IMDS

INTERVENTIONAL MEDICAL DEVICE SOLUTIONS

... increasing quality of life ...

Committed to improving outcomes in complex lesions

NHANCER RX

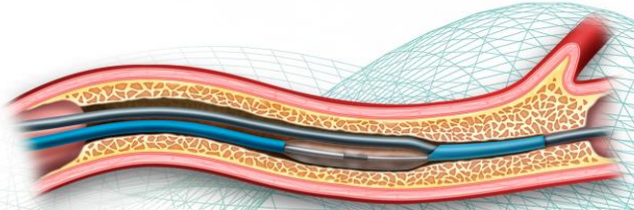
Full length variable braid technology providing precise torque control for accuracy and efficiency

GUIDION HYDRO

Full range of Rx Guide Extensions enabling Tailored Interventions

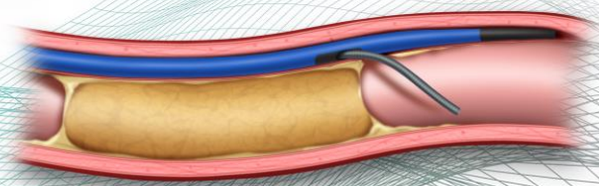
Trap it

Unique shaft stop design providing a fast and safe trapping balloon technique



BLiMP

Opens the toughest lesions



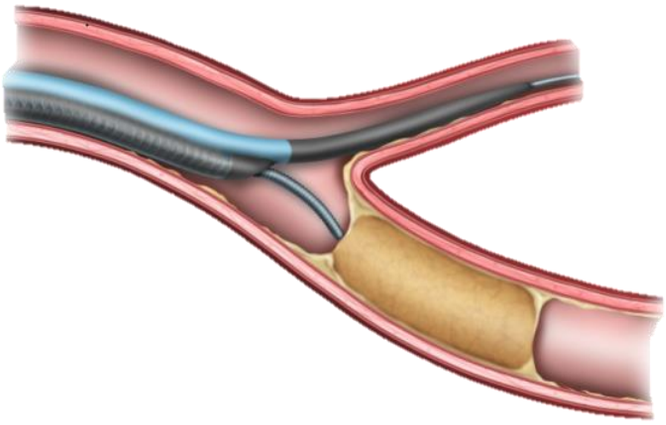
RECROSS

Redirection redefined

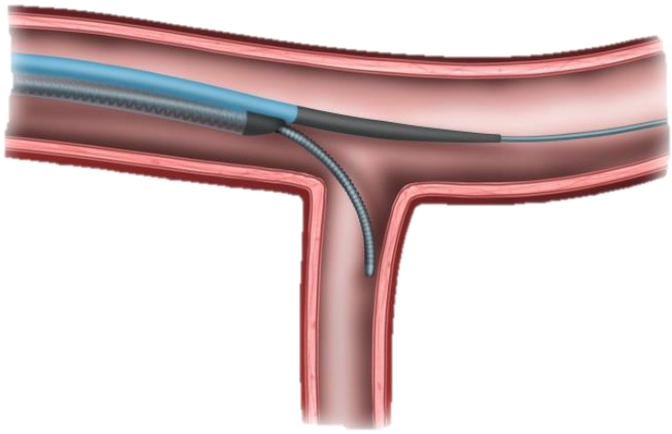
NHANCER RX

Dual lumen applications

Bifurcation CTO wiring

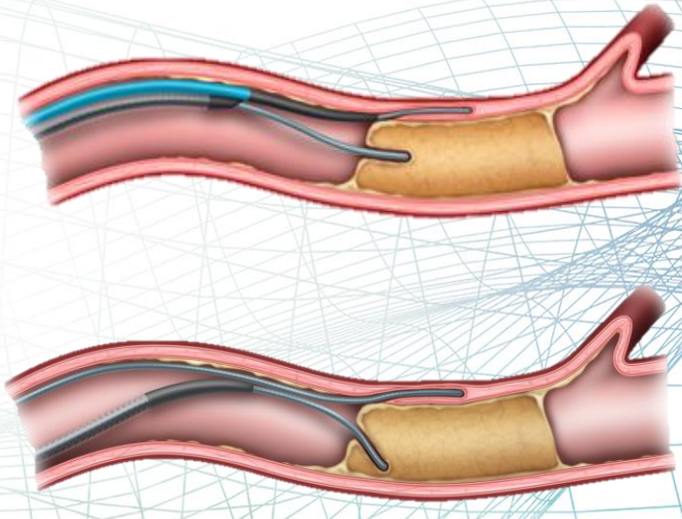


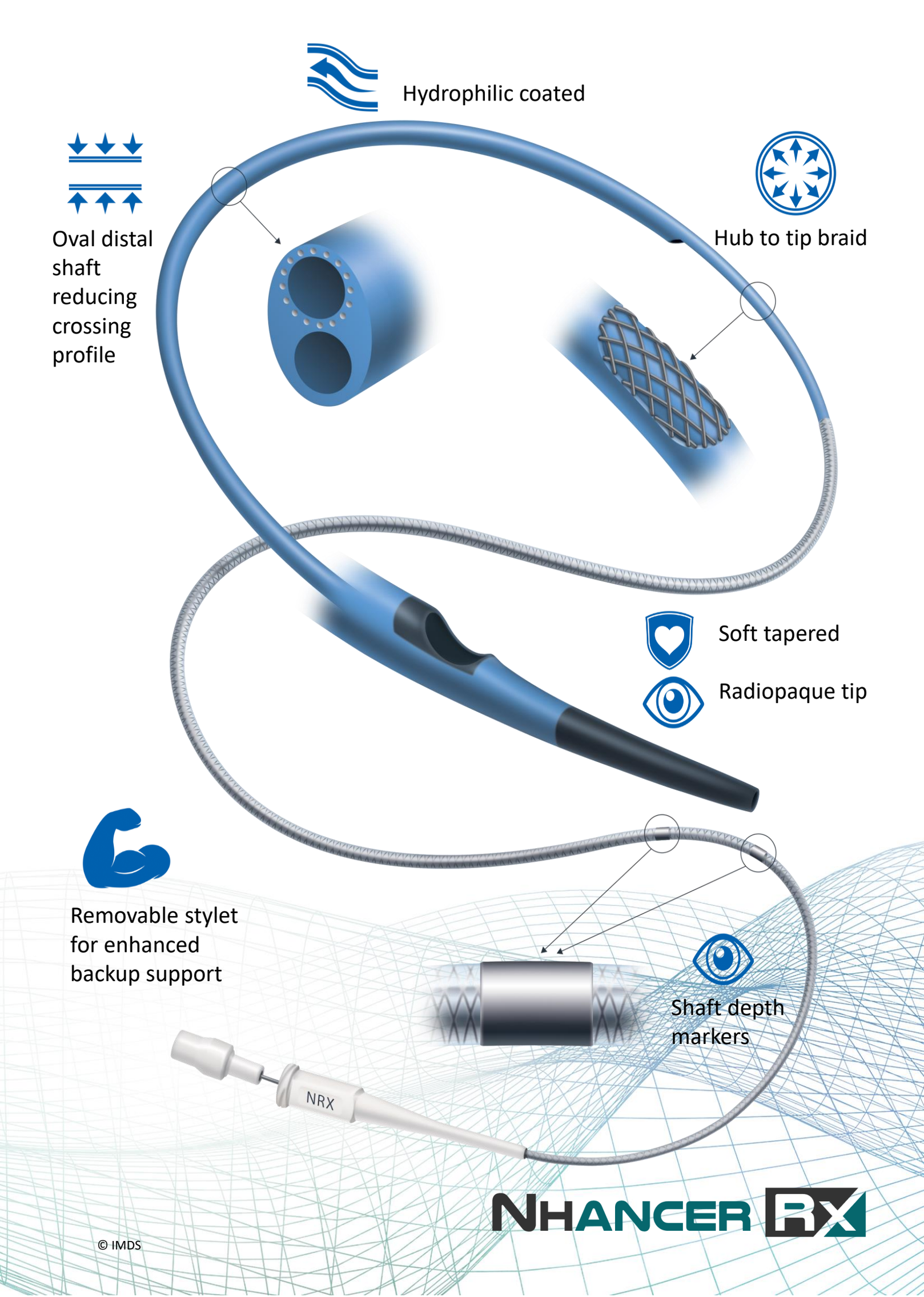
Wiring acute angulated bifurcations



- Side branch access through stent struts
- Protection of the side branch
- Reverse wire technique
- And more …

Parallel wiring technique

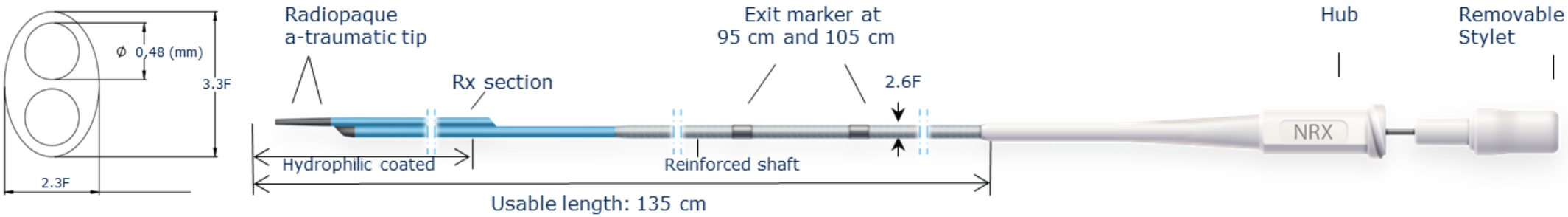


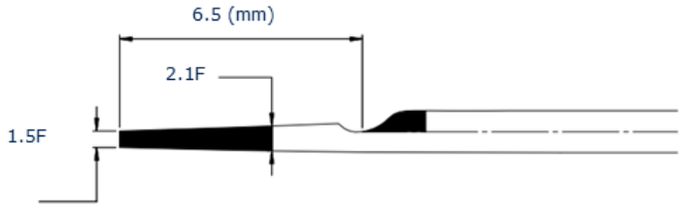


NHANCER RX

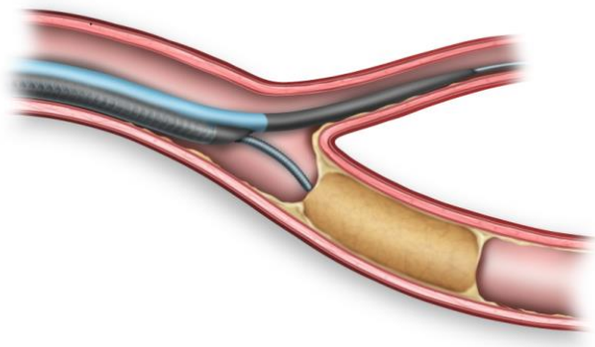
NHANCER RX

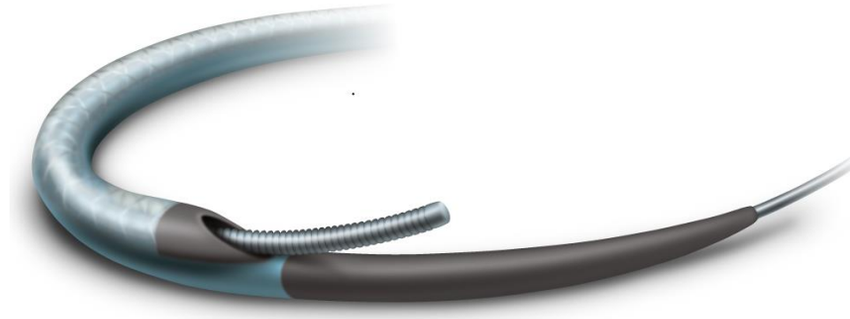
IMDS



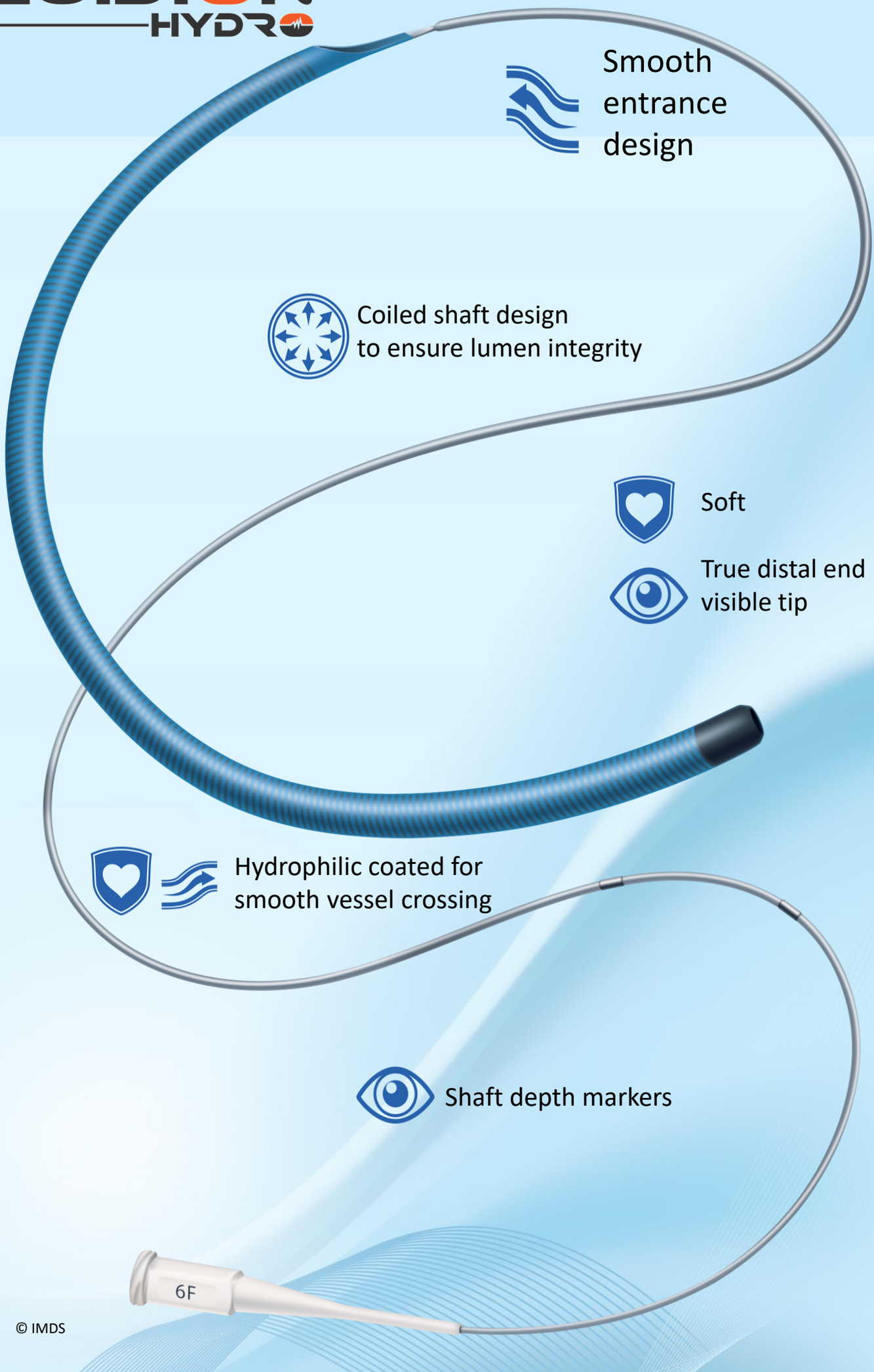


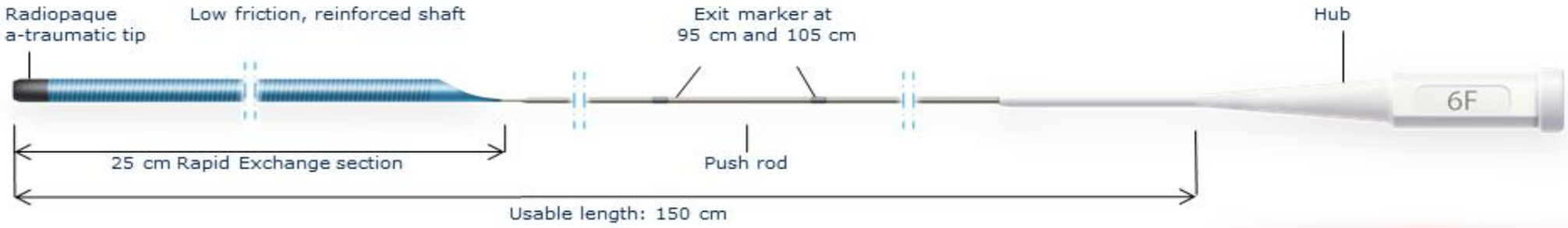
Technical specification	Model NRX1413518	Technical specification	Model NRX1413518
Guidewire compatibility OTW lumen	0.014"	Guiding cathether compatibility	5F
Guidewire compatibility Rx lumen	0.014"	Distal shaft coating	Hydrophilic (NDurance)
Usable length	135 cm	Rx lumen length	18 cm



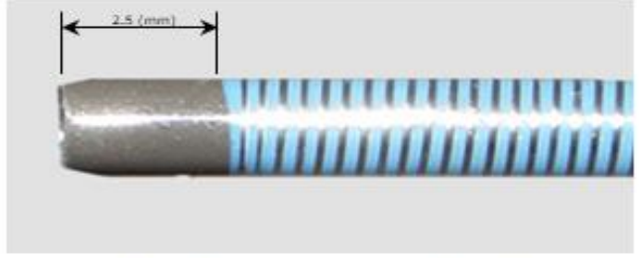


GUIDION HYDRO



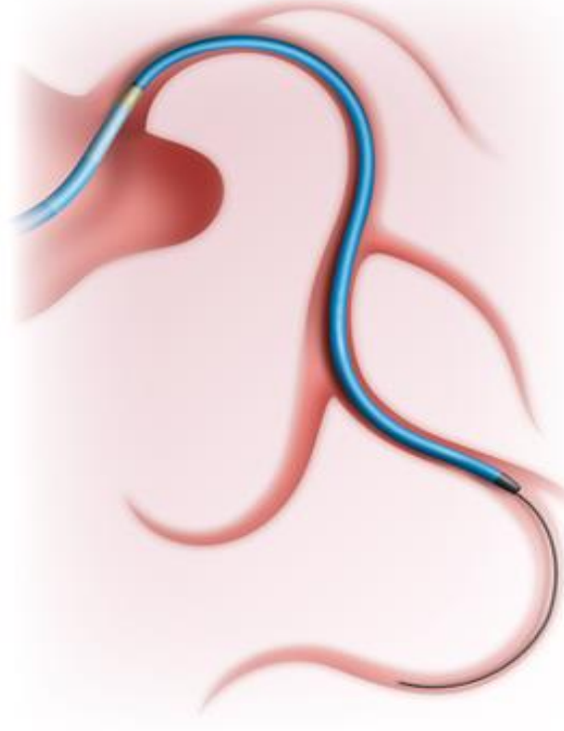


Model	Required guide catheter ID	Guidion ID	Rapid exchange length	Usable length
G50F25150	5F ID ≥0.056" (1.42 mm)	0.041" (1.04 mm)	25 cm	150 cm
G60F25150	6F ID ≥0.070" (1.78 mm)	0.056" (1.42 mm)	25 cm	150 cm
G70F25150	7F ID ≥0.078" (1.98 mm)	0.062" (1.57 mm)	25 cm	150 cm
G80F25150	8F ID ≥0.088" (2.24 mm)	0.071" (1.80 mm)	25 cm	150 cm



Radiopaque soft tip marker

Rapid exchange transition



Outstanding crossability

PERCUTANEOUS INTERVENTIONAL CARDIOVASCULAR MEDICINE

THE PCR-EAPCI TEXTBOOK

TABLE OF CONTENTS | CME FAQS | SOME HELP | BOOKSHOP | Updated on March 3, 2015

PART III CHAPTER 13

VOLUME II
Intervention I

CHRONIC TOTAL OCCLUSIONS

Gerald S. Werner

SUMMARY

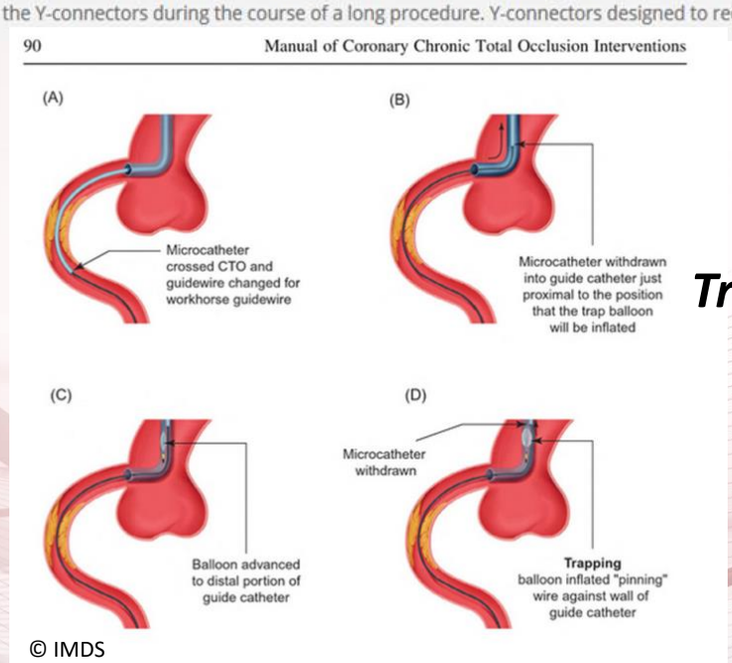
Chronically occluded coronary lesions make up about 20% of all coronary lesions, and the presence of a chronic total coronary occlusion (CTO) influences the decision on the therapeutic strategy. There are numerous studies to support the rationale of reopening a CTO if viability and ischaemia are demonstrated in the territory distal to the CTO. The reluctance of many operators to attempt CTOs as target lesions is often based on the complexity of the procedure, and the limited success rates. However, recent developments in the technical approach, both in strategy as well as available tools, have led to a greatly improved success rate for the recanalisation of a CTO in over 90% of cases. Furthermore, persistent patency and low lesion recurrence can now be achieved through the use of drug-eluting stents (DES). To attain these improvements in technical success, operators need to undertake specialised training, and must become familiar with the specific tools and techniques of CTO intervention.

CATHETER EXCHANGE TECHNIQUES

With the above described approach to CTOs, after successful wire passage, the OTW catheter or balloon needs to be exchanged for a first or subsequent balloon for dilatation. This can be achieved by the use of long wires from the beginning, or by dedicated extension wires. However, not all wires are available in 300 cm length, and not all extension wires fit all wires, and are not therefore universally applicable. One technique to overcome this problem is the flushing out of the microcatheter. This is easily done with a FineCross™ (Terumo Corp., Tokyo, Japan) or similar microcatheter, but may not always be easily achieved in the case of guidewire kinking or multiple wires within the guide catheter. The simplest method is just to place a 10cc saline filled syringe on the distal tip of the microcatheter with the distal 1cm of the wire protruding. Then with manual force the syringe is compressed leading to release of the microcatheter without moving the guidewire. The manual force can be reduced once the catheter is moving. If this does not work, a balloon inflation device can be attached to the distal end of the microcatheter, and under increasing pressure, up to 20atm, the catheter can be released. If this does not lead to active movement of the catheter, it can be gently retracted under control of the wire position. The wire is held in position by the pressure exerted on the microcatheter.

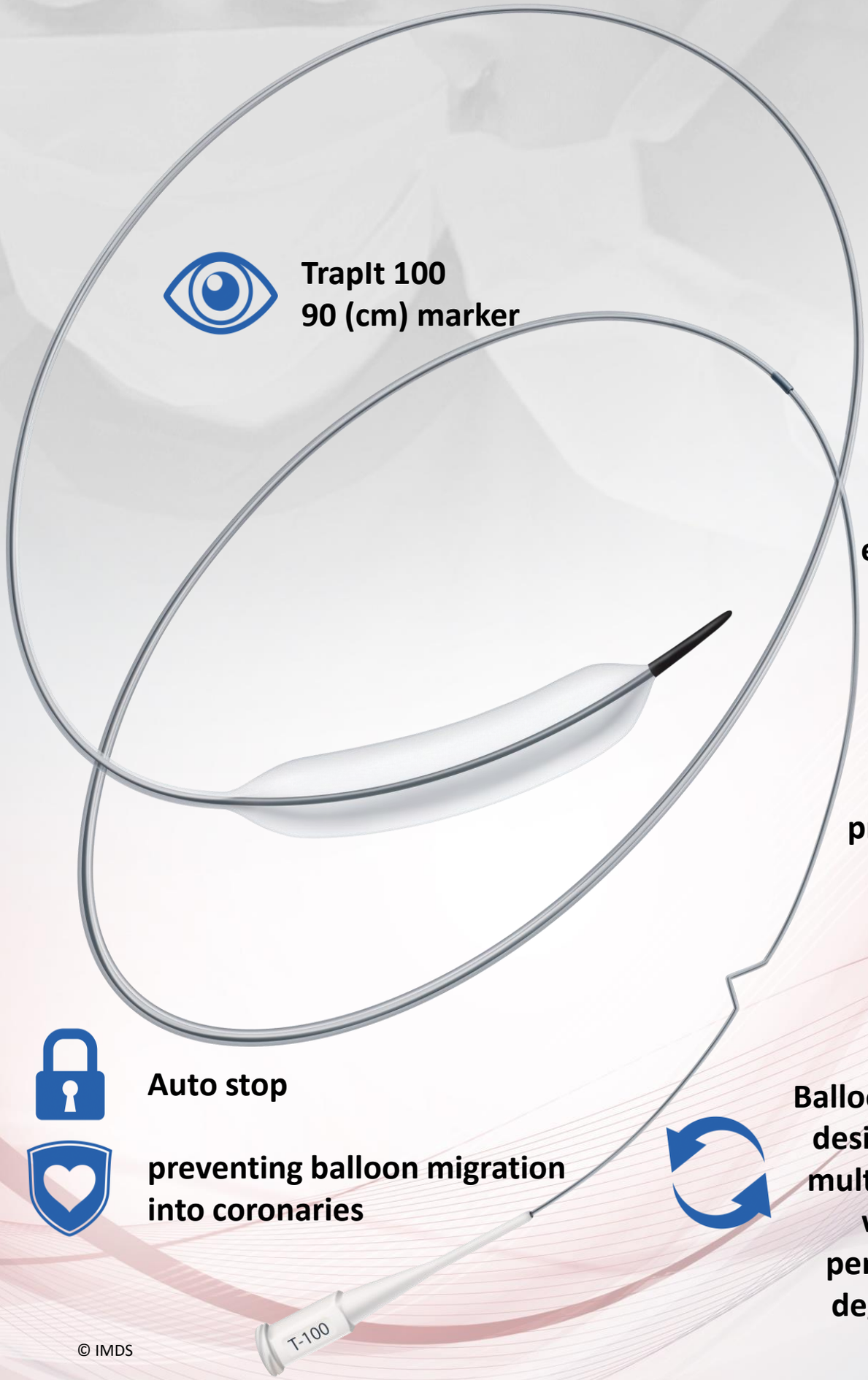
In case this does not work, or the operator is not sure about the security of the distal wire position, the safest way to exchange a wire is the "trapping technique": the microcatheter or OTW balloon is moved back as far as possible until the distal 1cm of the guidewire is protruding from its end. Then a balloon catheter is advanced without the need for a separate wire parallel to the microcatheter into the guide catheter to be positioned distal to the distal end of the microcatheter, but within the guide catheter, usually within the distal 3 to 4 cms. This balloon is inflated at 10 to 12 atm thus trapping the guidewire distal to the microcatheter, while the microcatheter can be safely retrieved without losing the wire position (Figure 15). To achieve a sufficient trapping effect, a 2.0mm balloon is required for a 6 Fr guide and a 2.5 mm balloon for a 7 Fr or 8 Fr guide. This technique should also be used to secure a stiff bare guidewire when a microcatheter needs to be advanced over this wire without the risk of inadvertent distal advancement of the wire.

One should keep in mind that multiple wire and balloon exchanges and the above described techniques may lead to a considerable loss of blood through the Y-connectors during the course of a long procedure. Y-connectors designed to reduce blood loss should be preferred.



Trapping is the recommended technique for OTW device exchanges

Safe & Effective Trapping



TrapIt 100
90 (cm) marker

True distal end visibility

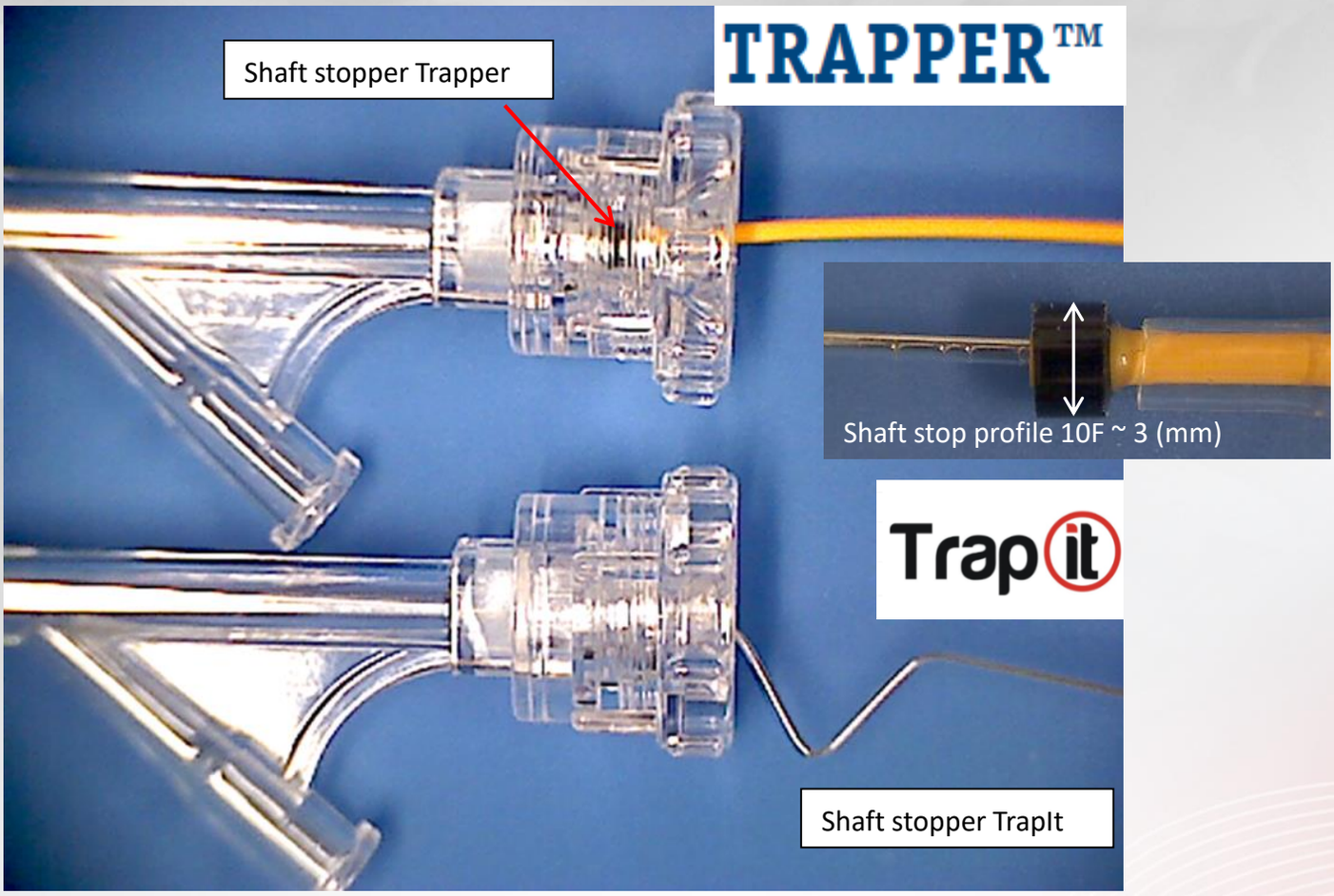
2F shaft profile vs. 2.5 of regular POBA

Auto stop

preventing balloon migration into coronaries

Balloon on a wire design enables multiple passes without performance degradation

Safe & Effective Trapping

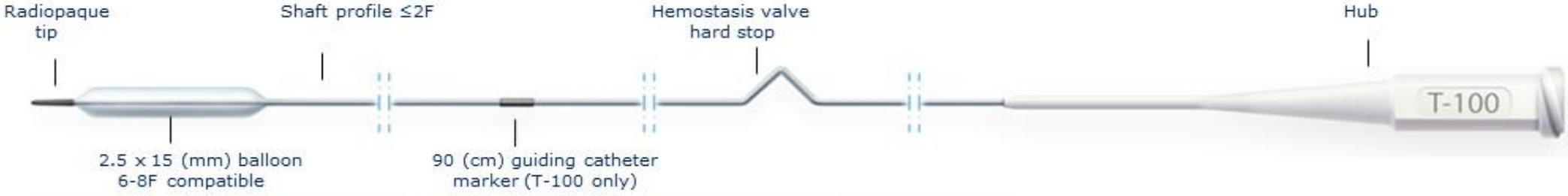


Product	TrapIt Guiding Catheter compatibility
Single Lumen Micro catheters NHancer Pro X; Corsair, FineCross, Caravelle, Turnpike	6F
Dual Lumen Micro catheters NHancer Rx; FineDuo; Crusade	6F
Dual Lumen Micro catheters TwinPass Torque	7F
Stingray LP CTO Re-Entry System	6F

Trap it

Trapping Balloon

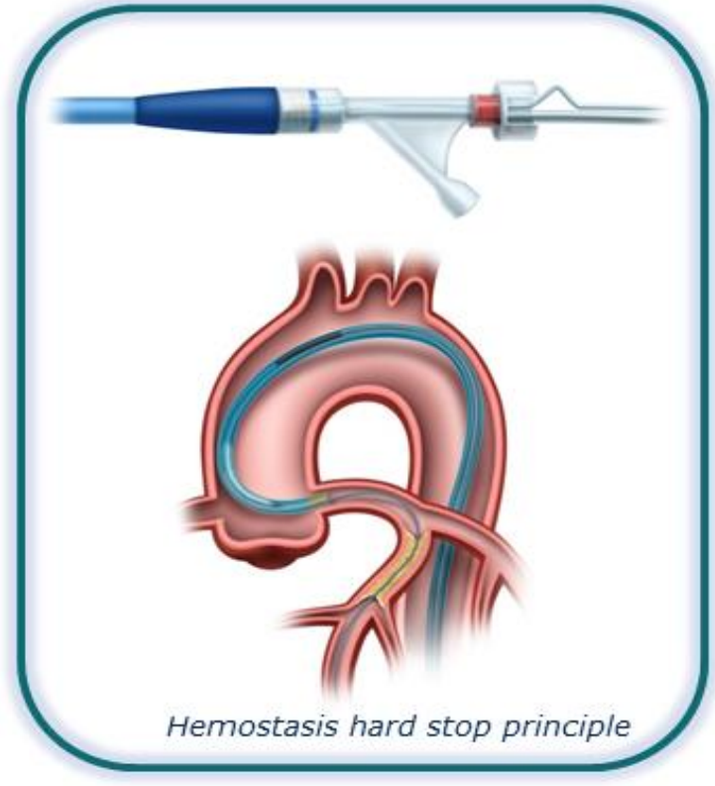
IMDS



Model	Balloon length	Balloon OD at nominal	Shaft OD	Guide catheter compatibility
TRP9015 (T-90)	15 mm	2.5 mm	2.0F (0.66 mm)	90 cm
TRP10015 (T-100)	15 mm	2.5 mm	2.0F (0.66 mm)	100 cm

Radiopaque tip

High pushable shaft design



Hemostasis hard stop principle

Required pressure for trapping 6 ATM

Balloon Uncrossable Lesions

Catheterization and Cardiovascular Interventions 90:12–20 (2017)

CORONARY ARTERY DISEASE

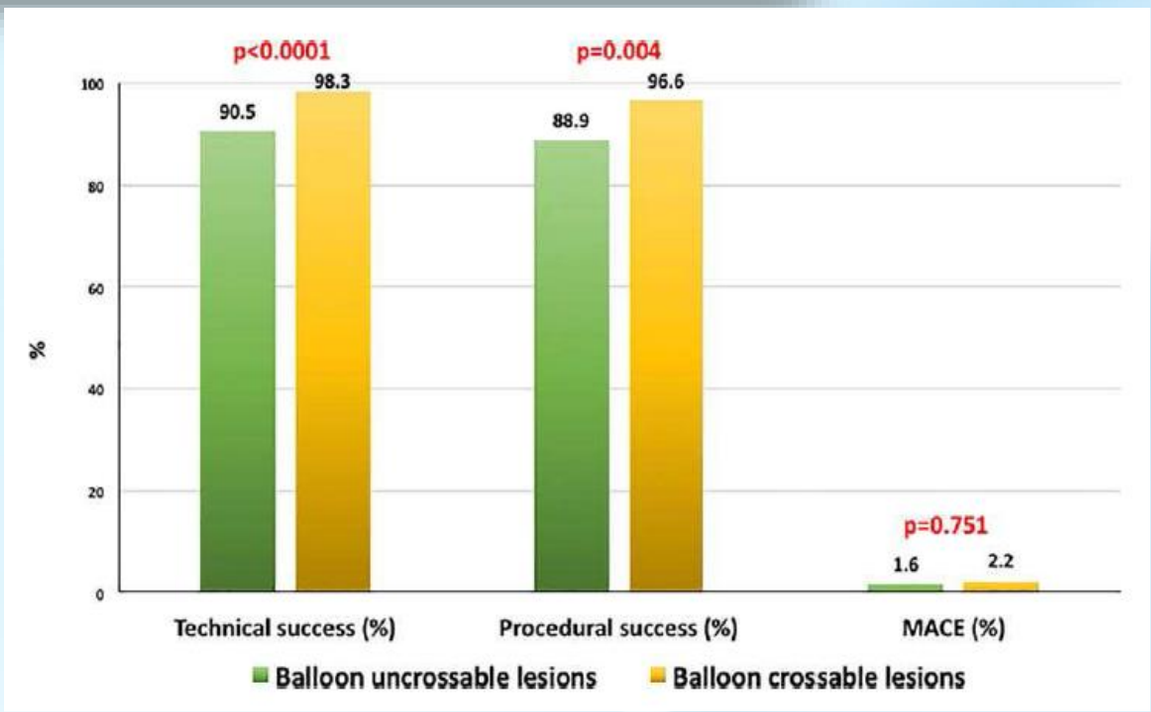
Original Studies

Prevalence, Indications and Management of Balloon Uncrossable Chronic Total Occlusions: Insights from a Contemporary Multicenter US Registry

Judit Karacsonyi,[1,2] MD, Dimitri Karmpaliotis,[3] MD, Khaldoon Alaswad,[4] MD, Farouc A. Jaffer,[5] MD, PhD, Robert W. Yeh,[6] MD, Mitul Patel,[7] MD, John Bahadorani,[7] MD, Anthony Doing,[8] MD, Ziad A. Ali,[3] MD, Aris Karatasakis,[1] MD, Barbara A. Danek,[1] MD, Bavana V. Rangan,[1] BDS, MPH, Aya J. Alame,[1] BA, Subhash Banerjee,[1] MD, and Emmanouil S. Brilakis,[1,9*] MD, PhD

Patient population:

- 718 CTO PCI 2012-2016;
- 9.0% in the PROGRESS registry;



Variable	Overall	Balloon uncrossable CTOs	Balloon crossable CTOs	*P*
Technical success	97.6%	90.5%	98.3%	<0.0001
Procedural success	95.9%	88.9%	96.6%	0.004
Procedural time (min)[a]	139 (96, 203)	208 (135, 258)	135 (94, 194)	<0.0001
Fluoroscopy time (min)[a]	48 (28, 79)	77 (52, 100)	45 (27, 75)	<0.0001
Air kerma radiation dose (Gray)[a]	3.37 (2.03, 5.00)	3.99 (2.73, 5.38)	3.30 (1.97, 4.78)	0.016
Contrast volume[a]	265 (200, 350)	275 (210, 350)	260 (200, 350)	0.731
MACE	2.1%	1.6%	2.2%	0.751
Death	0.4%	0%	0.5%	0.585
Acute MI	0.7%	1.6%	0.6%	0.388
Re-PCI	0.1%	0%	0.2%	0.753
Stroke	0.6%	0%	0.6%	0.529
Emergency CABG	0%	0%	0%	-
Pericardiocentesis	0.7%	1.6%	0.6%	0.388

Karacsonyi J et al, CCI 2017

BLIMP

Scoring balloon

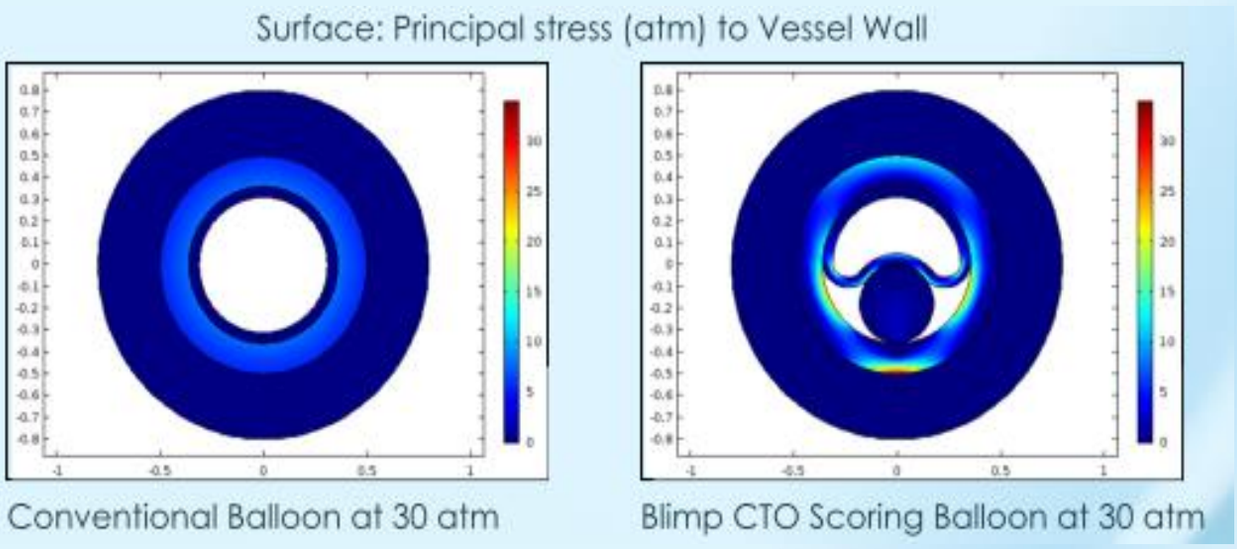
1.5F Entry & Shaft profile

High penetration capability due to core wire design

Guidewire scoring element increases principle stress x4

30 ATM rated burst translates up to **120 ATM** principle stress

Scoring balloon



Effect of guidewire scoring element.

The guidewire scoring element provide a local peak stress (see yellow/ red colors above) to the vessel wall been approximately 4x higher than the inflated pressure*

Blimp balloon inflation pressure	Equivalent peak stress to vessel wall
10 (ATM)	40 (ATM)
20 (ATM)	80 (ATM)
30 (ATM)	120 (ATM)
40 (ATM)	160 (ATM)

**Kawase et.al, Cardiovasc Interv and Ther, DOI 10.1007/s12928-013-0232-6*

RECROSS

Over The Wire Dual Lumen Micro Catheter