

# My experience with a next generation endograft: Bolton Treo

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May 21, 2016



# PRELIMINARY RESULTS OF THE TREO PHASE II CLINICAL TRIAL

## DISCLOSURE:

CONSULTANT BOLTON MEDICAL  
NATIONAL PI FOR TRIAL

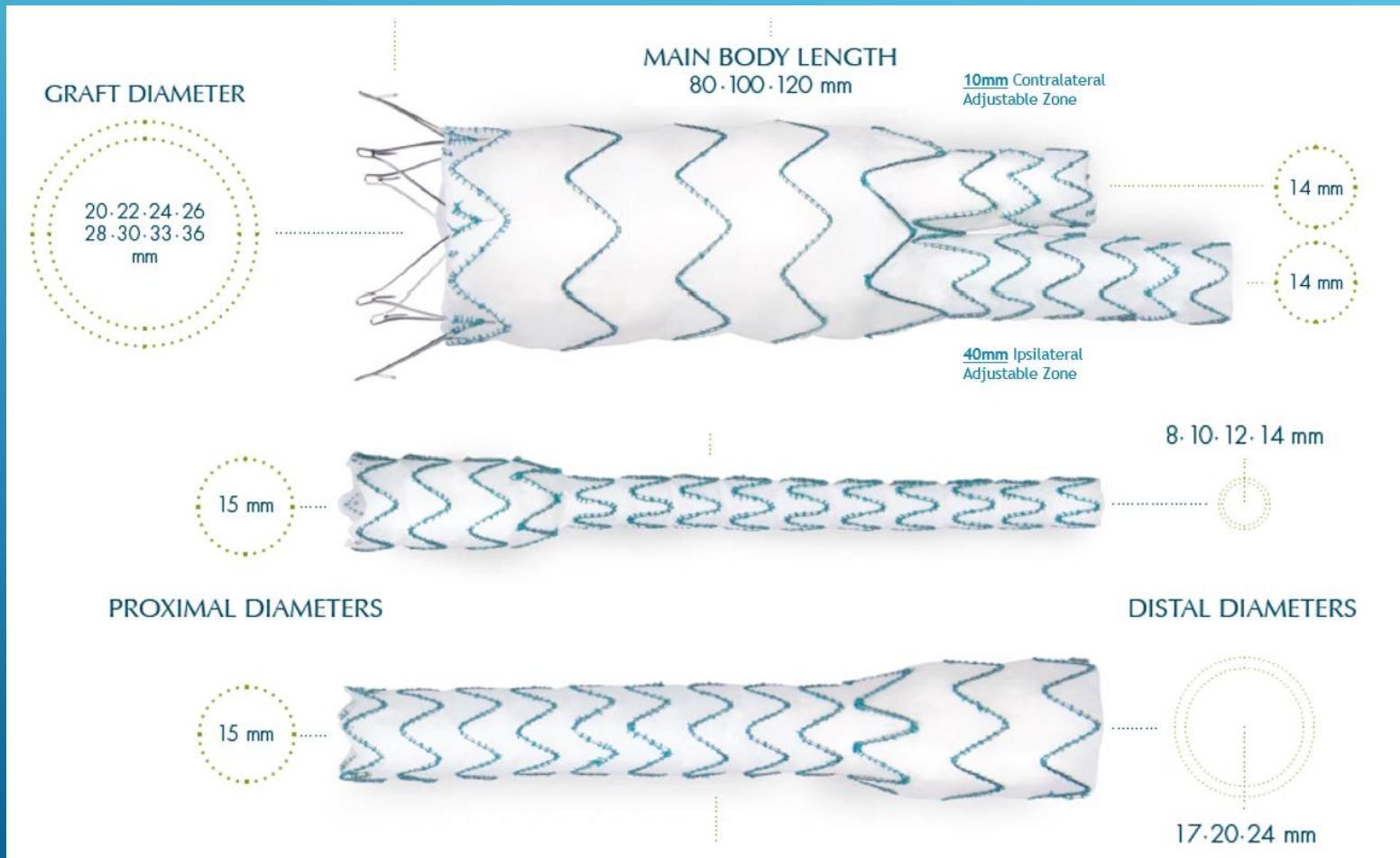


# TREOVANCE AAA STENT GRAFT SYSTEM FIRST GENERATION BOLTON AAA STENT GRAFT

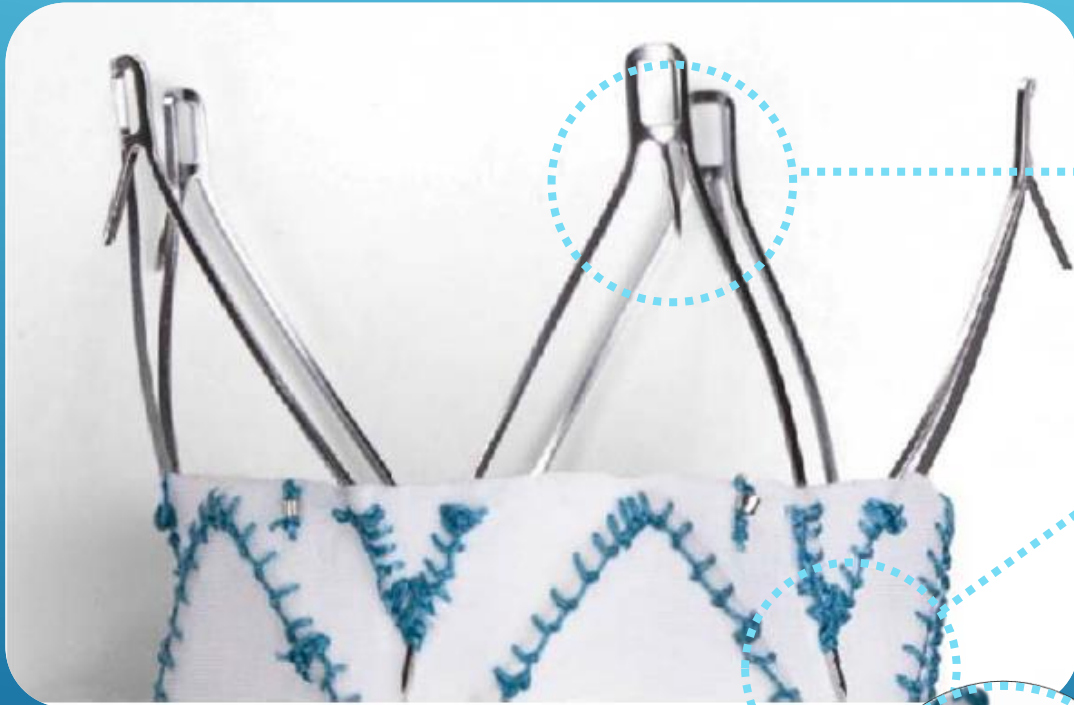


- ▶ 3-piece Endograft System
- ▶ Dual Proximal Fixation for Migration Resistance
- ▶ Low-Profile Delivery System

# PERSONALIZED TREATMENT OPTIONS WITH 3 PIECE SYSTEM



# DUAL PROXIMAL FIXATION DESIGNED FOR LONG TERM DURABILITY



## **Suparenal Fixation**

Provides primary proximal fixation

## **Infrarenal Fixation**

Provides supplemental fixation in angulated anatomies



# LOW-PROFILE DELIVERY SYSTEM FOR ENHANCED DELIVERY

MAIN BODY		ILLIAC LIMBS	
30 to 36mm	20 to 28mm	9 to 15mm	17 to 24mm
<b>19 F. (OD)</b>	<b>18 F. (OD)</b>	<b>13 F. (OD)</b>	<b>14 F. (OD)</b>



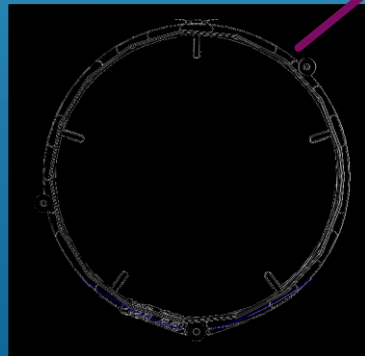
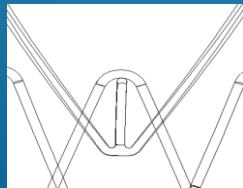
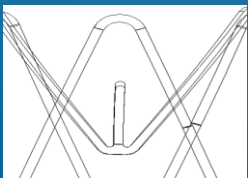
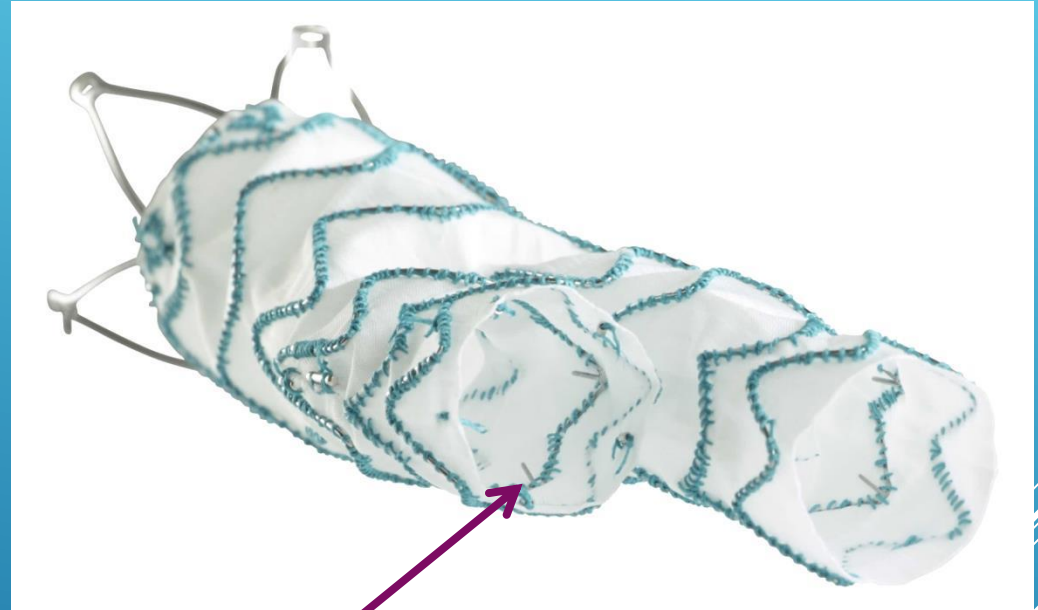
**TREO**<sup>™</sup>  
ABDOMINAL STENT GRAFT SYSTEM

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# LOCK STENT TECHNOLOGY SECURES LIMBS FOR LONG TERM DURABILITY

## Lock Stent Technology

- Dull barbs on the legs of the bifurcate graft
- Designed to prevent component separation;  
**Secures Limb and Main Body**



# CLINICAL EVIDENCE





# CLINICAL TRIALS



## ADVANCE Trial

- Prospective, multicenter, nonrandomized study
- 5 European centers, 30 patients



## BENEFIT Trial

- Prospective, multicenter, nonrandomized study
- 6 US centers, 30 patients

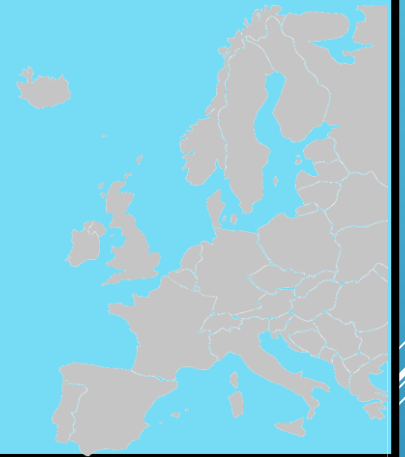


# PHASE I CLINICAL TRIAL: EUROPE



## ADVANCE Trial

- **Prospective, multi-center, non-randomized study**
- **5 European centers, 30 patients**



# ADVANCE TRIAL: SAFETY ENDPOINTS

<b>Adverse Events</b>	<b>30 Days (n=30)</b>	<b>1 Year (n=26)</b>
Aneurysm-related mortality	0	0
All-cause mortality	0	3*
Myocardial infarction	0	1
Stroke	0	0
Renal failure	0	0
Respiratory failure	0	0
Paraparesis/paraplegia	0	0
Bowel ischemia	0	0
Treated aneurysm rupture	0	0

\* 1 Car accident. 1 Pancreatic cancer. 1 Myocardial Infarction (not device related)

# ADVANCE TRIAL: EFFECTIVENESS MEASURES

<b>Endovascular Events</b>	<b>Treatment (n = 30)</b>	<b>1 year (n =26)</b>
Endoleak (Type I, III, IV)	0% (0/30)	3.8% (1*/26)
Endoleak (Type II)	13.3% (4/30)	11.5% (3/26)
Stent-Graft Occlusion / Loss of Patency	3.3% (1/30)	3.8% (1/26)
Migration	0% (0/30)	0% (0/26)
Wireform Fracture	0% (0/30)	0% (0/26)
Sac size changes		
• No change (increase/ decrease < 5mm)	N/A	40.0% (10/25)
• Decrease (> 5mm)	N/A	56.0% (14/25)
• Increase (> 5mm)	N/A	4.0% (1*/25)
Conversion to open surgery	0% (0/30)	3.8% (1/26)

\* Type Ia endoleak due to the progression of the disease with enlargement of the aorta and consequent growing of the aneurismatic sac.

# PHASE I / EUROPEAN TRIAL SUMMARY

- Treovance provides a versatile solution in a low-profile delivery system with an accurate deployment
- Successful initial results, even in challenging anatomies
  - 30% of BENEFIT patients presented with 61°-75° infrarenal angulations
- CE Mark received February 28, 2013
- Phase II US trial commenced November 2013

# NEXT GENERATION TREOVANCE (TREO )

## Expanded Patient Applicability

- Modified Mainbody for Shorter Anatomy
- AUI Configuration w/Occluder
- Lower Profile Limbs
- Expanded Limb Matrix

## Enhanced Ease of Use

- Standardized Delivery System
- Leave Behind Sheaths on Limbs
- Improved Valve Technology
- Enhanced Ergonomics



# TREOVANCE (TREGO) US PHASE II TRIAL *DESIGN*

Multi-center, non-blinded, non-randomized study of treatment with Treovance Stent-Graft in subjects with abdominal aortic aneurysms

Target Centers: 30 (29) US Hospitals

Patients: 150

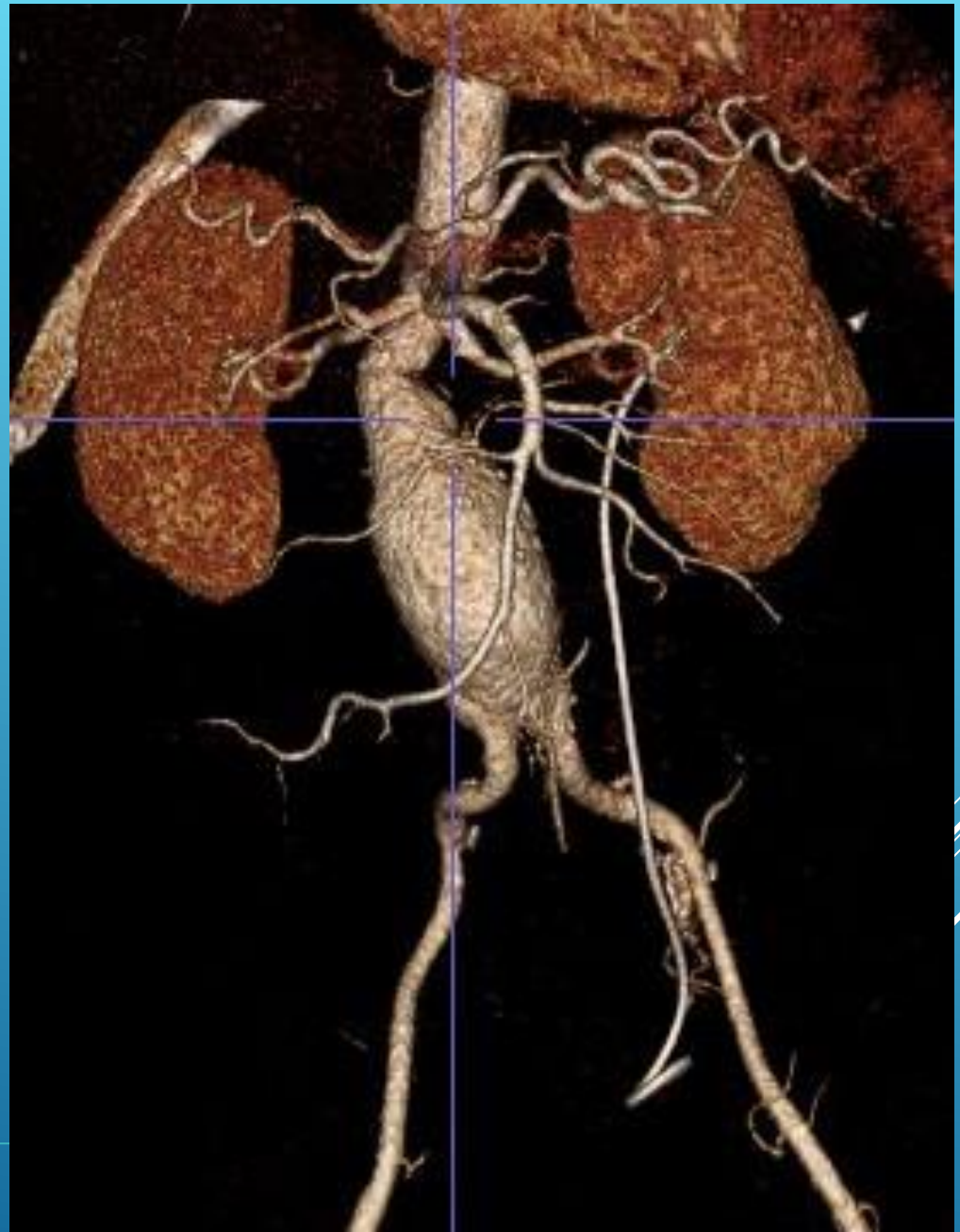
# TREOVANCE CASE – PREOP CT



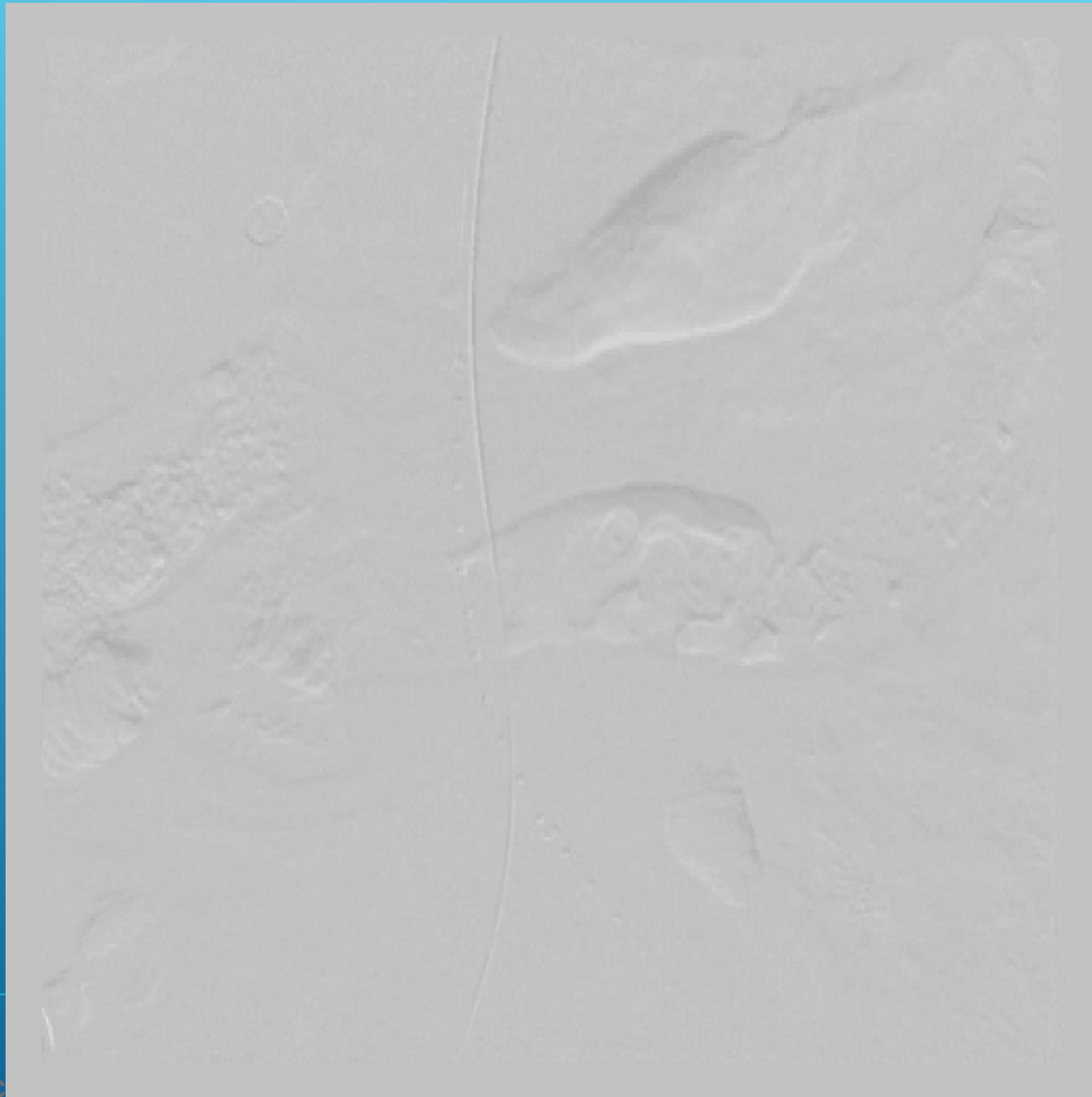


# TREOVANCE CASE: PREOP CT

- **Aortic sizing**
  - 24 mm neck
  - 12 mm length
  - 52 degree angle
  - 9 mm iliac diam.
- **Graft Sizing**
  - Main body:
    - 28-B2-28-100x
  - Iliac limbs:
    - 28-L2-11-100x



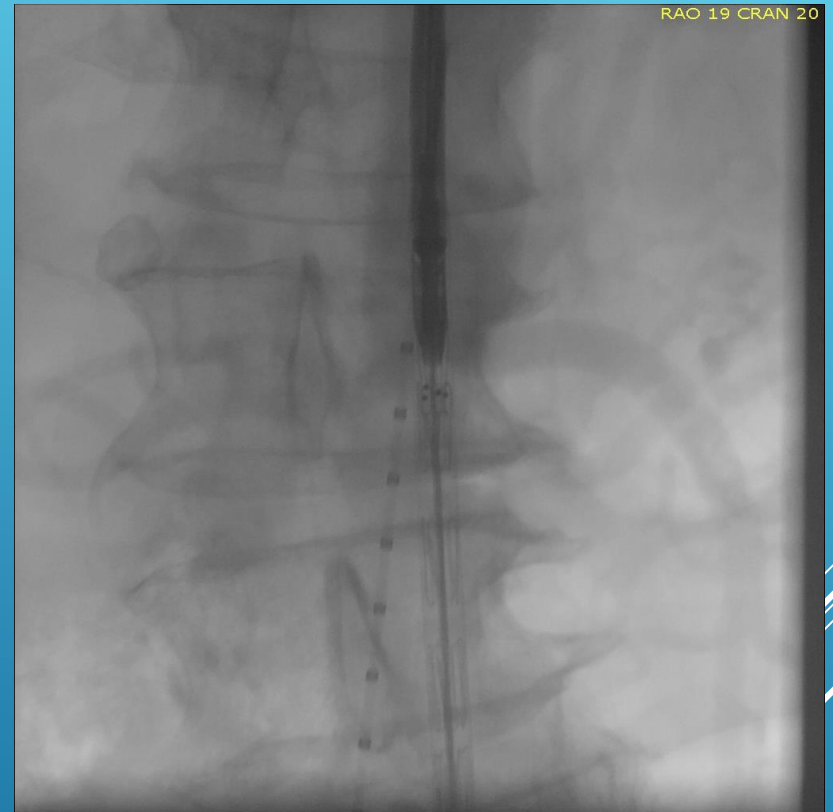
# TREOVANCE CASE - ANGIOGRAPHY



# PRE-INSERTION GRAFT ORIENTATION

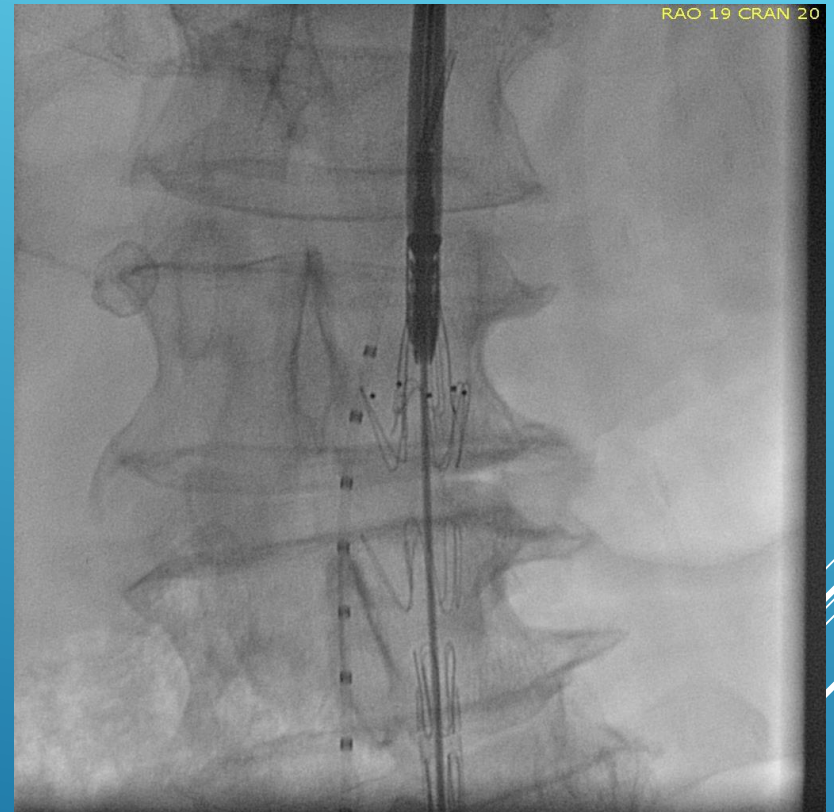


# PLACEMENT ADJACENT TO RENAL ARTERIES

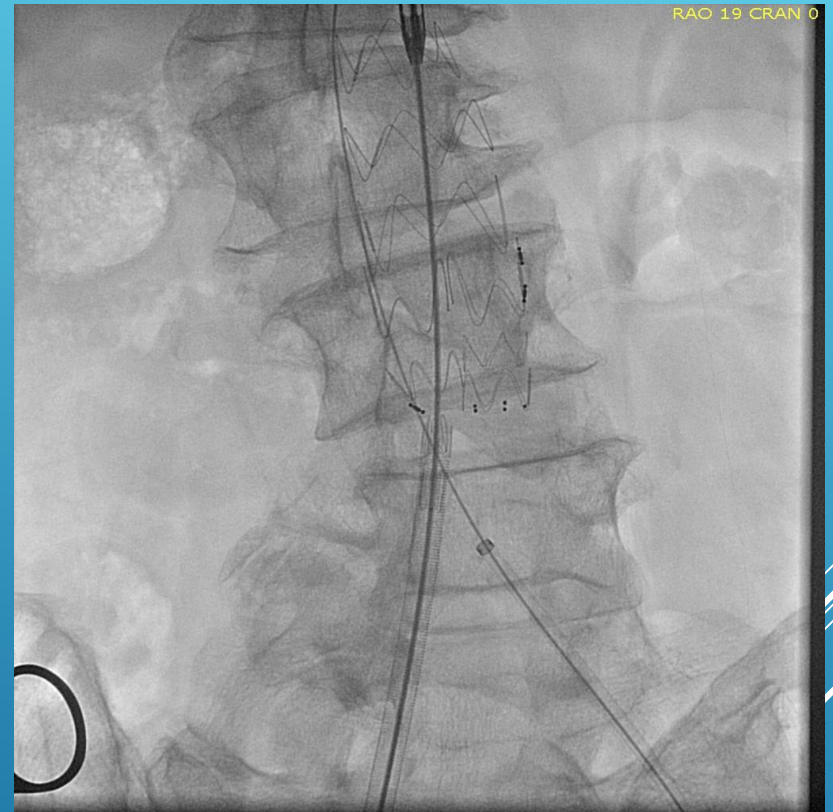
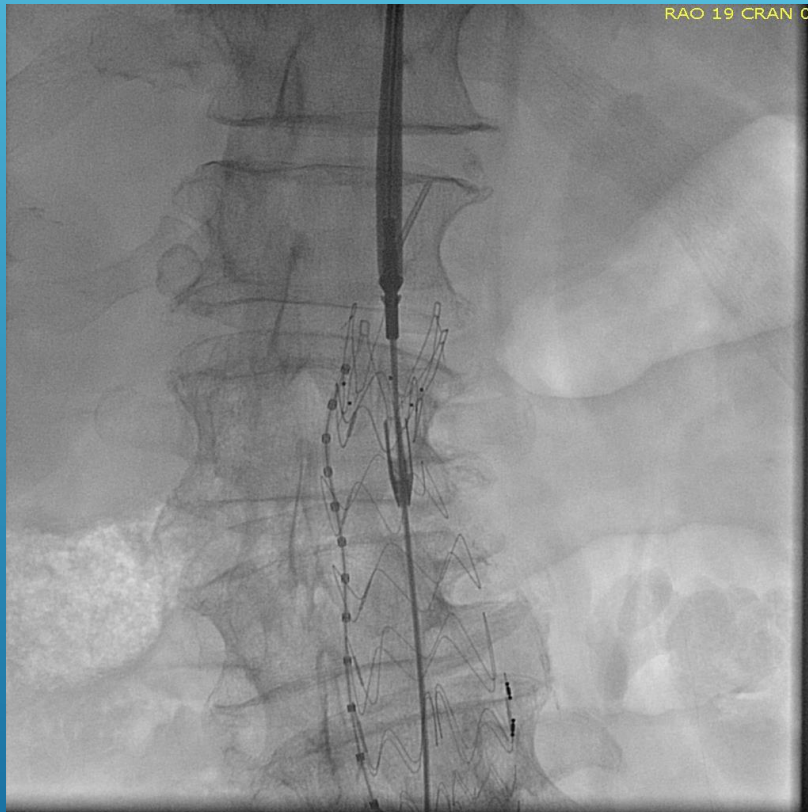




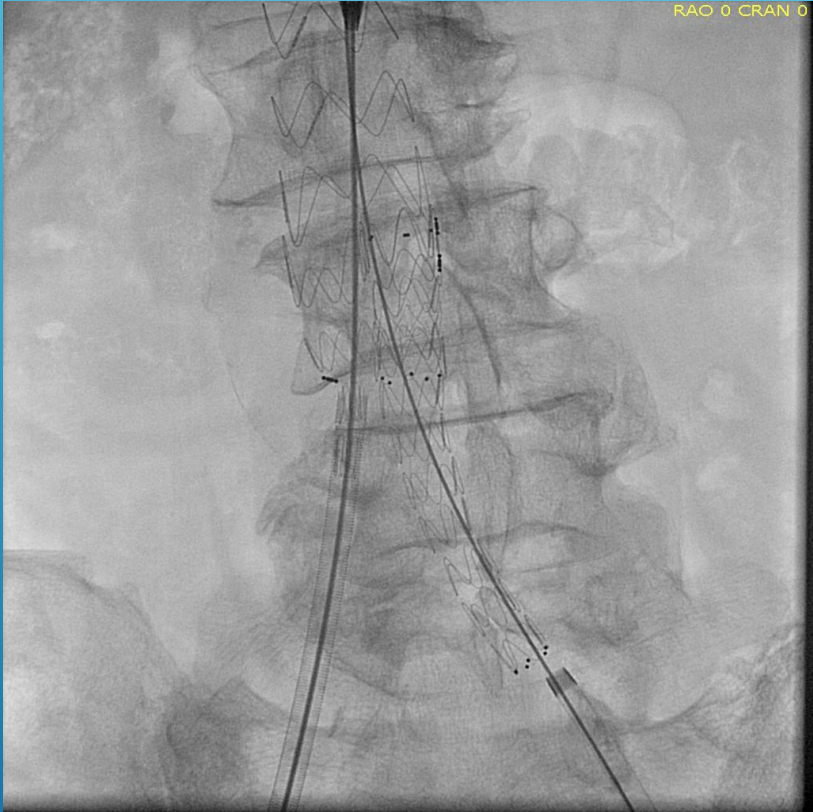
# PRECISE GRAFT DEPLOYMENT



# DEPLOYMENT OF GRAFT - CONTINUED



# CONTRALATERAL/IPSILATERAL LIMB PLACEMENT



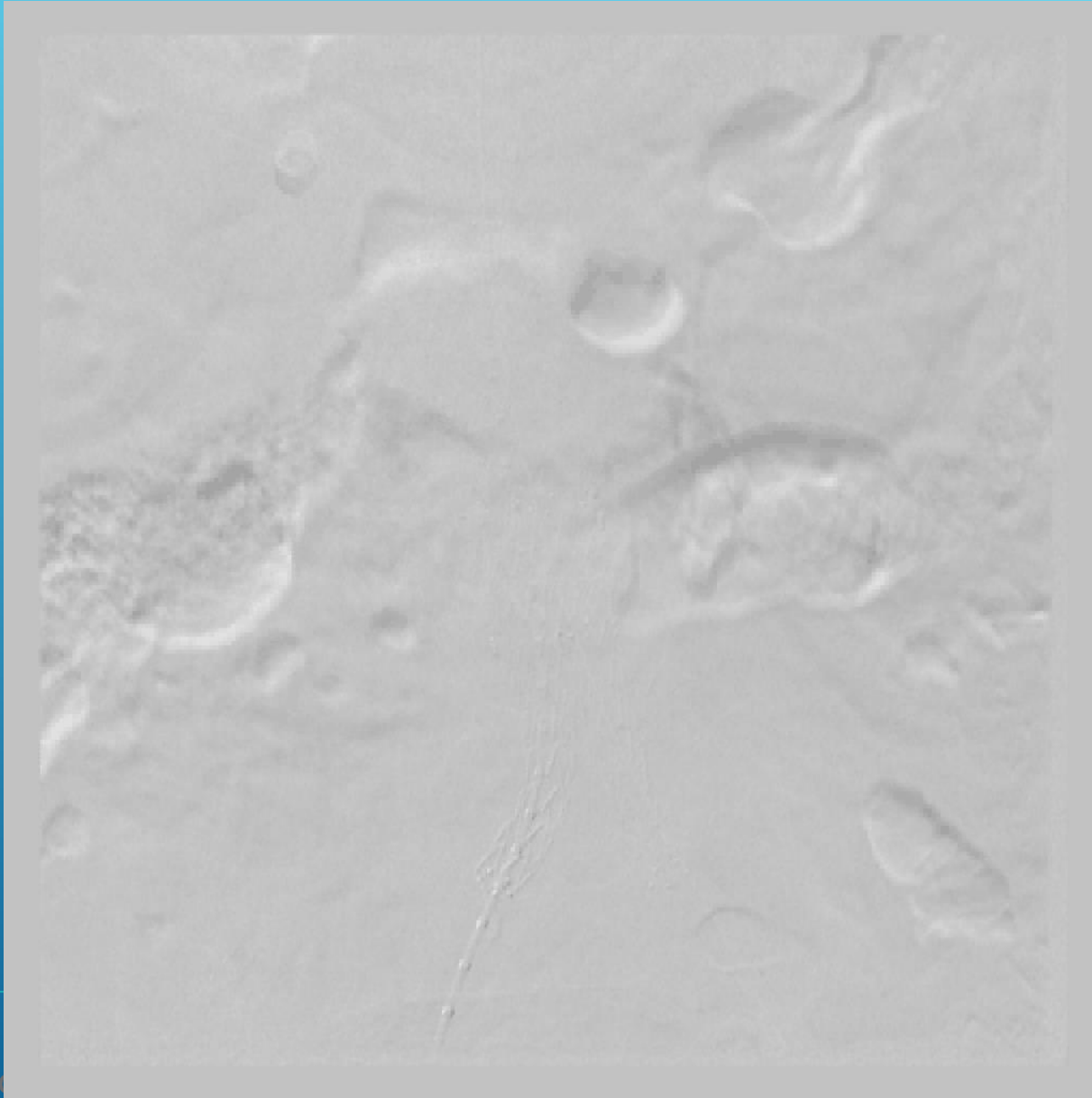


# PROXIMAL ANGIOPLASTY AND RENAL ASSESSMENT





# COMPLETION ANGIOGRAPHY



# FOLLOW UP CT



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# TREOVANCE (TREO) PHASE II SAFETY ENDPOINTS

<b>Adverse Events</b>	<b>≤ 30 days (n = 150)</b>	<b>&gt; 30 days (n = 148)</b>
Aneurysm-related mortality	0% (0/150)	0% (0/148)
All-cause mortality	0% (0/150)	4.05% (6/148)
Myocardial infarction	0.67% (1/150)	1.35% (2/148)
Stroke	0% (0/150)	0.68% (1/148)
Renal failure	0% (0/150)	0% (0/148)
Respiratory failure	0% (0/150)	0.68% (1/148)
Paraparesis/paraplegia	0% (0/150)	0% (0/148)
Bowel ischemia	0% (0/150)	0.68% (1/148)
Procedural blood loss of ≥1000 cc	0.67% (1/150)	0% (0/148)
Treated aneurysm rupture	0% (0/150)	0% (0/148)

# TREOVANCE (TREGO) PHASE II SAFETY ENDPOINTS

Endovascular Events	Treatment (n = 150)	1 mon (n =148)	6 mon (n =109)	12 mon (n =69)	2 yr (n =10)
Endoleak (Type I, III, IV)	2% (3/150)	0.68% (1/148)	1.83% (2/109)	1.45% (1/69)	0% (0/10)
Endoleak (Type II)	35.33% (55/150)	25.68% (38/148)	22.94% (25/109)	20.29% (14/69)	10% (1/10)
Stent-Graft Occlusion / Loss of Patency*	0% (0/150)	2.03% (3/148)	0% (0/109)	0% (0/69)	0% (0/10)
Migration	N/A	N/A	0% (0/109)	0% (0/69)	0% (0/10)
Wireform Fracture	0% (0/150)	0% (0/148)	0% (0/109)	0% (0/69)	0% (0/10)

- 3 patients experienced limb occlusion requiring intervention
  - 401-103 Occluded right limb at 11 days
  - 418-101 Occluded right limb at 29 days
  - 423-116 Occluded left limb at 9 days

# TREOVANCE (TREGO) PHASE II SAFETY ENDPOINTS

Endovascular Events	Treatment (n = 150)	1 mon (n =148)	6 mon (n =109)	12 mon (n =69)	2 yr (n =10)
Sac size changes (relative to diameter at 1-month evaluation)					
• No change (increase/ decrease $\leq$ 5mm)	N/A	N/A	68.81% (75/109)	53.62% (37/69)	60% (6/10)
• Decrease (>5 / <10 mm)	N/A	N/A	20.18% (22/109)	17.39% (12/69)	20% (2/10)
• Decrease ( $\geq$ 10mm)	N/A	N/A	11.01% (12/109)	28.99% (20/69)	20% (2/10)
• Increase (> 5mm)	N/A	N/A	0% (0/109)	0% (0/69)	0% (0/10)
Conversion to open surgery	0% (0/150)	0% (0/148)	0% (0/109)	0% (0/69)	0% (0/10)

# TREOVANCE PHASE II SUMMARY

- ▶ 100% Successful Deployment
- ▶ 100% Freedom from Rupture
- ▶ 100% Freedom from Conversion
- ▶ 100% Freedom from Migration
- ▶ 100% Freedom from Stent Fractures
- ▶ 100% Freedom from Sac Enlargement

# CONCLUSIONS

- ▶ Excellent early clinical outcomes from Bolton TREO Phase II clinical trial to date
- ▶ Anticipate continued long-term clinical success as additional follow up data is collected

THANK-YOU.

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