

Addressing the challenge of bifurcation with Ultimaster DES



Choosing the right stent for bifurcation PCI

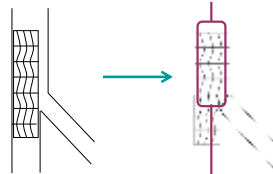
Consider the bifurcation **anatomy**

- Diameters
- Angles
- Plaque distribution (but beware limitations of 2D imaging)

Important to include anatomy + overall patient status in strategy-making process

Consider the required **techniques**

- Permanent DES are recommended
- Focus on optimal stenting of main branch first
- Size according to distal main vessel, with expansion to proximal segment (POT)



Key features: Ultimaster®

- Stent deliverability
- Vascular repair
- Challenging cases
- Multiple CE marked indications

Bio-inspired stent design

Hydrophilic coating on delivery system

Smooth balloon-stent transition

Low-entry profile

Ultimaster®

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Data on file at Terumo Corporation (Doc nr. Des08-T). 3

Key features: Ultimaster®

- Stent deliverability
- Vascular repair
- Challenging cases
- Multiple CE marked indications

No drug coating on parts of the stent that experience the most physical stress, preventing cracking and delamination

80 µm CoCr struts

Sirolimus 3.9 µg/mm stent

PDLLA-PCL polymer resorption time 3-4 months

Drug release kinetics match the biological response

Stent

Ultimaster®

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PDLLA-PCL, poly(D,L-lactide-co-caprolactone) copolymer. Data on file at Terumo Corporation (Doc nr. Des08-T). 4

Key features: Ultimaster®

Ultimaster®

- Stent deliverability
- Vascular repair
- Challenging cases
- Multiple CE marked indications

- Allows overexpansion
- Gradient coating for polymer integrity
- 2-link design for excellent side-branch access

Diameters from 2.25 mm to 4.00 mm

Lengths from 9 mm to 38 mm

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Data on file at Terumo Corporation (Doc nr. Des08-T). 5

Key features: Ultimaster®

Ultimaster®

- Stent deliverability
- Vascular repair
- Challenging cases
- Multiple CE marked indications

The wealth of data for Ultimaster® has been recognised with a remarkable **16 CE mark** approved indications, including **bifurcation**

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CE approval was received on February 3, 2017; The IFU will be updated to reflect the specified indications. 6

Designed for optimal outcomes in the treatment of bifurcation lesions

Ultimaster®

Excellent side-branch access

Uniform scaffolding

Radial strength

Overexpansion capacity

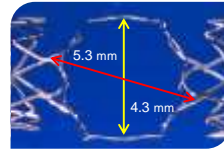
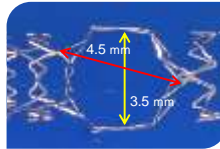
Polymer integrity

Trial data

Open-cell, 2-link design for excellent side-branch access

Φ2.25–3.0 mm

Φ3.5–4.0 mm



NC balloon catheter
Φ4.0 mm, NP
Area: 9.62 mm²

NC balloon catheter
Φ5.0 mm, NP
Area: 14.5 mm²



NP, nominal pressure; NC, non compliant
Test method: expand a cell with a balloon at nominal pressure. Φ, diameter.
Tests performed by, and data on file at, Terumo Corporation (Doc nr. SideBr03-T).

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Large stent cell size, and wide opening of side-branch cells

3,5 mm	Ultimaster	Xience	Synergy	Resolute Onyx	BioMatrix Alpha	Orsiro
Stent design						
Side-branch access (cell length)	21.5 mm	16.1 mm	14.7 mm	15.2 mm	13.8 mm	11.7 mm




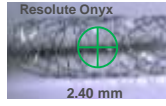
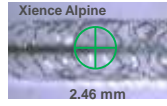
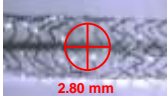
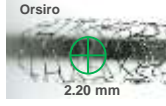
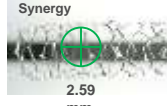
Data on file at Terumo Corporation


Designed for optimal outcomes in the treatment of bifurcation lesions

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- Trial data

Large expanded side-branch diameter after kissing balloon technique

 2.80 mm	 2.40 mm	 2.46 mm
	 2.20 mm	 2.59 mm



Cell expansion image after kissing balloon technique with 3.5 mm balloon
 Data on file at Terumo Corporation

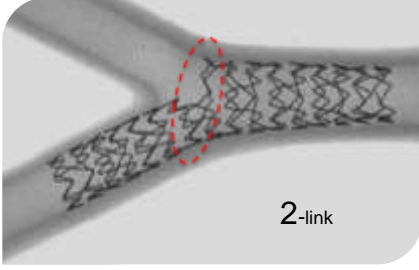
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Designed for optimal outcomes in the treatment of bifurcation lesions


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- Trial data

Uniform scaffolding for optimal coverage of bifurcation anatomy



2-link



Tests performed by, and data on file at, Terumo Corporation (Doc nr. SideBr03-T).

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Designed for optimal outcomes in the treatment of bifurcation lesions

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Uniform scaffolding

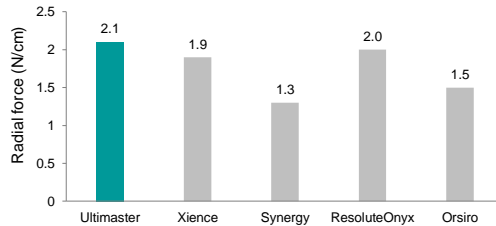
Radial strength

Overexpansion capacity

Polymer integrity

Trial data

Bench-tests highlight the high radial force achieved with Ultimaster



Tests performed by, and data on file at, Terumo Corporation (Doc nr. RadStr04-T). 11

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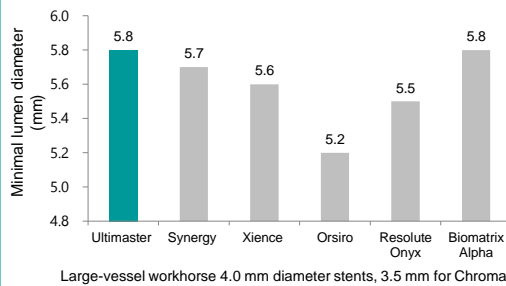
Radial strength

Overexpansion capacity

Polymer integrity

Trial data

Expansion capacity up to 5.8 mm
Results of independently initiated study



Samples of different stent sizes/models were deployed in vitro at nominal pressure. Subsequently, overexpansion for each design was tested with successive post-dilations using, first a 5.0x12 mm non compliant balloon followed by a 6.0x15 mm semi-compliant balloon with a pressure of 14 atm for the largest designs. Ng J et al. Int J Cardiol 2016;221:171-9. 12

Designed for optimal outcomes in the treatment of bifurcation lesions

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Uniform scaffolding

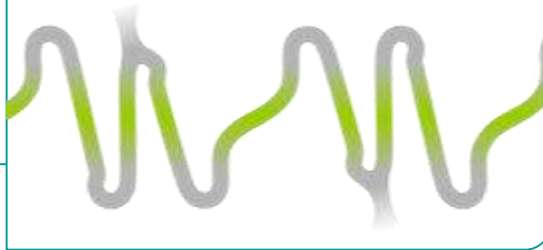
Radial strength

Overexpansion capacity

Polymer integrity

Trial data

Gradient coating ensures polymer integrity for reduced risk of delamination, even when overexpanded



Saito N et al. Med Devices 2016;9:33-43. 13

Designed for optimal outcomes in the treatment of bifurcation lesions

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Polymer integrity

Trial data

Two main studies supporting benefits of Ultimaster® in bifurcation lesions

CENTURY II¹
Randomised controlled trial

Ultimaster® vs Xience

194 patients with bifurcation lesions

e-Ultimaster²
Real-world registry

Pre-specified bifurcation substudy:
788 patients at 1-year follow-up



1. Kornowski R. Presented at EuroPCR 2017, abstract OP0707; 2. Monsegu J et al. Presented at EuroPCR 2017, abstract OP0758. 14

Designed for optimal outcomes in the treatment of bifurcation lesions

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Excellent side-branch access

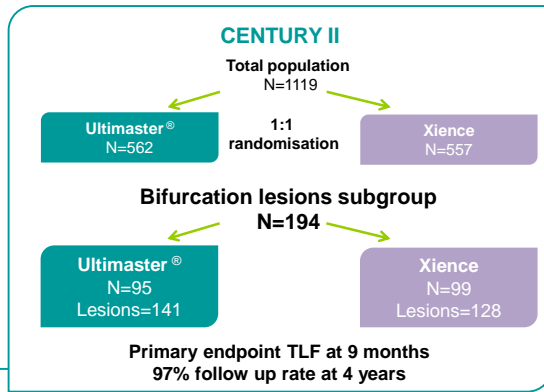
Uniform scaffolding

Radial strength

Overexpansion capacity

Polymer integrity

Trial data



TLF, target lesion failure.
Kornowski R. Presented at EuroPCR 2017, abstract OP0707. 15

Designed for optimal outcomes in the treatment of bifurcation lesions

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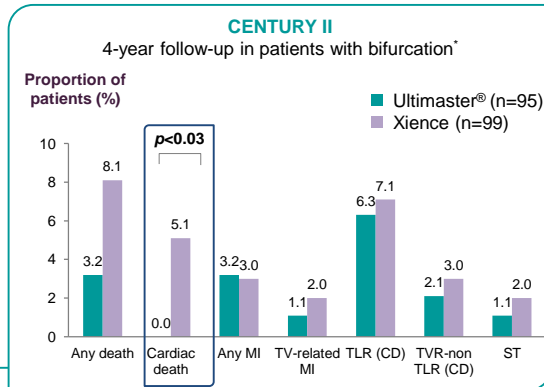
Uniform scaffolding

Radial strength

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Polymer integrity

Trial data



*All p values except for cardiac death were non significant.
CD, clinically driven; MI, myocardial infarction; ST, stent thrombosis; TLR, target lesion revascularisation; TVR, target vessel revascularisation.
Kornowski R. Presented at EuroPCR 2017, abstract OP0707. 16

Designed for optimal outcomes in the treatment of bifurcation lesions

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Polymer integrity

Trial data

CENTURY II

4-year follow-up in patients with bifurcation

Target lesion failure was low up to 4 years for patients with:

Bifurcation	True bifurcation*
<div style="background-color: #9966cc; color: white; padding: 5px; margin-bottom: 5px;"> Xiience (n=99) 11.11% (95% CI: 5.68 to 19.01%) </div> <div style="background-color: #008080; color: white; padding: 5px;"> Ultimaster® (n=95) 7.37% (95% CI: 3.01 to 14.59%) </div>	<div style="background-color: #9966cc; color: white; padding: 5px; margin-bottom: 5px;"> Xiience (n=36) 13.89% (95% CI: 4.67 to 29.50%) </div> <div style="background-color: #008080; color: white; padding: 5px;"> Ultimaster® (n=40) 2.50% (95% CI: 0.06 to 13.16%) </div>
<i>Log rank p=0.36</i>	<i>p=0.07</i>

*Classified as Medina 1.1.1, 1.0.1, or 0.1.1.
 Kornowski R. Presented at EuroPCR 2017, abstract OP0707.

Designed for optimal outcomes in the treatment of bifurcation lesions

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Excellent side-branch access

Uniform scaffolding

Radial strength

Overexpansion capacity

Polymer integrity

Trial data

e-Ultimaster

312 centres in 4 continents
20 000 patients enrolled (ongoing)

↓

First interim analysis
1-year follow-up (or death)
N=5468

↓

Bifurcation lesion treated
N=788

'True' bifurcations*
N=395

*Classified as Medina 1.1.1, 1.0.1, or 0.1.1.
 Monsegu J et al. Presented at EuroPCR 2017, abstract OP0758.

Designed for optimal outcomes in the treatment of bifurcation lesions

Ultimaster®

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Uniform scaffolding

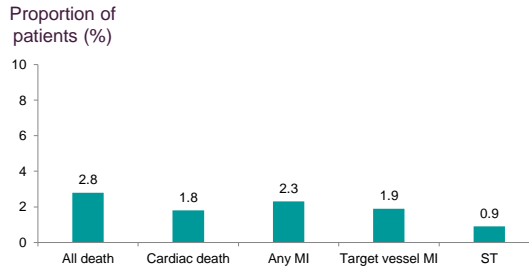
Radial strength

Overexpansion capacity

Polymer integrity

Trial data

e-ULTIMASTER interim analysis
1 year **safety** outcomes in patients with bifurcation (n=788)



Monségu J. Presented at EuroPCR 2017, abstract OP0758. 19

Designed for optimal outcomes in the treatment of bifurcation lesions

Ultimaster®

Excellent side-branch access

Uniform scaffolding

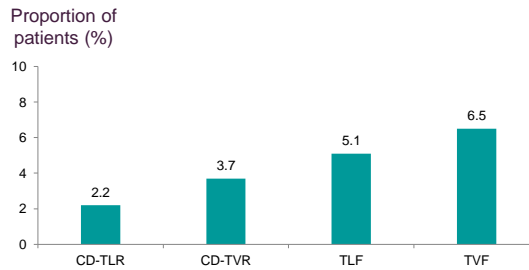
Radial strength

Overexpansion capacity

Polymer integrity

Trial data

e-ULTIMASTER interim analysis
1 year **efficacy** outcomes in patients with bifurcation (n=788)



Monségu J. Presented at EuroPCR 2017, abstract OP0758. 20

Designed for optimal outcomes in the treatment of bifurcation lesions

Ultimaster®

Excellent side-branch access

Uniform scaffolding

Radial strength

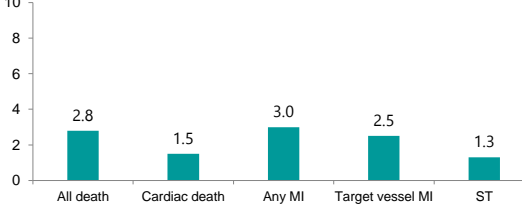
Overexpansion capacity

Polymer integrity

Trial data

e-ULTIMASTER interim analysis
1 year **safety** outcomes in patients with **true** bifurcation* (n=395)

Proportion of patients (%)



*Classified as Medina 1.1.1, 1.0.1, or 0.1.1.
Monségu J. Presented at EuroPCR 2017, abstract OP0758. 21

Designed for optimal outcomes in the treatment of bifurcation lesions

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Excellent side-branch access

Uniform scaffolding

Radial strength

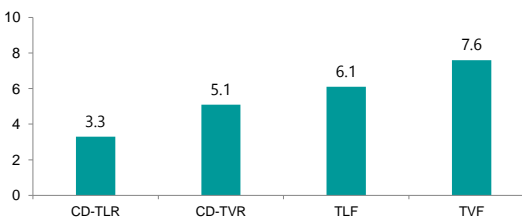
Overexpansion capacity

Polymer integrity

Trial data

e-ULTIMASTER interim analysis
1 year **efficacy** outcomes in patients with **true** bifurcation* (n=395)

Proportion of patients (%)



*Classified as Medina 1.1.1, 1.0.1, or 0.1.1.
Monségu J. Presented at EuroPCR 2017, abstract OP0758. 22

Designed for optimal outcomes in the treatment of bifurcation lesions

Ultimaster®

- Excellent side-branch access
- Uniform scaffolding
- Radial strength
- Overexpansion capacity
- Polymer integrity
- Trial data**

Consistent results supporting benefits of Ultimaster®

CENTURY II¹
Randomised controlled trial
4-year follow-up

e-Ultimaster²
Real-world registry
1-year follow-up

Ultimaster is an **effective option with a good safety profile** in the treatment of bifurcation lesions

Ultimaster showed excellent results in **true bifurcations**, despite the technically and clinically challenging nature of these lesions

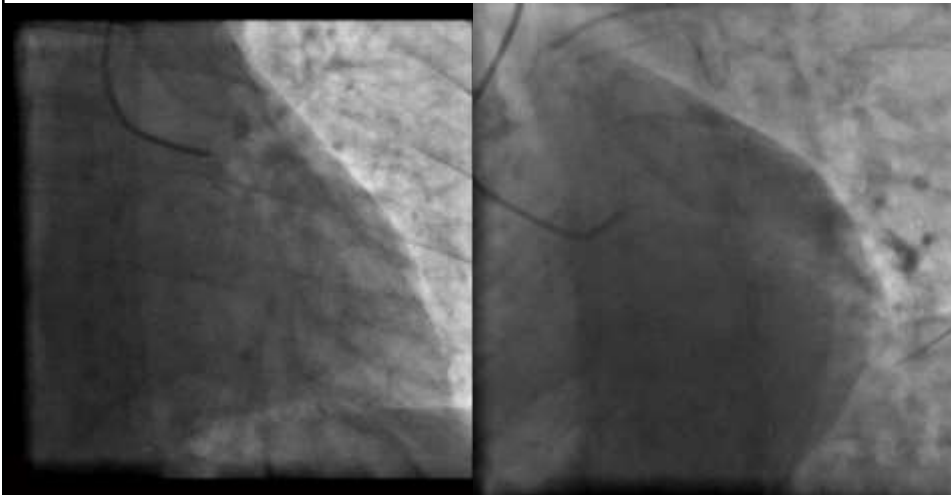
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1. Kornowski R. Presented at EuroPCR 2017, abstract OP0707; 2. Monsegu J et al. Presented at EuroPCR 2017, abstract OP0758. 23

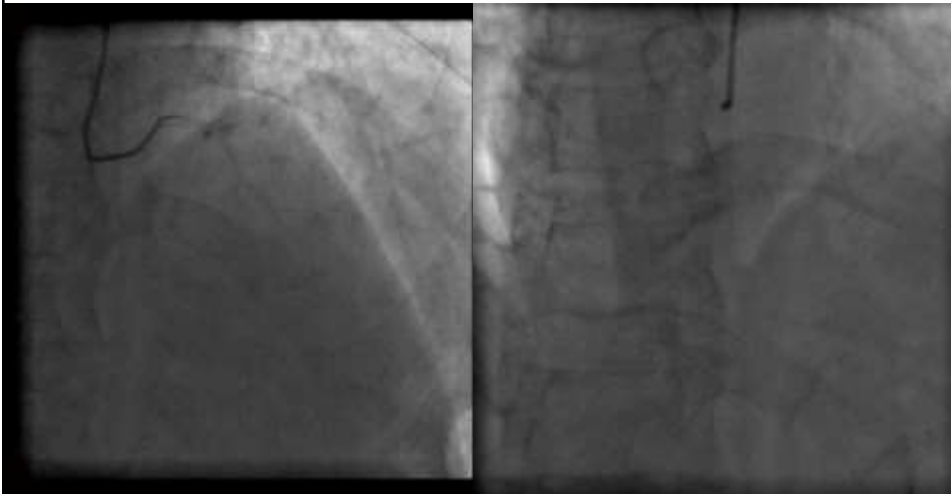
CASE

- **64 year old male**
- **Presented with unstable angina with ST changes at the lateral wall**
- **Risk factors: Hypertension, Dyslipidemia, Type 2 Diabetes Mellitus**
- **No past medial history**

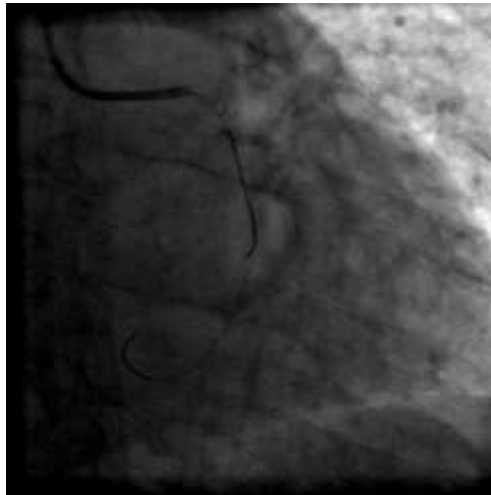
Diagnostic coronary angiography



Diagnostic coronary angiography

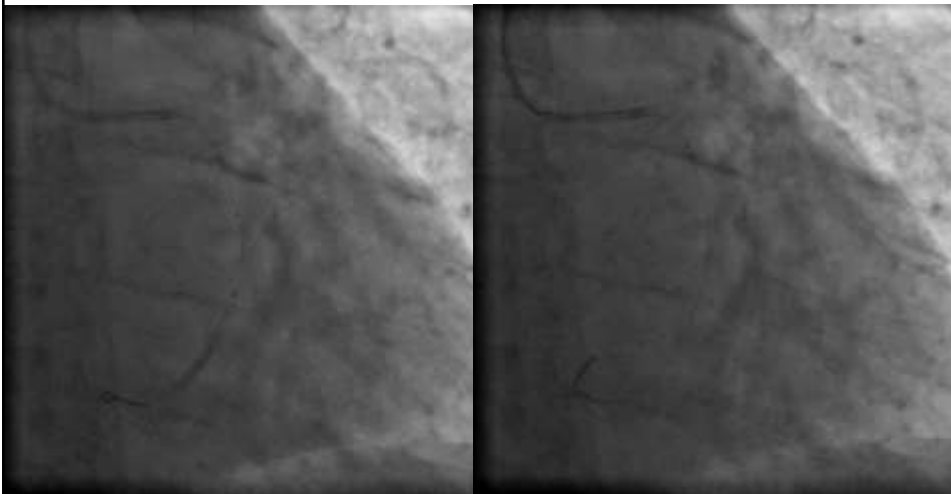


**LCX ATTEMPTED FIRST....
INABILITY TO CROSS THE BRANCH**



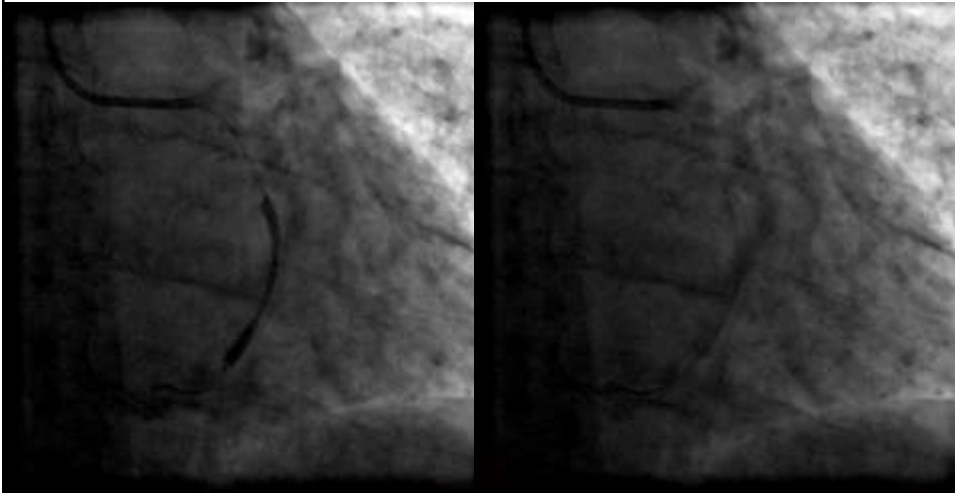
Pre-dilatation

SB occlusion



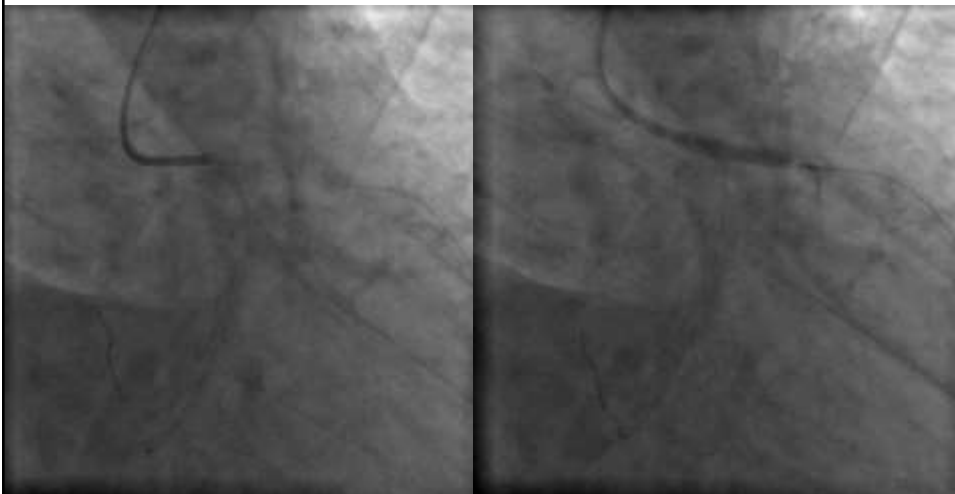
Balloon 2.0 x 20 mm

STENT IMPLANTATION

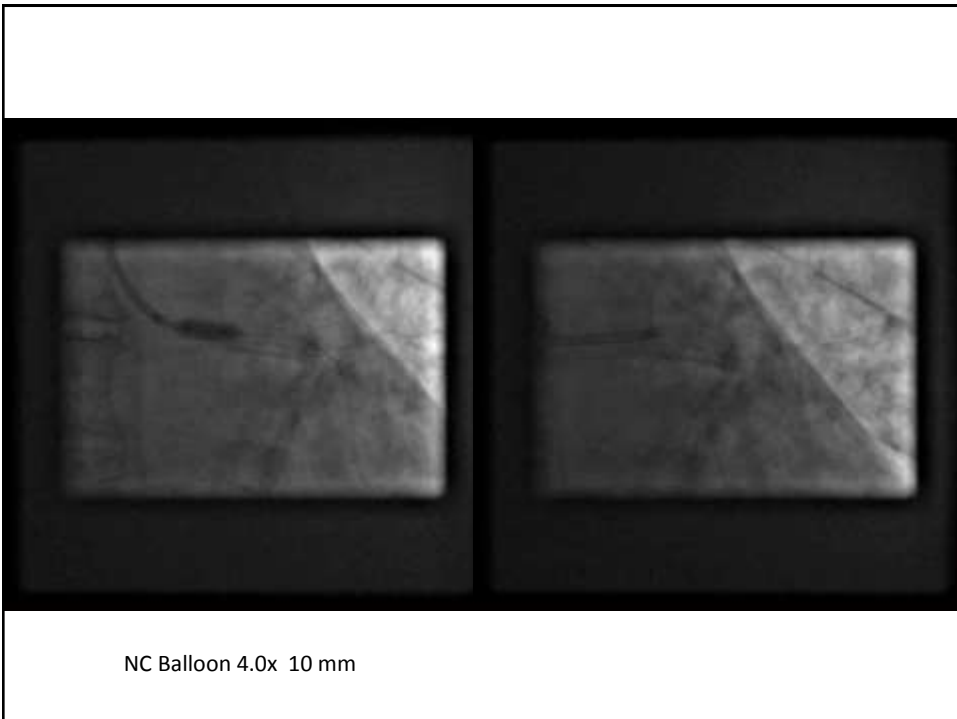
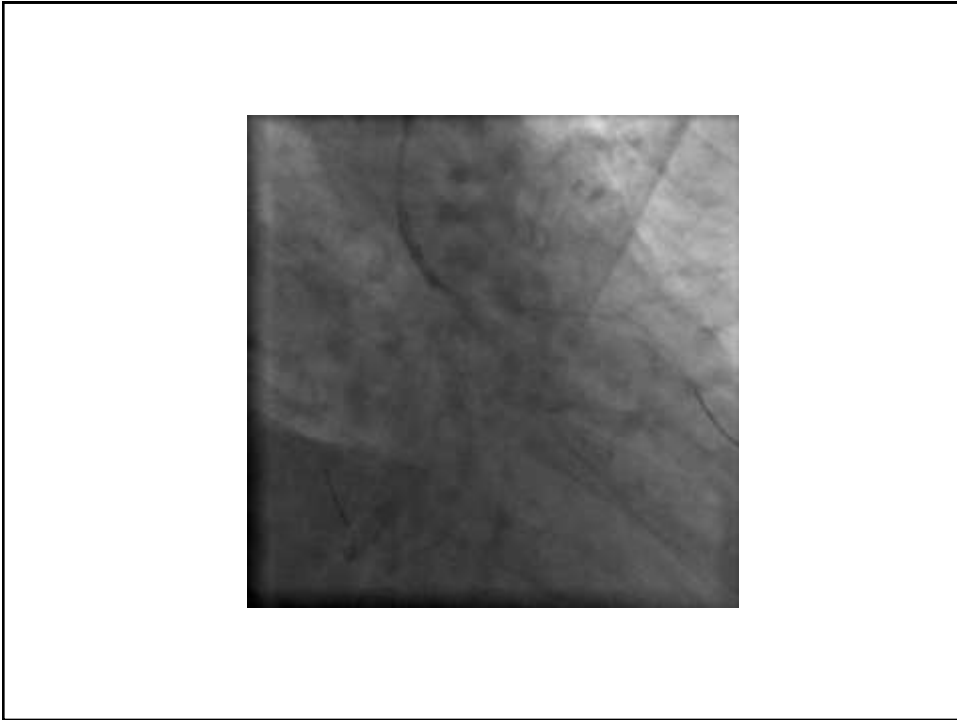


UM 3,0 x 38 mm

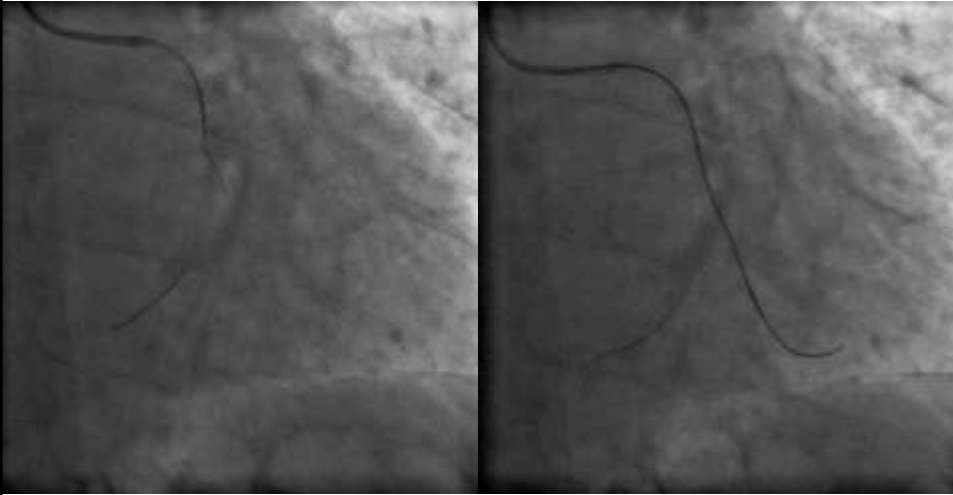
LM treatment; provisional stenting



UM 3,5 x 18 mm



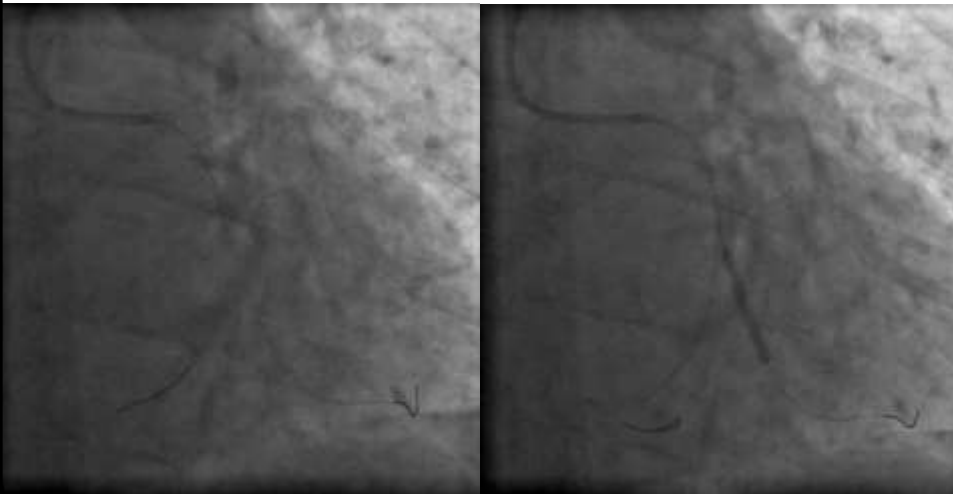
BRANCH RECROSSING



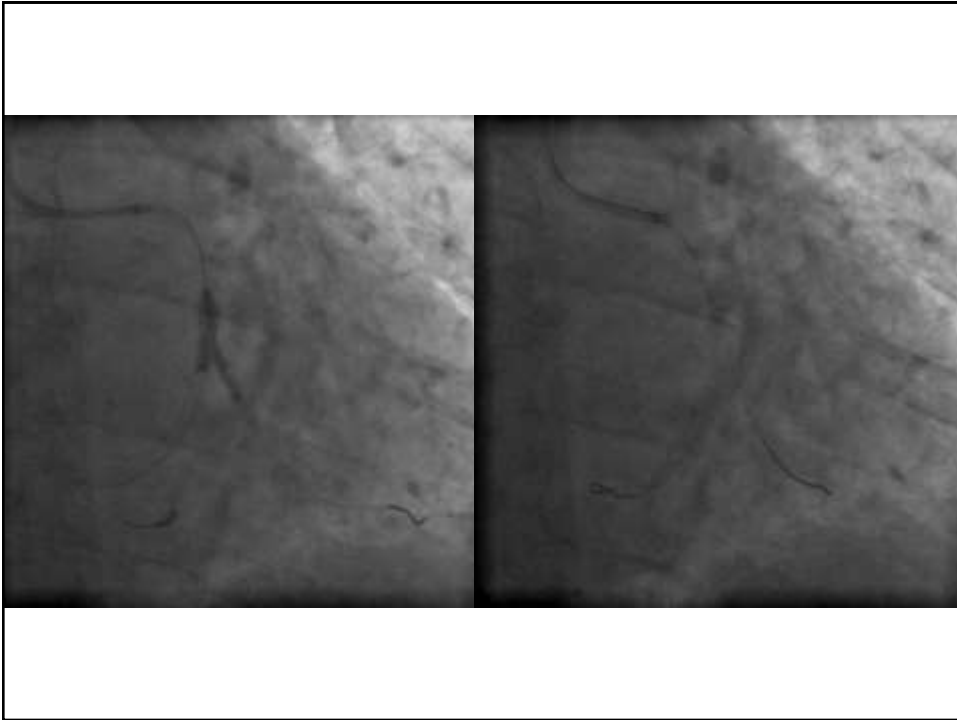
FIELDER FC

MIRACLE ULTIMATE

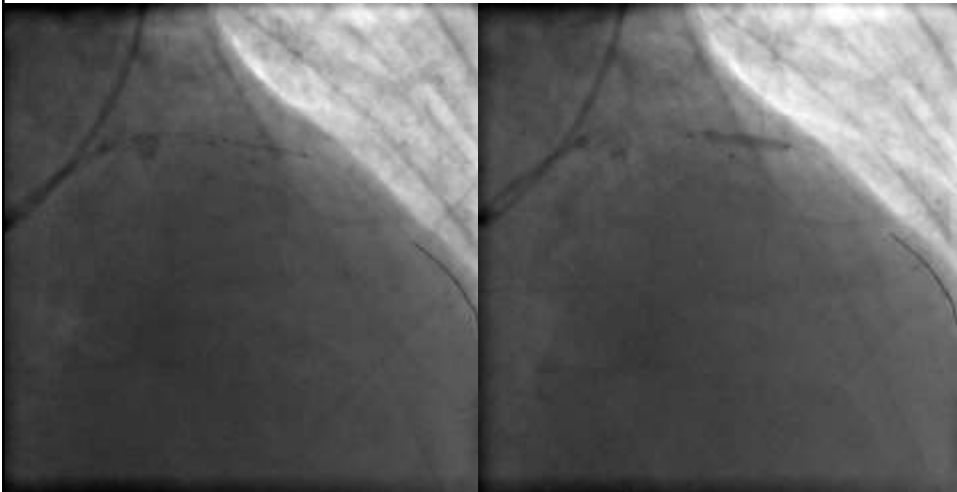
TAP TECHNIQUE



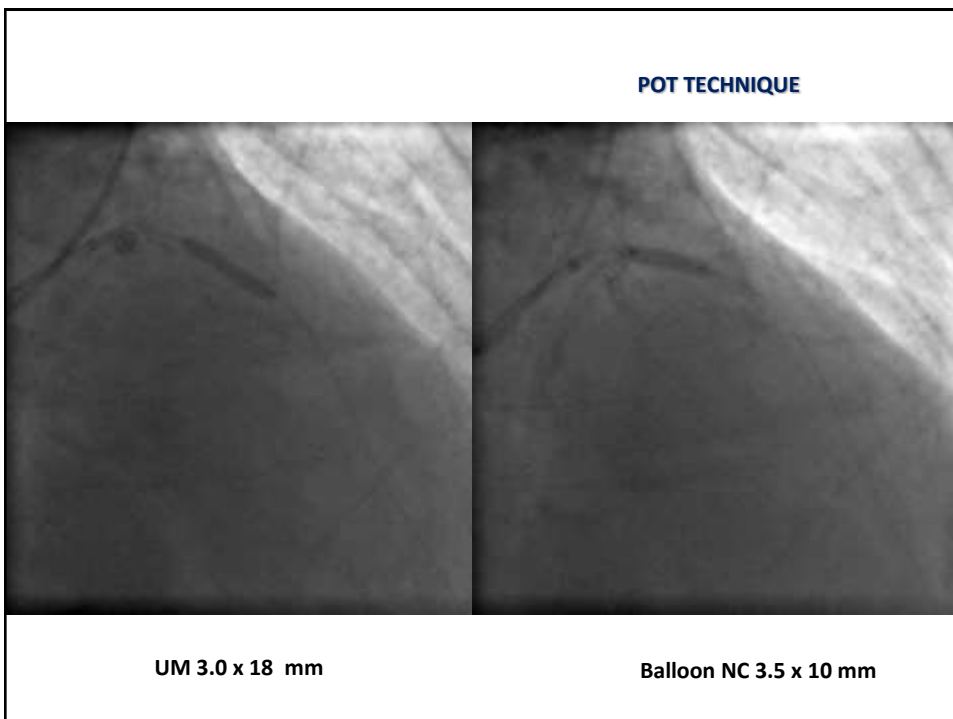
UM 2,5 x 24 mm



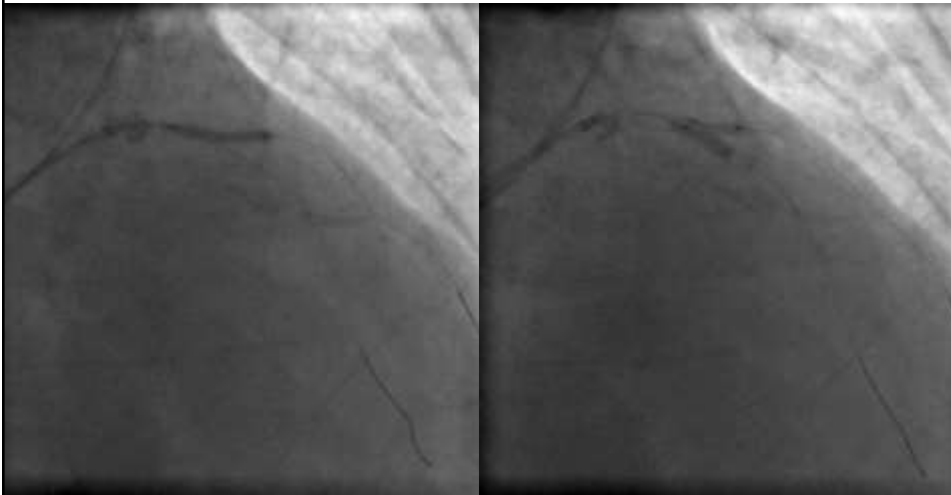
**LAD/D1 treatment
Mini-crush technique**



UM 2,5 x 15 mm



FINAL KISS



Balloon NC 2.5 x 10 mm D1
Balloon NC 3.5 x 10 mm D1

FINAL RESULT



A CASE OF THREE BIFURCATIONS

LM : PROVISIONAL STENTING DIRECTION LAD

LCX-OM: TAP TECHNIQUE

LAD-D1: MINI CRUSH TECHNIQUE