

**Zenith<sup>®</sup> Renu<sup>™</sup> AAA Ancillary Graft  
 Post-Market Surveillance Registry: Interim Data**

The Zenith Renu<sup>®</sup> AAA Ancillary Graft (Renu) was approved by FDA on June 9, 2005. It is intended to be used as a bailout device for situations in which a previously implanted (pre-existing) AAA stent graft does not provide adequate proximal fixation or seal (refer to [Instructions for Use](#) for complete indications, warnings, and precautions). A condition of approval was collection of physician experience with the Zenith Renu<sup>®</sup> AAA Ancillary Graft in a post-market surveillance registry. The registry was created with the specific aims to evaluate physician experience with the Zenith Renu<sup>®</sup> AAA Ancillary Graft and to confirm device performance as assessed by the absence of subsequent device-related events. Case accrual began on September 9, 2005, and this status report summarizes data entered into the registry as of April 13, 2010. To date, 151 Zenith Renu<sup>®</sup> AAA Ancillary Graft cases at 95 institutions have been reported in the registry. New cases are no longer being entered into this registry. The pre-existing grafts and their failure modes (based on site-reported data) are presented in Tables 1 and 2.

**Table 1. Pre-existing grafts treated with the Zenith Renu<sup>®</sup> AAA Ancillary Graft**

| Pre-existing Graft Type | Number | (%)   | Implantation time prior to treatment (months) <sup>2</sup> |
|-------------------------|--------|-------|--|
| AneuRx <sup>®</sup>     | 126    | 83.4% | 42.1 ± 17.1 (n=116)  |
| Ancure <sup>®</sup>     | 9      | 6.0%  | 55.1 ± 8.6 (n=8)   |
| Excluder <sup>®</sup>   | 6      | 4.0%  | 31.3 ± 26.2 (n=6)  |
| Talent <sup>™</sup>     | 3      | 2.0%  | 38.5 ± 0.7 (n=2)   |
| Vanguard <sup>™</sup>   | 2      | 1.3%  | 96.0 ± 0.0 (n=2)   |
| Other <sup>1</sup>      | 2      | 1.3%  | 75.0 ± 14.1 (n=2)  |
| Fortron <sup>™</sup>    | 1      | 0.7%  | 44.0 (n=1)   |
| Lifepath <sup>™</sup>   | 1      | 0.7%  | 38.0 (n=1)   |
| Zenith <sup>®</sup>     | 1      | 0.7%  | 15.0 (n=1)   |

<sup>1</sup> Hand made grafts (1 aortouni-iliac and 1 bifurcated).

<sup>2</sup> The implantation times of 10 AneuRx<sup>®</sup> grafts, 1 Ancure<sup>®</sup> graft, and 1 Talent<sup>™</sup> graft were not provided.

The average implantation time of pre-existing grafts treated with the Zenith Renu<sup>®</sup> AAA Ancillary Graft was 43.4 months (n=139). The implantation times of 10 AneuRx<sup>®</sup> grafts, 1 Ancure<sup>®</sup> graft, and 1 Talent<sup>™</sup> graft were not provided.

**Table 2. Failure modes of pre-existing grafts treated with the Zenith Renu<sup>®</sup> AAA Ancillary Graft<sup>1</sup>**

|                                     |                             | Pre-existing Graft |                     |                     |                       |                      |                       |                     |                       |                     |                    |
|-------------------------------------|-----------------------------|--------------------|---------------------|---------------------|-----------------------|----------------------|-----------------------|---------------------|-----------------------|---------------------|--------------------|
|                                     |                             | All                | AneuRx <sup>®</sup> | Ancure <sup>®</sup> | Excluder <sup>®</sup> | Fortron <sup>™</sup> | Lifepath <sup>™</sup> | Talent <sup>™</sup> | Vanguard <sup>™</sup> | Zenith <sup>®</sup> | Other <sup>2</sup> |
| Devices Treated                     |                             | <b>151</b>         | <b>126</b>          | <b>9</b>            | <b>6</b>              | <b>1</b>             | <b>1</b>              | <b>3</b>            | <b>2</b>              | <b>1</b>            | <b>2</b>           |
| Reported Failure Modes <sup>3</sup> | Endoleak                    | <b>108</b>         | <b>89</b>           | <b>6</b>            | <b>4</b>              | <b>1</b>             | <b>1</b>              | <b>2</b>            | <b>2</b>              | <b>1</b>            | <b>2</b>           |
|                                     | Proximal Type I             | <b>86</b>          | <b>74</b>           | <b>4</b>            | <b>2</b>              | <b>1</b>             | <b>1</b>              | <b>1</b>            | <b>1</b>              | <b>1</b>            | <b>1</b>           |
|                                     | Migration                   | <b>136</b>         | <b>120</b>          | <b>6</b>            | <b>2</b>              | <b>1</b>             | <b>1</b>              | <b>3</b>            | <b>2</b>              | <b>0</b>            | <b>1</b>           |
|                                     | Stent Fracture/<br>Breakage | <b>3</b>           | <b>3</b>            | <b>0</b>            | <b>0</b>              | <b>0</b>             | <b>0</b>              | <b>0</b>            | <b>0</b>              | <b>0</b>            | <b>0</b>           |
|                                     | Graft Tear                  | <b>3</b>           | <b>2</b>            | <b>1</b>            | <b>0</b>              | <b>0</b>             | <b>0</b>              | <b>0</b>            | <b>0</b>              | <b>0</b>            | <b>0</b>           |
|                                     | Component<br>Separation     | <b>2</b>           | <b>1</b>            | <b>0</b>            | <b>0</b>              | <b>0</b>             | <b>0</b>              | <b>0</b>            | <b>1</b>              | <b>0</b>            | <b>0</b>           |
|                                     | Occlusion                   | <b>2</b>           | <b>1</b>            | <b>1</b>            | <b>0</b>              | <b>0</b>             | <b>0</b>              | <b>0</b>            | <b>0</b>              | <b>0</b>            | <b>0</b>           |
|                                     | Kink                        | <b>7</b>           | <b>5</b>            | <b>1</b>            | <b>0</b>              | <b>0</b>             | <b>0</b>              | <b>0</b>            | <b>0</b>              | <b>0</b>            | <b>1</b>           |
|                                     | Other <sup>4</sup>          | <b>2</b>           | <b>1</b>            | <b>0</b>            | <b>1</b>              | <b>0</b>             | <b>0</b>              | <b>0</b>            | <b>0</b>              | <b>0</b>            | <b>0</b>           |

<sup>1</sup> Failure modes of pre-existing grafts are based on site-reported data.

<sup>2</sup> Hand made grafts (1 aortouni-iliac and 1 bifurcated).

<sup>3</sup> Ninety-nine pre-existing grafts were reported as having multiple failure modes. Failure mode(s) of one AneuRx<sup>®</sup> graft was not provided by one implanting institution. Per Cook representative present at the procedure, the pre-existing graft had both migrated and had a proximal type I endoleak. These failure modes were confirmed by evaluation of pre-operative imaging and have been included in this analysis.

<sup>4</sup> One AneuRx<sup>®</sup> was noted as having a loss of graft integrity discovered during the Renu procedure. One Excluder<sup>®</sup> was noted as having aneurysm sac growth due to the material.

The most common reported failure modes of pre-existing grafts were proximal type I endoleak (86 cases) and migration (136 cases). Other failure modes included additional endoleak, stent fracture, graft tear or leakage, component separation, kink, and occlusion. More than one failure mode was reported in 99 cases.

### Demographics

Recipients of the Renu device were primarily male (n=131) with an average age of 77 years (n=147).

### Device Deployment

Table 3 presents site-reported deployment data for the 89 Zenith Renu<sup>®</sup> converters and 62 Zenith Renu<sup>®</sup> main body extensions used to treat failed or failing pre-existing grafts. The Zenith Renu<sup>®</sup> AAA Ancillary Graft is often used in a bailout capacity in patients with challenging pre-existing graft and anatomical characteristics. Some difficulty deploying the Renu device is expected in this sub-optimal environment. Despite these challenges, a remarkably low occurrence of deployment problems was reported. In fact, no problems were reported for over 90% of the cases in each deployment category.

**Table 3. Device deployment for the Zenith Renu<sup>®</sup> AAA Ancillary Graft and H&L-B One-Shot<sup>™</sup> Introduction System**

| <b>Devices Used</b>                                       | <b>Percentage</b> | <b>Frequency</b>        |
|---|-------------------|-------------------------|
| Renu <sup>™</sup> converter was implanted                 | 58.9%             | (89/151)                |
| Renu <sup>™</sup> main body extension was implanted       | 41.1%             | (62/151)                |
| <b>Deployment Performance</b>                             |                   |                         |
| Renu <sup>™</sup> delivery system was inserted easily     | 96.7%             | (146/151)               |
| Renu <sup>™</sup> was deployed without difficulty         | 94.7%             | (143/151)               |
| Renu <sup>™</sup> was easily visualized under fluoroscopy | 96.7%             | (145/150 <sup>1</sup> ) |
| Renu <sup>™</sup> delivery system was easily removed      | 94.0%             | (142/151)               |
| Renu <sup>™</sup> was deployed in the desired position    | 92.1%             | (139/151)               |

<sup>1</sup> Information regarding visibility was not provided in one case.

Many of the cases with reported difficulty inserting or removing (e.g., retrieval of the top cap) the delivery system also reported tortuosity or angulation of the aorta, iliac arteries, or pre-existing graft. Angulation was also reported as contributing to difficult deployment in one case. The other remaining cases of reported deployment difficulty were a leaking hemostatic valve (1), migration of the device during deployment (1), difficulty retracting or removing the sheath (2), tilting of the Renu opposite the direction of the AneuRx<sup>®</sup> (1), and difficulty reaching the desired landing zone in an obese patient or a patient with a long aorta (2). Of the 12 devices reported as not deployed in the desired position, 8 were reportedly deployed too low (up to 10 mm), 1 was deployed high, but without any compromise to the renal artery, 2 were tilted and did not sit well with the pre-existing graft, and 1 did not acquire a one-stent overlap, so a main body extension was added.

All 151 implanted Zenith Renu<sup>®</sup> AAA Ancillary Grafts were deployed successfully (i.e., successful delivery and deployment of the device and successful removal of the delivery system). However, in 2 cases with reported problems during deployment, the physician converted intra-operatively (described further in [Table 7](#)). In both cases of conversion, the ultimate reason for conversion to open repair was unrelated to the deployment of the device (i.e., rupture of aortic wall proximal to the Renu device, and proximal type I endoleak).

### *Endoleak*

Identification and typing of endoleaks has, historically, been very difficult to accurately perform. The Renu post-market surveillance registry is no exception. Pre-operative imaging was accepted as long as it was adequate for planning and sizing of the Renu. In many instances, however, this imaging was insufficient to appropriately identify and type pre-existing endoleaks prior to the operation (e.g., inadequate or non-existent contrast on the CT imaging). At each time point, independent analysis of available imaging was performed by an angiographic core lab (CCF, Cleveland OH) to identify endoleak. Table 4 lists the endoleaks (using best available information) either pre-operatively or during the procedure, and the number still present at each follow-up time period.

**Table 4. Incidence of reported endoleaks by type**

| Endoleak Type                           | Identified Pre-procedure or Intra-operatively       |         | Endoleaks Present at 1-month Follow-up <sup>1</sup>           |         | Endoleaks Present at 12-month Follow-up <sup>2</sup> |         | Endoleaks Present at 24-month Follow-up <sup>3</sup>            |         | Endoleaks Present at 36-month Follow-up <sup>4</sup> |         | Endoleaks Present at 48-month Follow-up <sup>5</sup> |        |
|---|---|---------|---|---------|--|---------|---|---------|--|---------|--|--------|
| Cases available for endoleak evaluation | 151   |         | 139   |         | 113  |         | 60  |         | 39   |         | 22   |        |
| Proximal Type I                         | 96  | (63.6%) | 2   | (1.4%)  | 1  | (0.9%)  | 3   | (5.0%)  | 2  | (5.1%)  | 2  | (9.1%) |
| Distal Type I                           | 9   | (6.0%)  | 0   | (0%)    | 1  | (0.9%)  | 1   | (1.7%)  | 1  | (2.6%)  | 1  | (4.5%) |
| Type II                                 | 17  | (11.3%) | 21  | (15.1%) | 20   | (17.7%) | 9   | (15.0%) | 4  | (10.3%) | 1  | (4.5%) |
| Type III                                | 10  | (6.6%)  | 2   | (1.4%)  | 2  | (1.8%)  | 3   | (5.0%)  | 1  | (2.6%)  | 1  | (4.5%) |
| Type IV                                 | 0   | (0%)    | 0   | (0%)    | 0  | (0%)    | 0   | (0%)    | 0  | (0%)    | 0  | (0%)   |
| Unspecified/Unknown Endoleak            | 4   | (2.6%)  | 2   | (1.4%)  | 1  | (0.9%)  | 1   | (1.7%)  | 1  | (2.6%)  | 0  | (0%)   |
| <b>Total</b>                            | <b>136 endoleaks (111 cases, 73.5%)<sup>6</sup></b> |         | <b>27 endoleaks<sup>7</sup> (26 cases, 18.7%)<sup>8</sup></b> |         | <b>25 endoleaks<sup>9</sup> (25 cases, 22.1%)</b>    |         | <b>17 endoleaks<sup>10</sup> (16 cases, 26.7%)<sup>11</sup></b> |         | <b>9 endoleaks<sup>12</sup> (9 cases, 23.1%)</b>     |         | <b>5 endoleaks<sup>13</sup> (5 cases, 22.7%)</b>     |        |

<sup>1</sup> Imaging performed 0-6 months after Renu implantation was assessed as 1-month follow-up.

<sup>2</sup> Imaging performed 7-18 months after Renu implantation was assessed as 12-month follow-up.

<sup>3</sup> Imaging performed 19-30 months after Renu implantation was assessed as 24-month follow-up.

<sup>4</sup> Imaging performed 31-42 months after Renu® implantation was assessed as 36-month follow-up.

<sup>5</sup> Imaging performed 43-54 months after Renu® implantation was assessed as 48-month follow-up.

<sup>6</sup> Twenty-one cases were identified with 2 endoleaks and 2 cases were identified with 3 endoleaks.

<sup>7</sup> Nineteen endoleaks (proximal type I: 1; type II: 14; type III: 2; unknown/unspecified: 2) were first identified at the 1-month follow-up period. Eight endoleaks (proximal type I: 1; type II: 7) persisted.

<sup>8</sup> One case had multiple endoleaks at the 1-month follow-up period.

<sup>9</sup> Thirteen endoleaks (distal type I: 1; type II: 9; type III: 2; unknown: 1) were first identified at the 12-month follow-up period.

<sup>10</sup> Eleven endoleaks (proximal type I: 2; distal type I: 1; type II: 4; type III: 3; unknown/unspecified: 1) were first identified at the 24-month follow-up period.

<sup>11</sup> One case had multiple endoleaks at the 24-month follow-up period.

<sup>12</sup> Four endoleaks (distal type I: 1; type II: 1; type III: 1; unknown/unspecified: 1) were first identified at the 36-month follow-up.

<sup>13</sup> Four endoleaks (proximal type I: 1; distal type I: 1; type II: 1; type III: 1) were first identified at the 48-month follow-up.

One hundred and eleven (111) cases were identified with endoleaks prior to or during the procedure. Of those cases with endoleak, 96 included proximal type I endoleaks. The vast majority of new endoleaks at follow-up have been identified as type II. It is likely many had been previously overlooked, misidentified, or masked by other existing endoleaks during review at earlier time periods.

### *Renu Migration*

Migration of Renu components is based upon core laboratory determination with independent Clinical Event Committee (CEC) adjudication. One case of Renu migration has been confirmed to date. For this case, a 32 mm diameter Renu converter was implanted to treat a migrating (> 10 mm) 28 mm diameter AneuRx® with proximal type I endoleak 36 months after AneuRx® implantation. No endoleaks have been identified following the procedure; however, migration > 10 mm was identified at follow-up (12 months) by the core laboratory and confirmed by the

CEC. The patient died of lung cancer 30 months following Renu implantation, which was adjudicated by the independent CEC as unrelated to the Renu. No new cases of CEC-confirmed migration have been reported.

*Renu Patency*

Patency of Renu components is based upon core laboratory determination. One occlusion has been identified at the 24-month time period. Preliminary contact with the site suggests that a secondary intervention (femoral-femoral bypass) has been performed to maintain blood flow to both legs; however, information regarding the reason for the occlusion and the details of the secondary intervention has not yet been provided within the Renu Post-Market Surveillance Registry.

*Renu Device Integrity*

Integrity of Renu components is based upon core laboratory determination. The core lab identified one case of component separation, which has since been converted (see [Conversion](#) for additional information).

In addition, one case of Renu kink and one case of Renu in-folding have been identified. No proximal type I endoleak, type III endoleak, or occlusion has been noted by the site or core lab for either of these cases.

*Morbidity*

Table 5 lists the incidence of adverse events reported within 30 days, categorized by organ system.

**Table 5. Incidence of adverse events within 30 days, by category**

| Category                                     | Intra-operative           | Adverse events reported within 30 days  |
|--|---------------------------|---|
| Cases available for adverse event evaluation | 151                       | 142 <sup>1</sup>                        |
| Cardiovascular                               | 0                         | 0                                       |
| Pulmonary                                    | 0                         | 1                                       |
| Renal  | 0                         | 2                                       |
| Bowel  | 0                         | 1                                       |
| Neurologic                                   | 0                         | 0                                       |
| Vascular                                     | 0                         | 3                                       |
| Wound  | 0                         | 2                                       |
| Other  | 0                         | 3 <sup>2</sup>                          |
| <b>Total</b>                                 | <b>0 events (0 cases)</b> | <b>12 events (11 cases)<sup>3</sup></b> |

<sup>1</sup> Seven cases reached an endpoint (death, conversion, and/or lost to follow-up) prior to providing follow-up.

<sup>2</sup> Spontaneous retroperitoneal hematoma (1), allergic reaction (1), and fall with subsequent pubic ramus fracture (1).

<sup>3</sup> One case was reported with both a renal event and an ‘other’ event (spontaneous retroperitoneal hematoma).

Fourteen additional adverse events (10 cases) have been reported after 30 days. In total, 26 adverse events have been reported for 21 different cases since initiation of this registry. All events underwent medical review and, if necessary, were adjudicated by the independent clinical events committee (CEC) to determine whether the event was related to the endovascular intervention. If related to the endovascular intervention, the CEC further determined if the event was procedure-related, technique-related, or device-related (Renu™ or pre-existing graft). Table 6 lists each specific adverse event.

**Table 6. Reported adverse events**

| Adverse event category | Months after procedure | Specific adverse event   |
|------------------------|------------------------|--|
| Vascular               | 0                      | Brachial artery pseudoaneurysm repair 2 days after Renu implantation   |
| Renal                  | 0                      | On 3-day follow-up form, a serum creatinine rise > 30% above baseline resulting in a persistent value > 2.0 mg/dL was reported   |
| Other                  | 0                      | Patient fell in a nursing facility with resultant pubic ramus fracture 18 days after Renu implantation   |
| Vascular               | 0                      | Right groin exploration with revision of fem-fem bypass graft completed 1 day post-op  |
| Vascular               | 1                      | On the first follow-up form (completed at 7 days), a limb occlusion and secondary intervention (implantation of stents) to treat the adverse event were reported   |
| Bowel                  | 1                      | Jaundice, biliary obstruction  |
| Wound                  | 1                      | Persistent drainage at the groin incision requiring surgical intervention  |
| Other, Renal           | 1                      | 1) Spontaneous retroperitoneal hematoma<br>2) Renal failure requiring temporary dialysis <sup>1</sup>  |
| Other                  | 1                      | Allergic reaction  |
| Wound                  | 1                      | Groin wound seroma requiring operative debridement and closure   |
| Pulmonary              | 1                      | Intubation for pneumonia <sup>2</sup>  |
| Other, Pulmonary       | 4                      | 1) Suspected graft infection with negative cultures was reported at day 124. <sup>3</sup> As a continuation to that event, the physician noted that the patient was admitted for CT-guided drainage of an abdominal abscess 7 months after Renu implantation<br>2) Pulmonary embolism reported 4 months after Renu™ implantation   |
| Pulmonary              | 5 <sup>4</sup>         | Pneumonia  |
| Cardio-vascular        | 12                     | Patient underwent coronary bypass grafting   |
| Other                  | 14                     | Hospitalization for prostate enlargement   |
| Bowel                  | 14                     | Fall with c-spine injury and abdominal perforated viscus unrelated to aneurysm   |
| Vascular               | 23                     | Type III endoleak of the thoracic aortic aneurysm stent requiring a bridging stent   |
| Other                  | 24                     | Bladder wall soft tissue densities concerning for malignancy   |
| Neurologic             | 36                     | Lumbosacral spine surgery for nerve root impingement and back pain   |
| Renal                  | 38                     | Renal insufficiency  |
| Vascular               | 45                     | Iliac artery rupture and dissection of thoracic aorta during secondary intervention for distal type I endoleak. Patient was converted to open surgical repair for abdominal aortic aneurysm and iliac artery rupture and two thoracic Talent endovascular grafts were implanted to treat dissection and thoracic aneurysm. Patient died 2 days after conversion (see <a href="#">Conversion, Mortality</a> ) |

| Adverse event category | Months after procedure | Specific adverse event   |
|------------------------|------------------------|--|
| Cardio-vascular        | 47                     | Patient admitted through ER for new onset of atrial fibrillation   |
| Cardio-vascular        | 49                     | Patient admitted through ER with worsening shortness of breath (acute or diastolic heart failure)                          |
| Cardio-vascular        | 53                     | Diastolic CHF exacerbation/atrial tachyarrhythmia/atrial fibrillation/mitral valve regurgitation requiring hospitalization |

<sup>1</sup> The patient had a pre-existing renal morbidity (pre-procedure creatinine levels of 4.0 mg/dL).

<sup>2</sup> Patient is receiving pulmonary toilet and antibiotics.

<sup>3</sup> One-month scan revealed sac shrinkage without CT evidence of graft infection.

<sup>4</sup> Pulmonary event originally reported as occurring 13 months after Renu implantation. Additional information submitted by the site verified that pneumonia occurred 5 months after Renu implantation.

No adverse events have been considered related to the Zenith Renu® AAA Ancillary Graft to date, although nine reported events for eight cases have been considered related to the procedure in which the Renu was placed. One case of iliac artery rupture following secondary intervention to treat a distal type I endoleak is pending adjudication by the CEC.

### Secondary Intervention

Table 7 lists secondary interventions reported by the sites.

**Table 7. Secondary Interventions**

| Time from Procedure (months) | Secondary Intervention Type   | Reason for Secondary Intervention                                  |
|------------------------------|---|--|
| 1                            | Placement of additional stent   | Limb occlusion on opposite side from Renu delivery                 |
| 10                           | Placement of additional iliac leg graft component   | Persistent distal type I endoleak                                  |
| 12                           | Coil embolization   | Persistent type II endoleak  |
| 22                           | Placement of Zenith iliac leg graft to cover the endoleak   | Persistent type III endoleak in the limb of the original endograft |
| 24 <sup>1</sup>              | Angioplasty with implantation of a Palmaz stent   | Proximal type I endoleak   |
| 25 <sup>2</sup>              | Coil embolization   | Persistent proximal type I endoleak                                |
| 29 <sup>2</sup>              | Placement of additional stent at neck   | Persistent proximal type I endoleak                                |
| 30                           | Placement of Renu converter, TFLE leg extension, and occluder plug with a fem-fem bypass  | Device migration <sup>3</sup> with persistent type III endoleak    |
| 34 <sup>1</sup>              | Percutaneous angioplasty  | Proximal type I endoleak   |
| 38                           | Zenith stent-graft placed within original graft   | Persistent type III endoleak                                       |
| 38                           | Proximal Renu cuff implanted  | Persistent type I endoleak   |
| 44                           | Implantation of Branched iliac endograft  | Iliac artery dilatation at attachment site                         |
| 45                           | Two iliac limbs attempted (AneuRx and Talent) in difficult anatomy, which caused iliac artery to rupture. Patient underwent conversion to open surgical repair (see <a href="#">Conversion</a> ). Two thoracic endografts (both Talent) were implanted. | Distal type I endoleak   |

<sup>1</sup> Angioplasty with implantation at 24 months and additional angioplasty at 34 months was performed on the same patient to treat proximal type I endoleak.

<sup>2</sup> Coil embolization at 25 months and placement of an additional stent at the neck were performed on the same patient to treat proximal type I endoleak. When these interventions were not successful, conversion to open surgical repair was performed successfully at 30 months (see [Conversion](#) for additional information).

<sup>3</sup> Reported by site as migration of the pre-existing graft.

All secondary interventions except one have been reported by the sites as successful to date. Given that the limb occlusion treated at 1 month occurred on the side opposite of Renu implantation, both distal type I endoleaks occurred in an iliac limb (distal to the Renu main body extension), one coil embolization at 12 months was due to a type II endoleak, and the type III endoleak treated at 22 months in the original endograft was between the main body of the pre-existing graft and the leg of the pre-existing graft (distal to the Renu main body extension), these five secondary interventions are considered unrelated to the Renu component. One case of iliac artery dilatation at the attachment site (44 months after implantation of a Renu converter and iliac leg extension) was successfully treated with a branched iliac endograft. Four of the five remaining cases of endoleak were resolved at the end of the secondary intervention procedure. One case at 38 months was reported by the site as related to the pre-existing graft, not the Renu device; however, the exact location of the type III endoleak was not specified. The secondary interventions for one persistent proximal type I endoleak were not successful; therefore, the patient was successfully converted to open surgical repair (see [Conversion](#) for additional information). Of note, these endoleaks were identified during routine follow-up, highlighting the need for continued follow-up to mitigate the risk of aneurysm expansion and rupture due to the presence of endoleak.

#### *Aneurysm Enlargement*

Aneurysm enlargement is based upon core laboratory determination. Nine cases of aneurysm enlargement (aneurysm growth > 5 mm) have been identified to date. Seven of these cases also have been identified with endoleak (4 type II, 1 distal type I and type II, and 2 type III). Of the 9 cases with aneurysm enlargement, 3 have decreased in size based on the latest available imaging relative to the time period at which aneurysm expansion was noted and 1 has increased in size (1 mm expansion).

#### *Aneurysm Rupture*

Four aneurysm ruptures following Renu implantation have been identified since registry initiation. Three of the four patients were converted to open surgical repair following aneurysm rupture. The patient that was not converted to open surgical repair had previously declined surgery to treat a type II endoleak with subsequent aneurysm expansion and died following the aneurysm rupture (see [Mortality](#) for additional information). Of the three that were converted to open surgical repair, one subsequently recovered (see [Conversion](#) for additional information) and the other two deceased intra-operatively or post-operatively (see [Mortality](#) for additional information).

*Conversion*

Eight conversions to open repair have been reported to date. Each conversion is listed in Table 8.

**Table 8. Conversions**

| Months after procedure | Reason for conversion   |
|------------------------|---|
| 0                      | Rupture of aortic wall proximal to aneurysm and Renu device   |
| 0                      | Leakage due to incomplete sealing/ persistent blood flow into the aneurysm from patent vessels (proximal type I endoleak)                                     |
| 3                      | Leakage due to incomplete sealing of the aneurysm (proximal type I endoleak) <sup>1</sup>   |
| 12                     | Leakage due to incomplete sealing of the aneurysm, inadequate sealing between the Renu main body extension and the AneuRx®, and aneurysm rupture <sup>2</sup> |
| 12                     | Inadequate sealing between the Renu main body extension and the AneuRx® graft, and aneurysm rupture <sup>2</sup>  |
| 16                     | Leakage due to migration of pre-existing graft (AneuRx®) and aneurysm rupture   |
| 19                     | Infection of the pre-existing graft (AneuRx®) <sup>3</sup>  |
| 30                     | Leakage due to incomplete sealing of the aneurysm (proximal type I endoleak)  |
| 45                     | Rupture of external iliac artery during secondary intervention to treat distal type I endoleak (distal to Renu main body extension)                           |

<sup>1</sup> Proximal type I endoleak identified intra-operatively, but not treated.

<sup>2</sup> Failure to properly follow the instructions, warnings, and precautions in the [Instructions for Use](#) may lead to serious consequences or injury to the patient.

<sup>3</sup> Core lab analysis of pre-Renu™ imaging noted stranded contrast that was potentially indicative of infection. An independent CEC adjudicated this case to be unrelated to the Renu endovascular repair.

Two intra-operative conversions and seven late (> 30 day) conversions have been reported. The intra-operative conversions to open repair were due to rupture of the aortic wall proximal to the Renu device (1) and proximal type I endoleak (1). The patient with aortic wall rupture did not survive the conversion (see [Mortality](#) for additional information). The late conversions were related to a suspected graft infection (1), persistent proximal type I endoleak (2), inadequate sealing between the Renu main body extension and the AneuRx® graft leading to component separation and aneurysm rupture (3), and rupture of the external iliac artery during secondary intervention to treat distal type I endoleak (1). In both conversions (1 intra-operative and 1 late) due to proximal type I endoleak identified intra-operatively, the physician chose not to use additional components (e.g., Palmaz® stent, main body extension, etc.) during the Renu implantation procedure to resolve the proximal type I endoleak. Both patients were considered candidates for open surgical repair by their implanting physicians, thus additional components may not have been implanted to avoid complicating the eventual conversion to open repair. In the third conversion due to proximal type I endoleak, the site identified the endoleak during the 24-month follow-up time period. Two unsuccessful attempts were made to treat the endoleak (i.e., coil embolization and additional stenting) prior to the successful conversion to open repair. In all three late conversions due to inadequate sealing between the Renu main body extension

and the AneuRx® graft with subsequent aneurysm rupture, physician peer review of pre-procedure imaging noted that a Renu converter would be a better treatment choice. Despite the physician’s recommendation, one patient requested the main body extension because it required a less extensive intervention than the converter; however, the recommended overlap with the pre-existing graft was not achieved following Renu deployment. Subsequently, the pre-existing graft separated from the Renu (by 12 months), the patient declined an intervention to treat the separation, the aneurysm ruptured, and the patient was successfully converted to open surgical repair. The other two patients with aneurysm rupture died following the conversion (see [Mortality](#) for additional information). In the case of late conversion performed due to rupture of the external iliac artery during secondary intervention to treat a persistent distal type I endoleak, attempts to advance iliac limbs (AneuRx and Talent graft implantations were attempted) past a hairpin turn resulted in rupture of the iliac artery. The patient underwent conversion to open surgical repair, requiring aortic cross-clamping. Dissection of the aorta occurred a few centimeters above the celiac artery, possibly due to aortic cross-clamping or ballooning. Two thoracic endografts (Talent) were implanted. The patient left the operating room in stable condition with well-perfused limbs, but died two days following the secondary intervention due to cardiopulmonary arrest, respiratory failure, and renal failure. This event is pending adjudication by the CEC.

*Mortality*

Table 9 summarizes the 44 deaths that have been reported to date, along with the results from CEC adjudication of each death.

**Table 9. Deaths**

| Months after procedure | Age at registration | Cause of death  | CEC adjudication                        |
|------------------------|---------------------|---|---|
| 0                      | 82                  | Intra-operative rupture of aorta proximal to aneurysm and Renu device with subsequent conversion <sup>1</sup> | Procedure-related and technique-related |
| 1                      | 90 <sup>2</sup>     | Low platelet count, hematological complications <sup>3</sup>  | Procedure-related                       |
| 1                      | 78                  | Congestive heart failure 35 days post-procedure   | Not related <sup>4</sup>                |
| 2                      | 79                  | Wegener’s granulomatosis <sup>5</sup>   | Not related                             |
| 3                      | 80                  | Cardiopulmonary failure <sup>6</sup>  | Cause unable to be determined           |
| 4                      | 83                  | Direct cause of death not available to reporting institution <sup>7</sup>                                     | Not related                             |
| 7                      | 90 <sup>2</sup>     | Failure to thrive/old age   | Not related                             |
| 10                     | 73                  | Cardiorespiratory arrest secondary to hypotension and sepsis  | Procedure-related and technique-related |
| 10                     | 79                  | Myocardial infarction <sup>8</sup>  | Cause unable to be determined           |
| 11                     | 69                  | Recurrent cholangiocarcinoma  | Not related                             |
| 12                     | 77                  | Unknown, information unable to be obtained by reporting institution <sup>9</sup>                              | Not related                             |

| Months after procedure | Age at registration | Cause of death  | CEC adjudication                         |
|------------------------|---------------------|---|--|
| 12                     | 80                  | Metastatic lung cancer  | Not related                              |
| 12                     | 81                  | Multi-system organ failure following aortic aneurysm rupture and subsequent emergent conversion <sup>10</sup> | Renu-related                             |
| 13                     | 82                  | Cancer  | Not related                              |
| 14                     | 69                  | Pneumonia with fever and septic shock   | Not related                              |
| 16                     | 76                  | Cardiac arrest following aneurysm rupture and emergent conversion to open repair <sup>11</sup>                | Renu-related                             |
| 17                     | 77                  | Pulmonary emboli secondary to malignancy  | Not related                              |
| 17                     | 65                  | Cancer  | Not related                              |
| 18                     | 80                  | Paralysis secondary to cervical fracture from fall. Renal failure.  | Not related                              |
| 19                     | 75                  | Ventricular fibrillation, ischemic cardiomyopathy, and GI bleed   | Not related                              |
| 20                     | 73                  | Congestive heart failure and respiratory failure secondary to congestive heart failure                        | Not related                              |
| 20                     | 79                  | Pulmonary   | Not related                              |
| 21                     | 81                  | Complications from pneumonia and organ failure  | Not related                              |
| 21                     | 76                  | Heart attack  | Not related                              |
| 23                     | 85                  | Unknown, but believed by site to be unrelated to the Renu   | Cause unable to be determined            |
| 24                     | Not provided        | Unknown <sup>12</sup>   | Cause unable to be determined            |
| 27                     | 75                  | Unrelated to aneurysm, patient died at home <sup>13</sup>   | Cause unable to be determined            |
| 28                     | 67                  | Cardiac issues related to CHF   | Not related                              |
| 29                     | 82                  | Cancer  | Not related                              |
| 30                     | 69                  | Lung cancer   | Not related                              |
| 30                     | 78                  | Ruptured AAA after patient refused to return for repair of type II endoleak with aneurysm expansion           | Pre-existing graft-related <sup>14</sup> |
| 33                     | 84                  | Cardiopulmonary arrest  | Not related                              |
| 36                     | 67                  | Cancer  | Not related                              |
| 36                     | 61                  | Unknown <sup>15</sup>   | Cause unable to be determined            |
| 36                     | 71                  | CVA, respiratory failure, cancer 2008   | Not related                              |
| 36                     | 74                  | Cardiac causes  | Not related                              |
| 36                     | 77                  | Respiratory/cardiac arrest  | Not related                              |
| 36                     | 90 <sup>2</sup>     | Unknown <sup>16</sup>   | Cause unable to be determined            |
| 37                     | 82                  | Unknown – notification came from primary care physician   | Cause unable to be determined            |
| 40                     | 79                  | Cardiogenic shock following hip repair of femoral neck fracture   | Not related                              |
| 40                     | 90 <sup>2</sup>     | Respiratory failure   | Not related                              |
| 45                     | 78                  | Cardiopulmonary arrest, respiratory failure, renal failure 2 days after secondary intervention <sup>17</sup>  | Pending                                  |
| 48                     | 72                  | Urinary bacteremia, prostate cancer, MRSA   | Not related                              |
| Unknown                | 76                  | Unknown <sup>18</sup>   | Cause unable to be determined            |

<sup>1</sup> The patient failed to recover from conversion to open surgical repair, which was performed to treat a rupture of the aorta proximal to the Renu device. The aorta was ruptured by a spicule of calcium after Renu deployment, either during deployment of a Palmaz stent or ballooning of the Renu™ device.

<sup>2</sup> To comply with HIPAA regulations, the age of any patient ≥ 90 years old was recorded and reported as 90 years.

<sup>3</sup> The patient was admitted with a low platelet count and an AneuRx® with a proximal type I endoleak. The patient's aneurysm ruptured prior to the scheduled Renu™ implantation date, but was able to be treated emergently with the Renu™ converter.

<sup>4</sup> Previously reported as procedure-related; however, upon additional review of this event, the CEC adjudicated it to be unrelated to endovascular repair.

<sup>5</sup> Wegener's granulomatosis was reported to be a pre-existing comorbidity identified after the procedure in which the Zenith Renu<sup>®</sup> AAA Ancillary Graft was implanted.

<sup>6</sup> Exact cause of death was unknown. The family described the death as related to cardiopulmonary failure; the patient had a documented 10-year history of severe cardiopulmonary disease.

<sup>7</sup> Patient was undergoing evaluation for neuromuscular degeneration. Per institution, there was no indication that death was related to the aneurysm or the endograft.

<sup>8</sup> The patient died after an MI; however, the CEC was unable to adjudicate the death because the patient passed away at home and an autopsy was not performed.

<sup>9</sup> Cause of death was unknown. Per the reporting institution, an autopsy was performed and the death was related to a pre-existing comorbidity. Based on the available information, the CEC determined the death to be unrelated to the endovascular repair.

<sup>10</sup> Rupture with emergent conversion was secondary to separation of the Renu main body extension from the pre-existing AneuRx<sup>®</sup> graft. A Renu<sup>™</sup> converter had been recommended prior to the procedure.

<sup>11</sup> Rupture with emergent conversion was secondary to migration of the AneuRx<sup>®</sup> graft with subsequent type III endoleak. A Renu converter had been recommended prior to the procedure.

<sup>12</sup> Cause of death was unknown. Per the reporting institution, the death was reported to the physician by the family. The CEC was unable to adjudicate the death based on the information provided.

<sup>13</sup> The site noted this death to be unrelated to the aneurysm; however, the CEC was unable to adjudicate the death without confirmation that the site obtained the information from a death certificate or an autopsy was performed.

<sup>14</sup> CEC adjudicated death as related to endovascular intervention, but related to the pre-existing graft, not the Renu.

<sup>15</sup> Cause of death was unknown. Per the reporting institution, the death was related to a pre-existing comorbidity and the graft was fine 2 months prior to death.

<sup>16</sup> Cause of death was unknown. Per the reporting institution, a family member had called the office with the date of death, but the cause was unknown. The site noted that the patient was being treated for cancer.

<sup>17</sup> Secondary intervention was to treat distal type I endoleak. Iliac artery rupture during advancement of additional iliac limbs led to conversion to open surgical repair. Patient died 2 days following intervention/conversion.

<sup>18</sup> Cause of death was unknown. Per the reporting institution, information was not available about cause of death or time of death with respect to Renu implantation. The last contact the site had with the patient was at 1-month follow-up.

One intra-operative, one early ( $\leq 30$ -day), and 42 late ( $> 30$ -day) deaths have been reported. One intra-operative, endovascular intervention-related death occurred after the patient failed to recover from conversion to open repair following rupture of the aorta proximal to the Renu device. One early death occurred approximately 2 weeks after the initial procedure, where the patient died from a low platelet count and hematological complications. Of note, the patient was treated emergently with the Renu after being admitted with a low platelet count and after aneurysm rupture. This event was determined to be procedure-related.

Death beyond 30 days of the initial procedure occurred in 42 cases. Twenty-eight cases were determined to be unrelated to endovascular repair. Of the 14 remaining cases, 4 have been adjudicated as related to endovascular repair (i.e., procedure, technique, pre-existing graft and/or Renu-related), 9 are unable to be adjudicated due to insufficient information from the site (no additional information is able to be collected), and 1 is still pending review by the CEC. In one of the endovascular repair-related cases, death occurred 10 months after implantation and the cause was reported to be cardiorespiratory arrest secondary to hypotension and sepsis (procedure-related and technique-related). The second of the endovascular repair-related deaths (Renu-related) occurred prior to the 12-month follow-up exam. Anatomical changes in the patient over time contributed to device separation of the pre-existing graft from the Renu main body extension, leading to an eventual aneurysm rupture. The patient was subsequently converted to open surgical repair, but died post-operatively due to multi-system organ failure.

The third endovascular repair-related deaths (Renu-related and technique-related) occurred 16 months after implantation. Although 12-month follow-up form was not completed, 12-month imaging was provided. Core lab analysis of the 12-month imaging indicated component separation of the right leg component; however, a definitive type III endoleak was unable to be confirmed since non-contrast imaging was not provided. At 16 months, the physician noted that AneuRx<sup>®</sup> migration led to type III endoleak and rupture. The patient was emergently converted to open surgical repair, but did not survive the conversion. The last of the endovascular repair-related deaths occurred 30 months after implantation. Approximately 10 months prior to Renu implantation (19 months after implantation of the pre-existing graft), the patient had undergone coil embolization to treat a type II endoleak; however, the type II endoleak persisted based on either site or core lab analysis through 12 months with aneurysm expansion at 12 months. The physician discussed the need for additional intervention with the patient; however, the patient declined the surgery and died from aneurysm rupture 30 months following Renu implantation. The death was considered related to the pre-existing graft and not the Renu graft.

None of the CEC-adjudicated deaths were related to deployment of the Zenith Renu<sup>®</sup> AAA Ancillary Graft or Renu integrity. None of the endovascular repair-related deaths were unanticipated since they were noted as possibilities in the [Instructions for Use](#) of this device.

### *Summary*

In summary, the post-market surveillance registry provides important information about physician experience during treatment of pre-existing grafts with the Zenith Renu<sup>®</sup> AAA Ancillary Graft. The majority (83.4%, 126/151) of the grafts treated with the Zenith Renu<sup>®</sup> AAA Ancillary Graft were AneuRx<sup>®</sup> grafts. However, Ancure<sup>®</sup>, Excluder<sup>®</sup>, Fortron<sup>™</sup>, LifePath<sup>™</sup>, Talent<sup>™</sup>, Vanguard<sup>™</sup>, and Zenith<sup>®</sup> endovascular grafts have also been treated for proximal fixation and/or seal failure.

Proximal type I endoleaks were identified as one of the primary failure modes for pre-existing grafts, with 96 being identified pre-operatively or during the procedure. Of the proximal type I endoleaks reported, 99% (95/96) resolved without further intervention following Renu implantation, 1 persisted through 1-month follow-up and was converted to open surgical repair.

Nine adverse events, one intra-operative and two late conversions with subsequent death, 4 additional conversions (1 intra-operative, 3 late), and 3 additional deaths related to the procedure, technique, and/or Zenith Renu<sup>®</sup> AAA Ancillary Graft have been reported since registry initiation. One case of death following late conversion is pending CEC adjudication. Of note, no unanticipated adverse events have occurred to date (all procedure-related or device-related adverse events, deaths, and conversions were noted as possibilities in the [Instructions for Use](#) for this device).

Of the 151 registered cases of Renu implantation, 89.4% (135/151) have had no procedure or device-related adverse events, conversions, or deaths. These mid-term post-market registry data confirm that the Renu device may be used during secondary intervention to successfully treat proximal fixation failures.