Summary of Safety & Clinical Performance
Altura Endograft System

A summary of the safety and clinical performance of the device, intended for users/healthcare professionals

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients. The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1 Device trade name
Altura™ Endograft System
1.2 Legal manufacturer's name and address
Lombard Medical Ltd
Lombard Medical House, 4 Trident Park, Didcot, Oxfordshire, OX11 7HJ, United Kingdom
1.3 Legal manufacturer's SRN (single registration number)
GB-MF-000014515
1.4 Basic UDI-DI
05055715AO01BU
1.5 Medical device nomenclature description/text
GMDN: 46777 (Abdominal Aortic Stents)
EMDN: C019009 AORTIC OCCLUSION SYSTEMS
CND: P070102020201 – Simple Bifurcated Vascular Prosthesis in PTFE
1.6 Class of device
Class III
1.7 Year when the first (CE) was issued covering the device
2016
1.8 Authorised representative name, address and SRN
Medical Device Management Ltd
Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland
1.9 Notified Body name and single identification number
DQS (0297)

2. Intended use of the device

2.1 Intended purpose

The Altura Endograft System is intended to exclude aneurysms from blood circulation in patients diagnosed with abdominal aortic aneurysm (AAA). It is intended for use only by suitably trained physicians who are experienced in the diagnosis and endovascular treatment of aneurysmal disease. Standard techniques for the use of vascular access sheaths, angiography, guidewires and contrast media should be employed.

2.2 Indications and target populations

Indications for use

Altura Endograft System is indicated for treatment of patients with abdominal aortic and/or aorto-iliac aneurysms having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access that is compatible with vascular access techniques, devices, and/or accessories.
- Iliac/femoral access morphology compatible with 14 F introducer sheaths.
- Non-aneurysmal proximal aortic neck between the renal arteries and the aneurysm with:
  - Length of ≥15 mm
  - Inner wall diameter of 18-28 mm
  - Neck angulation of ≤60°
- Distal common iliac landing zone with:
  - Inner wall diameter of 8-18 mm
  - Length of ≥15 mm

Intended patient population

- The Altura Endograft System is designed to treat aortic neck diameters between 18 mm and 28 mm inclusive. The Altura Endograft System is designed to treat proximal aortic necks (distal to the lowest renal artery) of at least 15 mm in length. Iliac artery distal fixation site greater than or equal to 15 mm in length and diameters between 8 mm and 18 mm is required. These sizing measurements are critical to the performance of the endovascular repair.
- Key anatomical elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (>60 degrees) and irregular or circumferential thrombus and/or calcification at the sealing zones that may compromise sealing and fixation. In the presence of anatomical limitations, a longer seal zone may be required to obtain adequate sealing and fixation.
- Adequate iliac or femoral access is required to introduce the device into the vasculature. Access vessel diameter (measure inner wall to inner wall) and morphology (minimal tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and 14 F vascular introducer sheaths. Vessels that are significantly calcified, occlusive, tortuous, or thrombus-lined may preclude placement of the endovascular graft and/or may increase the risk of embolization. A vascular conduit technique may be necessary to achieve success in some patients.
- The Altura Endograft System is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endograft.
- The Altura Endograft System is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.
- Inability to maintain patency of at least one internal iliac artery or occlusion of an indispensable inferior mesenteric artery may increase the risk of pelvis/bowel ischemia.
- Multiple large, patent lumbar arteries, and a patent inferior mesenteric artery may predispose a patient to Type II endoleaks. Patients with un-correctable coagulopathy may also have an increased risk of Type II endoleaks or bleeding complications.

2.3 Contraindications and/or limitations

Contraindications

Patients with a systemic infection who may be at increased risk of endovascular graft infection.
Patients with known sensitivities or allergies to polyester, nitinol, tantalum, or polyethylene.

3. Device description

3.1 Description of the device

Stent grafts are devices known to medicine as wire supported conduits of artificial graft material and are principally used to exclude weakened, aneurysmal parts of the vasculature from the normal circulation.

Altura™ Endograft System is comprised of two (2) bilateral aortic endografts and two (2) iliac endografts. Each endograft is pre-loaded into a 14Fr single use, disposable delivery catheter. Each catheter is intended to be introduced into the femoral artery over a guidewire under fluoroscopic guidance. The two aortic endografts are advanced to the suprarenal abdominal aorta, aligned, and positioned. The endograft is deployed such that the proximal edge of the graft material is below the renal arteries within the non-aneurysmal neck. The aortic delivery catheters are removed over the indwelling guidewires. Two delivery catheters containing the iliac endografts are then delivered over the guidewires and positioned with respect to the intended sealing zone. After the iliac endografts are deployed the delivery catheters are removed over the indwelling guidewires. Balloon catheters may be inserted over the guidewires to dilate the endografts. A completion aortogram is performed to verify positioning and assess for endoleaks.

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

No other generations of Altura™ Endograft have been registered for sale.

3.3 Description of any accessories which are intended to be used in combination with the device

Required Materials
Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
Contrast media
Various syringes for flushing and balloon inflation (e.g., 10, 20, and 30 ml (cc))
Heparinized saline solution or equivalent
Sterile gauze pads
Vascular access kit
COOK® Medical 14.0 F introducers
Assorted 0.035" (0.89 mm) guidewires of adequate length
Stiff 0.035" (0.89 mm) guidewires, 260 or 300 cm length
Angiographic flush catheter with radiopaque markers
Compliant vascular occlusion balloons
Power injector
Various vascular introducers

3.4 Description of any other devices and products which are intended to be used in combination with the device

Recommended Materials
Various diameter dilators
Vascular closure devices
Snares

4. Risks and warnings

4.1 Residual risks and undesirable effects

Adverse events that may occur and/or require intervention include, but are not limited to:

- Allergic reaction and/or intolerance to contrast or procedural/post-procedural medications
- Amputation
- Anesthesia complications and subsequent attendant problems (e.g. aspiration) • Aneurysm enlargement
- Aneurysm rupture
- Aortic damage and subsequent attendant problems (e.g., bleeding, dissection, perforations, rupture)
- Aorto-enteric fistula
- Arterial and venous thrombosis and/or pseudoaneurysm
- Arterial venous fistula
- Bleeding, hematoma or coagulopathy
- Bowel complications and subsequent attendant problems (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock and lower limb)
- Conversion to open surgery • Death • Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endograft: improper endograft placement; incomplete endograft deployment; endograft migration; separation of graft material from stent; occlusion; allergic reaction to endograft material, infection; stent fracture; graft material wear; graft material failure; dilatation; erosion; puncture of graft material and perigraft flow; endograft deformity and/or kinking, corrosion
- Endoleak
- Fever or localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection, impotence)
- Impotence
- Incomplete aneurysm repair
- Increased risk of cancer due to radiation exposure
- Infection of the aneurysm, access site, including abscess formation, transient fever and pain
- Life-time annual requirement for follow-up examinations (involving radiation exposure and intravenous contrast agents) to verify that the endograft is continuing to function
- Liver failure
- Lymph fistula / complications
- Mechanical failure of the device
- Neurologic damage, local or systemic and subsequent attendant problems (e.g., stroke, paraplegia, paraparesis, transient ischemia, paralysis)
- Occlusion of the endograft or native vessels
- Pain
- Pulmonary or respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Reduced blood supply to distal limb and pelvic organs and subsequent attendant problems (e.g., leg pain, edema, amputation, buttock pain, reduced sexual function)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, hypertension)

- Surgery
- Vascular spasm or vascular trauma and subsequent attendant problems (e.g., ilio-femoral vessel dissection, infection, bleeding, rupture, pain, hematoma, arteriovenous fistula)
- Vessel damage
- Wound complications and subsequent attendant problems (e.g., infection, dehiscence, bleeding, pseudoaneurysm)

4.2 Warning and precautions

General

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- The Altura Endograft System should only be used by physicians and teams trained in endovascular interventional and surgical techniques. Specific training expectations are described in Section 9.1, Physician Training and Experience.
- Always have a qualified vascular surgery team available during the implantation procedure in the event that conversion to an open surgical repair is necessary.
- Additional endovascular interventions or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing clinical sequelae, an enlarging aneurysm, and/or endoleak. An increase in aneurysm size and/or persistent endoleak or migration may lead to aneurysm rupture.

Patient Selection, Treatment, and Follow-Up

- The Altura Endograft System is designed to treat aortic neck diameters between 18 mm and 28 mm, inclusive. The Altura Endograft System is designed to treat proximal aortic necks (distal to the lowest renal artery) of at least 15 mm in length. Iliac artery distal fixation site greater than or equal to 15 mm in length and diameters between 8 mm and 18 mm is required. These sizing measurements are critical to the performance of the endovascular repair.
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- The Altura Endograft System is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endograft.
- The Altura Endograft System is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements.
- Inability to maintain patency of at least one internal iliac artery or occlusion of an indispensable inferior mesenteric artery may increase the risk of pelvis/bowel ischemia.
- Multiple large, patent lumbar arteries, and a patent inferior mesenteric artery may predispose a patient to Type II endoleaks. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications.

- The Altura Endograft System has not been evaluated in the following patient populations:
  - Traumatic aortic injury o Leaking, dissecting, pending rupture, or ruptured aneurysms
  - Mycotic aneurysms
  - Pseudoaneurysms resulting from previous graft placement
  - Revision of previously placed endovascular grafts or previous AAA surgery o Uncorrectable coagulopathy o Dialysis or compromised renal and/or hepatic function
  - Genetic connective tissue disease (e.g. Marfans or Ehlers-Danlos Syndromes)
  - Concomitant thoracic aortic or thoracoabdominal aneurysms
  - Active systemic infections
  - Pregnant or nursing females
  - Morbidly obese patients
  - Less than 18 years of age
  - Patients with less than 15 mm in length or greater than 60 degrees angulation of the proximal aortic neck.
- Successful patient selection requires specific imaging and accurate measurements.

Pre-Procedure Measurement Techniques and Imaging

- Lack of non-contrast CT imaging may result in failure to appreciate iliac or aortic calcification, which may preclude access or reliable device fixation and seal.
- Pre-procedure imaging of a maximum reconstruction thickness of 3 mm may result in sub-optimal device sizing, or in failure to appreciate focal stenosis.
- Clinical experience indicates that contrast-enhanced spiral computed tomographic angiography (CTA) with 3-D reconstruction is the strongly recommended imaging modality to accurately assess patient anatomy prior to treatment with the Altura Endograft System. If contrast-enhanced spiral CTA with 3-D reconstruction is not available, the patient should be referred to a facility with these capabilities.
- Clinicians recommend positioning the x-ray C-arm during angiography such that the origins of the renal arteries, and particularly the lowest patient renal artery, are well demonstrated prior to deployment of the proximal edge of the endograft material. Additionally, angiography should demonstrate the iliac artery bifurcations such that the distal common iliacs are well defined relative to the origin of the internal iliac arteries bilaterally, prior to deployment of the iliac leg components.

Diameters

Utilizing CTA, diameter measurements should be determined by the vessel lumen to help with proper device sizing and device selection. Adjustment to the measured lumen diameters may be necessary in the presence of thrombus, plaque, or calcium that may remodel after implantation of the endografts. The contract-enhanced spiral CT scan must start 1 cm superior to the celiac axis and continue through the femoral bifurcations at an axial thickness slice of 2 mm or less.

Lengths

Utilizing CTA, length measurements should be determined to accurately assess the following: proximal infrarenal neck length, renal to aortic bifurcation length, common iliac length, iliac fixation length, and total length from renal to internal iliac artery length.

Device Selection Strict

Adherence to the Altura Endograft System IFU sizing guide is strongly recommended when selecting the appropriate device size. Appropriate device oversizing has been incorporated in the IFU sizing guide. Sizing outside of the range can result in endoleak, fracture, migration, or lumen loss.

Implant Procedure

- Appropriate procedural imaging is required to successfully position the Altura Endograft System and assure accurate apposition to the vessel walls.

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Minimize handling of the constrained endograft and delivery catheter during preparation and insertion to decrease the risk of endograft contamination and infection.
- Do not bend or kink the delivery catheters prior to insertion. Doing so may damage the delivery catheters and endografts.
- Maintain guidewire position during delivery catheter insertion.
- Fluoroscopy should be used during introduction, tracking, positioning, deployment, repositioning, and removal to confirm proper operation of the delivery catheter components, proper placement of the endograft, and desired procedural outcome. The use of the Altura Endograft System requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively. Care should be taken to limit the amount of contrast media used during the procedure and to observe preventative methods of treatment to decrease renal compromise (e.g. adequate hydration).
- Do not fully implant a single aortic endograft within the aorta without a paired aortic endograft positioned, aligned, and partially expanded alongside. Fully implanting only one aortic endograft at a time can result in misalignment and improper positioning of the endograft within the aortic neck, resulting in an inadequate seal.
- As the sheath and/or guidewire is withdrawn, anatomy and endograft position may change. Constantly monitor endograft position and perform angiography to check position as necessary.
- To avoid any twist in the endovascular endograft, during any rotation of the delivery catheter ensure rotation of the delivery catheter handle is translated into rotation of the distal end of the delivery catheter. Relieve built-up torque in the delivery catheter by twisting the delivery catheter handle in the opposite direction after rotating the distal end into the desired orientation.
- The Altura Endograft System incorporates a suprarenal stent with fixation barbs. Exercise extreme caution when manipulating interventional and angiographic devices in the region of the suprarenal stent.
- Do not rotate the aortic delivery catheter once the suprarenal stent is released.
- Proper alignment of the flat surface of the aortic endografts is critical to ensure a good seal across the septum of the endografts and the neck of the aorta. The flat surfaces of the aortic endografts must appose each other. The aortic endografts should not be offset by more than 10 mm.
- Unless medically indicated, do not deploy the Altura Endograft System in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Vessel occlusion may occur.
- Do not attempt to re-sheath the endograft by rotating the rear grip of the delivery catheter handle in the opposite direction as indicated after partial or completed deployment.
- Repositioning the endograft distally after deployment of the suprarenal stent may result in damage to the endograft, reduction in endograft lumen, and/or vessel injury.
- Inaccurate placement and/or incomplete sealing of the Altura Endograft System within the vessel may result in increased risk of endoleak, migration, or inadvertent occlusion of the renal or internal iliac arteries. Renal artery patency must be maintained to prevent/reduce the risk of renal failure and subsequent complications.
- Inadequate fixation of the Altura Endograft System may result in increased risk of migration of the endograft. Incorrect deployment or migration of the endograft may require surgical intervention.
- Verify iliac endograft size prior to insertion into patient. Once the suprarenal stent is released within the aorta, care must be taken to not apply tension to the aortic endograft as it is released

from the delivery catheter. This can result in endograft elongation, lumen reduction, and misalignment.

- During removal, care must be taken to prevent catching the delivery catheter on the endograft, anatomy, or the vascular introducer sheath. Using a vascular introducer sheath other than the brand and size specified in the IFU, Required Materials may result in difficultly in removing the delivery catheters or vessel damage. Do not use excessive force to advance or withdraw the delivery catheters when resistance is encountered.
- Care must be taken when advancing the iliac endograft through the previously deployed aortic endograft to prevent the iliac delivery catheter from catching on the aortic endograft.
- The iliac endograft should overlap at least 20 mm within the aortic endograft to ensure a seal between the iliac and aortic endografts. If a minimum 20 mm overlap is not achieved, a 13 mm iliac endograft should be placed over the junction.
- Care must be taken when deploying the iliac endograft to avoid unplanned internal iliac artery occlusion.
- Do not reposition the iliac endograft distally once the endograft makes contact with the iliac artery.
- Do not rotate the iliac delivery catheter once the iliac endograft has engaged the anatomy.
- Ensure that the top cap radiopaque marker of the iliac delivery catheter is outside the vascular introducer sheath before the iliac endograft is deployed.
- When injecting contrast into the iliac or aortic delivery catheters, injector pressure should not exceed 300 psi.
- The tip of the guidewire should remain in position within the thoracic aorta throughout the procedure.
- Use caution during manipulation of catheters, wires, endografts, and sheaths within the vasculature. Significant disturbances may dislodge fragments of plaque or thrombus, which can cause distal embolization or rupture of the aneurysm.
- Inadvertent partial deployment, misalignment, or migration of the endograft may require surgical intervention.
- Avoid damaging the endograft or disturbing endograft positioning after placement in the event reinstrumentation (secondary intervention) of the endograft is necessary.
- Ensure introducer sheath position is maintained during the entire implant procedure.
- Do not continue advancing any portion of the delivery catheter if resistance is felt during advancement of the guidewire or delivery catheter. Stop and assess the cause of resistance using fluoroscopic guidance; vessel, catheter, or endograft damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- Do not use a delivery catheter if the packaging is damaged, the sterile barrier is broken prior to opening the packaging, or the delivery catheter appears damaged after removal from the packaging.

Compliant Balloon Use

- Do not inflate the balloon in the vessel outside of the endograft, as doing so may cause damage to the vessel. Use the balloon in accordance with its labeling.
- Use care in inflating the balloon within the endograft in the presence of calcification, as excessive inflation may cause damage to the vessel.
- Confirm complete deflation of the balloon prior to repositioning.

MRI Information Non-clinical testing has demonstrated that the Altura Endograft System endografts are MR Conditional. Patients with this device can be scanned safely in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T)

- Maximum spatial gradient field less than or equal to 30 T/m (3000 gauss/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) Under the scan conditions defined above, the Altura Endograft System endografts are expected to produce a maximum temperature rise of 6.47°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 11 mm for the Altura Endograft System endografts when imaged with a gradient echo or spin echo pulse sequence in a 3.0 Tesla MRI system.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

N/A

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to equivalent device, if applicable

N/A – Altura Endograft System does not claim equivalence to any other devices.

5.2 Summary of clinical data from conducted investigations of the device

The combined dataset represents 206 patients treated with the Altura graft. There are 57 from the First-in-man (FIM) study, 46 from the follow-on Elevate study and then 105 from the Altitude study. The datasets have been combined into a single unified series and analyzed as a whole.

The FIM study was the first study undertaken at experienced endovascular centres in Santiago, Chile and Riga, Latvia. The Elevate study followed, and was undertaken across a number of European sites, including 4 sites in Germany, 2 in Poland, and 1 in Riga. The Altitude study was the third to be undertaken and includes sites in the UK, Latvia, and Norway.

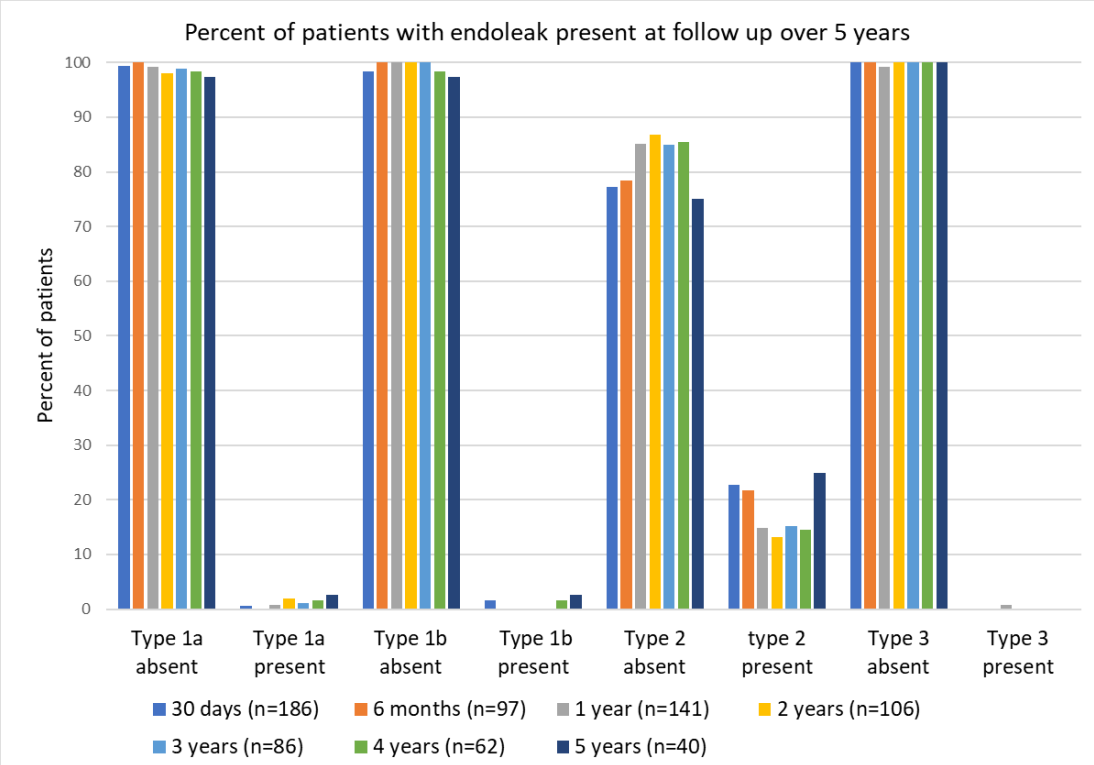
All 3 studies had formal written protocols and were approved by the relevant Ethics Committees or Institutional Review Boards. Studies were conducted in accordance with Good Clinical Practice and all patients consented to entry into the study. Data was collected prospectively in structured Case Report Forms and then collated centrally. All 3 studies captured standard data on demographics, pre-implant anatomy, the implantation procedure and recovery. The FIM and Elevate studies captured follow up data and imaging at 30 days, 6 months and then yearly. The Altitude study captured follow-up imaging and data at 30 days and one year. All 3 studies captured major adverse events or reinterventions prospectively outside these time points too.

30 day Major Adverse Event rate = 5.77% (12/208)

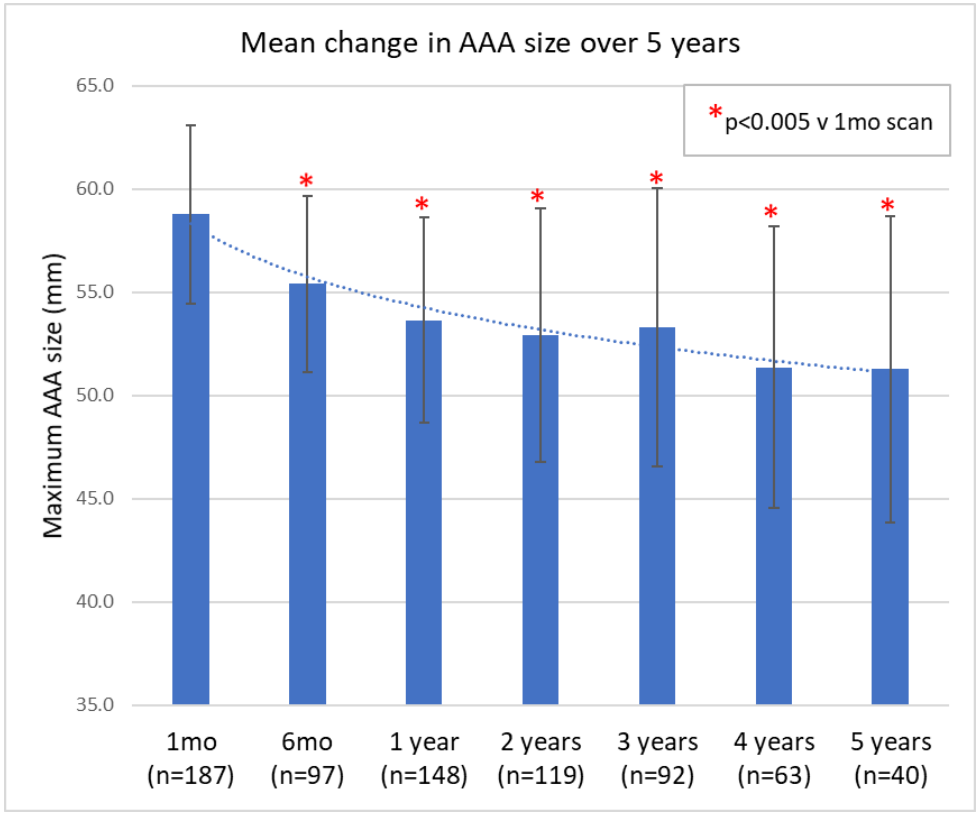
- 5/12 related to difficult access vessels
- Single death – unrelated to the device
- Only 3/12 “definitely” or “probably” related to the device

Incidence of :	30 days	1 year
All-cause mortality	0.5% (1/198)	4.7% (8/172)
Aortic related death	0.5% (1/198)	0.6% (1/172)
Delivery system complications	1.0% (2/198)	1.2% (2/172)
Stent fracture	0% (0/187)	0% (0/142)[5]
Graft occlusion	0.5% (1/186)	0.7% (1/141)

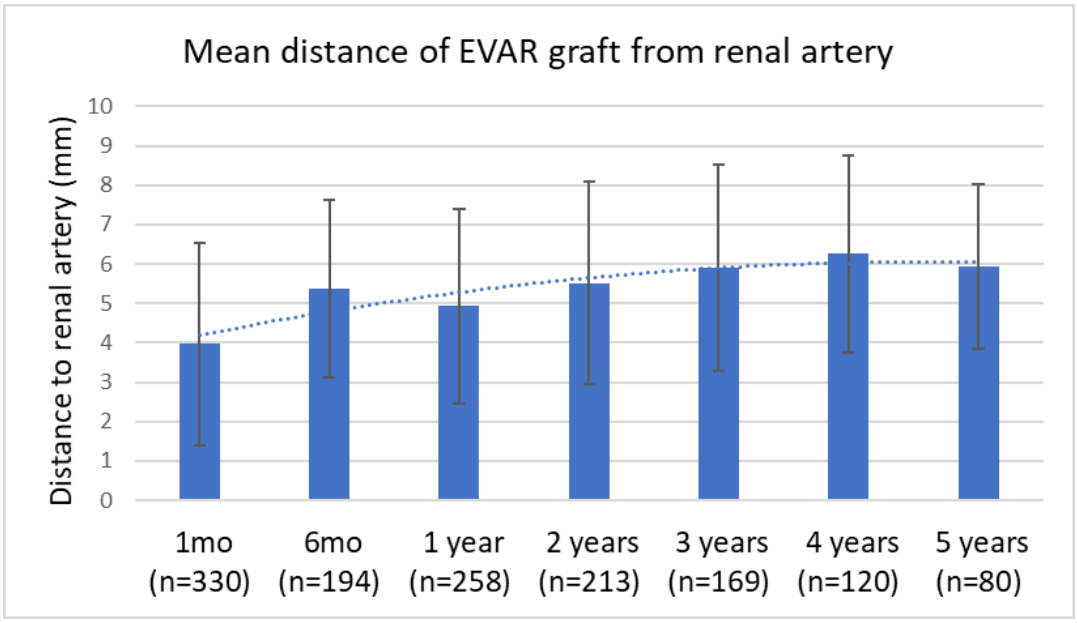
Endoleaks



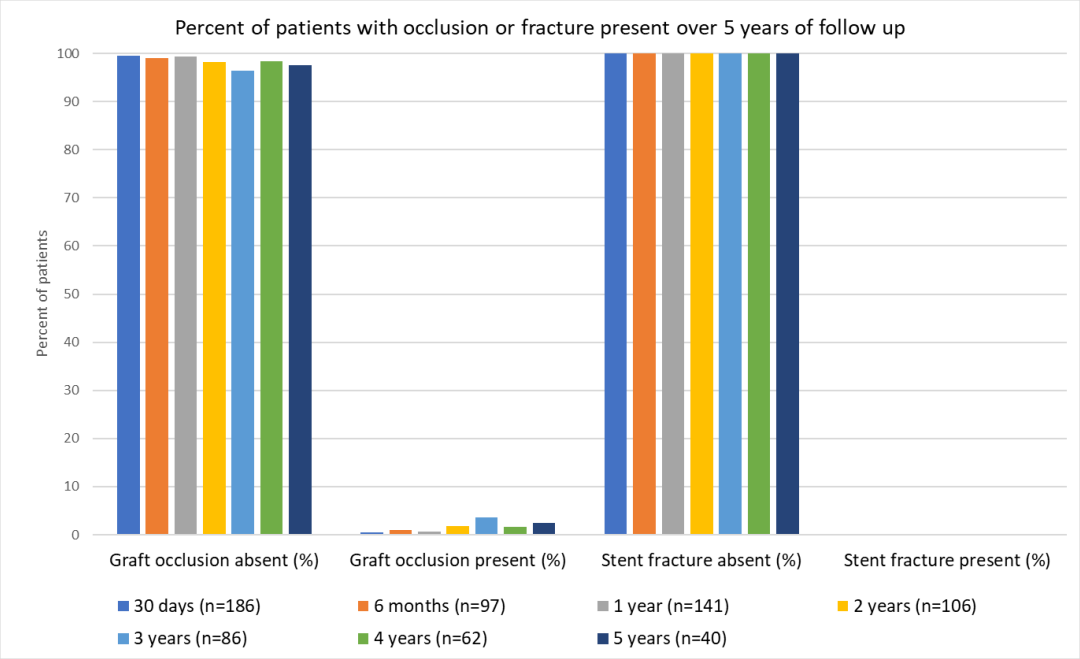
Change in sac size



Migration



Occlusions and Stent fractures



Reintervention

Event	Intervention	Incidence	Days to intervention
Access site issue	Endovascular	1	153
	Surgery	1	30
Iliac vessel event	Endovascular	3	43, 68, 324
	Surgery	1	21
Type 1a endoleak	Endovascular	5	127, 657, 736, 750, 783
	Surgery	2	938, 1456
Type 1b endoleak	Endovascular	5	29, 35, 49, 1146, 1471
Type 2 endoleak	Endovascular	6	197, 388, 412, 446, 455, 713
Renal	Endovascular	1	750

More than 5200 patient-months of follow up has been collected. 4 surgical reinterventions occurred

over 5 years. 84% were endovascular only interventions.

5.3 An overall summary of the clinical performance and safety

Through the data collected in 3 clinical studies, FIM, ELEVATE, and Altitude, Lombard Medical determine that Altura Endograft System is safe and effective for use within its intended purpose.

5.4 Ongoing or planned post-market clinical follow-up

Lombard Medical continue to actively collect data from the Altitude Registry.

6. Possible diagnostic or therapeutic alternatives

Treatment of abdominal aortic aneurysms (AAAs) consists of surgical repair. When indicated, an un-ruptured aneurysm can undergo elective surgical repair; a ruptured AAA calls for emergency repair. Possible approaches include the traditional open laparotomy, newer minimally invasive methodologies, and the placement of endovascular stents. Surgical repair should be performed as expediently as possible by an experienced surgeon.

The decision to treat an un-ruptured AAA is based on operative risk, the risk of rupture, and the patient's estimated life expectancy. Operative risk is based on patients' comorbidities and hospital factors.

There are two primary methods of AAA repair, open and endovascular. Open AAA repair requires direct access to the aorta via an abdominal or retroperitoneal approach. Open repair is well established as definitive treatment, having been in use for over 50 years. Generally, endovascular repair is advocated for patients who are at increased risk with open repair, but until results from randomized controlled trials are available, patient preference is the strongest determinant in deciding between endovascular and open approaches.

Open Repair

The aorta may be approached either trans-abdominally or through the retroperitoneal space. Juxtarenal and suprarenal aortic aneurysms are approached from the left retroperitoneal space. Depending on the anatomy, the aorta can be reconstructed with a tube graft, an aortic iliac bifurcation graft, or an aorto-femoral bypass.

7. Suggested profile and training for users

Intended for use by medical professionals trained in the use of Altura™ Endograft System.
Lombard Medical requires that medical practitioners using the system are adequately trained in surgical and in particular endovascular techniques.

8. Reference to harmonized standards and CS applied

Standard	Date	Title
Medical Device Regulation 2017/745	2017	Medical Device Regulation (MDR)
BS EN ISO 13485	2016/A11:2021	Quality Management Systems – Requirements for Regulatory Purposes.
BS EN ISO 14971	2019+A11:2021	Medical Devices: Application of Risk Management to Medical Devices.
BS EN ISO 7153-1	2016	Surgical Instruments. Metallic Materials. Stainless Steel.
BS EN ISO 11135	2014+A1:2019	Sterilization of health care products. Ethylene Oxide. Requirements for development, validation and routine control of a sterilization process for medical devices.

BS EN ISO 11138-2	2017	Sterilization of health care products. Biological indicators for ethylene oxide sterilization processes.
BS EN ISO 556-1	2001	Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices.
BS EN ISO 14644-1	2015	Cleanrooms and associated controlled environments. Classification of Air Cleanliness.
BS EN ISO 14644-4	2022	Cleanrooms and associated controlled environments – Part 4: Design, construction, and start-up
BS EN ISO 10993-1	2020	Biological evaluation of medical devices. Part 1- Evaluation and Testing within a risk management process
BS EN ISO 10993-3	2014	Biological evaluation of medical devices Part 3: Test for genotoxicity, carcinogenicity, and reproductive toxicity
BS EN ISO 10993-4	2017	Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
BS EN ISO 10993-5	2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-6	2016	Biological Evaluation of Medical Devices- Part 6: Tests for local effects after implantation
BS EN ISO 10993-7	2008+A1:2022	Biological Evaluation of Medical Devices- Part 7: Ethylene oxide sterilization residuals
BS EN ISO 10993-10	2023	Biological Evaluation of Medical Devices- Part 8: Tests for Irritation and Skin Sensitization
BS EN ISO 10993-11	2018	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
BS EN ISO 10993-12	2021	Biological Evaluation of Medical Devices- Part 12: Sample Preparation and Reference Materials
BS EN ISO 10993-15	2023	Biological Evaluation of Medical Devices- Part 15: Identification and Quantification of Degradation Products from Metals and Alloys
BS EN ISO 10993-23	2021	Biological evaluation of medical devices – Tests for irritation
BS EN ISO 11607-1	2020+A1:2023	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 20417	2021	Information supplied by the manufacturer with medical devices.
BS EN ISO 15223-1	2021	Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied.
BS EN ISO 25539-1	2017	Cardiovascular Implants. Endovascular devices. Endovascular Prosthesis.
BS EN ISO 14630	2006	General requirements for non-active surgical implants.
BS ISO 7198	2017	Cardiovascular implants – Tubular vascular prostheses.
BS EN ISO 10555-1	2013+A1:2017	Sterile, single-use intra-vascular catheters – General requirements.
BS 7252-13/ISO 13782	1997/2019	Metallic materials for Surgical Implants: Spec. for unalloyed Tantalum for surgical implant applications.
ISTA procedure 2a	2011	Transit Testing of Packages
BS EN ISO	2020	Clinical Investigation of Medical Devices for human subjects.

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ASTM F2503	2020	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
IEC 62366-1	2015	Medical Devices – Part 1: Application of Usability Engineering
MEDDEV 2.7.1 Rev 4	2016	Clinical evaluation: A guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12-1	8	Guidelines on a medical devices vigilance system.
(EU) 2023/607	2023	Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations 2017/745 and (EU) 2017/746 as regards the transitional provisions certain medical devices and in vitro diagnostic medical devices
MDCG 2019-9	2022	Rev 1 - Summary of safety and clinical performance: A guide for manufacturers and notified bodies
MDCG 2020-6	2020	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-7	2020	Post-market clinical follow-up Plan Template. A guide for manufacturers and notified bodies
MDCG 2020-8	2020	Guidance on PMCF evaluation report template
MDCG 2020-15	2020	Position paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
MDCG 2021-12	2021	FAQ on the European Medical Device Nomenclature (EMDN)
MDCG 2022-12	2022	Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional
MDCG 2019-8	2020	V2 Guidance document Implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices
MDCG 2021-11	2021	Guidance on Implant Card – Device types
MDCG 2022-16	2022	Guidance on Authorised Representatives
MDCG 2020-3	2023	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
MDCG 2018-1	2021	Rev 4 - Guidance on basic UDI-DI and changes to UDI-DI
MDCG 2021-19	2021	Guidance note on integration of the UDI within an organisation's quality management system

9. Revision history

SSCP revision number	Prepared by / Date issued	Change description	Revision validated by the Notified Body
1	Matthew Burden 07Dec2022	Document creation	☐ Yes ☒ No Validation language: English
2	Matthew Burden 16 Nov 2023	Applied standards updated. Removal of information intended for the patient. The patient is not the intended user.	☐ Yes ☒ No Validation language: English