# Ventana Fenestrated System: Current Indications and Limitations

ANDREW HOLDEN MBChB, FRANZCR Associate Professor of Radiology, Auckland University School of Medicine Auckland City Hospital Auckland, New Zealand







CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use. Not available for sale or marketing in the United States or abroad, including the European Economic Area.

# Disclosures

# Andrew Holden, MBChB, FRANZCR

For the 12 months preceding this CME activity, I disclose the following types of financial relationships:

Honoraria received from: Nil

#### **Consulted for:**

Abbott Vascular Laboratories Endologix Inc Cook Medical Systems 480 Biomedical

#### Held common stock in: Nil

# **Ventana Fenestrated System**

*In-situ* customization with *offthe-shelf* availability for pararenal and juxtarenal abdominal aortic aneurysms



CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use. Not available for sale or marketing in the United States or abroad, including the European Economic Area.

# **Ventana Fenestrated System**

Proximal Scallop for SMA \_\_\_\_\_\_ preservation

For use with AFX unibody bifurcated stent graft • Anatomical Fixation

Bifurcation Preservation





Steerable fenestrations *insitu* to address broad range of anatomies

Pre-cannulated fenestrations with 6.5Fr sheaths

Device fully constrained during renal cannulation

Integrated XPAND<sup>™</sup> Renal Stent Grafts







### **Exposing the Renal Sheaths**

Retract outer sheath until the R/O markers of the 6.5F renal sheaths are exposed 1-2cms blow the renal arteries Can retract down to the safety clip on the inner core



### **Cannulating the Renal Arteries**

- A key feature of the Ventana device is that it is *fully* constrained while the renal arteries are cannulated
- This stable platform plus a range of shaped catheters
  allows cannulation of even difficult renal artery anatomies
- This is a *major* point of difference with this device



















### **Advance Device to Deploy**

 Device advanced so that the base of SMA scallop (RO marker) lies close to the SMA



## **Deploy Proximal Section**

Proximal section deployed by advancing a pusher rod



## **Deploy Proximal Section**

- Complete deployment in the lateral position
- May initially deploy the device a little high so that the RO marker partly covers the SMA
- Can easily pull the whole device down into perfect position





## **Deploy Distal Section**

Outer sheath retracted to deploy the distal section



#### **Covered Renal Stents Deployed and Flared**

- Covered renal stents positioned so that ~ 5mm (2 stent elements) project into the aortic lumen
- Xpand Chromium cobalt stent with ePTFE covering
- Stents flared in the aortic section



- Unique Ventana feature
- Pushers allow the fenestrations to be advanced to the renal artery ostium and even into the renal artery
- This essentially creates a branch graft







- Multiple additional roles
- Facilitate horizontal orientation of flaring balloons



W 2300 : L 1768

## **Device Removed**



## **Completion Angiography**





# **Key Patient Selection Criteria**

- AAA Sac Diameter ≥5.5cm or Rapidly Expanding
- Infra-renal Neck <15mm Length</li>
- Infra-SMA Neck Length ≥15mm
- Diameter 18-34mm
- Renal Arteries at or below SMA 0-35mm
- Renal Arteries separated by between 90° and 210° and within ±30mm longitudinally
- Infra-SMA neck with an angle of  $\leq 60^{\circ}$  to the aneurysm sac
- Renal Arteries 4-8mm diameter lumens
- Renal Ostial Stenosis < 70%</li>



# **Key Patient Selection Criteria**

- AAA Sac Diameter ≥5.5cm or Rapidly Expanding
- Infra-renal Neck <15mm Length</li>
- Infra-SMA Neck Length ≥15mm
- Diameter 18-34mm
- Renal Arteries at or below SMA 0-35mm
- Renal Arteries separated by between 90° and 210° and within ±30mm longitudinally
- Infra-SMA neck with an angle of ≤60° to the aneurysm sac
- Renal Arteries 4-8mm diameter lumens
- Renal Ostial Stenosis < 70%</li>



### **FIM Trial (N=15)** Baseline Characteristics

Parameter	Result
Male gender	87%
Age, years	$77 \pm 5.6$
Serum Creatinine, mg/dL	$1.2 \pm 0.2$
COPD	60%
Hypertension	80%
Smoking History	60%
Sac Diameter, cm	$5.9 \pm 0.8$
Aneurysm Type	93% Juxtarenal; 7% Pararenal
Neck Length: Infra-SMA / Infrarenal, mm	$25 \pm 9.9$ 6.9 $\pm 5.6$
Infra-SMA Neck Diameter, mm	$24 \pm 2.2$
L to R Renal Artery, $^{\circ}$ (Clockface)	$147 \pm 23$

# **Primary Endpoint Results**

- Treatment Success at 30 Days: 93% (14/15)
  - 100% Procedural Technical Success
  - Limb Occlusion, n=1 (6.7%)
    - Due to kink in bifurcated limb present intraprocedurally but not recognized at the time
    - FFXO day 26
  - No Type I or III Endoleaks
  - No Renal Stenosis or Occlusion

#### CT @ 6 Months



#### CT @ 12 Months



## Other Results >30 Days to 16 Months

- Device Performance
  - No conversion to open or aneurysm rupture
  - No migration, stent fracture, graft failure
  - No Type I or III Endoleaks
  - No aneurysm sac expansion
  - eGFR preserved vs baseline; No renal infarcts
  - Small Type II Endoleaks in 3/15 patients (20%)
- Secondary Procedure
  - Renal Stenosis (n=1, 7 months post-op)
  - Reinforced renal stent





B

59mm X 54mm







#### 6 Months





#### 12 Months















# **Ventana: Current Plans**

- "First on man" trial successfully completed
- US "Pivotal Trial" and OUS "Feasibility Trial" underway
- Ventana is easy to use with a limited number of devices being used in most anatomies
- Constrained device during renal artery cannulation a major advantage
- Fenestration pushers very useful





