AORFIX: A Proven AAA Therapy Treats the Simplest to the Most Complex Anatomies with the Advanced INTELLIFLEX LP Delivery System

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Disclosure

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I have the following potential conflicts of interest to report:
- [x] Consulting – Clinical Investigator for Lombard Medical Inc
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)
Aorfix™ Endovascular Stent Graft

- Unique design
- Only device with FDA Approval to treat severe infra-renal neck angulation and severe iliac tortuosity
- Pythagorus US Pivotal Trial has shown excellent results beyond 2 years
- ARCHYTAS Registry – 500 patient global registry collecting “real world” clinical data on Aorfix

First ARCHYTAS Registry case performed at Auckland Hospital
Aorfix™ Endovascular Stent Graft

- Fishmouth
- Radiopaque markers on the stent graft body and legs for precise positioning
- Gate: Inter-locking helical design
- 8mm sealing zones at proximal and distal ends of stent graft
- Densely-arranged nitinol rings at the sealing zones are designed to enhance radial force
- Helical legs of the stents designed to maintain patency in tortuous anatomy
Why a Delivery System Design Change?

- Lower profile
- Integrated 18F/16F sheath (can be used as an exchange sheath to deliver limb extensions, moulding balloons etc)
- Intuitive deployment and ergonomic design
- Allows device applicability to expand beyond challenging anatomy to routine use in conventional anatomies
Why a Delivery System Design Change?

- In very angulated necks, a shoulder in the neck can restrict the current “supporting tubes” during deployment.
- The new “Y” mechanism positioned on the central lumen provides improved control and confidence during deployment of the fishmouth.

Supporting tubes in place

Supporting tubes retrieved
IntelliFlex™ Delivery System

- Flush both lumens
- Activate hydrophilic coating on sheath
- Flush tube anteriorly marks contralateral limb
Orientate the Device in the Patient

- Select view that profiles renal arteries (eg 15°CC, 15° LAO)
- Actively reposition and reorientate while deploying (can reposition at least until half the Y mechanism is open)
Step 1 – Deployment of Y Mechanism

- Rotate towards operator
- Deployment geared so ~ 1mm/click at cranial aspect of graft, faster for caudal aspect
Step 1 – Deployment of Y Mechanism

- Note: during deployment the troughs don’t move, the peaks hinge off the troughs
Step 2 – Remove Release Wires

- Usually do this after releasing the cannulation socket but can release the entire ipsilateral limb.
Step 3/4– Recapture Y Mechanism

- Fully deploy ipsilateral limb
- Withdraw protective shroud (Step 3)
- Rotate back handle away from operator – this retrieves the centre tube/nose cone as well as the attached Y mechanism (Step 4)
- Rotate distal end of the handle towards the operator and remove the back end, exposing a hemostasis valve
Hemostatic Valve

- Can introduce sheath dilator, limb extension or compliant angioplasty balloon and remain completely hemostatic
Contralateral Gate Cannulation

- Anterior cannulation socket easy to cannulate
Ipsi/Contralateral Limb Deployment

- Deploy graft, remove release wires, retrieve delivery system
Conclusions

- Aorfix already has an established role in EVAR for challenging abdominal aortic anatomies
- The IntelliFlex™ Delivery System provides improved control and confidence during deployment in these challenging anatomies
- The profile reduction, intuitive deployment and ergonomic design expands the applicability of this device to more routine anatomies
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