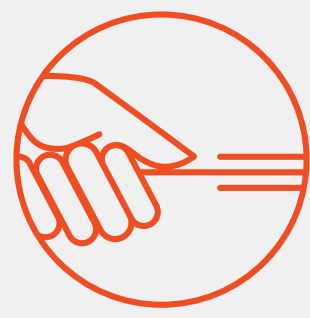




Patient history



Procedure description



Final clinical results



Technical data /
ordering info

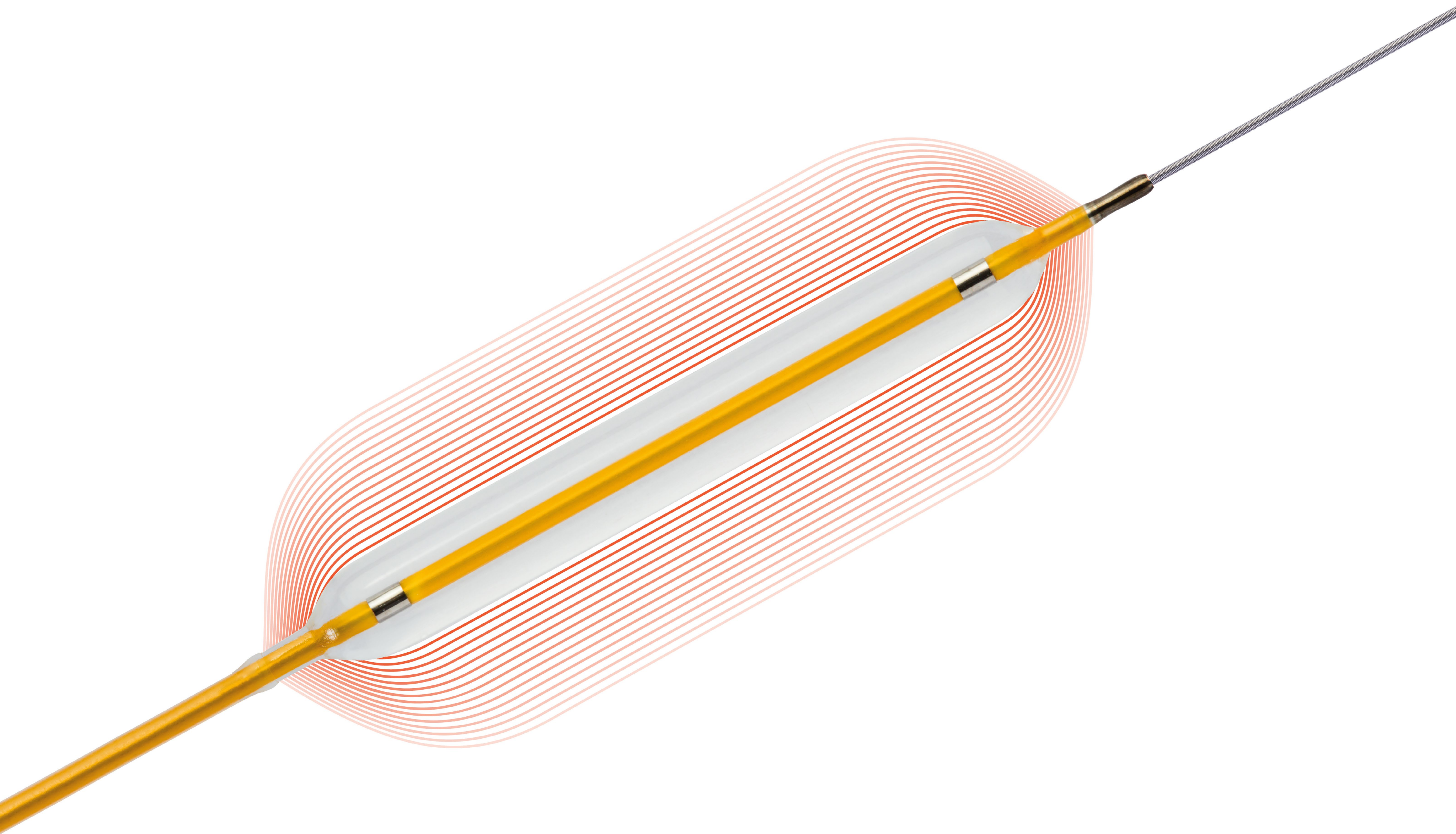


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Vascular Intervention // **Pantera LEO**
Covered Coronary Stent System

 **BIOTRONIK**
excellence for life

Case Report



Case report

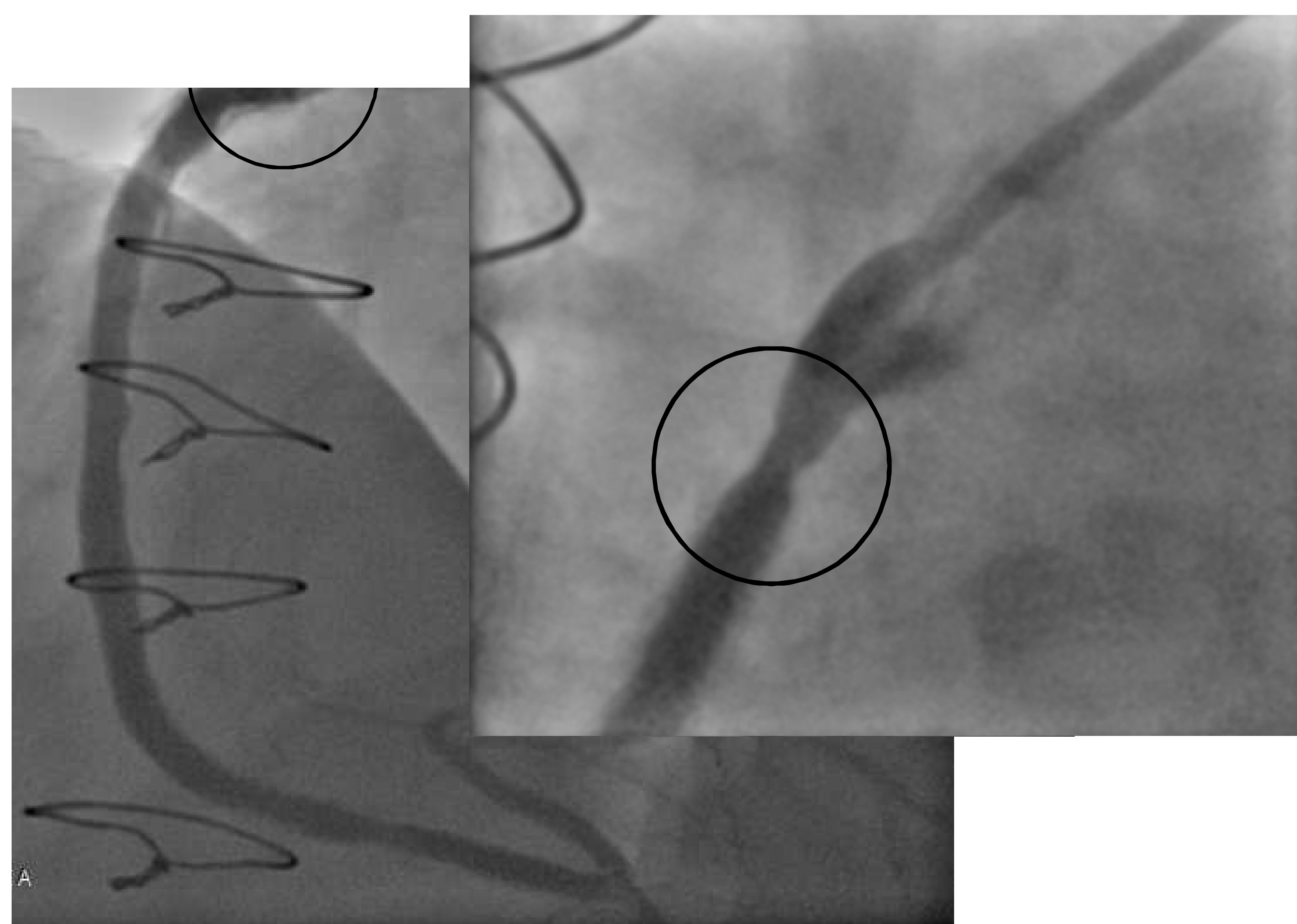
Diseased venous bypass with challenging stenosis with the **Pantera® LEO** High Pressure Balloon Catheter

Author

Dr. M. Schmid, University Hospital of Erlangen, Germany

1. Patient history

Symptomatic, 72 year old male patient with a 10-12 mm long, eccentric, 70% stenosis in the proximal segment of the saphenous vein graft to the ramus interventricularis posterior. Initially, the stenosis was obscured by the guide catheter. The operator gently disengaged the guide, now the stenosis was clearly visualized, located close to the proximal end of a stent implanted one year ago.

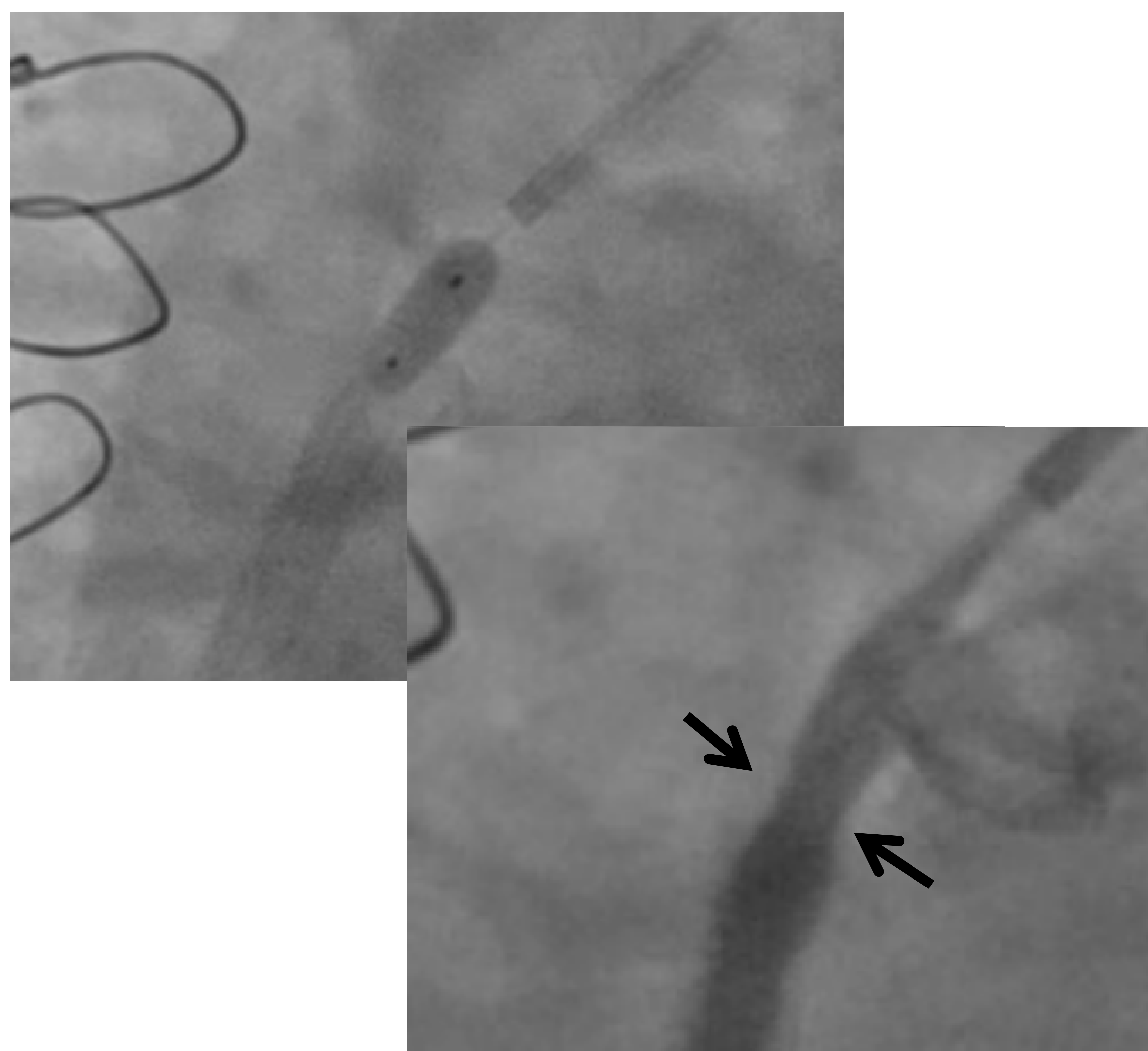


Baseline angiogram

2. Procedure description

Stent implantation

After wiring the lesion (Galeo® F) and placement of a protection device (Emboshield, Abbott) in the distal part of the bypass, a 4.5 x 12 mm stent (Taxus, Boston Scientific) was implanted. Unfortunately, the stent delivery balloon ruptured at 11 atm. Although the angiographic result appeared acceptable, there remained a narrowing. Switching to a 4.5 x 12 mm non-compliant balloon (NC Trek, Abbott) failed to fully expand the lesion because of balloon rupture at 10-12 atm. Two following balloons (NC Trek, Abbott) also ruptured at 10-12 atm.



Stent implantation

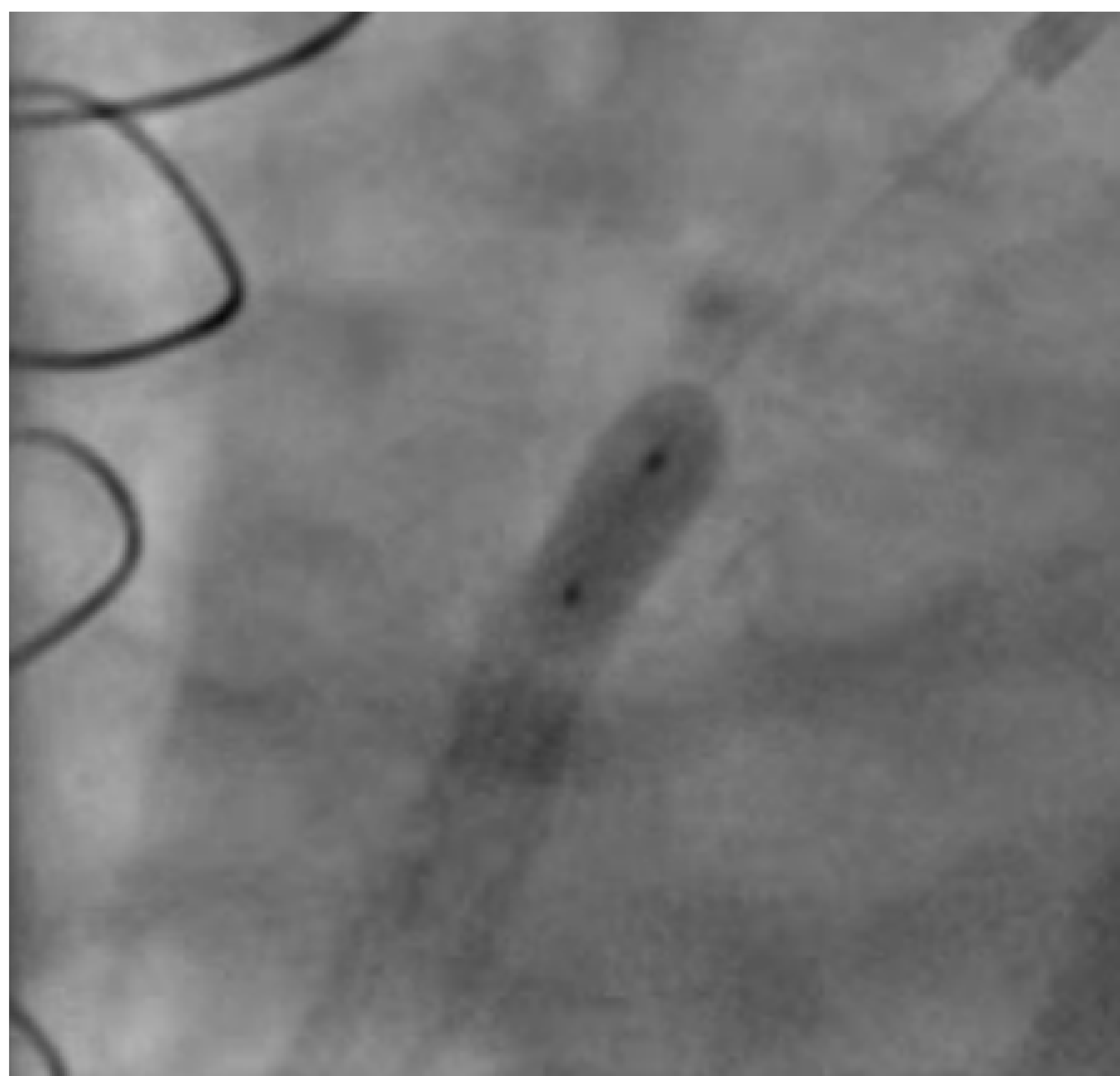
Case report

Diseased venous bypass with challenging stenosis with the **Pantera LEO** High Pressure Balloon Catheter

2. Procedure description

Post dilatation

Faced with a rigid and potentially undilatable lesion, the operator chose to perform a final attempt with a 4.5 x 8 mm Pantera LEO non-compliant balloon. The balloon could be fully expanded at 18 atm.



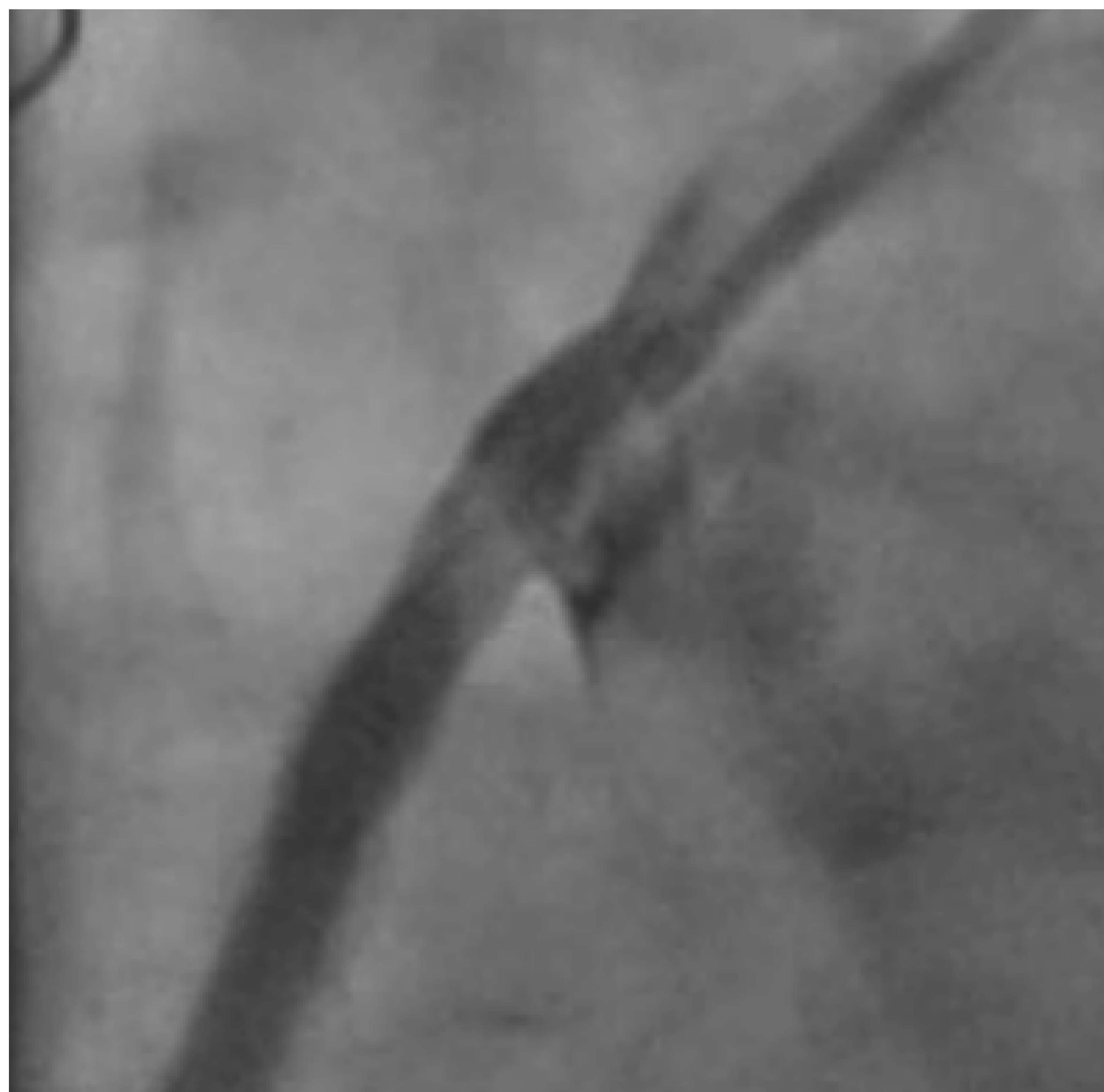
Post-dilatation with **Pantera LEO**

3. Final results and conclusion

Angiographic appearance after high pressure balloon inflation

Following post-dilatation with **Pantera LEO**, the patient had a good final result.

This case highlights the durability of the **Pantera LEO** non-compliant balloon. The rigid nature of the lesion surprised the operator, at this was not expected given the minimal extent of calcium noted by fluoroscopy. This case also provides an example of a potential risk of direct stenting (i.e. without balloon pre-dilatation) as this approach would almost have resulted in an underexpanded and poorly deployed stent. Failure to fully expand the stent often leads to an adverse outcome, including stent thrombosis or restenosis.

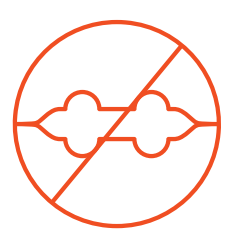


Final result

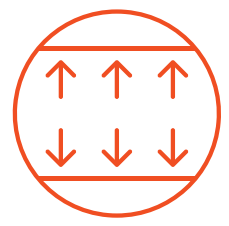


Pantera LEO

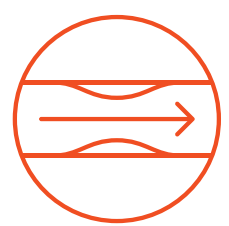
Indicated for stent post-dilatation and dilatation of a coronary artery or bypass graft stenosis.*



Lowest compliance in class avoiding dog-bone effect



Precise dilatation



Enhanced crossability and accurate placement

Technical Data

Proximal shaft

Design	Hypotube design
Diameter	2.0F
Shaft markers	92 cm and 102 cm from tip
Coating	Hydrophobic

Distal shaft

Guiding catheter	5F (min. I.D. 0.056")
Guide wire diameter	0.014"
Lesion entry profile	0.018"
Usable length	145 cm
Distal shaft length	34 cm
Balloon material	SCP (Semi Crystalline Polymer)
Balloon folding	3-fold
Balloon markers	Platinum-iridium
Coating	Hydrophilic (end of balloon to GW exit port); hydrophobic (balloon and tip)
Diameter	2.6F (ø 2.0 - 3.75 mm); 2.7F (ø 4.0 - 5.0 mm)

Compliance Chart

Balloon diameter x length (mm)

		ø 2.00	ø 2.25	ø 2.50	ø 2.75	ø 3.00	ø 3.25	ø 3.50	ø 3.75	ø 4.00	ø 4.50	ø 5.00
		x	x	x	x	x	x	x	x	x	x	x
		8-30	8-30	8-30	8-30	8-30	8-30	8-30	8-30	8-30	8-30	8-30
Nominal Pressure (NP)	atm**	14	14	14	14	14	14	14	14	14	14	14
	ø (mm)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
Rated Burst Pressure (RBP)	atm**	20	20	20	20	20	20	20	20	20	18	18
	ø (mm)	2.05	2.32	2.57	2.83	3.09	3.35	3.61	3.89	4.12	4.56	5.07

**1 atm = 1.013 bar

Ordering Information

Balloon ø (mm) Catheter length 145 cm Balloon length (mm)

	8	12	15	20	30
2.00	366991	367002	367013	367024	367035
2.25	366992	367003	367014	367025	367036
2.50	366993	367004	367015	367026	367037
2.75	366994	367005	367016	367027	367038
3.00	366995	367006	367017	367028	367039
3.25	366996	367007	367018	367029	367040
3.50	366997	367008	367019	367030	367041
3.75	366998	367009	367020	367031	367042
4.00	366999	367010	367021	367032	367043
4.50	367000	367011	367022	367033	367044
5.00	367001	367012	367023	367034	367045

5F

*Indication as per IFU.

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