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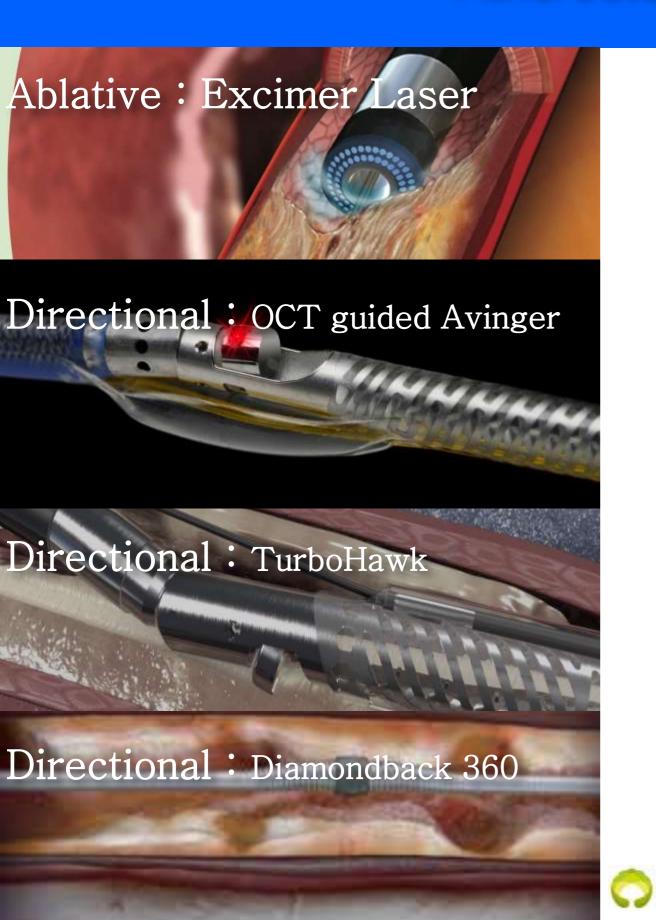


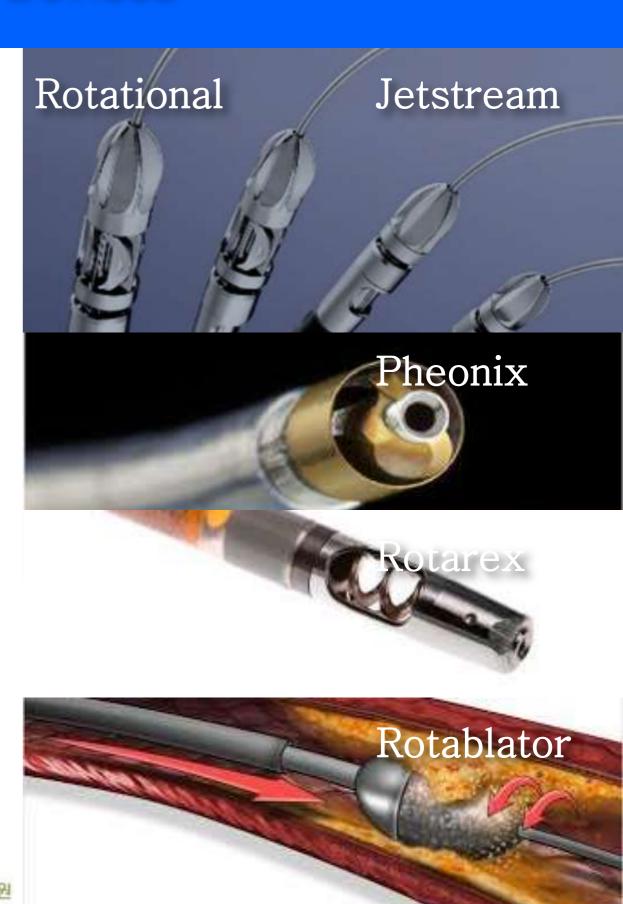
Atherectomy in treating Complex Lesions

- 1) Increase change of procedural success
- 2) Reduce Flow Limiting Dissections
- 3) Reduce Bail-out Stenting
- 4) Allow Optimal Stent Expansion
- 5) Improve Effectiveness of anti-proliferative drugs

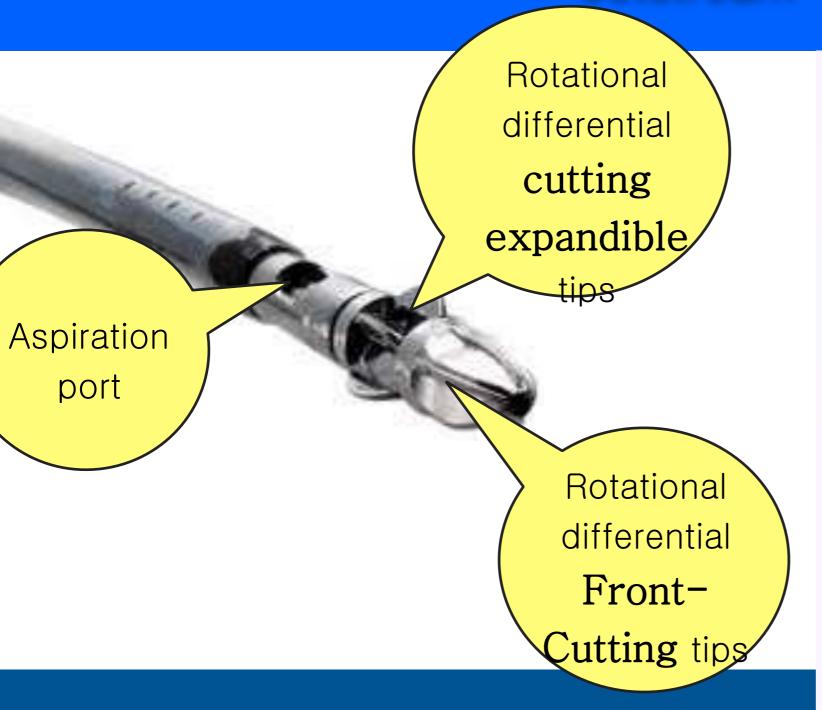


Atherectomy Devices





Jetstream



 Rotational cutter with aspiration capacity (thrombus, fibrotic, fatty, restenotic or calcified tissue

Thrombectomy devices



Catheter type of Jetstream



2.1/3.0 mm

Blades Down	3.0	mm
Blades Up	4.0	mm



2.4/3.4 mm

Blades Down	3.5	mm	
Blades Up	4.5	mm	



1.85 mm

Blades Down 2.75 mm



1.6 mm

Blades Down 2.5 mm



WHY? JETSTREM?

- 1) Facilitates both atherectomy & thrombectomy: Mixed morpho
- 2) Front Cutting: CTOs
- 3) Expandable Blade Technology: Single Device Solution
- 4) Circumferential Cutting: Concentric Lumens
- 5) Reduce Risk of Embolization: Active Aspiration



Jetstream Studies

Feasibility Studies

- Jetstream Calcium
- Jetstream ISR

Large Registries

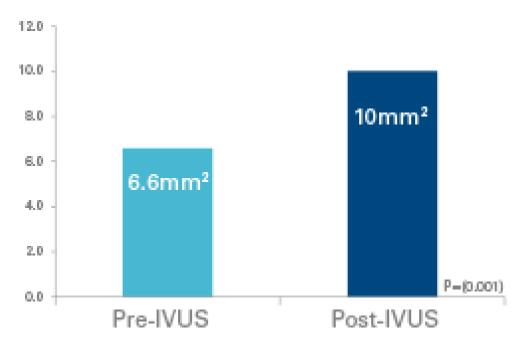
- Pathway PVD
- Jet Registry
- Jet SCE
- Jet ISR (NCT02730234)
- Jet Ranger (formerly Jet PCB) (NCT03206762)



Jetstream Calcium Study

- Prospective Single Arm, Multicenter study
- Severely Calcifed FP artery (superfical calcium > 90°, > 5mm by IVUS)
- 26 patients with moderate severe calcium
- SFA 76%, Popliteal 33%, CFA 5%
- Denovo lesion 90.5%
- Moderate calcium 33.3%, severe calcium 66.7%

Lumen Area Increase



60% of lumen gain was directly attributed to calcium reduction



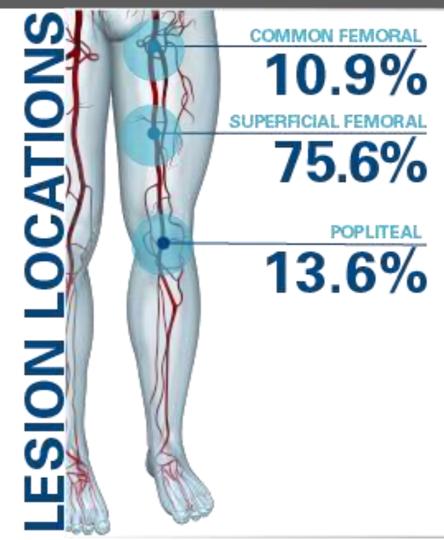
Jetstream Registry

- Multicenter, open label, non-randomized registy
- 241 patients with FP lesions
- 37 sites in USA
- Key inclusion: R1-3, denovo or restenosic, $\geq 70\%$ stenosis or occlusion, lesion length ≥ 4.0 cm, ≥ 1 patent runoff vessel
- Primary endpoints: binary restenosis at 12 mos (PSV with DUS > 2.5)

241 41% diabetic

258 lesions

16.4 cm average lesion length 36.1% occluded



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Jetstream Registry: Procedures

- 98.3% procedural success (≤ 30% residual diameter stenosis post-procedure)
- 84 patients (35%) received adjunctive stents
- embolic protection used in 22.4% of cases

Procedure Time	$73.4 \pm 37.5 \text{ min}$
Total Jetstream Run	$4.7 \pm 3.5 \text{ min}$
Number of Passes	
Blades Down	2.0 ± 1.5
Blades Up	1.8 ± 1.4

Post-treatment stenosis estimated, mean ± SD	Overall (N=258 lesions)	Non-stent (N=165 lesions)	Stent (N=93 lesions)
Post Jetstream	$44.4\% \pm 20.0\%$	$38.5\% \pm 16.2\%$	54.8% ± 22.0%
Post Adjunctive Treatment	$9.8\% \pm 11.4\%$	$11.6\% \pm 11.7\%$	6.6% ± 1.02%

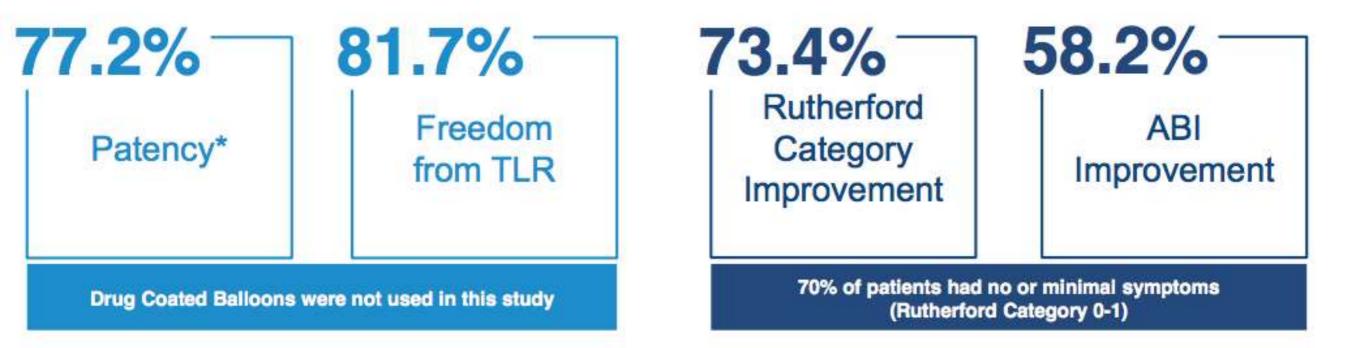


Jetstream Registry: Efficacy & Safety

EFFICACY	Overall Population (N=241)	Non-stent (N=157)	Stent (N=84)
Binary Stenosis, % (n/N)	(N-241)	(N-137)	(IN-04)
30 days	2.6% (3/116)	3.8% (3/80)	0.0% (0/36)
12 months	22.8%	20 5% (8/39)	27.8% (5/18)
	30 Days	12	Months
SAFETY	(N=219)	(cumula	tive: N=219)
MACE	2.3%		19.2%
Death	О	2.3%	
Amputation	О	0.5%	
Myocardial Infarction	О	0	
TVR or TLR	0.9%	17.4% (nonstent 19.4%, Stent 13.8%)	
Distal embolization	1.4%	1.4%	

Jetstream Registry: Results

At 12 months results showed ...



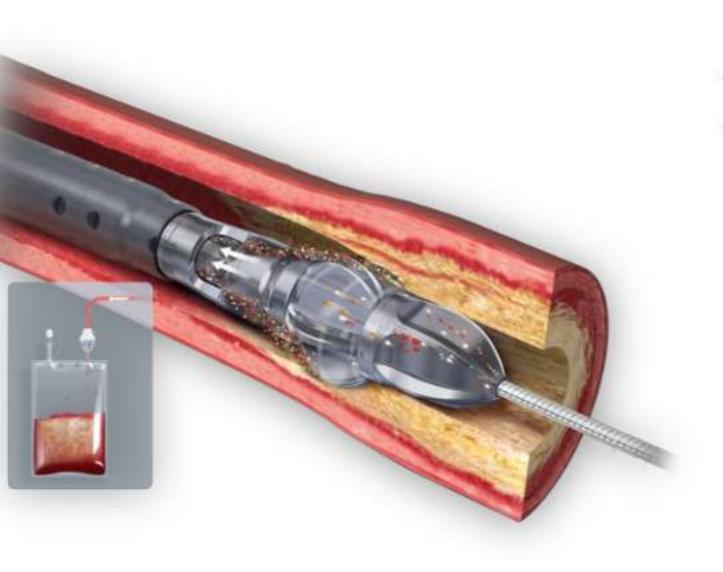
Post-Procedure: 98.3% of patients had ≤30% residual diameter stenosis

*Patency based on a DUS PSVR ≤2.5; Binary Restenosis was reported as 22.8%. The JET Registry had limited DUS follow-up at 12 months (57/241 patients)

Garcia L. LINC 2017 PI-464229-AA APR 2017



Jetstream Registry: safety issue



JET Registry results demonstrated a strong safety profile.

1.4%

Distal Embolization Rate

2.3%

Major Adverse Events at 30 days



Freedom from TLR in ISR studies



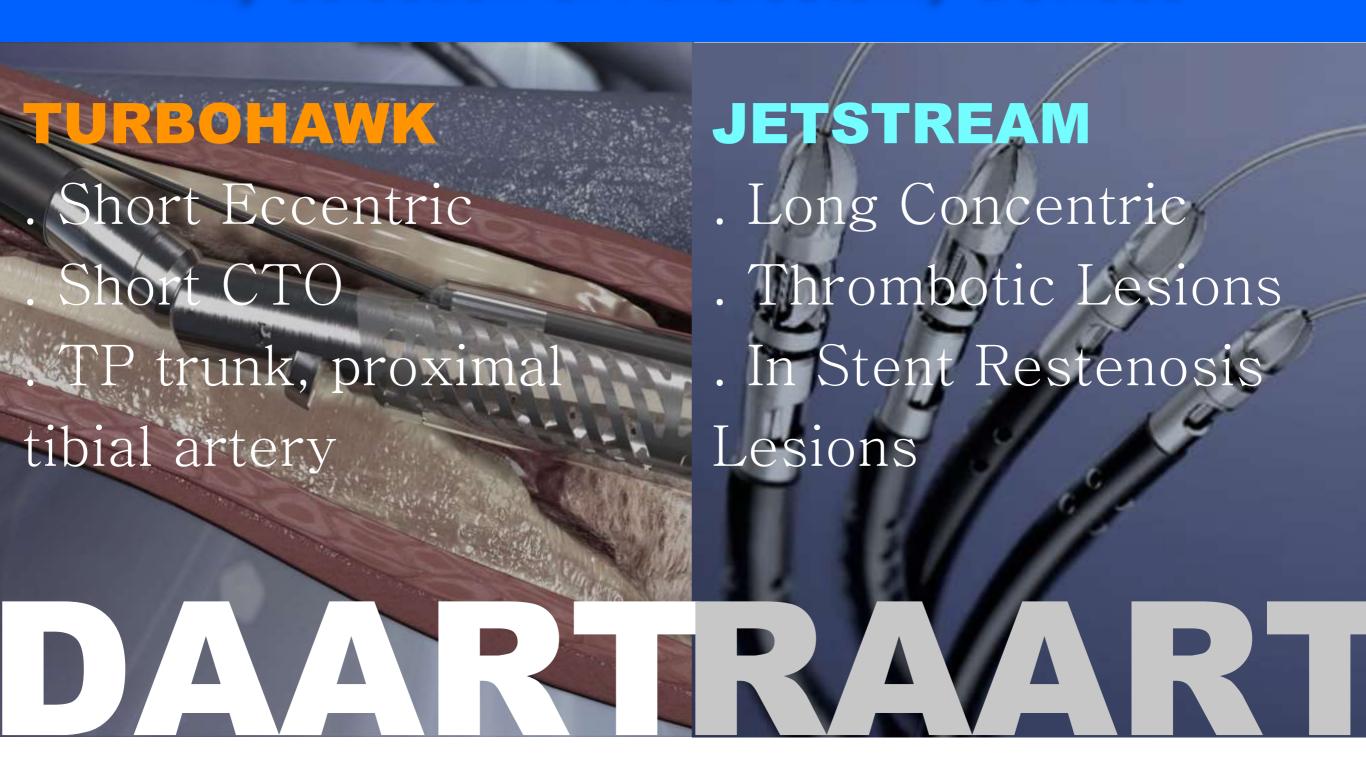


Distal Embolization with Jetstream in Studies

JetStream ISR Feasibility Study in FP ISR (JEVT 2016) (EFP 50%) (19.5cm)	
Distal Embolization Requiring Treatment	9.4%
No Filter	6.3%
Spider Filter	3.1%
Nav-6 Filter	0%
xIPAD NAV-6 Experience with Jetstream (all comers, unadjusted)(JIC 2016) (EFP 59%) (14.5cm)	
Without Nav-6	8%
With Nav-6	1.8%
JET Registry (preliminary) N=155 patients Denovo 90% (EFP 19%) (22cm)N	2%
Jetstream Calcium Study (EFP 0%)(very short lesion: 2.5cm)	0%



My selection of Atherectomy Devices





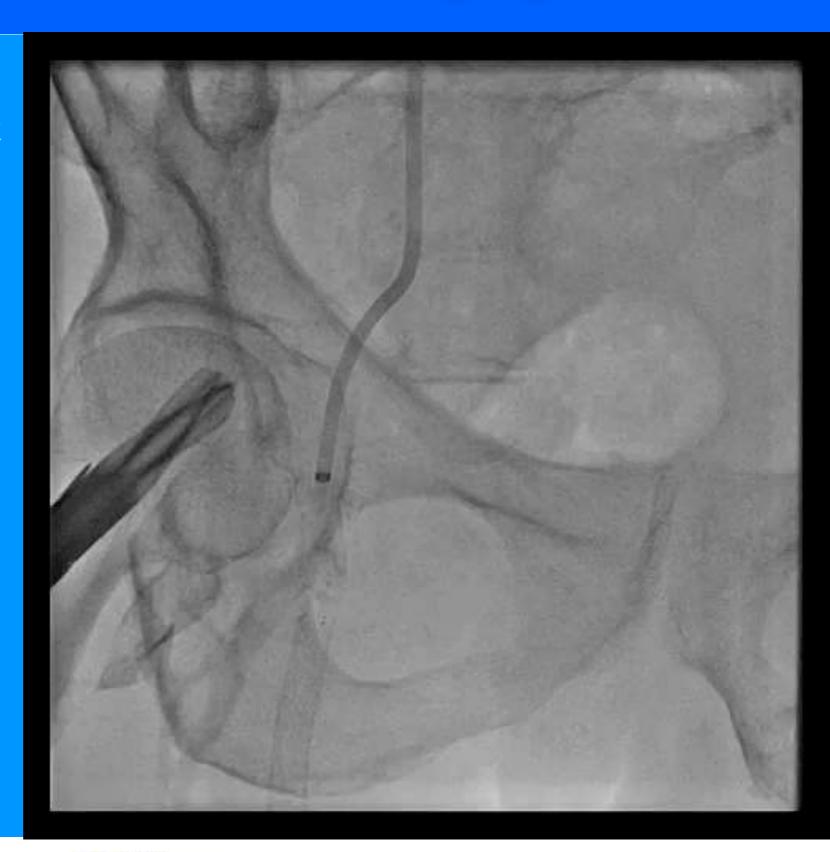
Reimbursement Guideline for DAART in KOREA

Lesion with Calcium	Atherectomy	Filter	DCB	DAART/RAA RT OK
	Hawk / Jetstream	Spider FX / Nav-6	IN.PACT / Lutonix	
Lesion without	Atherectomy	Filter	DCB	DAART/RAA
Calcium (length ≥ 10cm)	Hawk / Jetstream	Spider FX / Nav-6	IN.PACT / Lutonix	RT OK
Locion without	Atherectomy		DCB	DAART/RAA
Lesion without Calcium (length < 10cm)	Hawk / Jetstream	OR	IN.PACT / Lutonix	RT NO

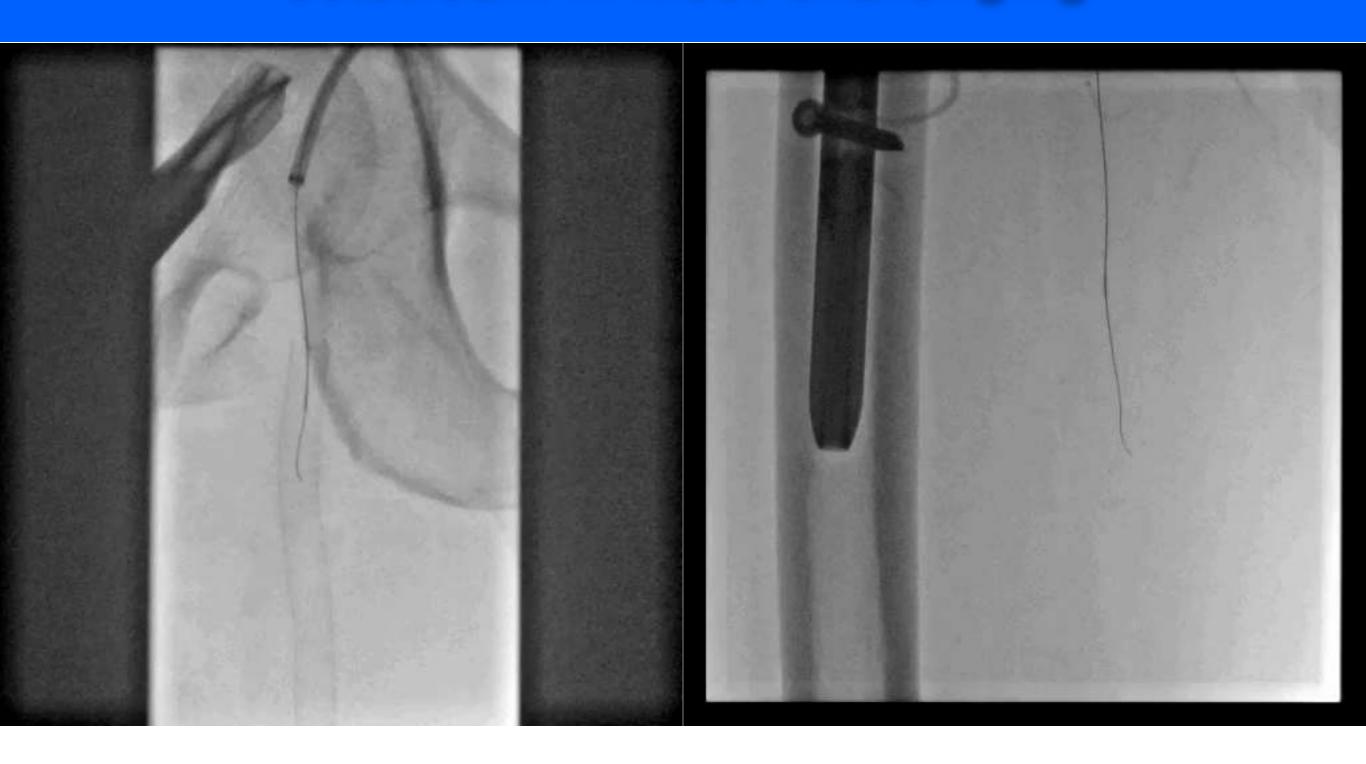
• In ISR lesions Atherectomy with Hawk system is not reimbursed



- 72 YO Male
- Right LE claudcation about 100 meter for 2 Mos
- ABI 0.65/0.95
- HTN, DM2
- 2 YA, PTA for RSFA CTO: 1 SNS at pSFA

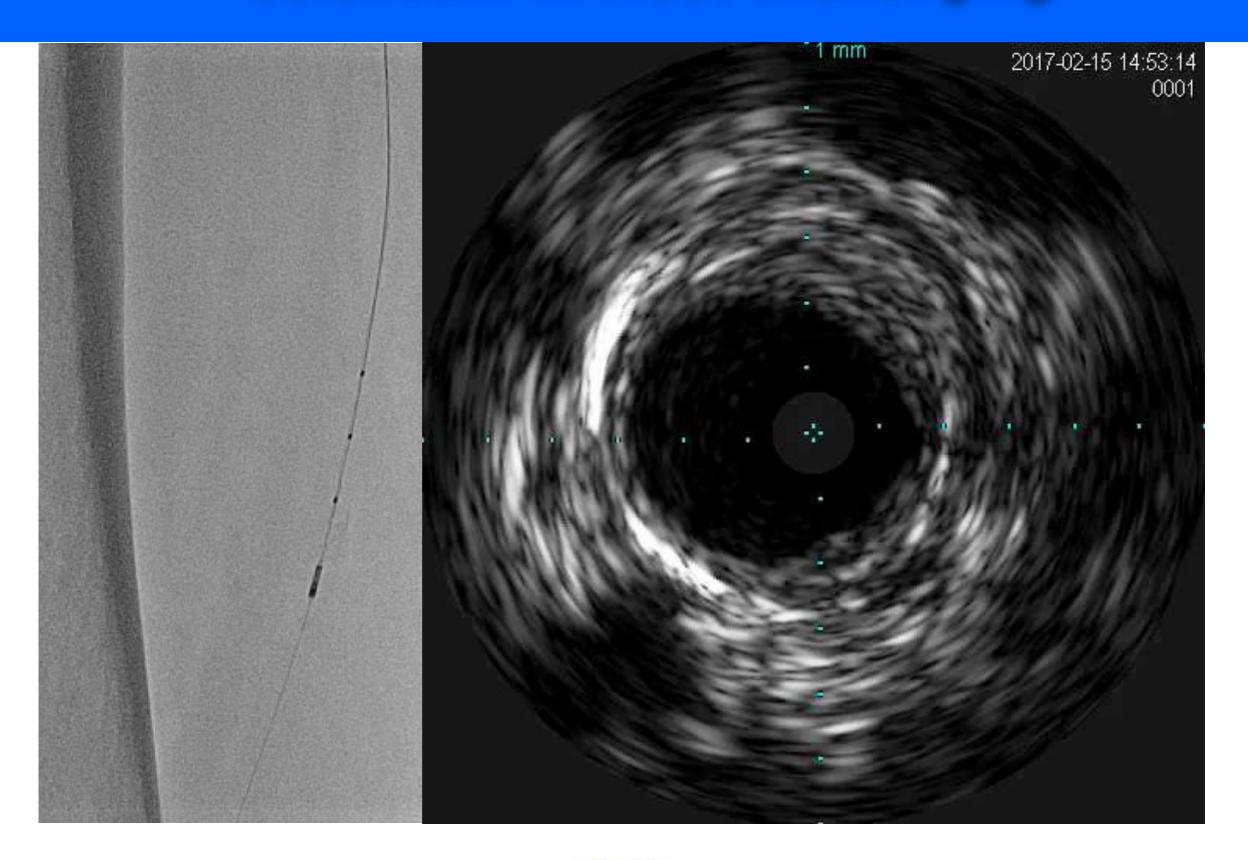






- CXI curved
- Astato XS 20g



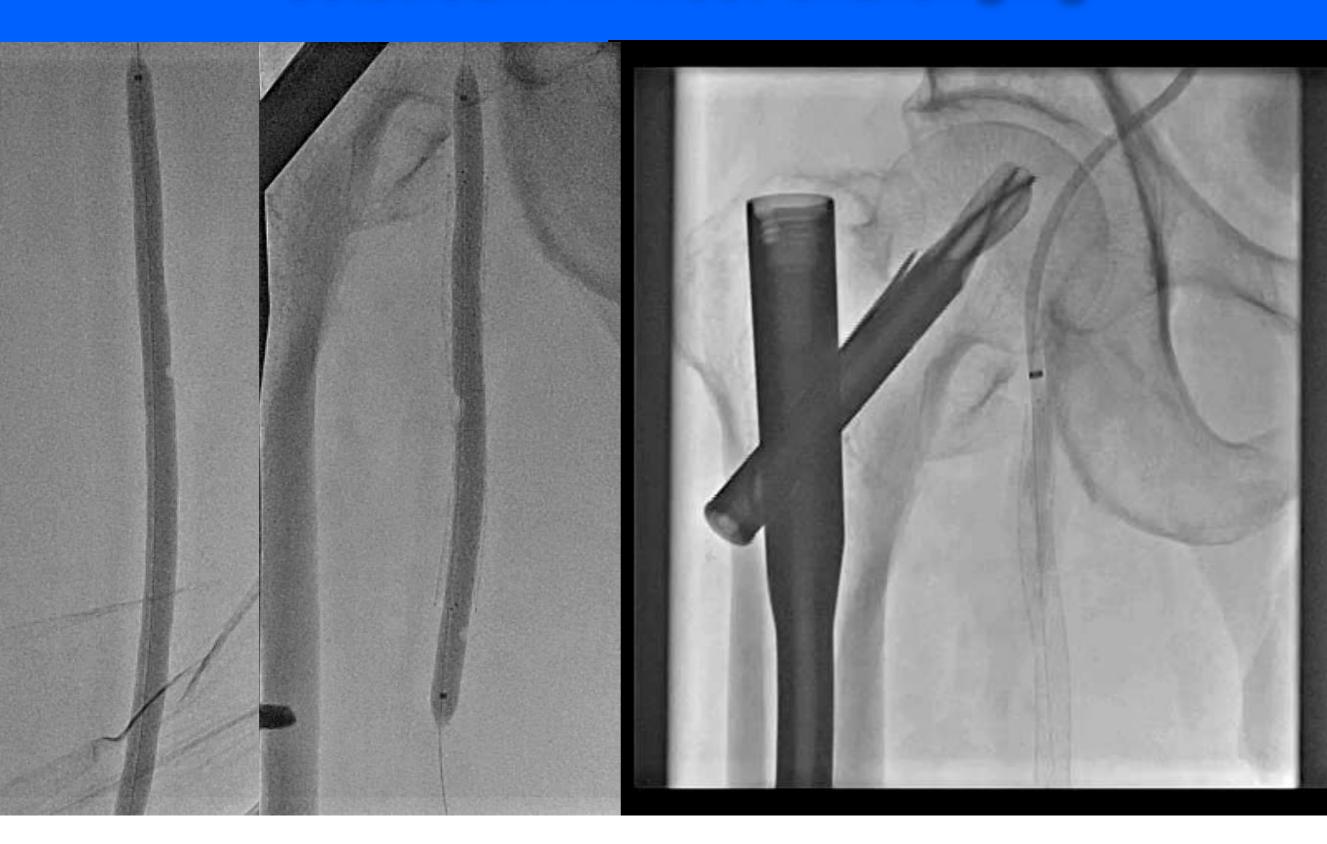














Why Jetstream is Better in Long Calcified FP lesions?



Many Reasons

- Save Time
- Save Efforts
- Short Learning Curve
- Decrease Radiation Exposure
- Get Concentric Lumen Gain
- Can Cut the Calcification
- Can Aspirate Thrombus
- Useful in ISR: Reimbursed in Korea





