ARCHYTAS Registry: Objective

**Objective**
- This Registry, is designed to compliment Pythagoras IDE study (Aorfix™ performance in neck angles of 0° to 90° and challenging anatomies) on a global stage.

ARCHYTAS Registry: Key Features

- **Global Multi-centre** nonrandomized single-arm prospective Registry
- **Real world clinical Registry** for Aorfix™
- 300 patients, 30 sites with an option to extend to 500 patients, 50 sites
- Inclusion/Exclusion criteria as per IFU → More challenging anatomies
- Physician lead patient follow-up schedule → Authentic and validated practice guidelines
- Core-lab assessed pre-op imaging → Solid bases for forming analysis groups
- Fully monitored data capture → Robust dataset
- Up to 5 years follow-up planned → Long term clinical performance of Aorfix™

Electronic Database

- **Internet-based**
- **Secure**
- **Training & Support provided**
- **Remote and on-site monitoring**
Imaging Guidelines

- Sites to follow standard of care for imaging
- Analysis by Independent Imaging Core Lab

<table>
<thead>
<tr>
<th>Imaging Type</th>
<th>Pre-Op</th>
<th>Discharge</th>
<th>Post-Op period to 6 months</th>
<th>12 months</th>
<th>Annually to 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT**</td>
<td>✓</td>
<td>AR</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Duplex Ultrasound</td>
<td>AR</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>X-ray KUB (4-view)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

** = contrast enhanced (preferred not mandatory); spiral CT, <3 mm slices, overlapping images. AR = As Required

Outcome Measures

- Primary Outcome Measures:
  - Treatment success (12 months)
  - Freedom from: sac expansion > 5mm, type I and III endoleaks requiring re-intervention, rupture, conversion to open surgery, graft migration, occlusion

- Secondary Outcome Measures:
  - Stent graft migration > 10 mm (12 months)
  - Stent graft patency (12 months)
  - Changes in aneurysm diameter (12 months)
  - Stent graft endoleaks (post-op and 12 months)
  - Aneurysm-related secondary procedures (12 months)
  - Adverse device effects, Technical observations, Aneurysm-related mortality (12 Months)
  - All-cause mortality (30 days and 12 months)
  - Major Adverse Events (30 days)

Inclusion/Exclusion Criteria

- Sites to screen and enroll consecutively

**Inclusion**
- Diagnosed abdominal aortic aneurysm with indication for endovascular repair
- Intention to electively implant the Aorfix™ Stent Graft System

**Exclusion**
- Patients unsuitable as outlined in IFU
- Unwilling or unable to return for follow-up visits
- Excludes use of Aorfix™ for re-do of competitor devices

Current and Planned Site Locations

Aorfix™ Registry will be expanded to further countries following local product approvals.

Active Sites at November 2015 (48)

Spain (5)
- All sites with Ethics Approval
- Hospital Clinic Barcelona (Lead PI)
- H. Universitari Dr. Josep Trueta, Girona
- Complexo Hosp. Universitario de Ourense
- H. Puerta del Mar, Cádiz
- Hospital Universitario Donostia
- H. Marqués de Valdecilla, Santander
- University Hospital S. Cecilio
- Hospital Gregorio Marañon, Madrid

Italy (6)
- Ethics Approval:
  - Policlinico San Donato Milanese
  - Approvals Pending:
    - Ospedale Papa Giovanni 23, Bergamo
    - Ospedale Santa Chiara della Fratte, Pergine
    - Ospedale Maggiore, Verona

United Kingdom (8)
- NHS Trust Approved:
  - NHS Northwick Park Hospital (Lead UK Site)
  - Royal Bournemouth Hospital
- Approvals Pending:
  - Portsmouth University Hospital
  - Ninewells Hospital and Medical School
  - Mid Essex Hospital - Broomfield
  - Royal Preston Hospital
  - Royal London Hospital

New Zealand (1)
- Ethics Approved:
  - Auckland Hospital

Site Selection Criteria

- High Volume sites with annual case volume >30 AAA Stent Graft Procedures
- Ability to enroll 10 patients per year
- Adequate experience implanting the Aorfix™ device
- Resources to perform research-related tasks and follow-up patients for 5 years
- Regulatory/ethics approval (and patient informed consent or data-release authorisation) where required

Current and Planned Site Locations

EU: Spain, Germany, Poland, Italy, UK
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Japan
Russia
Latin America
US
New Zealand
Active Sites at November 2015 (48)

**Germany (13)**
- University of Cologne (Lead German Site)
- Universitätsklinikum, Hamburg
- Klinikum Rechts der Isar der TU München
- Charité - Universitätsmedizin Berlin
- Elisabeth-Krankenhaus Essen
- Universitätsklinikum Würzburg
- Alfred Krupp Krankenhaus, Essen
- Ammerland Klinik GmbH, Wiesmoor
- St. Vincent's Hospital, Frankfurt
- Universitätsklinikum Leipzig
- Ammerland Klinik GmbH, Westerstede
- St. Vincenz-Krankenhaus Limburg
- Universitätsklinikum Würzburg
- Elisabeth-Krankenhaus Essen
- Universitätsklinikum Frankfurt
- Bonifatius Hospital, Lingen
- University Hospital Halle

**United States (16)**
- Temple University Hospital
- Eastern Maine Medical Center, Bangor
- Central Cardiology, Bakersfield
- Louisiana State University / West Jefferson Medical Center
- Mount Sinai Medical Center, Miami Beach
- Texas Heart Institute/Baylor University
- St. Luke’s Hospital
- University of Kentucky
- Western Vascular / St Joseph’s Phoenix
- New Hanover Regional Medical Center, Wilmington
- Memorial Health University Medical Center, Savannah

**Italy (2)**
- First Approvals - Jan 2016
- University Hospital of Lodi
- Medical University of Warsaw

**Summary**

ARCHYTAS is a global registry aimed to evaluate the AORFIX performance in highly angulated anatomies, with on label use basis and over 5-year follow up.

The ARCHYTAS worldwide post-market registry

Please contact Lombard Medical if you are interested in participating in the ARCHYTAS Registry:

www.lombardmedical.com