# Bifurcation Stenting with Ultimaster Stents


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# Ultimaster components

**Enhanced conformability**

-Bio-ergonomic stent design

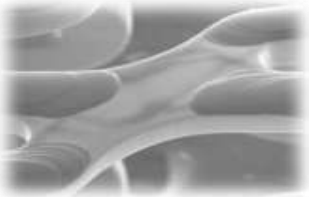
-Low width/thickness of the stent struts


**Improved deliverability**

- Strut thickness 80µm
- Flexibility of the stent system

**Optimized drug release technology**

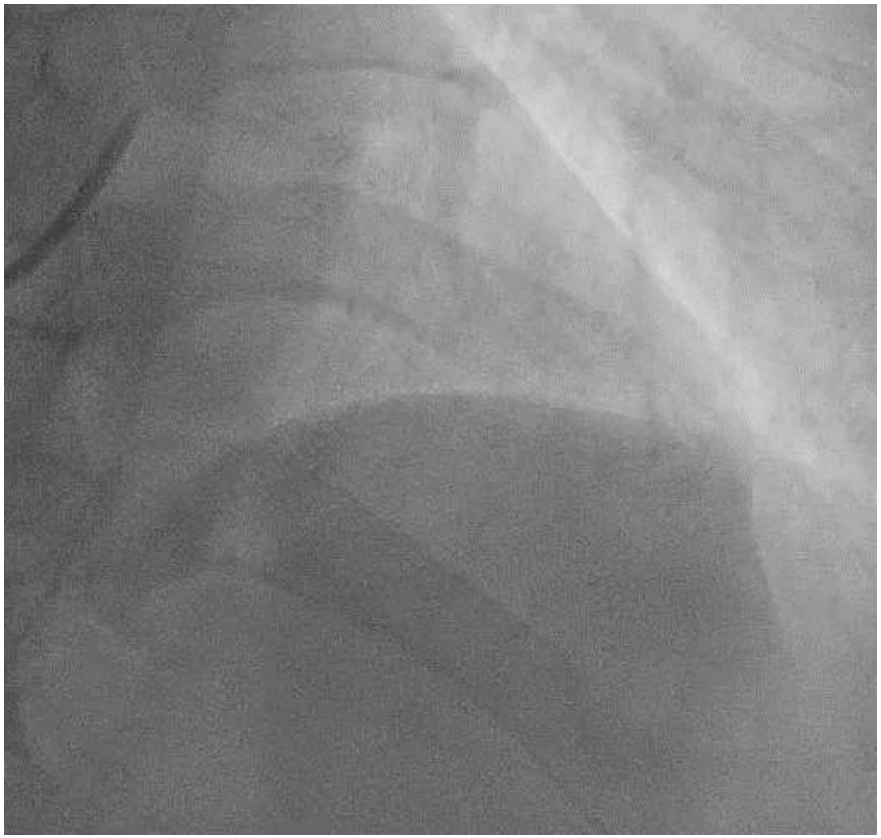
- Biodegradable polymer
- Synchronous drug release and polymer absorption

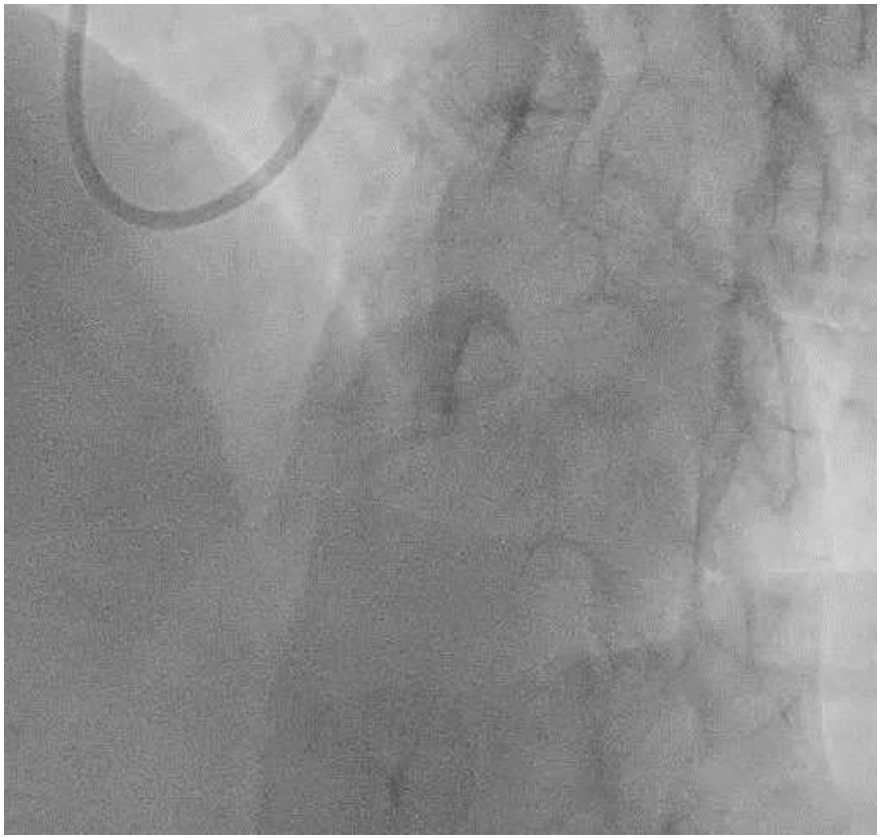


**Targeted drug release**

–Abluminal gradient coating

# DK Crush Bifurcation Stenting Using Ultimaster Stents

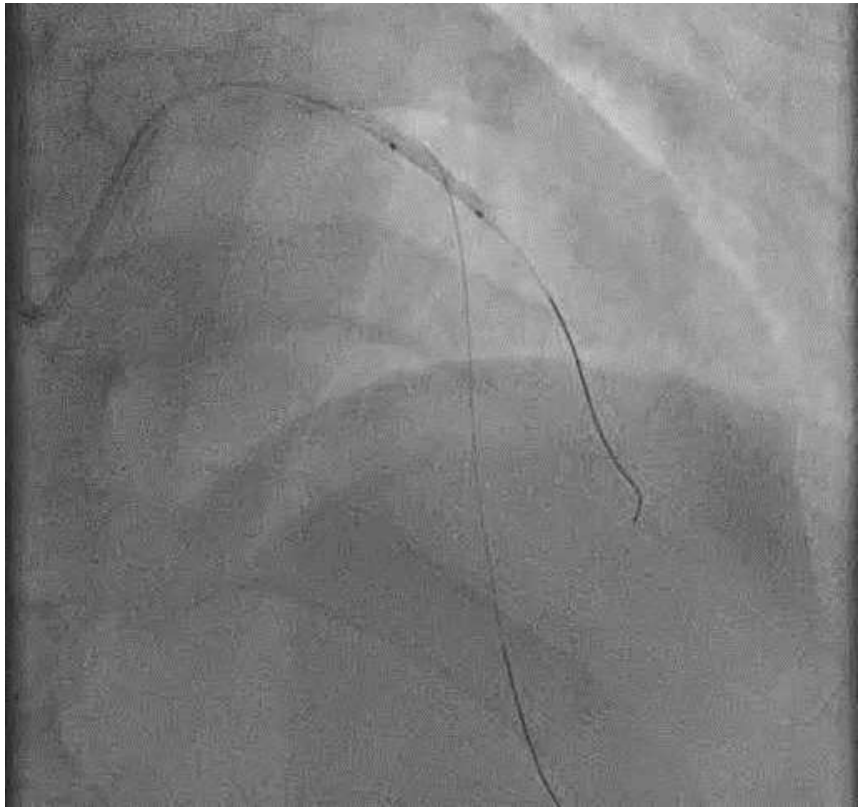




- 66 Year old
- Unstable Angina
- RCA stented

- LAD/D1 bifurcation lesions

# DK Crush Bifurcation Stenting Using Ultimaster Stents

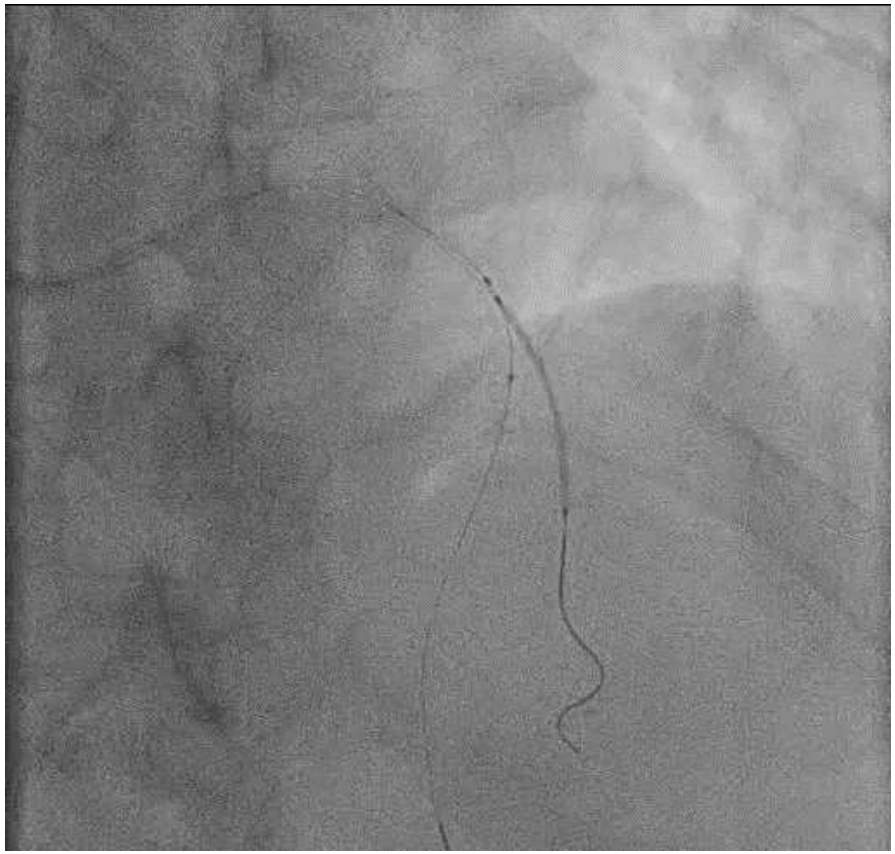


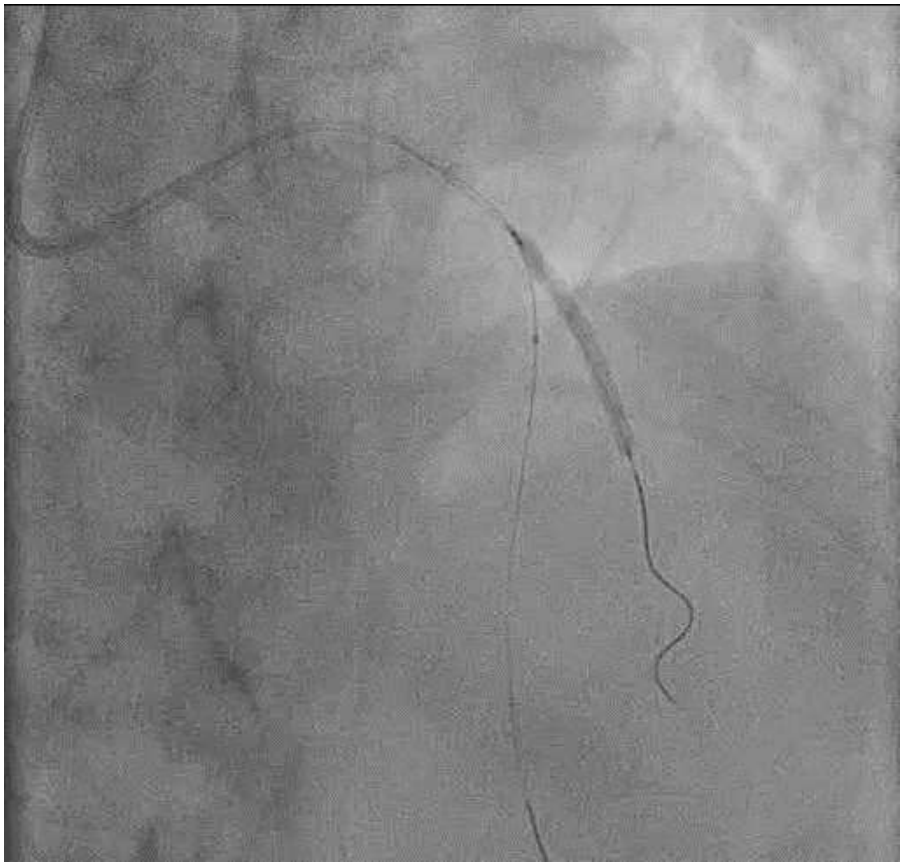
- LAD/D1 wired and predilated

# DK Crush Bifurcation Stenting Using Ultimaster Stents

- D1 stent Ultimaster 2.5 x 28mm

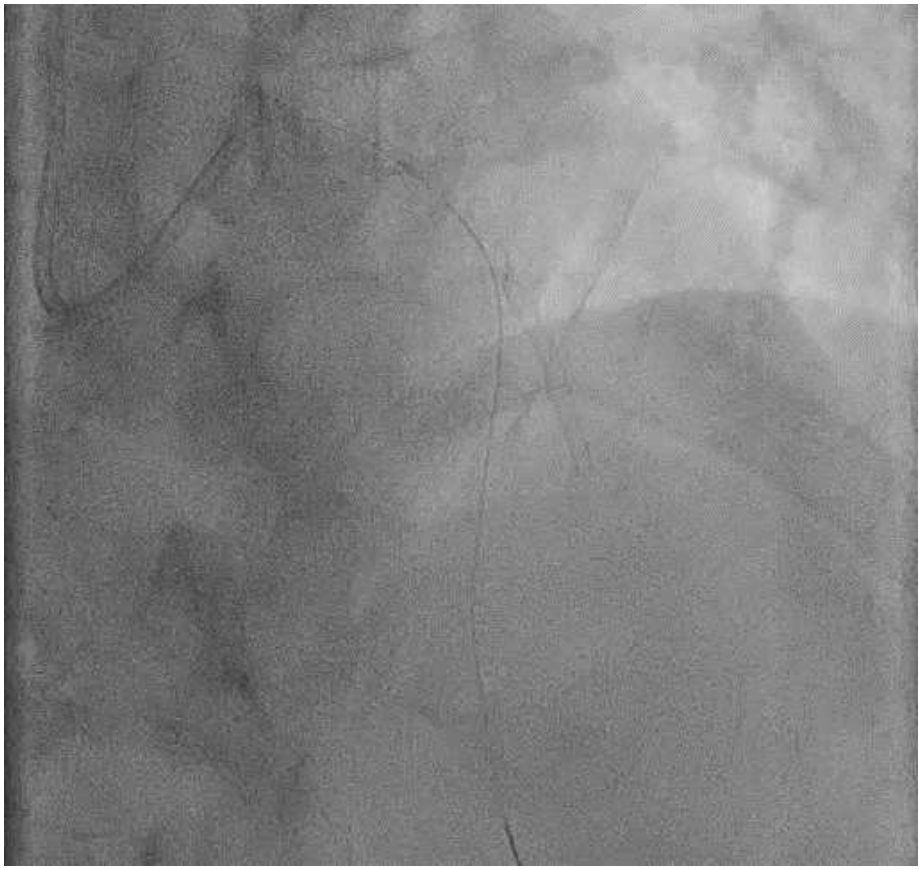
# DK Crush Bifurcation Stenting Using Ultimaster Stents





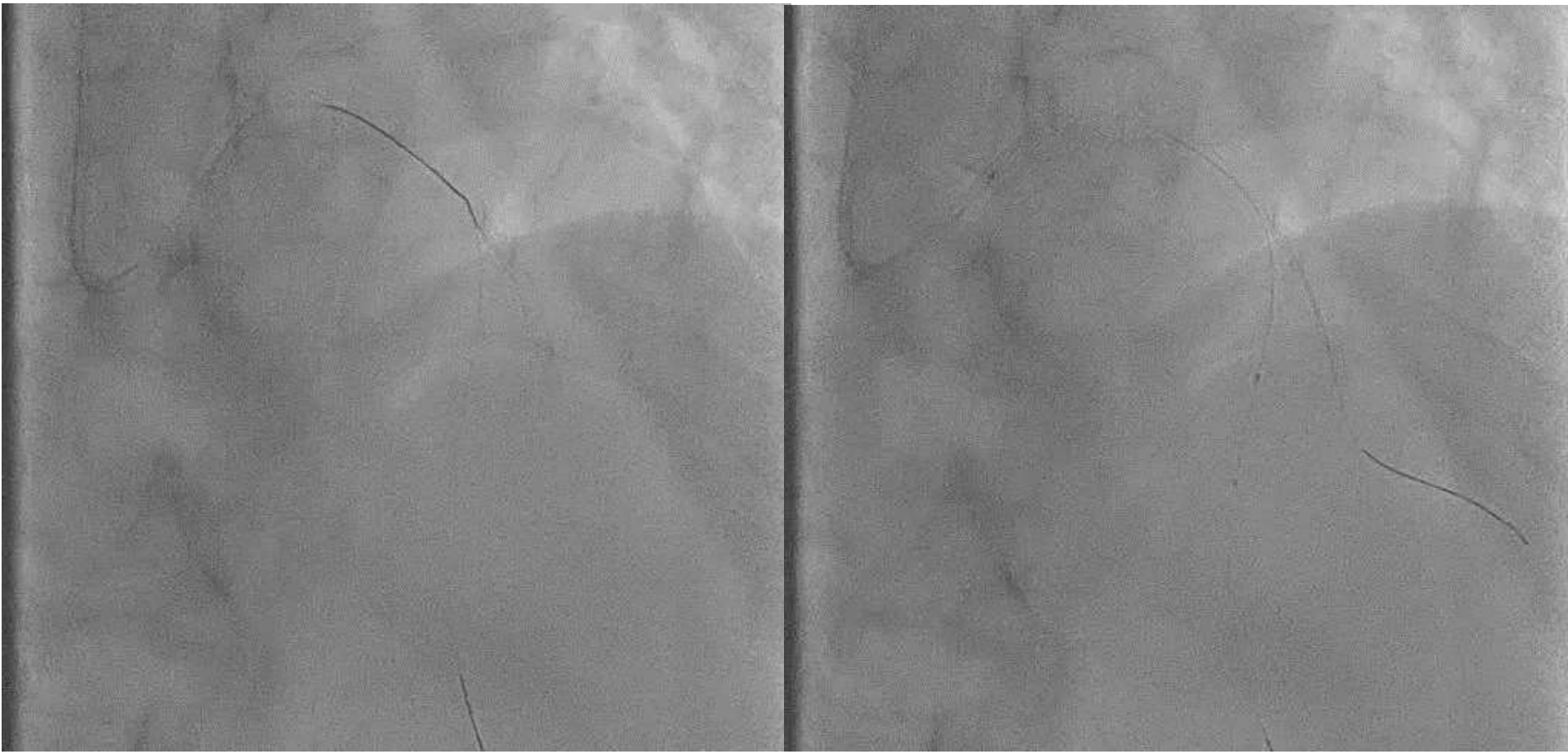
- D1 ULTIMASTER 2.5 x 28mm
- LAD 2.5 x 15mm balloon

# DK Crush Bifurcation Stenting Using Ultimaster Stents



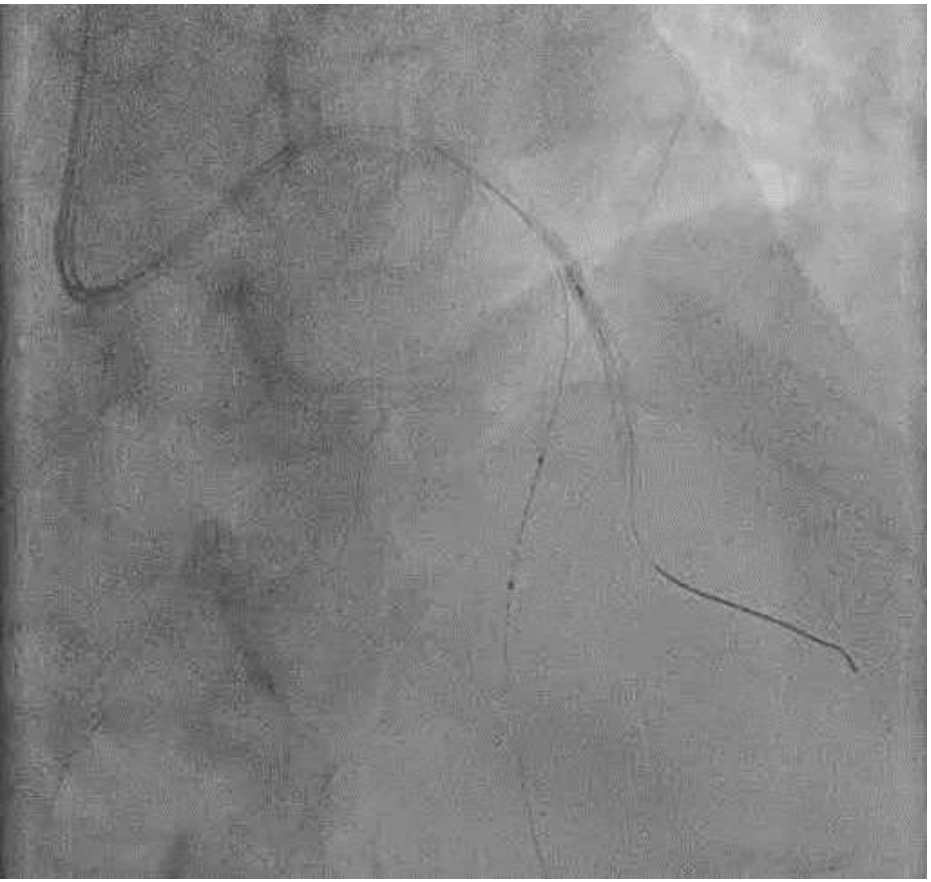
- D1 stent crushed with 2.5 x 15mm balloon in LAD

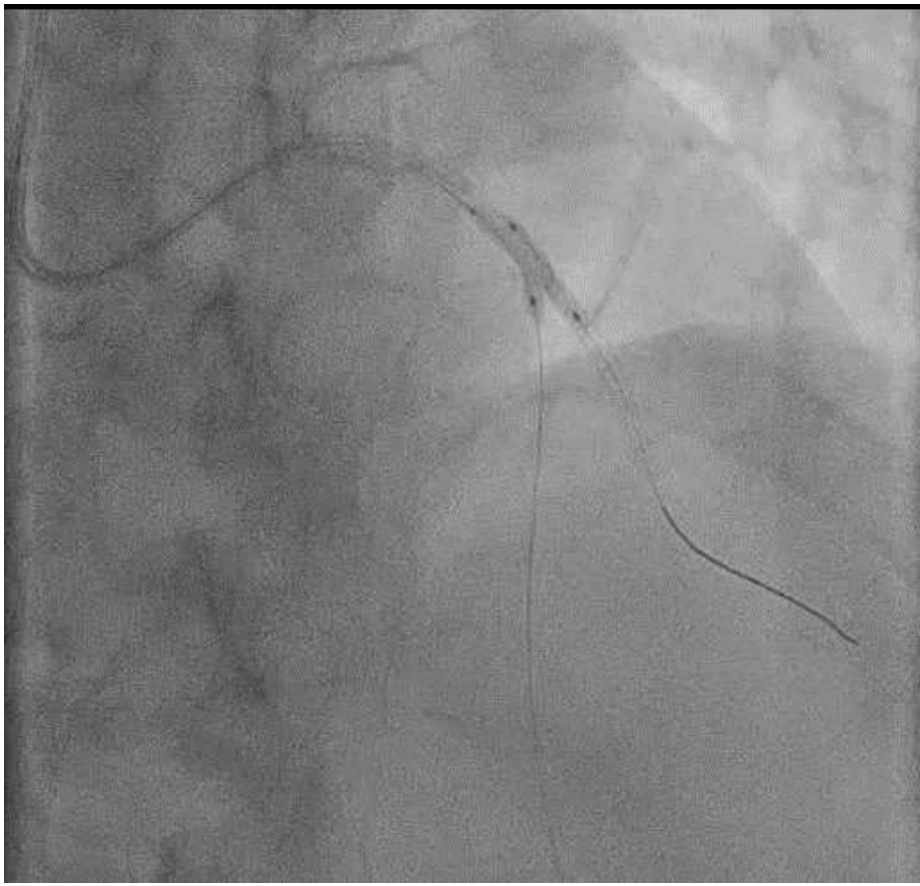
# DK Crush Bifurcation Stenting Using Ultimaster Stents



- D1 Rewired and 1.5 x 15mm balloon to D1

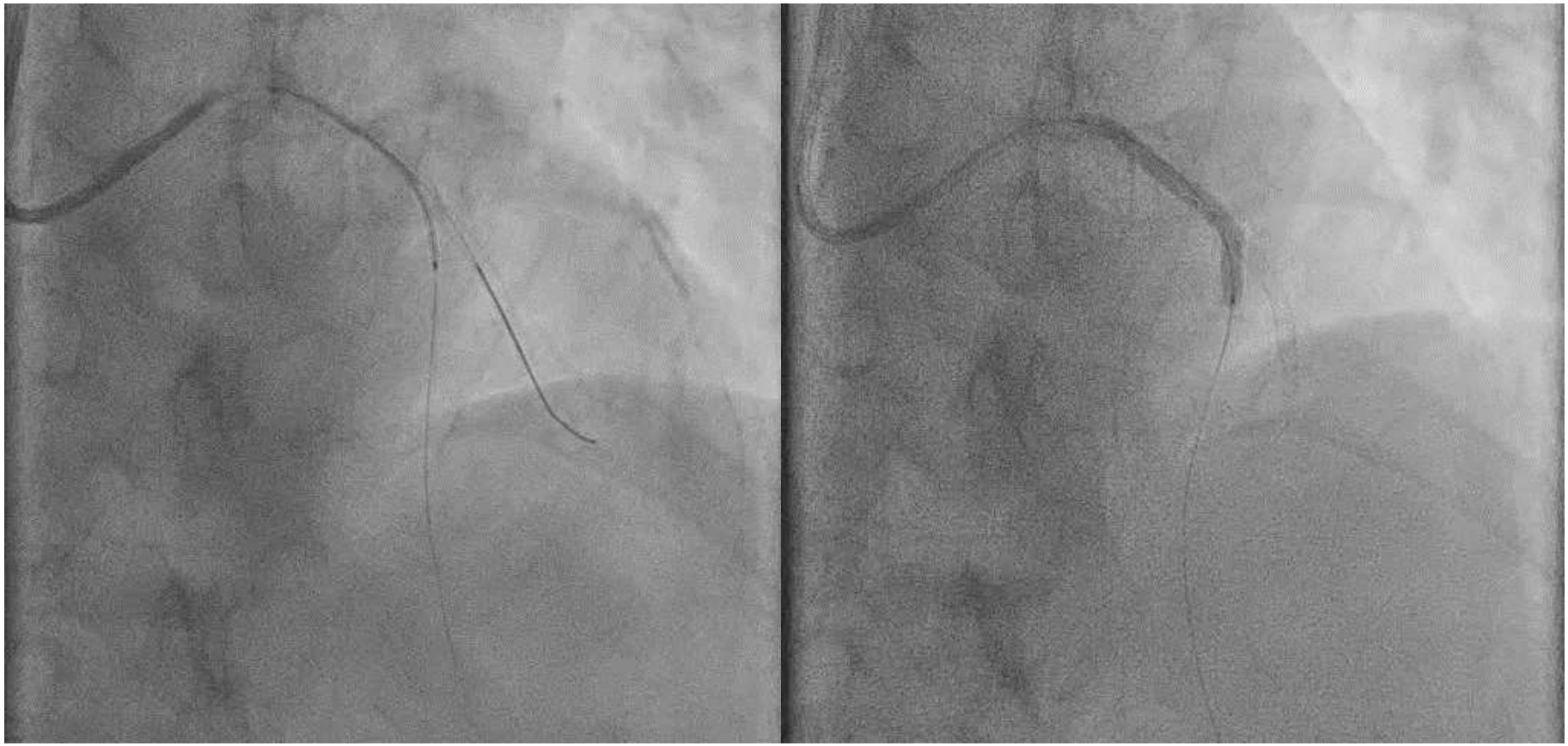
# DK Crush Bifurcation Stenting Using Ultimaster Stents





- 1st Kiss with 2.5 x 15mm (LAD), NC 2.5 x 15mm (D1)

# DK Crush Bifurcation Stenting Using Ultimaster Stents

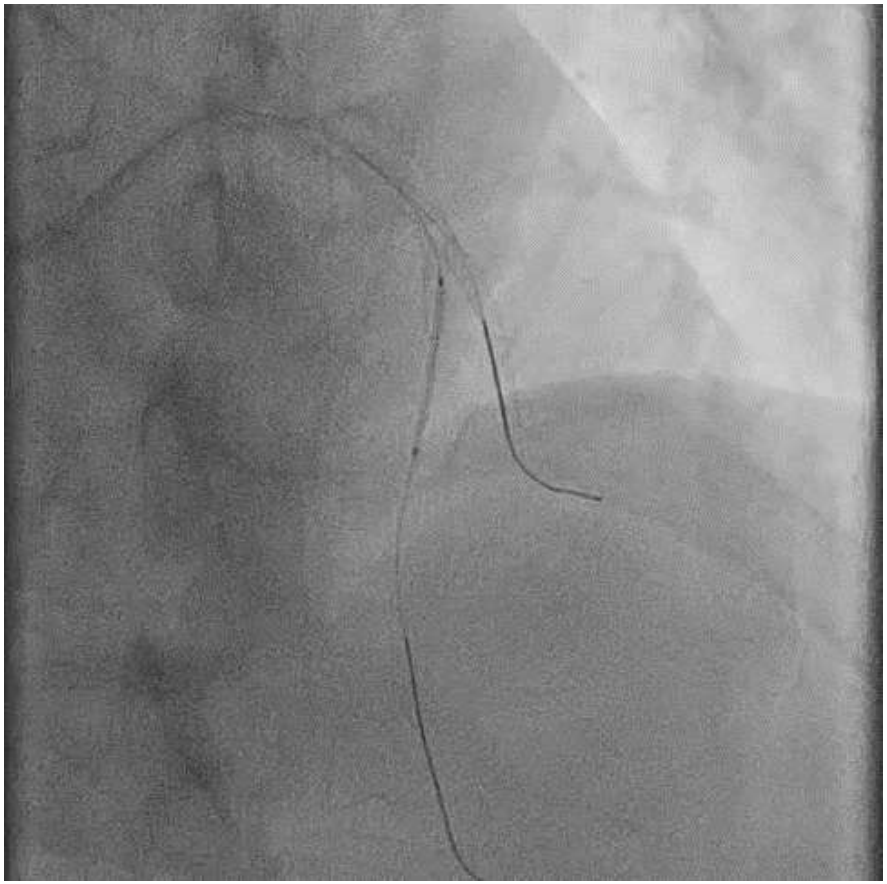


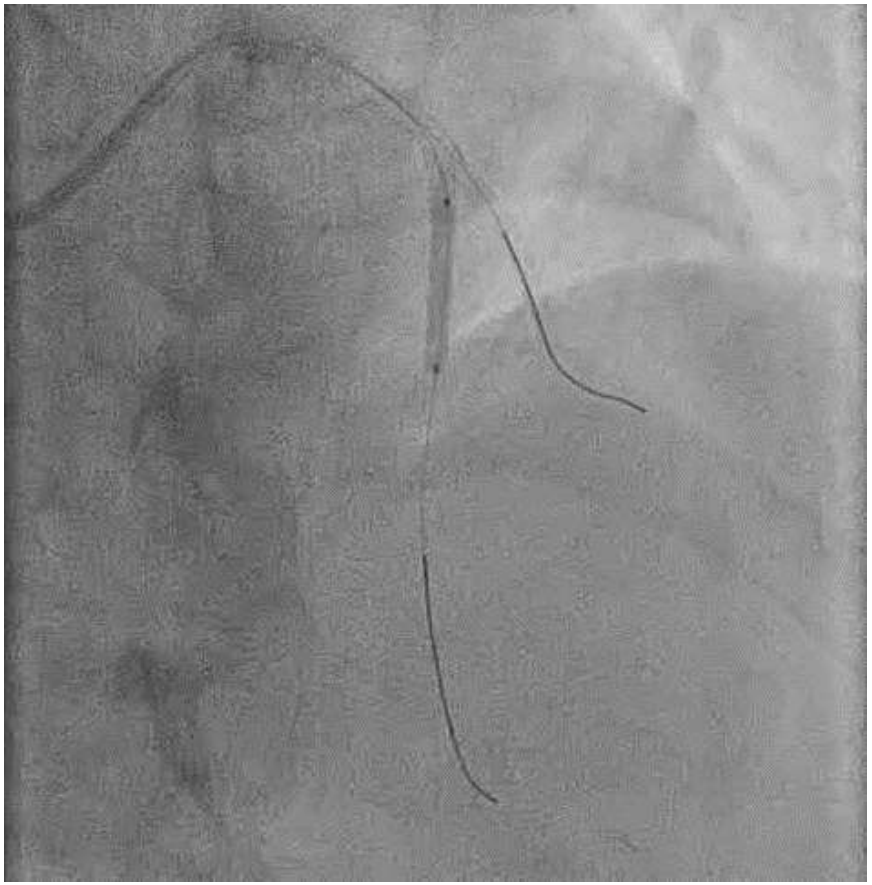
- LAD ULTIMASTER 3.0 x 38mm

# DK Crush Bifurcation Stenting Using Ultimaster Stents

- D1 Rewired

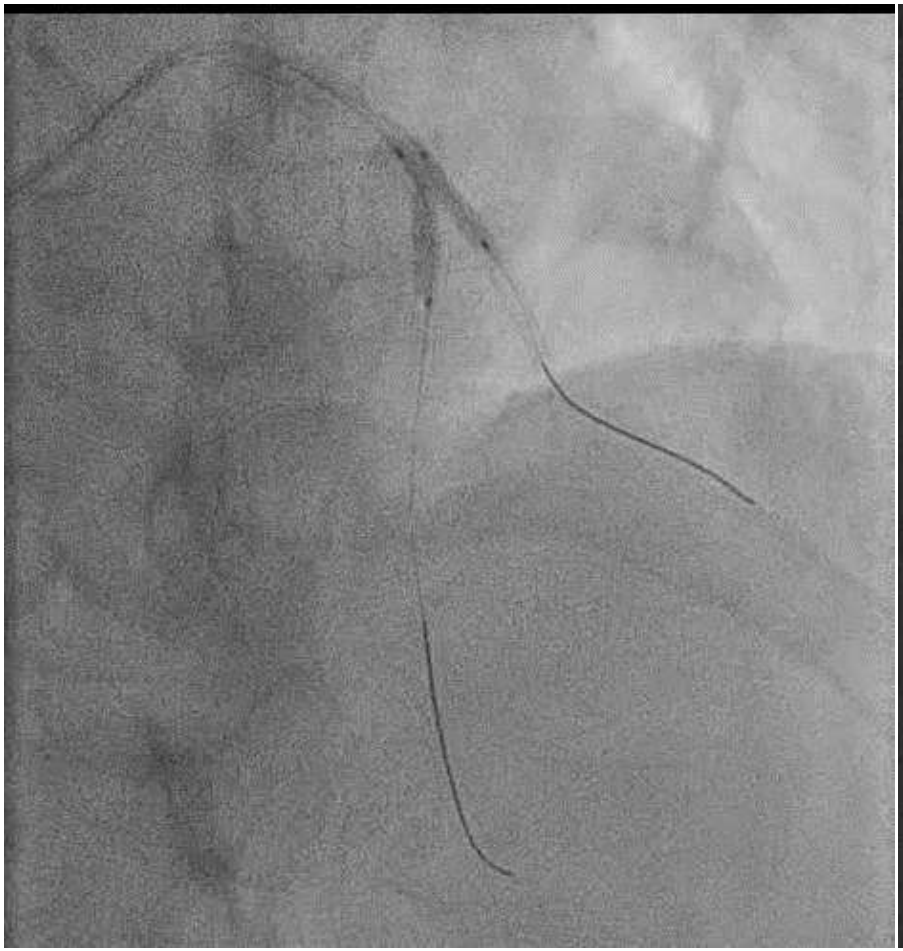
# DK Crush Bifurcation Stenting Using Ultimaster Stents

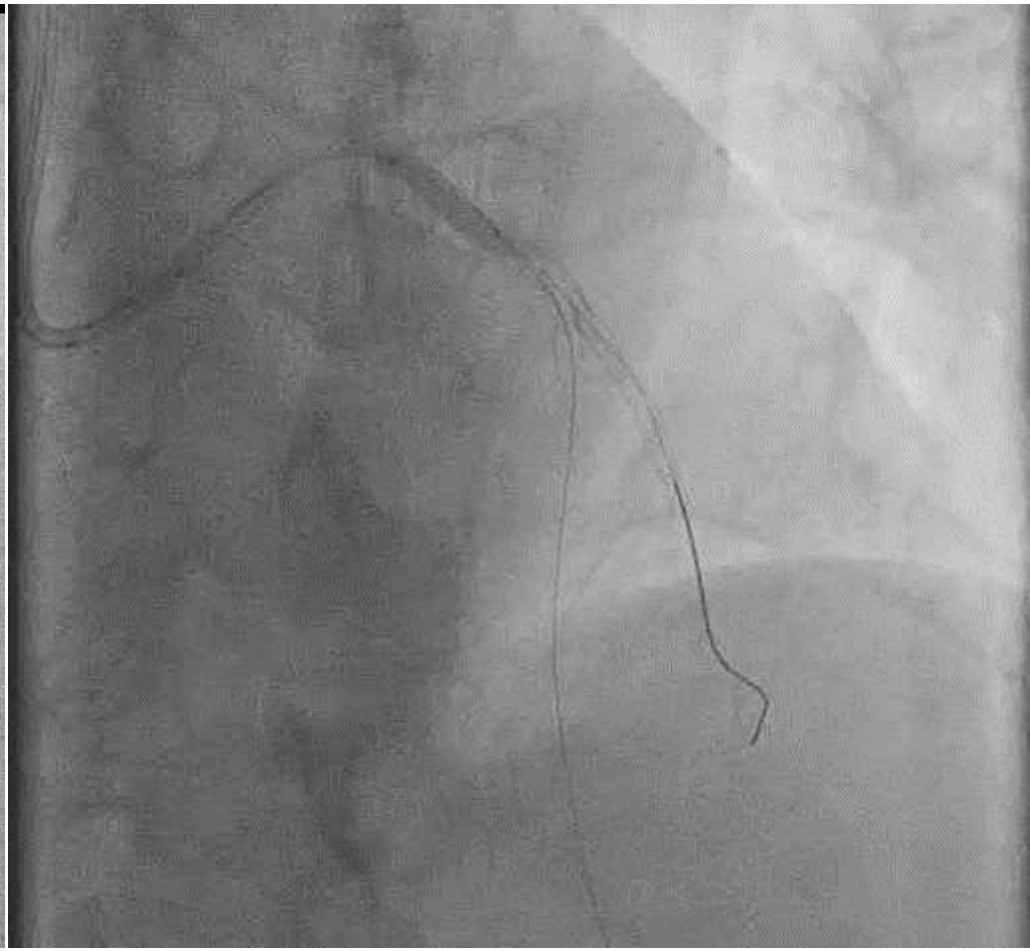




- Mid LAD ULTIMASTER 2.5 x 18mm

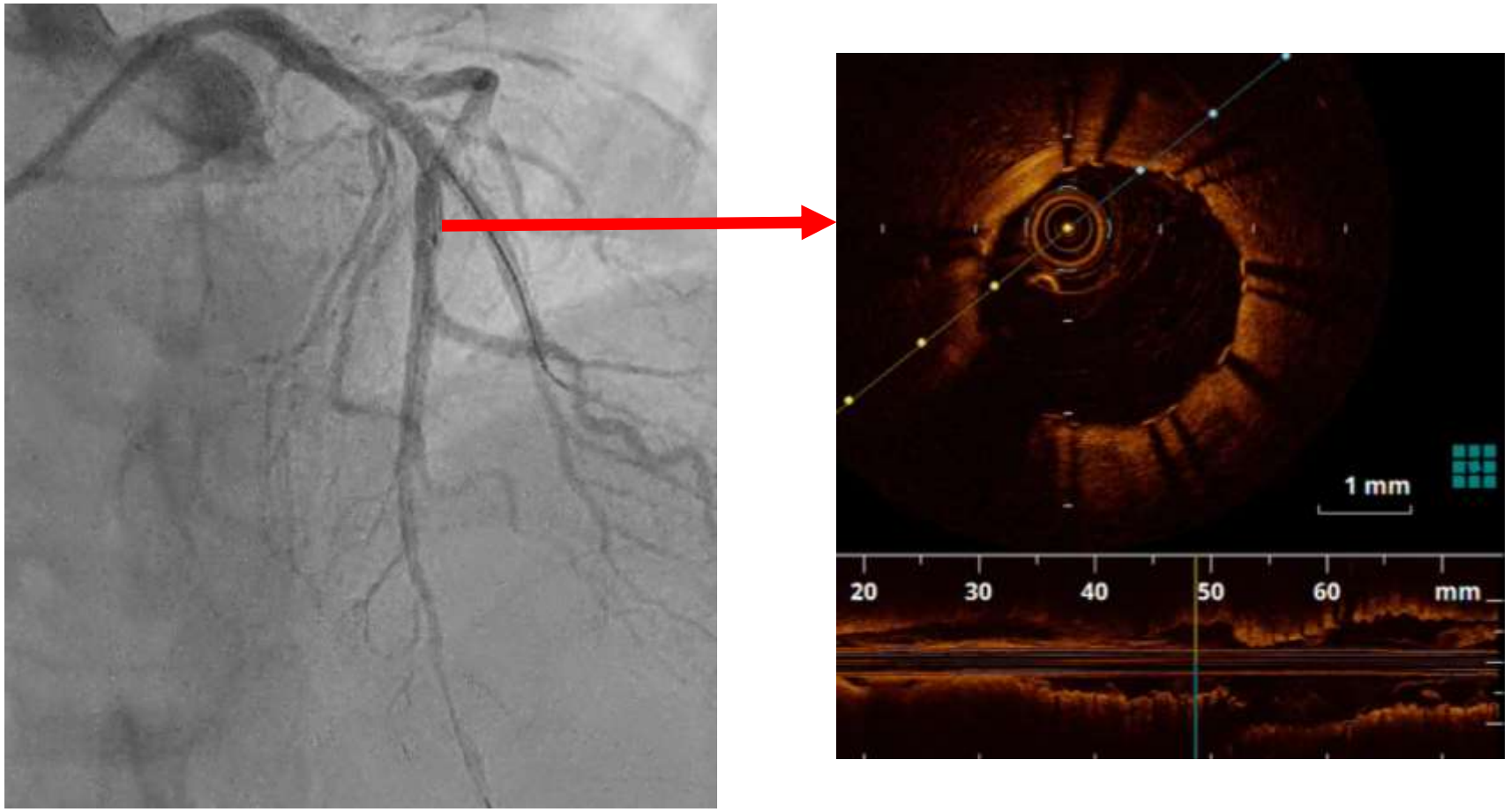
# DK Crush Bifurcation Stenting Using Ultimaster Stents



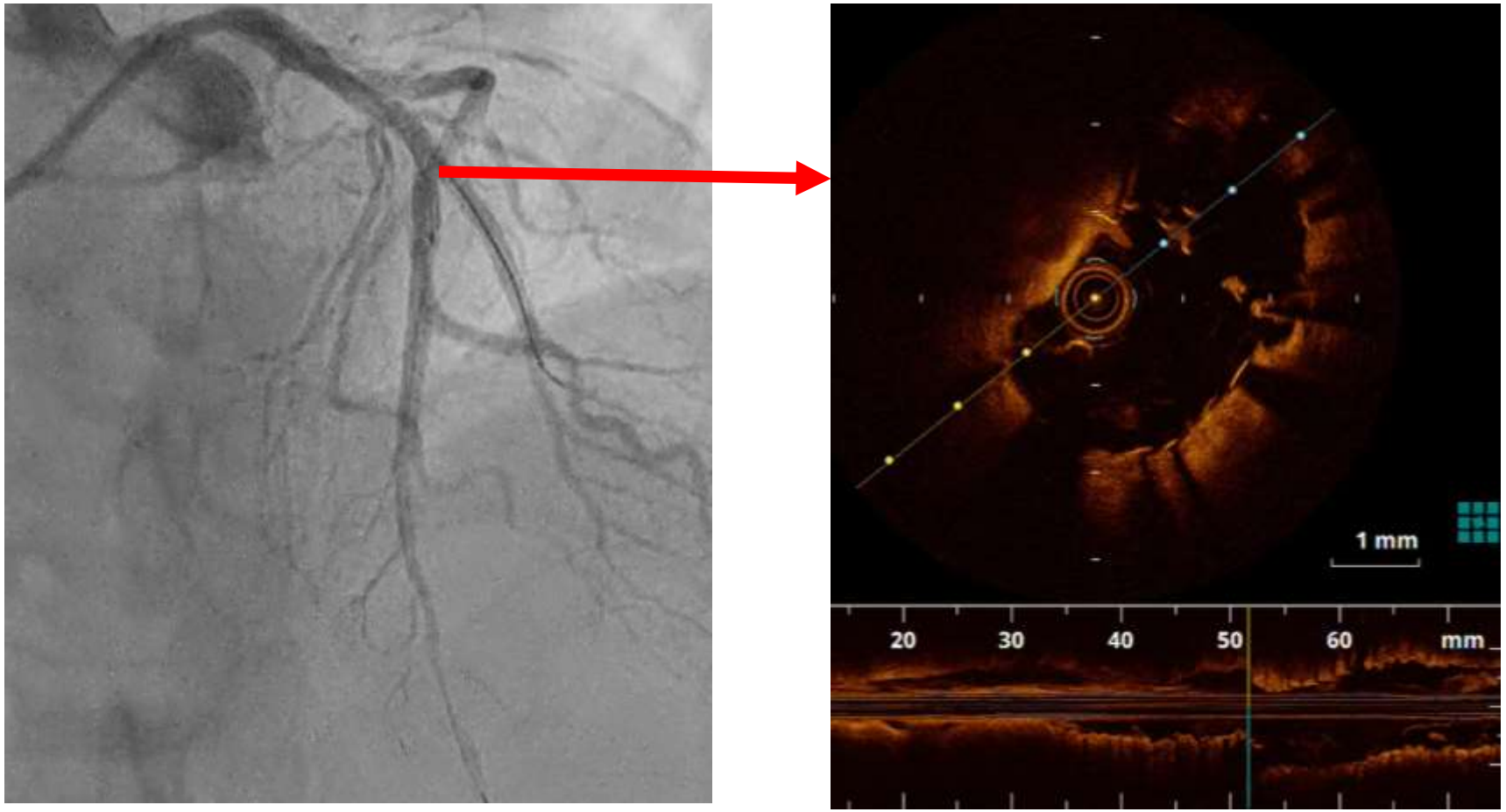


- Final Kiss with NC 3.0 x 15mm (LAD), NC 2.5 x 15mm (D1)
- POT with 3.5 x 15mm balloon in pLAD

# DK Crush Bifurcation Stenting Using Ultimaster Stents



# DK Crush Bifurcation Stenting Using Ultimaster Stents



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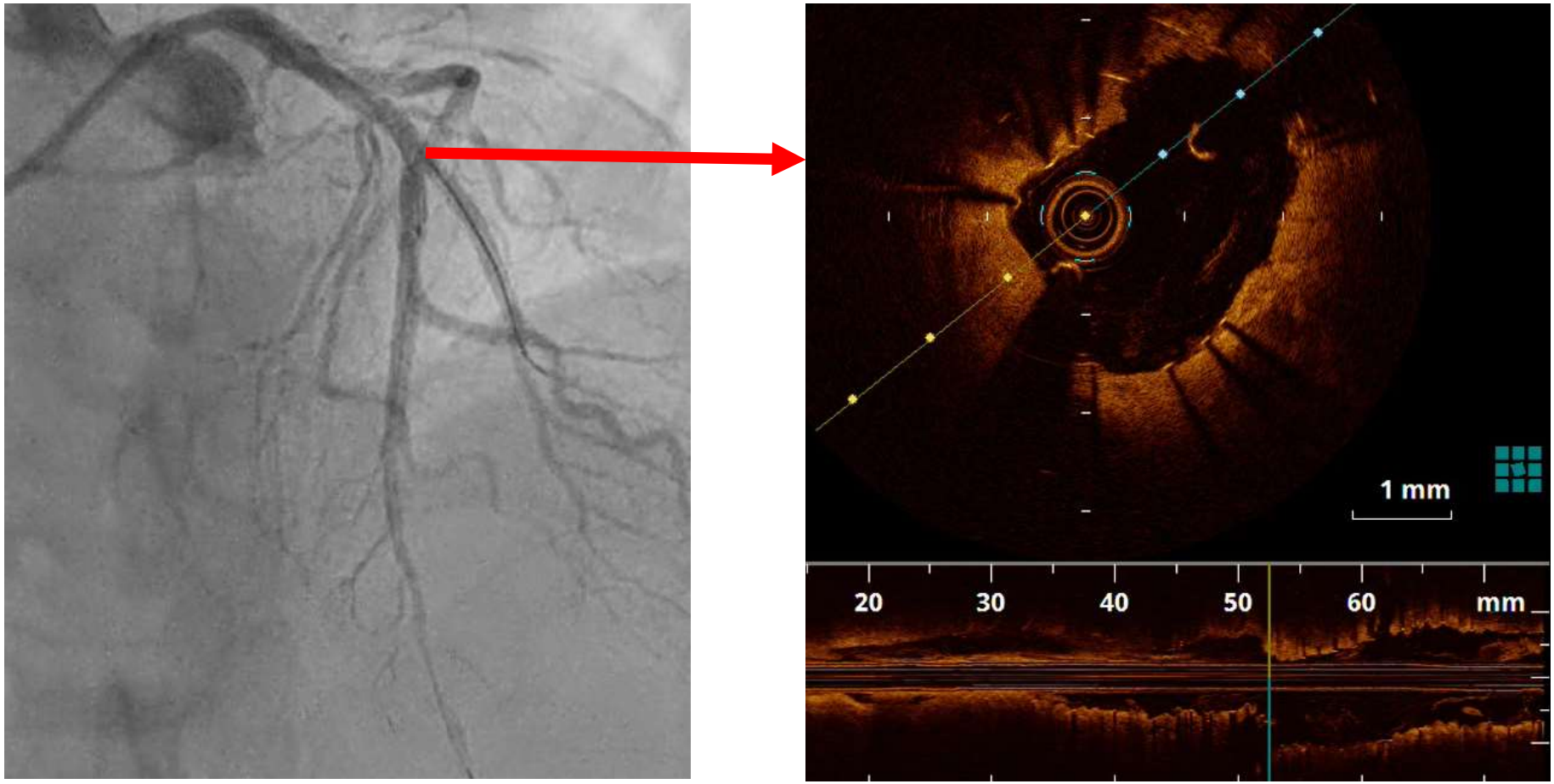

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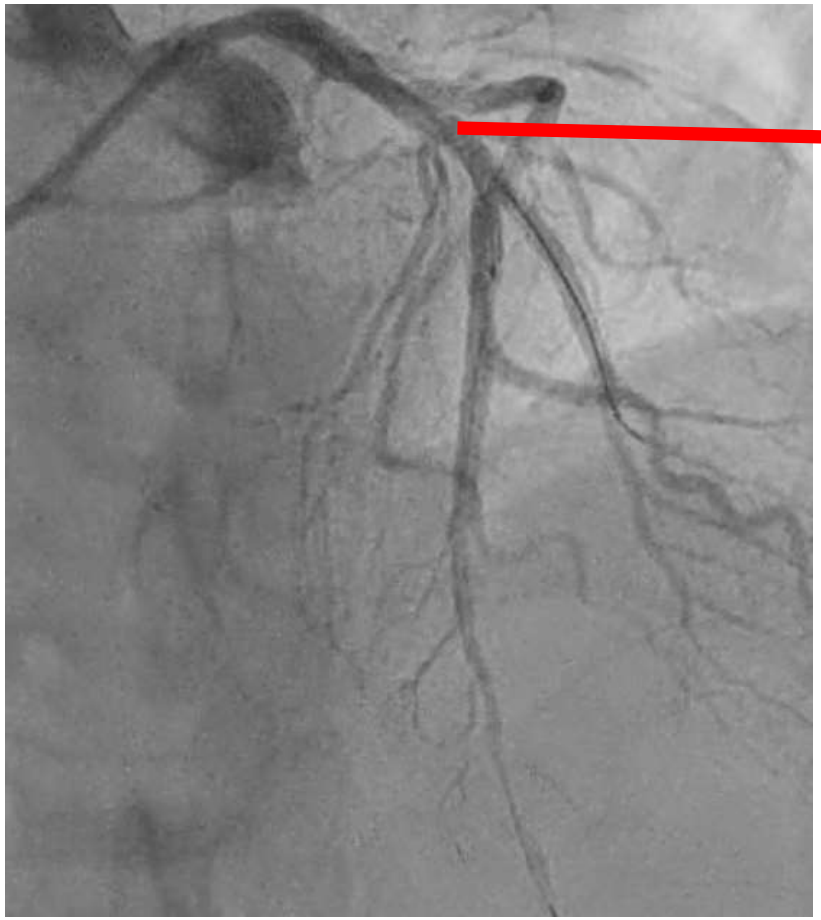

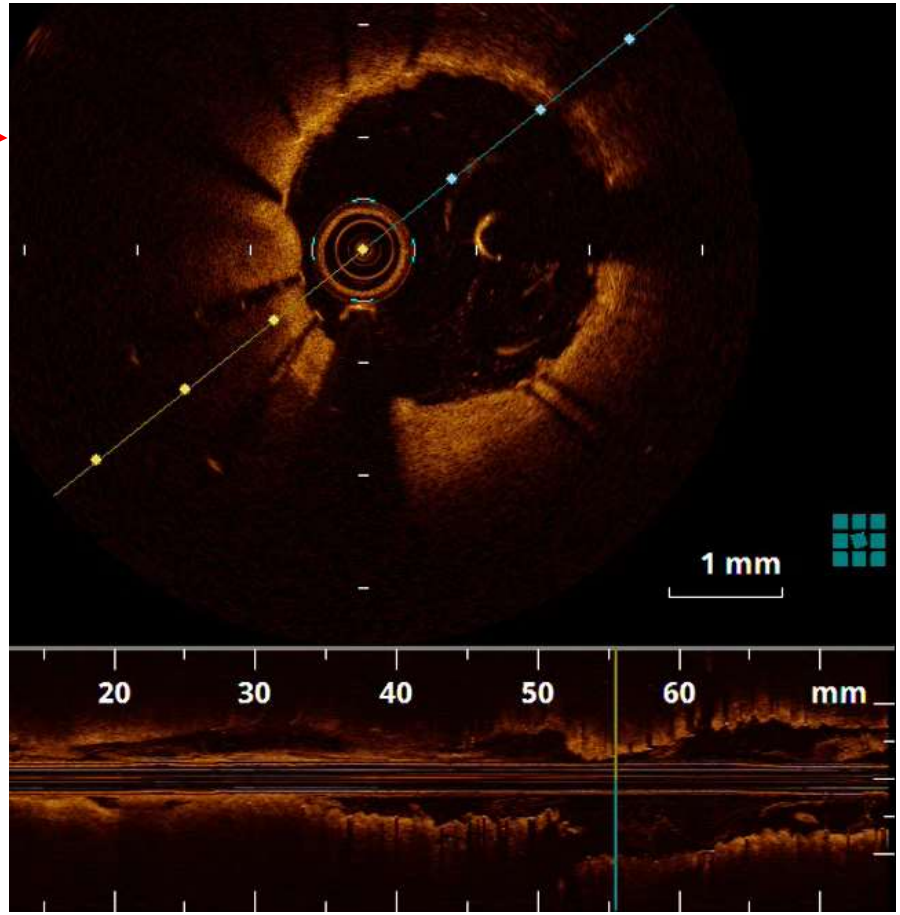

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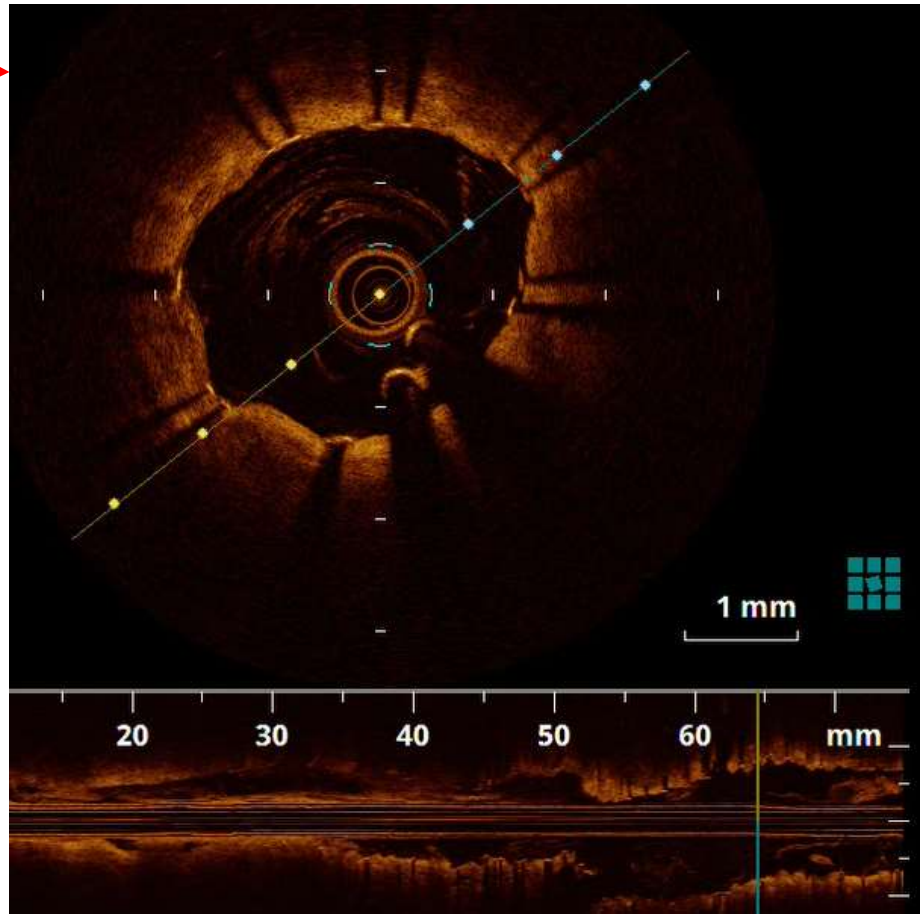

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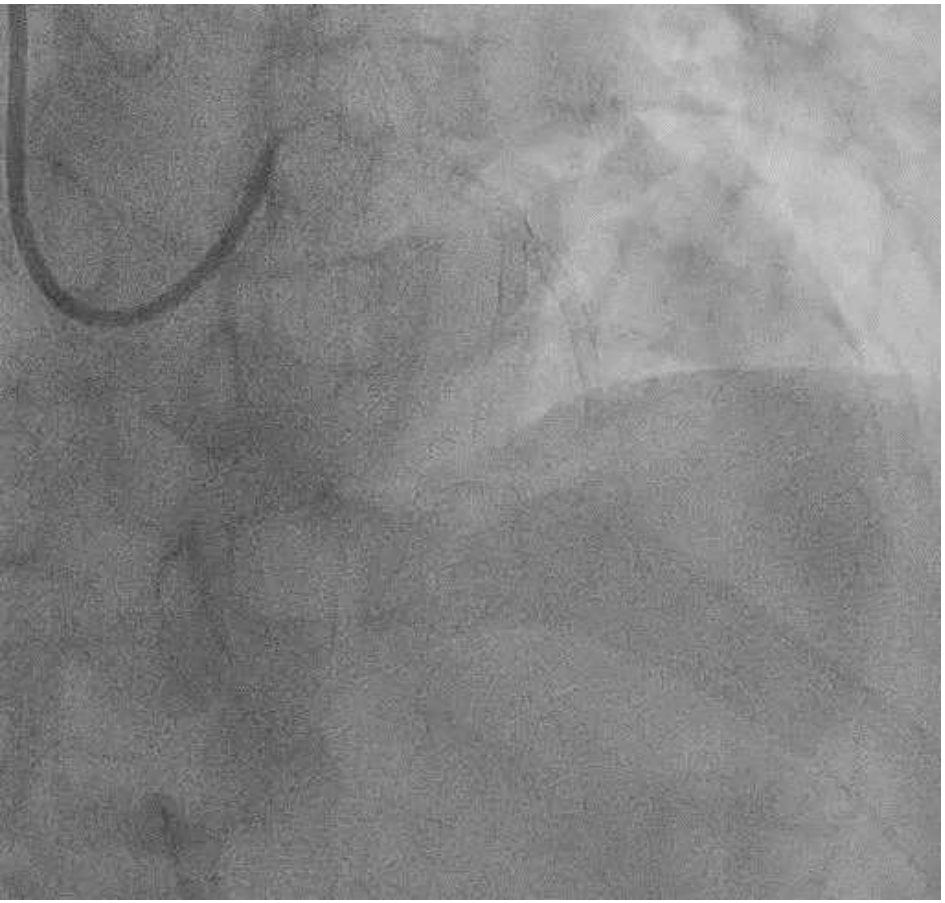
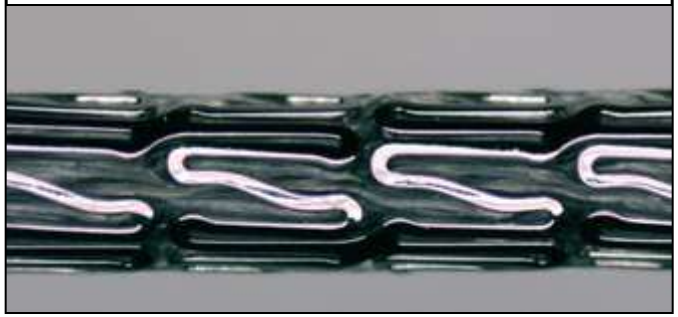
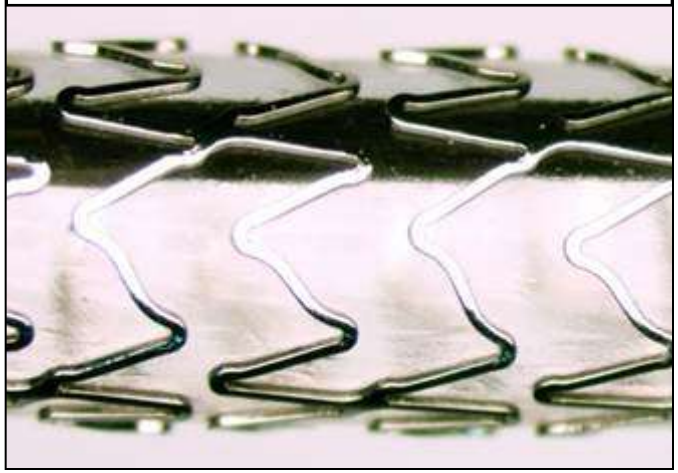


# ULTIMASTER Strut design

Before deployment



After expansion



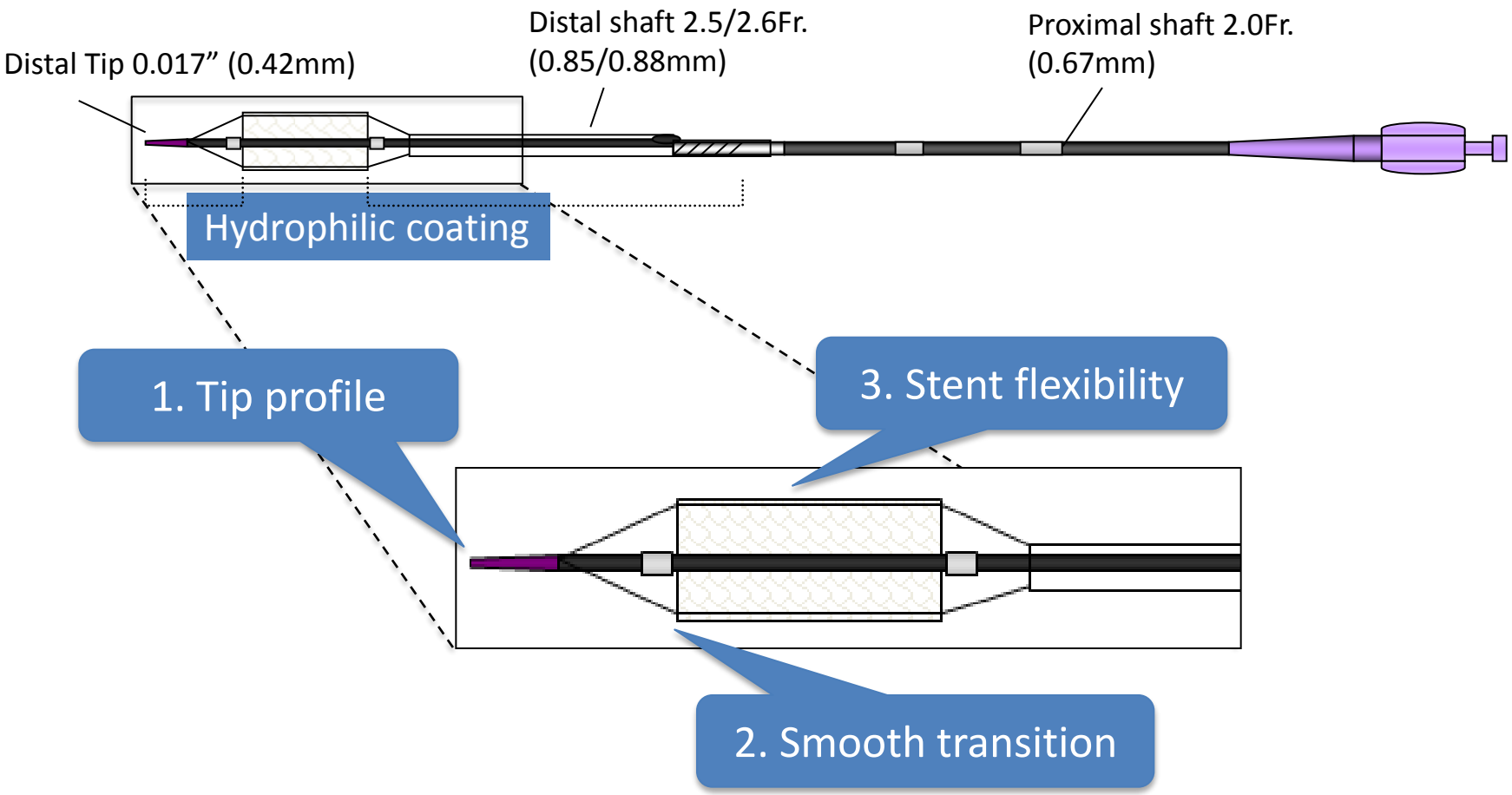
| material | CoCr（L605） |
|---|---|
| Thickness | 80μm |
| # of links | 2 |

Favorably low width/thickness of the CoCr stent struts:

- ✓ enhanced stent conformability to the vessel wall
- ✓ rapid endothelialisation
- ✓ reduced risk of vessel wall injury
- ✓ excellent radial force

**Faster healing process and better strut coverage**

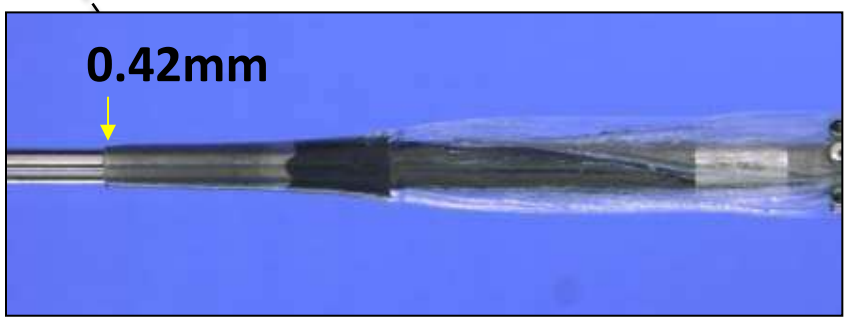
# Enablers of Ultimaster deliverability



# Enablers of Ultimaster deliverability

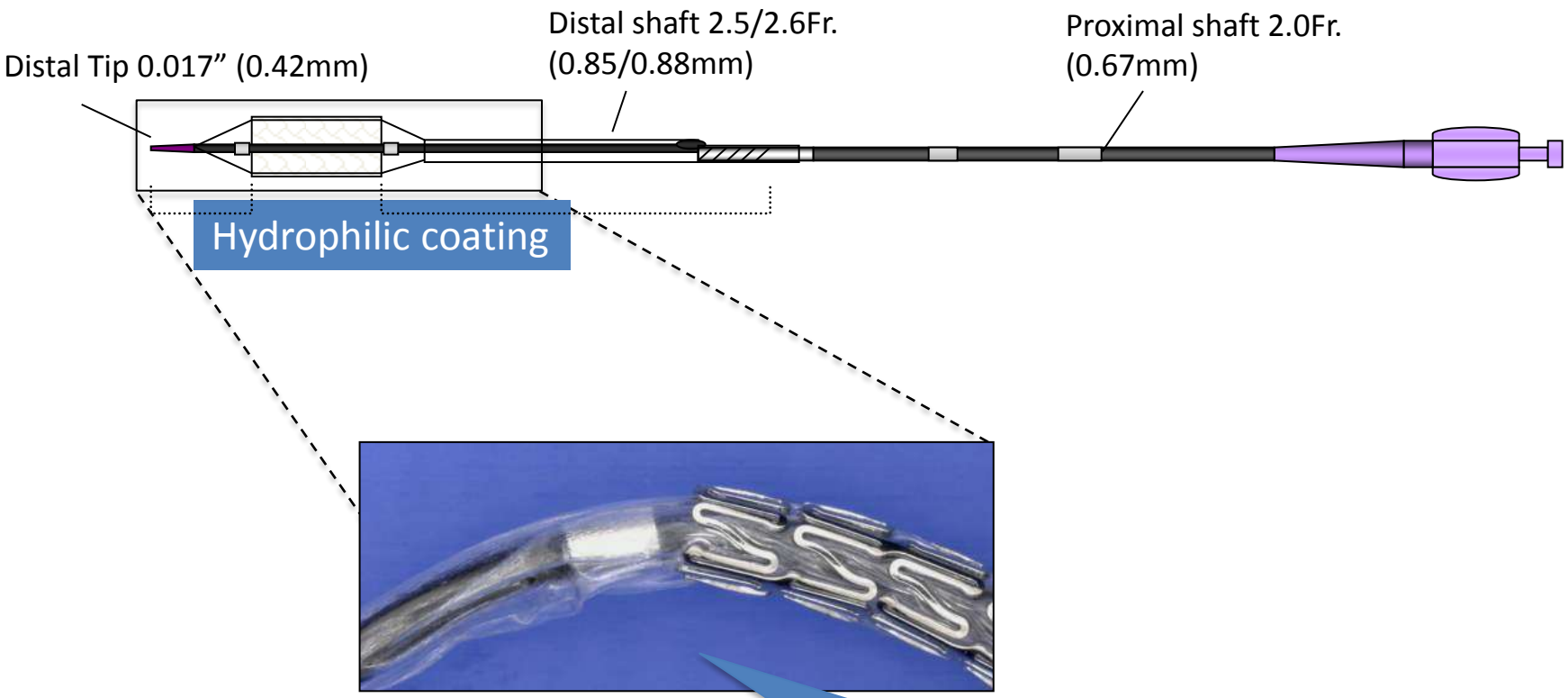

1. Tip profile

**Smallest entry profile**
- **Smooth balloon entry**
- **Less gap between tip and wire**




Ultimaster

# Enablers of Ultimaster deliverability

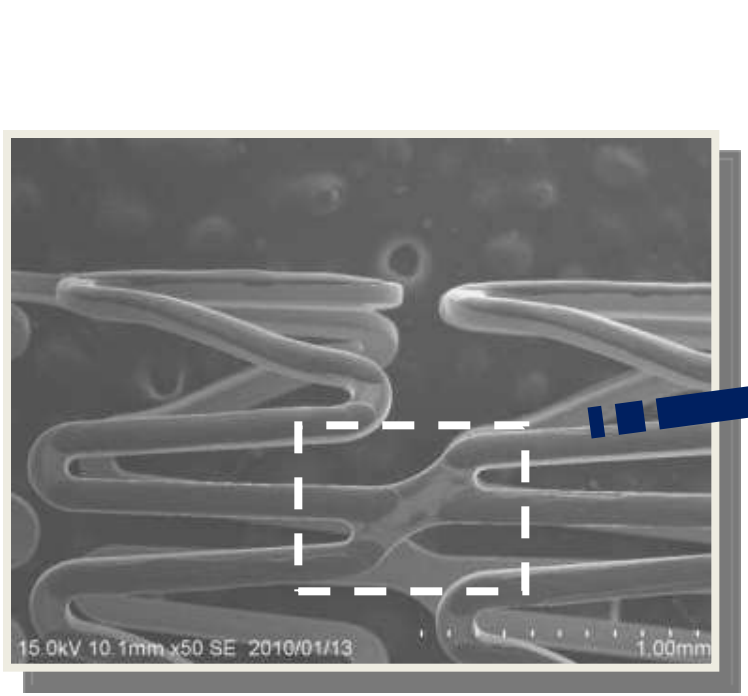



**Superior trackability**

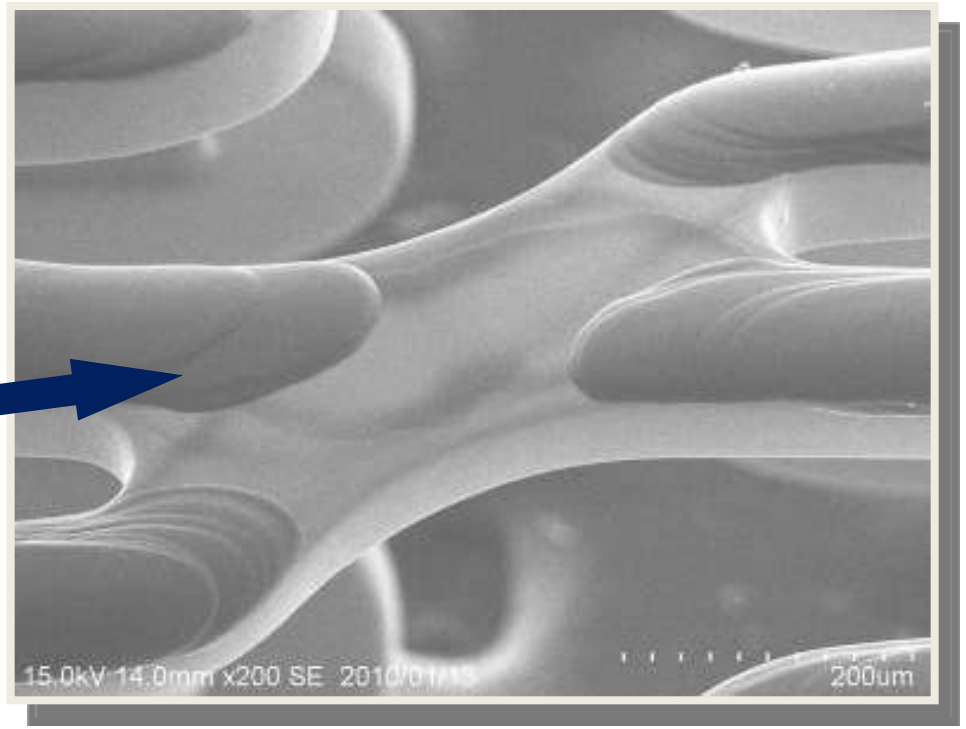
- **Smooth balloon folding**
- **Less gap between stent and balloon**

# Ultimaster employs gradient coating technology

- Partial coating to prevent coating layer from cracking or peeling off
- No compromise in drug distribution



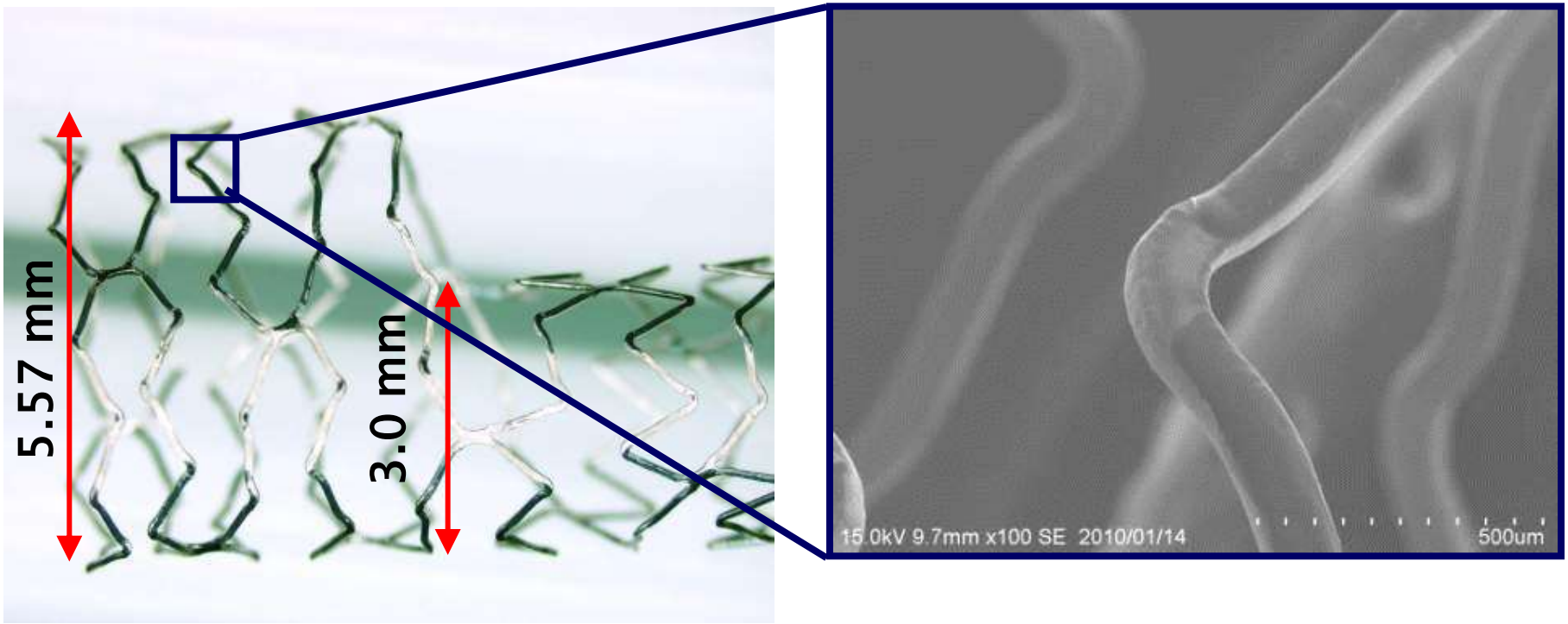

X 50




X 200

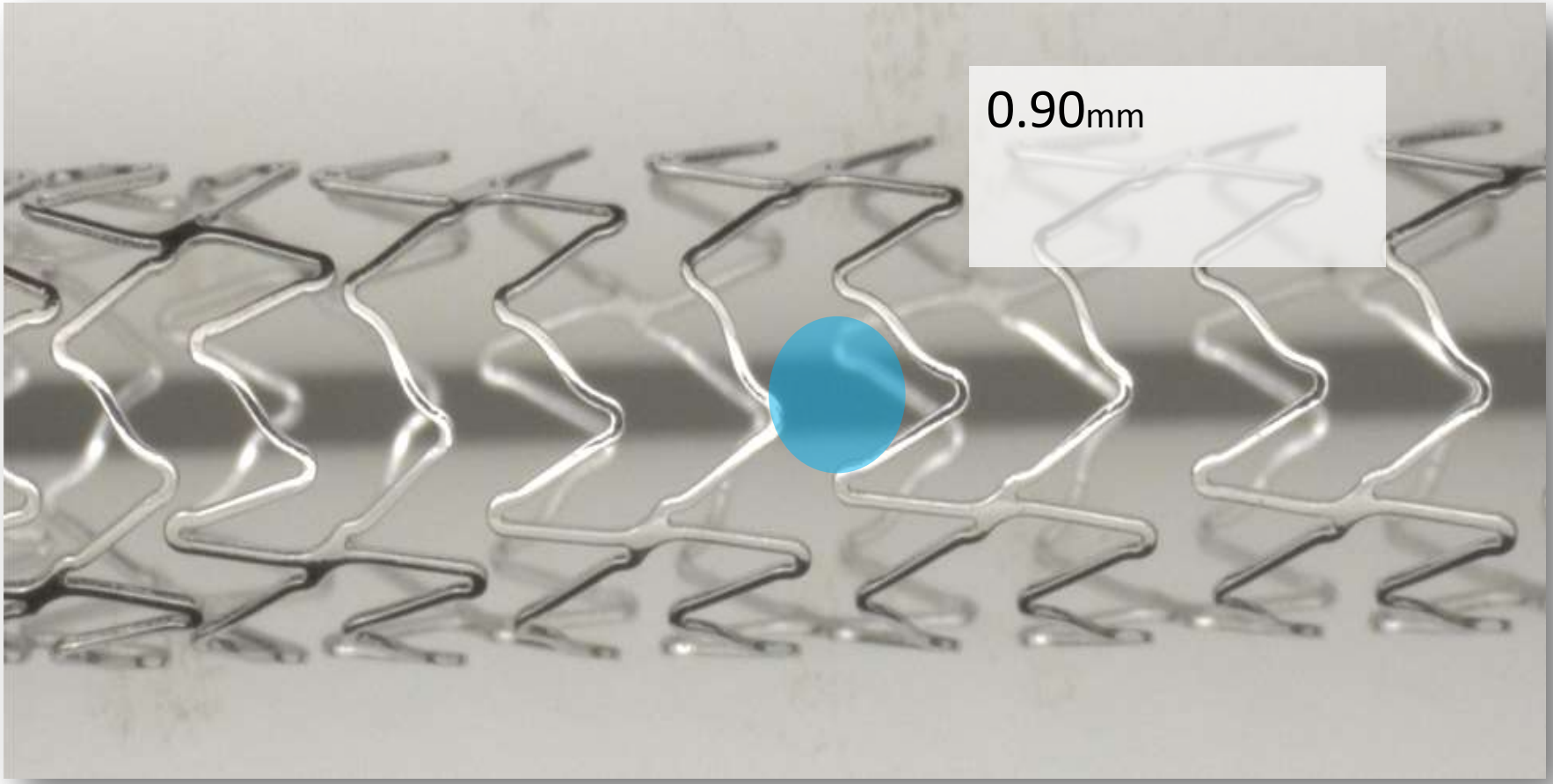
# Ultimaster employs gradient coating technology

- No cracking or peeling even after over expansion



# Side branch access (3.0mm NP)

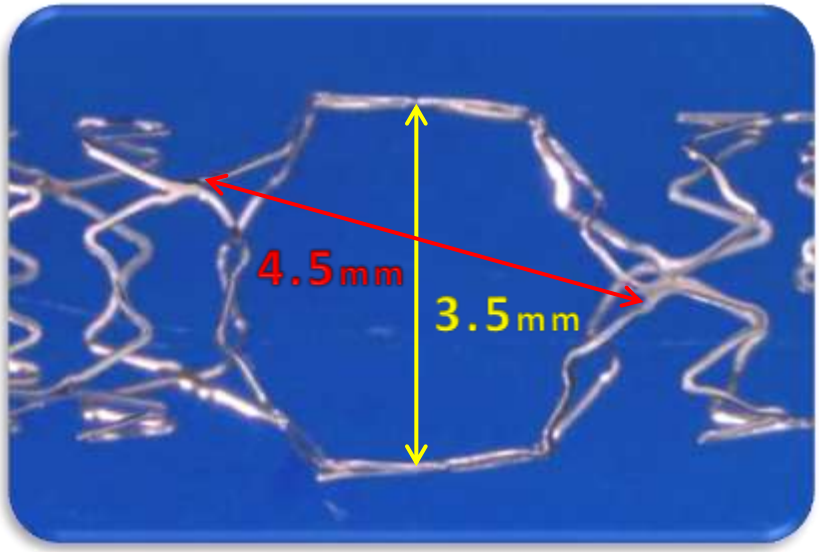
Ultimaster™



# Side branch expansion

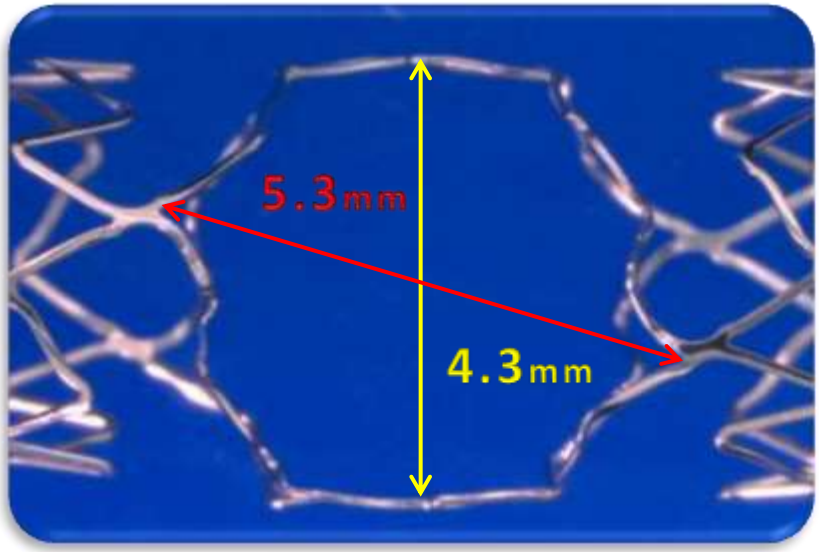
**Test method**
Expand a cell with a balloon
at Nominal Pressure

2.25mm - 3.0mm




Hiryu ϕ4.0mm NP

3.5mm - 4.0mm




Hiryu ϕ5.0mm NP

Internal test result

# CENTURY II – Study devices

| | 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 3-4 M** | PVDF-HFP non-erodable fluorinated copolymer |
| Coating | **Abluminal gradient coating technology** | Circumferential coating |
| Drug | **sirolimus**<br>70 µg/cm² | everolimus<br>100 µg/cm² |

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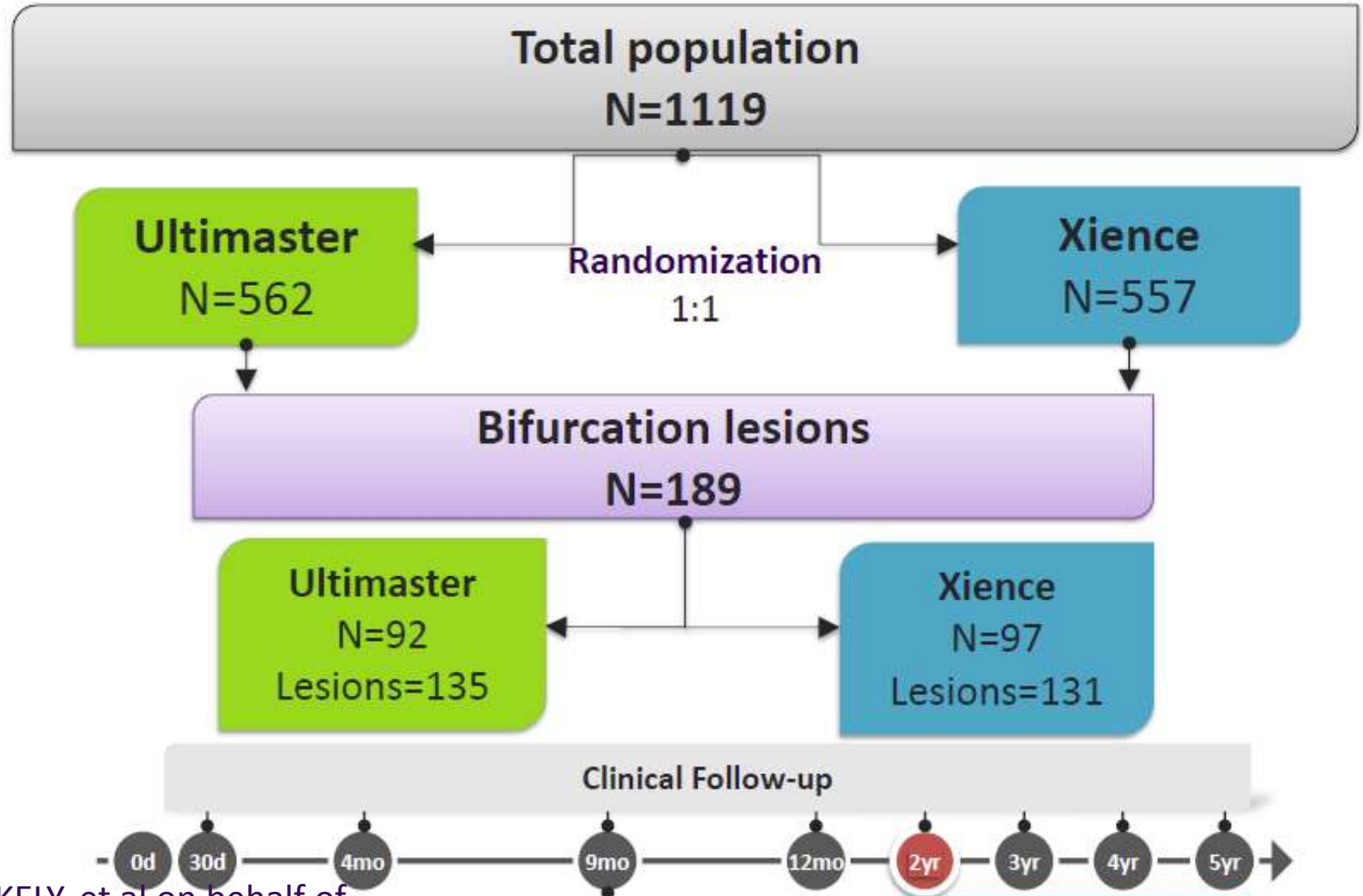
# CENTURY II study
# Bifurcation lesions

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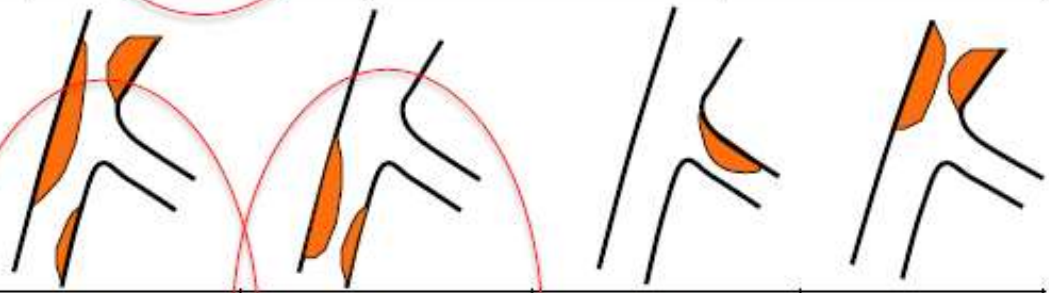
# CENTURY II Bifurcation lesions
# Medina classification

| | 1,1,1 | 1,0,1 | 0,1,1 |
|---|---|---|---|
| Ultimaster (%) | 23.5 | 4.1 | 13.3 |
| Xience | 19.4 | 11.7 | 6.8 |

P=0.89



| | 1,1,0 | 0,1,0 | 0,0,1 | 1,0,0 |
|---|---|---|---|---|
| Ultimaster (%) | 30.6 | 15.3 | 3.1 | 10.2 |
| Xience | 30.1 | 15.5 | 1.9 | 14.6 |

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# CENTURY II Bifurcation lesions
## Bifurcation treatment

| | Ultimaster ($N_{lesions}$=135) | Xience ($N_{lesions}$=131) | P |
|---|---|---|---|
| **Two-stent technique, %** | 6.8 | 7.6 | 1.00 |
| T-Stenting | 1.0 | 2.8 | 0.62 |
| V-Stenting | 1.0 | 0.0 | 0.49 |
| TAP | 2.0 | 1.0 | 0.61 |
| Crush | 2.0 | 1.9 | 1.00 |
| Culottes | 1.0 | 1.9 | 1.00 |
| **Stent in MB, balloon in SB,%** | 45.0 | 48.6 | 0.68 |
| **Only MB stenting,%** | 48.0 | 43.8 | 0.58 |
| **Kissing Balloon post-stent, %** | 50.0 | 50.5 | 0.94 |

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# CENTURY II – bifurcation lesions
# Clinical outcomes at 2 years

| | Ultimaster (N=92 pts) | Xience (N=97 pts) | P |
|---|---|---|---|
| Angina, % | 5.8 | 4.6 | 0.72 |
| Any hospitalization from 0-1 year, % | 23.9 | 33.0 | 0.17 |
| - Hospitalization for angina, % | 6.5 | 12.4 | 0.17 |
| Any hospitalization from 1-2 year, % | 15.2 | 10.3 | 0.31 |
| - Hospitalization for angina, % | 7.6 | 5.2 | 0.49 |
| DAPT, % | 24.1 | 34.1 | 0.15 |
| Bleeding, any % | 9.8 | 8.3 | 0.71 |

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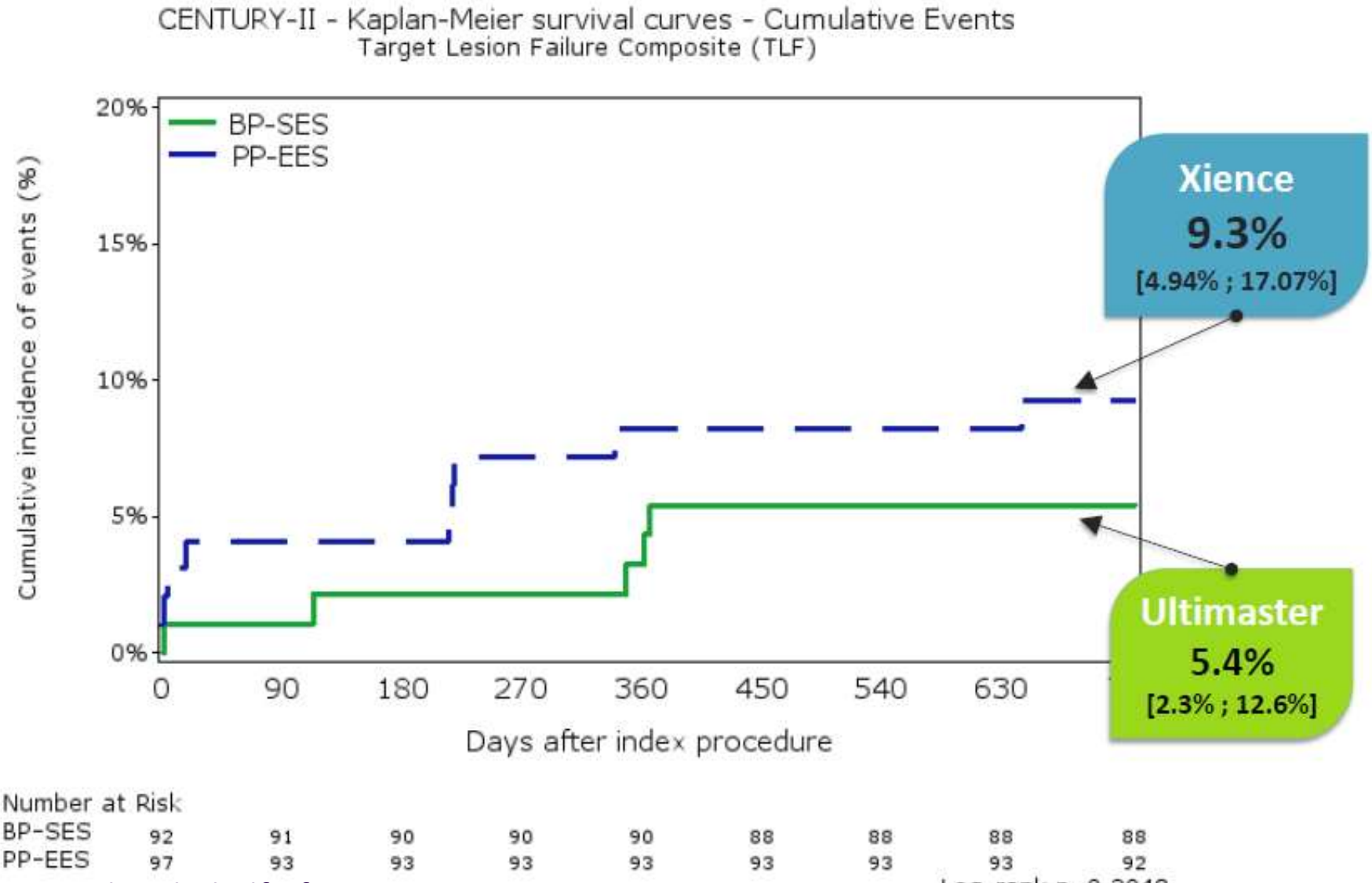
# CENTURY II Bifurcation lesions
# Target Lesion Failure at 24 months

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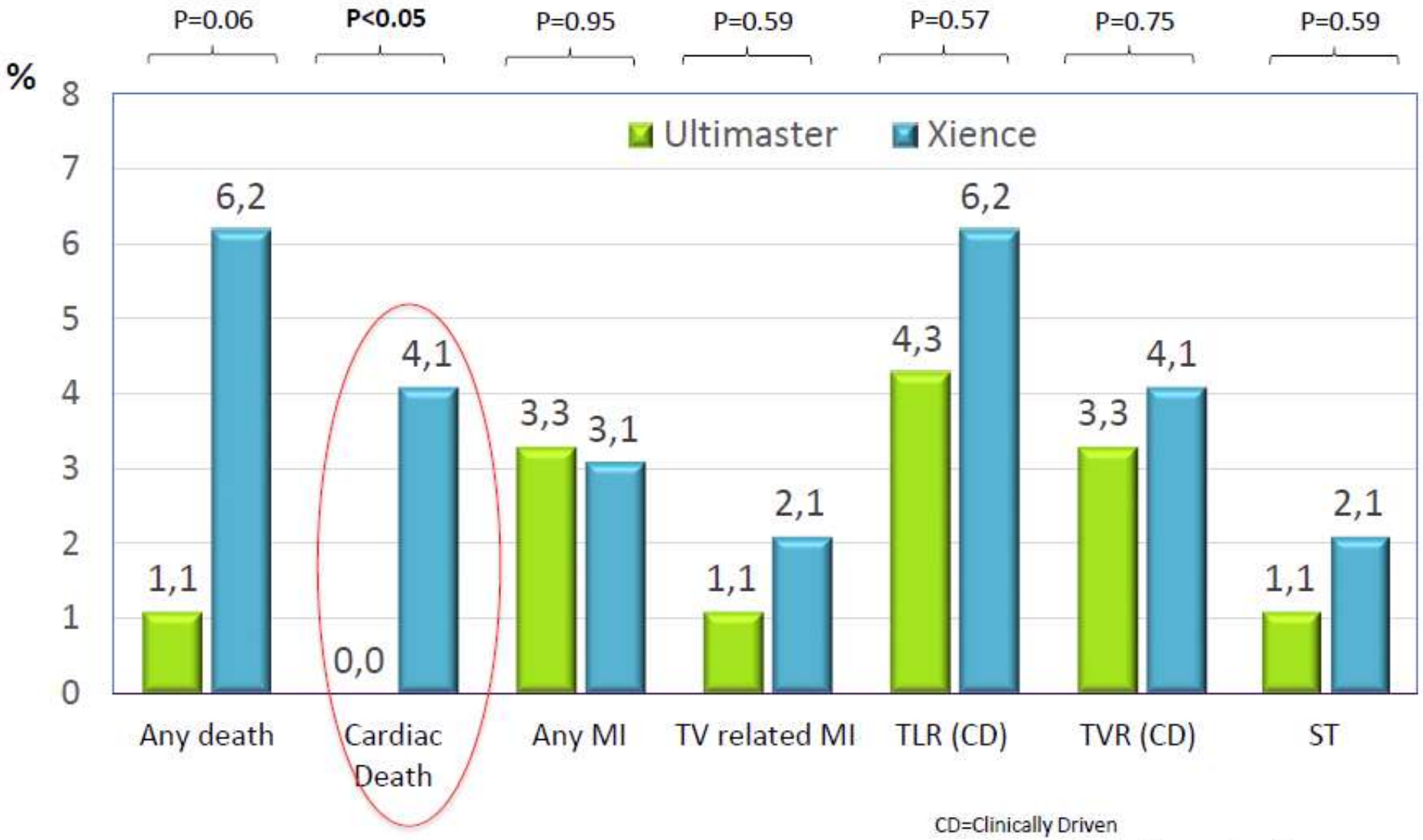
# CENTURY II Bifurcation lesions
# Clinical outcomes – 24 months FU




CD=Clinically Driven

ST=Definite and probable stent thrombosis

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Ultimaster

Drug-Eluting Stent

# Ultimaster – Easiest Stent To Use

- Bio-Egronomic Stent Design with Excellent Delivery System
- Thin Strut: 80μm
- Abluminal Gradient Coating
- 3-4 Month Polymer-Drug Bioresorbtion
- CENTURY & CENTRUY II Studies
- Suitable For All Complex Cases Especially Complex Bifurcation

# Thank You