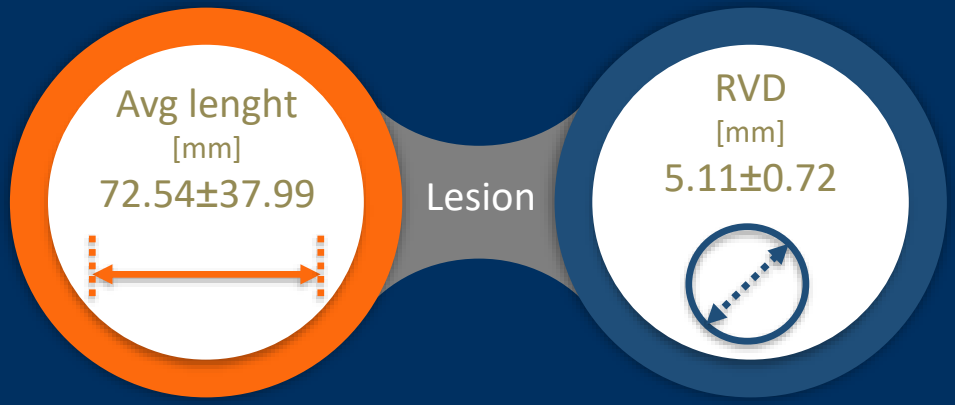
# ILLUMINA study baseline

| Baseline Characteristics | |
|---|---|
| Patients enrolled (n) | 100 |
| Mean age (y) | 67 |
| Male (n) | 78 |
| Smoker (n) | 39 |
| Diabetic (n) | 35 |
| Hypertension (n) | 69 |
| Hypercholesterolemia (n) | 54 |

# ILLUMINA study
# pre-procedure information

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# ILLUMINA study
# procedure results

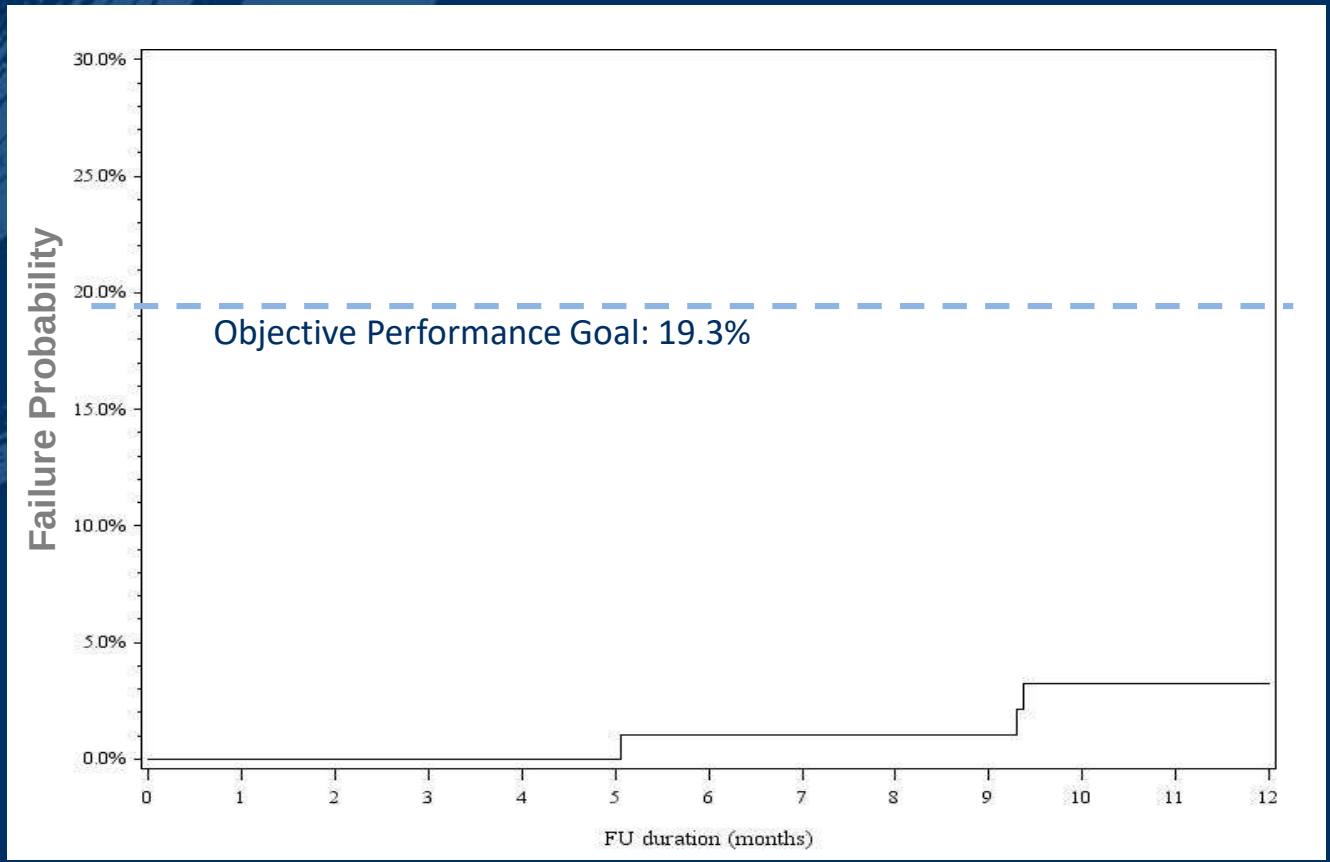
| Procedure results | |
|---|---|
| Stent deployment success | 100% |
| Procedural success | 100% |
| Stent per patient (n) | 1.09 ± 0.32 |
| Total mean length of stent (mm) | 86.7 ± 40.8 |

# ILLUMINA study
# 12 months results: safety

| Major Adverse Event (MAE) - numbers | |
|---|---|
| Clinically driven Target Lesion Revascularization (TLR) | 2 |
| Death* | 1 |
| Target limb amputation | 0 |
| Target limb ischemia requiring surgical intervention or surgical repair of the target vessel | 0 |
| Worsening of the Rutherford score by two classes, or class 5 and 6 | 0 |
| MAE | 3 |

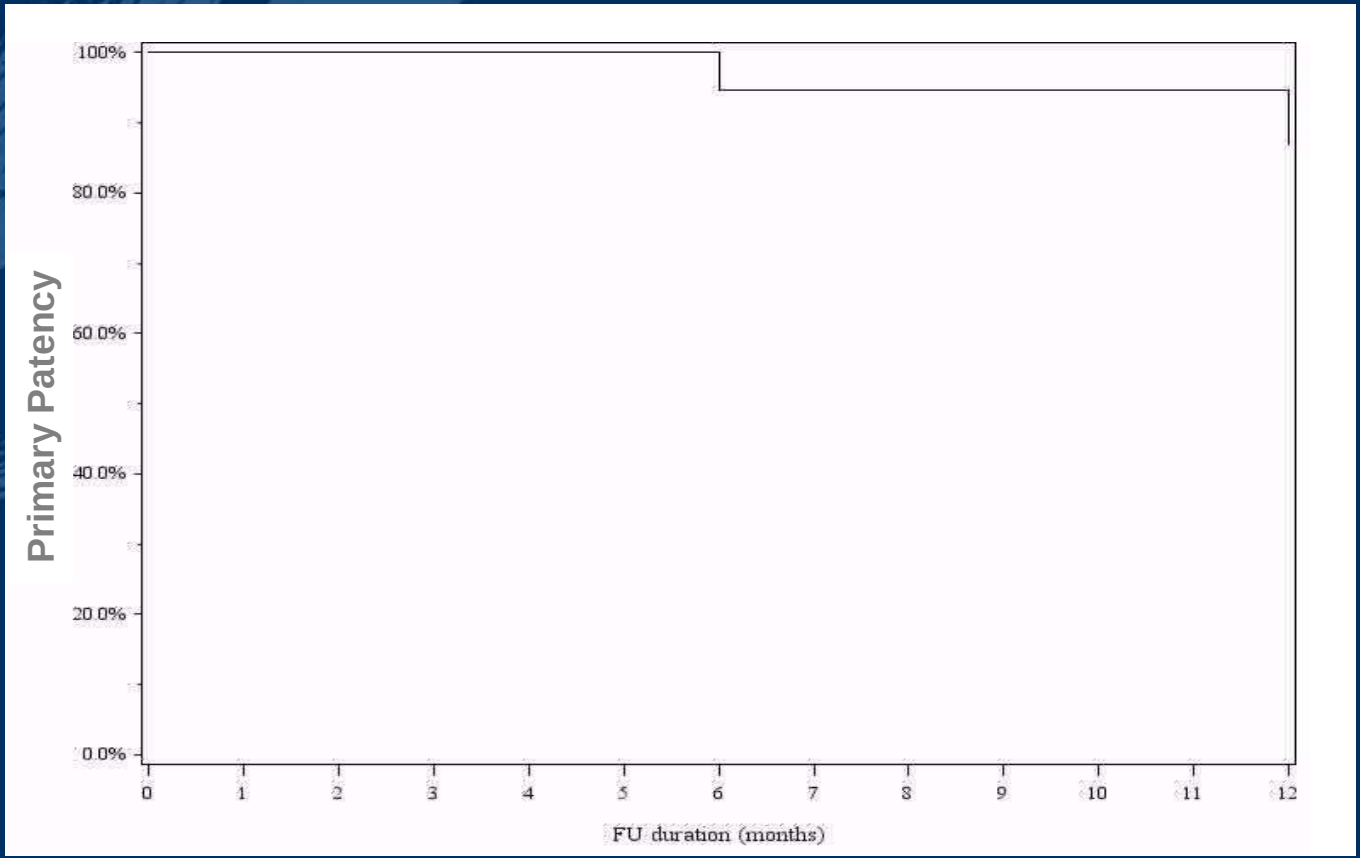
* Death due to Myocardial Infarction - non stent or procedural related

# ILLUMINA study
# 12 months results K-M: safety



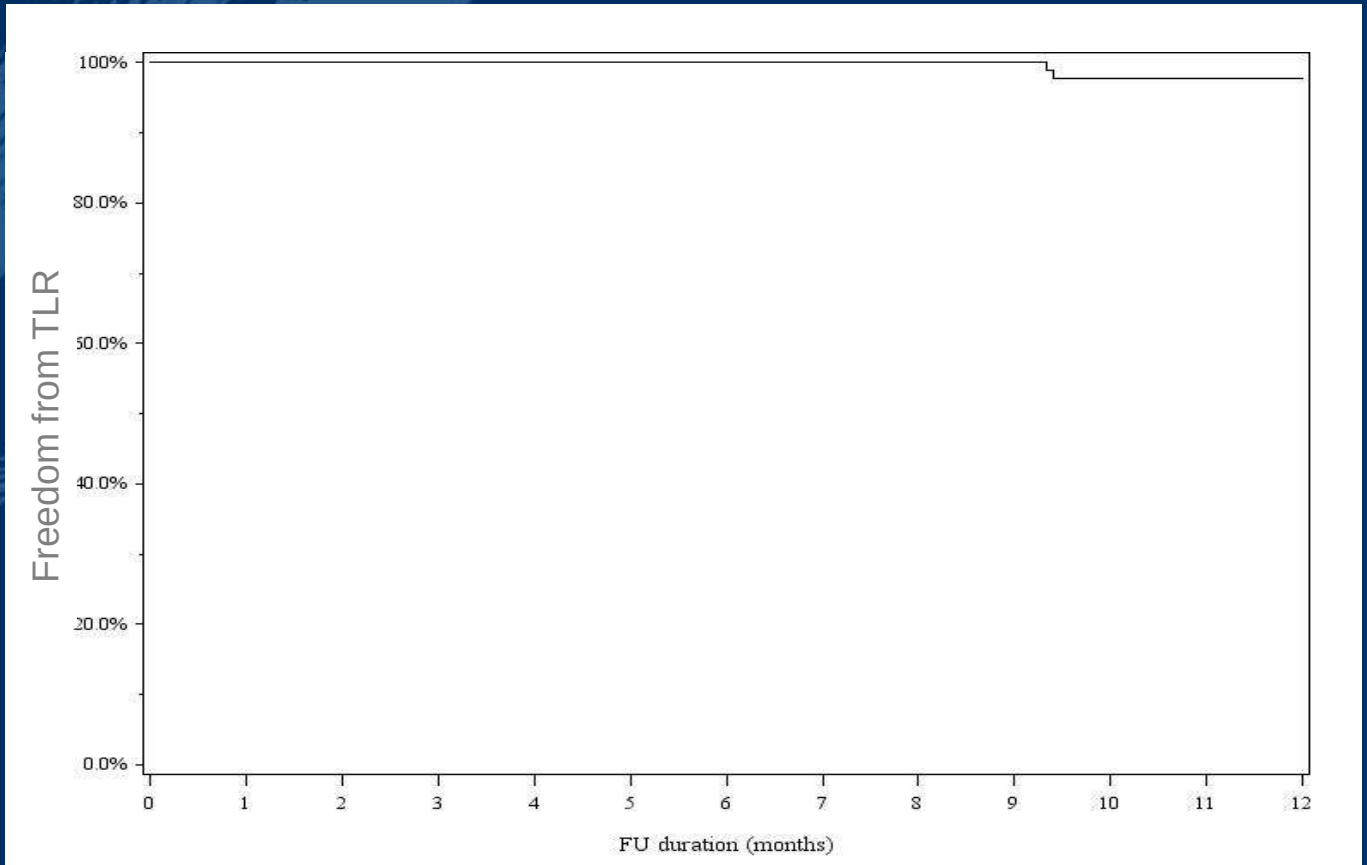

| | Safety endpoint | Lower 95.00% CL | Upper 95.00% CL | Remaining at Risk |
|---|---|---|---|---|
| 0-month | 0.0% | 0.0% | 0.0% | 100 |
| 1-month | 0.0% | 0.0% | 0.0% | 99 |
| 6-month | 1.1% | 0.1% | 7.2% | 94 |
| 12-month | 3.2% | 1.1% | 9.7% | 88 |

# ILLUMINA study
# 12 months results K-M: efficacy



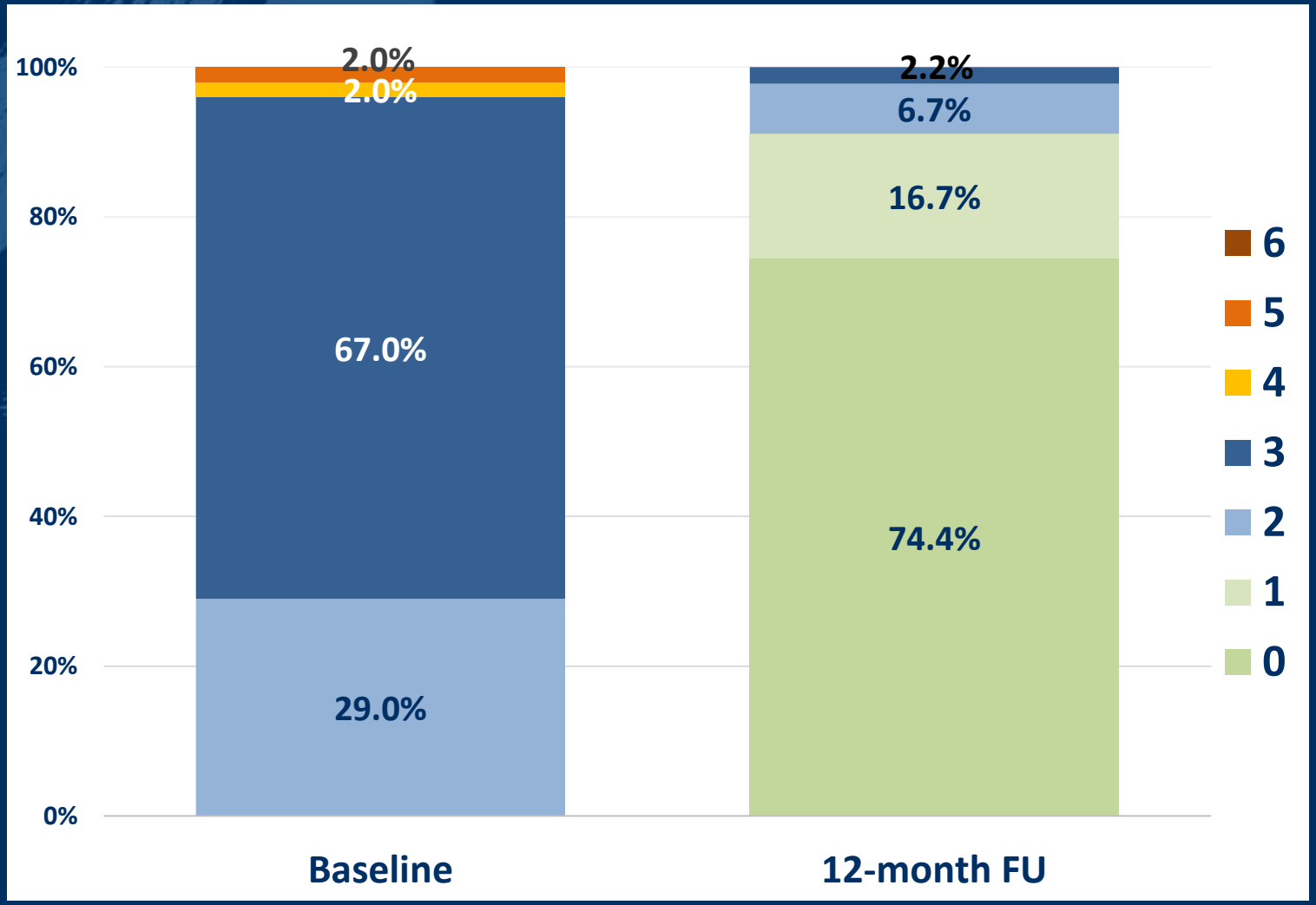

| | Efficacy endpoint | Lower 95.00% CL | Upper 95.00% CL | Remaining at Risk |
|---|---|---|---|---|
| 0-month | 100% | 100% | 100% | 100 |
| 1-month | 100% | 100% | 100% | 99 |
| 6-month | 94.7% | 87.7% | 97.8% | 89 |
| 12-month | 86.9% | 78.0% | 92.3% | 78 |

# ILLUMINA study
# 12 months results K-M: TLR




| | Freedom from TLR | Lower 95.00% CL | Upper 95.00% CL | Remaining at Risk |
|---|---|---|---|---|
| 0-month | 100% | 100% | 100% | 100 |
| 1-month | 100% | 100% | 100% | 99 |
| 6-month | 100% | 100% | 100% | 94 |
| 12-month | 97.8% | 91.5% | 99.4% | 88 |

# ILLUMINA study
## 12 months results: Rutherford improvement



# ILLUMINA study conclusions

- The ILLUMINA MAE rate, 3%, was much lower than the target (objective performance goal) set up together with the Notified Body which was 19.3%.
- 2 TLR and a high rate of Primary Patency demonstrated excellent device efficacy.
- Illumina results stand NiTiDES at the top of effectiveness in today DES scenario.

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