

**LONG TERM FOLLOW UP WITH THE  
MULTILAYER STENT FOR TREATMENT OF  
RENAL AND MESENTERIC ANEURYSMS**

**F.A.H.A., F.A.C.A., F.E.S.C., F.A.S.A., F.I.C.I.C.  
INTERVENTIONAL CARDIOLOGIST**

**A.**

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**NANCY – FRANCE**

**ATHENES - GREECE**

**\*CHIEF PATRON**

**GLOBAL VASCULAR INSTITUT**

# Disclosures

11/16/2010

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**CONSULTANT  
CARDIATIS BELGIUM**

**THE CARDIATIS MULTILAYER STENT IS  
NOT APPROVED FOR USE IN THE US  
STILL INVESTIGATIONAL**

# RENAL ARTERY ANEURYSM

- **PREVALENCE**

- **RELATIVELY RARE :**

- 0,09% OF THE GENERAL POPULATION
- 1% RENAL ANGIOGRAPHIC PROCEDURES

- **IN PATIENTS WITH SUSPECTED RENOVASCULAR HYPERTENSION:1,3%**

- **15 -22% OF ALL VISCERAL ARTERY ANEURYSMS**

- **ETIOLOGY**

- **ATHEROSCLEROSIS**

- **F.M.D.**

- **CONGENITAL – MARFAN - EHLERS DANLOS SYNDROM**

- **FEMALE PREDILECTION**



# RENAL ARTERY ANEURYSM

- **MOST ARE ASYMPTOMATIC AND FOUND INCIDENTALLY**
- **SOME PATIENTS COMPLAIN OF FLANK PAIN AND/OR HEMATURIA (30% OF THE CASES)**
- **MAY CONTRIBUTE TO HYPERTENSION ( 73% OF CASES )**
  - **MECHANICAL EFFECTS ON RENAL ARTERY**
  - **ALTERED RENAL BLOOD FLOW**
  - **EMBOLIZATION TO DISTAL PARENCHYMA**
  - **RENAL ARTERY THROMBOSIS**
  - **CHRONIC RENAL DYSFUNCTION**
- **HIGH RISK OF RUPTURE AND LIFE THREATENING CONDITIONS WITH MORTALITY OF 20 - 75%**
  - **RELATED TO THE SIZE**
  - **HIGHER RISK :**
    - **Ø>2,3 cm**
    - **PREGNANT FEMALES**

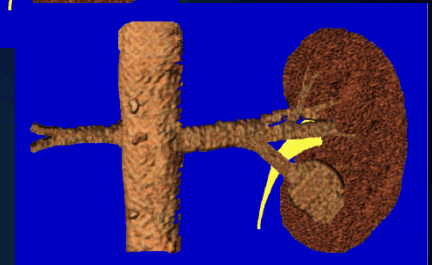
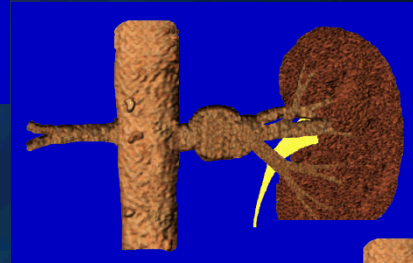
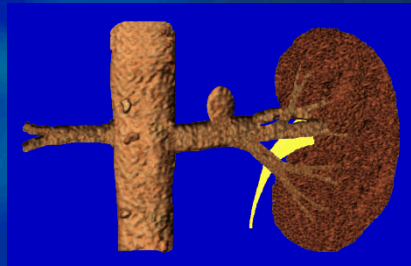
# **RENAL ARTERY ANEURYSM INDICATIONS FOR TREATMENT**

- **SIZE >2cm REGARDLESS OF BLOOD PRESSURE STATUS BUT RUPTURE HAVE BEEN REPORTED WITH AN. < 2cm**
- **SIZE >1cm IF HYPERTENSION DIFFICULT TO CONTROL**
- **INCREASING ANEURYSM SIZE**
- **FEMALE GENDER AND CONCURRENT HYPERTENSION**
- **ACUTE DISSECTION**
- **COEXISTENT RENAL ARTERY STENOSIS**
- **PREGNANCY / YOUNG WOMEN WITH ANTICIPATED PREGNANCY**
- **FLANK PAIN**
- **DISTAL EMBOLI**
- **PATIENT WITH RENAL RISK (SINGLE KIDNEY, RENAL INSUFFICIENCY)**

# RENAL ARTERIAL DISEASES ANATOMY

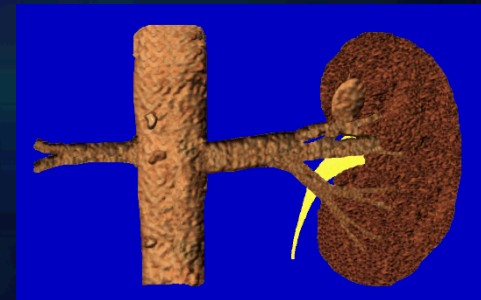
## ■ TYPES

- SACCULAR  
(MOST OF THE CASES)
- FUSIFORM

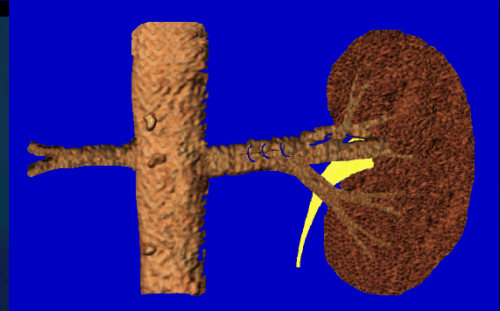


## ■ LOCATION

- EXTRAPARENCHYMAL
  - CAN INCLUDE MAIN RENAL ARTERY AND OR PRIMARY BRANCHES
- INTRAPARENCHYMAL

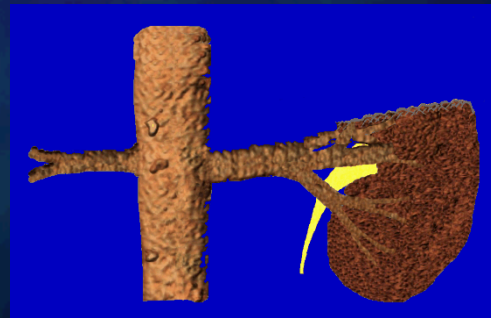


# RENAL ARTERY ANEURYSM TREATMENT



## ■ SURGERY

- IN SITU / EX VIVO REPAIR
- ANEURYSM EXCISION AND RENAL ARTERY REPAIR
- AORTO RENAL BYPASS
- PARTIAL / TOTAL NEPHRECTOMY



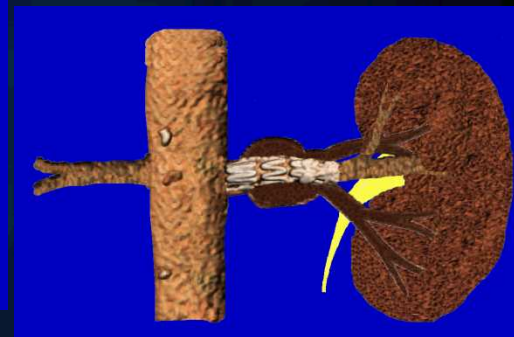
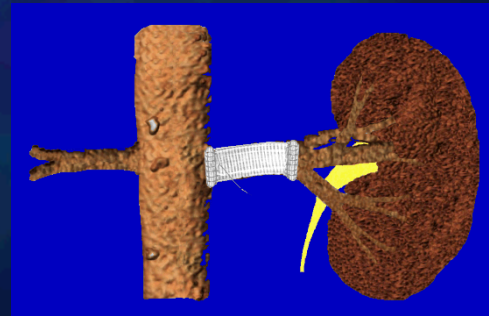
- MORBIDITY / MORTALITY : 10%



# RENAL ARTERY ANEURYSM TREATMENT

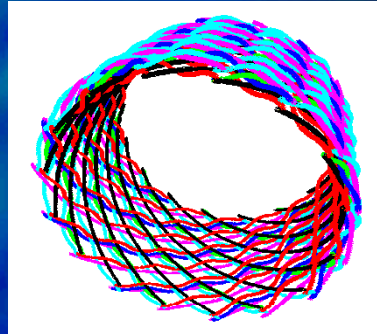
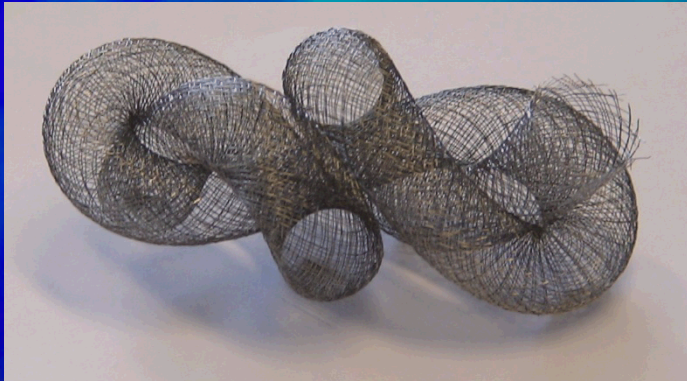
## • ENDOVASCULAR TECHNIQUES:

- CATHETER, DIRECTED EMBOLIZATION WITH COILS, DETACHABLE BALLOONS, USE OF ONYX
- BARE METAL STENTS WITH LOW POROSITY
- STENT ASSISTED COIL EMBOLIZATION
- STENT GRAFT:
  - RISK OF BRANCH OCCLUSION AND RENAL INFARCTION, CONTRAINDICATION IF LARGE BRANCHES MUST BE COVERED
  - POSSIBILITY OF DELAYED RECANALIZATION OF THE ANEURYSM DUE TO COLLATERAL BRANCHES
  - RISK OF STENT THROMBOSIS

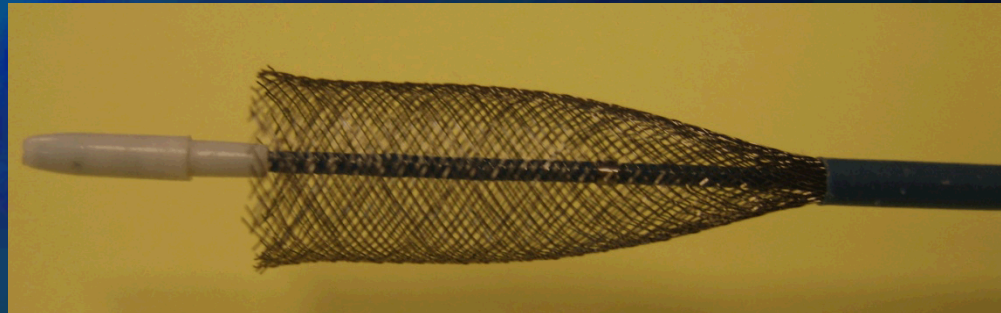
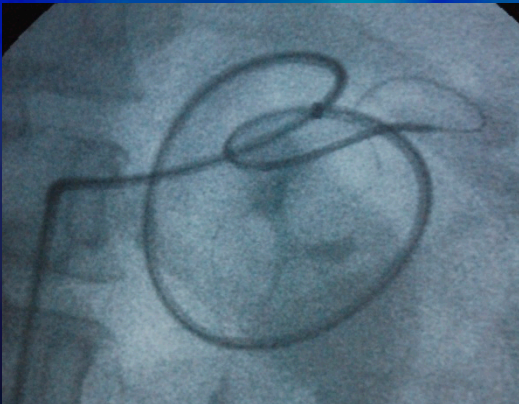


- NEW TECHNIQUE : MULTILAYER STENT

# MULTILAYER STENT : 3DIMENSIONAL TECHNOLOGY



Cardatis Multilayer Stent is a self-expandable device with a tridimensional mesh made of metallic cobalt alloy wires interconnected in multiple layers: this structure allows the mesh layers number to adapt to diameter, morphology, dimension and course of the target artery



The delivery consists of a guided-catheter with a minimally traumatic soft tip

**.Stent Diameter : 2-50 mm      Length : 30 to 150 mm**

**Guide wire compatible : 0.018 (small stents)   0.035 (larger stents)**

The sheath is connected by a hemostatic Y valve to the delivery: when the valve is closed, the sheath is fixed to the support, as a safety lock.

# **MULTILAYER STENT**

**HOW DOES IT WORK ?**

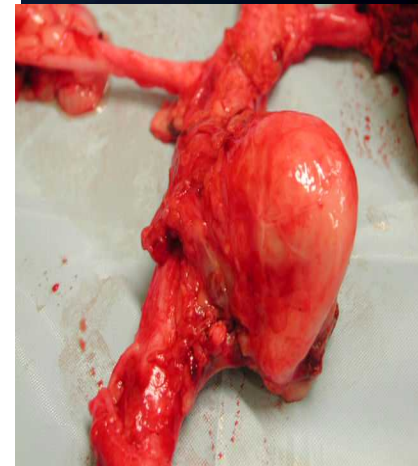
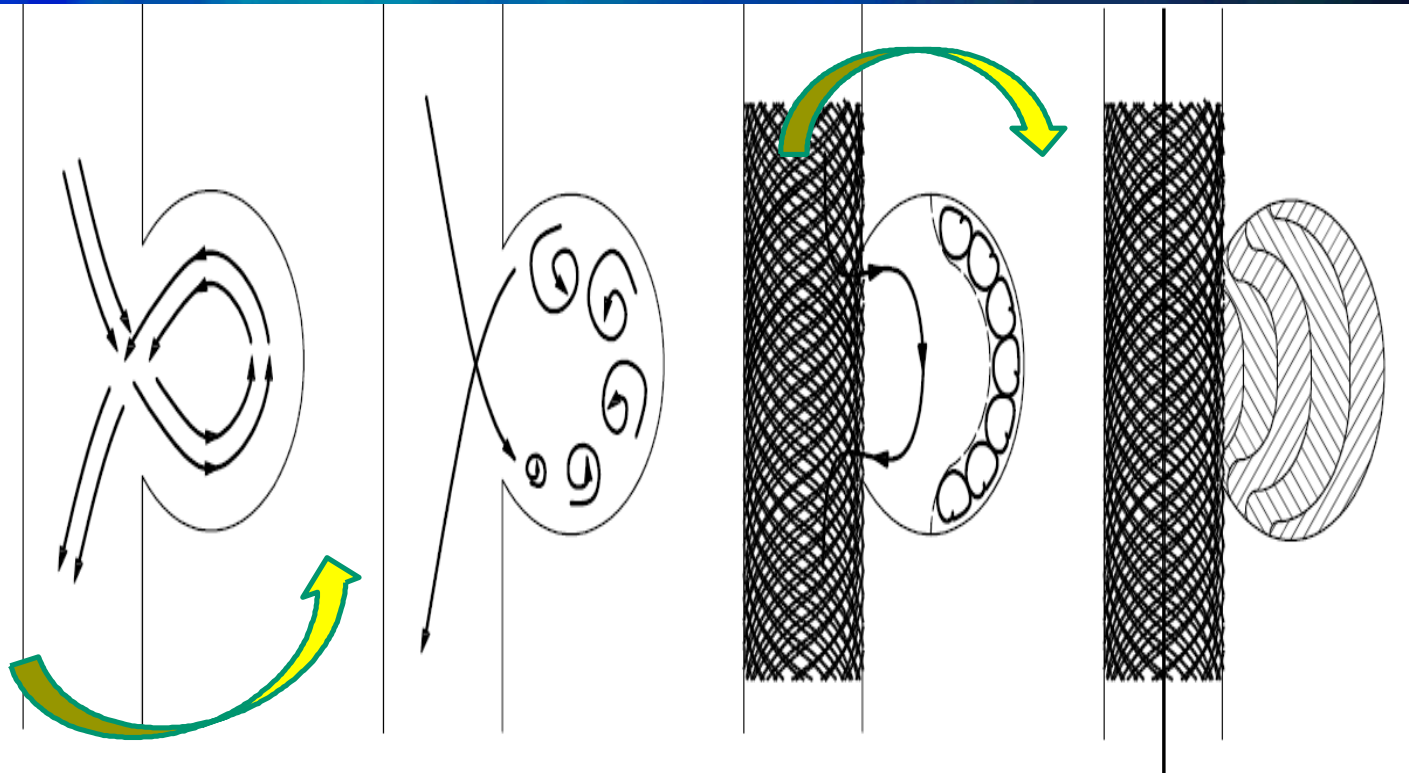
**EFFECTS ON ANEURYSMS**

# **MULTILAYER STENT**

**SACULAR ANEURYSM  
WITHOUT COLLATERAL  
BRANCH**



# SACCULAR ANEURYSM WITHOUT SIDE BRANCH



**STENT REMOVES THE STRESS  
FROM THE NECK**

**THE STENT INVERSES THE FLOW ,  
BREAKDOWNS AND MODULATES  
THE VELOCITY**

**REDUCTION OF VORTEX VELOCITY BY 90%**

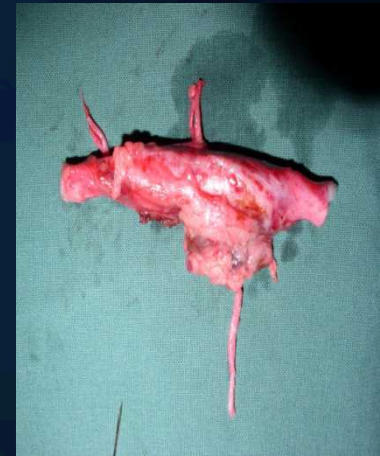
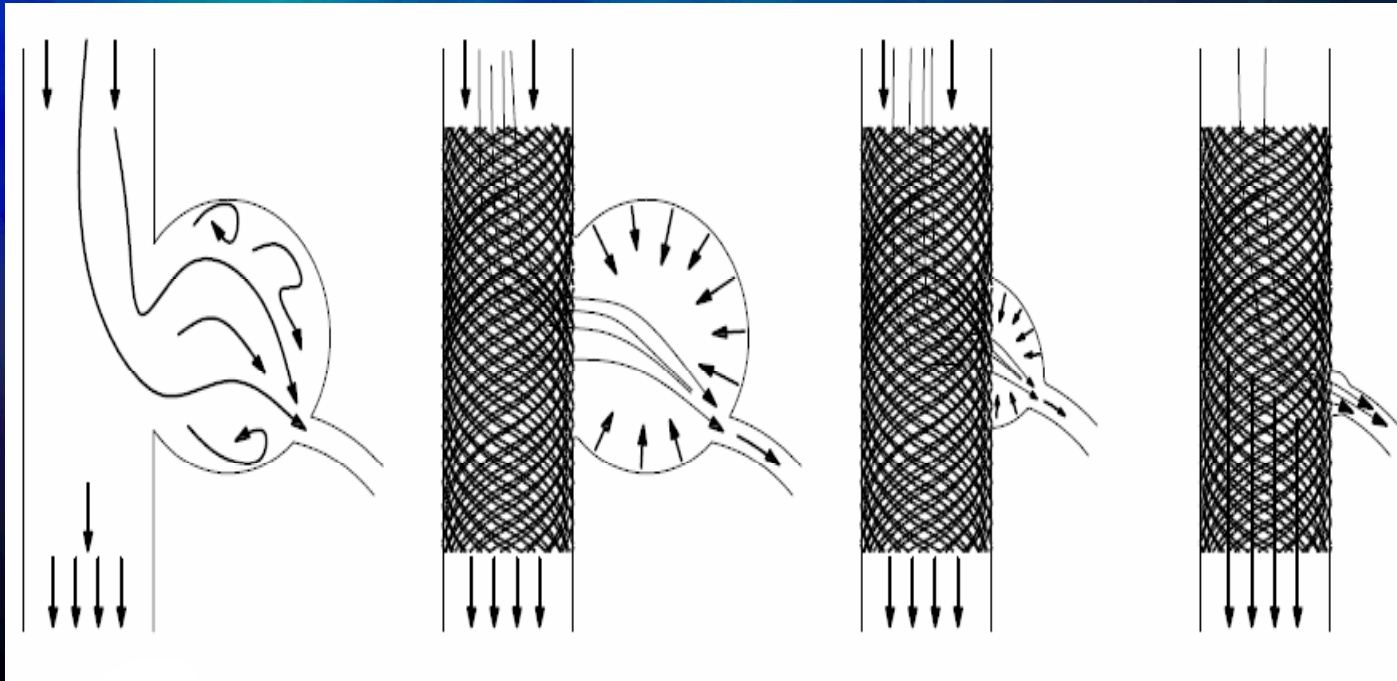
**IMMEDIATE THROMBOSIS**

# **MULTILAYER STENT**

**SACCULAR ANEURYSM  
WITH COLLATERAL BRANCH**

# SACCULAR ANEURYSM WITH COLLATERAL BRANCH

**FLOW DIRECTED THROUGH LAYERS TOWARDS BRANCH  
FLOW LAMINATION IN BRANCH KEEPS COLLATERAL PATENT**



**ALLOWS FOR PHYSIOLOGICAL SHRINKING WHILE PRESERVING  
COLLATERAL**

**MULTILAYER STENT**

**FUSIFORM ANEURYSM**

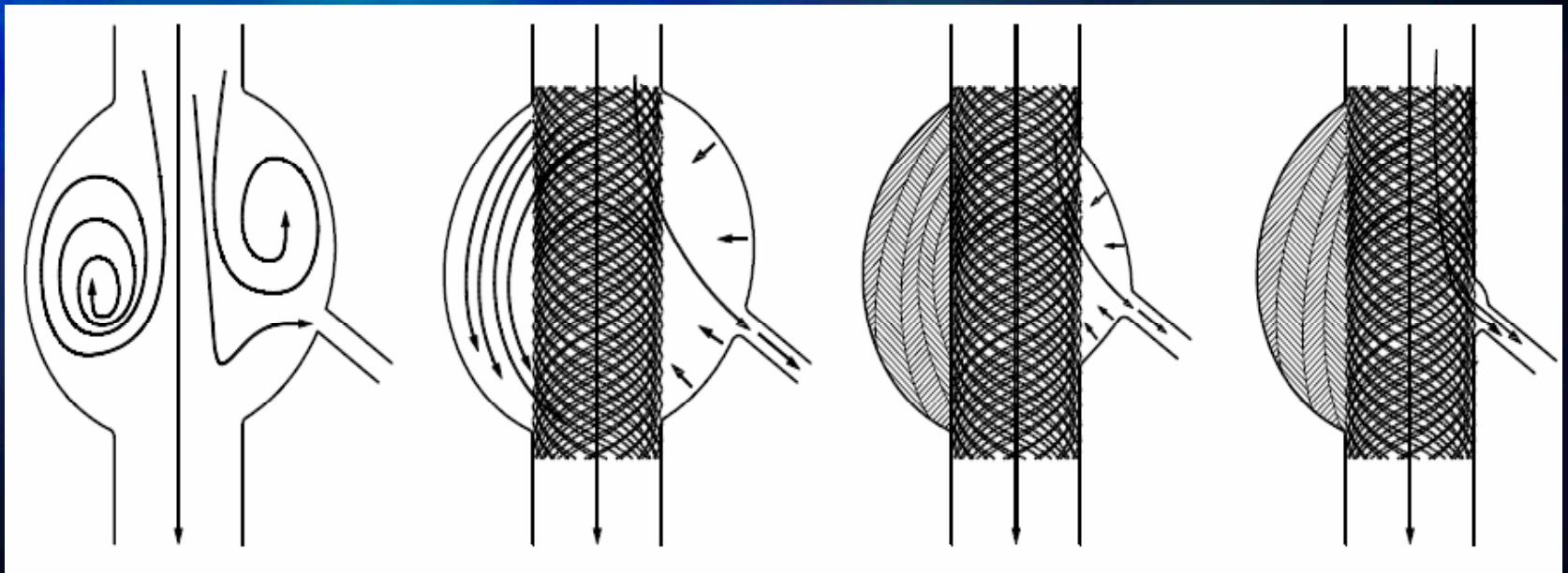
**AORTIC ANEURYSM**



# FUSIFORM ANEURYSM ANEURYSM MODELING

W/O STENT:TURBULENT FLOW

WITH STENT: FLOW LAMINATED ALONG WALL W/O  
BRANCH (PHYSIOLOGICAL ORGANISED THROMBUS)



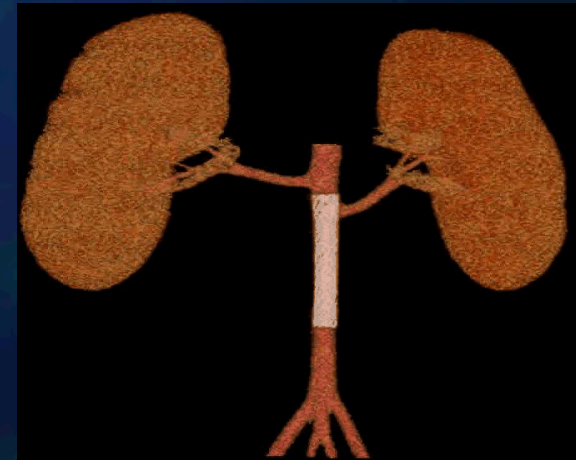
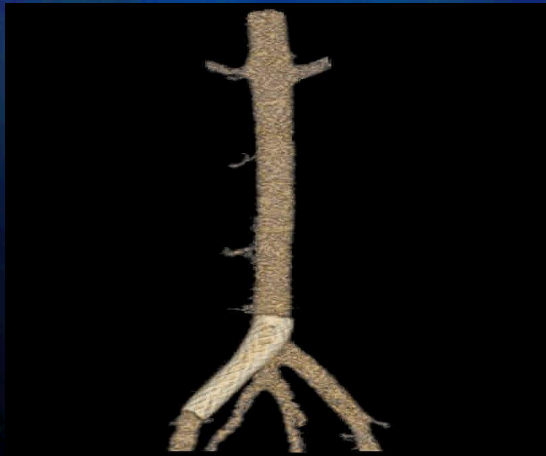
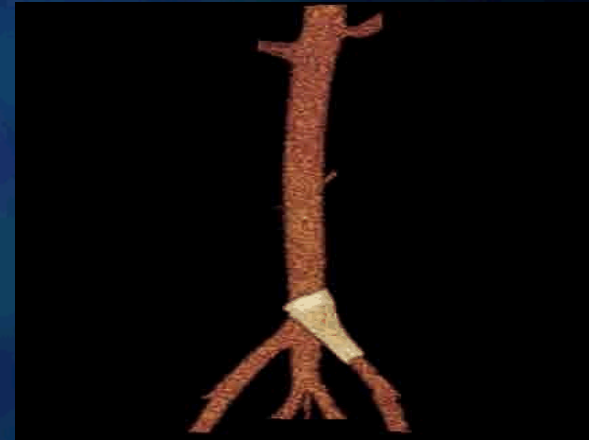
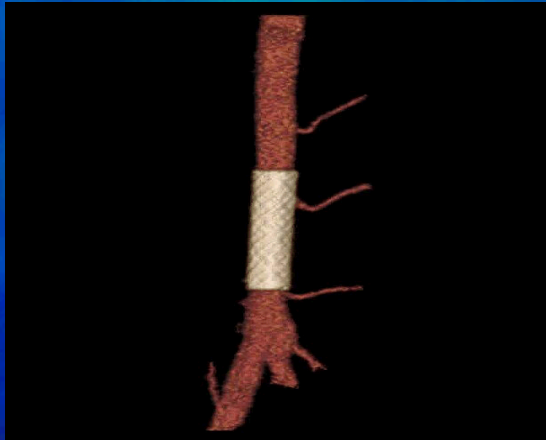
FLOW DIRECTED TO THE BRANCH OTHER SIDE  
AND INCREASED IN THIS BRANCH  
( PROGRESSIVE COLLAPSE OF ANEURYSMAL WALL)

# MULTILAYER STENT

## EFFECTS ON COLLATERALS

- LAMINATES THE FLOW IN COLLATERALS
- ALL THE COLLATERALS REMAIN PATENT

# MULTILAYER STENT ANIMAL DATA 6 MONTH F.U.

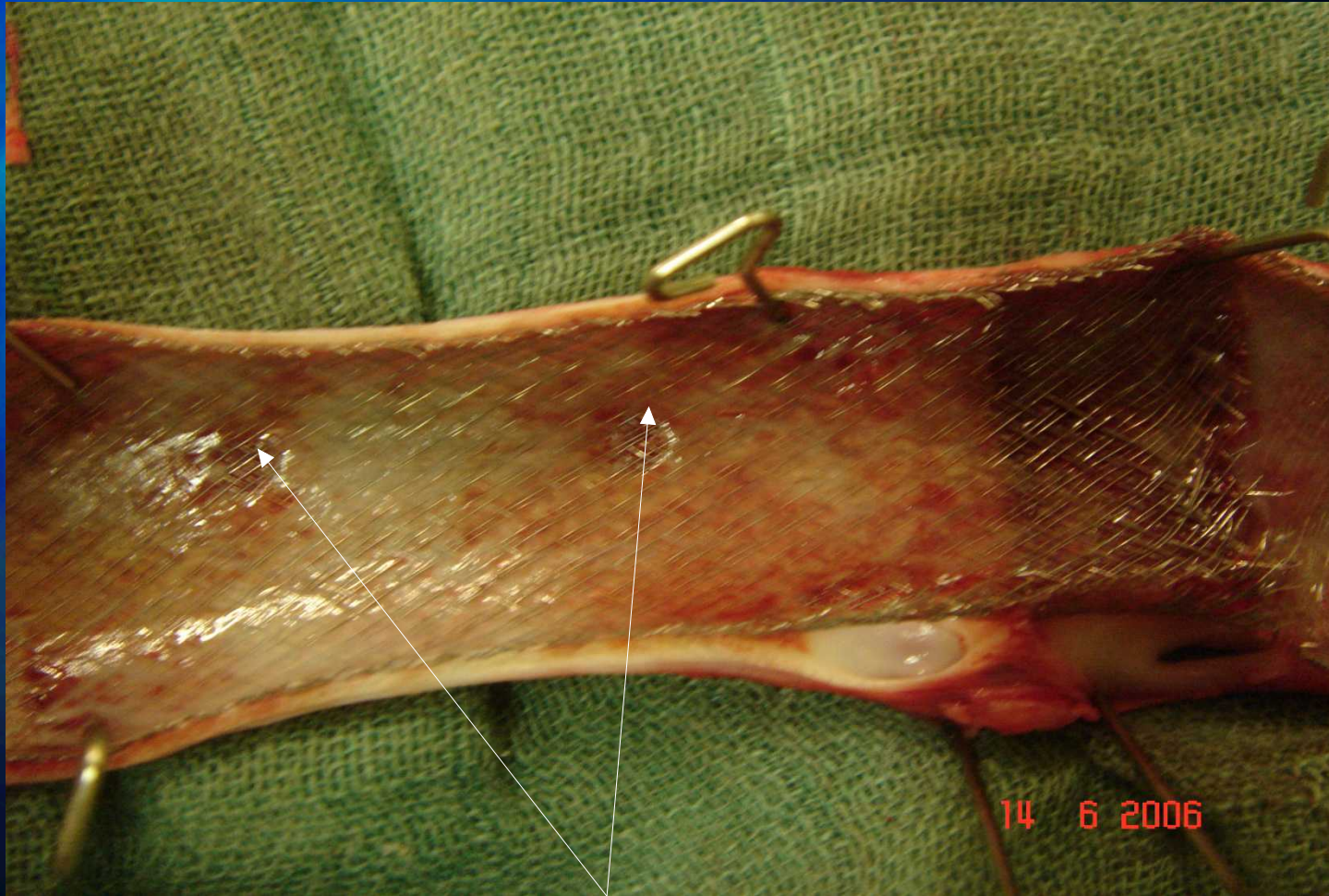


**ALL ARTERIES REMAIN PATENTS**

**COURTESY DR E. DIETRICH**



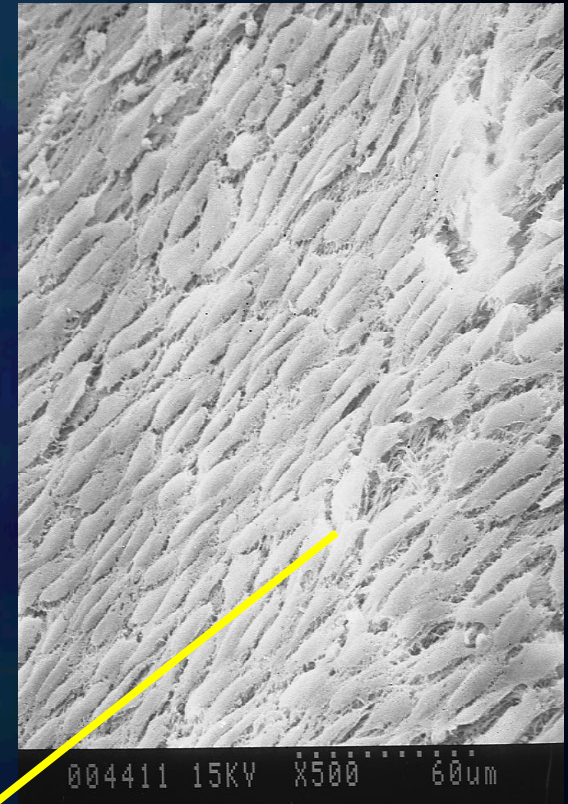
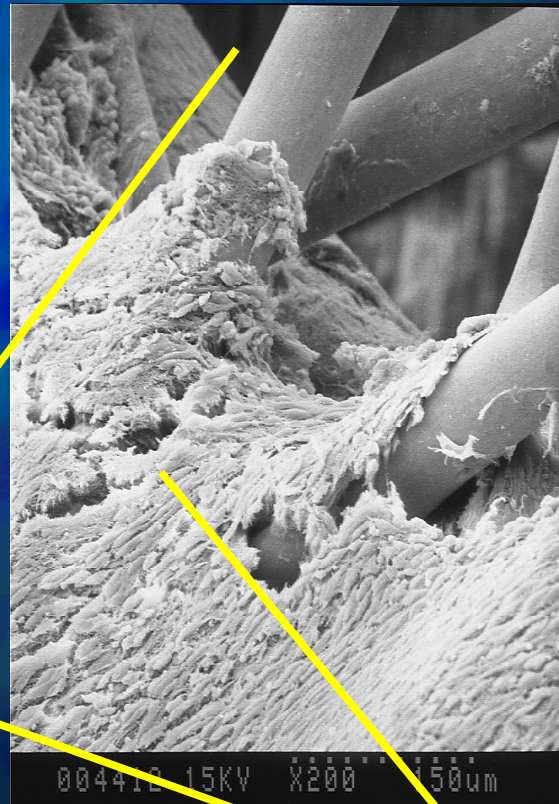
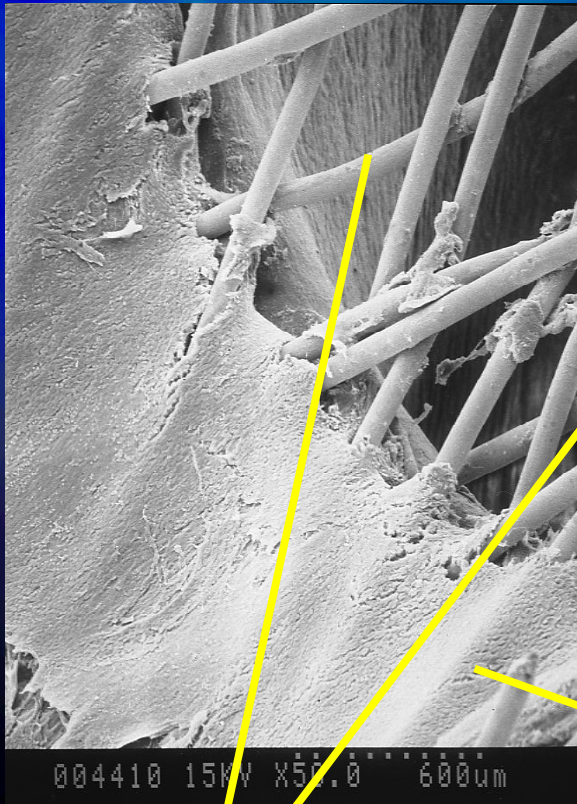
# CLINICAL EFFECTS ON PIG MODEL



**PATENT COLLATERAL  
AFTER 1 MONTH**



# BRANCH MAGNIFICATION



**PATENT BRANCH**

**ENDOTHELIAL  
CELLS**

**MULTILAYER STENT**

**HUMAN STUDY**

# **MULTILAYER STENT RENAL ANEURYSM**

## **FIRST HUMAN CASE RENAL ANEURYSM**

**HENRY M. et al J.E.V.T. 2008 ;15:231 -236**

**7 CASES**

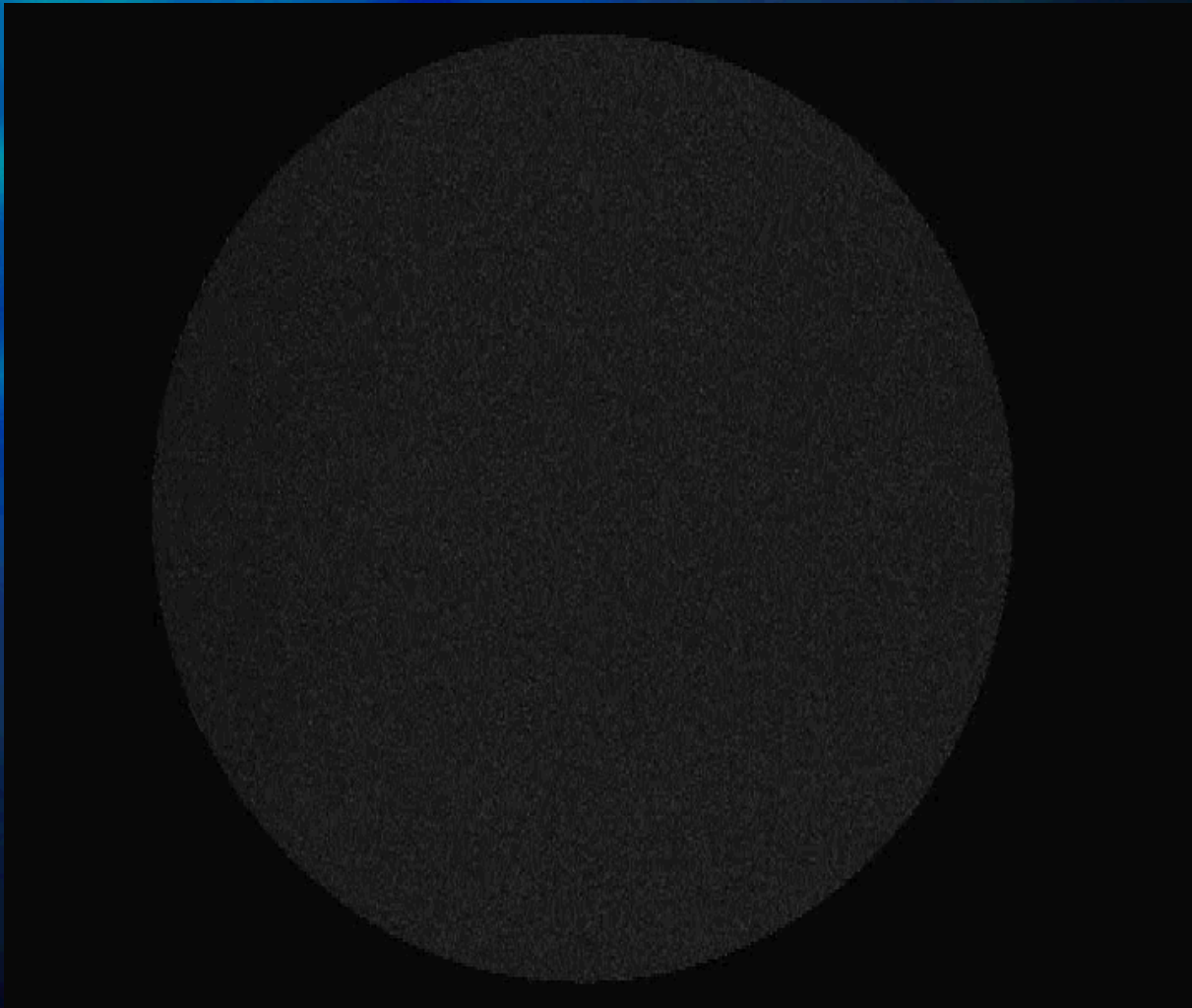


# RENAL ANEURYSM

**MALE 75Y.OLD**  
**HTN**  
**TRIPLE VESSEL**  
**CORONARY DISEASE**  
**Ø : 28-33mm**

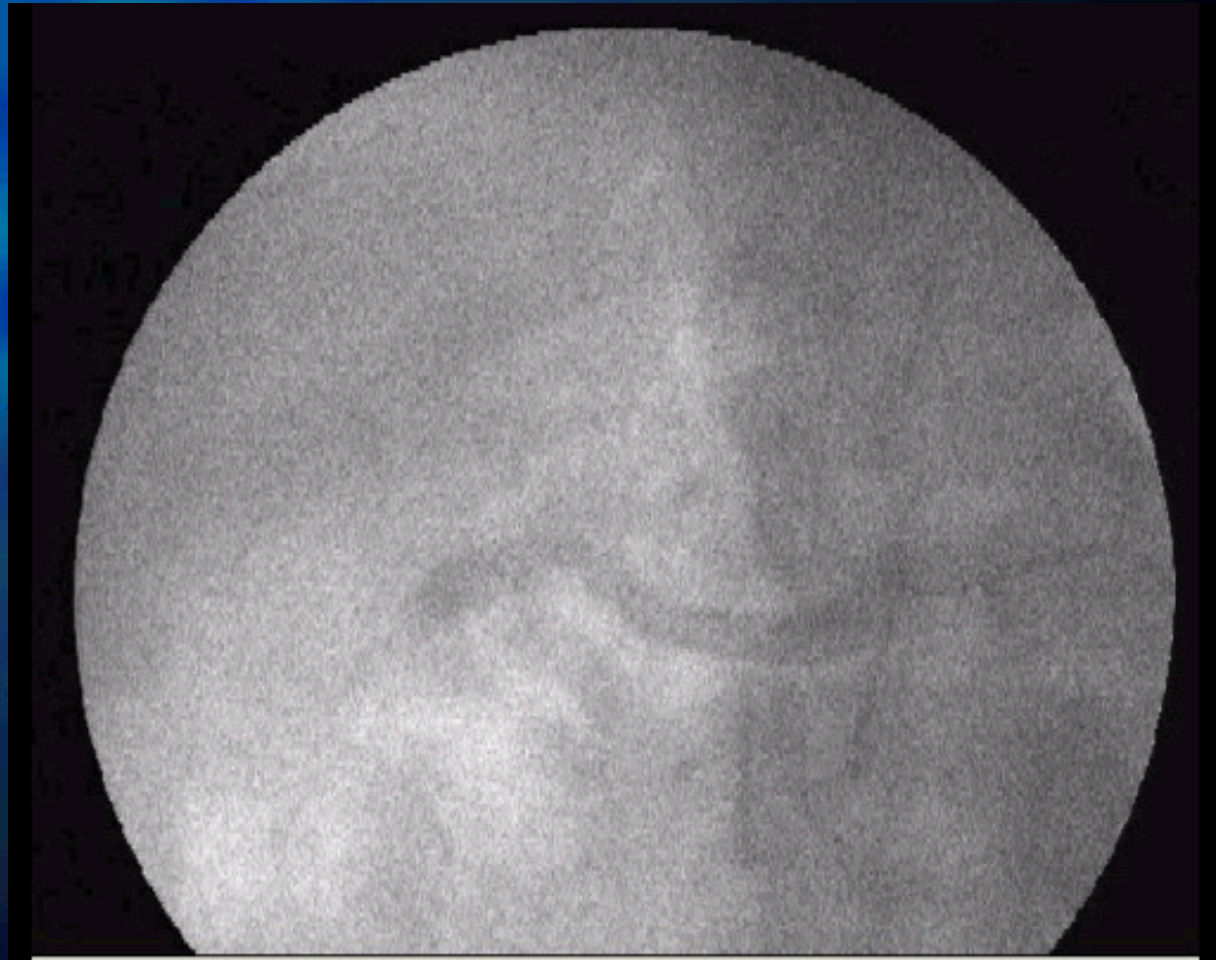


# MULTILAYER STENT RENAL ANEURYSM



# MULTILAYER STENT RENAL ANEURYSM

**12 MONTH  
FOLLOW-UP**

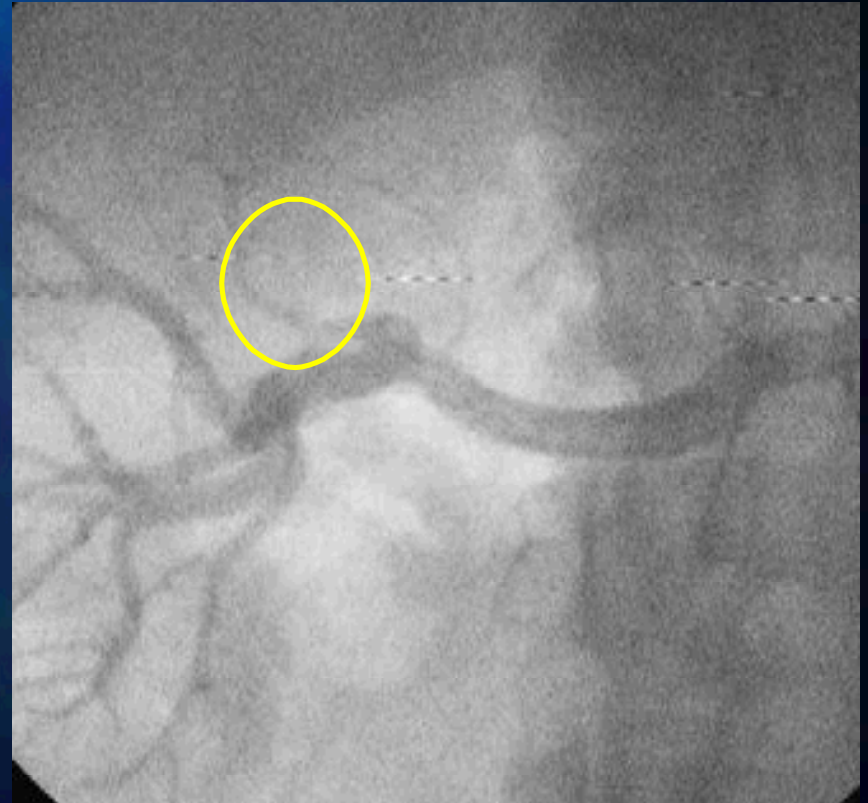
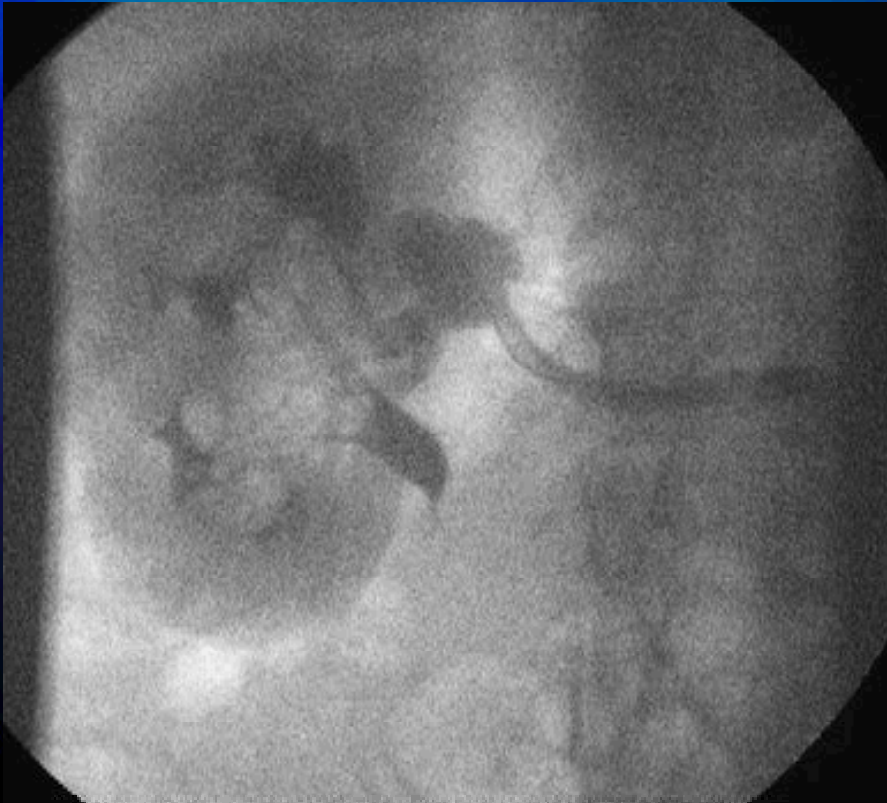




# RENAL ANEURYSM

## FIRST HUMAN STUDY

MALE 75Y.OLD HTN TRIPLE VESSEL CORONARY DISEASE

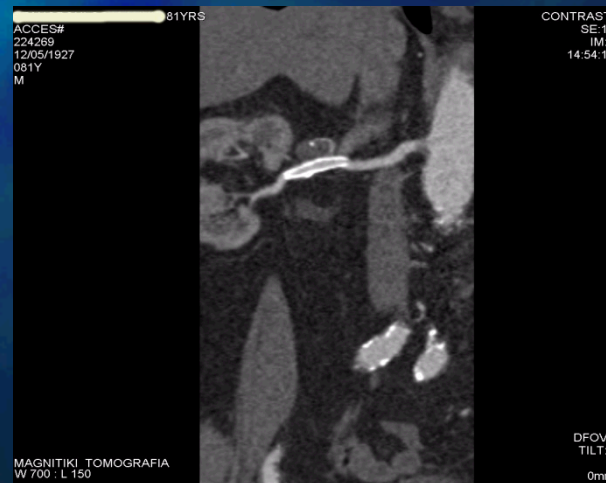
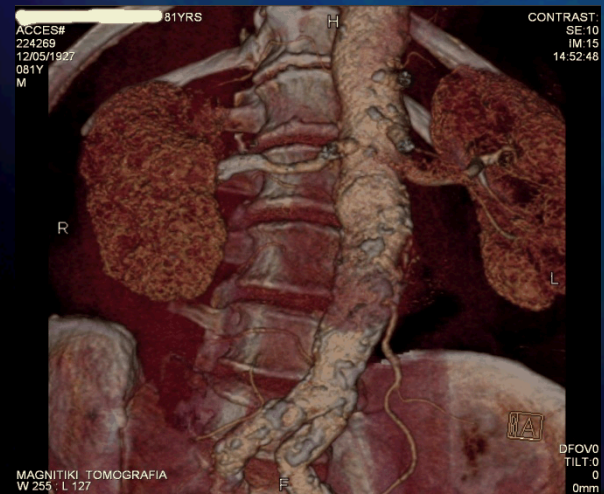
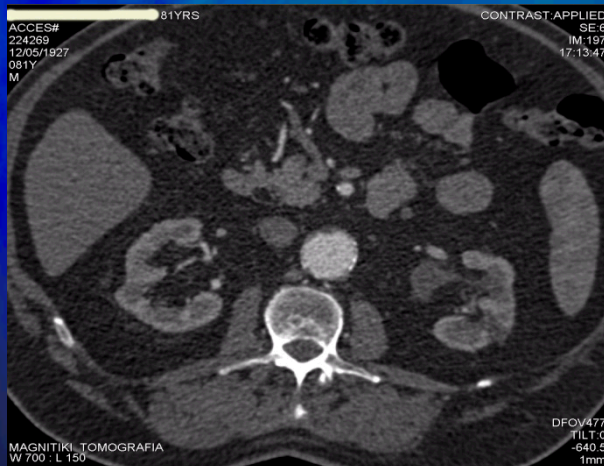


1 YEAR FOLLOW UP

# MULTILAYER STENT RENAL ANEURYSM

## 30 MONTH FOLLOW-UP

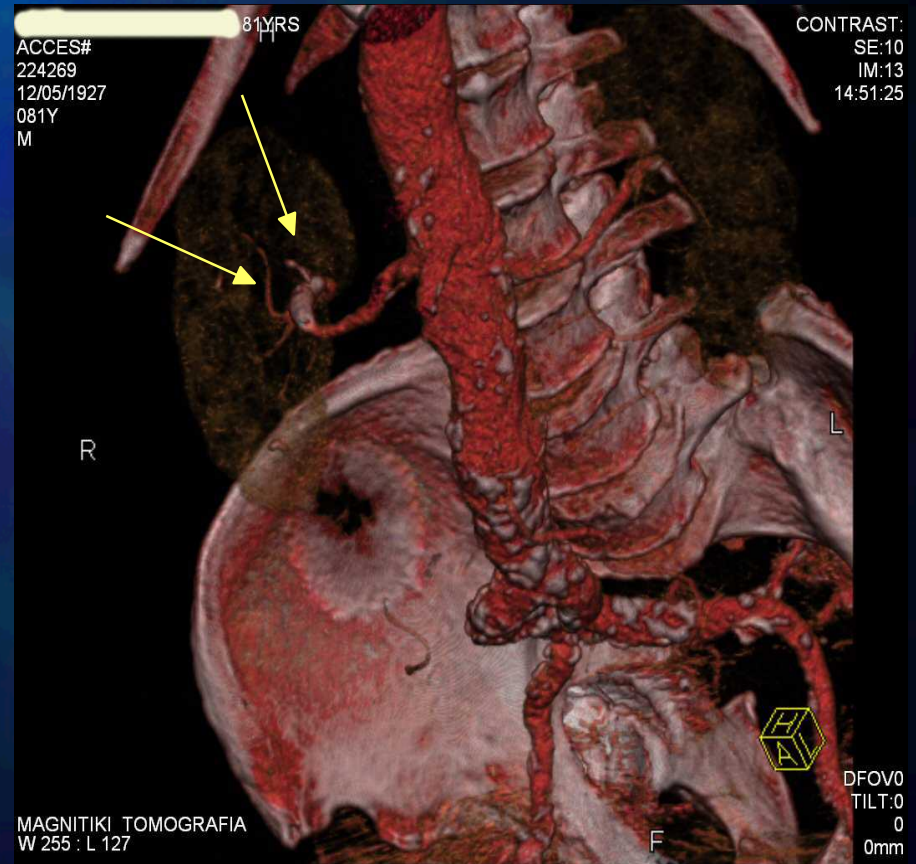
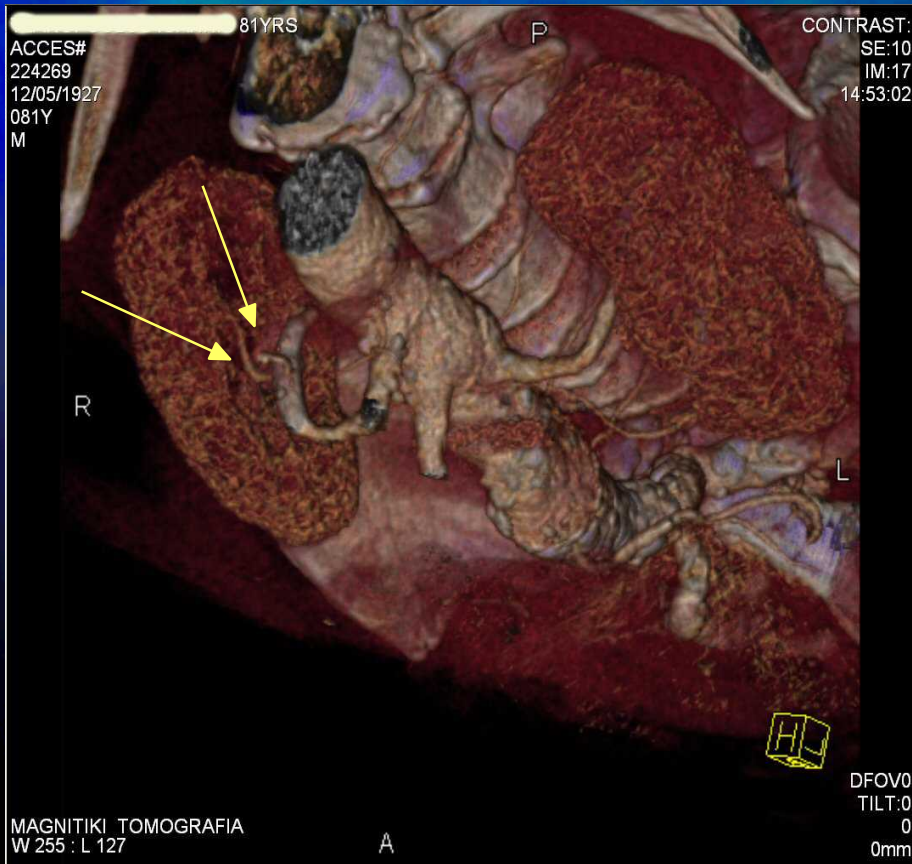
**COMPUTED TOMOGRAPHY SHOWED  
EXCELLENT PATENCY OF THE STENT, WITH  
A NORMAL KIDNEY AND A TOTAL  
THROMBOSIS OF THE ANEURYSM**





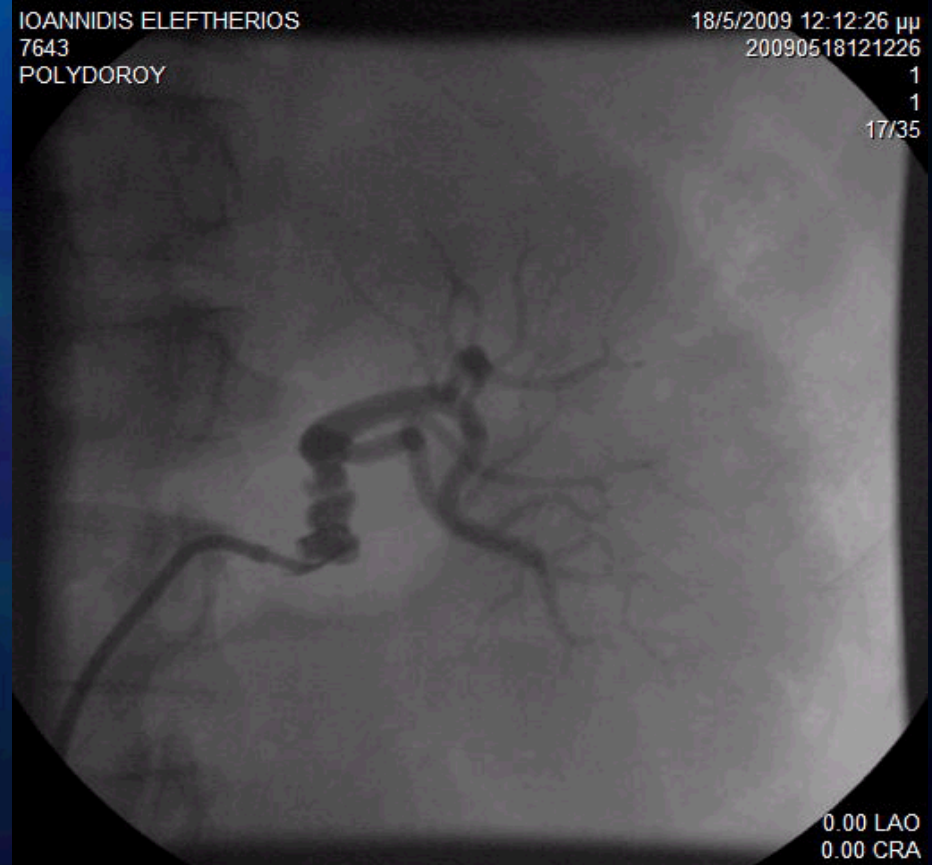
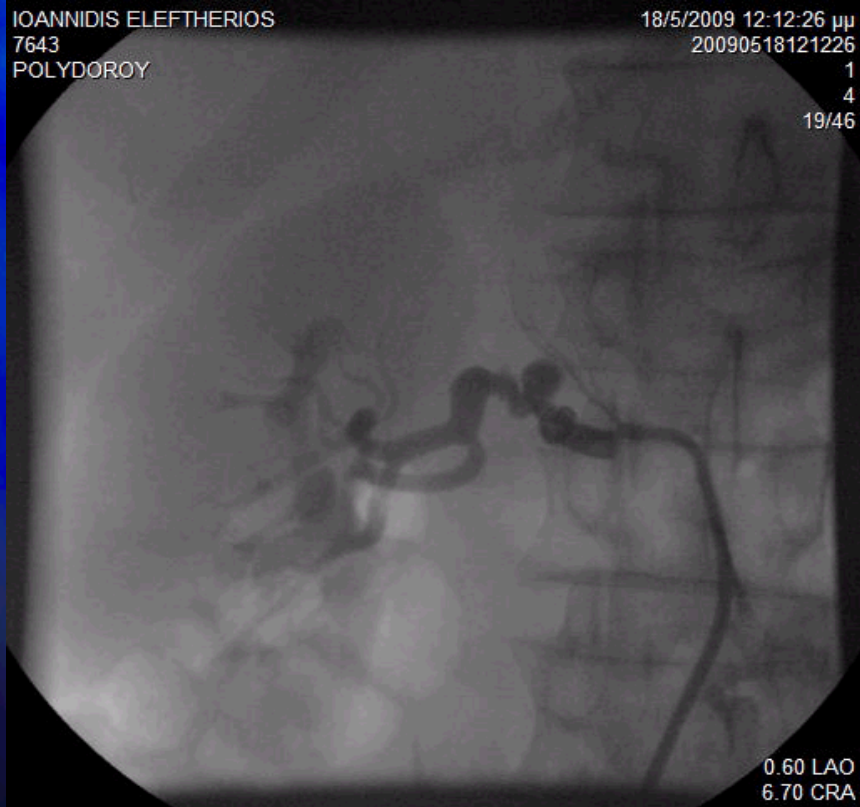
# MULTILAYER STENT RENAL ANEURYSM

## 30 MONTH FOLLOW-UP



**EXCELLENT PATENCY OF COLLATERAL BRANCHES**

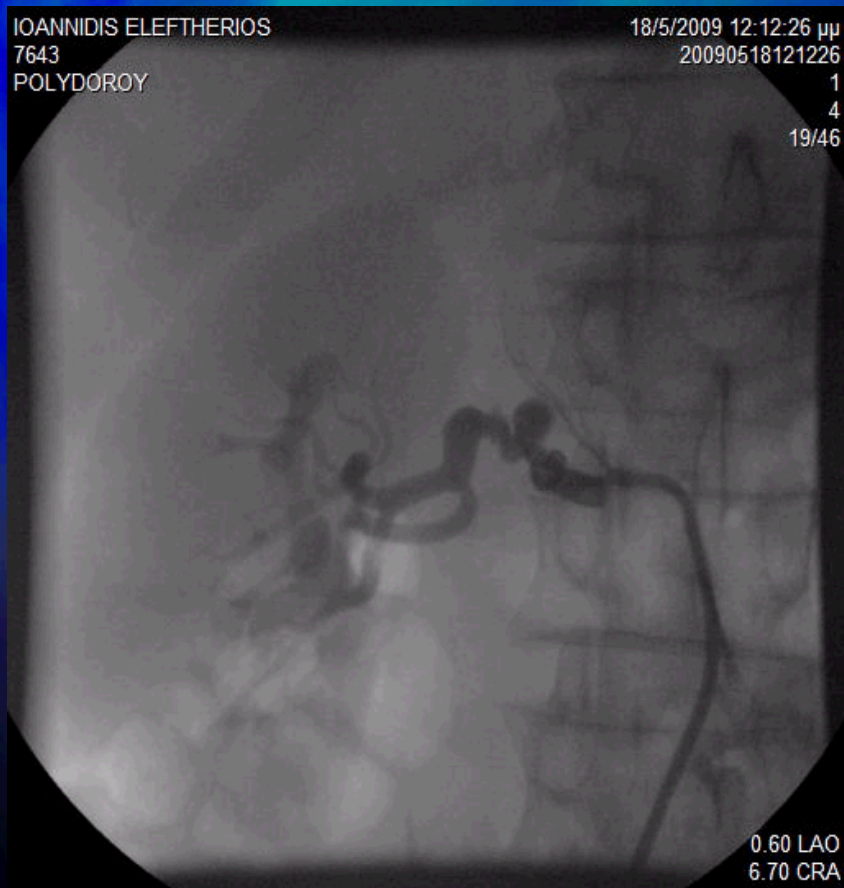
# RENAL ANEURYSM



**MALE 45Y HTA F.M.D.**



# RENAL ANEURYSM

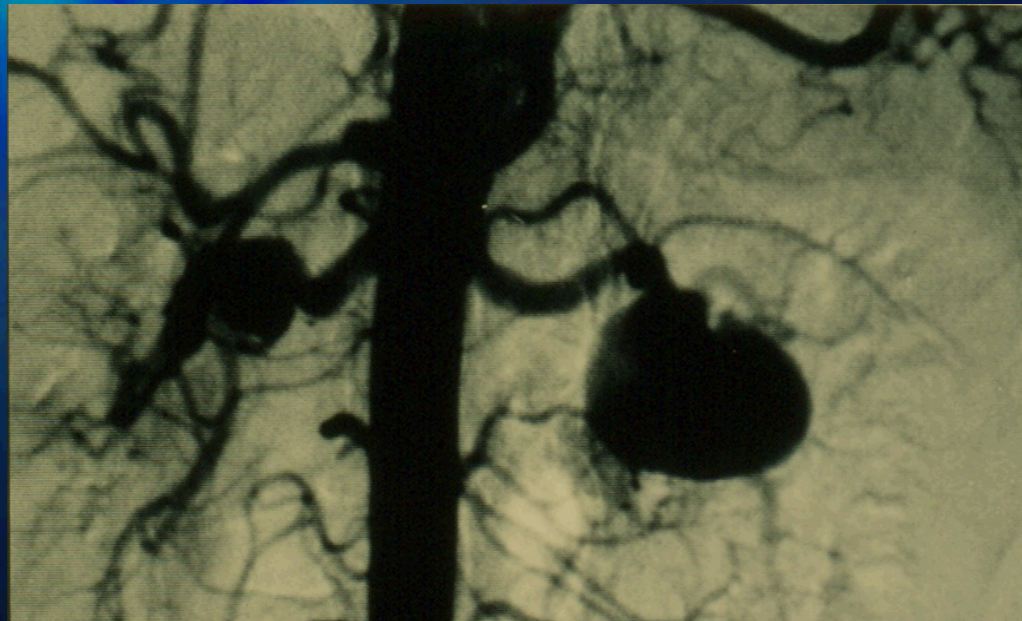


**24 HOURS**

**MALE 46Y. HTN F.M.D.**

# BILATERAL RENAL ANEURYSMS

- 53 YEARS OLD PATIENT
- BILATERAL RENAL ANEURYSM
- LEFT RENAL TRANSPLANTATION - 13 YEARS AGO
- MULTILAYER STENT RENAL ANEURYSM - 3 YEARS AGO FOR RIGHT





# **BILATERAL RENAL ANEURYSMS**



**LEFT SIDE  
SURGERY  
13 YEARS AGO**

# BILATERAL RENAL ANEURYSMS

**RIGHT  
MULTILAYER**



**CT SCAN AT 1 MONTH**



**CT SCAN AT 6 MONTHS**



# RIGHT SACCULAR CALCIFIED RENAL ANEURYSM

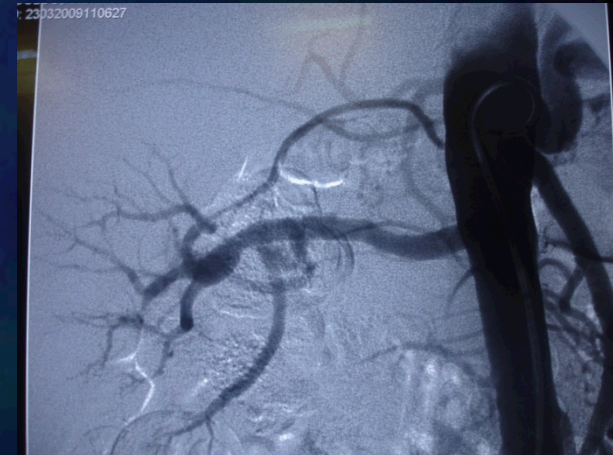
## MULTILAYER STENT



**PRE  
TREATMENT**



**AT  
1 MONTH**



**AT  
3 MONTHS**

# RIGHT SACCULAR RENAL ANEURYSM

OSPEDALE CODOGNO

17/02/2010

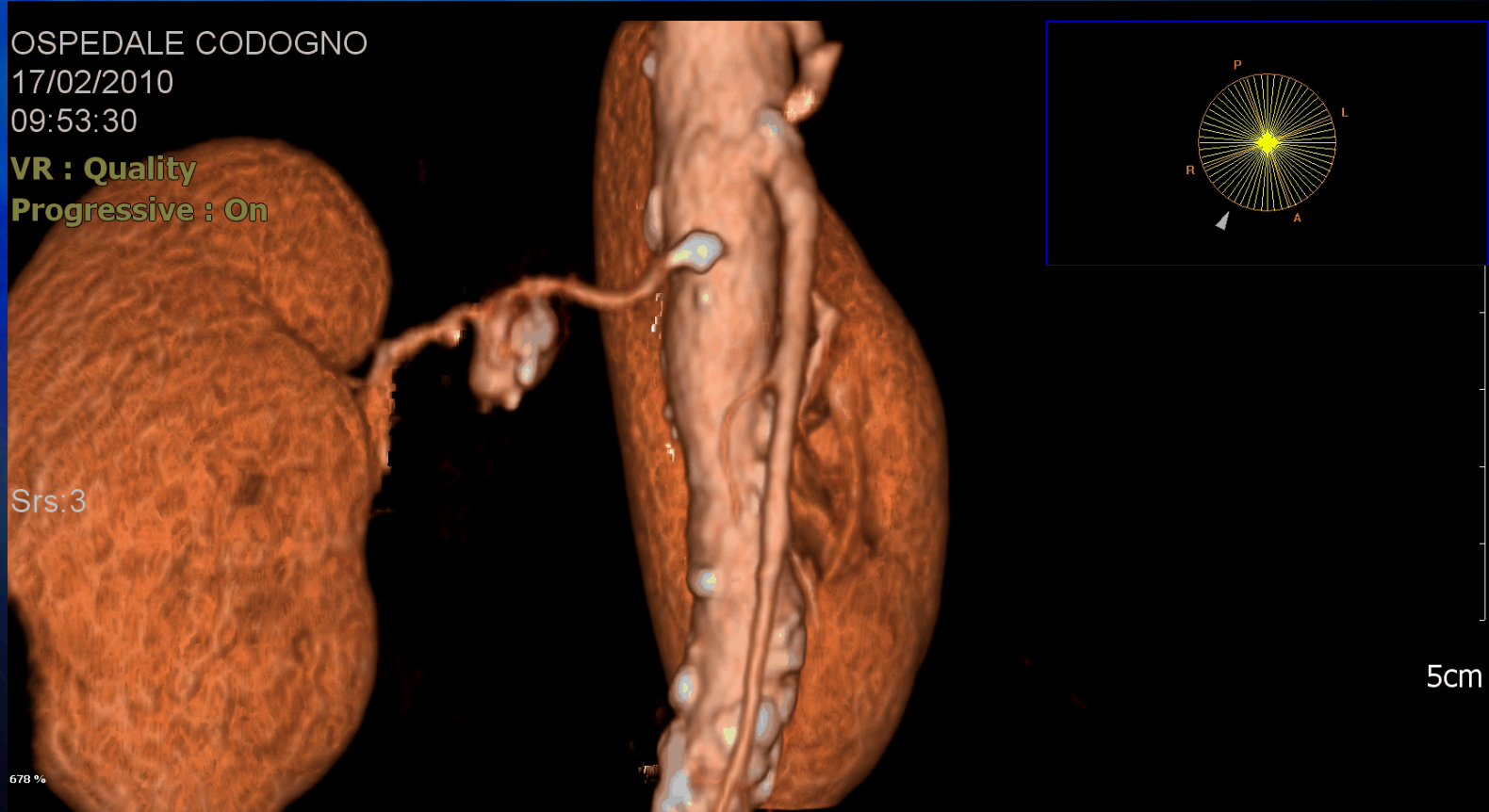
09:53:30

**VR : Quality**

**Progressive : On**

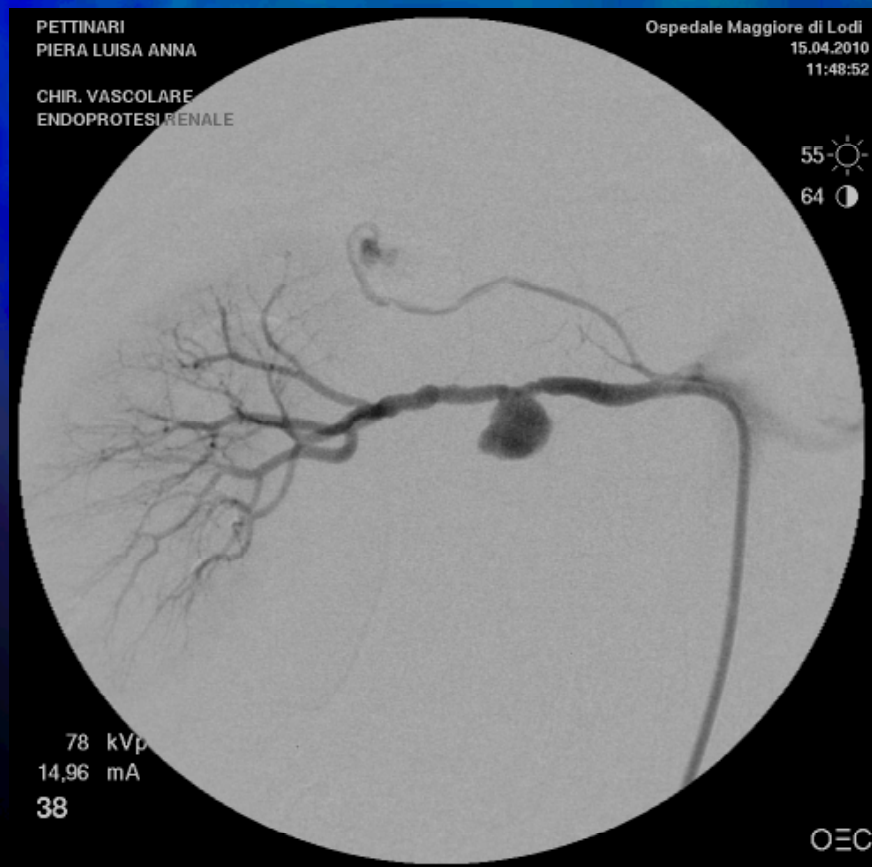
Srs:3

678 %





# RIGHT SACCULAR RENAL ANEURYSM



# RIGHT SACCULAR RENAL ANEURYSM

OSPEDALE CODOGNO

17/02/2010

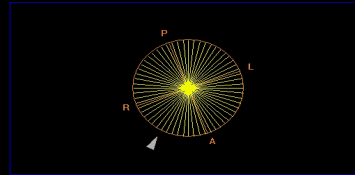
09:53:30

VR : Quality

Progressive : On

Srs:3

678 %



A.O. LODI

19/04/2010

12:10:52

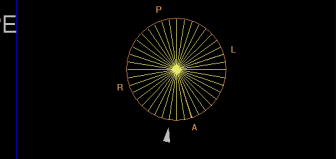
VR : Quality

Progressive : On

Srs:3

342 %

PE

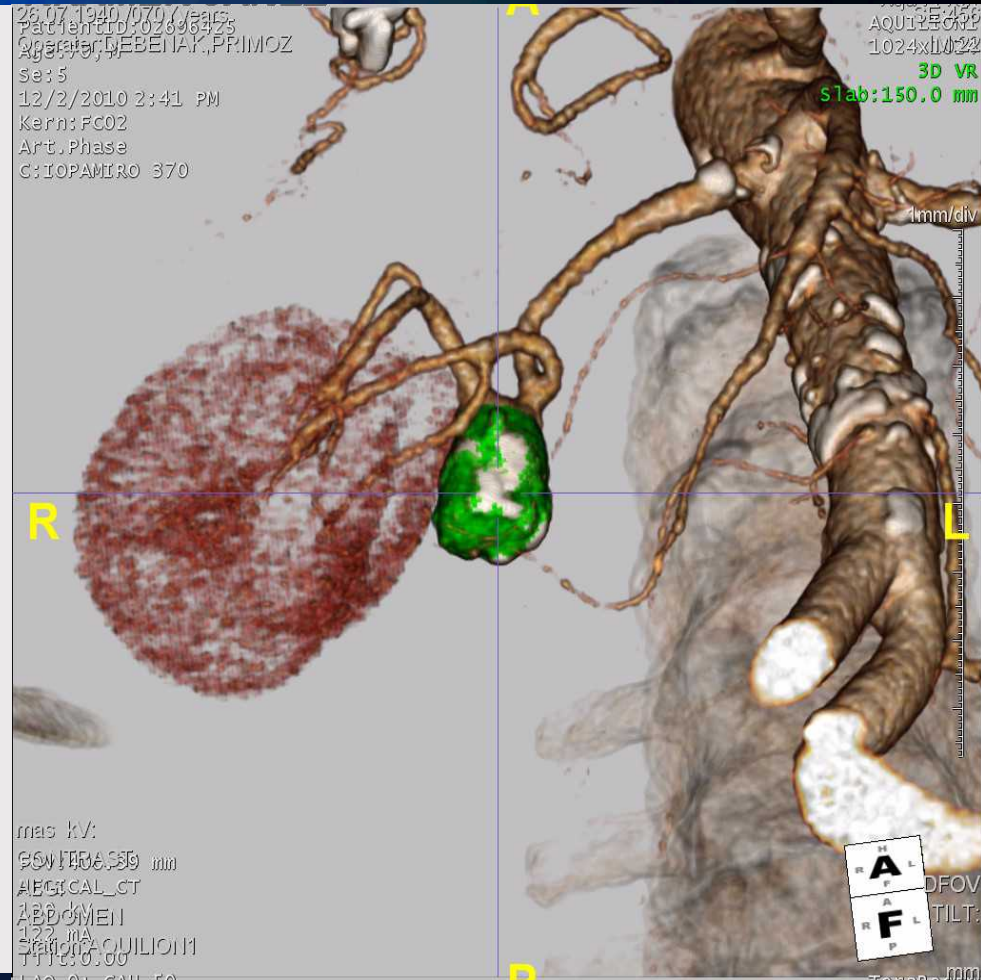


8cm

SHRINKAGE  
AT 2 MONTHS

# RIGHT SACCULAR RENAL ANEURYSM

- 65 male in good general condition
- accidental finding of 35 x 45 mm big sacular aneurysm with wide neck at the beginnig of the dorsal segmental renal artery just as it descends from the main right renal artery
- patient refused surgical treatment





# RIGHT SACCULAR RENAL ANEURYSM

## PROCEDURE

- clopidogrel 75 mg - 5 days prior the procedure
- mild anxiolytic therapy before the procedure
- normal coagulation and renal functional parameters
- femoral access 9 FR renal sheath left, 5 FR sheath right; 5 Fr SIM1 catheter
- 5000 IE Heparin





# RIGHT SACCULAR RENAL ANEURYSM

## PROCEDURE

- deployment of a 5 x 40 mm MARS over a roadrunner extra stiff 0,18 wire





# RIGHT SACCULAR RENAL ANEURYSM

## PROCEDURE

control angiography





# RIGHT SACCULAR RENAL ANEURYSM

## PROCEDURE

deployment of another 5 x 30 mm MARS stent



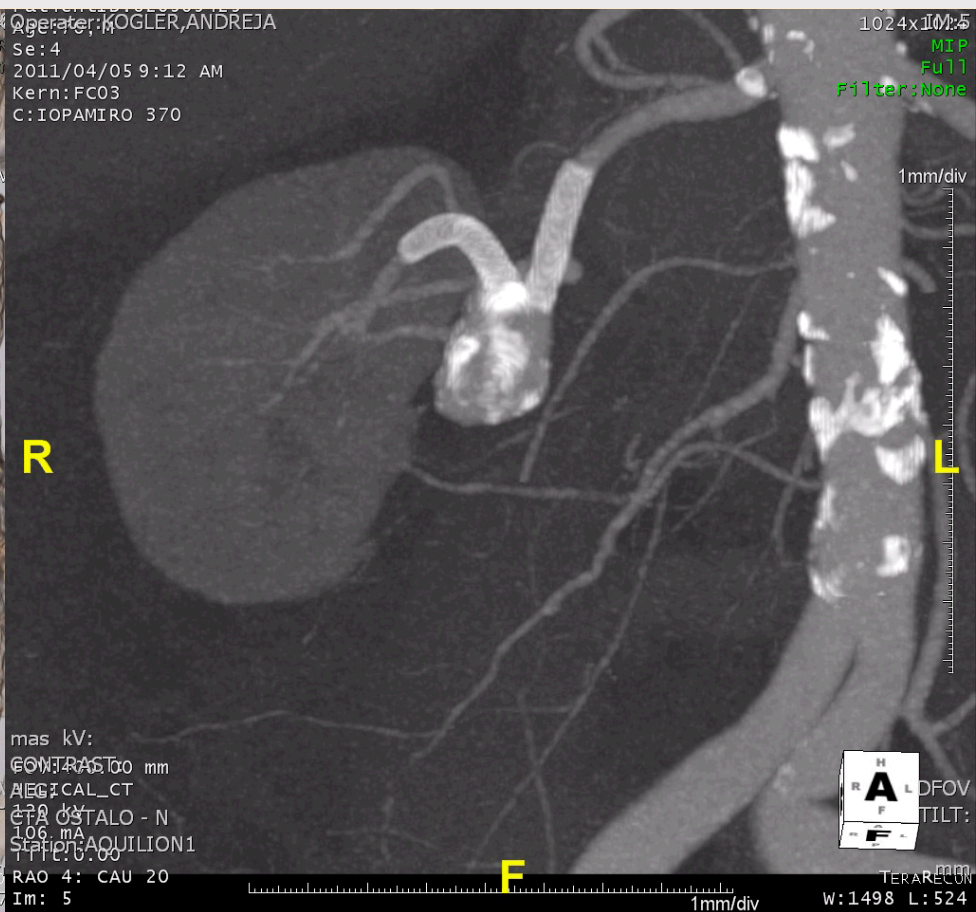
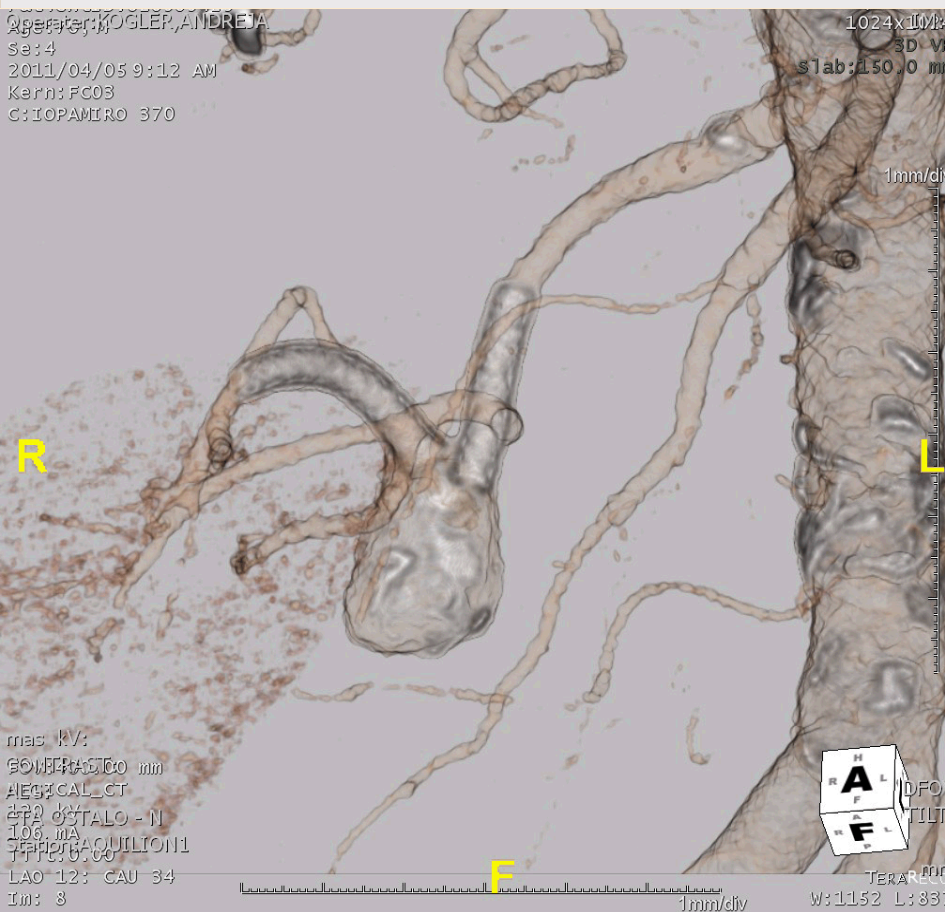
0:00 ART REN DEX CAUD PO STENT



# RIGHT SACCULAR RENAL ANEURYSM

## CONTROL CTA after 1 month

- both stents slipped apart and partially in the aneurysmal sac

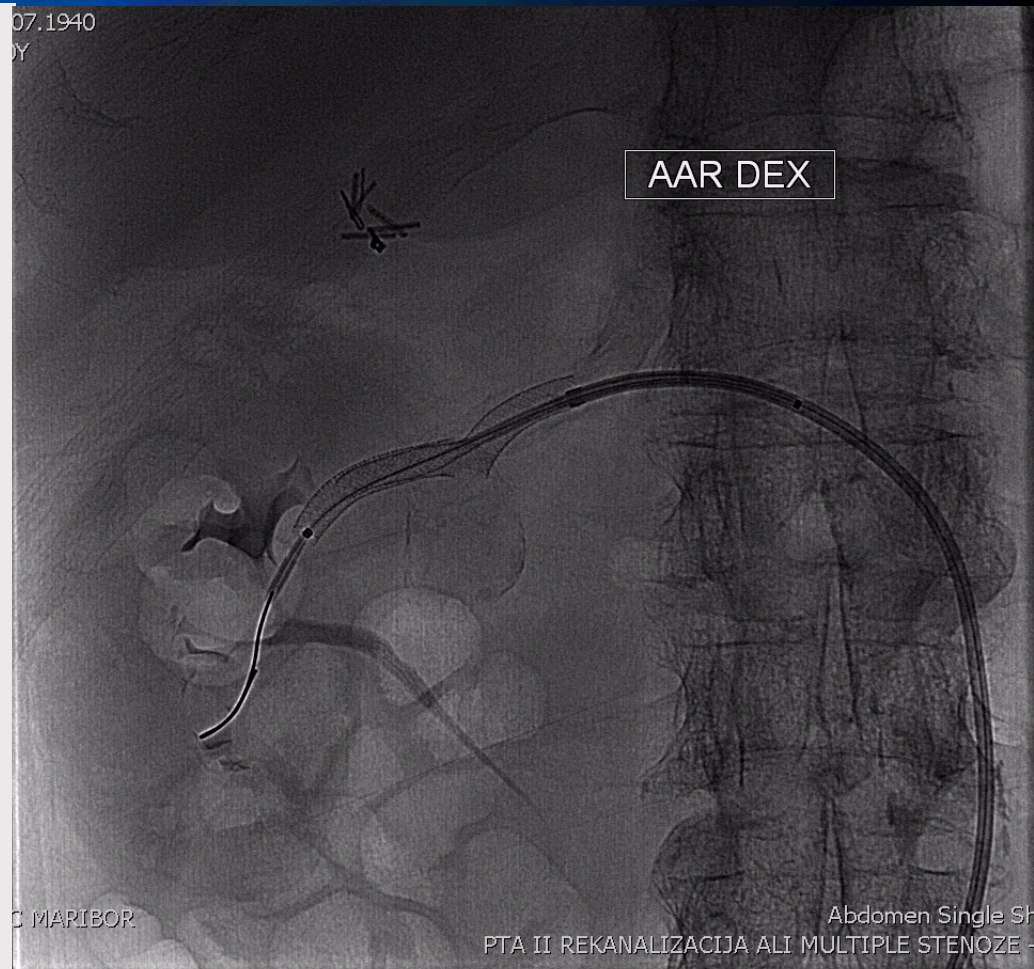




# RIGHT SACCULAR RENAL ANEURYSM

## PROCEDURE 2

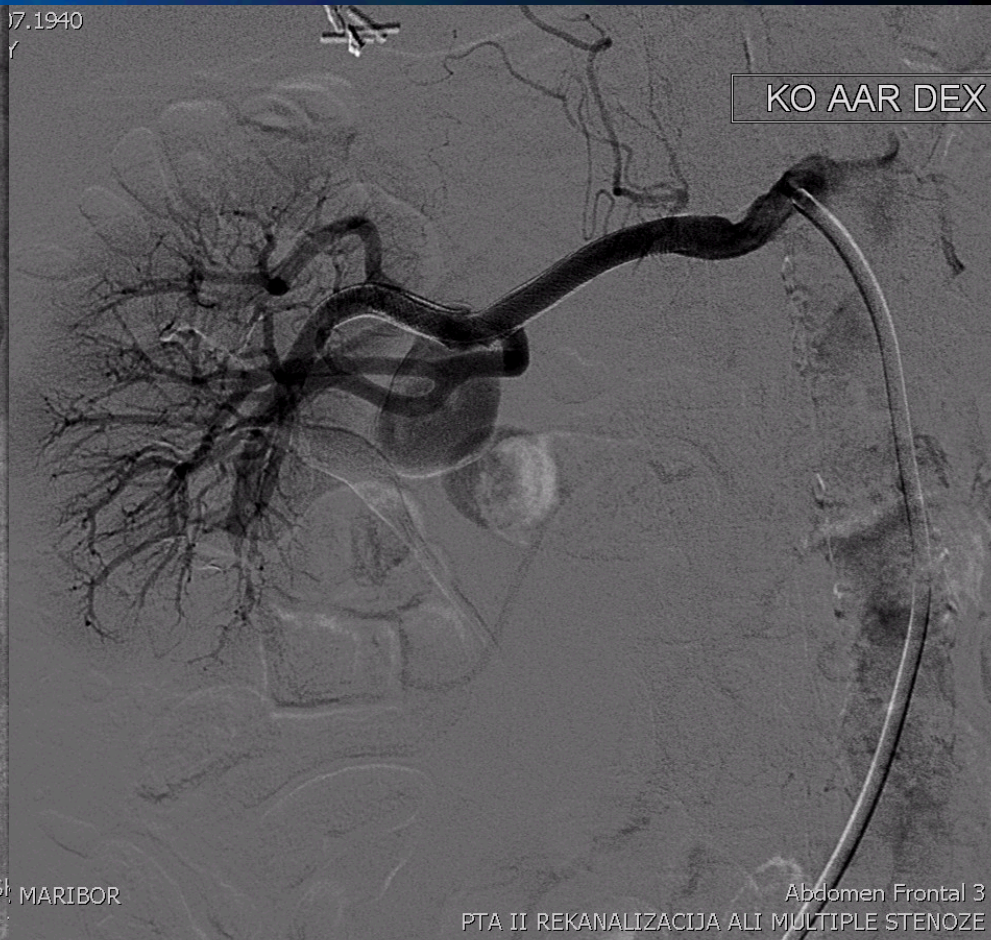
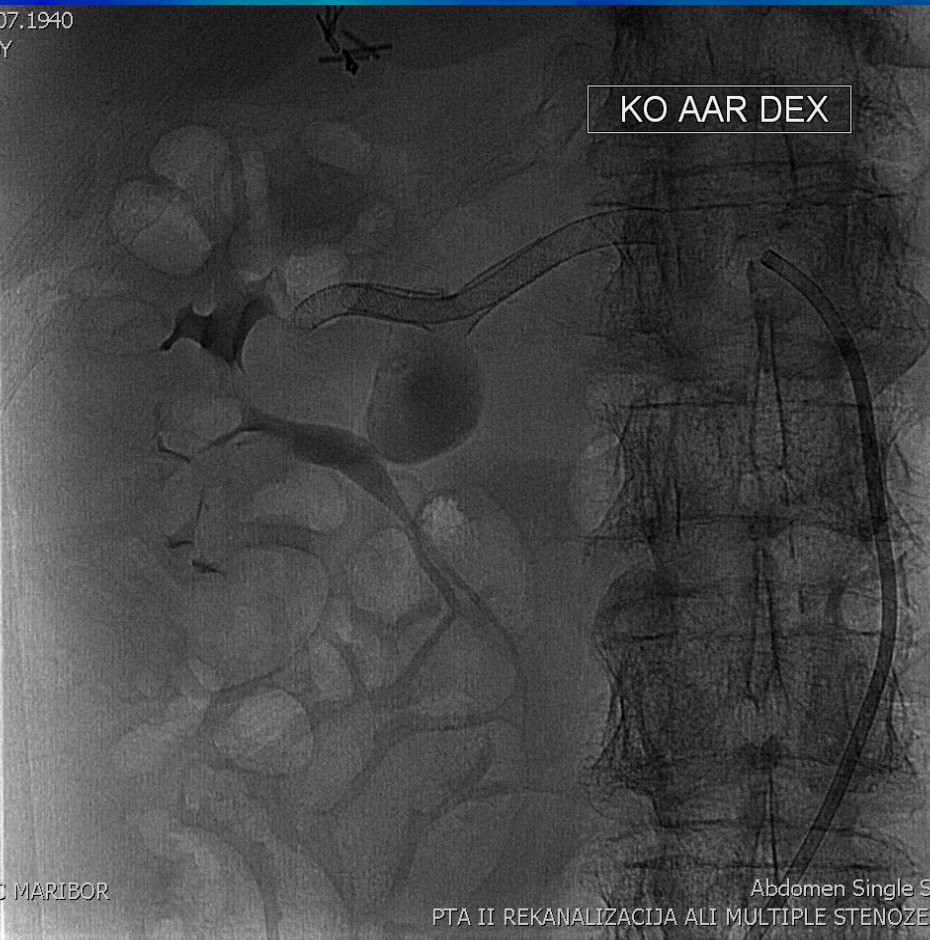
- femoral acces, 8 FR renal sheath
- passage with a Terumo guide wire and a Sos omni catheter through lumen of both stents
- 5000 IE Heparin
- deployment of MARS 6 x 60 mm
- clopidogrel for 3 months





# RIGHT SACCULAR RENAL ANEURYSM

## PROCEDURE 2



# RIGHT SACCULAR RENAL ANEURYSM

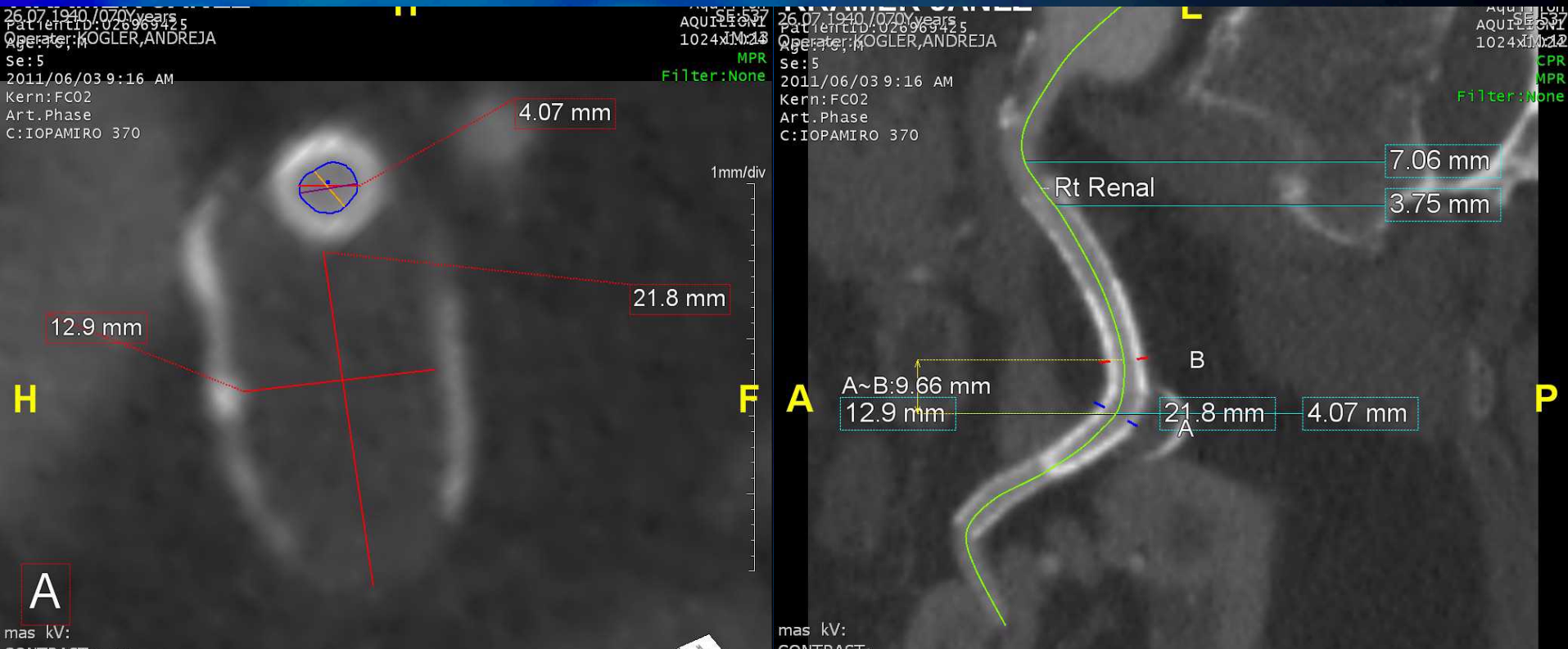
## CONTROL CTA

- one month after third stent deployment
- good patency without migration of the stents
- aneurysm exclusion and minor aneurysmal sac shrinkage
- all blood vessels patent, also that one arising from the stent





# RIGHT SACCULAR RENAL ANEURYSM CONTROL CTA



- finally showed excellent result with aneurysm exclusion and all side branches patent



# LEFT SACCULAR RENAL ANEURYSM

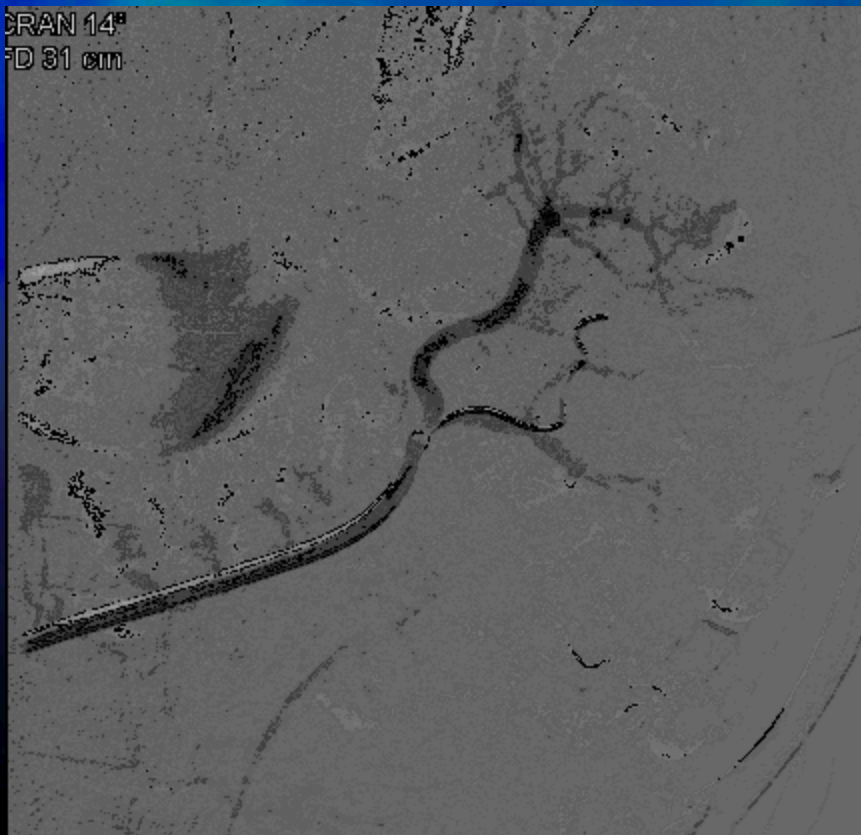
**F. 56 Y.**

**SOLITARY KIDNEY  
(RIGHT RENAL CANCER)**

**H.T.A.**



# LEFT SACCULAR RENAL ANEURYSM



# LEFT SACCULAR RENAL ANEURYSM





# MULTILAYER STENT RENAL ANEURYSM

## RESULTS

- *Successful deployment in all patients*
- *100% occlusion of the aneurysms with side branches remaining patent*

# MULTILAYER STENT

## MESENTERIC ANEURYSM

# MULTILAYER STENT MESENTERIC ANEURYSM

**M. 37Y.**

**ABDOMINAL PAIN**





# MULTILAYER STENT MESENTERIC ANEURYSM



# MULTILAYER STENT MESENTERIC ANEURYSM



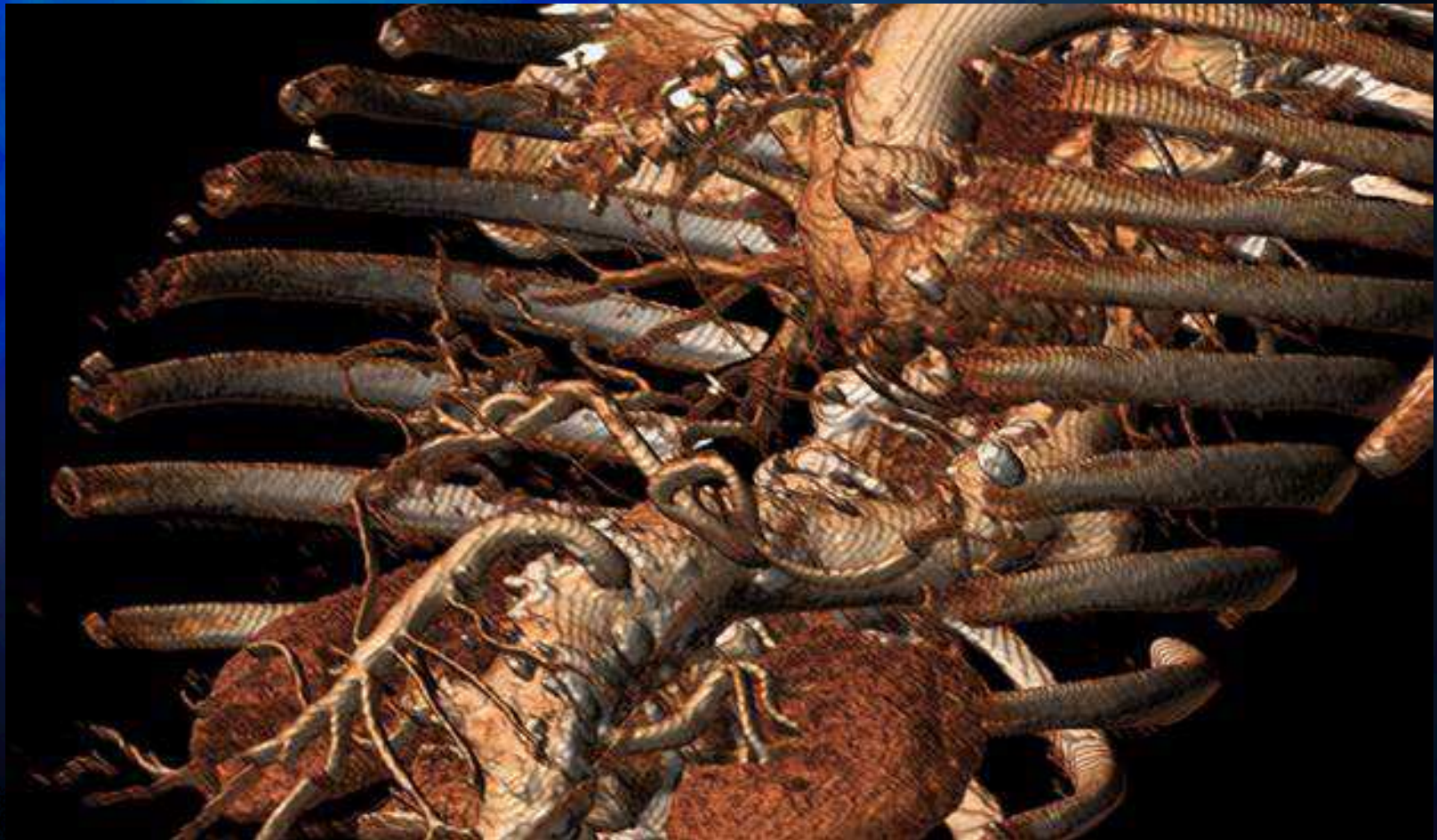
# MULTILAYER STENT MESENTERIC ANEURYSM



AFTER 10 mn



# MULTILAYER STENT MESENTERIC ANEURYSM



**AFTER 1 YEAR**

# MULTILAYER STENT CONCLUSIONS

- **THE MULTILAYER STENT REPRESENTS AN ALTERNATIVE TO CURRENT DEVICES FOR THE TREATMENT OF PERIPHERAL AND VISCERAL ANEURYSMS ( CE MARK )**
- **SUITABLE FOR ALL TYPES OF ANEURYSMS: AAA ,TAAA ( STUDY IN FRANCE IN 25 CENTERS - CE MARK FOR TAAA )**
- **COULD ALSO BE USED TO TREAT DISSECTIONS ( ONGOING STUDIES )**
- **THEORETICAL BASIC PRINCIPLES OF THE DEVICE ARE VERY ATTRACTIVE**
- **THE MOST IMPORTANT.....IT PRESERVES THE COLLATERALS AND IMPROVES THEIR FLOW**

# MULTILAYER STENT CONCLUSIONS

- **SAC THROMBOSIS DOES NOT USUALLY OCCUR IMMEDIATELY. SEVERAL FACTORS ( COLLATERAL BRANCHES AND THEIR IMPORTANCE...) COULD PLAY A ROLE AND HAVE TO BE STUDIED AND DETERMINED**
- **PRELIMINARY CLINICAL RESULTS ARE SATISFACTORY AND PROMISING**
- **LARGER EXPERIENCE AND LONGER FOLLOW UP ARE NEEDED**