THE MULTILAYER FLOW MODULATOR STENT 
FOR THE TREATMENT OF PERIPHERAL & VISCERAL ANEURYSMS
DO THE ANEURYSMS SHRINK IN SIZES
LONG-TERM RESULTS IN 47 PATIENTS

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PERIPHERAL - VISCERAL ANEURYSMS
■ RELATIVELY UNCOMMON DISEASES
■ ASYMPTOMATIC AND FOUND INCIDENTALLY
  (ANGIO, CT SCAN, MRI ...)
■ SYMPTOMATIC FOLLOWING COMPLICATIONS
  RUPTURE WITH LIFE THREATENING CONDITIONS (25-75 %)
  DEPENDING ON LOCATION
  COMPRESSION OF ADJACENT STRUCTURES
  THROMBOEMBOLISM ...
■ ETIOLOGY
  ■ ATHEROSCLEROSIS: MOST COMMON CAUSE
  ■ F.M.D.
  ■ ARTERITIS
  ■ OTHER: INFECTION, TRAUMA, DISSECTION, POST OPERATIVE
    INJURY, COLLAGEN DISEASES

PERIPHERAL - VISCERAL ANEURYSMS TREATMENT
■ SURGERY: HIGH RISK
  MORBIDITY/ MORTALITY (4-25 %)
■ ENDOVASCULAR PROCEDURES
  COVERED STENTS
  STENT-GRaFTS
  BARE STENTS + COILS……

PERIPHERAL - VISCERAL ANEURYSMS TREATMENT
■ ALL THESE TECHNIQUES HAVE A NUMBER OF
  LIMITATIONS, DISADVANTAGES, DRAWBACKS,
  COMPLICATIONS
  ENDOTRAN
  EARLY THROMBOSIS
  BRANCH OCCLUSION → ORGAN INFARCTION
  ANEURYSM RUPTURE  ....
  INFECTION
  MIGRATION
  DISTAL EMBOLIZATION
  DIFFICULTIES TO DEPLOY COVERED STENTS IN TORTUOUS
  ANGULATED VESSELS
  "THE MULTILAYER FLOW MODULATOR"

MULTILAYER FLOW MODULATOR TECHNOLOGY FOR PAA / VAA
■ STENT DIAMETER: 5-16 mm
■ LENGTH: 50 to 150 mm
■ GUIDE WIRE COMPATIBLE: 0.025
■ 110 cm Teflon Coated DELIVERY SYSTEM

SELF EXPANDABLE STENT

APPROACH WAYS
■ FEMORAL RETROGRADE
■ FEMORAL ANTERGRADE
■ CONTRALATERAL
■ BRACHIAL

3593 MFM IMPLANTED WORLDWIDE
When MFM is implanted one of its main effect is to reduce the force applied by arterial flow on the wall which cause the aneurysm growing.

The sudden and key action of the MFM is on the flow. The MFM act reversing the degrading flow (with vortex) to a physiological laminar flow aligned to the wall. This lead to gradual organized thrombus formation (lines of Zahn) that rebuild the aneurysm wall healing the artery.

A reduction of the force applied by the flow on the wall is clearly confirmed via numerical simulation.

- **PERSONAL SERIES**
  - 47 Pts (33 Males, Mean Age 62±8 Years)
  - Location: PAA: 34, VAA: 13
    - Iliac: 23
    - Femoral: 7
    - Popliteal: 6
    - Renal: 9
    - Mesenteric: 2
    - Celiac Trunk: 2
    - Carotid: 2
    - Subclavian: 2
  - 60 MFM Implanted (Ø: 5 to 14 mm, L: 40 to 120 mm)
  - Through a 6 to 12 F Sheath
  - Approach Ways
    - Femoral: 46
    - Right Brachial: 1

COURTESY J.MATELA
Un-physiological reversed flow with recirculation regions in the aneurysm sac before the implantation (on the left), is instantly converted into a laminated flow (on the right) leading with time to organized thrombus formation (lines of Zahn).

Clinical evidence

MULTILAYER FLOW MODULATOR

ILIAC ANEURYSM

23 CASES

MULTILAYER FLOW MODULATOR

CASE 1
7 YEARS AGO
ILIAC AN. WITH OCCLUSION OF INT. ILIAC ARTERY
MULTILAYER FLOW MODULATOR
ILiac Aneurysm
AMA K. MALE 53 Y.
3 WEEKS

4 YEARS
MULTI LAYER FLOW MODULATOR
AORTIC DISSECTION + ILIAC AN.
DAY 1

MULTILAYER FLOW MODULATOR
ILIAC ANEURYSM
DAY 1

MULTILAYER FLOW MODULATOR
POPLITEAL ANEURYSM
72 YEARS OLD MALE
SEVERE CORONARY DISEASE / HYPERTENSION
POPLITEAL VEIN COMPRESSION WITH LEG EDEMA
DAY 1
1 YEAR FOLLOW UP

MULTILAYER FLOW MODULATOR
ILIAC ANEURYSM
2 YEARS

MULTILAYER FLOW MODULATOR
ILIAC ANEURYSM
2 YEARS

MULTILAYER FLOW MODULATOR
POPLITEAL ANEURYSM
9 CASES
FIRST HUMAN CASE
RENAL ANEURYSM (DEC. 2006)


MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

MALE 75 Y. OLD    HTN   TRIPLE VESSEL CORONARY DISEASE
FEM. APPROACH 8F GUIDING CATHETER

1 YEAR FOLLOW UP

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

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

30 MONTH FOLLOW-UP - PROOF ON CLINICAL

EXCELLENT PATENCY OF COLLATERAL BRANCHES

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

EXCELLENT PATENCY OF COLLATERAL BRANCHES

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

PROOF ON CLINICAL

EXPLANATION 36 months (3 years)

ORGANIZED & STABLE THROMBUS

% Reinforcement of the wall (3*) which regulates the vascular tonus and strength as a normal wall
% Avoid any rupture

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

MEN 65 Y. HTA
SACCULAR AN. D = 35 45mm
REFUSED SURGERY

SLDENR. J. MATEJA
MARIBOR SLOVENIA

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

CONTROL CTA

6 MONTH F.U.
• finally showed excellent result with aneurysm exclusion and all side branches patent

SUPRA AORTIC VESSELS ANEURYSMS

■ UP TO APRIL 2013: 128 ANEURYSMS (PAA:88 , VAA: 40 )
■ TECHNICAL SUCCESS: 100%
■ VERY LOW COMPLICATION RATE
■ AT 30 DAYS
  > 2 DEATHS NOT DEVICE RELATED (1 PULM. EMBOLISM, 1 M.I.)
  > SURVIVAL RATE: 97.7%

METAANALYSIS: OUR RESULTS + LITERATURE DATA

■ DURING THE FOLLOW UP ( RANGE 5 – 36 MONTHS )
  > NO ANEURYSM RUPTURES
  > NO ANEURYSM GROWTH
  > ENDOLEAKS DUE TO MISPLACEMENT OF STENT (2 CASES)
  > OVERALL SURVIVAL: 95.5%
  > COMPLETE ANEURYSM EXCLUSION: 94.3%
  > WITH SIGNIFICANT SHRINKAGE IN 83%
  > ALL SIDE BRANCHES COVERED BY MFM REMAINED PATENT EXCEPT ONE IN A PT WITH THROMBOPHILIA
IN THE FOLLOW-UP WE OBSERVE A PROGRESSIVE 
THROMBOSIS AND SHRINKAGE OF THE ANEURYSM SAC. 
THE SHRINKAGE PATTERN IS VARIABLE ACCORDING TO THE 
DIAMETER OF THE EFFERENT VESSELS, THE INITIAL 
ANEURYSM SAC SIZE AND THE WEAKNESS OF THE 
ANEURYSMAL WALL.

EXCLUSION WITH THE MFM MAY TAKE SEVERAL WEEKS OR 
MONTHS, BUT THE ANEURYSMAL WALL IS NO LONGER 
SUBJECTED TO LOCAL PEAK WALL SHEAR STRESS, THUS 
PREVENTING AGAINST RUPTURE.

THE MULTILAYER FLOW MODULATOR (MFM) REPRESENTS AN ALTERNATIVE TO 
CURRENT DEVICES (CE MARKED).

LOCAL PRESSURE, AN. WALL STRESS ARE IMMEDIATELY RELIEVED ONCE MFM IS 
IN PLACE, WHICH PROTECTS AGAINST AN. RUPTURE.

PRESERVING COLATERALS (97–100% BRANCH PATENCY).

PROGRESSIVE SAC THROMBOSIS AND SHRINKAGE DEPENDING ON THE 
IMPORTANCE OF COLATERALS, INITIAL AN. SIZE (1, 6, 12 … MONTHS?).

DIAMETER REDUCTION.

SAVE PROCEDURE, LOW COMPLICATIONS RATE, NO 30 DAY MORTALITY.

HARD ENDPOINTS, SEVERE GUIDELINES MUST BE RESPECTED TO 
HAVE GOOD RESULTS.

MFM IS A BREAKTHROUGH, A HOPE, NOT A HOAX.