# Drug-eluting stent with biodegradable polymer in patients with NSTEMI: four-year clinical outcomes of the randomised CENTURY II study

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- ❑ **I do not have any potential conflict of interest**

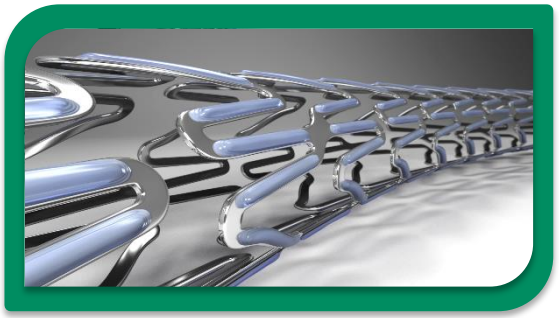
- ❑ **I have the following potential conflicts of interest to report:**
  - Honorarium:
  - Institutional grant/research support:
  - Consultant:
  - Employment in industry:
  - Owner of a healthcare company:
  - Stockholder of a healthcare company:
  - Other(s):

# CENTURY II study and NSTEMI substudy
## Why this study?

- CENTURY II study is designed to demonstrate the safety and efficacy of Ultimaster, a new sirolimus eluting stent with abluminally, gradient-coated bioresorbable polymer by comparing it with Xience everolimus-eluting stent with circumferentially coated durable polymer

- Our aim was to assess long-term outcomes in NSTEMI patients treated with bioresorbable polymer sirolimus eluting DES or permanent polymer everolimus eluting DES

# CENTURY II – study devices
# What did we study?



| | Ultimaster DES | Xience DES |
|---|---|---|
| **Platform** | Thin-strut (80µm) Co-Cr<br>Open cell design | Thin-strut (81µm) Co-Cr |
| **Drug Carrier** | PDLLA-PCL copolymer<br>resorbed within 3-4m | PVDF-HFP non-erodable<br>fluorinated copolymer |
| **Coating** | Abluminal gradient<br>coating technology | Circumferential<br>coating |
| **Drug** | sirolimus<br>70 µg/cm² | everolimus<br>100 µg/cm² |

# CENTURY II – Patient eligibility

**Inclusion criteria**

- Age ≥ 18 years (≥20 years Japan)
- Suitable for treatment with DES
- RVD matching stents 2.5-4.0 mm
- Diameter stenosis >50%
- Eligible for DAPT

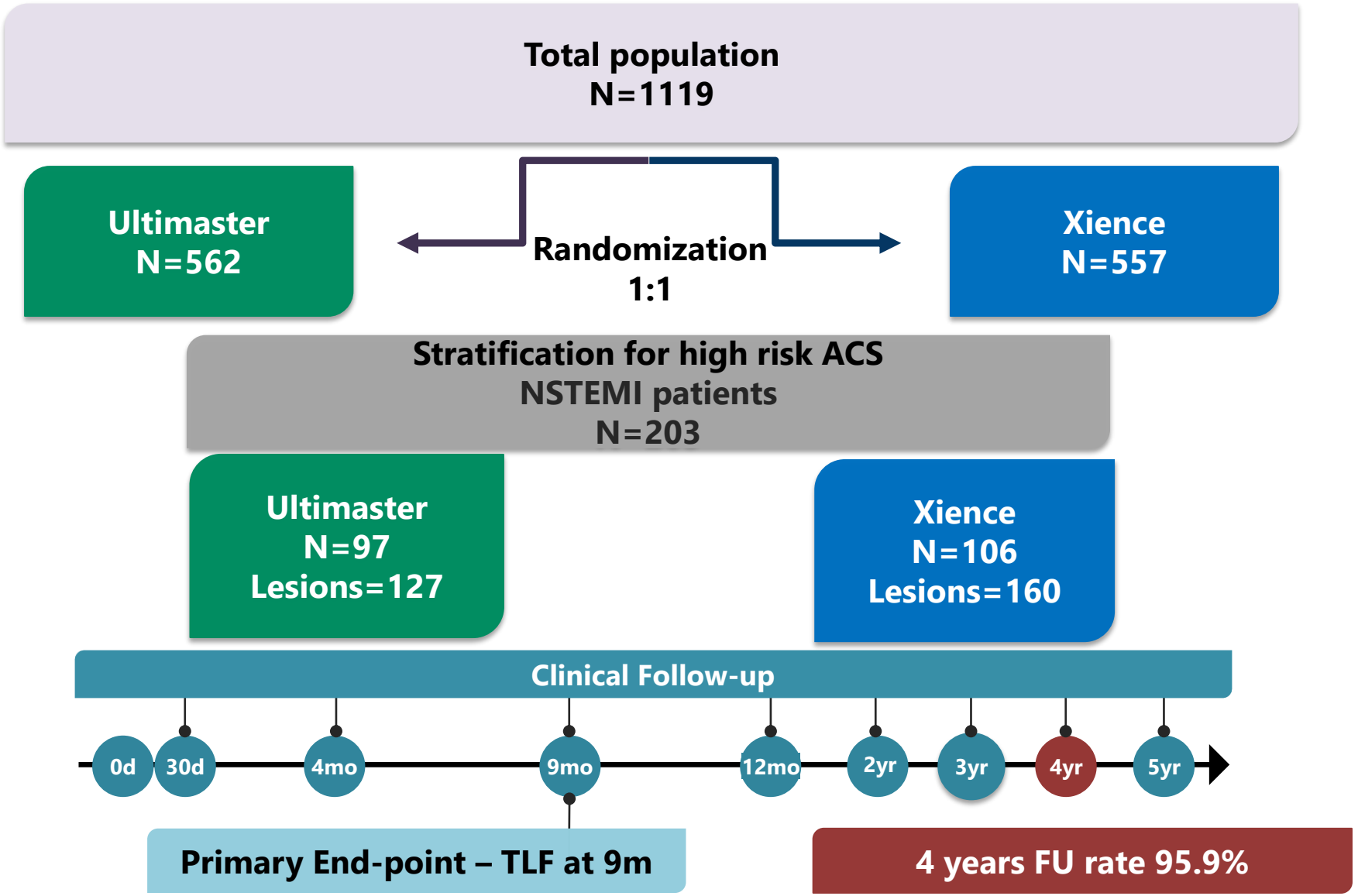
**Main exclusion criteria - general**

- EF<25%
- Renal failure
- Cardiogenic shock
- Planned staged procedure

**Additional exclusion criteria - Japan**

- AMI < 48h
- Target lesion located in left-main trunk
- Ostial lesions
- Lesion in venous or arterial graft
- Previous (<1month) PCI with stenting
- Previous stenting in target lesion

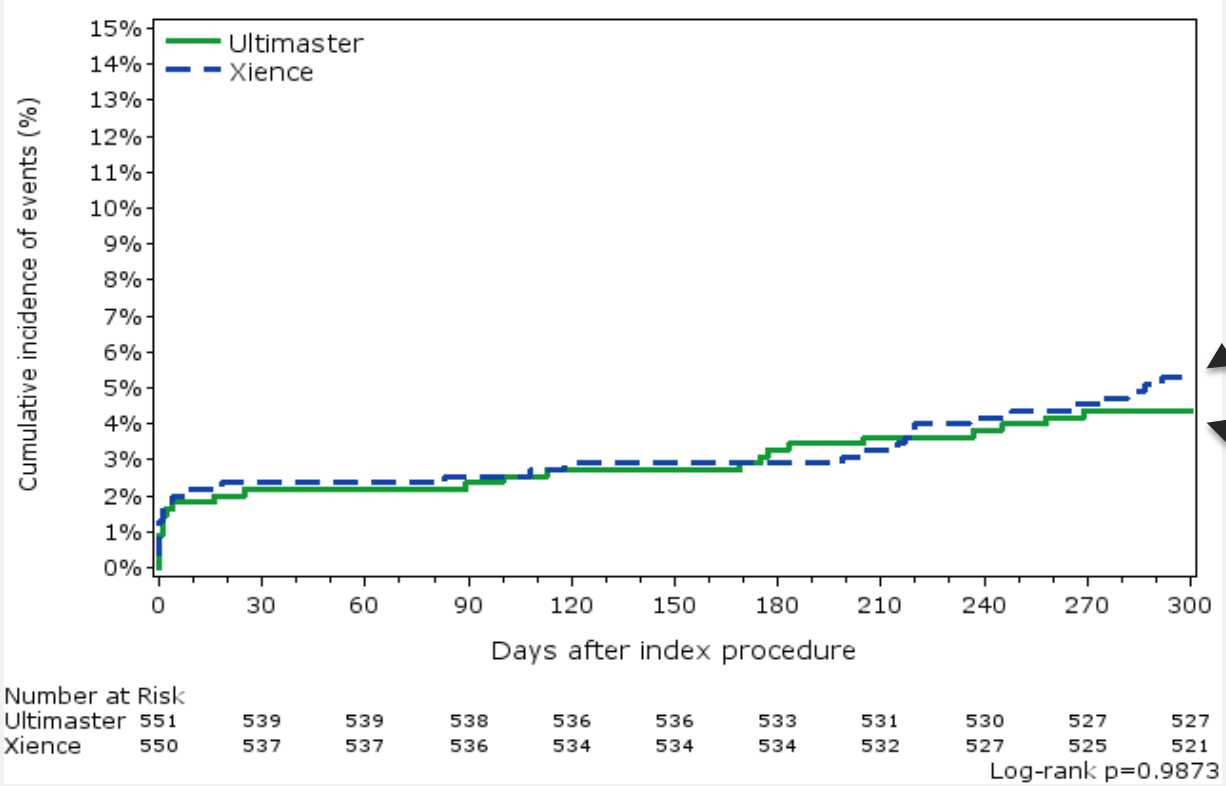
# CENTURY II and NSTEMI subset
# How was the study executed?



# CENTURY II – primary endpoint
# What are the essential results?

**Total population**

## TLF Kaplan-Meier curves – 9 months




**Xience**
**5.27%**
**[3.69% ; 7.50%]**

**Ultimaster**
**4.36%**
**[2.94% ; 6.43%]**

# CENTURY II NSTEMI subset
# Baseline patient characteristics

| | Ultimaster (N=97) | Xience (N=106) | P |
|---|---|---|---|
| Age, N | 63 ± 11 | 65 ± 12 | 0.33 |
| Gender, Males (%) | 79.4 | 86.8 | 0.16 |
| Diabetes (%) | 23.7 | 24.5 | 0.89 |
| Insulin-dependent Diabetes (%) | 30.4 | 11.5 | 0.11 |
| Hypertension (%) | 63.5 | 61.3 | 0.75 |
| Dyslipidaemia (%) | 49.5 | 57.7 | 0.25 |
| Family history of CAD (%) | 26.1 | 27.8 | 0.80 |
| Current smoker (%) | 37.2 | 31.4 | 0.39 |
| Previous PCI (%) | 24.7 | 20.8 | 0.50 |
| Previous CABG (%) | 1.0 | 3.8 | 0.21 |
| Previous MI (%) | 33.0 | 34.9 | 0.77 |
| Previous stroke (%) | 3.1 | 0.0 | 0.07 |
| Cerebrovascular disease (%) | 5.2 | 0.0 | 0.02 |

# CENTURY II NSTEMI subset
## Baseline lesion and procedural characteristics

| | Ultimaster (N=97) | Xience (N=106) | P |
|---|---|---|---|
| Multivessel disease (%) | 47.4 | 55.7 | 0.24 |
| Multivessel treatment (%) | 16.5 | 25.5 | 0.12 |
| | **Ultimaster (Nlesions=127)** | **Xience (Nlesions=160)** | **P** |
| Vessels diseased location: | | | |
| - RCA (%) | 38.1 | 46.2 | 0.25 |
| - LAD (%) | 59.8 | 68.9 | 0.18 |
| - Cx (%) | 50.5 | 56.6 | 0.39 |
| - LM (%) | 1.0 | 2.8 | 0.36 |
| Syntax Score, mean+SD | 8.8±6.0 | 10.0±7.0 | 0.27 |
| Lesion type B2-C (%) | 78.7 | 77.6 | 0.87 |
| Ostial lesion (%) | 4.1 | 7.9 | 0.20 |
| Bifurcated lesion (%) | 10.2 | 11.3 | 0.78 |
| CTO present (%) | 0.8 | 2.0 | 0.22 |

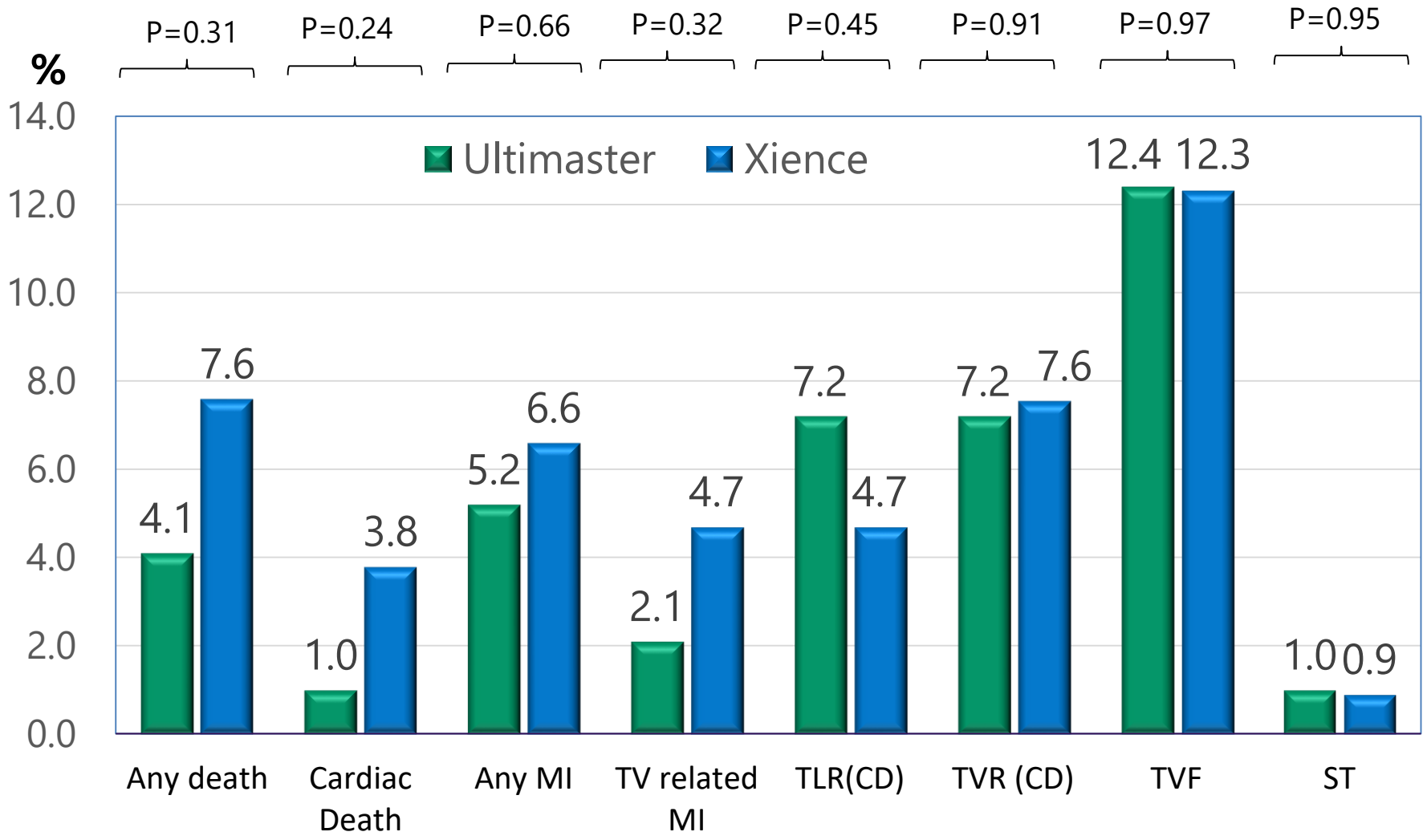
# CENTURY II NSTEMI subset
# Procedural characteristics

| | Ultimaster (N=97) (Nlesions=127) | Xience (N=106) (Nlesions=160) | P |
|---|---|---|---|
| Total Nr of lesions treated per pt, mean±SD | 1.31±0.62 | 1.51±0.75 | 0.02 |
| Nr of stents per lesion, mean±SD | 1.14±0.45 | 1.09±0.43 | 0.45 |
| Nr of stents per patient, mean±SD | 1.49±0.77 | 1.61±0.95 | 0.60 |
| Total implanted stent length/pt (mm) | 29.5±17.9 | 33.4±21.4 | 0.35 |
| Radial access (%) | 77.3 | 76.4 | 0.88 |
| RVD (mm), mean+SD | 2.7±0.6 | 2.6±0.6 | 0.16 |
| MLD (mm), mean+SD | 0.8±0.4 | 0.7±0.4 | 0.72 |
| Pre-procedure Lesion length (mm), mean+SD | 18.1±10.9 | 15.3±7.7 | 0.14 |
| Direct stenting performed (%) | 24.4 | 27.5 | 0.56 |
| Post-dilatation performed (%) | 38.6 | 44.6 | 0.31 |

# CENTURY II – NSTEMI subset
# Clinical outcomes at 4 years

| | Ultimaster (N=97 pts) | Xience (N=106 pts) | P |
|---|---|---|---|
| Angina, % | 2.2 | 3.1 | 0.70 |
| Unstable angina, % | 0.0 | 1.0 | 0.33 |
| DAPT, % | 6.5 | 7.1 | 0.85 |
| Any bleeding, % | 16.5 | 16.0 | 0.93 |
| Bleeding, BARC type3-5 | 3.1 | 3.8 | 0.79 |

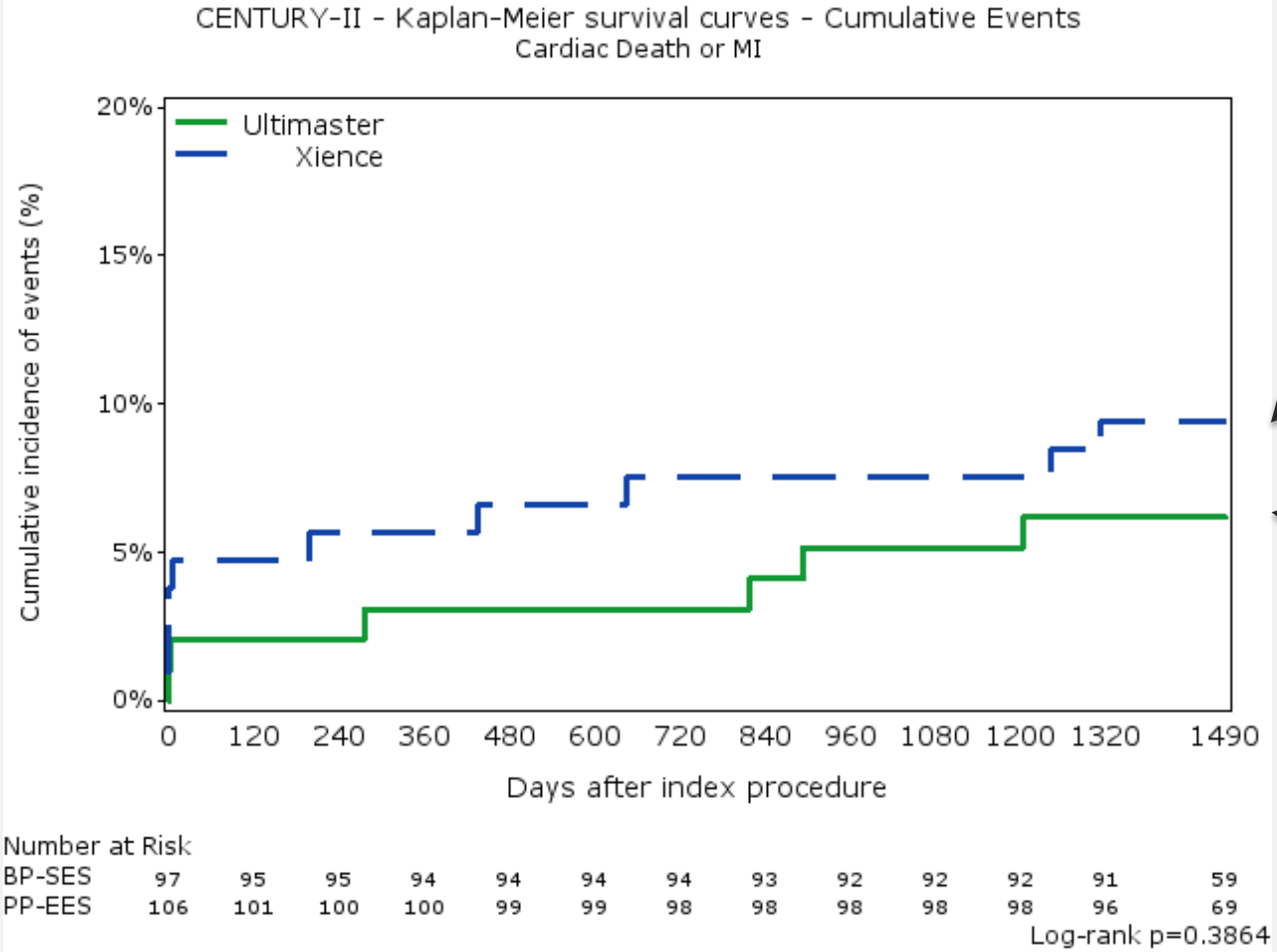
# CENTURY II NSTEMI subset
# Clinical outcomes – 48 months FU




CD=Clinically Driven ST=Definite and probable stent thrombosis- 1 subacute ST in each arm

# CENTURY II NSTEMI subset
# Cardiac death or MI at 48 months

## Cardiac death or MI Kaplan-Meier curves – 4 years




**Xience**
**9.43%**
**[5.19% ; 16.82%]**

**Ultimaster**
**6.19%**
**[2.83% ; 13.25%]**

# CENTURY II NSTEMI conclusions
# Why is this important?

- The Ultimaster DES with bioresorbable polymer (in comparison to Xience DES and in absolute terms) is proven to be **safe and effective** in treating patients that present with NSTEMI;
- Favorable 48 months clinical outcomes for the high-risk population of patients presenting with **NSTEMI**, assure the safe use of Ultimaster DES in daily practice.

# The essentials to remember

- **Why?** To assess long-term outcomes in NSTEMI patients
- **What?** Bioresorbable polymer sirolimus eluting stent
- **How?** In a substudy of CENTURY II trial.
- **What are the results?** Ultimaster DES is proven to be safe and effective in NSTEMI patients.
- **Why is this important?** Provided long term safety and efficacy and assured the use of this DES in daily practice.