

ASAHI Product

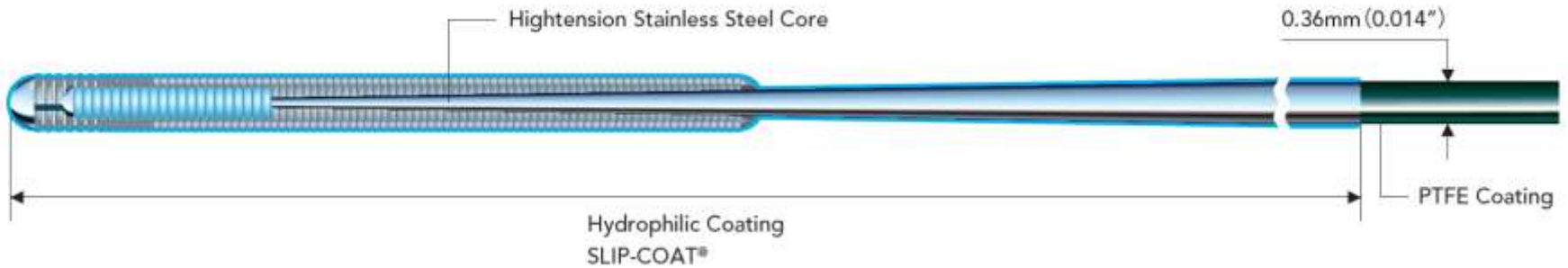
Concept and Usage

Satoru Otsuji, MD.



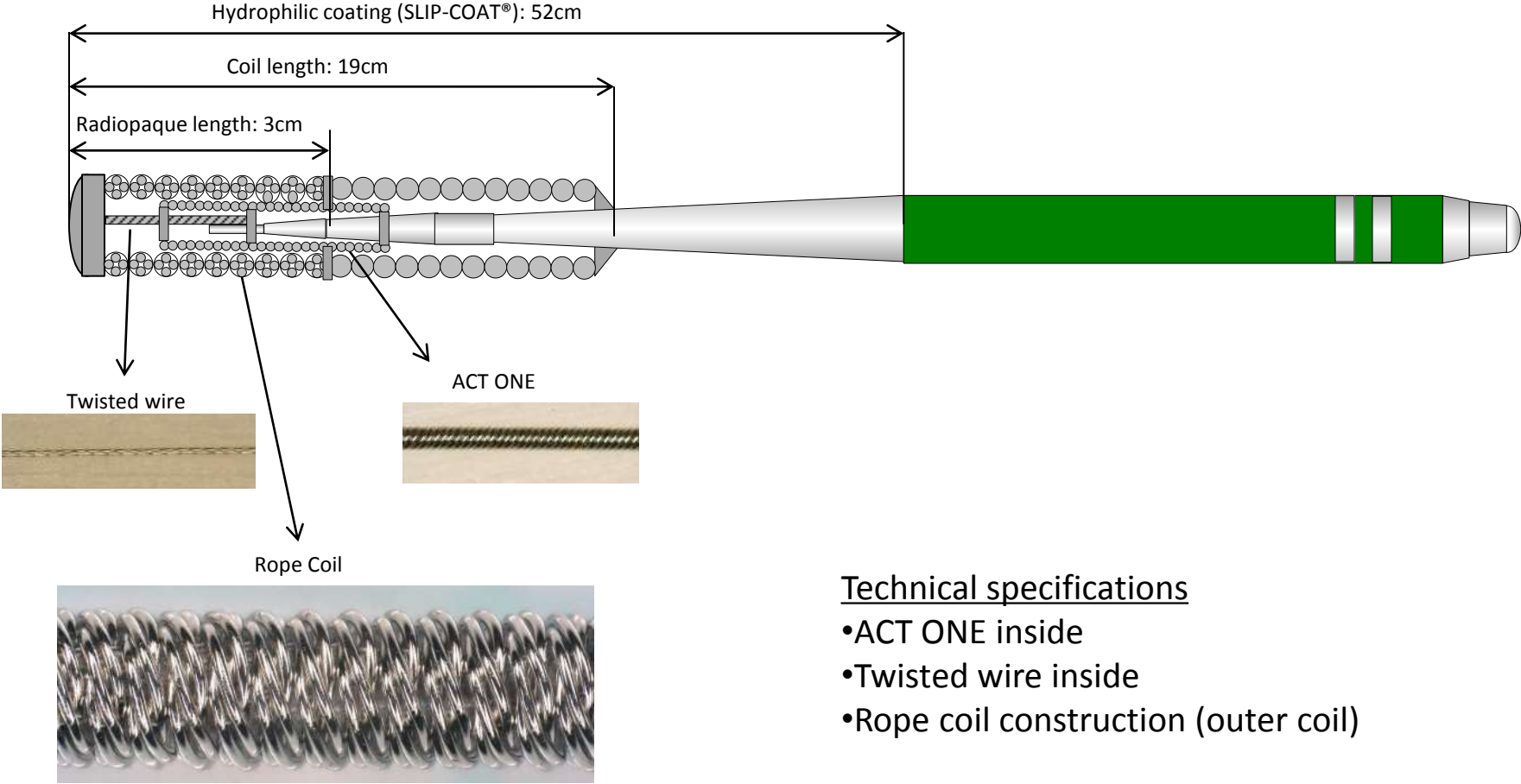
Higashi Takarazuka Satoh Hospital
Japan

SUOH 03



- Usable length : 190cm/300cm
- Hydrophilic coating length : 52cm
- Coil length : 19cm
- Radiopaque length : 3cm
- Tip Load : 0.3gf
- Tip Shape : Straight/ Pre-shape

SUOH 03



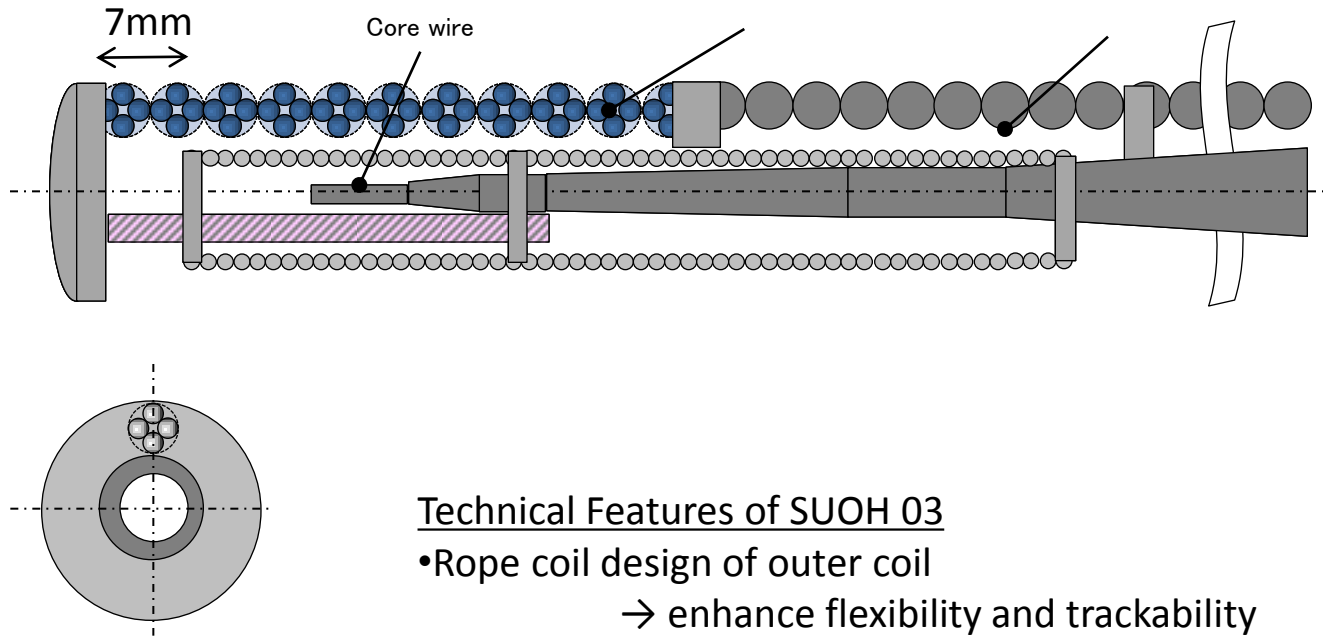
Technical specifications

- ACT ONE inside
- Twisted wire inside
- Rope coil construction (outer coil)

Coated with SLIP-COAT® coating.

*This illustrates image of Rope coil design. Not indicate real product design.

SUOH 03



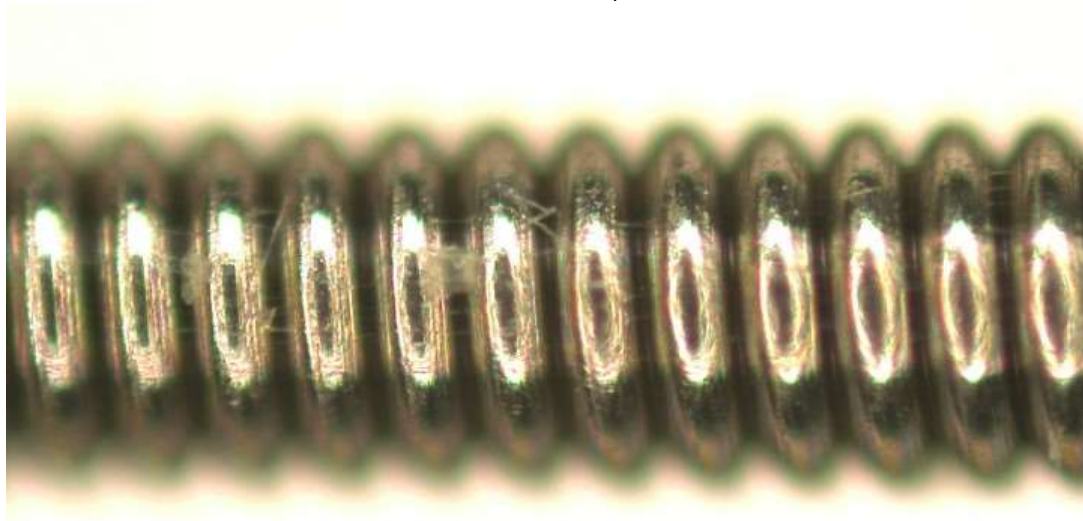
Technical Features of SUOH 03

- Rope coil design of outer coil
→ enhance flexibility and trackability
- 7mm very distal tip is neither core wire nor ACT ONE
→ enhance flexibility and in order for 0.3gf tip load
- Twisted wire extended to ball tip
→ enhance flexibility, high tensile strength

SUOH 03



ASAHI SUOH 03's Rope coil

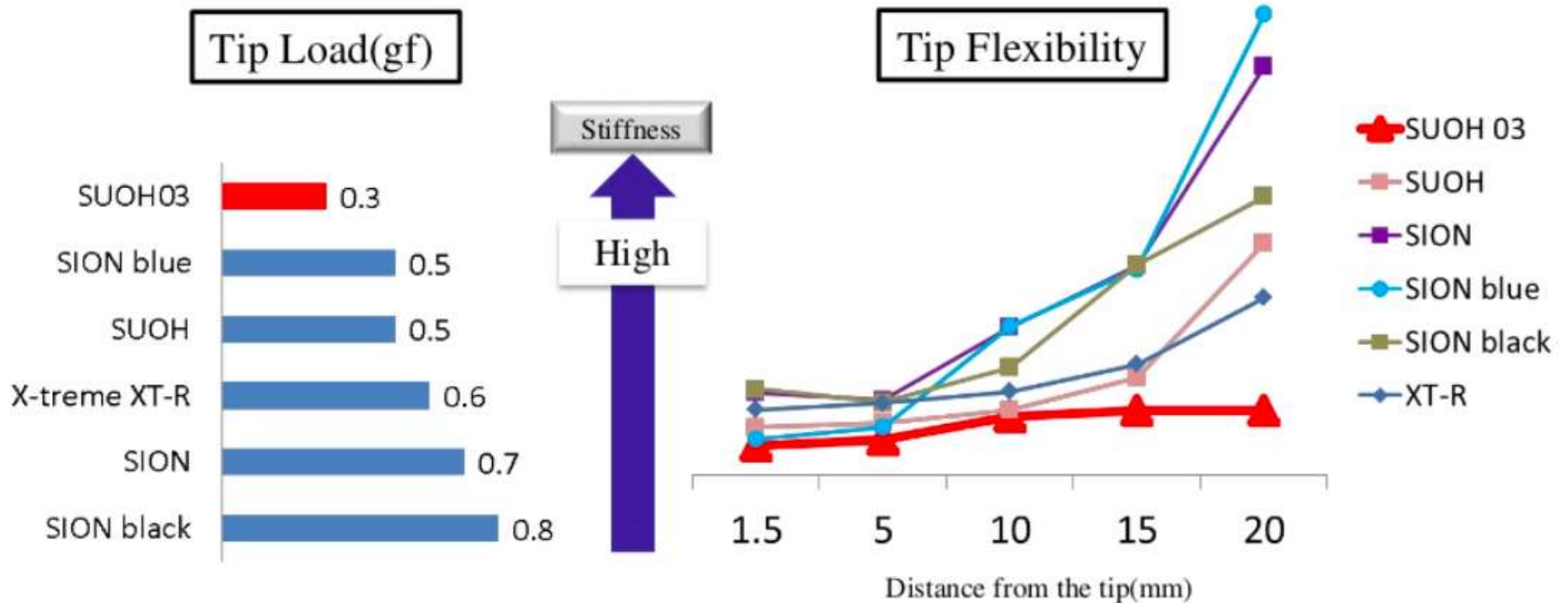
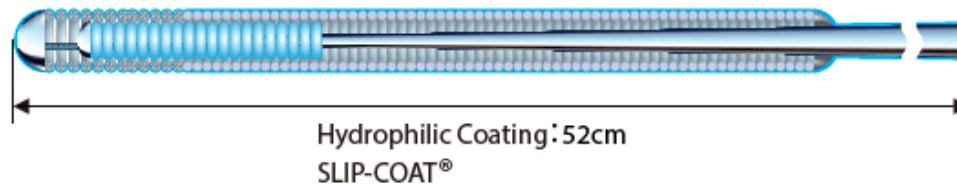


ASAHI's Conventional Coil

SUOH 03

SUOH03 is a **very flexible** wire, flexibility maintained from tip to its proximal part.

It facilitates to cross the small bended vessel by using its increased flexibility and track-ability.



Retrograde summit registry data 2012-2014



Case enrollment : 4,472 CTO-PCIs



122 cases were excluded due to insufficient case card information

Final subject for analysis:
4,350 CTO-PCIs

	Total	2012	2013	2014
CTO-PCIs	4,350	1,553	1,676	1,121
- Ante group	3,021	1,063	1,138	820
- Retro group	1,329 (31%)	490 (32%)	538 (32%)	301 (27%)

Retrograde procedure outcome



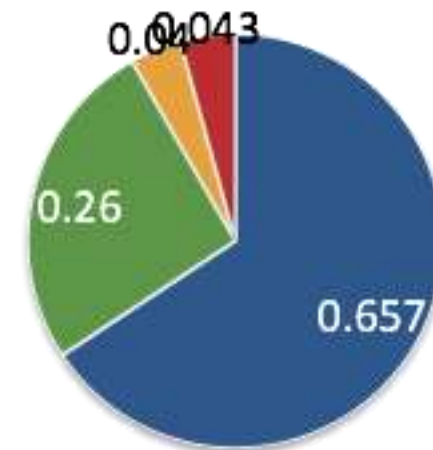
Retrograde procedure success

Retro group	Total (1329)	2012 (490)	2013 (538)	2014 (301)	P
<i>Retro overall</i>	69% (917)	69% (344)	66% (363)	68% (210)	0.0218

Reason of retrograde procedure failure (412)

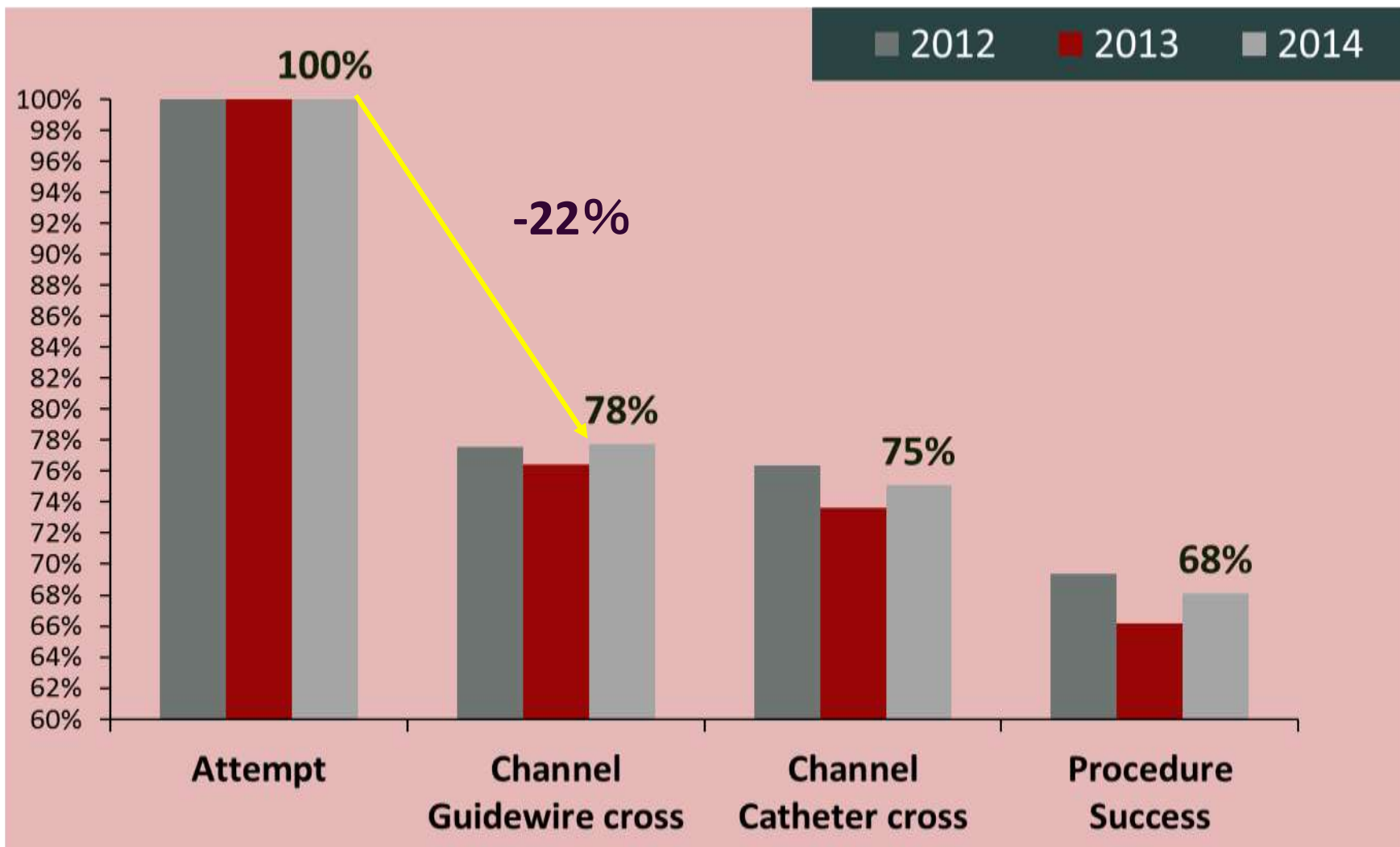


- Couldn't cross collateral channel
- Couldn't cross CTO by GW
- Couldn't cross CTO by any catheter
- Procedure discontinuation due to complication



Switched to antegrade approach ; 76% (313)

Retrograde procedure outcome

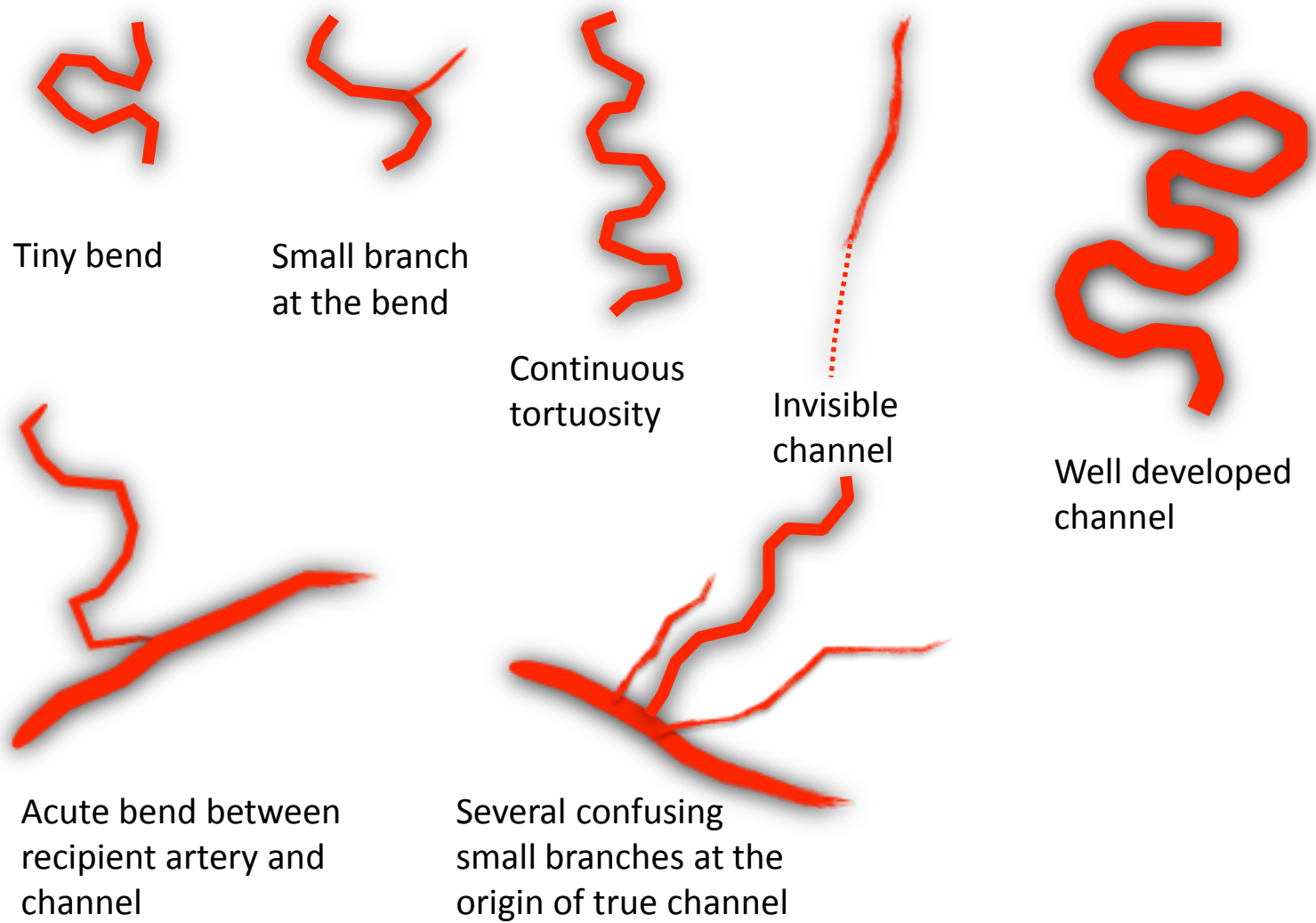


Collateral channel crossing is the first step of retrograde procedure and the main reason whether the procedure will succeed or not.

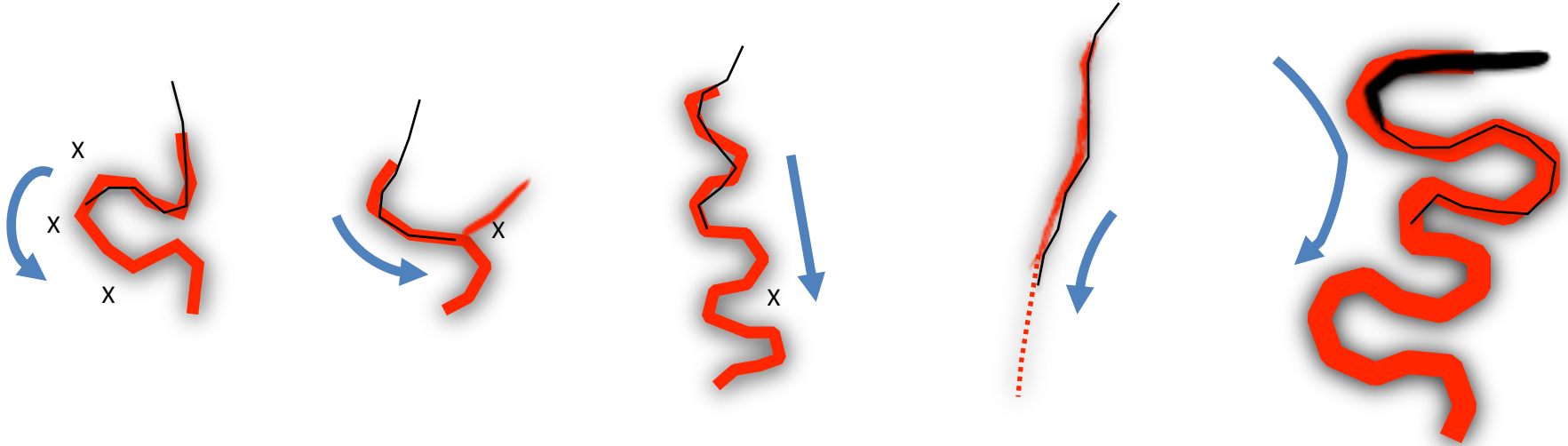


Why is the collateral channel crossing difficult?

Several factors that affect collateral crossing



What is the ideal wire?



- Tip flexibility
- Tip lubricity
- Push transmission

- Tip flexibility
- Torque ability
- appropriate tip curve

- Tip flexibility
- Tip lubricity
- Tiny tip curve

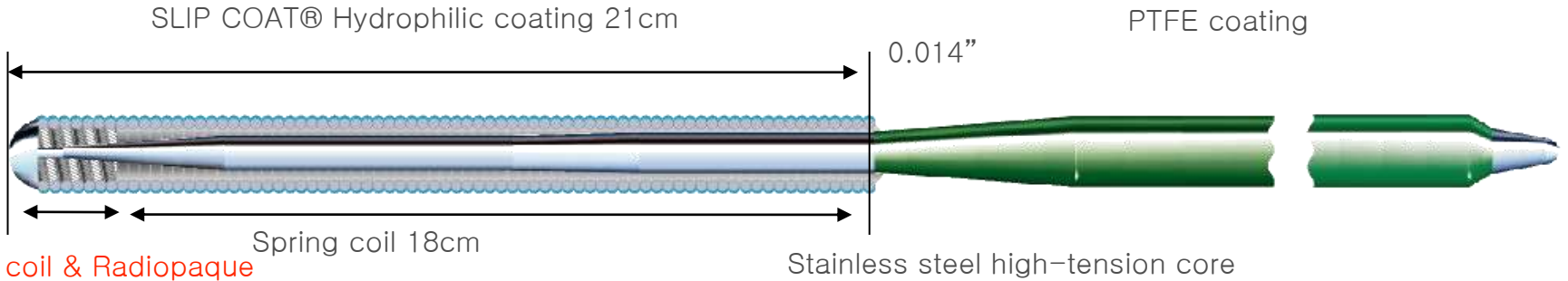
- Lower tip profile
- Tip lubricity

- Torque ability
- Lubricity
- Micro catheter assistance



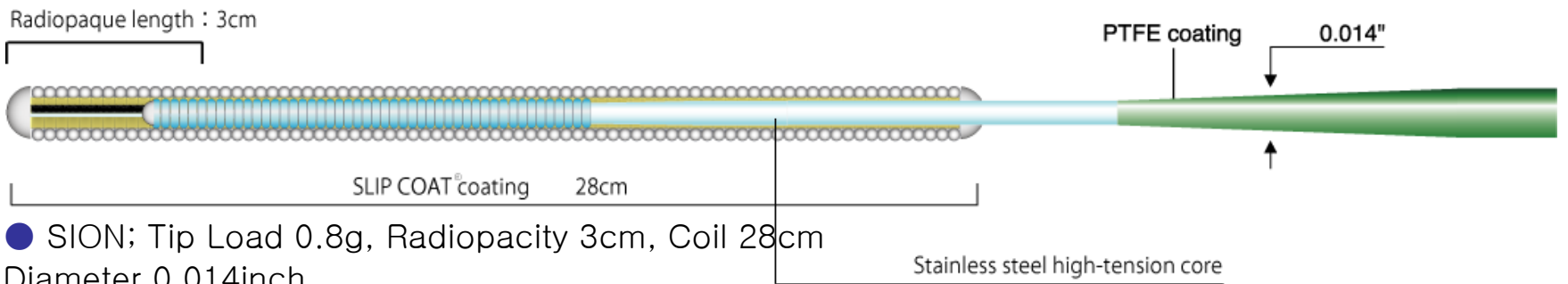
Stretching the collateral by the wire and micro catheter is important

Guide wires for collateral crossing

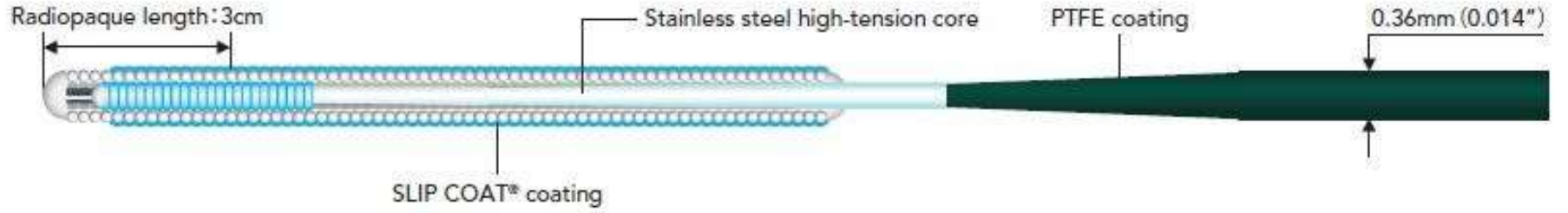


Rope coil & Radiopaque segment 3cm

● SUOH; Tip Load 0.5g, Coil 21cm, Diameter 0.014inch

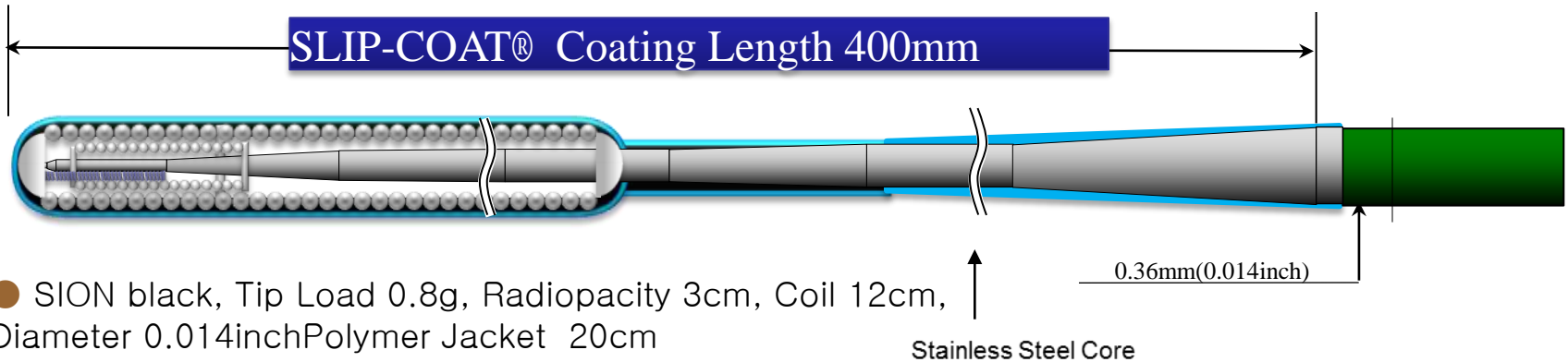


● SION; Tip Load 0.8g, Radiopacity 3cm, Coil 28cm
Diameter 0.014inch

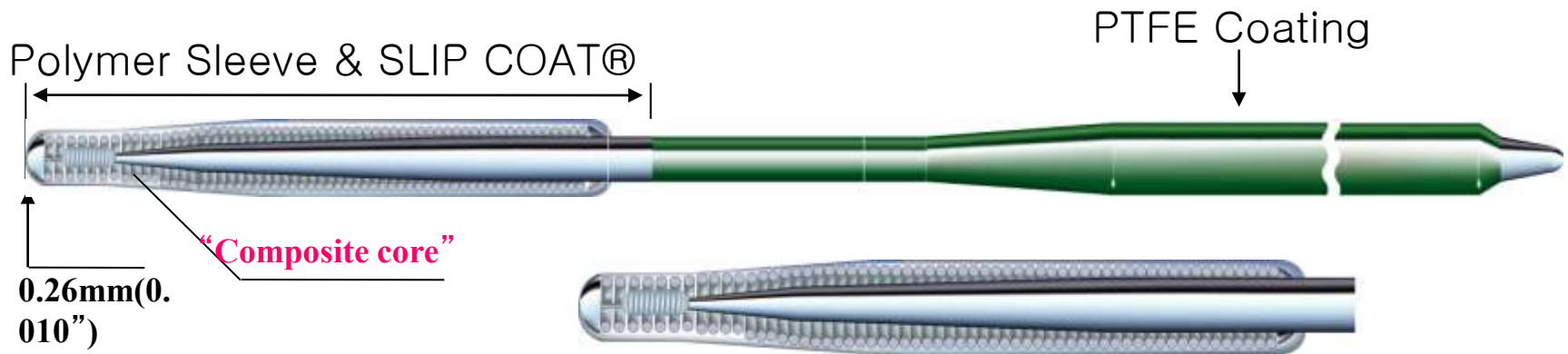


● SION blue; Tip Load 0.5g, Radiopacity 3cm, Coil 20cm
Diameter 0.014inch

Guide wires for collateral crossing



- SION black, Tip Load 0.8g, Radiopacity 3cm, Coil 12cm, Diameter 0.014inch Polymer Jacket 20cm Slip Coat 40cm



- Fielder XTR, Tip Load 0.6g, Radiopacity 16cm, Coil 16cm, Diameter 0.014inch, Tip diameter 0.010 inch Polymer Jacket



Retrograde relevant complications

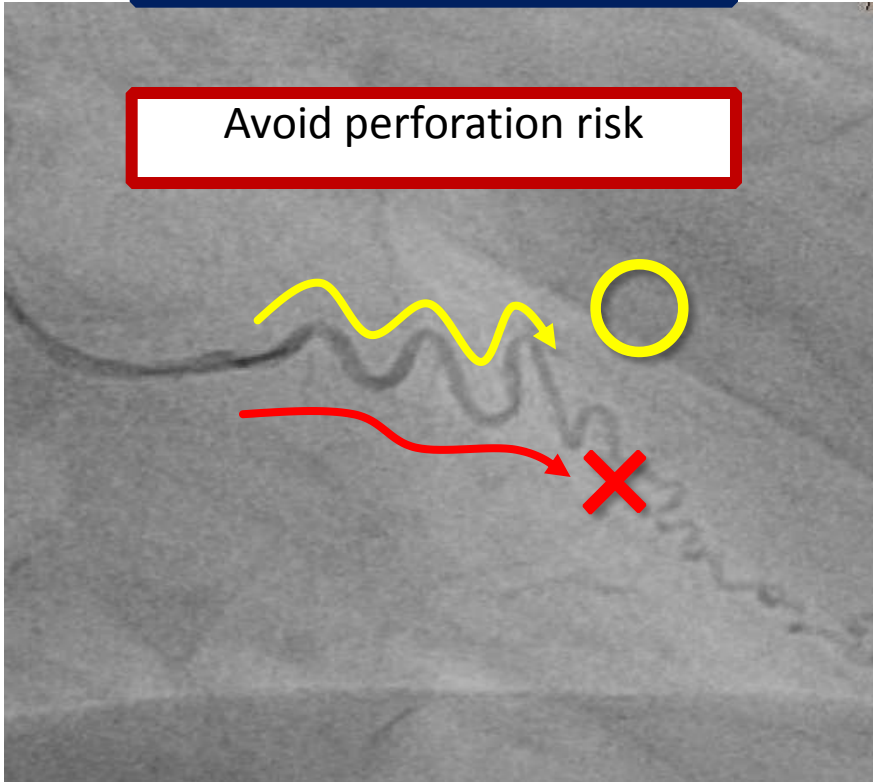
	2012 (490)	2013 (538)	2014 (281)	P
Retrograde approach relevant	11.4% (56)	8.9% (48)	7.8% (22)	<i>0.2040</i>
Channel injury	10.6% (52)	8.4% (45)	7.5% (21)	0.2703
Additional treatment required	4.1% (20)	3.0% (16)	2.5% (7)	0.4274
Cardiac tamponade	0.4% (2)	0.2% (1)	1.4% (4)	0.0623
Donor artery trouble	0.2% (1)	0.2% (1)	0.4% (1)	0.8803

Including minor events

Guide wire suitable for collateral crossing

Not to damage the channel

Avoid perforation risk



To cross the channel

Need trackability in the tortuosity
=Tip flexibility

Control of contact resistance = Lubricity

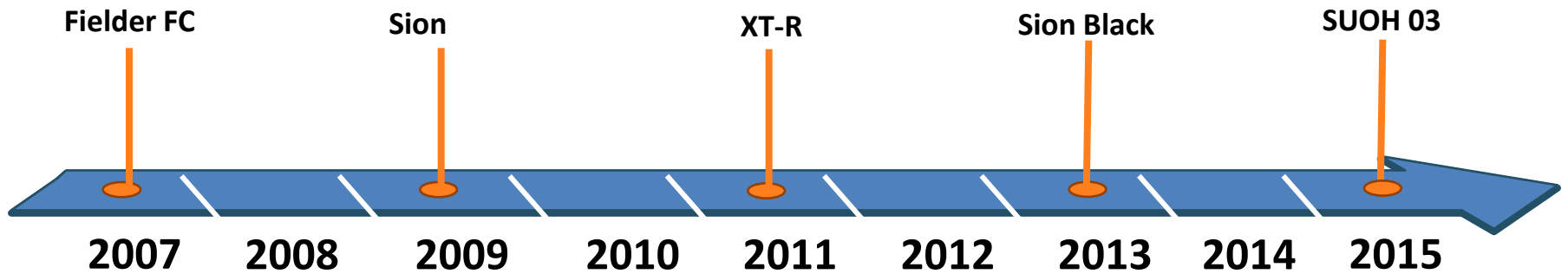
Keep maneuverability = Torque

Maintain maneuverability = Tip durability

Won't cause deformation

Technological progress of the guide wire

- 1) Fielder FC
- 2) Sion/Sion blue
- 3) XT-R/Sion black
- 4) SUOH 03



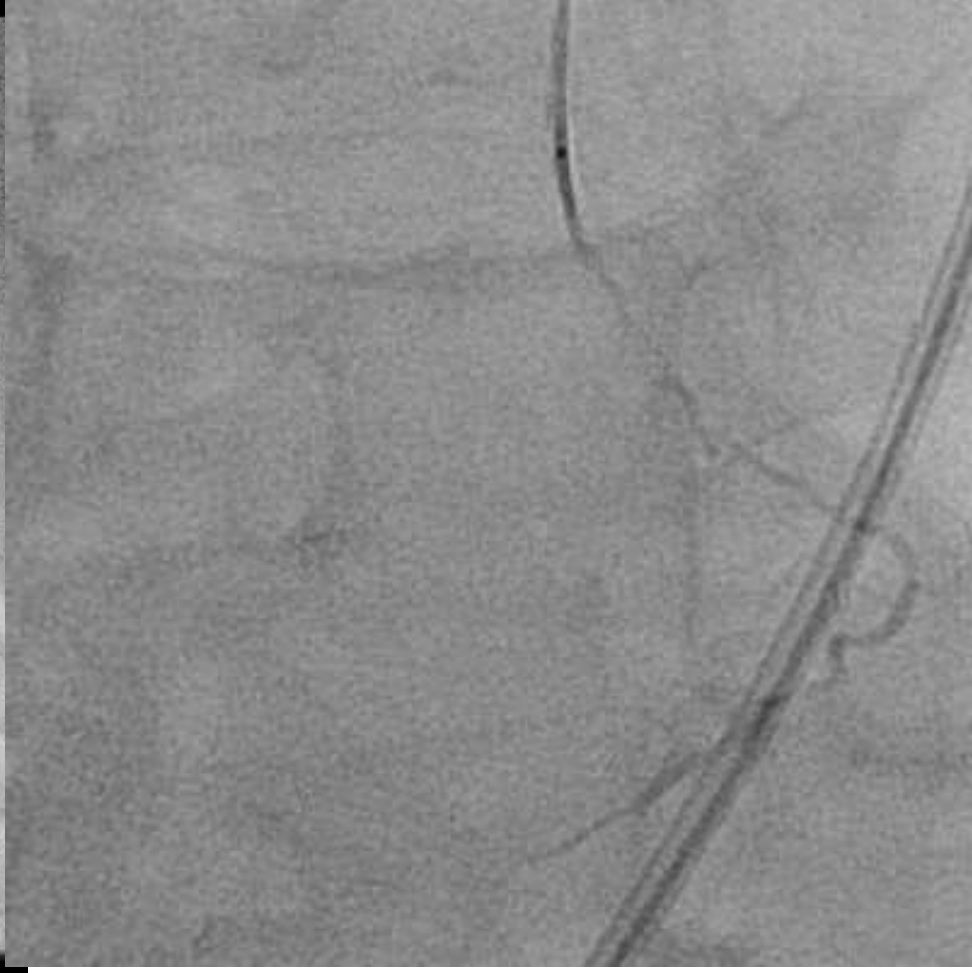
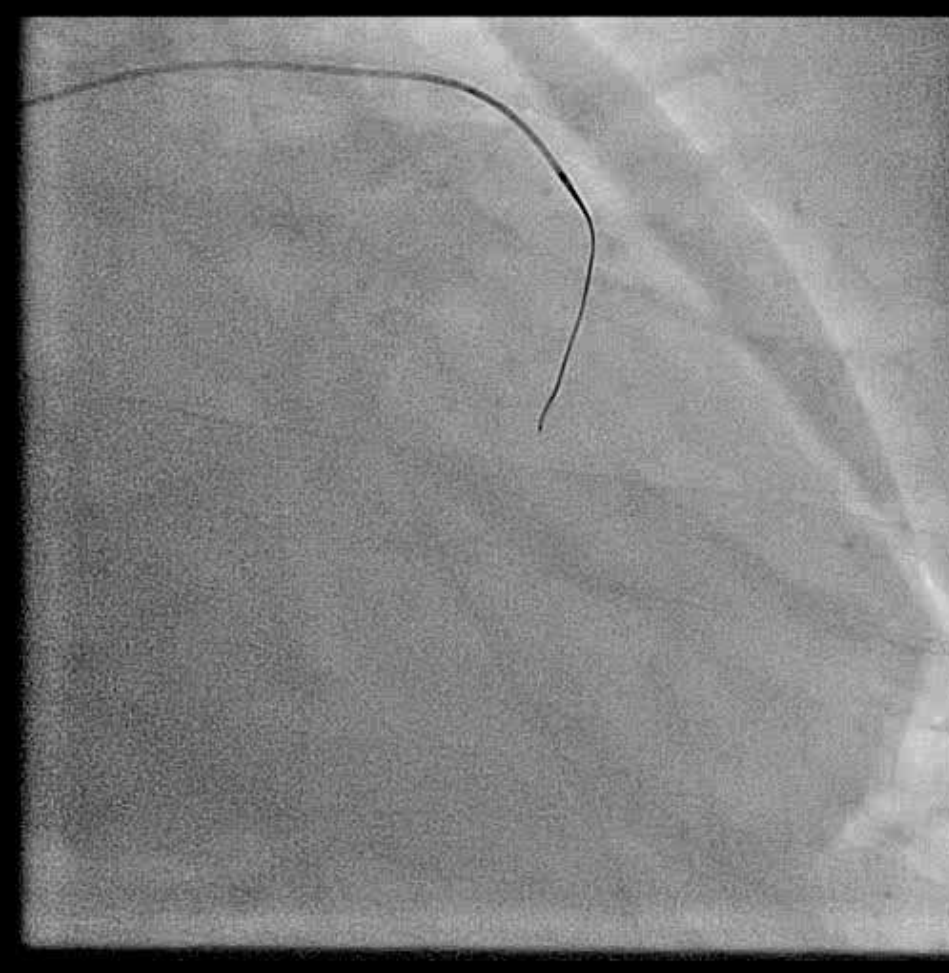
RCA ISR CTO



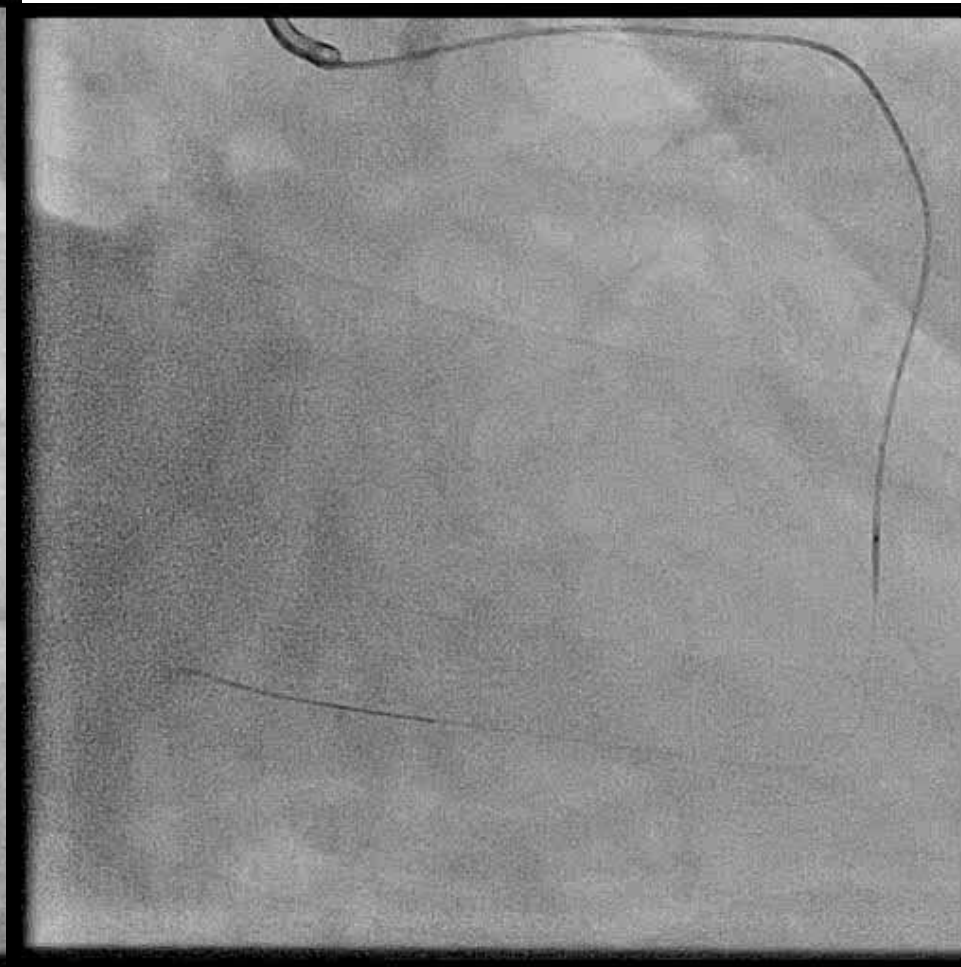
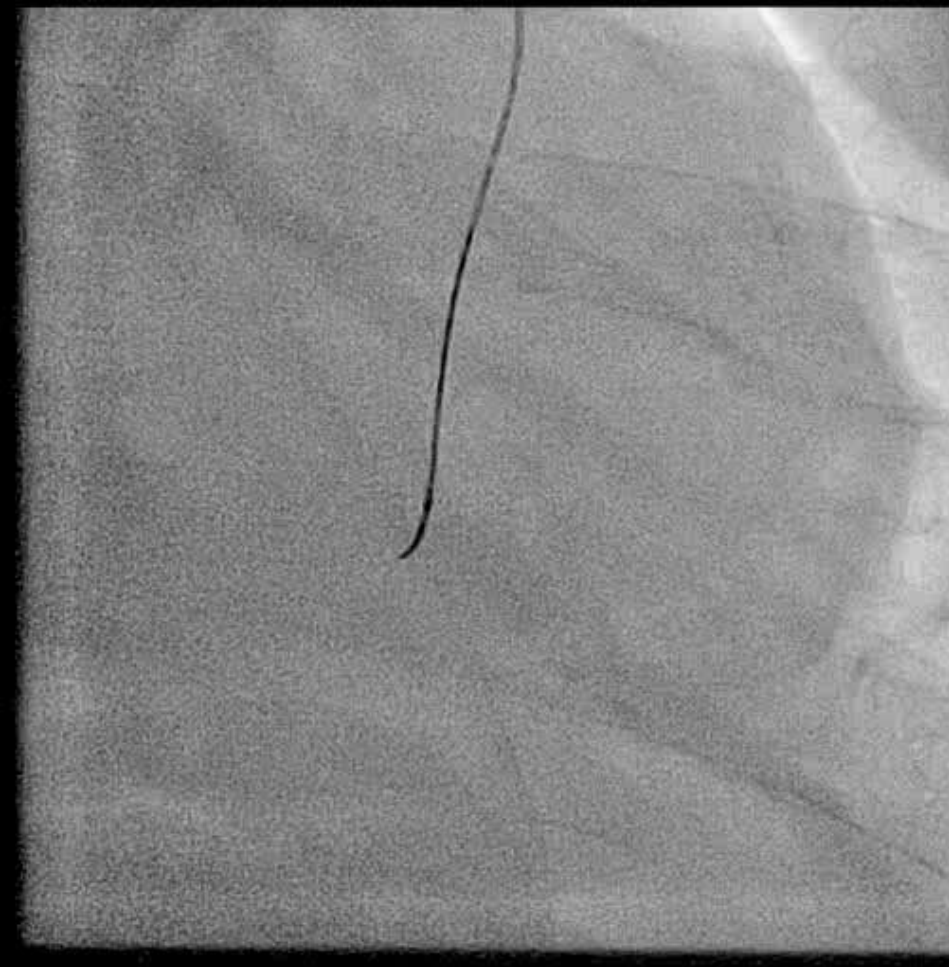
Septal channel with many bends



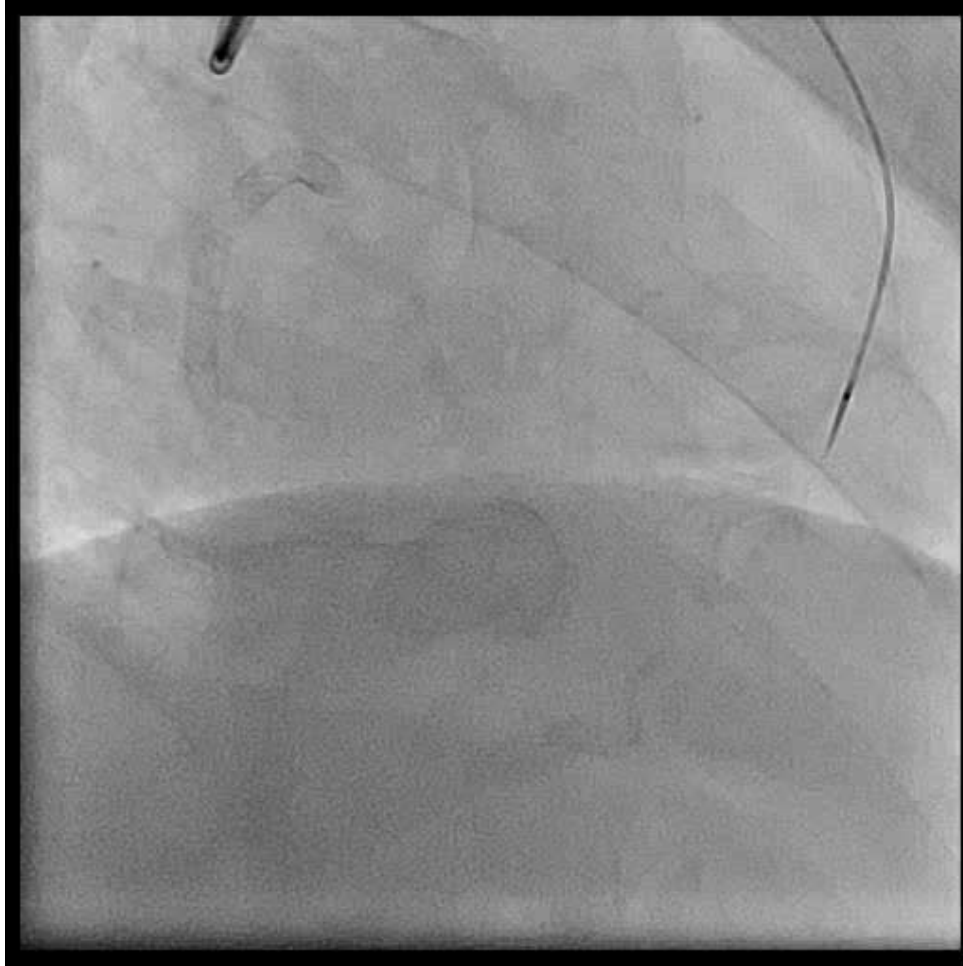
Wiring with SION and tip injection at the distal part



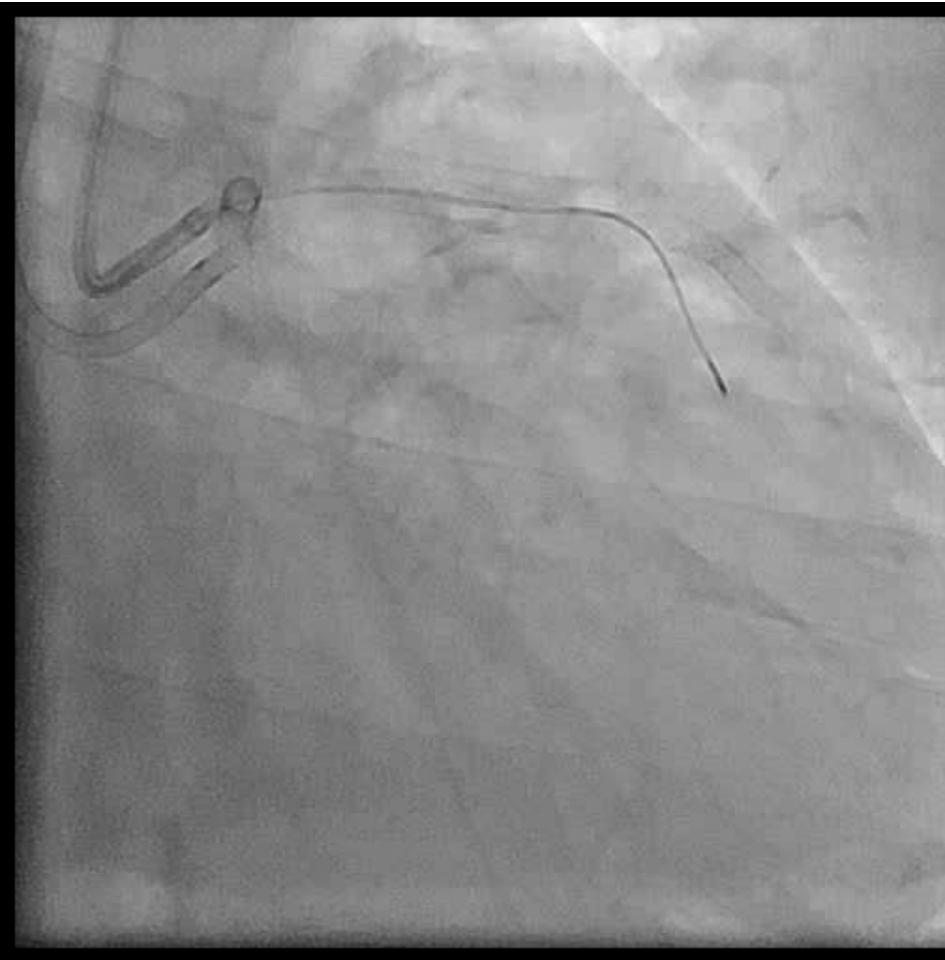
Further manipulation and advancement of Corsair



What happened?



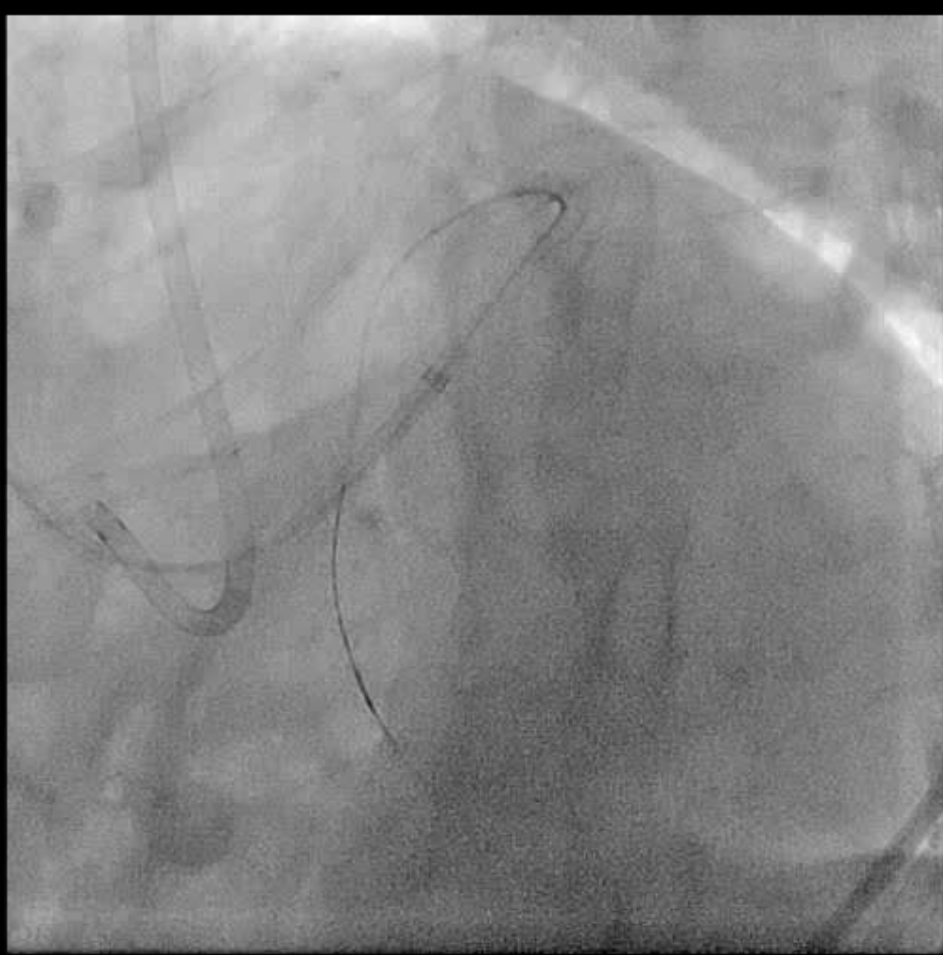
Second try



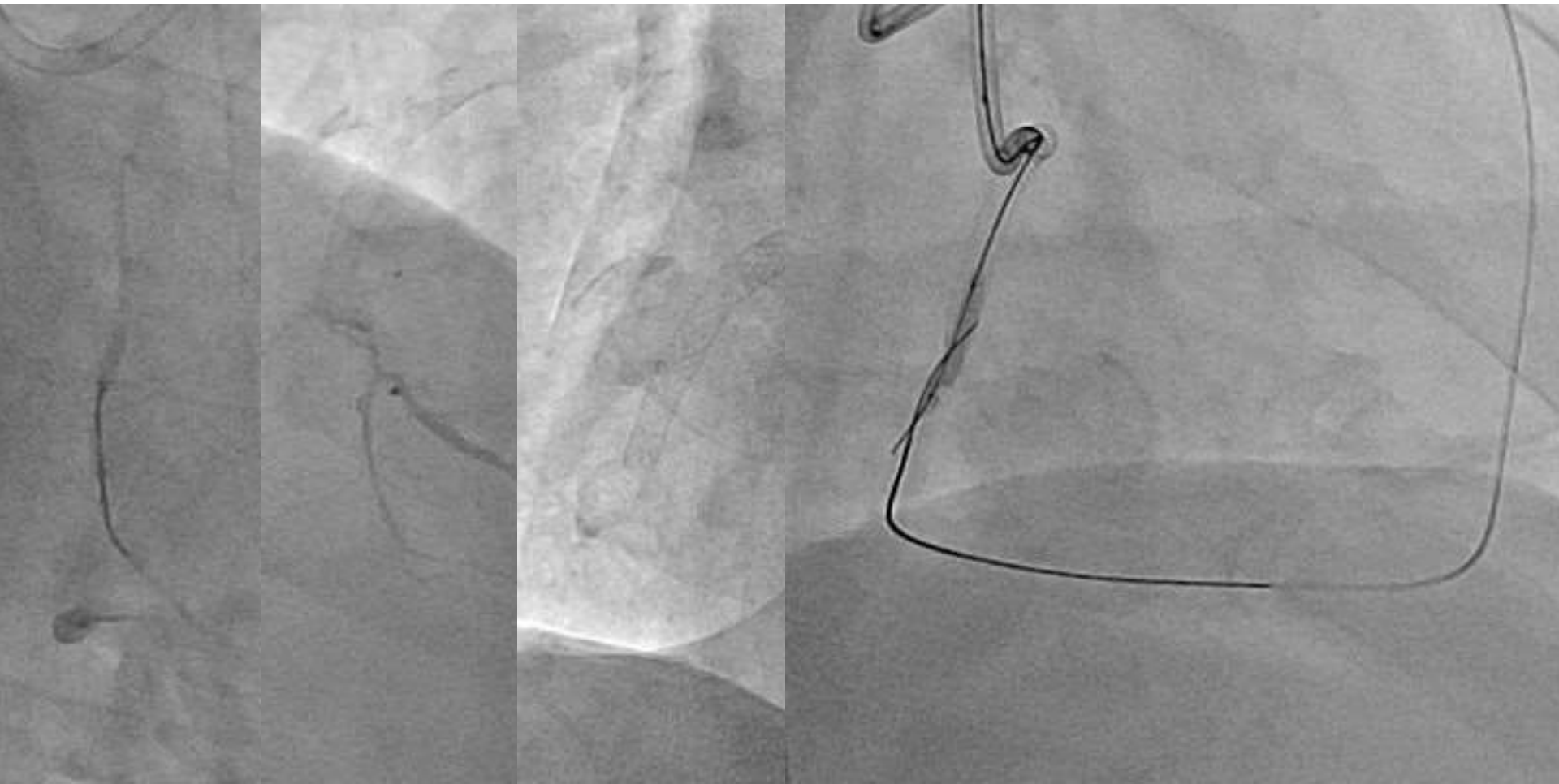
Septal channel



Channel tracing by SUOH 03



Reverse CART



Final angiograms



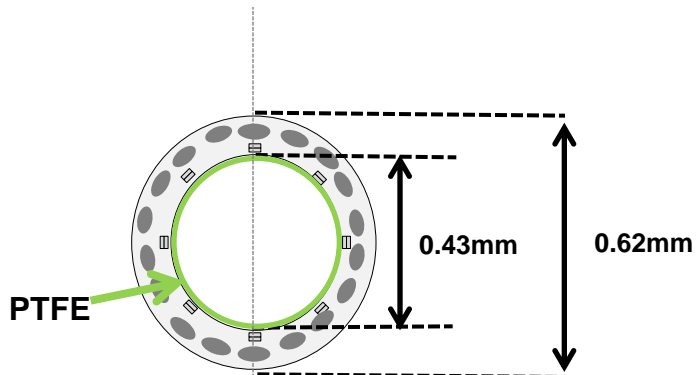
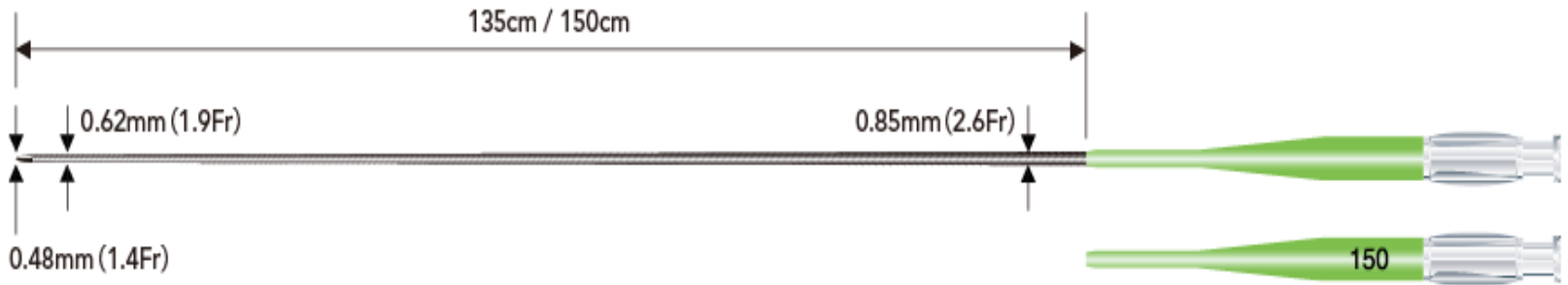
Retrograde channel crossing

Guide wire selection for complex channel

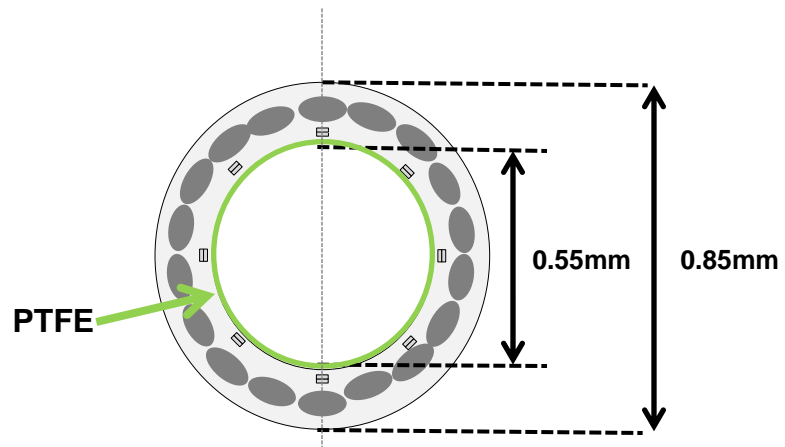
Crossing septal channel, a guide wire with good maneuverability is needed. The frontline wire is **SION**. However, usage of **SUOH03** is increasing because of its improved maneuverability and flexibility.

Crossing epicardial channel, guide wire with tip flexibility is need to avoid vessel injury. Therefore, the frontline wire is now **SUOH03**.

Anatomy	Recommendable GW	
	Septal	Epicardial
Continuous tortuosity	1. SION 2. SUOH 03 3. XT-R	1. SUOH 03 2. SION 3. XT-R(if a small vessel) SION black(if a large vessel)
Small side branch At a bend of the artery	1. SION 2. SUOH 03 3. XT-R(if a small vessel) SION black(if a large vessel)	1. SUOH 03 2. SION 3. XT-R(if a small vessel) SION black(if a large vessel)
Acute bend	1. SUOH 03 2. SION 3. SION black	1. SUOH 03 2. SION 3. SION black
Crossing invisible channel	1. XT-R 2. SION black 3. SION	Don't touch



Caravel Dis.



Caravel Prox.

Products	O.D.			I.D.			Length	Coating Length
	Entry	Distal	Proximal	Entry	Distal	Proximal		
ASAHI Caravel	0.48 mm (1.4 Fr)	0.62 mm (1.9 Fr)	0.85 mm (2.6 Fr)	0.40 mm (0.016inch)	0.43 mm (0.017inch)	0.55 mm (0.022inch)	135cm	75cm
ASAHI Corsair	0.42 mm (1.3 Fr)	0.87 mm (2.6 Fr)	0.93 mm (2.8 Fr)	0.38 mm (0.015inch)	0.45 mm (0.018inch)	0.45 mm (0.018inch)	135cm 150cm	60cm

Advantage and Limitation of Corsair

Advantages for ASAHI Corsair

- Hydrophilic coating and catheter rotation provide exceptional crossability
- Superior tracking for guidewire due to flexible distal tip
- High support performance of distal shaft improves guide wire control and penetration force
- Flexible urethane tip enables selective angiogram for side branch by tip injection

Limitations for Corsair

- Cannot fit IVUS and Corsair in 7Fr. GC at same time
- Not possible to use 2 Corsair at same time in 6Fr. GC
- Does not easily cross circumferential calcified lesion
- Can only use 0.014" guide wires
- Difficult to use Nanto-technique for device exchange
- Due to larger OD, rotation is needed to overcome friction and advance catheter to distal anatomy

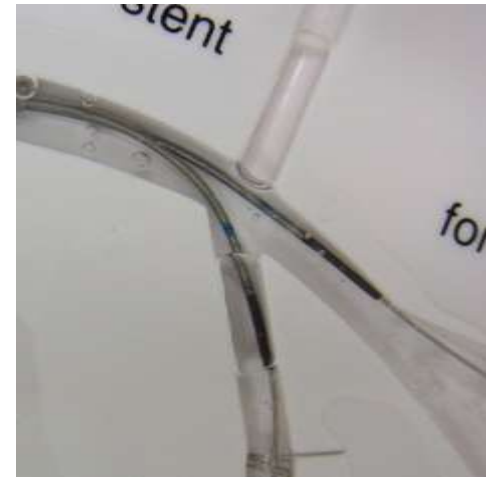
Less limitation of devices

● 2 Caravels in the 6 Fr. Guide

Guide

ASAHI Hyperion 6Fr

(ID. 0.071inch / 1.80mm)



● Caravel and IVUS catheter in the 7Fr Guide

Guide

ASAHI Hyperion 7Fr

(ID. 0.081inch / 2.05mm)



EAGLE EYE+ASAHI Caravel
(VOLCANO)



View IT+ ASAHI Caravel
(Terumo)

Superior Trackability

● Penetration test for bend

Test equipment

PCI trainer for expert

Optional devices

GW: SION

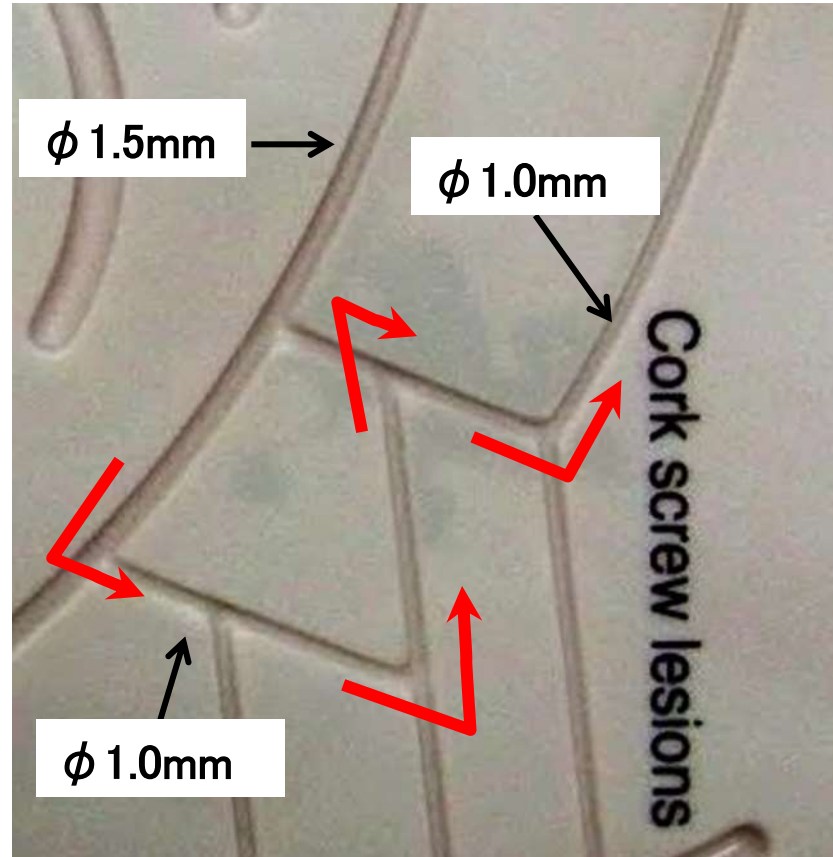
GC: Hyperion 7Fr PB

Test sample

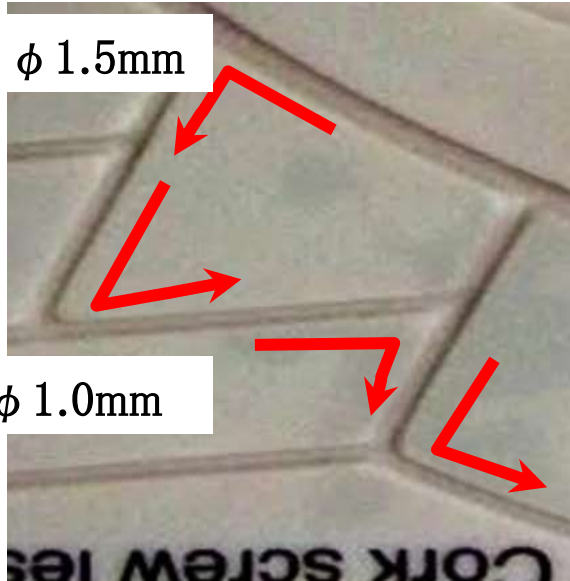
ASAHI Caravel

Competitor M

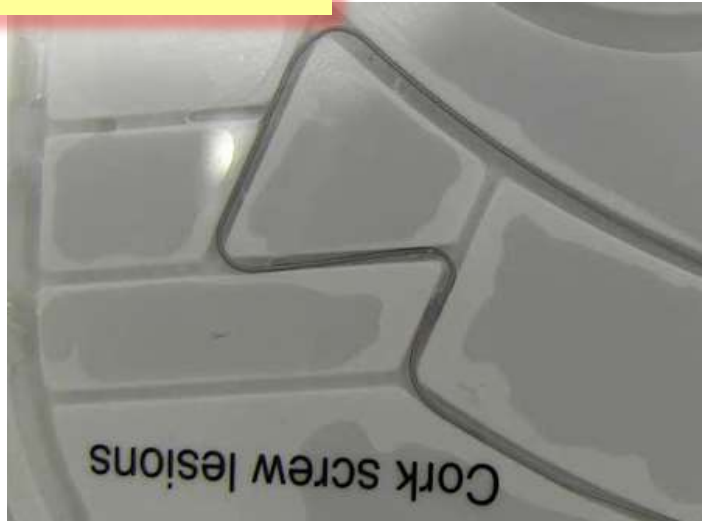
Competitor G



Superior Trackability



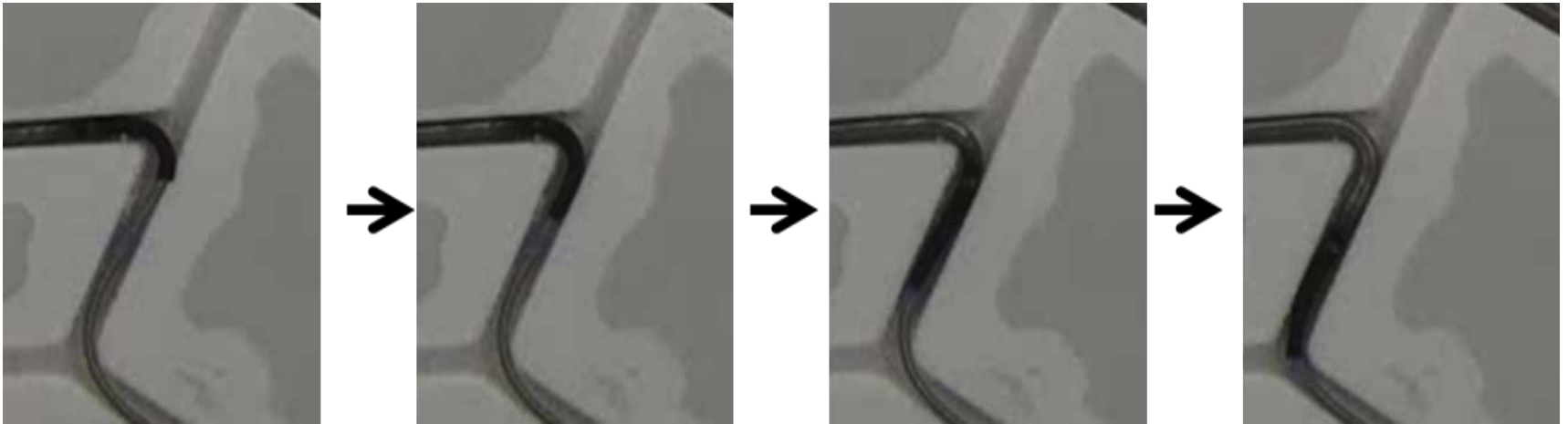
ASAHI Caravel



Superior Trackability

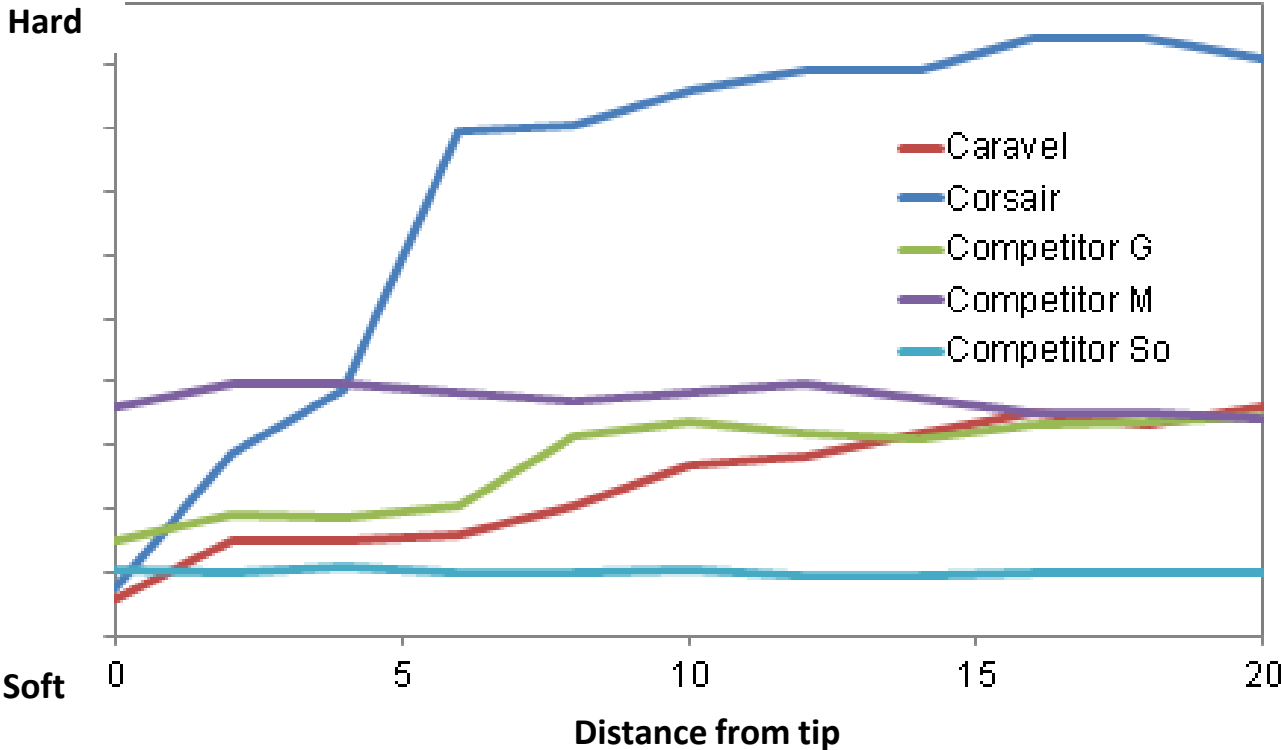
Less rigidity gap

Rigidity change from flexible tip to shaft is smooth and easy to track even in acute bend.



Superior Trackability

Tip stiffness



Competitor

+

ASAHI Corsair



ASAHI Caravel

Less limitations for device selection

Great guidewire support

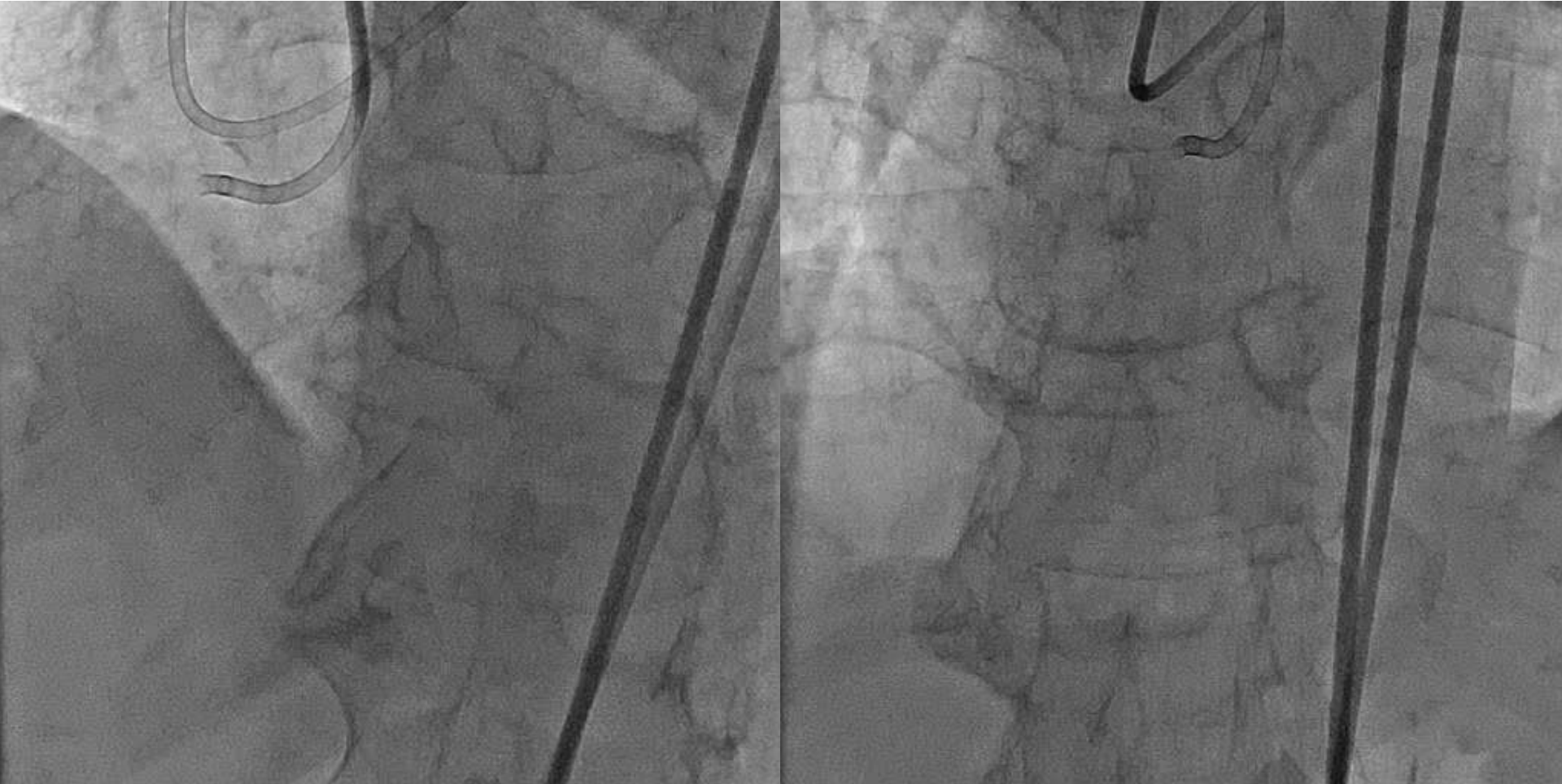
Good trackability

Good crossability

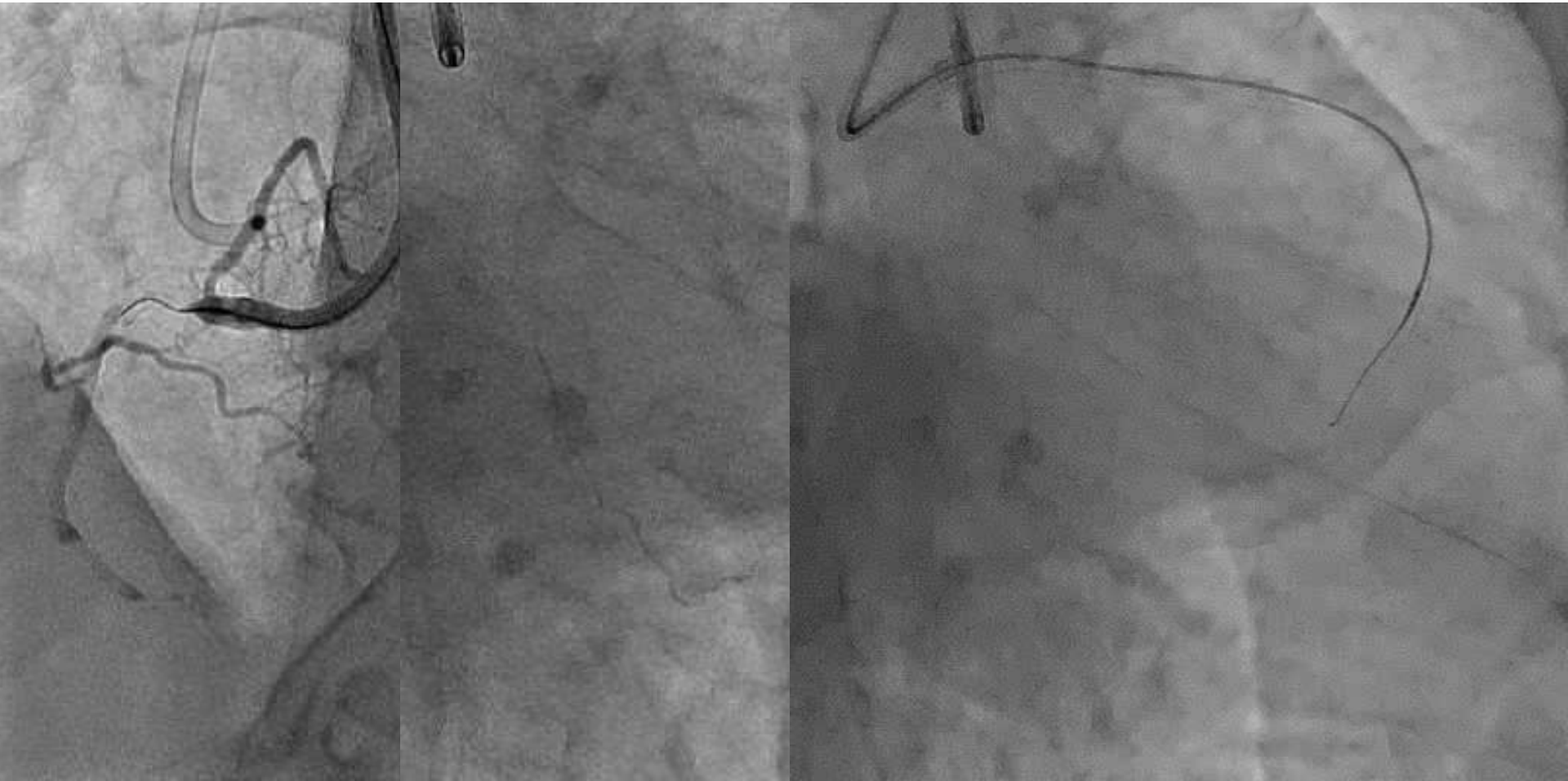
Good guidewire control

Easy to do Nanto technique

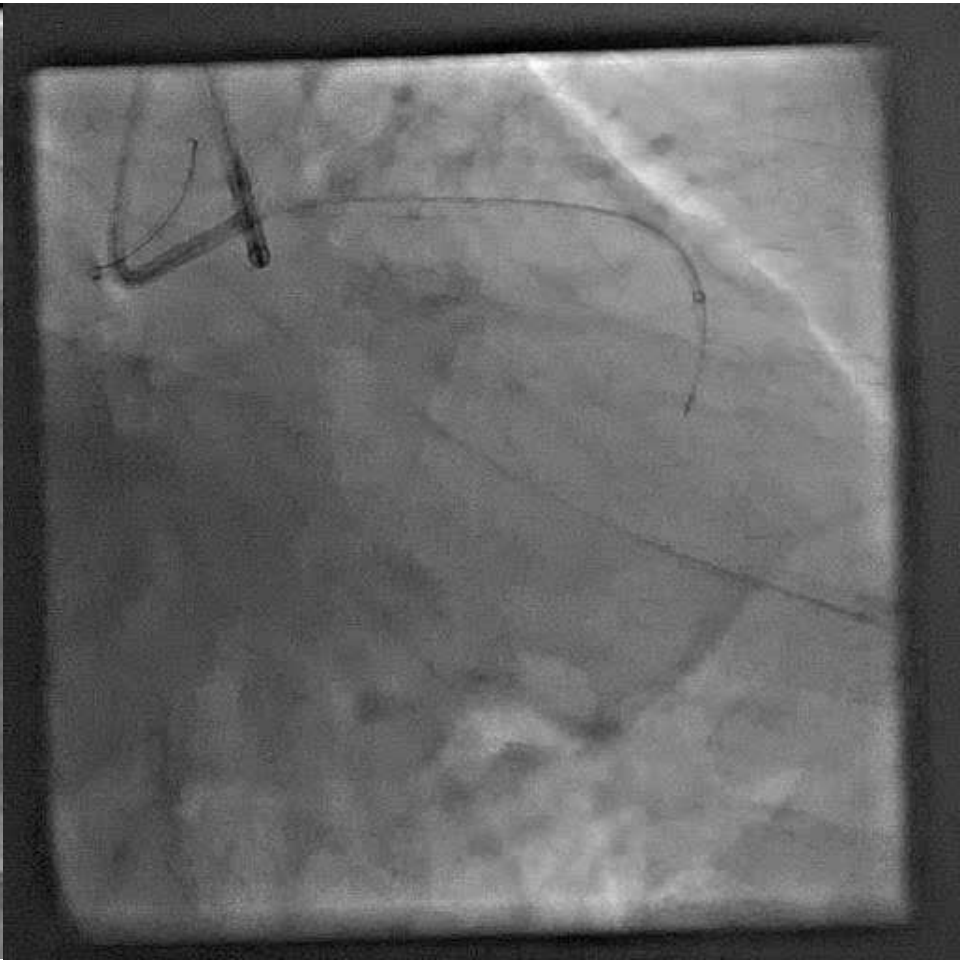
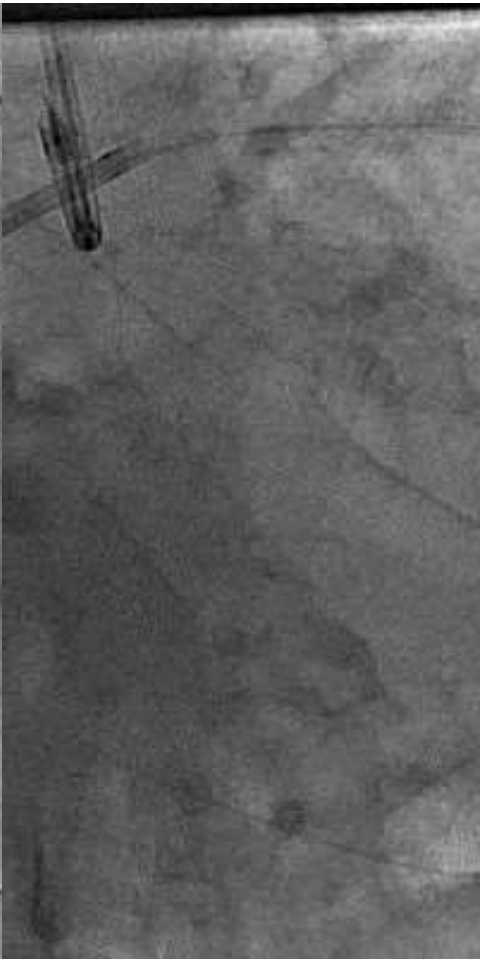
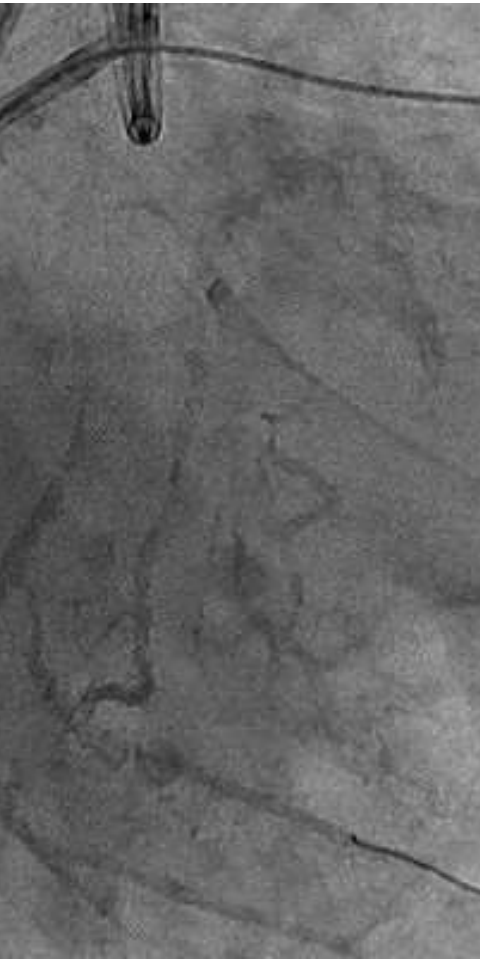
RCA CTO



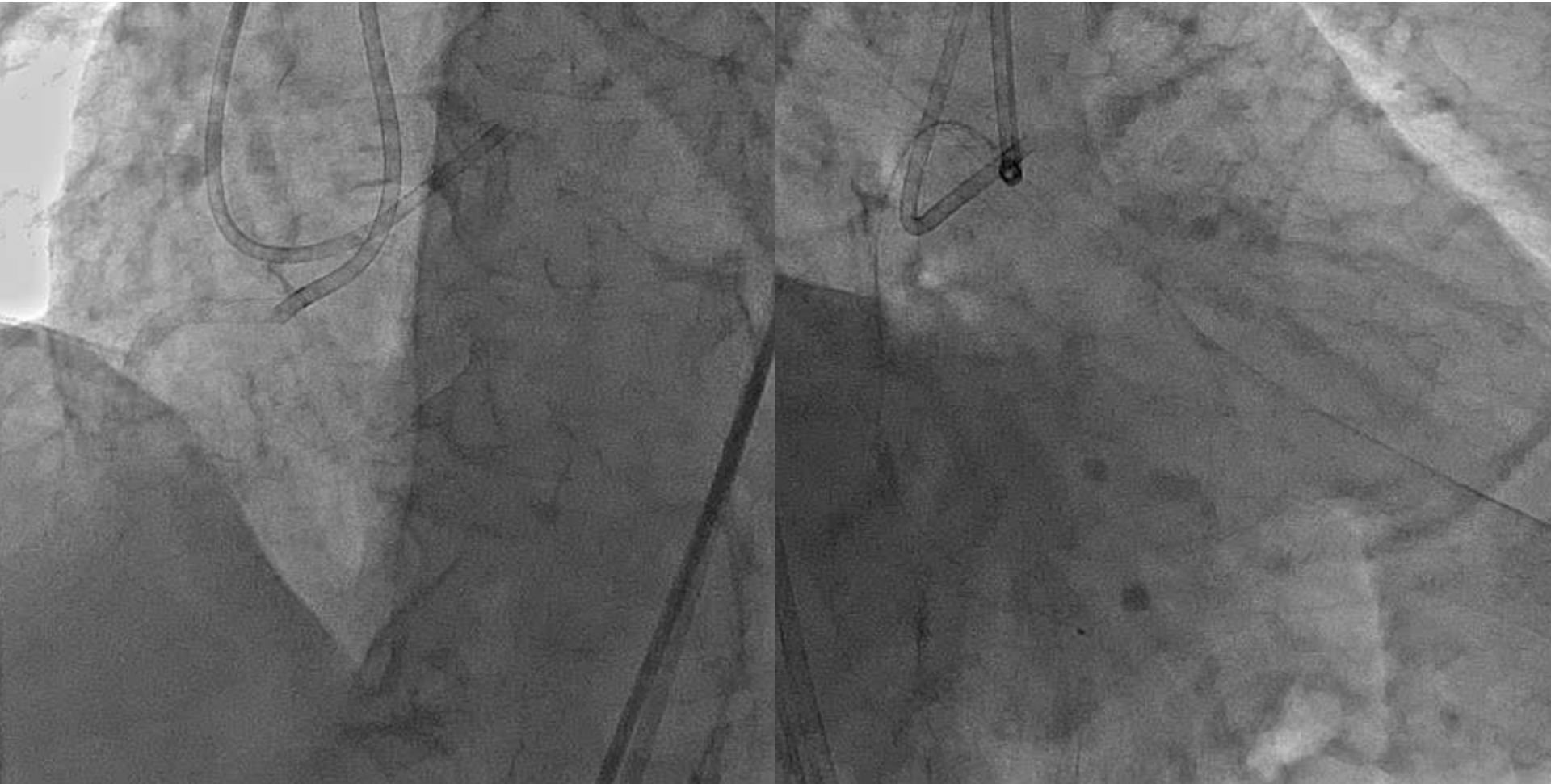
Septal channel tracing



Caravel pass the channel



Final angiograms



Corsair Pro: Concept of the product

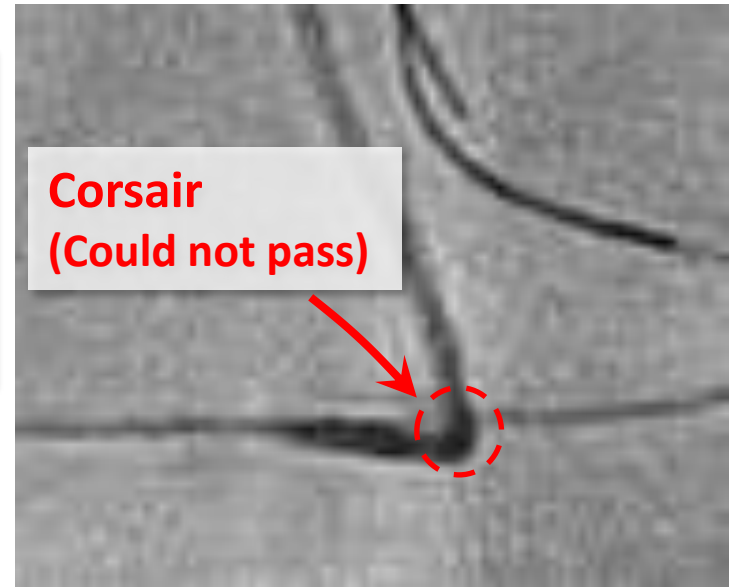
Current ASAHI Corsair's problem

There are cases in which Corsair could not cross because of the severe bending in collateral channel.



Aim of ASAHI Corsair Pro

By minimizing the stiffness difference between the tip and the shaft, Corsair Pro will be able to track tortuous vessels, which improves its ability to cross challenging anatomy.



Corsair Pro: Improvement

Improved performance

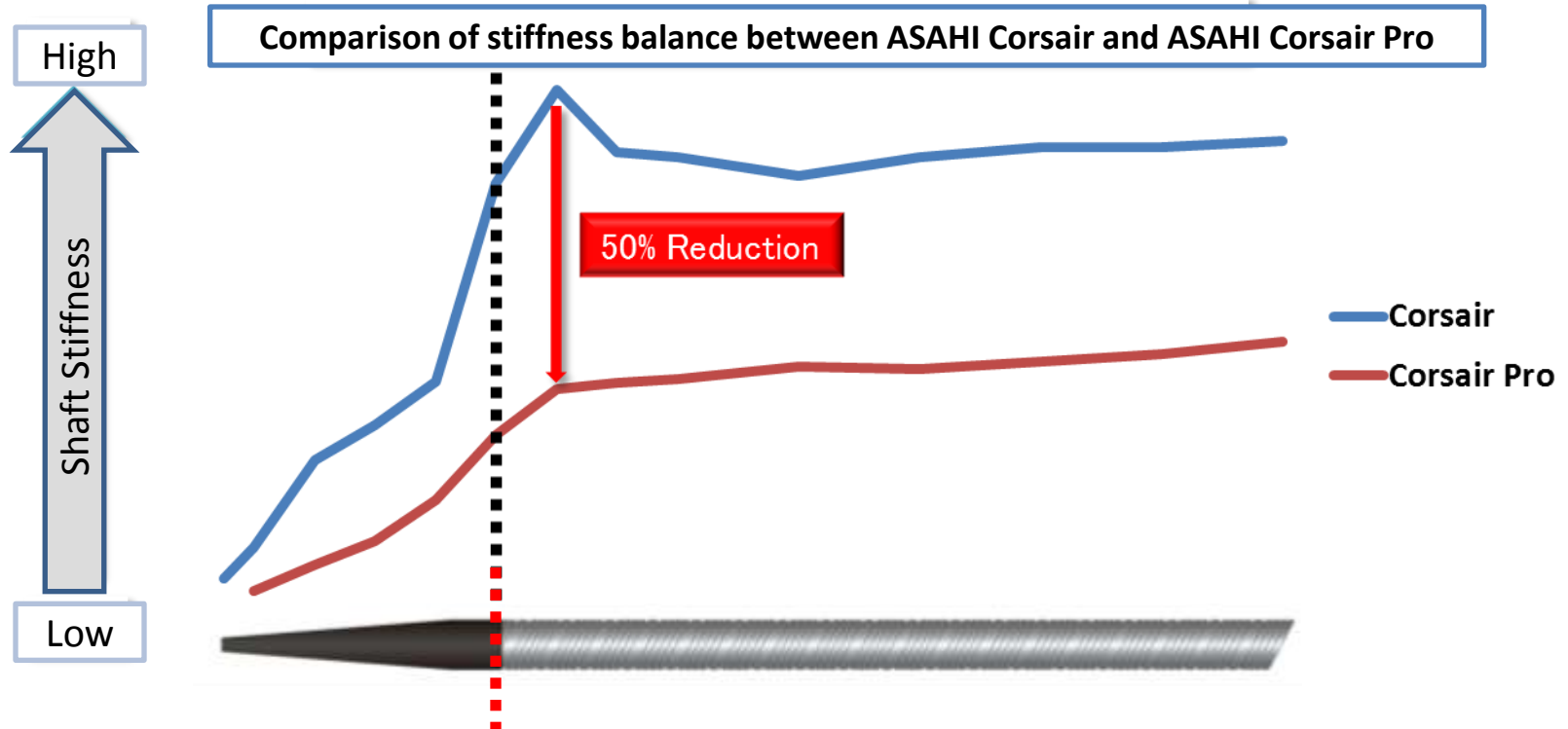
- Optimization of catheter stiffness profile
- Removing of coil marker

Tracking ability

- Spiral protector

Kink resistance at proximal shaft


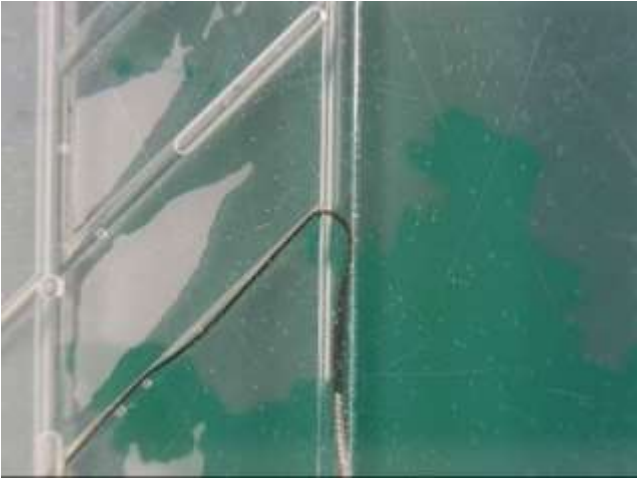
Optimization of catheter stiffness(1)



Compared to Corsair, the Corsair Pro's stiffness profile has a more linear increase which improves the catheter flexibility and trackability for enhanced performance in tortuous anatomy.

Optimization of catheter stiffness(2)

Evaluation of improved crossing using a bending model in which Corsair could not pass.

	Corsair	Corsair Pro
Movie		
Result	Could not track across tortuous segment by pushing or torqueing catheter	<u>Crossed tortuous segment with pushing alone.</u>

Proximal Hub Protector

Use of spiral protector

Flexibility of the Proximal hub is improved to improve catheter durability.

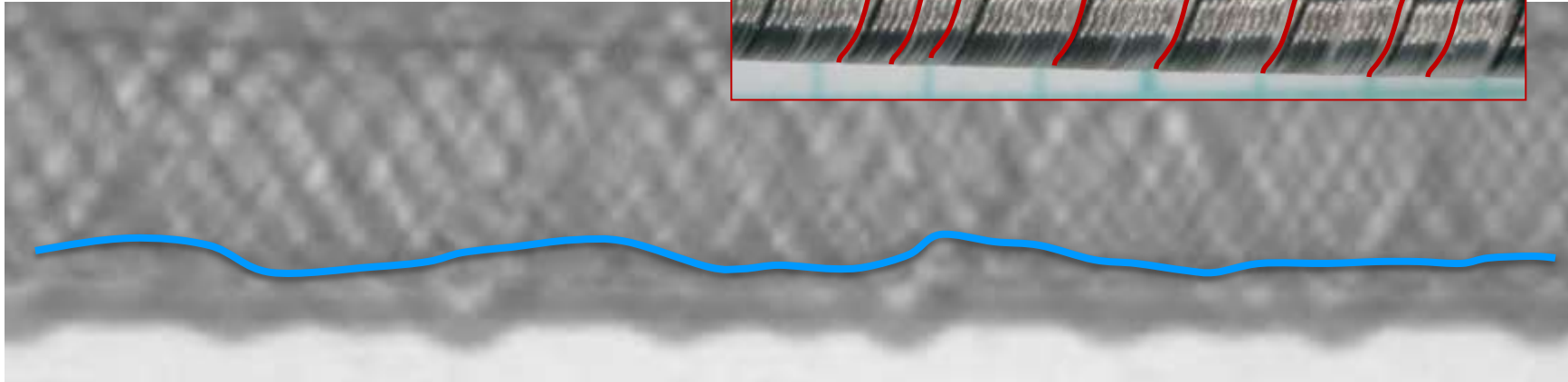


Improved proximal hub protects the proximal shaft when bent during catheter advancement or withdrawal



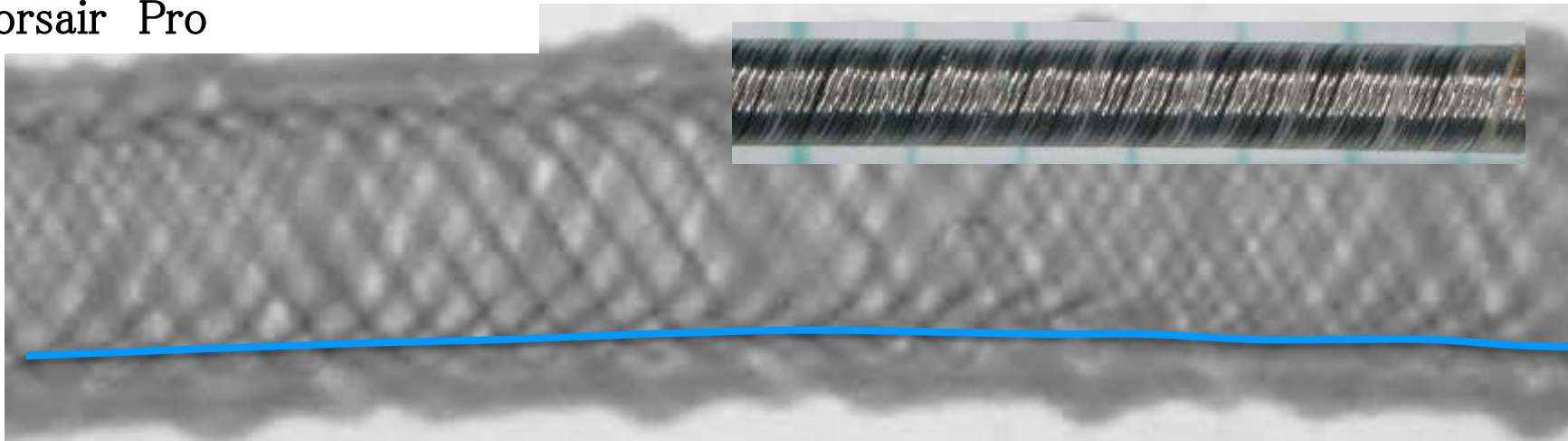
Proximal Hub Protector

Corsair

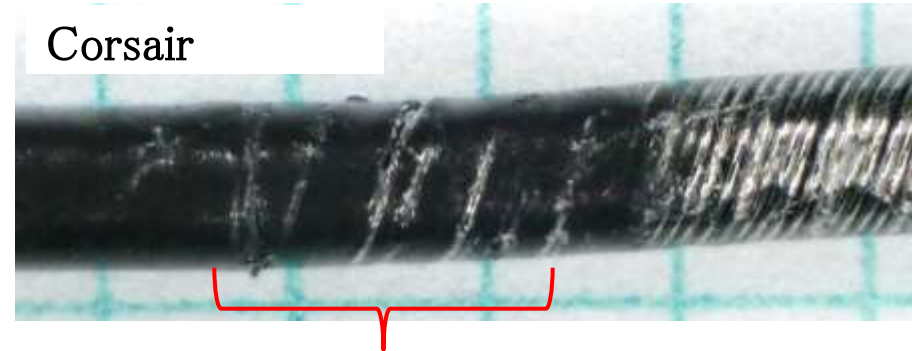


Coating on the Corsair shaft was worn and braid structure was damaged.
Outline of the catheter distorted (blue line)

Corsair Pro



Tip to Shaft Connection



Damage occurs at concentrated stress point.

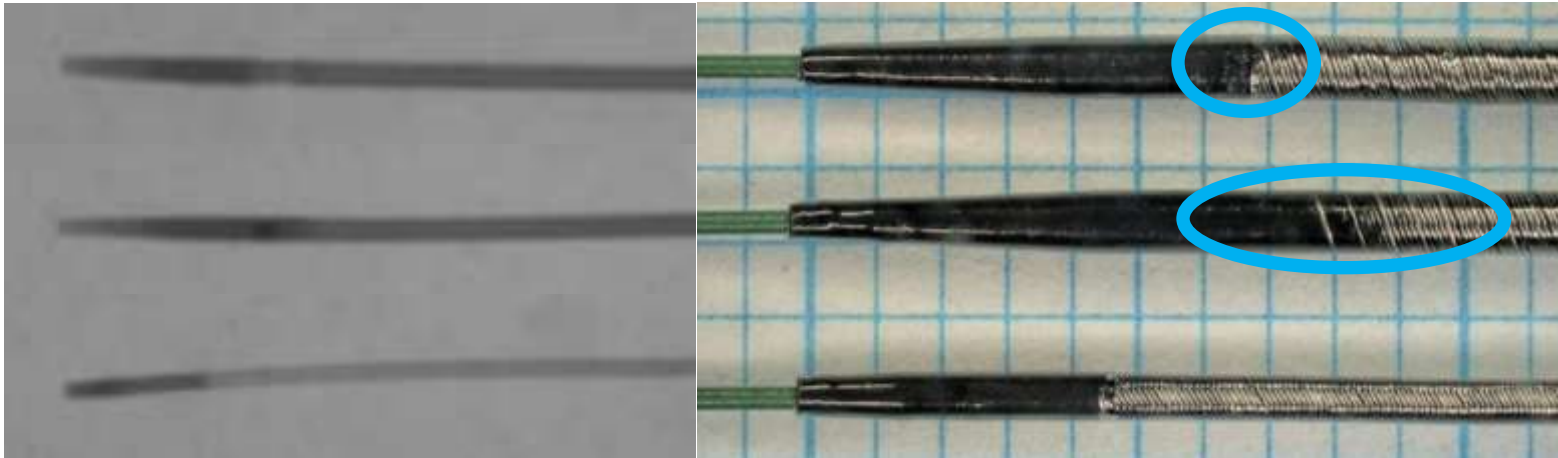


Tested Corsair and Corsair Pro in a test model. The optimized support profile allowed the catheter to cross the tortuous anatomy with minimal impact to catheter performance.

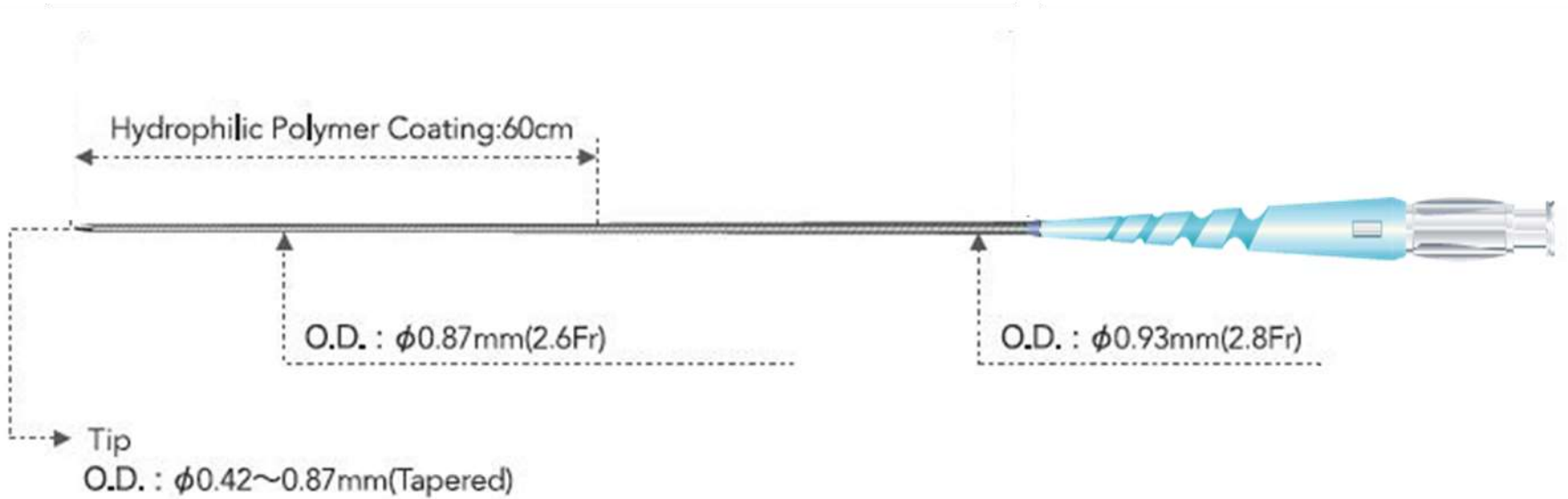
VISIBILITY

Good visibility

Corsair Pro tip is visible under fluoroscopy due to the **urethane tip infused with tungsten powder**

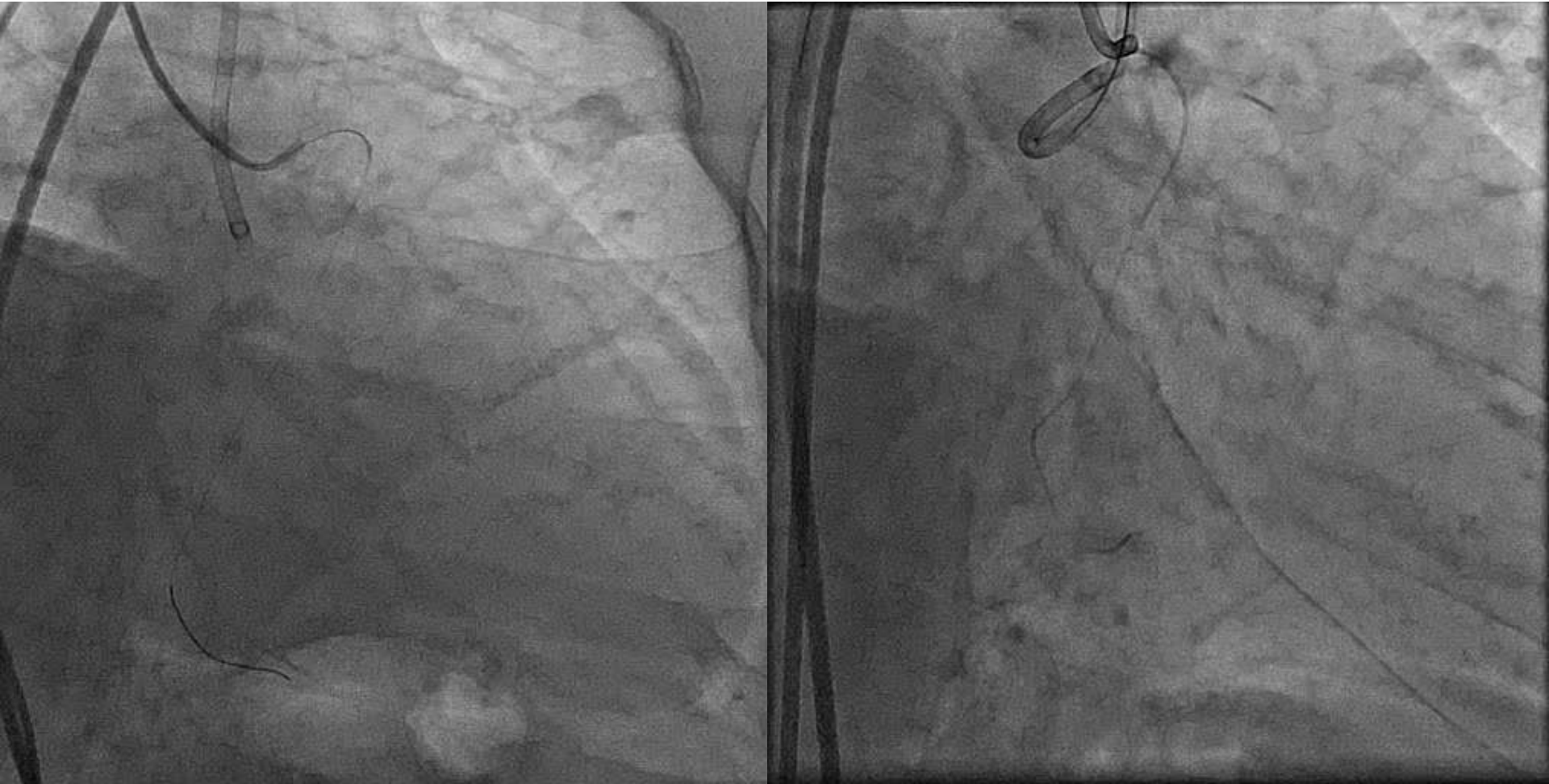


Structure

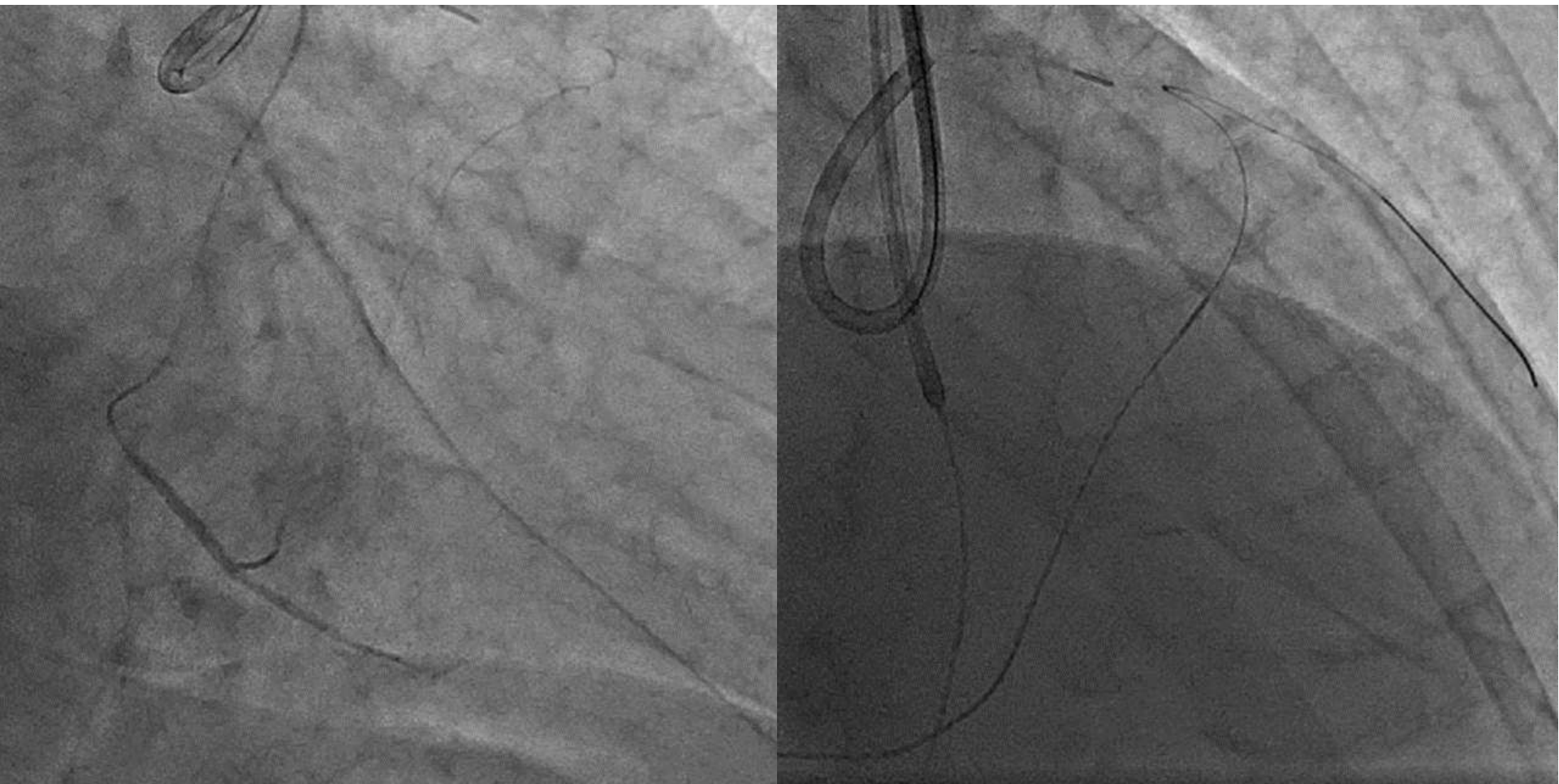


Catalogue No.	Shaft O.D. (Distal)	Shaft O.D. (Proximal)	Tip I.D.	Shaft I.D.	Usable length	Rec. GW
CSR135-26P	0.87mm (2.6Fr)	0.93mm (2.8Fr)	0.38mm (0.015")	0.45mm (0.018")	135cm	0.36mm (0.014")
CSR150-26P	0.87mm (2.6Fr)	0.93mm (2.8Fr)	0.38mm (0.015")	0.45mm (0.018")	150cm	0.36mm (0.014")

Tiny septal channel



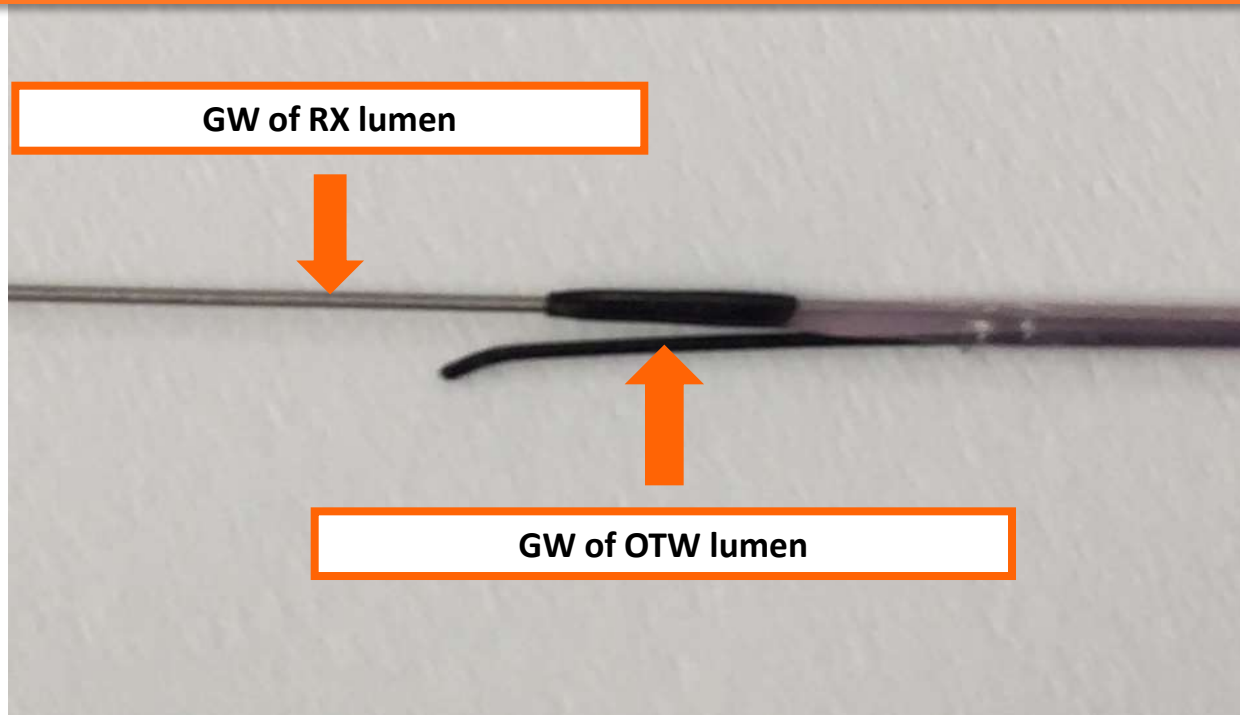
Crossing using by SUOH 03 and Corsair Pro



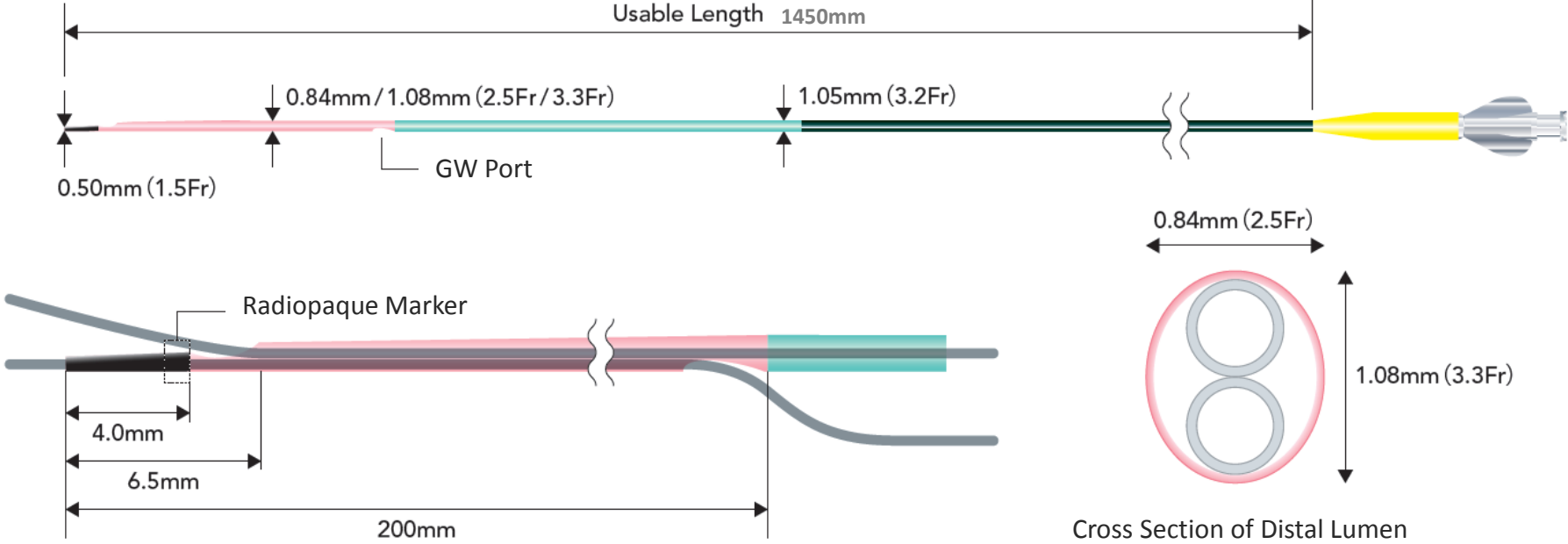
What is MFC? (Multi Function Catheter)

What is MFC?

There are two lumens; Rx lumen and OTW lumen.
It is used for side branch access and CTO cases to enhance the control ability of GWs.



Structure



Product	Catalog No.	Outer Diameter			Inner Diameter		Usable Length	Recommended GW	Hydrophilic Coating Length
		Tip	Distal Shaft	Proximal Shaft	Tip	Shaft			
ASAHI SASUKE	SA145-33N	0.50mm (1.5Fr)	0.84mm/1.08mm (2.5Fr/3.3Fr)	1.05mm (3.2Fr)	0.40mm (0.016inch)	0.43mm (0.017inch)	1450mm	0.36mm (0.014inch)	380mm

Indications

Increase GW maneuverability

◆ Stable GW manipulation

- ✓ Suppress the wobbling of the GW inside the Guiding catheter ⇒ GW control is enhanced

Side branch Access

- ◆ Prevent GW entanglement during side branch access
- ◆ Ease the selection of acute angled branches when Reversed guidewire technique is necessary
- ◆ Ease stent measuring when performing Bifurcation stenting

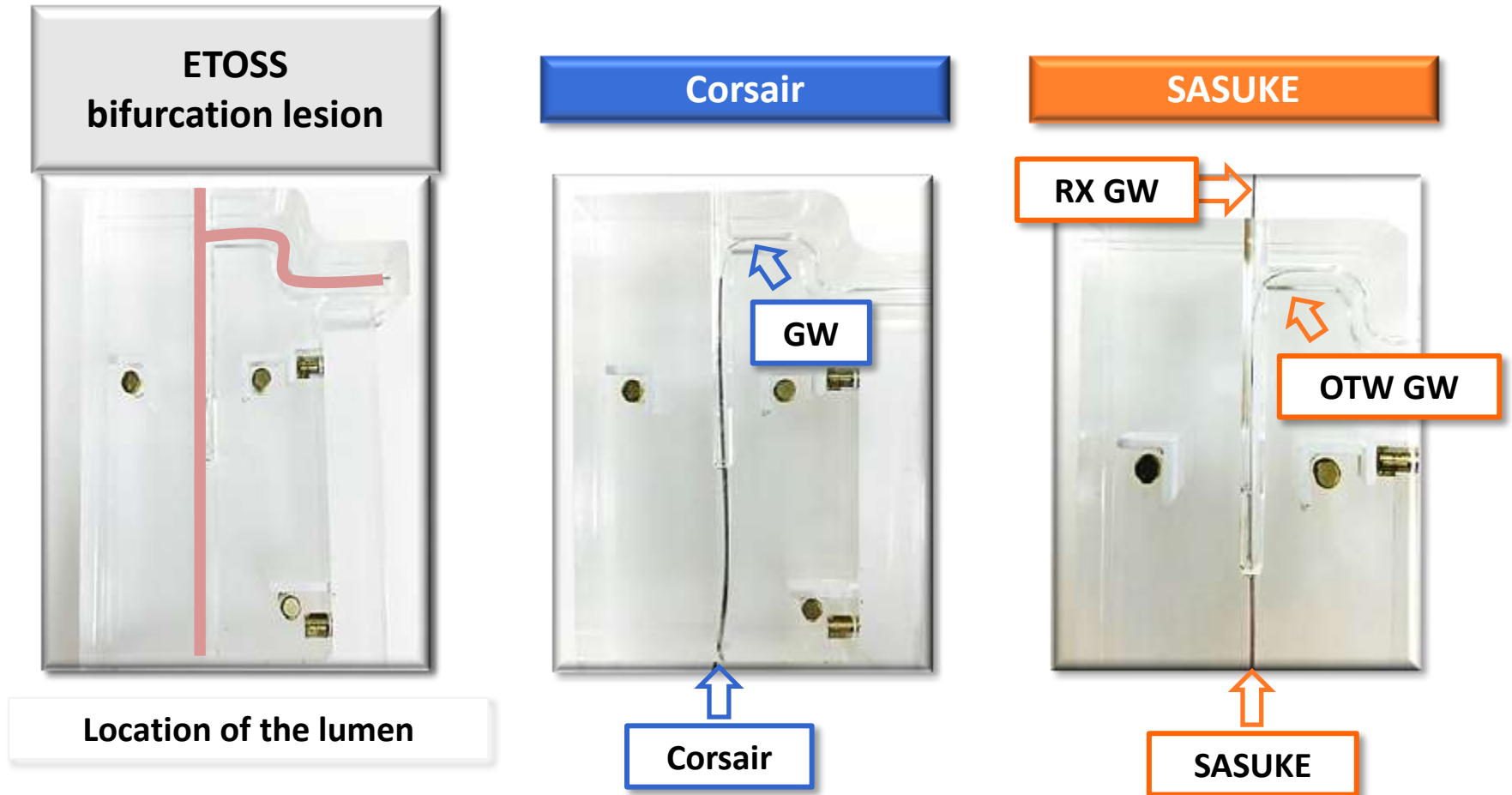
+

Parallel Wiring

- ◆ Prevent GW entanglement during Parallel guidewire technique
- ◆ Ease guide wire rerouting

Accessing side branch:

Comparison of stability between SASUKE and Corsair with ETOSS



Location of the lumen

Corsair

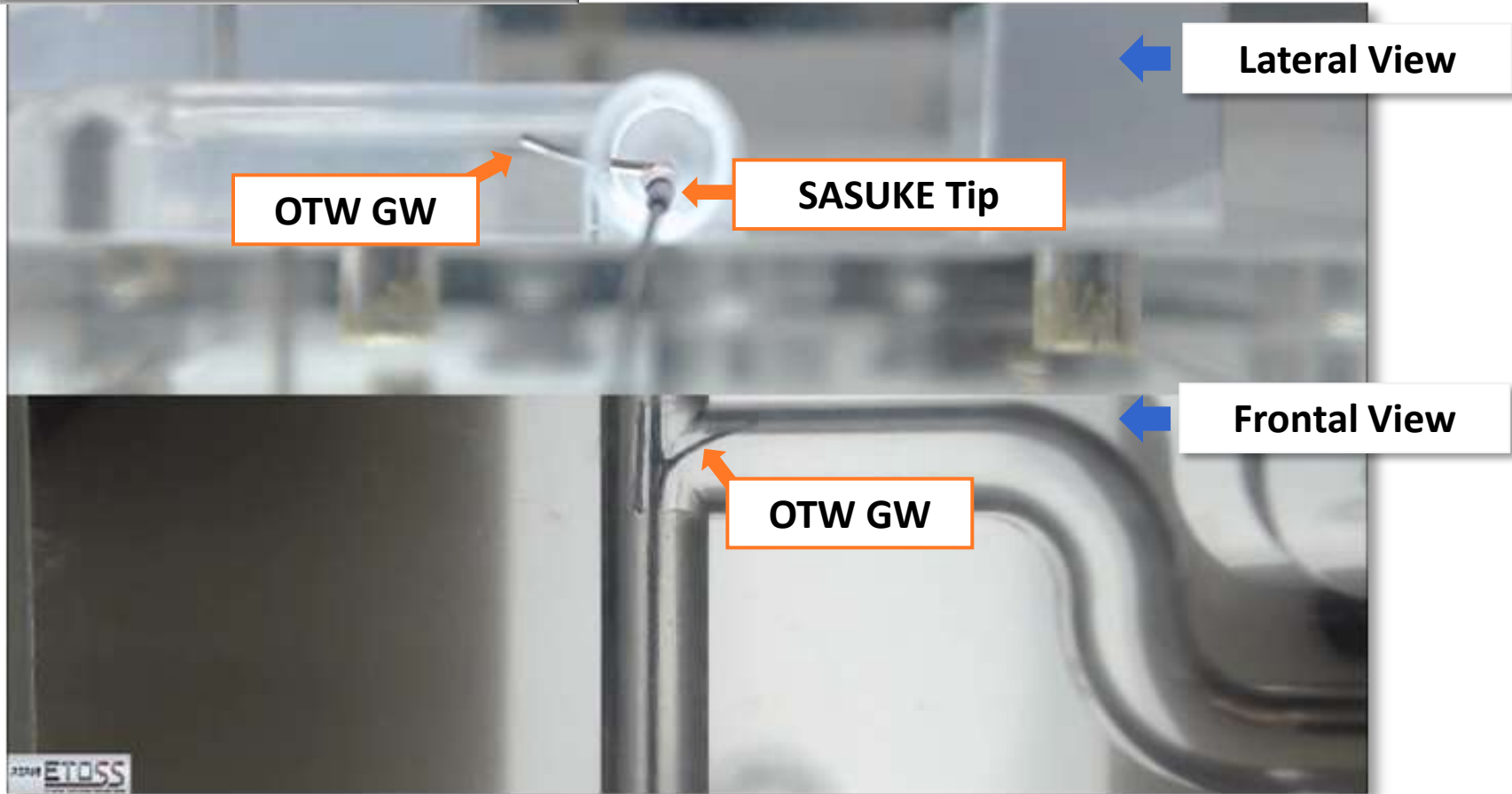
SASUKE

✓ Observe the catheter movement when selecting side branch by GW.

Accessing side branch:

Comparison of stability between SASUKE and Corsair with ETOSS

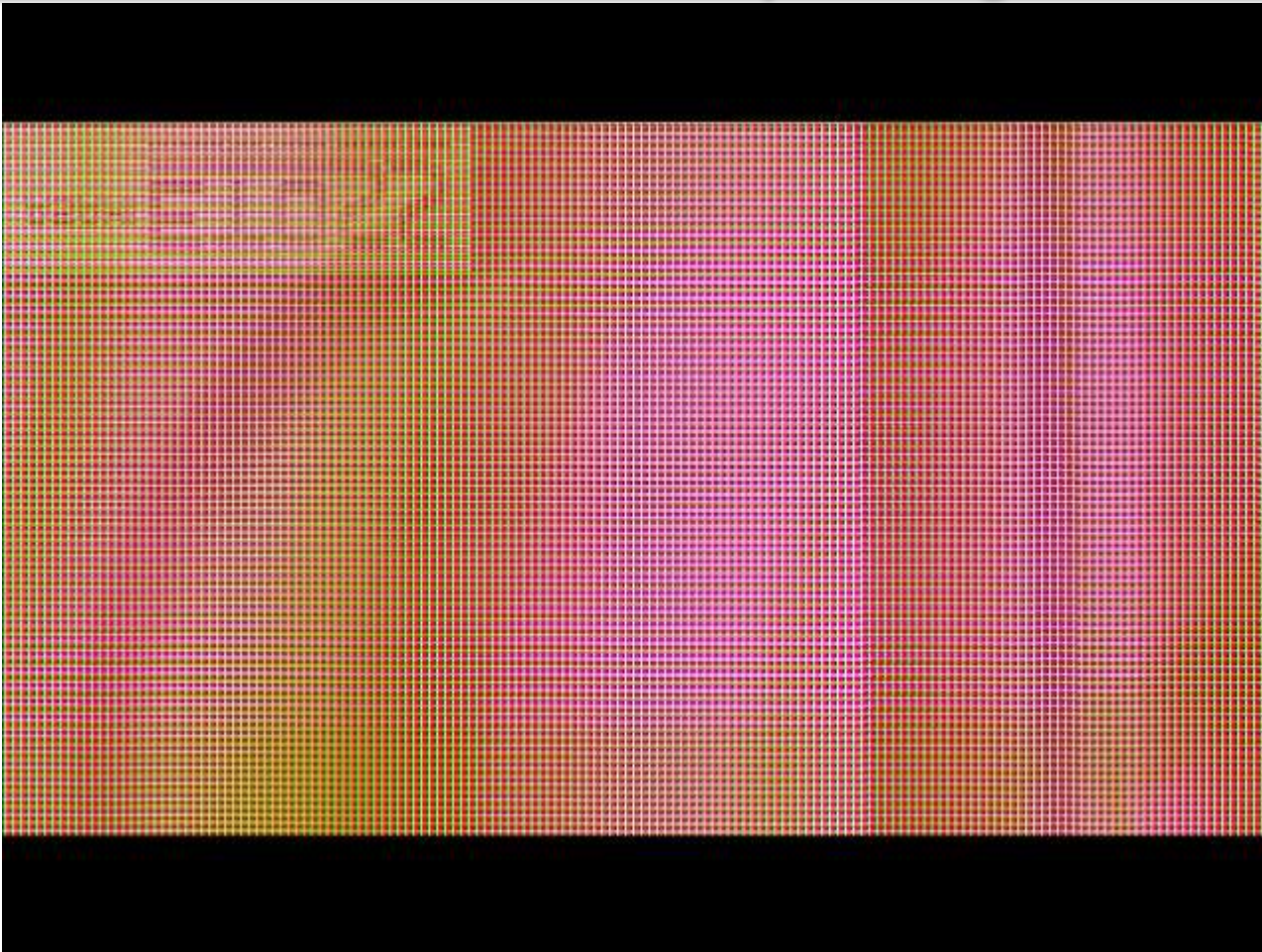
Ex. ETOSS



Accessing side branch:

Comparison of stability between SASUKE and Corsair
with ETOSS

◆ Penetration catheter movement
caused by rotating GW



Accessing side branch:

Comparison of stability between SASUKE and Corsair with ETOSS

◆ Reduction of catheter movement
caused by rotating GW



Accessing side branch:

Comparison of stability between SASUKE and Corsair with ETOSS

SASUKE



Corsair



Improvement of stability

Catheter moves when rotating GW to approach side branch.

This movement can be seen significantly when using Corsair, on the other hand, when using SASUKE, catheter is stabilized by anchor effect of RX GW.

Device Key Features

Double Lumen Multifunctional Catheter

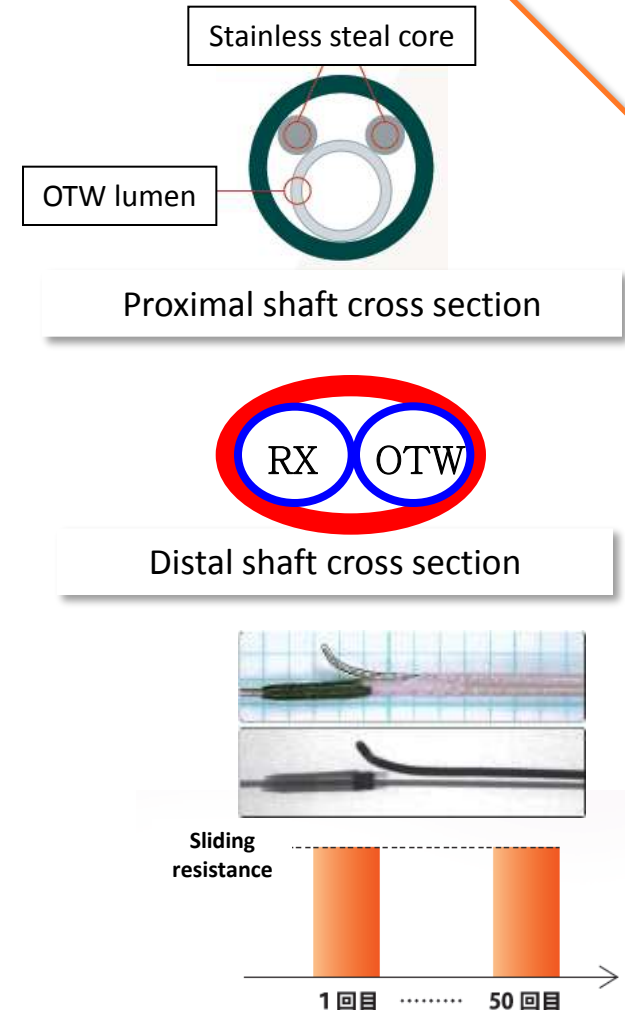
- ◆ High trackability
- ◆ Avoid distal shaft damage when using stiff GW in OTW lumen
- ◆ Anti kinking structure at proximal shaft and RX GW port
- ◆ Increased tip visibility
- ◆ Increased GW manipulation
- ◆ Durable and highly lubricous hydrophilic coating

SASUKE Key message

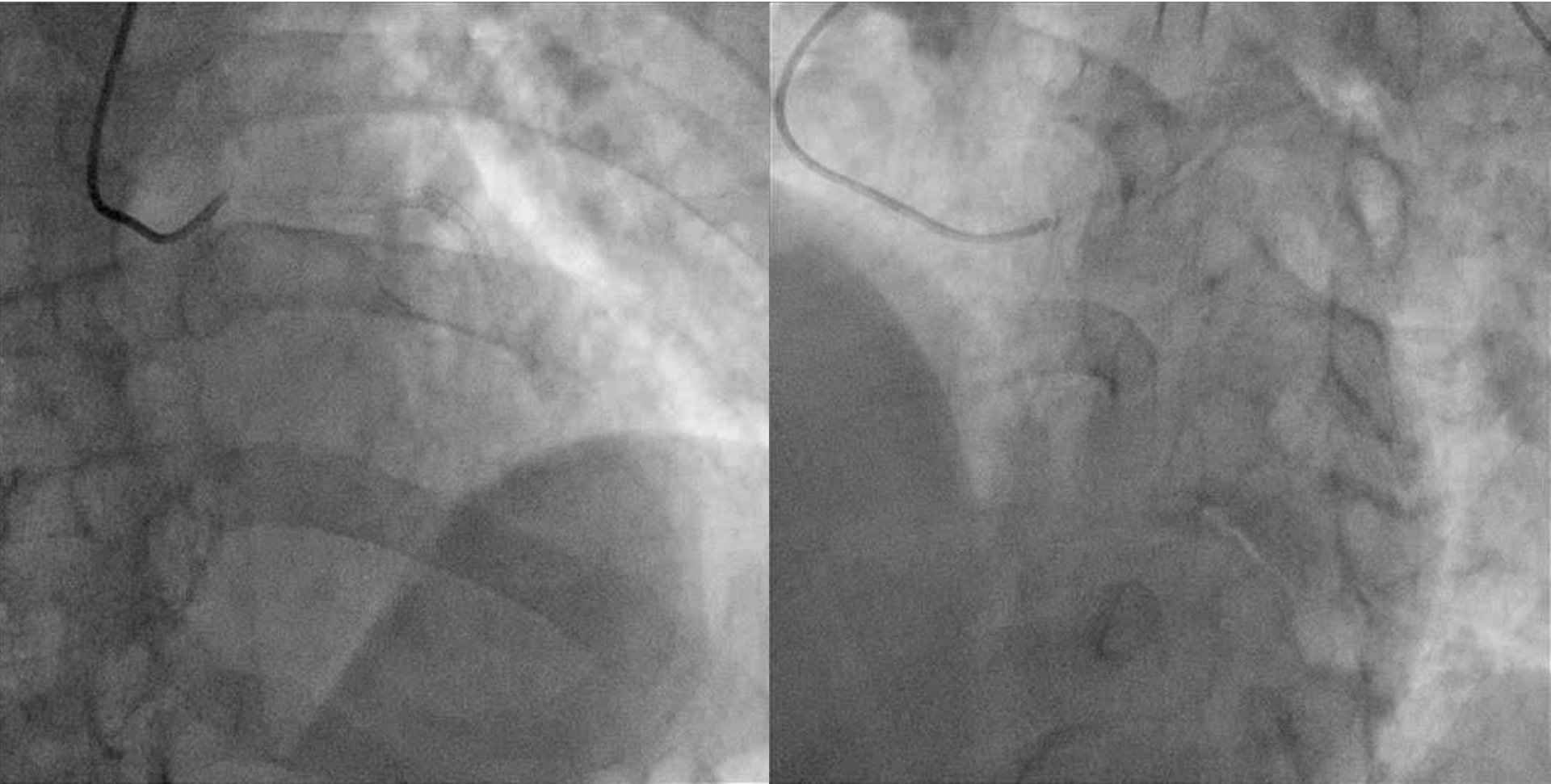
Double lumen MFC allows GW stability and enhanced GW control

SASUKE characteristics

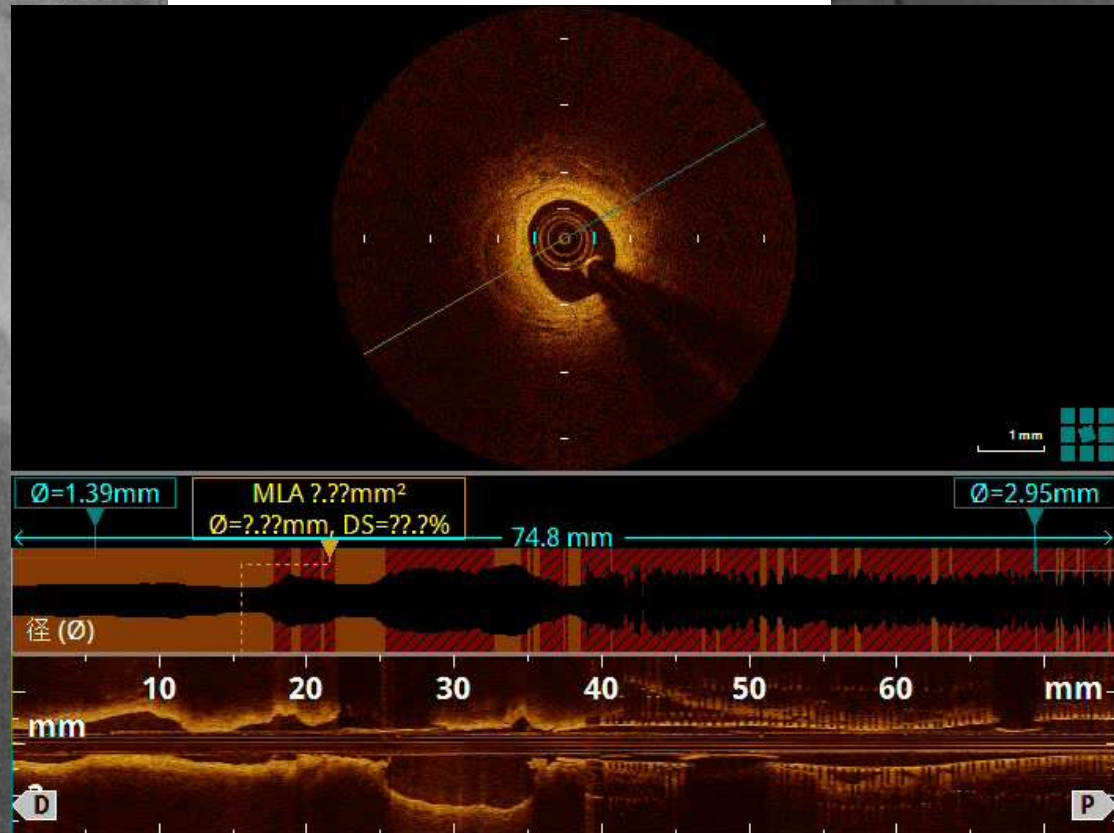
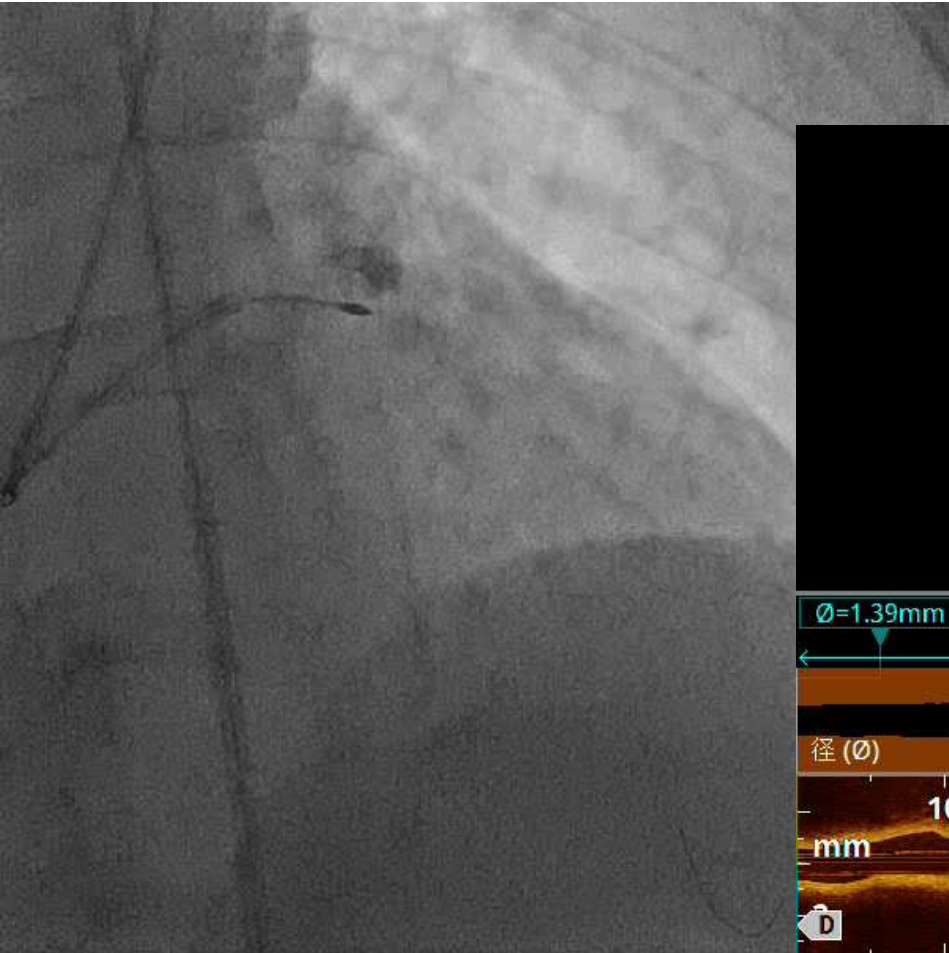
- ① **Double Stainless Steel Core**
 - ✓ Maintaining high kink resistance
- ② **Oval Shaft Design**
 - ✓ Equalized the thickness of distal shaft
 - Reduction of the risk of perforation distal lumen by stiff GW
- ③ **Tapered Soft Tip**
 - ✓ Loading Tapered Soft Tip as well as Corsair / Caravel
 - Bringing good visibility and high track ability
- ④ **L³ coating (Long Lasting Lubricity Coat)**
 - ✓ Improving initial lubricity and coating durability



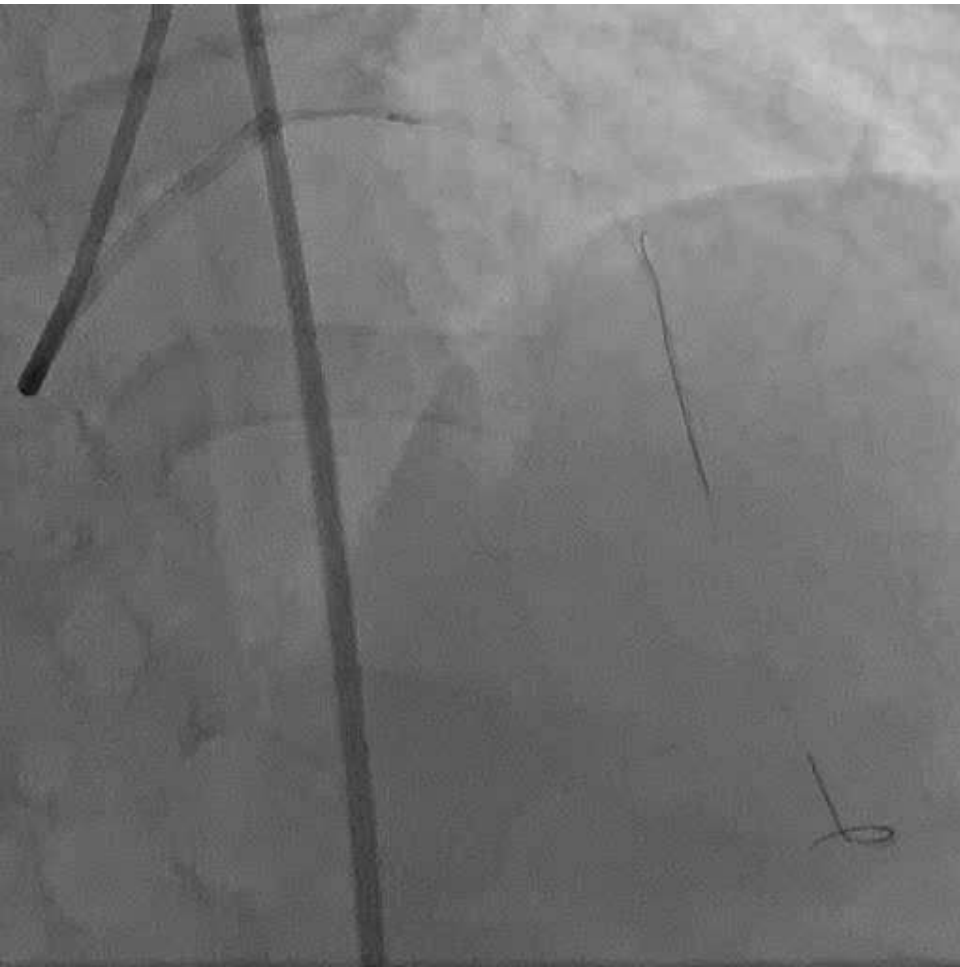
LAD severe calcified bifurcation lesion



OCT



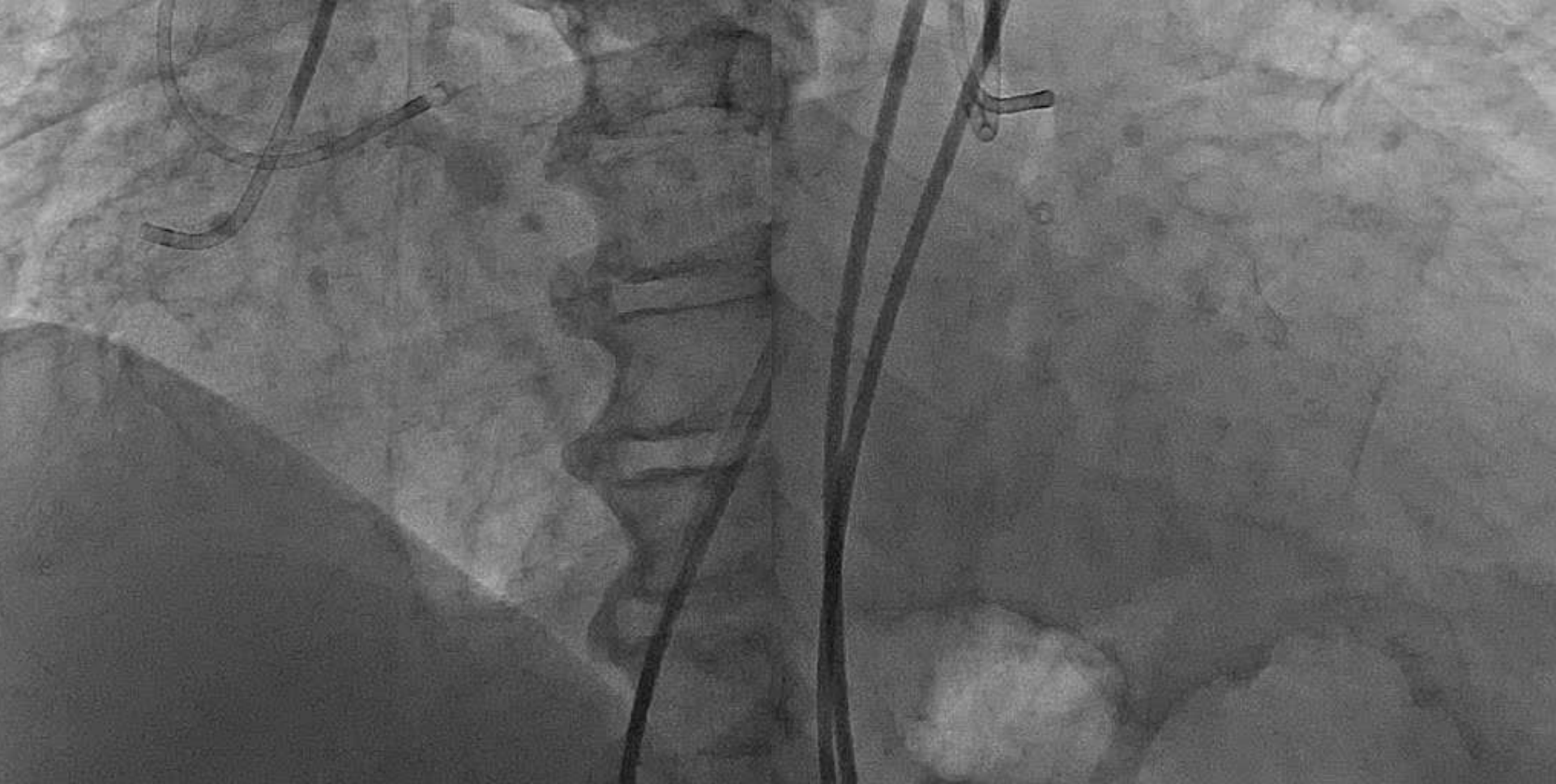
Reverse wire using Sasuke and stenting via jailed balloon technique



Final angiograms



RCA CTO



Tiny septal channel with branch



Channel tracing using XTR



Reverse CART



Messages

ASAHI new devices contribute to improve and facilitate complex PCI procedure.

We can challenge more complex lesions by using these ASahi new devices.