How to Overcome Limitations of Current Stent Grafts

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Disclosure

- Research funds

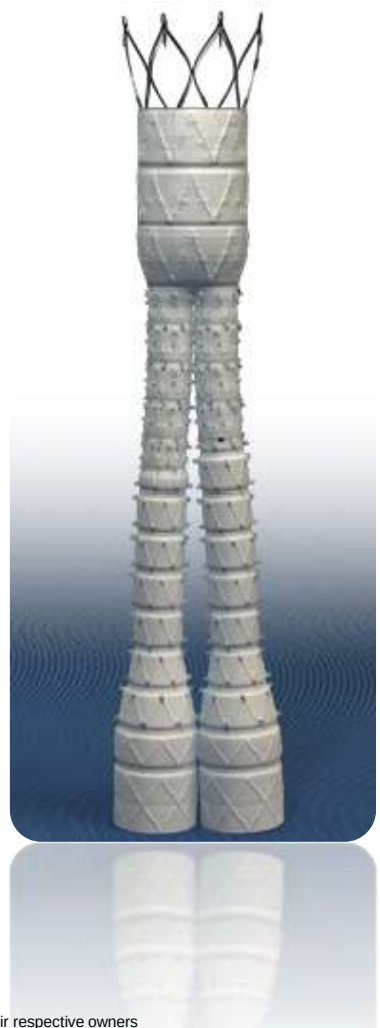
  - *Cook*
  - *Medtronic*
  - *Boston scientific*
  - *Cordis*
  - *Otsuka*
  - *Korea United Pharm*
  - *Dong-A Pharmaceutical*

- *Severance Cardiovascular Intervention (SCI) Workshops in cooperation with Medtronic, Cordis, Abbott, Cook, Boston Scientific*

INCRAFT® AAA Stent Graft System Overview

- Ultra-low profile delivery system
  - ✓ 14F OD delivery system with integrated sheath*
  - ✓ Catheter-like shaft flexibility
  - ✓ Minimized procedure steps

- The Endograft
  - ✓ Composed of 3 interlocking modular pieces
  - ✓ Intended to allow bilateral in-situ customization
  - ✓ Created for broader anatomical coverage with fewer devices
  - ✓ Designed for accurate placement



**The 34mm bifurcate comes in a 16F OD delivery system*

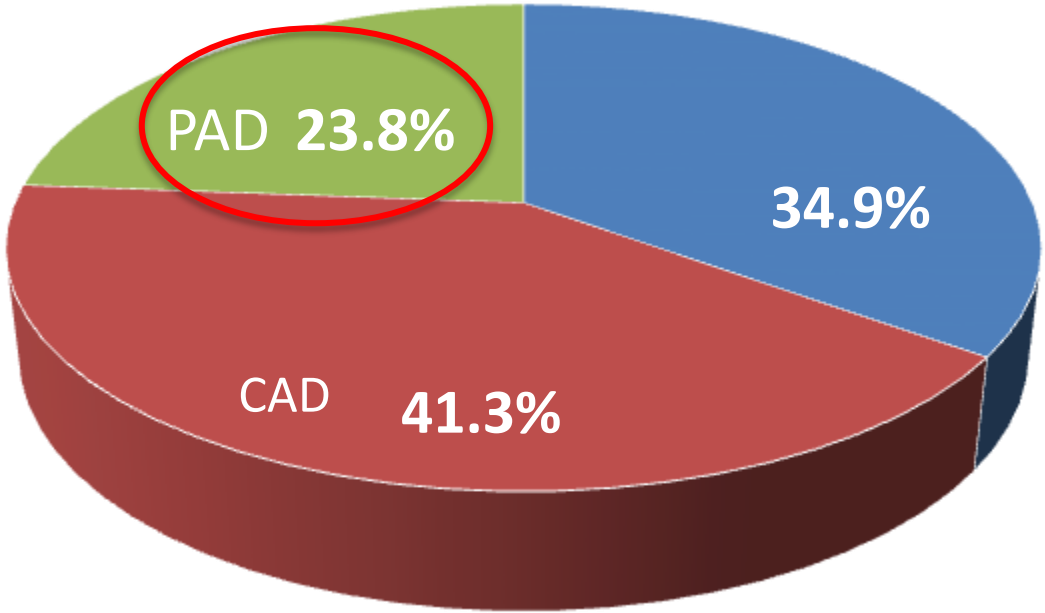
EU481-2 07/16

Advantages of Ultra-Low Profile Device

- Increased applicability
- Reduced trauma
- Percutaneous access
- Local anesthesia
- Early discharge

Prevalence of PAD Among Patients with AAA in Severance Hospital

Total 475 patients



■ AAA only ■ AAA with CAD ■ AAA with PAD ± CAD

Prevalence of PAD

Screening for Peripheral Arterial Disease and Carotid Artery Disease in Patients With Abdominal Aortic Aneurysm

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Abstract

Screening for concomitant atherosclerotic disease is important in cardiovascular risk reduction. This study assessed the prevalence of carotid artery disease (CAD) and peripheral arterial disease (PAD) in patients with known abdominal aortic aneurysm (AAAs). All patients with AAA attending the vascular laboratory between the January 1, 2007, and December 31, 2009, were eligible for a carotid ultrasound and measurement of ankle brachial indices. A total of 389 (305 males) patients were identified on the AAA surveillance program with a mean (±standard deviation) age of 76 (±8) years. The mean age of the males was 75.4 (±7.8) years, and the mean age of the females was 77 (±11) years. A total of 332 patients were assessed for CAD, and 101 (30.4%) of those were found to have significant disease. A total of 289 patients were assessed for PAD of which 131 (45.3%) were found to have PAD at rest, and 289 patients were assessed for both and 59 (20.4%) patients had significant CAD + PAD. Patients with AAAs are at high risk of other atherosclerotic disorders, and, therefore, they should receive intensive medical optimization.

Keywords

screening, peripheral arterial disease, abdominal aortic aneurysm, carotid artery disease

Introduction

Atherosclerosis is a systemic disease, with peripheral arterial disease (PAD), carotid artery disease (CAD), and coronary artery disease often coexisting.[1] There is a close relationship between coronary artery disease and CAD, and PAD is associated with an increased cardiovascular (CV) risk and death.[2-6] Patients with abdominal aortic aneurysms (AAAs) commonly have CV disease, yet there is little in the literature to assess whether screening these patients for other vascular disorders is worthwhile.[7]

The accuracy of color duplex ultrasound (CDU) is high, but mass screening is not cost effective.[8,9] The identification of patients at high risk of occult CAD would allow focused screening. The CAD is associated with a risk of stroke that increases with the severity of the internal carotid artery (ICA) disease.[10,11] Asymptomatic CAD may become symptomatic within 3 to 4 years.[12] Thus, there may be merit in treating asymptomatic patients, by medical therapy or interventional procedures, although recent optimized medical therapy has improved.[13,14] The Asymptomatic Carotid Surgery Trial (ACST) initially demonstrated a 5-year stroke risk, or death, in patients who underwent carotid endarterectomy and was found to be 6.4% compared to the 11.8% in the patients treated medically.[15,16] More recent results show less advantage to surgery, and as a consequence, it is usually recommended that optimized best medical treatment is the first-line treatment.[17]

Peripheral arterial disease is a marker of CV ischemic events. It is easily detected by the measurement of ankle brachial indices (ABIs) and is an indicator of atherosclerosis in other vascular territories.[8,18] The ABIs have an interobserver variability as low as 7%, a sensitivity of 90%, and a specificity of 98% for the detection of arterial lesions >50% in the lower limbs.[19] The PAD is a strong predictor of future CV outcomes such as myocardial infarction, stroke, and death.[20] Identification of a high-risk group for PAD is important in CV risk reduction in the population. The objective of this study was to determine the presence and severity of asymptomatic CAD and PAD in patients with known AAA.

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Prevalence:

- PAD 45.3%
- Carotid artery disease 20.4%

EVAR Devices Available in Korea:

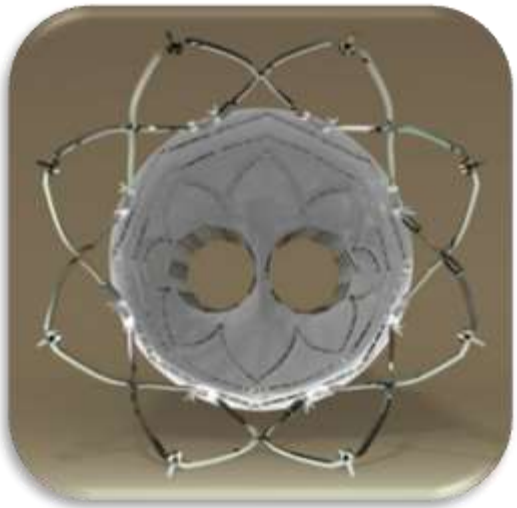
IFU Indications

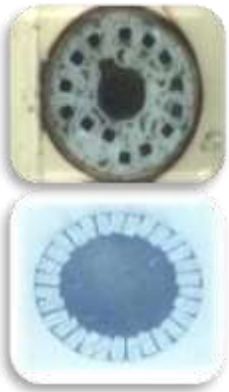
Company	Device	Profile	Neck length	Neck diameter	Iliac diameter
Cook	Zenith Flex	18 ~ 22F	15 mm	32 mm	20 mm
Medtronic	Endurant	18 ~ 20F	10 mm	32 mm	25 mm
Endologix	AFX2	19F	15 mm	32 mm	20~23 mm
Cordis	INCRAFT	14F	15 mm	31 mm	22 mm

Designed for packing efficiency without sacrificing durability*

Advantages of laser-cut stents with integral barbs for supra-renal fixation:

- More efficient packing = Lower profile
- Fracture resistance
- Corrosion resistance relative to welded barbs
- Low profile without relying on unknown polymer technology





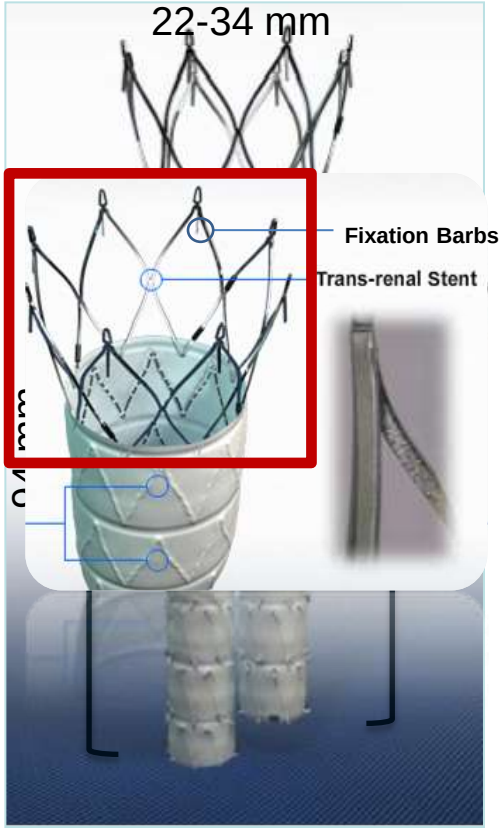
Expanded Stent

Packed Sten

*Pre-clinical and mid-term clinical data is available, long-term durability data is however pending.

INCRAFT® System: Main Body Design

- **Flared bare trans-renal stent**
  - ✓ Cranial migration resistance
  - ✓ Main Body Stability - Perpendicular deploy ment
  - ✓ Higher radial force compared to Z-Stent
- **Laser-cut supra-renal fixation barbs**
  - ✓ More efficient packing = lower profile with n o durability compromises*
  - ✓ Fracture resistance
  - ✓ Corrosion resistance relative to welded barb s
- **4 diameter sizes (22, 26, 30, 34mm)**
  - ✓ allowing treatment of proximal aortic neck d iameters from 17-31mm



Pre-clinical and mid-term clinical data is available, long-term durability data is however pending.

Minimized Procedure Steps: Two Steps to Complete Proximal Deployment

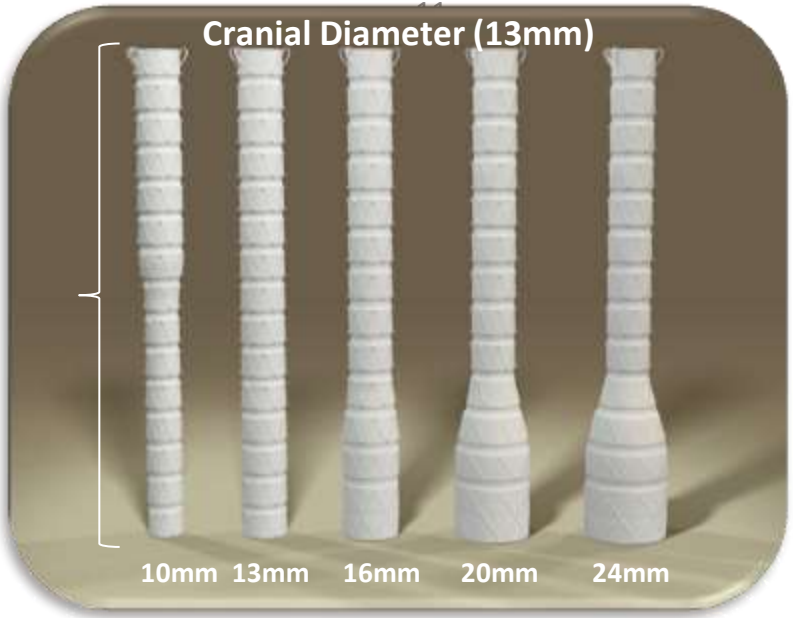
- **STEP 1:** Design intended for a rapid and accurate positioning through Superior V isualization:
  - 4 Cranial True Graft Edge Markerbands
  - Sheath Tip Marker
  - Contralateral Orientation Marker

- **STEP 2:** Accurate Positioning After 2nd R elease:
  - Distal end design allows for fully perpend icular deployment
  - Mechanism designed to inhibit caudal mi gration after 2nd release

G. Torsello et al; JJ Cardiovascular Surg 2011; 52:661-7

InCraft: Iliac Limbs

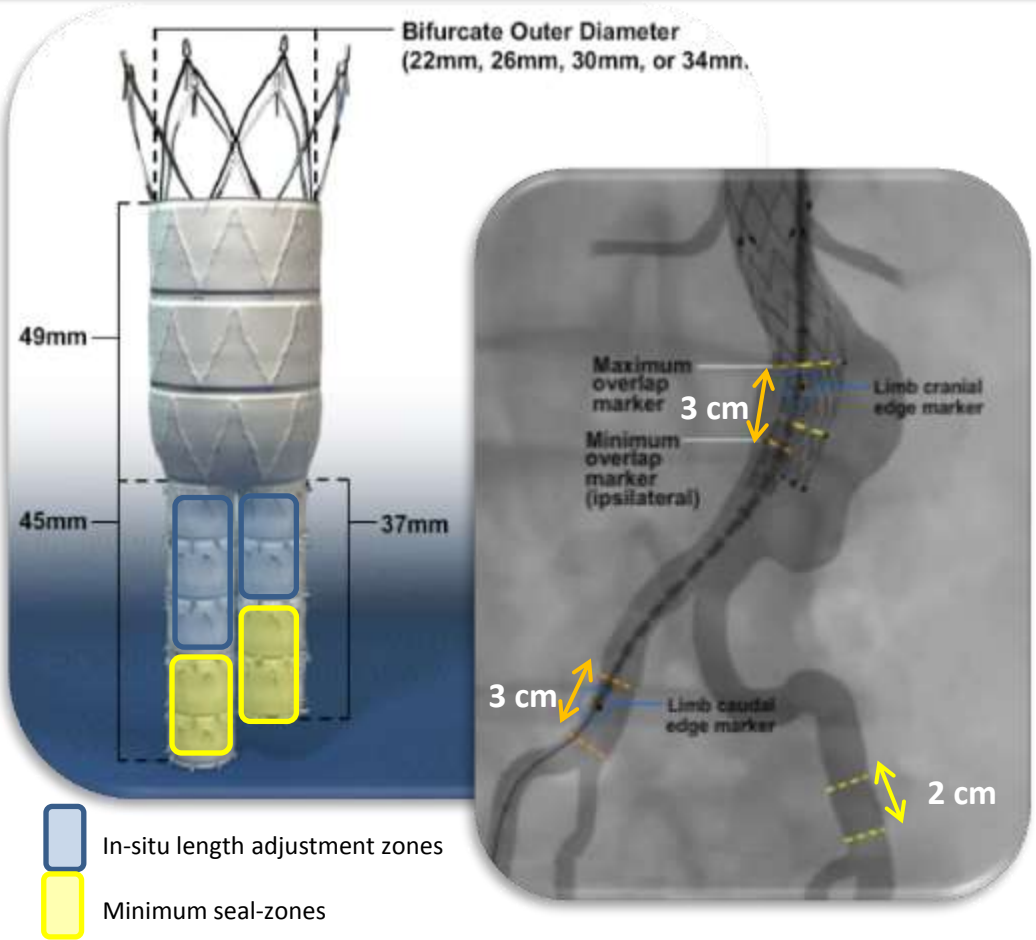
- Available in 5 diameters distally (10, 13, 16, 20 and 24mm) accommodating iliac arteries ranging from 7-22mm.
- 4 limb lengths (8, 10, 12, and 14cm*) to treat a overall treatment length range of 12-21 cm.
- Profile of delivery system for the Iliac Limbs is 12F O.D. (13 F for 24 mm IL)
- 19 limb codes in total



Caudal Diameter

Trimodular Design: In-situ Customization

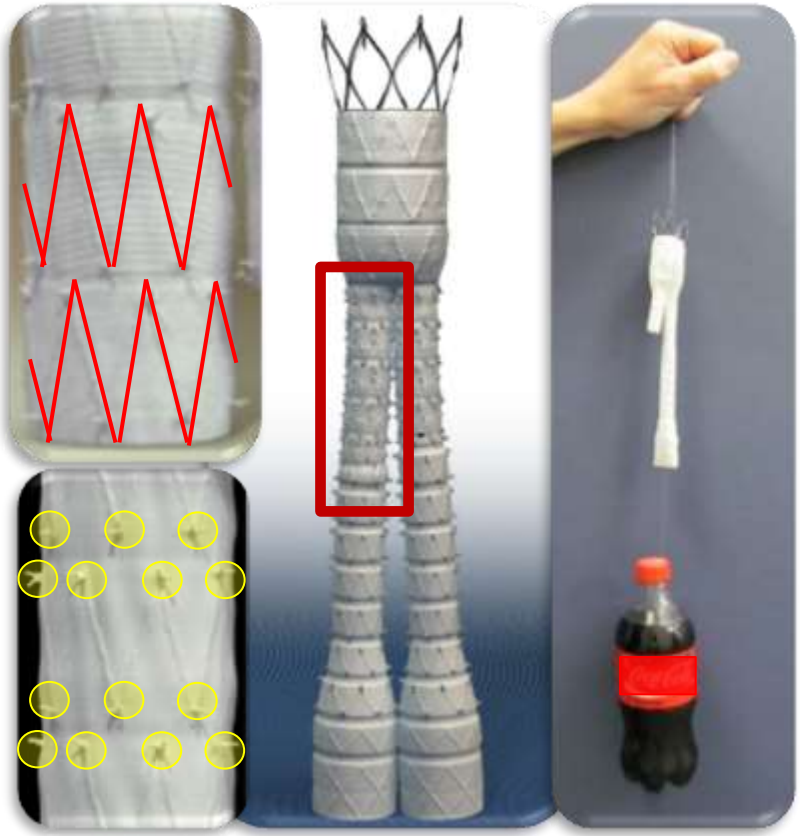
- During procedure each limb can be telescoped into the respective Aortic Bifurcate leg[1]
- The varying overlaps ("in-situ sizing") allow for length adjustment up to 3cm of assembled implant during the procedure[1]:
  - ➢ 3cm ipsi
  - ➢ 2cm contra
- No other major competitor product offers this feature[2-4]



[1] G. Torsello et al; JJ Cardiovascular Surg 2011; 52:661-7
[2] Gore Excluder product brochure.
[3] Cook Medical Zenith product brochure.
[4] Medtronic Endurant product brochure.

Tri-modular Design: Modular Junction Strength

- **Aortic Bifurcate-Limb interlocking system:**
- Suture knots on the limb graft interlock with the endoskeletal Z-stents on the inside of the aortic bifurcate legs
- Leads to increased modular junction strength



Device Sizes

BIFURCATES

Aortic Bifurcate Prosthesis Dimensions/Sizing Guide

Product Code	AB Size (mm)	Treatment Range (mm)	Delivery System ID (F)	Delivery System OD (F)	Ipsi Length (mm)	Contra Length (mm)
AB2298	22	17.0–19.9	13	14	94	86
AB2698	26	20.0–22.9	13	14	94	86
AB3098	30	23.0–26.9	13	14	94	86
AB3498	34	27.0–31.0	15	16	94	86

Bifurcate and Limb Delivery Systems

Aortic Bifurcate Delivery System working length: 54 cm
Iliac Limb Delivery System working length: 77 cm

LIMBS

Iliac Limb/Limb Extension Prosthesis Dimensions/Sizing Guide

Product Code	IL Size (mm)	Treatment Range (mm)	IL Length (mm)	Delivery System OD (F)	Ipsi Length (mm)	Contra Length (mm)
IL1008	10	7.0–8.9	82	12	128–156	128–147
IL1010	10	7.0–8.9	101	12	147–175	147–166
IL1012	10	7.0–8.9	120	12	166–194	166–185
IL1014	10	7.0–8.9	138	12	184–212	184–203
IL1308	13	9.0–10.9	82	12	128–156	128–147
IL1310	13	9.0–10.9	101	12	147–175	147–166
IL1312	13	9.0–10.9	120	12	166–194	166–185
IL1314	13	9.0–10.9	138	12	184–212	184–203
IL1608	16	11.0–13.9	82	12	128–156	128–147
IL1610	16	11.0–13.9	101	12	147–175	147–166
IL1612	16	11.0–13.9	120	12	166–194	166–185
IL1614	16	11.0–13.9	138	12	184–212	184–203
IL2008	20	14.0–17.9	82	12	128–156	128–147
IL2010	20	14.0–17.9	101	12	147–175	147–166
IL2012	20	14.0–17.9	120	12	166–194	166–185
IL2014	20	14.0–17.9	138	12	184–212	184–203
IL2410	24	18.0–22.0	101	13	147–175	147–166
IL2412	24	18.0–22.0	120	13	166–194	166–185
IL2414	24	18.0–22.0	138	13	184–212	184–203

The INNOVATION Study

OBJECTIVE

- To assess the technical success and safety of the Cordis INCRAFT® Stent Graft System in subjects with AAA

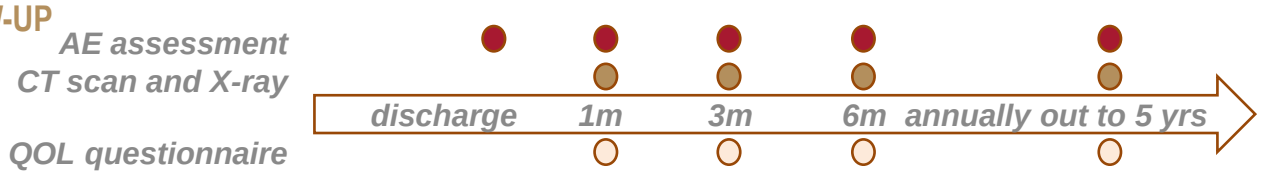
PRIMARY ENDPOINTS

- Successful deployment at desired location and absence of Endoleaks (I, III or IV) at conclusion of procedure
- Absence of device or procedural related major adverse events (MAE) 1 month post-procedure

MAJOR SECONDARY ENDPOINTS

- Absence of aneurysm enlargement ≥5 mm
- Absence of stent graft migration ≥10 mm
- QOL
- Endoleg patency at 1,3,6 and 12 months and annually through 5 years post-procedure
- Absence of stent graft fracture
- Absence of MAE and Endoleaks (I, III, or IV) at 3, 6 and 12 months and annually out to 5 years post-procedure

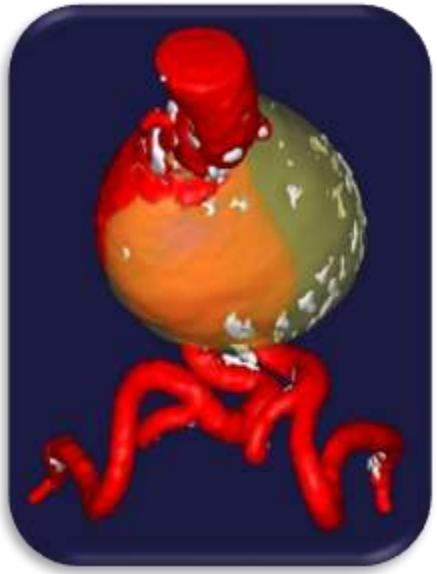
FOLLOW-UP



Site enrollment

INVESTIGATOR	STUDY SITE	ENROLLMENT
Prof. D. Scheinert	Leipzig, Germany	10
Prof. G.Torsello	Münster, Germany	17
Prof J. Brunkwall	Köln, Germany	4
Prof. G. Coppi	Modena, Italy	7
Prof. C. Pratesi	Firenze, Italy	14
Prof. R. Chiesa	Milano, Italy	8
	Total	60

Patient Characteristics

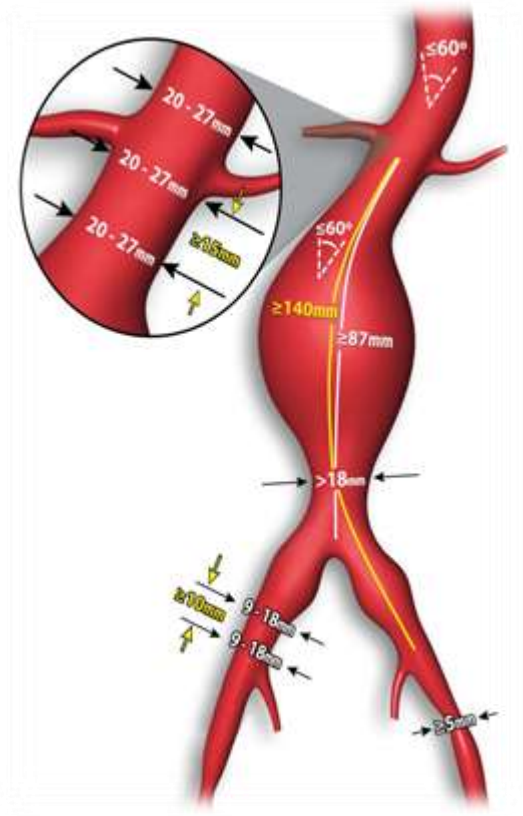


	N = 60
Age (years)	74.4 ± 6.9
Male	95%
Mean BMI	26.7 ± 3.05
Current Smoker	10%
Diabetes	21.7%
Hypertension	95%
Hyperlipidemia	70%
Creatinine ≥ 1.5 mg/dL	8.4%
Chronic obstructive pulmonary disease	25%
Coronary artery disease	16.7%
History of Myocardial Infarction	25%
History of Peripheral vascular disease	8.3%

Inclusion Criteria vs. Measurements

InCraft AAA Stent Graft System

KEY INCLUSION CRITERIA



KEY ANATOMICAL MEASUREMENTS (CORELAB)

	MEAN (N = 60)	RANGE (N = 60)
Infra-renal angle	34.4°	6.9-67.3°
Proximal neck Ø	22.3mm	17-29.5
Neck Length	26.9 mm	5-50
AAA maximum Ø	52.6 mm	35-101
Min. Aortic bifurcation Ø	20.5 mm	11-33
Left iliac seal zone Ø	13.9mm	9.3-20.5
Right iliac seal zone Ø	13.1mm	9.6-16.5
Left min. access Ø	7.1mm	3.6-10
Left Iliac Tortuosity	1.19	1.00-2.07
Right min. access Ø	7.2mm	4.3-10
Right Iliac Tortuosity	1.27	1.00-2.00

Hostile anatomy treated with the INCRAFT® System

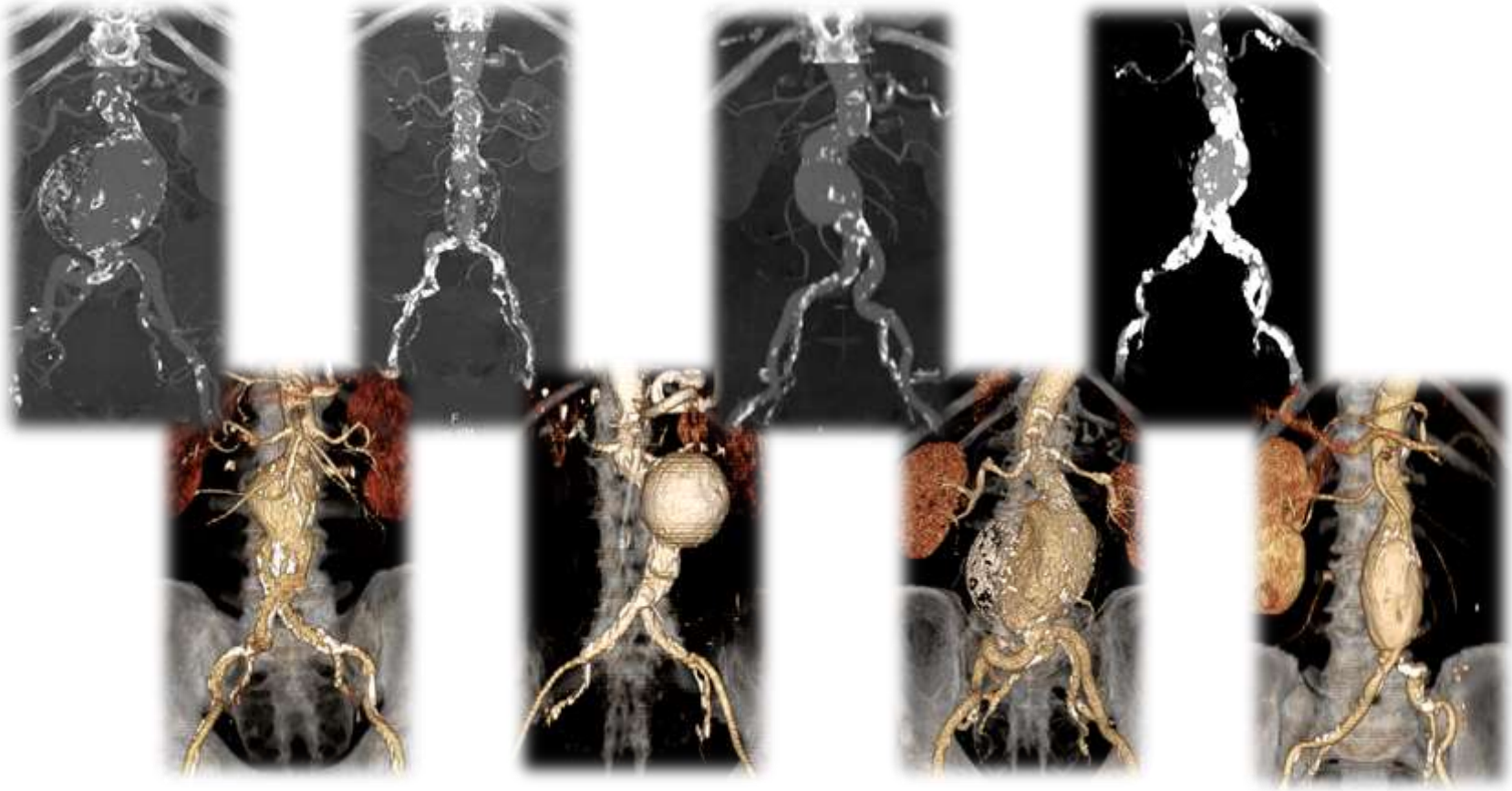
SHORT NECKS

CALCIFICATIONS

ANGLES

TORTUOSITIES

SMALL ACCESS



Hostile anatomy distribution *(based on CoreLab assessments)*

	HOSTILE ANATOMY ATTRIBUTE	CATEGORIZATION*	ABSENT	MILD	MODERATE	SEVERE
PROXIMAL	Neck length (mm)	*(>25; 25-15; 15-10; <10)*	60%	23%	8%	8%
	Infra-renal angle (°)	*(<20; 20-40; 40-60; >60)*	13%	57%	25%	5%
	Supra-renal angle (°)	*(<20; 20-40; 40-60; >60)*	85%	13%	2%	0%
	Aortic thrombus	*(Subjective analysis)*	5%	73%	17%	5%
	Aortic calcification	*(Subjective analysis)*	7%	82%	12%	0%
DISTAL	Minimal aortic bifurcation ø	*(>22; 22-20; 20-18; <18)*	38%	10%	18%	33%
	Left iliac sealing length (mm)	*(>30; 30-20; 20-10; <10)*	15%	12%	33%	40%
	Right iliac sealing length (mm)	*(>30; 30-20; 20-10; <10)*	18%	20%	30%	32%
	Left minimal access ø (mm)	*(>10; 10-8; 8-7; <7)*	2%	29%	24%	46%
	Right minimal access ø (mm)	*(>10; 10-8; 8-7; <7)*	2%	30%	24%	44%
	Iliac Tortuosity (τ)	*(<1,25; 1,25-1,5; 1,5-1,6; >1,6)*	85%	12%	0%	2%

Ultra-Low Profile and Durability: 4 Year Outcomes*
INNOVATION experience

InCraft AAA Stent Graft System

	Operative	30 days	1 Year	2 Years	3 Years	4 Years
Successful deployment at desired location	98.3% (59/60)	-	-	-	-	-
Freedom from Endoleak* Type I Type III	98.3%*(59/60) 100% (60/60)	96.6%‡ (56/58) 100% (58/58)	100% (53/53) ‡ 100% (53/53)	100% (50/50) 100% (50/50)	95.6% (43/45)′ 100.0% (45/45)	97.4% (38/39) 100.0% (39/39)
Stent graft patency	100% (60/60)	100% (58/58)	100% (53/53)	100% (45/45)⅄	97.8% (44/45)	97.6% § (40/41)
Freedom from Migrations	NA	NA	100% (53/53)	100% (50/50)	100.0% (44/44)	100.0% (38/38)
Freedom from Fracture	NA	100% (54/54)	100% (52/52)	100% (46/46)	97.7% (42/43)	97.5%¥ (39/40)
Freedom from Sac Enlargement	NA	NA	100% (53/53)	100% (50/50)	95.6% (43/45)	89.7% # (35/39)
Freedom from MAE (death, QMI, CVA, renal failure)	100% (60/60)	100% (58/58)	98.2% (55/56)	88.5% (46/52)✦	87.3%% (48/55)	82.4%″ (42/51)

INCRAFT® System - Endoleaks

Endoleaks	Subjects w/ Endoleak Present at 1 Month % (m/n)	Subjects w/ Endoleak Present at 48 Months % (m/n)
Endoleaks of any type*	51.7% (30/58)	28.2% (11/39)
Type I	3.4% (2/58)	2.6% (1/39)
Type II	50.0% (29/58)	28.2% (11/39)
Type III	0.0% (0/58)	0.0% (0/39)
Type IV	0.0% (0/58)	N/A
Endoleak, type undetermined	0.0% (0/58)	0.0% (0/39)

- The Type II endoleak rate is high compared to older generation endografts.
- However the potential cause of this high prevalence of small leaks could be explained by the narrow-access vessels and, as such, increased collateral flow resulting from the challenging and narrow distal anatomy in treated population.
- A similar rate in Type II endoleaks can be found with other new ultra-low profile endografts† and have also been reported in the latest results of the OVER study‡
- Out of 60 patients 4 have been associated with AAA enlargement associated with Type II EL.

Prof. G Pratesi, LINC 2016

† J Vasc Surg. 2014 Jan;59(1):65-73
‡ J Vasc Surg 2015;62:1394-404

INNOVATION: 5-year Results

Events	At 5 Years
Freedom from Endoleak Type Ia Type Ib Type III	 100% (38/38) 97.4% (37/38) 100% (38/38)
Stent Graft Patency	97.4% (38/39)
Freedom from Migrations	100% (37/37)
Freedom from Fracture	97.4% (38/39)
Freedom from Sac Enlargement	92.1% (35/38)

INSIGHT Post-Market Study primary endpoint & 30-day results

Univ.-Prof. Dr. med. Giovanni Torsello
Universitätsklinikum Münster

Charing Cross – Thursday 27 April 2017

INSIGHT centers – 23 sites in 8 European countries

Normal versus Challenging Anatomy

based on Corelab assessments

	Hostile Anatomy Attribute	*Categorization*	Absent	Mild	Moderate	Severe
PROXIMAL	Neck length (mm)*	*(L≥25; 15≤L<25;10≤L<15; L<10)*	45 %	30 %	16%	9 %
	Neck Diameter - ACRD (mm)*	*(d<24; 24≤d<26; 26≤d<28; d≥28)*	52%	20 %	19%	9 %
	Infra-renal angle (°)	*(ϕ≤20; 20<ϕ≤40; 40<ϕ≤60; ϕ>60)*	57%	32%	9%	1%
DISTAL	Aortic bifurcation ø	*(d≥22; 20≤d<22; 18≤d<20; d<18)*	38%	18%	17%	27%
	Left iliac tortuosity index*	*(τ≤1.25; 1.25<τ≤1.5; 1.5<τ≤1.6; τ>1.6)*	31%	51%	11%	8%
	Right iliac tortuosity index*	*(τ≤1.25; 1.25<τ≤1.5; 1.5<τ≤1.6; τ>1.6)*	29%	52%	12%	7%
	Left iliac sealing length (mm)*	*(L≥30; 20≤L<30; 10≤L<20; L<10)*	58%	5%	14%	24%
	Right iliac sealing length (mm)*	*(L≥30; 20≤L<30; 10≤L<20; L<10)*	49%	7%	16%	28%
	Left minimal access ø (mm)*	*(d≥10; 8≤d<10; 7≤d<8; d<7)*	6%	33%	27%	33%
	Right minimal access ø (mm)*	*(d≥10; 8≤d<10; 7≤d<8; d<7)*	8%	29%	24%	40%

* Categorization thresholds applied as specified per article 'Identifying and grading factors that modify the outco me of endovascular aortic aneurysm repair', Chaikof et al, Journal of Vascular Surgery, May 2002.

Procedural Results

Procedural results	Procedure
Successful delivery and deployment of stent-graft	100.0% (150/150)
Deployment at the intended location	99.3% (149/150)*
Successful placement of stent-graft relative to renal and hypogastric arteries	98.7% (148/150)
Complete percutaneous access (ipsi and contra)	64.7%
Sac Rupture	0.0% (0/150)

* Right stent-graft limb placed too low causing partial unintentional occlusion of internal iliac artery

Primary Endpoint
MAE up to 1 Month Follow-Up

Primary endpoint	
MAE rate through 30 days	0.7% (1/150)
Death	0.0% (0/150)
Stroke/CVA	0.0% (0/150)
Myocardial infarction	0.7% (1/150)*
New onset renal failure (requiring dialysis)	0.0% (0/150)

*Site reported NSTEMI; to be confirmed if event meets CEC definition of Q-wave MI.

Reported Events at 1 Month Follow-Up

Site Reported Outcomes	At 1 Month
Occlusion	0
Type Ia Endoleak	2.0% (3/149)*
Type Ib Endoleak	0.7% (1/149)
Type III Endoleak	0
Secondary interventions <30 days	0
Stenosis of flow channel >50% but less than 100%	0
Device Deficiencies	0

*2 of these endoleaks type Ia occurred in subjects with severe angulation out of IFU (80°and 73°)

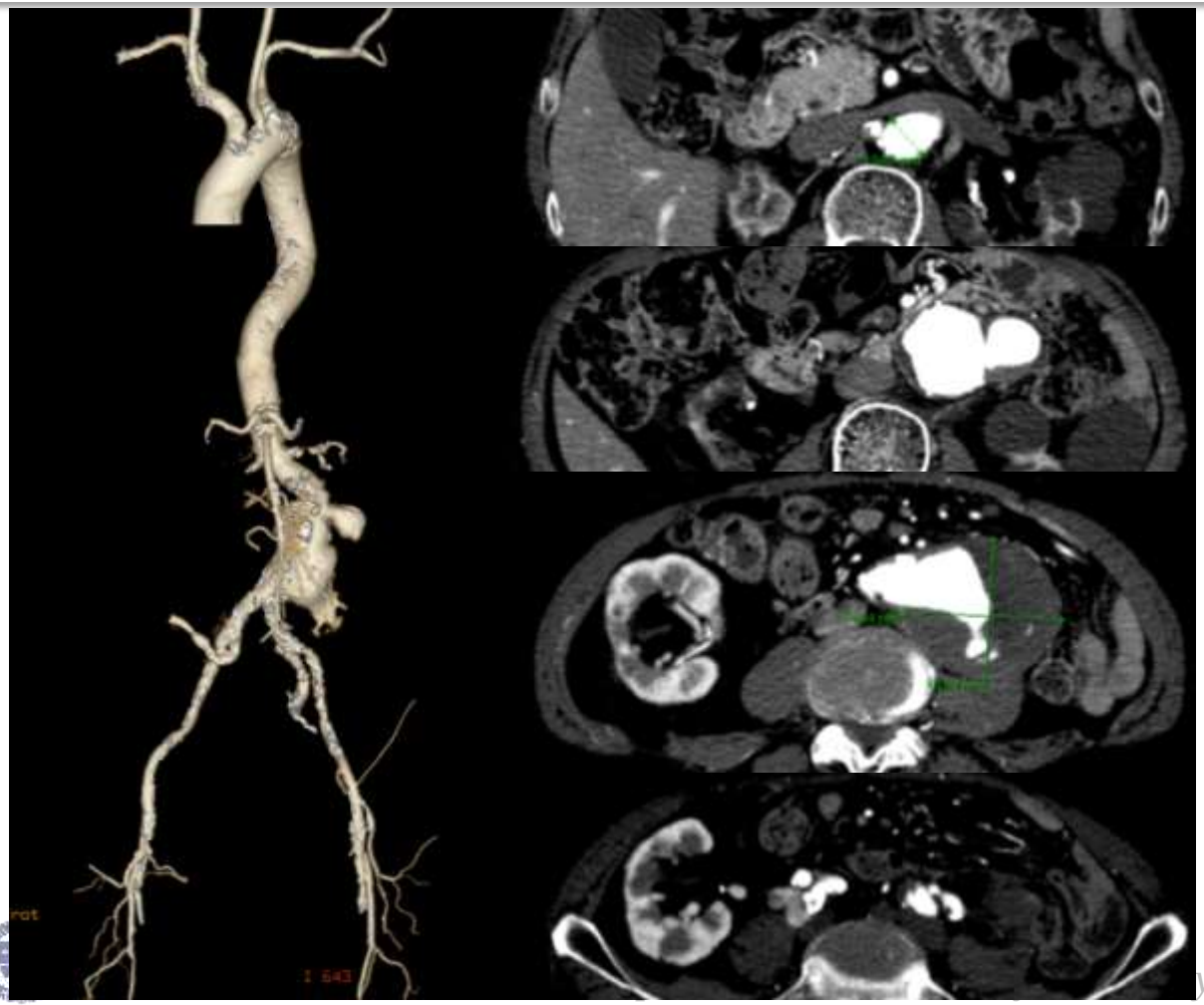
M/63 (KCK,#2003905)

- CC: Abdominal discomfort
- PHx:

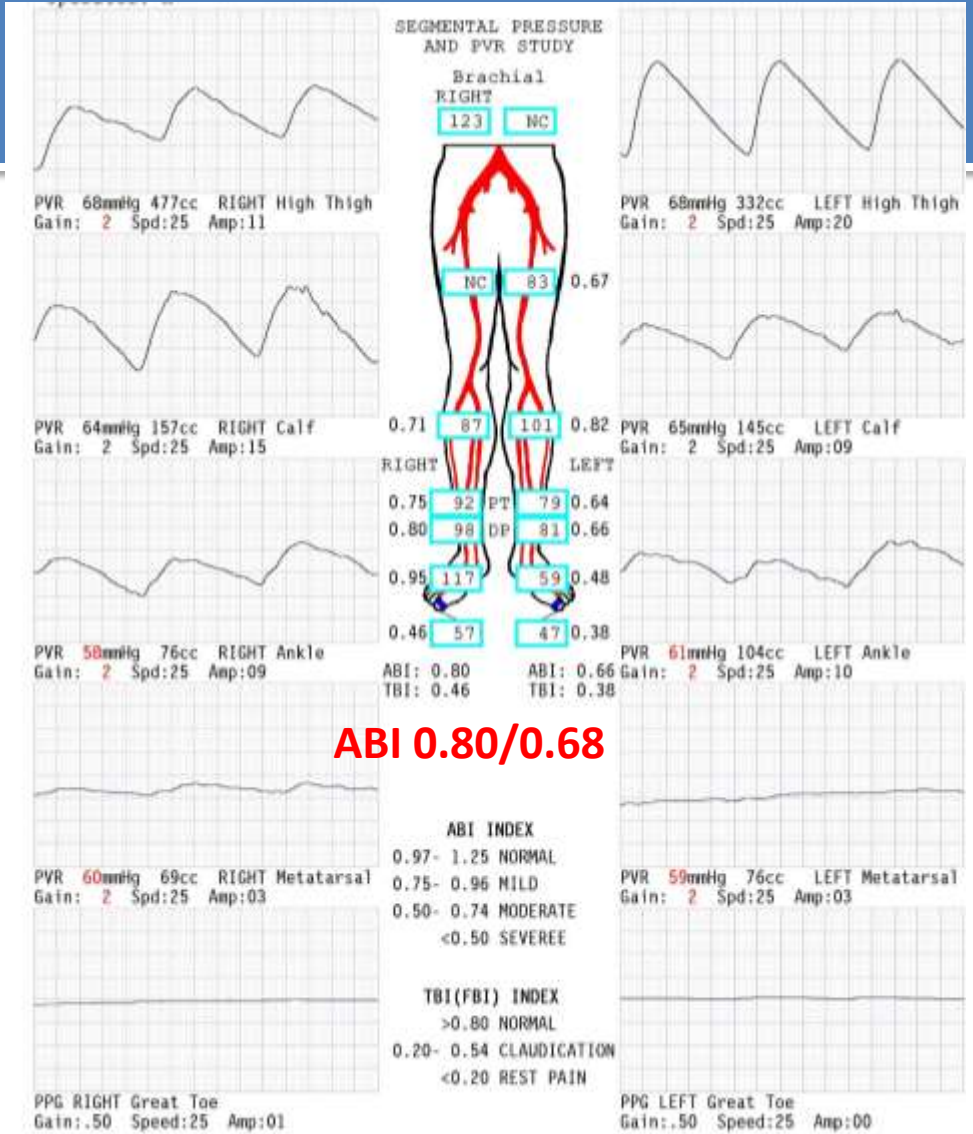
  - HTN, DM

  - S/P Kidney transplantation (20 yrs ago)
- Lab: Cr 1.4 mg/dL

Baseline CT



ABI

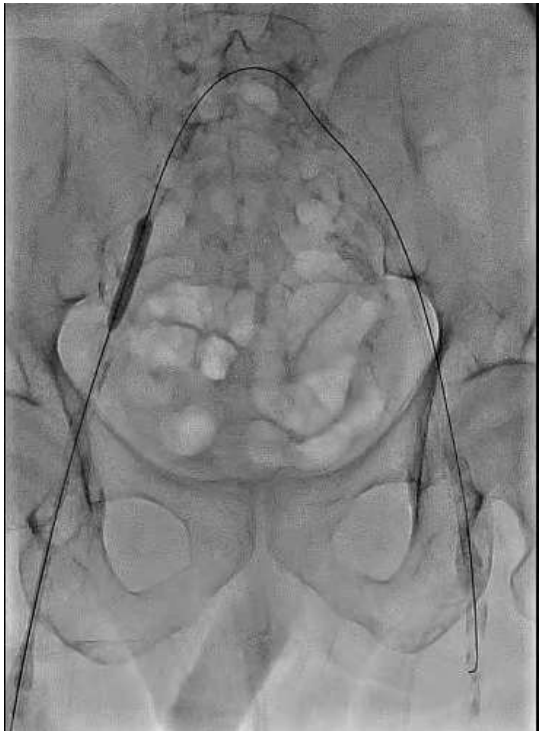

SEGMENTAL PRESSURE
AND PVR STUDY
Brachial
RIGHT
123
NC
PVR 68mmHg 477cc RIGHT High Thigh
Gain: 2 Spd:25 Amp:11
PVR 68mmHg 332cc LEFT High Thigh
Gain: 2 Spd:25 Amp:20
NC
83
0.67
PVR 64mmHg 157cc RIGHT Calf
Gain: 2 Spd:25 Amp:15
PVR 65mmHg 145cc LEFT Calf
Gain: 2 Spd:25 Amp:09
0.71
87
101
0.82
RIGHT
LEFT
0.75
92
PT
79
0.64
0.80
98
DP
81
0.66
0.95
117
59
0.48
0.46
57
47
0.38
PVR 58mmHg 76cc RIGHT Ankle
Gain: 2 Spd:25 Amp:09
PVR 61mmHg 104cc LEFT Ankle
Gain: 2 Spd:25 Amp:10
ABI: 0.80
TBI: 0.46
ABI: 0.66
TBI: 0.38
ABI 0.80/0.68
PVR 60mmHg 69cc RIGHT Metatarsal
Gain: 2 Spd:25 Amp:03
PVR 59mmHg 76cc LEFT Metatarsal
Gain: 2 Spd:25 Amp:03
ABI INDEX
0.97- 1.25 NORMAL
0.75- 0.96 MILD
0.50- 0.74 MODERATE
<0.50 SEVEREE
TBI(FBI) INDEX
>0.80 NORMAL
0.20- 0.54 CLAUDICATION
<0.20 REST PAIN
PPG RIGHT Great Toe
Gain:.50 Speed:25 Amp:01
PPG LEFT Great Toe
Gain:.50 Speed:25 Amp:00

Iliac Arteries

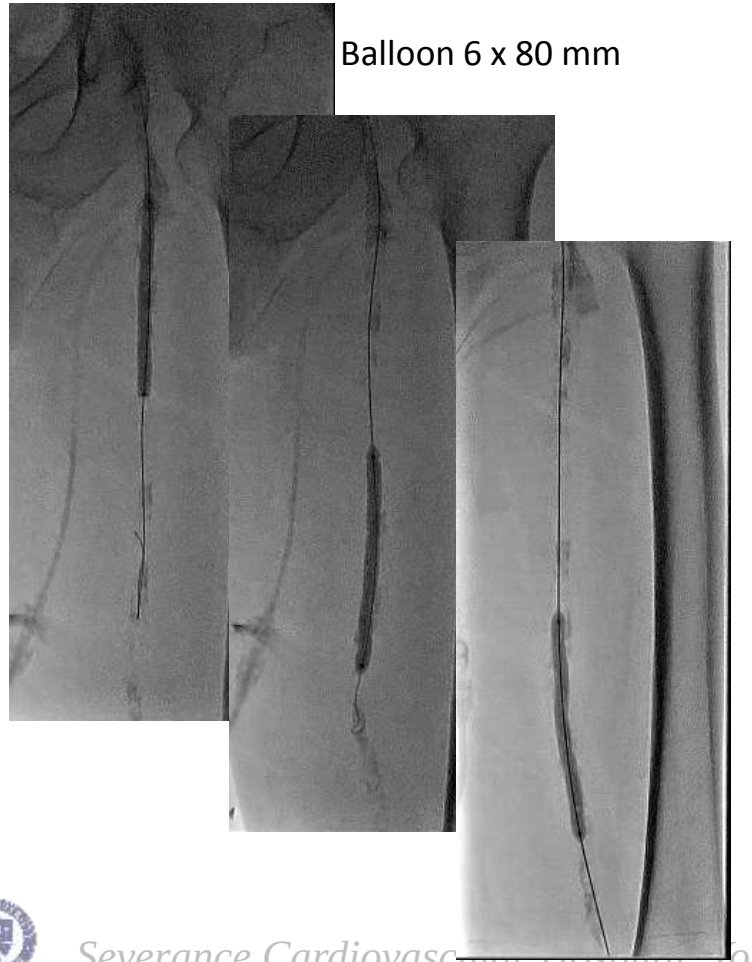
Vascular access preclosure: 1 Proglide for each side

Balloon Angioplasty

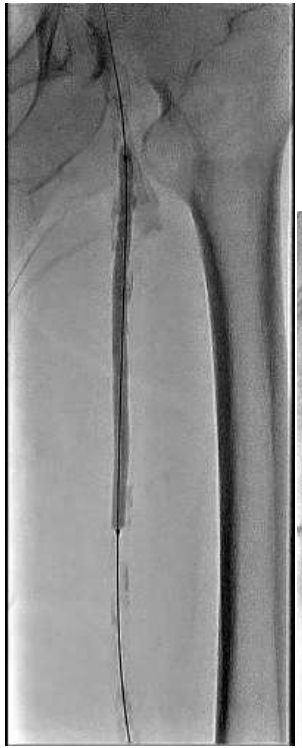
Balloon 7x 40 mm



Angioplasty at Left SFA

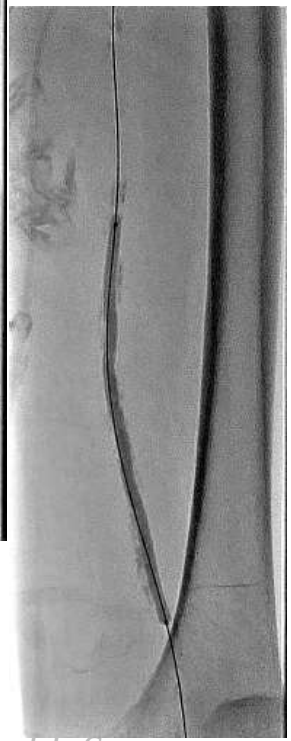


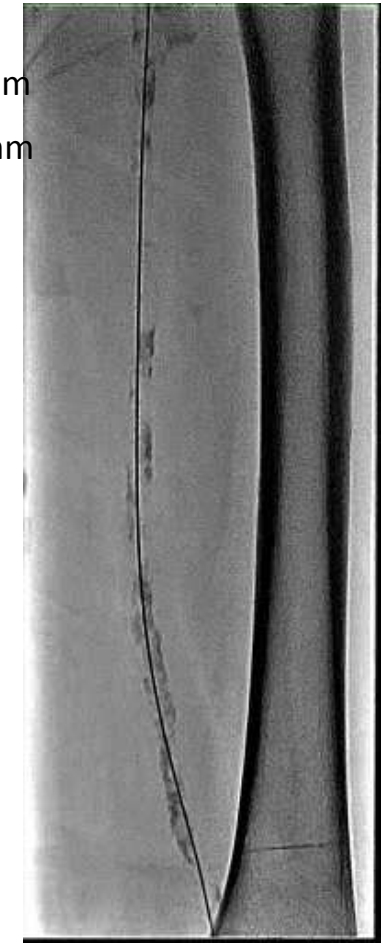
Balloon 6 x 80 mm



InPact DEB 6 x 150 mm

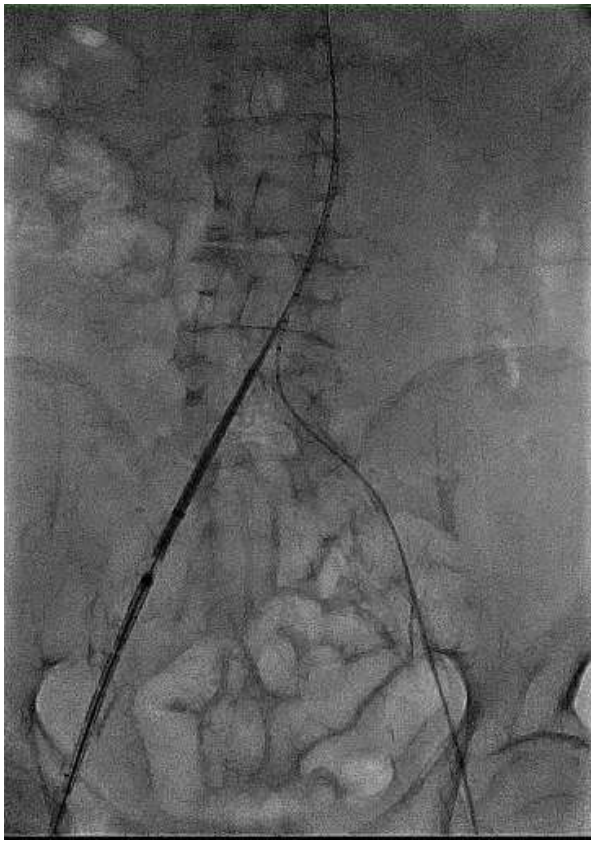
InPact DEB 5 x 150 mm

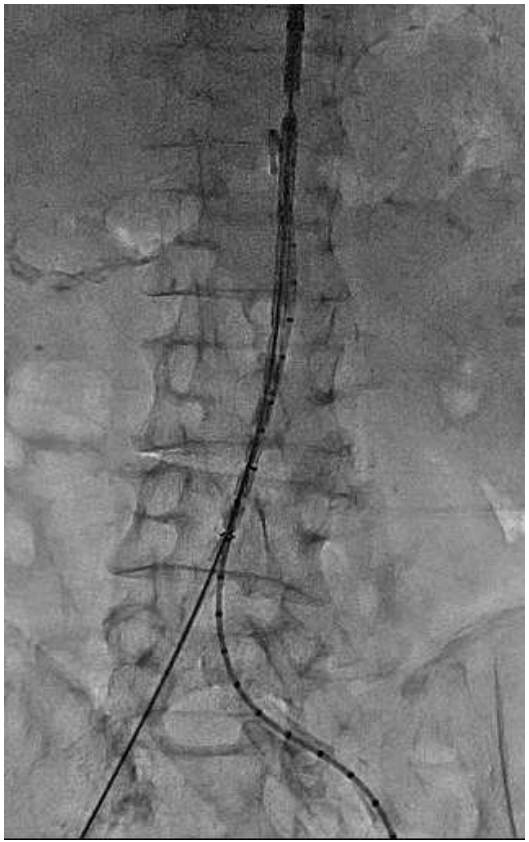


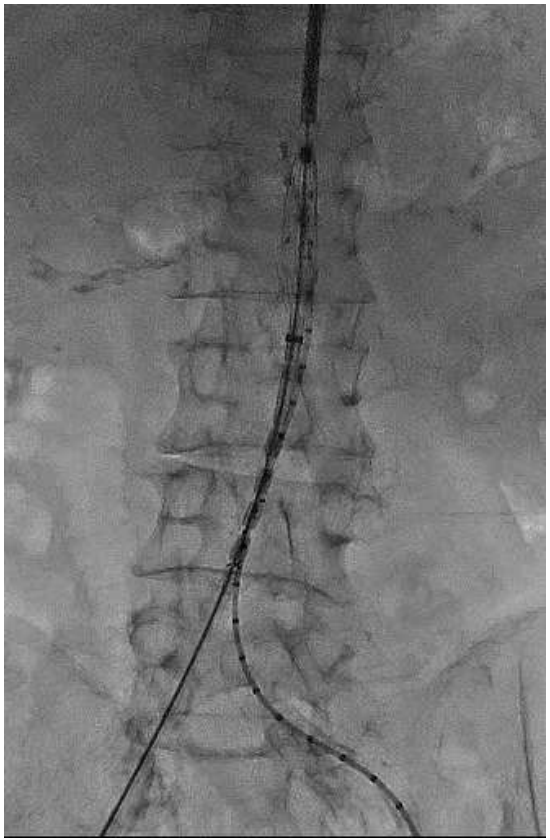


InCraft Main Body

Main body 26 mm

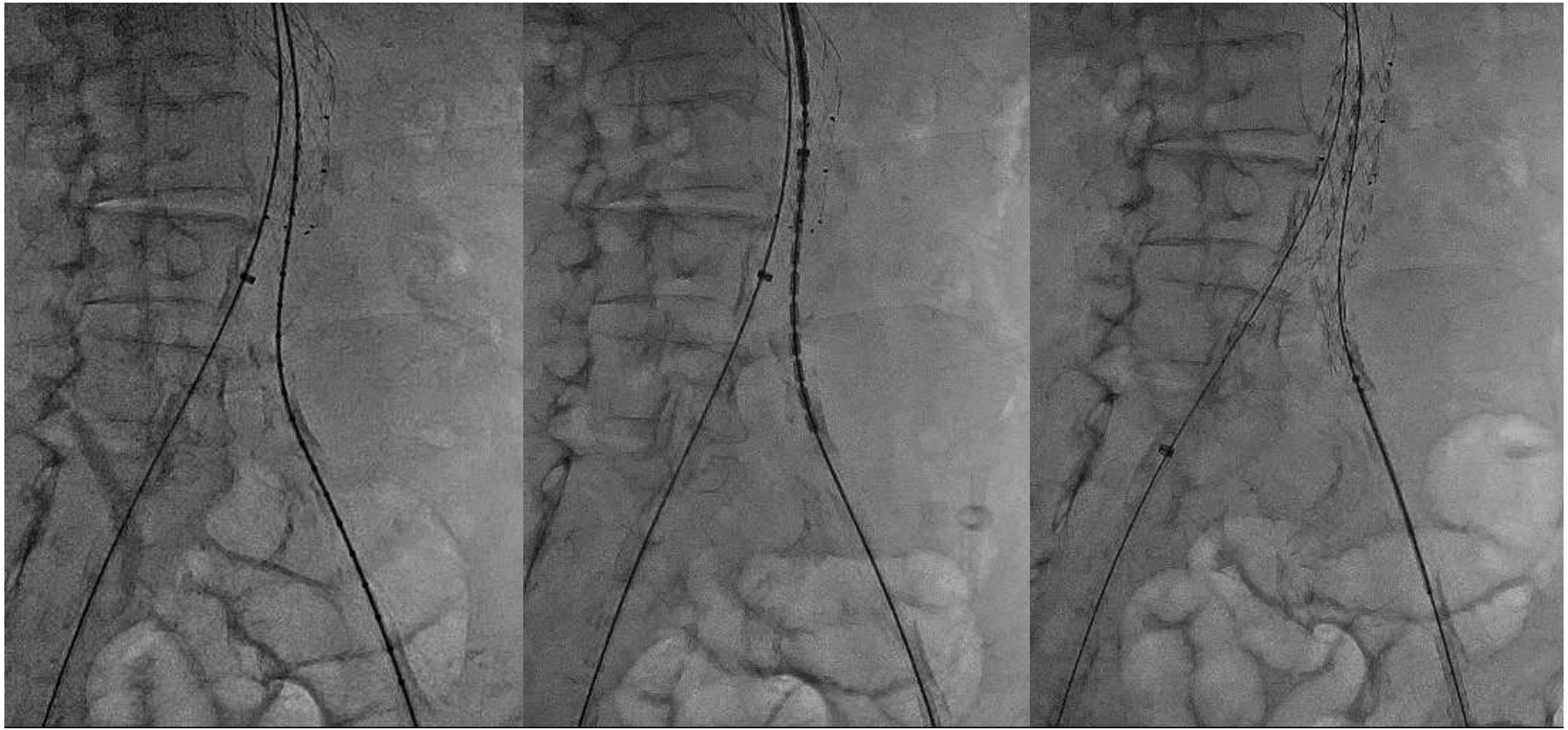






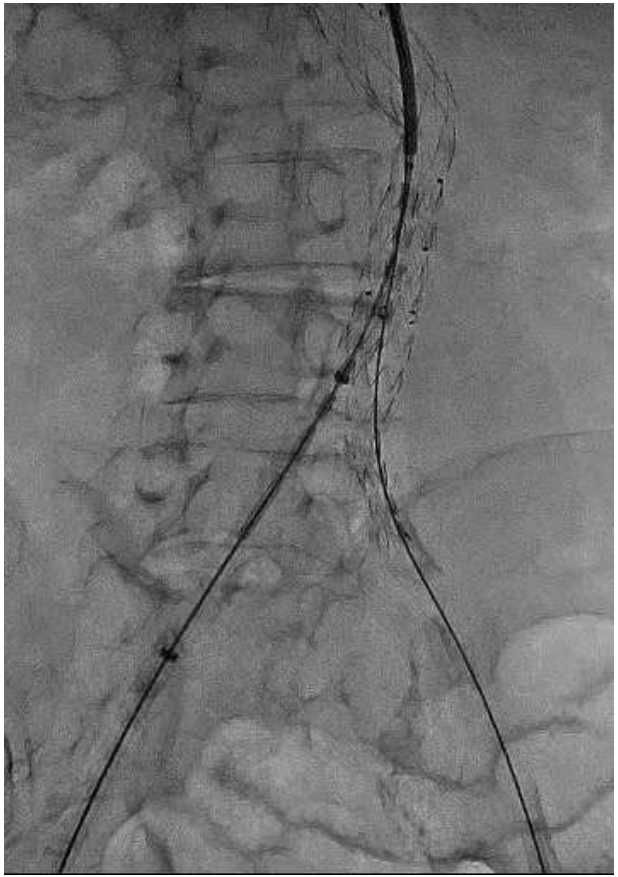
Lt. Iliac Limb Endograft & Stent

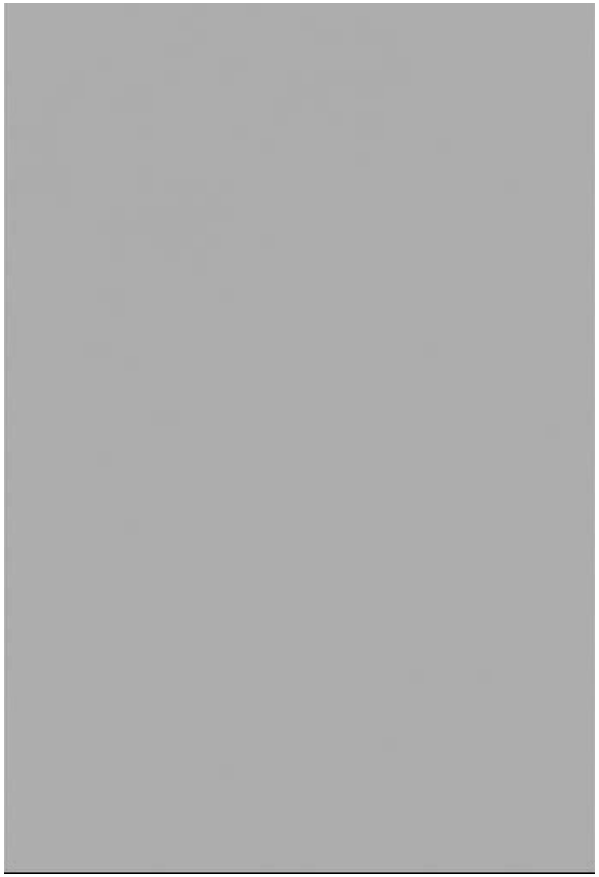
Limb 13-100 Epic 8 x 60



Rt. Iliac Limb Endograft

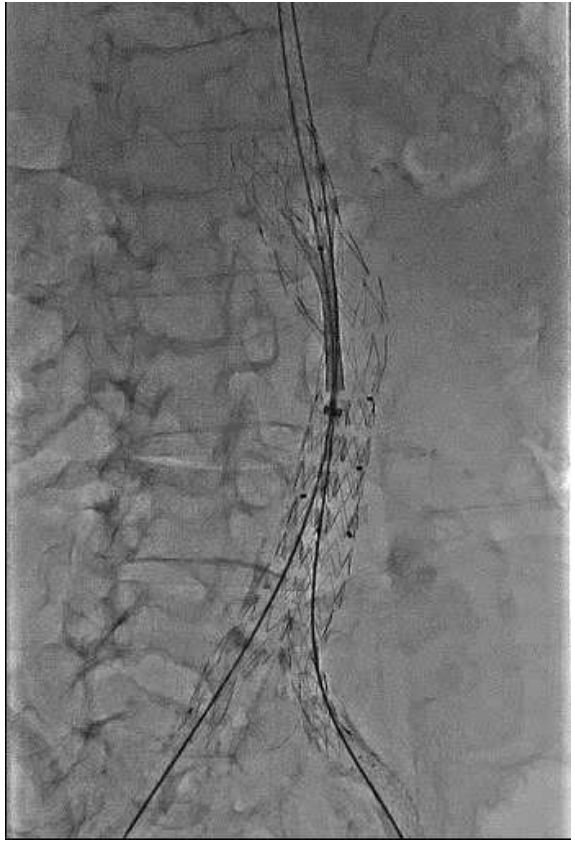
Limb 16-100

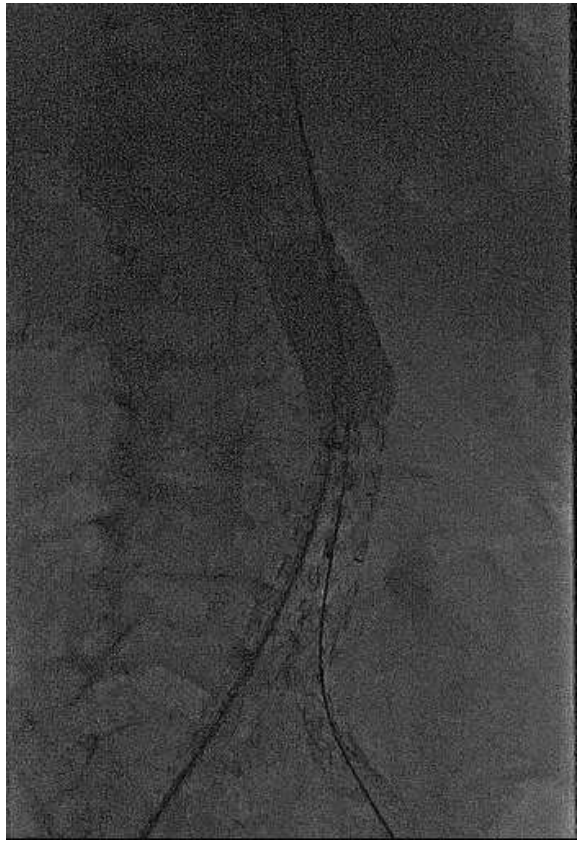


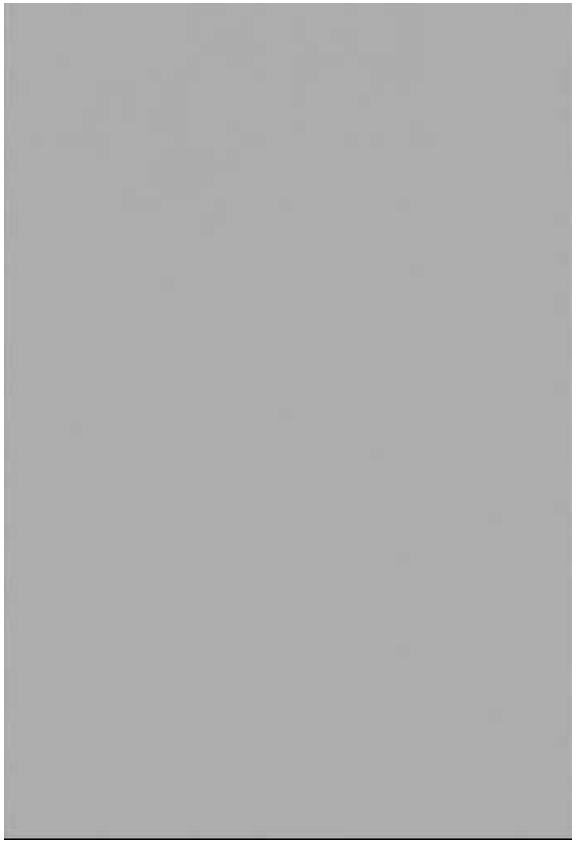


Final Aortogram

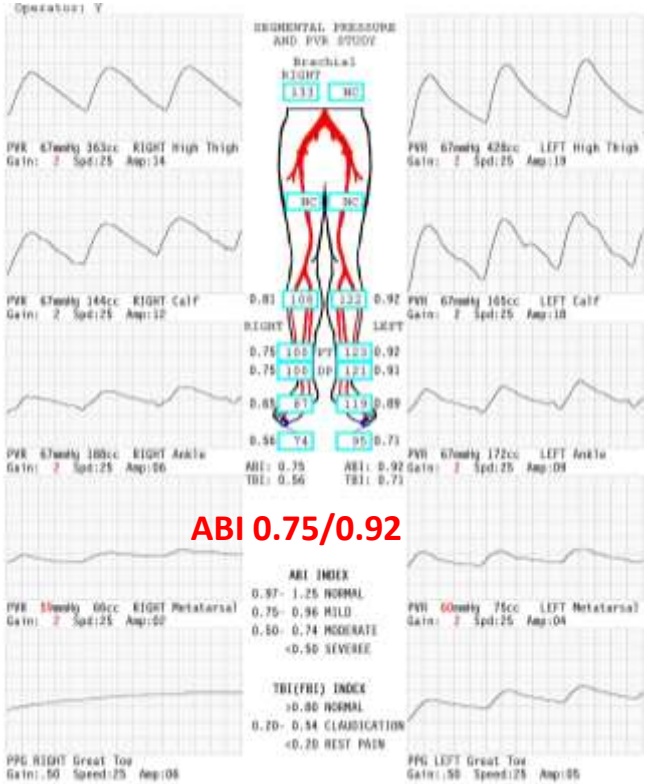
Palmaz 5014







Follow-up CT at 3 Days



Take Home Message

- INCRAFT is a ultralow profile endograft with broader applicability and enhanced feasibility of PEVAR.
- In addition, it enables controlled deployment of the endograft and the the selection of the limb device length more convenient.
- Prospective registry data demonstrate favorable outcomes after EVAR using INCRAFT in challenging anatomies.
- However, so far, there are only limited data available on the efficacy and safety of INCRAFT.
- We need more prospective data in the future.

Thank you
for your attention!