APPENDIX B

ANCURE® ENDOGRAFT® System
Instructions for Use

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ANCURE® ENDOGRAFT® System

ESSENTIAL PRESCRIBING INFORMATION (EPI) and OPERATOR'S INSTRUCTIONS FOR USE

Warning:	Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.

Caution:	Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner) trained in vascular interventional techniques and in the use of this device.

PPL18435 Rev. A 3/06

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1. DEVICE DESCRIPTION

The Guidant ANCURE® ENDOGRAFT® System (ANCURE System) consists of the ANCURE ENDOGRAFT Vascular Graft (graft) and the ANCURE Delivery Catheter. The ANCURE System is available in tube, bifurcated, and aortoiliac configurations.

The ANCURE graft is a woven PET polyester vascular graft with attachment systems affixed to the ends. Each attachment system consists of angled metal attachment hooks and a self-expanding cylindrical metal frame. The attachment systems create an anastomosis between the graft and the vessel wall. Radiopaque markers in the trunk and limbs assist with the visualization under fluoroscopy. The attachment systems and radiopaque markers are made from metallic alloys. Sizing information is provided in Section 7.3. See Section 9 for labeled device figures.

2. INDICATIONS

The ANCURE Tube System is indicated for the endovascular treatment of infrarenal abdominal aortic aneurysms (AAA) in patients having:

- adequate iliac/femoral access,
- infrarenal non-aneurysmal neck length of at least 15 mm and a diameter of no greater than 26 mm,
- distal segment neck length of 12 mm and diameter of no greater than 26 mm, and
- morphology suitable for endovascular repair.

The ANCURE Bifurcated System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms in patients having:

- adequate iliac/femoral access,
- infrarenal non-aneurysmal neck length of at least 15 mm and a diameter of no greater than 26 mm,
- distal segment lengths of at least 20 mm and diameters no greater than 13.4 mm, and
- morphology suitable for endovascular repair.

The ANCURE Aortoiliac System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms in patients whose anatomy does not allow the use of a tube or bifurcated device and having:

- adequate iliac/femoral access,
- infrarenal non-aneurysmal neck length of at least 15 mm and a diameter of no greater than 26 mm,
- one distal segment length of at least 20 mm and diameters no greater than 13.4 mm, and
- morphology suitable for endovascular repair.

3. CONTRAINDICATIONS

There are no identified contraindications for these devices.

4. WARNINGS AND PRECAUTIONS

GENERAL

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.
- The ANCURE System should only be used by physicians and teams who are trained in vascular interventional techniques, and who have successfully completed the Guidant Physician Training Program in the use of the ANCURE System. Specific training expectations are described in Section 11.1.
- DO NOT use the ANCURE System in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies as described in Section 11.
- DO NOT use the ANCURE System in patients with a known sensitivity or allergy to the device materials (PET polyester, silicone treated polyester sutures, platinum, cobalt, chromium, and nickel).
- The long-term performance of the graft has not been established. Patients should be regularly monitored for perigraft flow and aneurysm growth.
- The safety and effectiveness of the ANCURE System has not been studied in pregnant women or in persons under 21 years of age.
- The safety and effectiveness of the ANCURE System for the treatment of AAA has not been studied in patients with inflammatory aneurysms, in patients that have an active systemic infection, in patients with impending aneurysm rupture, in patients with a ruptured or leaking aneurysm, in patients whose aneurysm etiology was other than degenerative/atherosclerosis, in patients who have non-iatrogenic bleeding diatheses, or in patients with infrarenal necks <15 mm in length.
- The safety and effectiveness of a stent within a graft has not been established.
- The safety and effectiveness of an access conduit, and secondary graft placement within the initial graft has not been established.
- The safety and effectiveness of any user modifications of the graft have not been established.
- The aortoiliac device should be used in patients whose anatomy does not allow the use of a tube or bifurcated device.
- After implantation of an aortoiliac graft, reduced blood flow through the single graft limb may lead to serious impairment of blood perfusion to the lower half of the body. The implanting physician must emphasize to the patient that graft occlusion can have life threatening consequences. The patient should be counseled to seek medical attention immediately if he/she experiences pain in both legs, or if both legs become pale and/or cool.

- Lack of blood flow in the aortoiliac graft may lead to thrombosis with serious perfusion problems. To minimize the amount of time when there is little or no outflow of the aortoiliac graft, consider performing the femoro-femoral bypass prior to insertion of the aortoiliac system.

PATIENT SELECTION, TREATMENT, AND FOLLOW-UP

- Narrow, calcified, and/or tortuous vessels may make delivery catheter insertion, and/or removal, and/or jacket retraction, and/or endograft implantation difficult.
- Tortuous and narrow vessels may impede blood flow through the graft limbs.
- The results of the clinical studies indicate that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to standard surgical repair are likely to have increased complications arising from both procedures (i.e., arterial trauma, renal insufficiency, bleeding).
- The results of the clinical studies indicate that women treated with the ANCURE System are at an increased risk of conversion to standard surgical repair.
- Intervention or conversion to standard surgical repair following endovascular repair should be considered for patients experiencing an increase in the size of their AAA and/ or endoleak. An increase in aneurysm size, and/or endoleak may lead to aneurysm rupture.
- Use of the ANCURE System should be carefully evaluated in patients with a contraindication to standard surgery.
- Always have a vascular surgery team available in the event that conversion to standard surgical repair is necessary.
- The use of the ANCURE System requires administration of radiographic agents. The results of clinical studies indicated that patients with preexisting renal insufficiency had an increased risk of renal failure postoperatively.
- Proper use of the ANCURE System requires accurate fluoroscopic imaging. The ANCURE System is not recommended for patients whose weight exceeds 350 lbs. (150 kg) or whose weight may impede accurate fluoroscopic imaging.
- Factors including, but not limited to, severe angulation, circumferential calcification, or thrombus, may cause or contribute to inadequate fixation or hemostatic seal of the graft.
- The results of the clinical studies indicate that subjects experiencing reduced blood flow through the graft limbs may be required to undergo secondary interventions or minor surgical procedures to restore limb patency.
- All patients should be monitored closely and checked periodically for increase in the size of their AAA or occlusion of blood vessels. Patients who experience perigraft flow should undergo imaging studies more frequently.
- Systemic anticoagulation must be achieved once the arterial vasculature has been accessed. If heparin is contraindicated, an alternative anticoagulant must be used.

STORAGE AND HANDLING

- The ANCURE System is intended for single use only. DO NOT reuse. Use the catheter prior to the "Use Before" date specified on the package.
- Never attempt to re-sterilize the ANCURE System. Re-sterilization may adversely affect the proper mechanical function of the system and could result in patient injury and/or conversion to a standard surgical repair.
- Always inspect the ANCURE System and packaging to verify that no damage has occurred as a result of shipping and that the sterile barrier has not been compromised. If damage occurs, return the ANCURE System to Guidant.

MRI SAFETY

- Although the graft is MRI safe up to 1.5 Tesla static magnetic field at 540 G/cm field gradient, it may cause minimal artifacts in MRI scans due to distortion of the magnetic field.

IMPLANT PROCEDURE

- The access site (left or right) must be pre-determined for the variable limb length graft. Always use the side with the longest iliac attachment site as the access site to ensure proper order of deployment for the long and short limbs of the graft. Failure to observe this precaution may lead to improper sizing of the graft, possibly resulting in the need for additional medical intervention, including a conversion to standard surgical repair.
- Difficulties with delivery catheter removal may be encountered more frequently in patients that require grafts with variable limb lengths.
- Always use fluoroscopy for guidance and observation of the ANCURE System within the vasculature.
- ANCURE System implantation should be performed in an operating room or similar sterile environment with appropriate personnel, and fluoroscopic imaging equipment.
- Systemic anticoagulation must be achieved once the arterial vasculature has been accessed. If heparin is contraindicated, an alternative anticoagulant must be used.
- DO NOT use excessive force to advance or withdraw the delivery catheter when resistance is encountered, as this may damage the vessel or catheter.
- Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels to avoid vessel injury.
- DO NOT deploy the graft in a location that may occlude arteries necessary to supply blood flow to organs or extremities (e.g., a single, patent internal iliac or mesenteric artery); perfusion through at least one internal iliac artery should be maintained.
- After jacket retraction, the hooks on the superior attachment system and the superior capsule edge are exposed. The attachment system frame is not deployed. At this point care must be exercised while advancing or retracting the delivery catheter to avoid arterial trauma.
- After deployment of the superior attachment system hooks, the graft can only be removed in an open surgical procedure.
- DO NOT rotate, advance, or retract the catheter while the aortic balloon is inflated. DO NOT over-inflate the aortic or iliac balloons.
- DO NOT continue to pull the balloon grip if resistance is felt and the inferior (TUBE) / ipsilateral (BIFURCATED / AORTOILIAC) attachment system has not been deployed. This may prevent deployment of the inferior/ipsilateral attachment system.

- Inflating/deflating the aortic balloon is similar to placing/removing a cross clamp. The patient may experience a significant change in arterial pressure.
- Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

5. ADVERSE EVENTS

5.1. Observed Adverse Events

A total of 653 patients were enrolled in the EGS clinical study (153 tube, 268 bifurcated, 121 aortoiliac, and 111 control), and a total of 349 patients were enrolled in the ANCURE clinical study (44 tube and 305 bifurcated). Both trials provide the basis for the observed event rates. Adverse event data are summarized in Tables 1 and 2.

In the EGS clinical study, the operative mortality rate was less than five percent in all treatment groups (0.0% tube, 2.6% bifurcated, 4.2% aortoiliac and 2.7% control subjects). For the bifurcated subjects, five of the seven deaths occurred early in the investigators' experience and two of the deaths occurred in subjects who required an intraoperative conversion. One bifurcated subject died of myocardial infarction following a second unrelated surgery for cancer. There were no deaths among the tube subjects. In the aortoiliac studies, five operative deaths occurred. One subject expired intraoperatively, three patients expired prior to discharge (one had been converted to standard AAA repair) and one patient expired after hospital discharge. Three control patients died in the operative period.

In the ANCURE clinical study, the operative mortality rate was 1.0%. Three ANCURE bifurcated subjects expired in the early postoperative period. One of these three patients died from a myocardial infarction on post-operative day two. Another, who required an intraoperative conversion, died from cardiovascular collapse on the sixth postoperative day. The third, who required an intraoperative conversion, died from multisystem organ failure on the sixth postoperative day. There were no operative deaths among the ANCURE tube subjects.

Table 1. Adverse Events ≤ 30 days (Listed Alphabetically)

Event	Tube ANCURE %	Tube ANCURE (n/N)	Bifurcated ANCURE %	Bifurcated ANCURE (n/N)	Tube EGS %	Tube EGS (n/N)	Bifurcated EGS %	Bifurcated EGS (n/N)	Aortoiliac EGS[1] %	Aortoiliac EGS[1] (n/N)	Control[2] %	Control[2] (n/N)
Deaths – Operative	0.0%	(0/44)	1.0%	(3/305)	0.0%	(0/153)	2.6%	(7/268)	4.2%	(5/118)	2.7%	(3/111)
Other Adverse Events												
Arterial Trauma[3]	6.8%	(3/44)	10.2%	(31/305)	7.2%	(11/153)	16.0%	(43/268)[3]	9.3%	(11/118)	0.0%	(0/111)
Bleeding	6.8%	(3/44)	20.7%	(63/305)	8.5%	(13/153)	15.7%	(42/268)	15.3%	(18/118)	39.6%	(44/111)
Bowel	2.3%	(1/44)	0.3%	(1/305)	5.2%	(8/153)	3.0%	(8/268)	5.9%	(7/118)	8.1%	(9/111)
Cardiac	4.5%	(2/44)	6.6%	(20/305)	10.5%	(16/153)	13.4%	(36/268)	22.0%	(26/118)	20.7%	(23/111)
Coagulopathy	2.3%	(1/44)	1.0%	(3/305)	0.7%	(1/153)	3.0%	(8/268)	1.7%	(2/118)	4.5%	(5/111)
Conversions[4] / Cases Aborted	6.8%	(3/44)	5.2%	(16/305)	7.8%	(12/153)	9.7%	(26/268)	5.8%	(7/121)	N/A	
Deep Vein Thrombosis	0.0%	(0/44)	0.7%	(2/305)	0.7%	(1/153)	1.1%	(3/268)	1.7%	(2/118)	0.9%	(1/111)
Embolism – Lower Extremity Ischemia	4.5%	(2/44)	5.2%	(16/305)	3.9%	(6/153)	3.0%	(8/268)	1.7%	(2/118)	0.9%	(1/111)
Hematoma	4.5%	(2/44)	4.9%	(15/305)	10.5%	(16/153)	9.3%	(25/268)	8.5%	(10/118)	1.8%	(2/111)
Impotence	0.0%	(0/44)	0.0%	(0/305)	0.0%	(0/153)	0.0%	(0/268)	0.0%	(0/118)	1.8%	(2/111)
Paraplegia/ Paraparesis	0.0%	(0/44)	0.0%	(0/305)	0.0%	(0/153)	0.4%	(1/268)	0.8%	(1/118)	0.0%	(0/111)
Perigraft Flow[5, 7], Discharge	17.1%	(7/41)	27.3%	(78/286)	44.4%	(60/135)	48.4%	(106/219)	51.8%	(58/112)	N/A	
Prosthetic Thrombosis	0.0%	(0/44)	3.3%	(10/305)	0.0%	(0/153)	2.6%	(7/268)	1.7%	(2/118)	0.0%	(0/111)
Reduced Limb Flow[6, 7]	N/A		37.2%	(108/290)	N/A		31.8%	(77/242)	28.3%	(32/113)	N/A	
Renal Insufficiency	2.3%	(1/44)	3.0%	(9/305)	3.3%	(5/153)	8.2%	(22/268)	6.8%	(8/118)	1.8%	(2/111)
Respiratory	0.0%	(0/44)	1.0%	(3/305)	7.2%	(11/153)	10.1%	(27/268)	11.9%	(14/118)	22.5%	(25/111)
Stroke	0.0%	(0/44)	1.0%	(3/305)	0.0%	(0/153)	0.7%	(2/268)	0.8%	(1/118)	0.9%	(1/111)
TIA	2.3%	(1/44)	0.3%	(1/305)	0.7%	(1/153)	0.7%	(2/268)	0.8%	(1/118)	0.0%	(0/111)
Wound	0.0%	(0/44)	6.6%	(20/305)	5.2%	(8/153)	3.4%	(9/268)	7.6%	(9/118)	1.8%	(2/111)

1. Of the total 121 aortoiliac subjects, three discontinued their participation at discharge and were alive at that time. These subjects are included in the analysis only through surgical implantation.
2. 94 of the Control subjects received tube grafts and 17 bifurcated grafts.
3. One bifurcated EGS arterial trauma resulted in limb amputation.
4. Three aortoiliac subjects had their treatment abandoned without conversion to open repair.
5. For EGS patients, Perigraft Flow was evaluated by an independent core laboratory. For Ancure patients, Perigraft Flow was evaluated by the investigators.
6. One Ancure patient with reduced limb flow underwent amputation of a 5th toe.
7. The analyses included only implanted patients.

Table 2. Adverse Event Rates at 12 months[1] (Listed Alphabetically)

Event	Tube Ancure (%)	Bifurcated Ancure (%)	Tube EGS (%)	Bifurcated EGS (%)	Aortoiliac EGS (%)	Control[2] (%)
Deaths	2.4%	8.2%	6.0%	7.1%	11.9%	5.4%
Other Adverse Events						
Arterial Trauma	9.2%	10.2%	7.2%	16.1%	10.2%	1.0%
Bleeding	6.8%	21.0%	8.5%	15.7%	16.1%	39.6%
Bowel	4.7%	1.4%	5.9%	3.0%	6.8%	11.0%
Cardiac	12.0%	12.5%	16.5%	22.3%	38.1%	24.6%
Graft Migration[3]	0.0%	0.0%	0.7%	0.4%	0.0%	N/A
Perigraft Flow[3]	8.8%	26.1%	25.0%	31.3%	33.0%	N/A
Renal Insufficiency	7.1%	4.0%	4.7%	10.6%	8.5%	1.8%
Respiratory	2.6%	4.5%	9.9%	16.3%	19.5%	24.3%
Wound	0.0%	6.9%	5.9%	3.8%	9.3%	1.9%

1. Event rates are cumulative and are based on Kaplan Meier methodology
2. 94 of the Control subjects received tube grafts and 17 received bifurcated grafts.
3. These events were assessed at discrete time points (discharge, 6 mos., 12 mos.) therefore Kaplan Meier estimates of the rates were not performed. For EGS patients, Perigraft Flow was evaluated by an independent core laboratory. For Ancure patients, Perigraft Flow was evaluated by the investigators.

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5.2. Potential Adverse Events

The following adverse events (in alphabetical order) may be associated with endovascular AAA repair:

Table 3. Potential Adverse Events

Acute myocardial infarction	Hematoma
Amputation	Hypotension/Hypertension
Anastomotic false aneurysm	Impotence
Aneurysm rupture	Infection
Arrhythmias	Infection and pain at insertion site
Arterial trauma/dissection	Lymphatic complications
Attachment system fractures	Paraplegia/paraparesis
Bleeding, requiring transfusion	Perforation
Bowel ischemia/bowel obstruction/adynamic ileus	Perigraft flow
Claudication	Prosthesis extrusion/erosion
Coagulopathy	Prosthetic infection
Congestive heart failure	Pulmonary embolism
Conversion to standard AAA surgery	Reduced limb flow
Death	Renal insufficiency/failure
Deep vein thrombosis	Respiratory failure/atelectasis/pneumonia
Drug reactions to antiplatelet agents/contrast medium	Spasm
Emboli, distal (air, tissue or thrombotic emboli)	Stroke/cerebrovascular event
Femorofemoral thrombosis	Thrombosis/occlusion of graft
Fistula (aortoenteric, aortocaval)	TIA
Graft dilatation	Wound dehiscence
Graft migration	

6. CLINICAL SUMMARY

Two clinical studies were conducted. In the first study, referred to as the EGS clinical study, a total of 20 centers participated in the Tube EGS protocol, 18 centers in the Bifurcated EGS protocol, and 15 in the Aortoiliac EGS protocol. All used a first generation delivery catheter. This prospective, multi-center, non-randomized clinical study compared patients treated with the tube, bifurcated, and aortoiliac EGS Systems to a concurrent control group.

The second clinical study, referred to as the ANCURE clinical study, was conducted at 21 investigational sites, using a second generation delivery catheter. This prospective, multi-center, non-randomized clinical study compared patients treated with the tube and bifurcated ANCURE Systems to the EGS System.

Vascular surgeons as well as an interventional radiologist served as principal investigators in the clinical studies. When the procedure was performed by the interventional radiologist, a vascular surgeon performed the cutdown and closure and was available during the procedure in the event that conversion to standard surgical repair was necessary.

6.1. Patients Studied

Table 4. Demographics

Variable	Tube ANCURE (N=44) n	%	Bifurcated ANCURE (N=305) n	%	Tube EGS (N=153) n	%	Bifurcated EGS (N=268) n	%	Aortoiliac EGS (N=121) n	%	Control (N=111)[1] n	%
Male	36	(81.8%)	284	(93.4%)[2]	131	(85.6%)	240	(89.6%)	112	(92.6%)	85	(76.6%)
Age (yrs) Mean ±SD	72.9 ± 8.8		72.8 ± 7.8		73.8 ± 7.1		72.7 ± 7.7		73.2 ± 7.1		71.6 ± 7.0	
Race (Caucasian)	43	(97.7%)	295	(97.0%)[2]	145	(94.8%)	254	(94.8%)	113	(93.4%)	108	(97.3%)
CAD	22	(50.0%)	160	(52.5%)	85	(55.6%)	165	(61.6%)	79	(65.3%)	68	(61.3%)
MI	16	(36.4%)	95	(31.2%)	45	(29.4%)	105	(39.2%)	56	(46.3%)	43	(38.7%)
Arrhythmia[3]	23	(52.3%)	155	(50.8%)	40	(26.1%)	89	(33.2%)	45	(37.8%)	21	(18.9%)
c/alvular Heart Disease	6	(13.6%)	40	(13.1%)	20	(13.1%)	32	(11.9%)	14	(11.6%)	10	(9.0%)
CHF	4	(9.1%)	29	(9.5%)	18	(11.8%)	35	(13.1%)	21	(17.4%)	8	(7.2%)
Stroke	5	(11.4%)	16	(5.3%)	24	(15.7%)	34	(12.7%)	11	(9.1%)	13	(11.7%)
Hypertension	35	(79.6%)	196	(64.3%)	91	(59.5%)	166	(61.9%)	76	(62.8%)	79	(71.2%)
PAOD	3	(6.8%)	22	(7.2%)	16	(10.5%)	37	(13.8%)	31	(25.6%)	12	(10.8%)
COPD	7	(15.9%)	71	(23.3%)	43	(28.1%)	77	(28.7%)	48	(39.7%)	33	(29.7%)
Smoking[4]	32	(72.7%)	253	(83.0%)	117	(76.5%)	217	(81.0%)	109	(90.8%)	100	(90.1%)
Diabetes	6	(13.6%)	32	(10.5%)	18	(11.8%)	32	(11.9%)	15	(12.4%)	11	(9.9%)
Anesthesia Risk												
I	0	(0.0%)	1	(0.3%)	0	(0.0%)	1	(0.4%)	0	(0.0%)	1	(0.9%)
II	5	(11.4%)	26	(8.5%)	27	(17.9%)	36	(13.5%)	16	(13.2%)	14	(12.6%)
III	34	(77.3%)	217	(71.2%)	103	(68.2%)	175	(65.8%)	86	(71.1%)	79	(71.2%)
IV	5	(11.4%)	61	(20.0%)	21	(13.9%)	54	(20.3%)	19	(15.7%)	17	(15.3%)

1. 94 of the Control subjects received tube grafts and 17 received bifurcated grafts.
2. One subject is missing gender data. One subject is missing race data.
3. Two aortoiliac subjects are missing arrhythmia data.
4. One aortoiliac subject is missing smoking data.

Table 5. Aneurysm Diameter Distribution

Diameter Range	Tube ANCURE (N=44) n	%	Bifurcated ANCURE (N=305) n	%	Tube EGS (N=153) n	%	Bifurcated EGS (N=268) n	%	Aortoiliac EGS (N=121) n	%	Control (N=111)[1] n	%
< 30 mm	1	(2.3%)	1	(0.3%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
30 mm – 39 mm	1	(2.3%)	5	(1.6%)	8	(5.3%)	7	(2.6%)	2	(1.7%)	2	(2.0%)
40 mm – 49 mm	16	(37.2%)	87	(28.5%)	60	(39.5%)	75	(28.2%)	24	(19.8%)	28	(27.5%)
50 mm – 59 mm	18	(41.9%)	149	(48.9%)	65	(42.8%)	116	(43.6%)	50	(41.3%)	42	(41.2%)
60 mm – 69 mm	4	(9.3%)	48	(15.7%)	13	(8.6%)	44	(16.5%)	29	(24.0%)	21	(20.6%)
70 mm – 79 mm	2	(4.7%)	8	(2.6%)	5	(3.3%)	19	(7.1%)	15	(12.4%)	6	(5.9%)
80 mm – 89 mm	1	(2.3%)	5	(1.6%)	1	(0.7%)	5	(1.9%)	1	(0.8%)	3	(2.9%)
≥ 90 mm	0	(0.0%)	2	(0.7%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)

1. 94 of the Control subjects received tube grafts and 17 received bifurcated grafts.

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6.2. *Summary of the EGS® Clinical Study*

Purpose: This clinical study compared the rates of (proportions of patients with) major complications for patients treated with the tube, bifurcated, and aortoiliac EGS Systems to the standard surgical treatment for AAA. Primary outcome measures were: 1) the rate of complications; 2) the length of hospital stay; and 3) the rate of aneurysm enlargement and rupture in the first 12 months.

Study Design: This prospective, multi-center, non-randomized clinical study compared patients treated with the tube, bifurcated, and aortoiliac EGS Systems to a concurrent control group. All patients had a grade I (tube) or II (bifurcated and aortoiliac) infrarenal AAA and were candidates for surgical treatment of AAA. The concurrent control group included patients whose vascular anatomy may not have been suitable for endovascular AAA repair based on arterial access size and proximal and distal neck lengths. Patients were followed at 6 weeks, 6 months, and 12 months from surgery. Aneurysm diameter changes and graft patency were evaluated by core laboratory assessment of contrast enhanced CT scans, abdominal ultrasounds, and x-rays. The study enrolled 153 tube, 268 bifurcated, 121 aortoiliac, and 111 control patients.

Table 6. Principal Safety and Effectiveness Results for EGS (Comparison Measures)

Outcome Measure	Treatment Group	%	(n/N)	EGS-Control [1] Difference [95% CI]
Operative Mortality (≤ 30 days)	Tube	0.0%	(0/153)	-2.7% [-11.1, 2.0]
	Bifurcated	2.6%	(7/268)	-0.1% [-8.3, 4.6]
	Aortoiliac [2]	4.2%	(5/118)	1.5% [-5.7, 12.2]
	Control	2.7%	(3/111)	--
Major Complications [3] (≤ 30 days)	Tube	19.6%	(30/153)	-24.5% [5] [-35.7, -13.4]
	Bifurcated	28.7%	(77/268)	-15.4% [6] [-26.1, -4.7]
	Aortoiliac [2]	35.6%	(42/118)	-8.6% [-21, 4.0]
	Control	44.1%	(49/111)	--
Need for ICU Stay (%)	Tube	35.5%	(54/152)	-60.8% [5] [-70.5, -50.9]
	Bifurcated	39.1%	(102/261)	-57.2% [5] [-66.0, -48.6]
	Aortoiliac [2]	38.9%	(44/113)	-57.7% [-59.1, -55.6]
	Control	96.3%	(104/108)	--
Thrombosis/Occlusion	Tube	0.0%	(0/153)	0.0% [-6.6, 3.8]
	Bifurcated	2.6%	(7/268)	2.6% [-2.4, 7.5]
	Aortoiliac [2]	1.7%	(2/118)	1.7% [-3.6, 9.8]
	Control	0.0%	(0/111)	--
		Median	**(N)**	
Hospital Stay (days)	Tube	2	(152)	-4.0 [5] [-4.0, -3.0]
	Bifurcated	3	(262)	-3.0 [5] [-4.0, -3.0]
	Aortoiliac [2]	3	(113)	-3.0 [-3.0, -2.0]
	Control	6	(108)	--
ICU Stay (hours) [4]	Tube	24.0	(54)	-3.0 [6] [-10.0, 0.0]
	Bifurcated	24.0	(101)	-3.0 [5] [-8.0, -1.0]
	Aortoiliac [2]	24.0	(44)	-6.0 [-12.2, -1.0]
	Control	27.0	(104)	--
Operative Time (min)	Tube	159.5	(152)	-7.5 [-15.0, 10.0]
	Bifurcated	130.0	(266)	-37.0 [5] [-42.0, 19.0]
	Aortoiliac [2]	240.0	(118)	77.0 [62.0, 92.0]
	Control	167.0	(111)	--
Operative Blood Loss (cc)	Tube	200	(151)	-600 [5] [-675, -500]
	Bifurcated	300	(268)	-500 [5] [-550, -350]
	Aortoiliac [2]	400	(118)	-400 [-500, -300]
	Control	800	(111)	--

1. Confidence intervals for differences in percentages were calculated by the exact (binomial) method; confidence intervals for differences in medians center on the Hodges-Lehmann estimator.
2. Of the total 121 aortoiliac subjects, three discontinued their participation at discharge and were alive at that time. These subjects are included in the analysis only through surgical implantation.
3. Major Complications = significant respiratory, cardiac, bleeding, bowel, wound, renal, arterial trauma, neurological and ischemic complications, and death.
4. ICU Stay duration includes only subjects who went to the ICU.
5. $p<0.01$
6. $p<0.05$

Table 7. Principal Safety and Effectiveness Results for EGS at 12 months (Other Measures)

Outcome Measure	Treatment Group	n/N	% (95% CI)
Intraop Conversions [1]	Tube	12/153	7.8% [17, 34]
	Bifurcated	26/268	9.7% [6.4, 14]
	Aortoiliac [2]	7/121	5.8% [2.4, 11.6]
Postop Conversions	Tube	1/141	0.7% [0.2, 3.9]
	Bifurcated	2/235	0.9% [0.1, 3.0]
	Aortoiliac	0/113	0.0% [0, 0.03]
Aneurysm Rupture	Tube	0/141	0.0% [0, 1.9]
	Bifurcated	0/242	0.0% [0.1, 3.0]
	Aortoiliac	0/113	0.0% [0, 0.03]
Reduced Limb Flow [3]	Tube	N/A	N/A
	Bifurcated	93/242	38.4% [32, 45]
	Aortoiliac	34/113	30.1% [21.6, 38.5]
Perigraft Flow, Discharge	Tube	60/135	44.4% [36, 53]
	Bifurcated	106/219	48.4% [42, 55]
	Aortoiliac	58/112	51.8% [45.2, 61.0]
Perigraft Flow	Tube	26/104	25.0% [17, 34]
	Bifurcated	40/128	31.3% [23, 40]
	Aortoiliac	33/100	33% [23.8, 42.2]
Increased Aneurysm Size (≥ 5 mm)	Tube	6/103	5.8% [2.2, 12]
	Bifurcated	3/134	2.2% [0.5, 6.4]
	Aortoiliac	4/98	4.1% [0.2, 8.0]
Decreased Aneurysm Size, (≥ 5 mm)	Tube	44/103	42.7% [33, 53]
	Bifurcated	64/134	47.8% [39, 57]
	Aortoiliac	46/98	46.9% [37.1, 56.8]
Graft Migration	Tube	1/141	0.7% [0.0, 3.9]
	Bifurcated	1/242	0.4% [0, 2.3]
	Aortoiliac	0/113	0.0% [0, 0.03]

1. Intraop Conversions = access failure or failure to deploy. Protocol required these subjects to undergo standard AAA repair.
2. There were four aortoiliac intraoperative conversions and in three patients, the implant procedure was abandoned.
3. Reduced Limb Flow = intraoperative or postoperative intervention during the first 12 mos. to treat reduced limb patency.

Table 8. Claudication Complications Versus Site of Distal Attachment and Contralateral Occlusion for Aortoiliac Subjects at ≤ 30 days[1]

Configuration	N=110	Leg Claudication n	Leg Claudication %	Buttock/Thigh Claudication n	Buttock/Thigh Claudication %
Landing zone in common, contra occlusion in common; fem-fem; both internal iliac arteries remain patent.	54	0	0%	1	1.9%
Landing zone in common, contra. occlusion in external and internal, fem-fem; the ipsilateral internal iliac artery remains patent.	13	0	0%	1	7.7%
Landing zone in external, contra. occlusion in common, fem-fem; the contralateral internal iliac artery remains patent.	32	0	0%	7	21.9%
Landing zone in external, contra. occlusion in external and internal, fem-fem.	6	0	0%	0	0%
Any landing zone, preexisting contra. occlusion	5	0	0%	0	0%

1. 113 patients successfully implanted; missing data for three subjects.

6.3. Summary of the ANCURE® Clinical Study

Purpose: The ANCURE and EGS Systems are different delivery systems that deploy the same tube and bifurcated grafts. The purpose of this clinical study was to evaluate the safety and efficacy of the ANCURE delivery system in comparison to the EGS delivery system.

Study Design: This prospective, multi-center clinical study compared patients treated with the ANCURE Tube and Bifurcated Systems to patients previously treated in the clinical study of the EGS System. All patients had a grade I (tube) or II (bifurcated) infrarenal AAA and were candidates for surgical treatment of AAA. Patients were followed at scheduled intervals from surgery up to 12 months. Efficacy was evaluated using contrast enhanced CT scans, abdominal ultrasounds, and x-rays. Safety was assessed by physical exams. The study enrolled 44 tube and 305 bifurcated patients.

Table 9. Comparison of ANCURE and EGS Systems

Outcome Measure		ANCURE % (n/N)	EGS % (n/N)	EGS-ANCURE [1] Difference [95% CI]
Operative Mortality (≤ 30 days)	Tube	0.0% (0/44)	0.0% (0/153)	0.0% [-12.9, 4.3]
	Bifurcated	1.0% (3/305)	2.6% (7/268)	1.6% [-1.5, 5.5]
Major Complications [2] (≤ 30 days)	Tube	20.5% (9/44)	19.6% (30/153)	-0.8% [-14.3, 12.6]
	Bifurcated	28.9% (88/305)	28.7% (77/268)	-0.1% [-7.6, 7.3]
Need for ICU Stay (%)	Tube	15.9% (7/44)	35.5% (54/152)	19.6% [6.4, 32.8]
	Bifurcated	28.8% (87/302)	39.1% (102/261)	10.3% [2.5, 18.1]
Thrombosis/Occlusion (≤ 30 days)	Tube	0.0% (0/44)	0.0% (0/153)	0.0% [-12.9, 4.3]
	Bifurcated	3.3% (10/305)	2.6% (7/268)	-0.7% [-4.7, 3.2]
Intraop Conversions [3]	Tube	6.8% (3/44)	7.8% (12/153)	1.0% [-13.2, 11.4]
	Bifurcated	4.9% (15/305)	9.7% (26/268)	4.8% [-0.2, 10.5]
Postop Conversions	Tube	2.4% (1/41)	0.7% (1/141)	-1.7% [-16.9, 4.8]
	Bifurcated	0.3% (1/289)	0.9% (2/235)	0.5% [-2.0, 3.9]
Aneurysm Rupture	Tube	0.0% (0/41)	0.0% (0/141)	0.0% [-13.7, 4.6]
	Bifurcated	0.0% (0/290)	0.0% (0/242)	0.0% [-2.2, 2.3]
Reduced Limb Flow [4] (≤ 12 months)	Tube	N/A	N/A	N/A
	Bifurcated	42.4% (123/290)	38.4% (93/242)	-4.0% [-12.4, 4.4]
Perigraft Flow [5], Discharge	Tube	17.1% (7/41)	44.4% (60/135)	27.4% [10.1, 42.7]
	Bifurcated	27.3% (78/286)	48.4% (106/219)	21.1% [12.7, 29.5]
Perigraft Flow [5], 12 mo	Tube	8.8% (3/34)	25% (26/104)	16.2% [-1.8, 31.7]
	Bifurcated	26.1% (65/249)	31% (40/128)	5.1% [-4.6, 14.9]
Increased Aneurysm Size [5] (≥ 5 mm), 12 mo	Tube	16.1% (5/31)	5.8% (6/103)	-10.3% [-32.5, 4.3]
	Bifurcated	6.0% (12/201)	2.2% (3/134)	-3.7% [-9.8, 2.6]
Decreased Aneurysm Size [5] (≥ 5 mm), 12 mo	Tube	38.7% (12/31)	42.7% (44/103)	4.0% [-16.3, 24.6]
	Bifurcated	51.2% (103/201)	47.8% (64/134)	-3.5% [-14.8, 7.7]
Graft Migration [6]	Tube	0.0% (0/41)	0.7% (1/141)	0.7% [-10.9, 6.3]
	Bifurcated	0.0% (0/290)	0.4% (1/242)	0.4% [-0.4, -1.2]
		Median (N)	**Median (N)**	
Hospital Stay (days)	Tube	2 (44)	2 (152)	0 [0,1]
	Bifurcated	2 (302)	3 (262)	0 [0, 1]
ICU Stay (hours) [7]	Tube	27.0 (7)	24.0 (54)	N/A
	Bifurcated	24.5 (87)	24.0 (101)	-1.5 [-5, 1]
Operative Time (min)	Tube	144.5 (44)	159.5 (152)	19 [1, 35]
	Bifurcated	184.0 (305)	130.0 (266)	-52 [-62, -43]
Operative Blood Loss (cc)	Tube	250 (43)	200 (151)	-25 [-100, 25]
	Bifurcated	450 (302)	300 (268)	-100 [-150, -50]

1. Confidence intervals on percentages used exact binomial methods when required by small numbers of events; confidence intervals for differences in medians center on the Hodges-Lehmann estimator, which may differ from the observed differences between medians.
2. Major Complications = significant respiratory, cardiac, bleeding, bowel, wound, renal, arterial trauma, neurological and ischemic complications, and death.
3. Intraop Conversions = access failure or failure to deploy. EGS protocols required these subjects to undergo standard AAA repair.
4. Intraoperative or postoperative intervention during the first 12 mos. to treat reduced limb patency.
5. Perigraft Flow and Aneurysm Size were evaluated by an independent core laboratory for EGS subjects; for Ancure subjects, they were evaluated by the investigators.
6. For EGS subjects, graft migration was evaluated by the core laboratory and adjudicated by Guidant. For Ancure subjects, it was evaluated by the investigators.
7. ICU Stay duration includes only subjects who went to the ICU.

6.4. Conversions for ANCURE® and EGS® Systems

Table 10. Conversion to Standard Surgical Repair

Reason for Conversion	Tube ANCURE Conversions (N=44) n % [95% CI]	Bifurcated ANCURE Conversions (N=305) n % [95% CI]	Tube EGS Conversions (N=153) n % [95% CI]	Bifurcated EGS Conversions (N=268) n % [95% CI]	Aortoiliac EGS Conversions (N=121) n % [95% CI]
Total Conversion/Cases aborted ≤ 30 days	**3 6.8% [1.4, 18.7]**	**16 5.2% [3.0, 8.4]**	**12 7.8% [4.1, 13.3]**	**26 9.7% [6.4, 13.9]**	**7 5.8% [2.9, 11.6]**
Failure to Access	2 4.5% [0.6, 15.5]	1 0.3% [0.0, 1.8]	8 5.2% [2.3, 10]	11 4.1% [2.1, 7.2]	4 3.3% [1.4, 8.3]
Failure to Accurately Place (Total)	1 2.3% [0.1, 12.0]	14 4.6% [2.5, 7.6]	4 2.6% [0.7, 6.6]	15 5.6% [3.2, 9.1]	2 1.7% [0.5, 5.8]
Arterial Trauma	0 0.0% [0.0, 8.0]	0 0.0% [0.0, 1.2]	1 0.6% [0, 3.5]	4 1.5% [0.4, 3.8]	0 0.0% [0.0, 3.0]
Failure to Retract Jacket	0 0.0% [0.0, 8.0]	7 2.3% [0.9, 4.7]	0 0.0% [0, 1.9]	0 0.0% [0, 1.1]	0 0.0% [0.0, 3.0]
Improper Graft Position	1 2.3% [0.1, 2.0]	2 0.7% [0.1, 2.4]	3 2.0% [0.4, 5.6]	1 0.4% [0, 2.1]	0 0.0% [0.0, 3.0]
Perigraft Flow	0 0.0% [0.0, 8.0]	0 0.0% [0.0, 1.2]	0 0.0% [0, 1.9]	2 0.7% [0.1, 2.7]	0 0.0% [0.0, 3.0]
Reduced Limb Flow	0 0.0% [0.0, 8.0]	2 0.7% [0.1, 2.4]	0 0.0% [0, 1.9]	0 0.0% [0, 1.1]	0 0.0% [0.0, 3.0]
Twist	0 0.0% [0.0, 8.0]	3 1.0% [0.2, 2.9]	0 0.0% [0, 1.9]	3 1.1% [0.2, 3.2]	0 0.0% [0.0, 3.0]
Unable to Remove Delivery Catheter	0 0.0% [0.0, 8.0]	0 0.0% [0.0, 1.2]	0 0.0% [0, 1.9]	5 1.9% [0.6, 4.3]	2 1.7% [0.5, 5.8]
Change in anatomy	0 0.0% [0.0, 8.0]	1 0.3% [0.0, 1.8]	0 0.0% [0, 1.9]	0 0.0% [0, 1.1]	1 0.8% [0.2, 4.5]
Total Conversion > 30 days (LATE)	**1 2.3% [0.1, 12.0]**	**0 0.0% [0.0, 1.2]**	**1 0.6% [0, 3.5]**	**2 0.7% [0.1, 2.7]**	**2 1.7% [0.5, 5.8]**
Perigraft Flow and Aneurysm Enlargement	0 0.0% [0.0, 8.0]	0 0.0% [0.0,1.2]	1 0.6% [0, 3.5]	2 0.7% [0.1, 2.7]	1 0.8% [0.0, 4.5]
Improper Graft Position	1 2.3% [0.1, 12.0]	0 0.0% [0.0, 1.2]	0 0.0% [0, 1.1]	0 0.0% [0, 1.1]	0 0.0% [0.0, 3.0]
Reduced Limb Flow	N/A	0 0.0% [0.0, 1.2]	N/A	0 0.0% [0, 1.1]	1 0.8% [0.0, 4.5]

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6.5. Perigraft Flow for EGS Graft

Table 11. Perigraft Flow for EGS Subjects Over Time[1]

	Discharge n/N	Discharge % [95% CI]	6 Months n/N	6 Months % [95% CI]	12 Months n/N	12 Months % [95% CI]
Tube						
Attachment Site Flow	15/135	11.1% [6.4, 17.7]	9/123	7.3% [3.4, 13.4]	4/104	3.8% [1.1, 9.6]
Branch Flow	36/135	26.7% [19.4, 35]	21/123	17.1% [10.9, 24.9]	20/104	19.2% [12.2, 28.1]
Graft Permeability	0/135	0.0% [0, 2.2]	0/123	0.0% [0.0, 2.4]	0/104	0.0% [0, 2.8]
Source Unknown	9/135	6.7% [3.1, 12.3]	1/123	0.8% [0.0, 4.4]	2/104	1.9% [0.2, 6.8]
Bifurcated						
Attachment Site Flow	11/219	5.0% [2.5, 8.8]	14/195	7.2% [4, 11.8]	3/128	2.3% [0.5, 6.7]
Branch Flow	78/219	35.6% [29.3, 42.4]	50/195	25.6% [19.7, 32.4]	34/128	26.6% [19.2, 35.1]
Graft Permeability	0/219	0.0% [0, 1.4]	0/195	0.0% [0, 1.5]	0/128	0.0% [0, 2.3]
Source Unknown	17/219	7.8% [4.6, 12.1]	15/195	7.6% [4.4, 12.4]	3/128	2.3% [0.5, 6.7]
	Discharge n/N	**Discharge % [95% CI]**	**6 Months n/N**	**6 Months % [95% CI]**	**12 Months n/N**	**12 Months % [95% CI]**
Aortoiliac						
Attachment Site Flow	8/112	7.1% [2.4, 11.9]	6/88	6.8% [2.5, 14.4]	4/100	4.0% [0.2, 7.8]
Branch Flow	35/112	31.3% [22.7, 39.8]	23/88	26.1% [17.3, 36.6]	19/100	19.0% [11.3, 26.7]
Contralateral Occlusion Site Flow	8/112	7.1% [2.4, 11.9]	10/88	11.4% [5.6, 19.9]	7/100	7.0% [2.0, 12.0]
Source Unknown	7/112	6.3% [1.8, 10.7]	3/88	3.4% [0.7, 9.6]	3/100	3.0% [0.0, 6.3]
	24 Months n/N	**24 Months %**	**36 Months n/N**	**36 Months %**	**48 Months n/N**	**48 Months %**
Aortoiliac						
Attachment Site Flow	1/67	1.5%	0/37	0.0%	0/12	0.0%
Branch Flow	18/67	26.9%	6/37	16.2%	3/12	25.0%
Contralateral Occlusion Site Flow	2/67	3.0%	0/37	0.0%	0/12	0.0%
Source Unknown	3/67	4.5%	2/37	5.4%	0/12	0.0%

1. Includes implanted subjects eligible for follow-up at each time period.

6.6. Aneurysm Size Change for EGS® Graft

Table 12. Change in Aneurysm Diameter[1]

	Tube EGS(N=103) Discharge to 12 months			Bifurcated EGS(N=134) Discharge to 12 months			Aortoiliac EGS (N=88) Discharge to 12 months		
	n	% [95% CI]	Mean Change (mm)	n	% [95% CI]	Mean Change (mm)	n	% [95% CI]	Mean Change (mm)
Increase (+ ≥5 mm)	6	5.8% [2.2, 12.2]	+7.85	3	2.2% [0.5, 6.4]	+7.10	4	4.1% [0.2, 8.0]	+8.7
No Change (± <5 mm)	53	51.5% [41.4, 61.4]	-0.15	67 [2]	50.0% [41.2, 58.8]	-0.95	48	49.0% [39.1, 58.9]	-1.4
Decrease (- ≥5 mm)	44	42.7% [33, 52.8]	-10.22	64	47.8% [39.1, 56.6]	-10.04	46	46.9% [37.1, 56.8]	-11.3
	Aortoiliac Discharge to 24 months (N=65)			**Aortoiliac Discharge to 36 months (N=36)**			**Aortoiliac Discharge to 48 months (N=11)**		
	n	%	Mean Change (mm)	n	%	Mean Change (mm)	n	%	Mean Change (mm)
Increase (+ ≥5 mm)	2	3.1%	+15.8	2	5.6%	+17.9	1	9.1%	+6.6
No Change (± <5 mm)	22	33.8%	-1.5	12	33.3%	-2.05	2	18.2%	-2.6
Decrease (- ≥5 mm)	41	63.1%	-14.1	22	61.1%	-16.9	8	72.7%	-16.3

1. Includes implanted subjects who have follow-up data at each time period.
2. One subject experienced a decrease from discharge to six months, and an increase from six months to 12 months.

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6.7. Perigraft Flow Status versus Aneurysm Size Change for EGS® Graft

Table 13. Aneurysm Diameter by Perigraft Flow Status

Perigraft Flow Status	Aneurysm Diameter Change					
	Decrease (≥5 mm)		No Change (± <5 mm)		Increase (≥5 mm)	
	n/N	% [95% CI]	n/N	% [95% CI]	n/N	% [95% CI]
Tube EGS at 12 months						
No Perigraft Flow	40/76	52.6% [40.8, 64.2]	33/76	43.4% [32.1, 55.3]	3/76	4.0% [0.8, 11.1]
Perigraft Flow	4/26	15.4% [4.4, 34.9]	19/26	73.1% [52.2, 88.4]	3/26	11.5% [2.4, 30.2]
Bifurcated EGS at 12 months						
No Perigraft Flow	47/85	55.3% [44.1, 66.1]	37/85	43.5% [32.8, 54.7]	1/85	1.2% [0, 6.4]
Perigraft Flow	13/40	32.5% [18.6, 49.1]	25/40	62.5% [45.8, 77.3]	2/40	5.0% [0.6, 16.9]
Perigraft Flow Status	**Decrease (≥5 mm) n/N %**	**[95% CI]**	**No Change (± <5 mm) n/N %**	**[95% CI]**	**Increase (≥5 mm) n/N %**	**[95% CI]**
Aortoiliac EGS at 12 months						
No Perigraft Flow	33/62	53.2% [40.8, 65.6]	29/62	46.8% [34.4, 59.2]	0/62	0.0% [0.0, 0.05]
Perigraft Flow	12/33	36.4% [20.0, 52.8]	17/33	51.5% [24.5, 68.6]	4/33	12.1% [1.0, 23.3]
Perigraft Flow Status	**Decrease (≥5 mm) n/N %**		**No Change (± <5 mm) n/N %**		**Increase (≥5 mm) n/N %**	
Aortoiliac EGS at 24 months						
No Perigraft Flow	29/37	78.4%	8/37	21.6%	0/3	0.0%
Perigraft Flow	9/23	39.1%	12/23	52.2%	2/2	8.7%
Aortoiliac EGS at 36 months						
No Perigraft Flow	17/22	77.3%	5/22	22.7%	0/22	0.0%
Perigraft Flow	2/8	25.0%	4/8	50.0%	2/8	25.0%

6.8. Reduced Limb Flow for ANCURE® Bifurcated, Bifurcated EGS®, and Aortoiliac EGS® Grafts

Table 14. Types of Interventions to Optimize Bifurcated and Aortoiliac Graft Limb Flow

	Intraoperative		Postoperative[4]		Total	
	n/N	% [95% CI]	n/N	% [95% CI]	n/N	% [95% CI]
Bifurcated EGS						
Stent [1]	34/242	14.0% [9.9, 19.1]	19/242	7.8% [4.8, 12]	53/242	21.8% [16.9, 27.6]
PTA only	28/242	11.6% [7.8, 16.3]	0/242	0.0% [0, 1.2]	28/242	11.6% [7.8, 16.3]
Surgical [2]	5/242	2.1% [0.7, 4.8]	4/242	1.6% [0.5, 4.2]	9/242	3.7% [1.7, 6.9]
Other [3]	1/242	0.4% [0, 2.3]	2/242	0.8% [0.1, 3]	3/242	1.2% [0.3, 3.6]
(Total)	68/242	28.1%	25/242	10.3%	93/242	38.4%
Bifurcated ANCURE						
Stent [1]	68/290	23.4% [18.7, 28.8]	21/290	7.2% [4.5, 10.9]	89/290	30.7% [25.4, 36.4]
PTA only	15/290	5.2% [2.9, 8.4]	1/290	0.3% [0.0, 1.9]	16/290	5.5% [3.2, 8.8]
Surgical [2]	8/290	2.8% [1.2, 5.4]	7/290	2.4% [1.0, 4.9]	15/290	5.2% [2.9, 8.4]
Other [3]	1/290	0.3% [0.0, 1.9]	2/290	0.7% [0.1, 2.5]	3/290	1.0% [0.2, 3.0]
(Total)	92/290	31.7%	31/290	10.7%	123/290	42.4%
Aortoiliac EGS						
Stent [1]	19/113	16.8% [9.9, 23.7]	12[5]/113	10.6.% [4.9, 16.3]	31/113	27.4% [19.2, 35.7]
PTA only	4/113	3.5% [0.1, 6.9]	0/113	0.0% [0, 0.03]	4/113	3.5% [0.1, 6.9]
Surgical [2]	1/113	0.9% [0.0, 2.6]	2/113	1.8% [0, 4.2]	3/113	2.7% [0.0, 5.6]
Other	0/113	0.0% [0, 0.03]	0/113	0.0% [0, 0.03]	0/113	0.0% [0, 0.03]
(Total)	24/113	21.2%	14/113	12.4%	38/113	33.6%

1. Includes some subjects who had PTA or other non-surgical interventions and stent.
2. Includes Femoro-Femoral Bypass and surgical revision. Includes some patients who may have had stents, PTA, or other non-surgical interventions.
3. Includes thrombolysis, thrombectomy, and anticoagulants.
4. Patients who had interventions performed both intraoperatively and postoperatively, were only included in the postoperative data.
5. One of these subjects had one stent intraoperatively. Another subject had a surgical limb attachment intraoperatively.

7. PATIENT SELECTION AND TREATMENT

7.1. Use in Specific Populations

See Warnings and Precautions – Patient Selection and Treatment

7.2. Individualization of Treatment

- The patient must have clearance for undergoing general, regional, or local anesthesia.
- The patient must have at least one femoral or iliac artery permitting access by a 23.5 Fr (7.8 mm) device.
- Patients treated with the bifurcated graft must have a contralateral femoral artery or iliac artery permitting access by a 12 Fr (4.0 mm) device.
- The patient must have an infrarenal non-aneurysmal neck length of at least 15 mm and a diameter of no greater than 26 mm.
- Patients treated with a bifurcated graft must have distal segment lengths of at least 20 mm and diameters no greater than 13.4 mm.
- Patients treated with a tube graft must have a distal segment neck length of 12 mm and diameter of no greater than 26 mm.
- Patients treated with an Aortoiliac graft must have one distal segment length of at least 20 mm and diameters no greater than 13.4 mm.
- Patients treated with an Aortoiliac graft must be carefully evaluated prior to the procedure to determine the need and timing for closure of an iliac artery to prevent backflow into the aneurysm sac.

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- It is best if the superior neck does not contain an angle of greater than 60 degrees.
- Patients should not have significant femoral/iliac artery occlusive disease that would impede inflow or outflow through the graft(s).
- Preoperative evaluation of the donor and recipient femoral artery run-off should be done.

7.3. ENDOGRAFT® Vascular Graft Sizing

Note: The following information is provided as a guide. Final sizing will be determined based on patient anatomy. Using Table 15, 16, 17, 18, 19 or 20 choose an appropriate ANCURE graft size based on the preoperative diagnostic tests. Over-sizing is not required for these devices.

Table 15. ANCURE Tube ENDOGRAFT Vascular Graft Diameter Sizing Guide

Prosthesis Diameter[1] (mm)	Maximum Vessel Diameter (mm)	Hook-to-Hook Lengths[2] (cm)
20	20.0	9 to 16 (in 1 cm increments)
22	22.0	
24	24.0	
26	26.0	

1. The graft size selected is determined by the attachment site requiring the largest diameter.
2. The hook-to-hook length is the usable length of the prosthesis. To calculate the length of the graft only, subtract 0.6 cm from the hook-to-hook length.

Table 16. ANCURE Bifurcated ENDOGRAFT Vascular Graft Diameter Sizing Guide

Prosthesis Diameter[1] (Trunk mm/Limb mm)	Maximum Vessel Diameter (Aorta mm / Iliac mm)	Standard Hook-to-Hook Lengths[2] (cm)	Variable Hook-to-Hook [1] Lengths[2] (cm)	
			Ipsilateral	Contralateral
20 / 10	20.0 / 10.4	12 to 19 (in 1 cm increments)	15	13
22 / 11	22.0 / 11.4		16	13 to 14
24 / 12	24.0 / 12.4		17	14 to 15
26 / 13	26.0 / 13.4		18	15 to 16
			19	16 to 17

1. The prosthesis diameter is determined by the diameters of the superior neck (trunk) and inferior (limb) attachments. The graft size selected is determined by the attachment site requiring the largest diameter.
2. The hook-to-hook length is the usable length of the prosthesis. To calculate the length of the graft only, subtract 0.8 cm from the hook-to-hook length on the ipsilateral side and 1.5 cm on the contralateral side
1. The access site (left or right) must be pre-determined for the variable limb length graft. Always use the side with the longest iliac attachment site as the access site to ensure proper order of deployment for the long and short limbs of the graft. Failure to observe this precaution may lead to improper sizing of the graft, possibly resulting in the need for additional medical intervention, including a conversion to standard surgical repair.

Table 17. ANCURE Aortoiliac ENDOGRAFT Vascular Graft Diameter Sizing Guide

Prosthesis Diameter[1] (Trunk mm/Limb mm)	Maximum Vessel Diameter (Aorta mm / Iliac mm)	Hook-to-Hook Lengths[2] (cm)
20 / 10	20.0 / 10.4	12 to 25 (in 1 cm increments)
22 / 11	22.0 / 11.4	
24 / 12	24.0 / 12.4	
26 / 13	26.0 / 13.4	

1. The prosthesis diameter is determined by the diameters of the superior neck (trunk) and inferior (limb) attachment. The graft size selected is determined by the attachment site requiring the largest diameter.
2. The hook-to-hook length is the usable length of the prosthesis. To calculate the length of the graft only, subtract 0.8 cm from the hook-to-hook length.

Table 18. ENDOGRAFT Trunk and Limb Dimensions (Bifurcated)

Available Trunk/ Limb Diameters (mm)	Total Graft Length (hook-to-hook)* (cm)	Trunk Length (graft only) (cm)	Ipsilateral Limb Length (graft only) (cm)	Contralateral Limb Length (graft only) (cm)
20/10, 22/11, 24/12, 26/13	12.0	6.5	4.7	4.2
	13.0	6.5	5.7	5.2
	14.0	6.5	6.7	6.2
	15.0	6.5	7.7	7.2
	16.0	7.0	8.2	7.7
	17.0	8.0	8.2	7.7
	18.0	9.0	8.2	7.7
	19.0	10.0	8.2	7.7

* Trunk length plus limb length plus exposed attachment system length.

Table 19. ENDOGRAFT Trunk and Limb Dimensions (Bifurcated with Variable Limb Lengths)

Available Trunk/Limb Diameters (mm)	Total Graft Length (hook-to-hook on ipsilateral side)	Trunk Length (graft only) (cm)	Ipsilateral Limb Length (graft only) (cm)	Contralateral Limb Length (graft only) (cm)
			(Overall Length)-(trunk length)-(3mm*)-(5mm**)= ipsi limb length	(Overall Length)-(trunk length)-(3mm*)-(10mm**)= contra limb length
20/10, 22/11, 24/12, 26/13	15 x 13	6.5	7.7	5.2
	16 x 13	7.0	8.2	4.7
	16 x 14	7.0	8.2	5.7
	17 x 14	8.0	8.2	4.7
	17 x 15	8.0	8.2	5.7
	18 x 15	9.0	8.2	4.7
	18 x 16	9.0	8.2	5.7
	19 x 16	10.0	8.2	4.7
	19 x 17	10.0	8.2	5.7

* = distance between superior attachment system hooks and graft.
** = length of exposed iliac attachment system.

Table 20. ENDOGRAFT Trunk and Limb Dimensions (Aortoiliac)

Available Trunk/Limb Diameters (mm)	Total Graft Length (hook-to-hook) (cm)	Trunk Length (graft only) (cm)	Ipsilateral Limb Length (graft only) (cm)
			(hook-to-hook length)-(trunk length)-(3mm*)-(5mm**)= ipsi limb length
20/10, 22/11, 24/12, 26/13	12	6.5	4.7
	13	6.5	5.7
	14	6.5	6.7
	15	6.5	7.7
	16	6.5	8.7
	17	6.5	9.7
	18	6.5	10.7
	19	6.5	11.7
	20	6.5	12.7
	21	6.5	13.7
	22	6.5	14.7
	23	6.5	15.7
	24	7.0	16.2
	25	8.0	16.2

* = distance between superior attachment system hooks and graft.
** = length of exposed iliac attachment system.

8. PATIENT COUNSELING INFORMATION

The following are recommended points to discuss with patients or responsible family members concerning AAA repair with the ANCURE System:

- The differences between endovascular repair and standard surgical repair of AAAs and the possibility of conversion to standard surgical repair.
- The risks associated with endovascular repair (see Section 5. Adverse Events).
- What to expect following the endovascular repair procedure. The patient may experience some grogginess, loss of appetite and soreness at the incision site. The typical patient is back to normal activity within 2 weeks vs. 6 – 8 weeks for standard surgical repair.
- Importance of seeking prompt medical attention if they experience any signs of limb occlusion or aneurysm rupture. Signs of graft limb occlusion include pain in the hip(s) or leg(s) during walking, or discoloration or coolness of the leg skin. Signs of aneurysm rupture include pain, numbness, weakness in the legs, any back, chest, abdominal, or groin pain, dizziness, fainting, rapid heartbeat, or sudden weakness.
- Although routine post-operative follow-up evaluations are recommended for all patients, the frequency of recommended follow-up visits is dependent on the patient situation and whether there is any evidence of perigraft flow. A recommended schedule is provided in Section 11.5.
- The importance of keeping the Patient Implant Card with them and showing it to future health practitioners, especially if they are undergoing diagnostic procedures (such as MRI).

9. DETAILED DEVICE DESCRIPTION

The ANCURE Tube System consists of a tubular ENDOGRAFT Vascular Graft packed in the ANCURE Delivery Catheter (see Figures 1 and 2). The ANCURE Bifurcated System consists of a bifurcated ENDOGRAFT Vascular Graft packed in the delivery catheter (see Figures 1 and 3). The ANCURE Aortoiliac System consists of an ENDOGRAFT Vascular Graft with a single iliac limb segment packed in the delivery catheter (see Figures 1 and 2). The ANCURE Bifurcated System is also packaged with the ANCURE Contralateral Torque Catheter and ANCURE Contralateral Cutter (see Figures 4 and 5).

Figure 1. ANCURE Delivery Catheter Handle Components

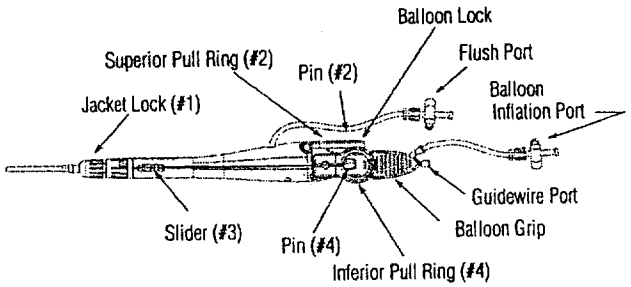


Figure 2. Other Components: ANCURE Tube and Aortoiliac System

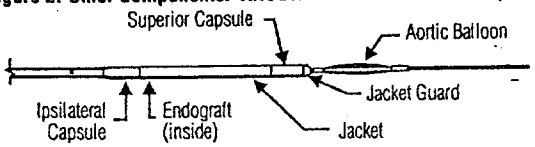


Figure 3. Other Components: ANCURE Bifurcated System

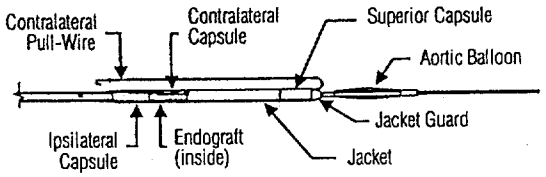


Figure 4. ANCURE Contralateral Torque Catheter

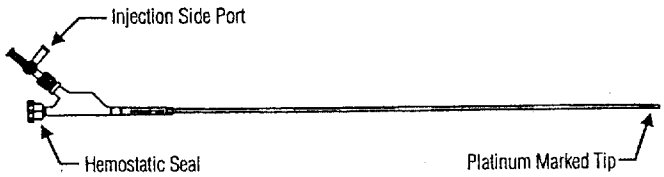
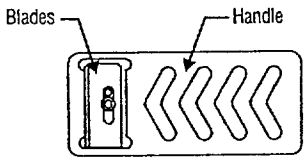


Figure 5. ANCURE® Contralateral Cutter



10. HOW SUPPLIED

The ANCURE System is supplied STERILE and non-pyrogenic in a sealed pouch. The graft is housed within the delivery catheter. An Implant Data Form and Patient Identification Card are packaged with each ANCURE System. Complete the information on the Implant Data form and return to Guidant. Complete the Patient Identification Card and give to the patient. See Warnings and Precautions – Storage and Handling.

11. CLINICIAN USE INFORMATION

11.1. User Training and Experience

The following list presents the skill sets required by the team performing endovascular grafting:

- arterial cutdown and closure;
- arteriotomy;
- arteriotomy repair;
- catheter angiography;
- fluoroscopic imaging interpretation;
- radiologic interventional skills, i.e.: percutaneous arterial puncture, wire/catheter passage and exchange into/in the vascular system, selective arterial cannulation, branch vessel embolization, balloon angioplasty, and stent placement; and
- selective vascular bypass procedures.

All physicians are required to complete a training program in the use of the ANCURE Systems. Training and demonstrations will be provided for all O.R. personnel and any backup personnel, as needed.

11.2. Directions for Use: ANCURE® Tube ENDOGRAFT® System

Note: This is a suggested sequence for the procedure. Variations may be used based upon patient anatomy and condition.

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11.2.1. Accessory Device Preparation

- Use of the ANCURE Expandable Sheath and a marker catheter are recommended. Prepare the expandable sheath and marker catheter according to the Instructions for Use packaged with the devices.
- Prepare inflation devices with 10 – 20% contrast, according to the manufacturer's instructions.

11.2.2. Patient Preparation

11.2.2.1. Vasculature

- Compare the labeling on the outer package to the pouch of the ANCURE Delivery Catheter and confirm graft size.
- The ipsilateral common femoral artery is exposed.
- Perform an angiogram of the abdominal aorta using the marker catheter from the ipsilateral side.
- Select an image from the angiogram run that demonstrates the renal arteries and the aortic bifurcation, and anatomical/radiopaque landmarks enabling return to the correct position for deployment.
- Draw a line on the monitor screen with an erasable marker at the renal arteries, at the aortic bifurcation, and anatomical/radiopaque landmarks enabling return to the correct position for deployment.
- Return to live fluoroscopy and align the radiopaque markers with the lines on the monitor screen indicating the renal arteries and the aortic bifurcation.

Caution: Avoid inadvertent movement of the C-arm, table, image intensifier, or the patient between acquiring the angiogram and marking the anatomical radiopaque landmarks. This could result in inaccurate placement of the graft due to changes in parallax.

- Use the markers on the marker catheter to measure the distance between the renal arteries and the aortic bifurcation.
- Select a graft based on the infrarenal aortic length measurement.
- Remove the marker catheter over a 0.035" (0.89 mm) stiff exchange length guidewire.

11.2.2.2. Sheath(s)

- Introduce the ANCURE Expandable Sheath over the 0.035" (0.89 mm) exchange length stiff guidewire in the ipsilateral femoral artery.
- Apply a water soluble lubricant to the sheath to facilitate insertion.
- Actuate the spring valve while advancing the coaxial dilator system.
- Leave the dilator system fully advanced for one minute so that the folded distal tip of the sheath is expanded.
- Unlock the dilator lock and retract the inner dilator until the sheath tip cover nests on the outer dilator.
- Tighten the dilator lock and remove the dilator system.
- Secure the expandable sheath to the patient with suture, if necessary.
- Attach a pressurized bag of heparinized saline to the flush port on the expandable sheath.
- Infuse the saline at a controlled rate to prevent backflow of blood through the flush port.
- An optional 6 Fr (2.0 mm) sheath may be introduced in the contralateral femoral artery. This provides access for performing an angiogram at any time during the procedure, and for positioning a crossover wire from the ipsilateral to the contralateral side for clear identification of the aortic bifurcation.

11.2.3. ANCURE® Tube System Preparation

- Flush the ANCURE System with heparinized saline via the flush port to displace air. Turn the stopcock to the "off" position.
- Flush the guidewire port with heparinized saline.
- Aspirate air from the aortic balloon with a syringe via the balloon inflation port. Turn the stopcock to the "off" position.

11.2.4. ANCURE® Tube System Introduction

- Wet the surface of the jacket with heparinized saline.
- Load the ANCURE Delivery Catheter onto the stiff guidewire. Insert the delivery catheter into the expandable sheath.
- Advance the delivery catheter until the superior attachment system is in alignment with a radiopaque marker identifying the renal arteries.

Warning: DO NOT use excessive force to advance or withdraw the delivery catheter when resistance is encountered as this may damage the vessel or catheter.

Caution: Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels to avoid vessel injury.

Caution: Ensure the delivery catheter is advanced into a straight portion of the aorta in preparation for jacket retraction, as jacket retraction forces are greater when the delivery catheter is bowed or kinked.

- Attach a pressurized bag of heparinized saline to the flush port on the delivery catheter handle.
- Infuse the saline at a controlled rate to prevent backflow of blood from the delivery catheter.
- Retract the expandable sheath, as appropriate to below the intended inferior attachment site. The radiopaque marker on the expandable sheath is used to confirm sheath location.

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11.2.5. ANCURE® Tube System Use

- Unlock the Jacket Lock #1 (see Figure 1) by turning the blue knob one rotation counterclockwise.

Warning: DO NOT deploy the graft in a location that may occlude arteries necessary to supply blood flow to organs or extremities.

- To facilitate jacket retraction a vigorous flush with 30-60 cc of heparinized saline is recommended.
- Retract the jacket.

Warning: Failure to completely retract the jacket will result in the inability to deploy the graft. If this occurs, it is recommended that the ANCURE System be removed via standard AAA surgery due to exposed superior attachment system hooks.

- Keep the delivery catheter stationary while retracting the jacket.
- Snap the jacket lock into the delivery catheter handle.

Caution: DO NOT re-lock the jacket lock to the main catheter. This will prohibit slider movement.

Caution: After jacket retraction, the hooks on the superior attachment system and the superior capsule edge are exposed. The attachment system frame is not deployed. At this point, care must be exercised while advancing or retracting the delivery catheter to avoid arterial trauma.

11.2.5.1. Superior Attachment System Deployment

11.2.5.1.1. Positioning

- Ensure that the superior attachment system hooks are in alignment with the radiopaque markers identifying the renal arteries.

Caution: Retracting the jacket results in loss of column strength; therefore, it may be difficult to advance the delivery catheter after jacket retraction. Take care not to retract the superior attachment system below the target zone.

Caution: If any changes are made in C-arm settings (i.e., longitudinal movement, angulation of, or raising or lowering of the image intensifier), another angiogram and realignment of the radiopaque markers should be performed for accurate placement of the attachment systems.

- Verify acceptable rotational alignment of the graft.

Caution: There is a hole in the jacket guard used during assembly which may be visualized under fluoroscopy. This should not be used for orientation of the graft during deployment.

- Fill the inflation device with dilute contrast and attach it to the balloon inflation port prior to deployment of the superior attachment system.

11.2.5.1.2. Deployment

Caution: A confirmation angiogram may be performed via the catheter in the contralateral iliac artery. The image intensifier should be centered over the renal arteries and magnified x 2. This technique can minimize parallax errors due to the divergent beam effect and enhance precise placement of the superior attachment system.

- Deploy the superior attachment system by removing Pin #2 and retracting the Superior Pull Ring #2 (see Figure 1). The superior pull ring and its release wire should be completely removed.

Warning: DO NOT retract the delivery catheter handle after deployment of the superior attachment system. Retraction of the delivery catheter could dislodge the superior attachment system hooks.

Warning: After deployment of the superior attachment system hooks, the graft can only be removed in an open surgical procedure.

11.2.5.1.3. Securing

- Unlock the aortic balloon lock.
- Secure the position of the delivery catheter and retract the balloon handle until the working area of the balloon is centered within the superior attachment system.
- Two radiopaque bands in the center of the aortic balloon identify the working area of the balloon. Place these bands in the center of the attachment system to ensure balloon contact on the hooks. Take care not to place the working area of the balloon above the attachment system as this may displace the attachment system downward.

Caution: DO NOT continue to pull the balloon grip if resistance is felt and the inferior attachment system has not been deployed. This may prevent deployment of the inferior attachment system.

Caution: Inflating/deflating the aortic balloon is similar to placing/removing a cross clamp. The patient may experience a significant change in arterial pressure.

- Lock the aortic balloon into position.
- Compare the diameter of the superior aortic neck to the diameter of the superior attachment system prior to aortic balloon inflation.

Warning: DO NOT inflate the aortic balloon without using a pressure measurement gauge such as that included on a balloon inflation device.

Warning: DO NOT over-inflate the aortic balloon as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

- Inflate the aortic balloon for one minute to vessel profile using a standard inflation device under fluoroscopic monitoring. Do not exceed 2 atm (30 psi, 200 kPa). Decrease balloon inflation pressure to less than 2 atmospheres if aortic balloon diameter exceeds diameter of the native artery. Deflate the balloon.

Warning: DO NOT rotate, advance, or retract the catheter while the aortic balloon is inflated. DO NOT over-inflate the aortic or iliac balloons.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

- Perform three one-minute inflations in the superior attachment system.

11.2.5.2. Inferior Attachment System Deployment

11.2.5.2.1. Positioning

- Check the aortic balloon under fluoroscopy to ensure that the balloon has completely deflated.
- Assess the graft for twist and overall length. Twist resolution is achieved by rotating the entire delivery catheter.
- Actuate the spring valve of the expandable sheath while rotating the delivery catheter to prevent damage to the hemostatic valve.
- A hand injection of contrast medium through the expandable sheath may be administered to identify the aortic bifurcation for accurate placement of the inferior attachment system.
- Reposition the aortic balloon if necessary. (The working area of the balloon may no longer be adjacent to the superior attachment system.)
- Inflate the aortic balloon to vessel profile to secure the superior attachment system while the inferior attachment system is being deployed.

Warning: DO NOT over inflate the aortic balloon as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

Warning: DO NOT rotate, advance, or retract the delivery catheter while the aortic balloon is inflated as damage to the aorta or aortic balloon may occur.

11.2.5.2.2. Deployment

Warning: DO NOT move the delivery catheter handle during slider retraction. Retraction of the delivery catheter could displace the superior attachment hooks.

- Retract the Slider **#3** (see Figure 1) to expose the inferior attachment system.
- Deploy the inferior attachment system by removing Pin **#4** and retracting the Inferior Pull Ring **#4** (see Figure 1). The inferior pull ring and its release wire should be completely removed.

Warning: If resistance is felt, STOP. DO NOT continue to retract the inferior release wire. This may lead to wire breakage and may result in patient conversion to standard care.

- If resistance is felt when retracting the inferior release wire,
  - verify that pin **#4** has been removed,
  - deflate and advance the aortic balloon 5 mm, while maintaining the position of the delivery catheter,
  - re-inflate the aortic balloon to secure the superior attachment system,
  - continue retraction with inferior release pull wire **#4**.
- **Check the patient's mean arterial pressure prior to deflating the aortic balloon.**
- Deflate the aortic balloon.

11.2.5.2.3. Securing

- Check the aortic balloon under fluoroscopy to ensure that the balloon has completely deflated.
- Retract the entire delivery catheter to align the aortic balloon in the inferior attachment system.

Warning: DO NOT apply excessive force when retracting the delivery catheter. This may cause displacement of the superior attachment system hooks or damage to the delivery catheter resulting in separation of components.

- **Gently** inflate the aortic balloon for one minute to vessel profile under fluoroscopy to secure the hooks in the vessel wall.

Warning: DO NOT over-inflate the aortic balloon as this may result in rupture of the distal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck. The aortic balloon may extend into the common iliac artery. Rupture of the iliac artery could result.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

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- Perform three one-minute inflations at the inferior attachment system.

11.2.6. Completion of the ANCURE® Tube System Procedure

11.2.6.1. Removal of the ANCURE® Delivery Catheter

- Deflate the aortic balloon.
- Remove the delivery catheter, taking care to maintain access of the stiff guidewire within the graft.
- Prepare the ANCURE Iliac Balloon Catheter according to the Instructions for Use packaged with the device.
- Inflate two iliac balloons, inserted through both groins (kissing balloons), to seat all interior hooks.

Warning: DO NOT over-inflate the iliac balloon. Over-inflation of the iliac balloon could result in arterial trauma.

11.2.7. Post Implant Procedures

- Perform a final angiogram to assess the graft position and to document complete exclusion of the aneurysm.

Caution: A completion angiogram using a power injector must be performed allowing for sufficient time to detect Type II Endoleaks.

- If no other interventions are required, remove the angiography catheter and introducer sheaths.
- Maintain wire access until closure.
- Close arteriotomies and cutdowns according to standard practice.

Caution: Although the graft is MRI safe up to 1.5 Tesla static magnetic field at 540 G/cm field gradient, it may cause minimal artifacts in MRI scans due to distortion of the magnetic field.

11.3. Directions for Use: ANCURE® Bifurcated ENDOGRAFT® System

Note: This is a suggested sequence for the procedure. Variations may be used based upon patient anatomy and condition.

11.3.1. Accessory Device Preparation

- Use of the ANCURE Expandable Sheath and a marker catheter are recommended. Prepare the expandable sheath and marker catheter according to the Instructions for Use packaged with the devices.
- Use of the DualPASS™ Tear-Away Sheath Introducer is recommended. Prepare the introducer according to the Instructions for Use packaged with the device.
- Prepare inflation devices with 10 – 20% contrast, according to the manufacturer's instructions.
- Prepare the snare catheter and 12 Fr (4.0 mm) sheath according to the manufacturer's instructions.
- Prepare the ANCURE Iliac Balloon Catheters according to Instructions for Use packaged with the device.

11.3.2. Patient Preparation

11.3.2.1. Vasculature

Caution: The access site (left or right) must be pre-determined for the variable limb length graft. Always use the side with the longest iliac attachment site as the access site to ensure proper order of deployment for the long and short limbs of the graft. Failure to observe this precaution may lead to improper sizing of the graft, possibly resulting in the need for additional medical intervention, including a conversion to standard surgical repair.

- Compare the labeling on the outer package to the pouch of the ANCURE Delivery Catheter and confirm graft size.
- The common femoral artery is exposed bilaterally.
- Perform an angiogram of the abdominal aorta using the marker catheter from the ipsilateral side.
- Select an image from the angiogram run that shows the renal arteries and the aortic bifurcation.
- Draw a line on the monitor screen with an erasable marker at the renal arteries, at the aortic bifurcation, and anatomical radiopaque landmarks enabling return to the correct position for deployment.
- Return to live fluoroscopy and align the radiopaque markers with the lines on the monitor screen indicating the renal arteries and the aortic bifurcation.

Caution: Avoid inadvertent movement of the C-arm, table, image intensifier, or the patient between acquiring the angiogram and marking the anatomical radiopaque landmarks. This could result in inaccurate placement of the graft due to changes in parallax.

- Use the markers on the marker catheter to measure the distance between the renal arteries and the aortic bifurcation.
- Select a graft based on the infrarenal aortic length measurement plus the length between the bifurcation and the predetermined iliac attachment zone.
- Remove the marker catheter over a 0.035" (0.89 mm) stiff exchange length guidewire.

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11.3.2.2. Sheath(s)

- Introduce the ANCURE Expandable Sheath over the 0.035" (0.89 mm) exchange length stiff guidewire in the ipsilateral femoral artery.
- Apply a water soluble lubricant to the sheath to facilitate insertion.
- Actuate the spring valve while advancing the coaxial dilator system.
- Leave the dilator system fully advanced for one minute so that the folded distal tip of the sheath is expanded.
- Unlock the dilator lock and retract the inner dilator until the sheath tip cover nests on the outer dilator.
- Tighten the dilator lock and remove the dilator system.
- Secure the expandable sheath to the patient with suture, if necessary.
- Attach a pressurized bag of heparinized saline to the flush port on the expandable sheath.
- Infuse the saline at a controlled rate to prevent backflow of blood through the flush port.
- Introduce a 12 Fr (4.0 mm) sheath in the contralateral femoral artery.

11.3.3. ANCURE® Bifurcated System Preparation

- Flush the ANCURE System with heparinized saline via the flush port to displace air. Turn the stopcock to the "off" position.
- Flush the guidewire port with heparinized saline.
- Aspirate air from the aortic balloon with a syringe via the balloon inflation port. Turn the stopcock to the "off" position.
- Flush the guidewire/injection lumen of the contralateral torque catheter with heparinized saline.

11.3.4. ANCURE® Bifurcated System Introduction

- If using the DualPASS Tear-Away Sheath Introducer, backload the introducer over the 0.035" (0.89 mm) stiff exchange guidewire (refer to the Instructions for Use packaged with the DualPASS Introducer).
- Introduce a snare in the contralateral sheath and position it in the patient's distal aorta.
- Position the loop of the snare near the aortic bifurcation or in the superior neck rather than in the aneurysm sac. This can facilitate capturing the contralateral pull-wire. If the iliac arteries lie in different planes (review CT image of the aortic bifurcation), snaring at the renal level may be easier.
- Introduce the delivery catheter's contralateral pull-wire in the patient's ipsilateral side. If using the DualPASS Introducer, feed the contralateral pull-wire through the "MEDIAL" port.
- Snare the contralateral pull-wire and then pull it around the aortic bifurcation and out the contralateral sheath.

Warning: DO NOT drag the contralateral pull-wire across the aortic bifurcation. As the contralateral operator is pulling the contralateral pull-wire with the snare, the ipsilateral operator should advance the contralateral pull-wire to prevent trauma to the aortic bifurcation.

- Hold the snare tautly inside the snare catheter to prevent the contralateral pull-wire from slipping out of the snare.
- Remove the DualPASS Tear-Away Sheath Introducer, if used.
- Wet the surface of the jacket with heparinized saline.
- Load the delivery catheter onto the stiff guidewire.

Warning: DO NOT use excessive force to advance or withdraw the delivery catheter when resistance is encountered as this may damage the vessel or catheter.

Caution: Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels to avoid vessel injury.

- Attach a pressurized bag of heparinized saline to the flush port on the delivery catheter handle.
- Infuse the saline at a controlled rate to prevent back flow of blood from the delivery catheter.
- Insert the delivery catheter into the expandable sheath.
- Contralateral pull-wire wrap around the delivery catheter is assessed at the bifurcation. If wrap is present rotate the delivery catheter until wrap is resolved.
  - Withdraw the catheter 5 - 8 cm and simultaneously rotate the delivery catheter 180 degrees counterclockwise. Advance the delivery catheter 5 - 8 cm while simultaneously rotating the catheter another 180 degrees. If wrap is corrected no further action is necessary.
  - If wrap is unresolved rotate the catheter 180 degrees in a clockwise direction during withdrawal and another 180 degrees clockwise during advancement of the delivery catheter.
- Slowly advance the entire delivery catheter and the pull-wire until the interior attachment systems are superior to the patient's native aortic bifurcation while maintaining orientation of the delivery catheter handle.

Caution: Ensure the delivery catheter is advanced into a straight portion of the aorta in preparation for jacket retraction, as jacket retraction forces are greater when the delivery catheter is bowed or kinked.

- Observe under fluoroscopy the original parallel alignment of the stiff guidewire and the contralateral pull-wire within the jacket. Twist is indicated when the contralateral pull-wire crosses the stiff guidewire.
- Visualize the contralateral pull-wire and the contralateral capsule as landmarks. Both the contralateral pull-wire and the contralateral capsule should face the contralateral side.

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- Retract the expandable sheath and, as appropriate, the 12 Fr (4.0 mm) sheath below the intended inferior attachment sites. The radiopaque marker on the expandable sheath is used to confirm sheath location.

11.3.5. ANCURE® Bifurcated System Use

- Unlock the Jacket Lock #1 (see Figure 1) by turning the blue knob one rotation counterclockwise.
- Place tension on the contralateral pull-wire.

Caution: It is important to maintain adequate tension on the contralateral pull-wire during jacket retraction to prevent it from getting entangled with the superior attachment system.

- Retract the contralateral pull-wire and the jacket simultaneously to uncover the graft. The superior attachment system hooks are now exposed, but not deployed.
- To facilitate jacket retraction a vigorous flush with 30 – 60 cc of heparinized saline is recommended.

Warning: If the pull-wire becomes entangled on the superior attachment system, relieve tension on pull-wire and continue with jacket retraction to avoid possible displacement of the figure 8.

- If the contralateral pull-wire becomes entangled, insert a fully braided catheter with a minimum diameter of 0.086" over the contralateral pull-wire to the level of the attachment system.
- Lift the contralateral pull-wire off the hooks using the fully braided catheter as a support.

Warning: Failure to completely retract the jacket will result in the inability to deploy the graft. If this occurs, it is recommended that the ANCURE System be removed via standard AAA surgery due to exposed superior attachment system hooks.

- Keep the delivery catheter stationary while retracting the jacket.
- Snap the jacket lock into the delivery catheter handle.

Caution: DO NOT re-lock the jacket lock to the main catheter. This will prohibit slider movement.

Caution: After jacket retraction, the hooks on the superior attachment system and the superior capsule edge are exposed. The attachment system frame is not deployed. At this point, care must be exercised while advancing or retracting the delivery catheter to avoid arterial trauma.

11.3.5.1. Superior Attachment System Deployment

11.3.5.1.1. Positioning

Caution: If any changes are made in C-arm settings (i.e., longitudinal movement, angulation of, or raising or lowering of the image intensifier), another angiogram and realignment of the radiopaque markers should be performed for accurate placement of the attachment systems.

Warning: DO NOT deploy the graft in a location that may occlude arteries necessary to supply blood flow to organs or extremities (e.g., a single, patent internal iliac or mesenteric artery); perfusion through at least one internal iliac artery should be maintained.

- Retract the entire delivery catheter until the superior attachment system hooks are in alignment with the radiopaque markers identifying the renal arteries.

Caution: A confirmation angiogram may be performed via a flush catheter in the 12 Fr. sheath in the contralateral iliac artery. The image intensifier should be centered over the renal arteries and magnified x 2. This technique may minimize parallax errors due to the divergent beam effect and enhance precise placement of the superior attachment system.

- Verify acceptable rotational alignment of the graft.

Caution: There is a hole in the jacket guard used during assembly which may be visualized under fluoroscopy. This should not be used for orientation of the graft during deployment.

- The contralateral pull-wire extension should be parallel with the stiff guidewire.
- Extreme trunk rotation may result in the graft limbs crossing in the aneurysm sac. The limbs crossing in the aneurysm sac may shorten the overall length of the graft and could potentially affect limb patency.

Caution: Retracting the jacket results in loss of column strength; therefore, it may be difficult to advance the delivery catheter after jacket retraction. Take care not to retract the superior attachment system below the target zone.

Caution: Another angiogram and realignment of the radiopaque markers should be performed for accurate placement of the attachment systems if any changes are made in C-arm settings, i.e. longitudinal movement, angulation of, or raising or lowering of the image intensifier.

- Fill the inflation device with dilute contrast and attach it to the balloon inflation port prior to deployment of the superior attachment system.

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11.3.5.1.2. Deployment

Caution: A confirmation angiogram may be performed via the catheter in the contralateral iliac artery. The image intensifier should be centered over the renal arteries and magnified x 2. This technique can minimize parallax errors due to the divergent beam effect and enhance precise placement of the superior attachment system.

- Deploy the superior attachment system by removing Pin #2 and retracting the Superior Pull Ring #2 (see Figure 1). The superior pull ring and its release wire should be completely removed.

Warning: DO NOT retract the delivery catheter handle after deployment of the superior attachment system. Retraction of the delivery catheter could dislodge the superior attachment system hooks.

Warning: After deployment of the superior attachment system hooks, the graft can only be removed in an open surgical procedure.

11.3.5.1.3. Securing

- Unlock the aortic balloon lock.
- Secure the position of the delivery catheter and retract the balloon handle until the working area of the balloon is centered within the superior attachment system.
- Two radiopaque bands in the center of the aortic balloon identify the working area of the balloon. Place these bands in the center of the attachment system to ensure balloon contact on the hooks. Take care not to place the working area of the balloon above the attachment system as this may displace the attachment system downward.

Caution: DO NOT continue to pull the balloon grip if resistance is felt and the ipsilateral attachment system has not been deployed. This may prevent deployment of the ipsilateral attachment system.

Caution: Inflating/deflating the aortic balloon is similar to placing/removing a cross clamp. The patient may experience a significant change in arterial pressure.

- Lock the aortic balloon into position.
- Compare the diameter of the superior aortic neck to the diameter of the superior attachment system prior to aortic balloon inflation.

Warning: DO NOT inflate the aortic balloon without using a pressure measurement gauge such as that included on a balloon inflation device.

Warning: DO NOT over-inflate the aortic balloon as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

- Inflate the aortic balloon for one minute to vessel profile using a standard inflation device under fluoroscopic monitoring. Do not exceed 2 atm (30 psi, 200 kPa). Decrease balloon inflation pressure to less than 2 atmospheres if aortic balloon diameter exceeds diameter of the native artery. Deflate the balloon.

Warning: DO NOT rotate, advance, or retract the catheter while the aortic balloon is inflated. DO NOT over-inflate the aortic or iliac balloons.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

- Perform three one-minute inflations in the superior attachment system

11.3.5.2. Contralateral Attachment System Deployment

11.3.5.2.1. Positioning

- Re-inflate the aortic balloon to vessel profile to secure the superior attachment system while the contralateral attachment system is being deployed.
- Introduce the contralateral torque catheter over the contralateral pull-wire until the tip of the torque catheter engages the contralateral capsule barb.
- Tighten the torque catheter's hemostatic valve over the reinforcement tube of the contralateral pull-wire.
- Assess the contralateral limb for twist. Twist resolution is achieved by rotating the torque catheter.

Caution: The contralateral limb is folded on itself when packed into the delivery catheter. To ensure that the limb is not deployed in its compressed state, make a visual check of the markers on the ENDOGRAFT Vascular Graft limb. The markers should be evenly spaced.

11.3.5.2.2. Deployment

- Place the pull-wire in the slot on the side of the cutter. Advance the cutter cephalad until it meets the hemostatic seal of the torque catheter.
- A hand injection of contrast medium through the sheath or the ANCURE Contralateral Torque Catheter may be administered to identify the internal iliac artery for accurate placement of the contralateral limb.
- Retract the cutter at least 5 cm, rotate 90°, then re-advance. The fusion joint should be released. If not, manually remove the free ends of the fusion joint, which may still be attached to the pull wire.
- Under fluoroscopic magnification, release the contralateral attachment system holding the contralateral pull-wire fixed while retracting the torque catheter.

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Caution: Care must be taken to maintain access of the pull-wire in the contralateral limb while removing the contralateral torque catheter.

- **Check the patient's mean arterial pressure prior to deflating the aortic balloon.**
- Deflate the aortic balloon and advance the contralateral pull-wire well into the graft.

11.3.5.2.3. Securing

- Advance the ANCURE Iliac Balloon Catheter over the contralateral pull-wire until the active area of the balloon is within the contralateral attachment system.
- Inflate the balloon to secure the hooks to the vessel wall. If the iliac balloon extends into the external iliac artery, limit inflation pressure to less than 2 atmospheres (30 psi, 200 kPa) (inflate to vessel profile).

Warning: DO NOT over-inflate the iliac balloon. Over-inflation of the iliac balloon could result in arterial trauma.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

- Perform two one-minute balloon inflations to vessel profile.
- Advance the balloon into the graft limb under fluoroscopic magnification to avoid dislodging the attachment system.
- Inflate the iliac balloon along the entire length of the contralateral limb to fully expand the graft limb.
- Remove the iliac balloon catheter. Maintain wire access.

11.3.5.3. Ipsilateral Attachment System Deployment

11.3.5.3.1. Positioning

- Check the aortic balloon under fluoroscopy to ensure that the balloon has completely deflated.
- Assess the ipsilateral limb for twist. Twist resolution is achieved by rotating the entire delivery catheter.
- Actuate the spring valve of the expandable sheath while rotating the delivery catheter to prevent damage to the hemostatic valve.
- A hand injection of contrast medium through the expandable sheath may be administered to identify the internal iliac artery for accurate placement of the ipsilateral limb.
- Reposition the aortic balloon if necessary. (The working area of the balloon may no longer be adjacent to the superior attachment system).
- Inflate the aortic balloon to vessel profile to secure the superior attachment system, in preparation for ipsilateral limb deployment.

Warning: DO NOT over-inflate the aortic balloon as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

Warning: DO NOT rotate, advance, or retract the catheter while the aortic balloon is inflated.

- Retract the sheath, if necessary, to avoid deployment of the iliac attachment system in the sheath.

11.3.5.3.2. Deployment

Warning: DO NOT move the delivery catheter handle during slider retraction. Retraction of the delivery catheter could displace the superior attachment hooks.

- Retract the Slider #3 (see Figure 1) to expose the ipsilateral attachment system.
- Deploy the ipsilateral attachment system by removing Pin #4 and retracting the Inferior Pull Ring #4 (see Figure 1). The inferior pull ring and its release wire should be completely removed.

Warning: If resistance is felt, STOP. DO NOT continue to retract the inferior release wire. This may lead to wire breakage and may result in patient conversion to standard care.

- If resistance is felt when retracting the inferior release wire,
  - verify that pin #4 has been removed,
  - deflate and advance the aortic balloon 5 mm, while maintaining the position of the delivery catheter,
  - re-inflate the aortic balloon to secure the superior attachment system,
  - continue retraction with inferior release pull wire #4, and
  - deflate the aortic balloon.

11.3.5.3.3. Securing

- Check the aortic balloon under fluoroscopy to ensure that the balloon has completely deflated.
- Retract the entire delivery catheter to align the aortic balloon in the ipsilateral iliac attachment system. If resistance is felt when retracting the delivery catheter ensure that the aortic balloon is completely deflated and re-attempt removal of the delivery catheter. If unsuccessful, the jacket guard may have encountered an area of local stenosis in the limb. Refer to Section 12.A, Delivery Catheter Removal.

Caution: Difficulties with delivery catheter removal may be encountered more frequently in patients that require grafts with variable limb lengths.

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Warning: DO NOT apply excessive force when retracting the delivery catheter. This may cause displacement of the superior attachment system hooks or damage to the delivery catheter resulting in separation of components.

- **Gently** inflate the aortic balloon for one minute to vessel profile under fluoroscopy to secure the hooks in the vessel wall.

Warning: DO NOT over-inflate the aortic balloon in the iliac attachment system. Rupture of the iliac artery could result.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

- Perform two one-minute balloon inflations to vessel profile.

11.3.6. Completion of the ANCURE® Bifurcated System Procedure

11.3.6.1. Removal of the ANCURE® Delivery Catheter

- Deflate the aortic balloon.
- Remove the delivery catheter taking care to maintain access of the stiff guidewire within the graft.
- Advance the ANCURE Iliac Balloon Catheter over the stiff guidewire until the active area of the balloon is within the ipsilateral attachment system.
- Inflate the balloon to secure the hooks to the vessel wall.

Warning: DO NOT over-inflate the iliac balloon. Overinflation of the iliac balloon could result in arterial trauma.

- Perform two one-minute balloon inflations to vessel profile.
- Perform balloon inflations along the entire length of the limb to fully expand the graft.
- Simultaneous inflation of the graft limbs with balloons (kissing balloons) may enhance patency of the limbs. Bilateral balloon inflation may protect one limb from compression that could occur during unilateral balloon inflation.
- Remove the iliac balloon(s) leaving both guidewires in place.

11.3.7. Post Implant Procedures

- Perform a final angiogram from the ipsilateral side to assess the vascular graft position and to document complete exclusion of the aneurysm. This should be done from the ipsilateral side over the standard guidewire.

Caution: A completion angiogram using a power injector must be performed allowing for sufficient time to detect Type II Endoleaks.

- If no other interventions are required, remove the angiography catheter, contralateral pull-wire and introducer sheaths.
- Following implantation of the bifurcated graft, the following can be performed to assess graft limb patency: angiography or Intravascular Ultrasound (IVUS) as well as pressure gradient measurements.
- Maintain wire access until closure.
- Close arteriotomies and cutdowns.

Caution: Although the graft is MRI safe up to 1.5 Tesla static magnetic field at 540 G/cm field gradient, it may cause minimal artifacts in MRI scans due to distortion of the magnetic field.

11.4. Directions for Use: ANCURE® Aortoiliac ENDOGRAFT® System

Note: This is a suggested sequence for the procedure. Variations may be used based upon patient anatomy and condition.

11.4.1. Pre-procedural Anatomical Considerations

- In order to prevent backflow into the aneurysm sac, permanent occlusion of the iliac artery will be required for most patients. Anatomy should be carefully evaluated prior to the procedure to determine the appropriate method and timing for occlusion of the iliac artery. This may be accomplished through methods selected by the physician. If complete atherosclerotic obstruction of the vessel(s) is already present, occluding the iliac artery may not be necessary.

  Note: If the iliac attachment zone is in the external iliac artery, it may be necessary to embolize the internal iliac artery.

11.4.2. Accessory Device Preparation

- Use of the ANCURE Expandable Sheath and a marker catheter are recommended. Prepare the sheath and marker catheter according to the Instructions for Use packaged with the devices.
- Prepare inflation devices with 10 – 20% contrast, according to the manufacturer's instructions.
- Prepare the ANCURE Iliac Balloon Catheter according to the Instructions for Use packaged with the device.

11.4.3. Patient Preparation

11.4.3.1. Vasculature

- Compare the labeling on the outer package to the pouch of the ANCURE Delivery Catheter and confirm graft size.
- The ipsilateral common femoral artery is exposed.

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- Perform an angiogram of the abdominal aorta using the marker catheter from the ipsilateral side.
- Select an image from the angiogram run that demonstrates the renal arteries and the aortic bifurcation.
- Draw a line on the monitor screen with an erasable marker at the renal arteries, at the aortic bifurcation, and anatomical/radiopaque landmarks enabling return to the correct position for deployment.
- Return to live fluoroscopy and align the radiopaque markers with the lines on the monitor screen indicating the renal arteries and the aortic bifurcation.

Caution: Avoid inadvertent movement of the C-arm, table, image intensifier, or the patient between acquiring the angiogram and marking the anatomical radiopaque landmarks. This could result in inaccurate placement of the graft due to changes in parallax.

- Use the markers on the marker catheter to measure the distance between the renal arteries and the aortic bifurcation.
- Select a graft based on the infrarenal aortic length measurement plus the length between the bifurcation and the predetermined iliac attachment zone.
- Remove the marker catheter over a 0.035" (0.89 mm) stiff exchange length guidewire.

11.4.3.2. Sheath(s)

- Introduce the ANCURE Expandable Sheath per the instruction for use packaged with the device.
- An optional 6 Fr sheath may be introduced in the contralateral femoral artery. This provides access for performing an angiogram during the procedure.

11.4.4. ANCURE® Aortoiliac System Preparation

- Flush the ANCURE System with heparinized saline via the flush port to displace air. Turn the stopcock to the "off" position.
- Flush the guidewire port with heparinized saline.
- Aspirate air from the aortic balloon with a syringe via the balloon inflation port. Turn the stopcock to the "off" position.

11.4.5. ANCURE® Aortoiliac System Introduction

- Wet the surface of the jacket with heparinized saline.
- Load the ANCURE Delivery Catheter onto the stiff guidewire. Insert the delivery catheter into the sheath.
- Advance the delivery catheter until the superior attachment system is at the renal arteries.

Warning: DO NOT use excessive force to advance or withdraw the delivery catheter when resistance is encountered, as this may damage the vessel or catheter.

Caution: Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels to avoid vessel injury.

Caution: Ensure the delivery catheter is advanced into a straight portion of the aorta in preparation for jacket retraction, as jacket retraction forces are greater when the delivery catheter is bowed or kinked.

- Attach a pressurized bag of heparinized saline to the flush port on the delivery catheter handle.
- Infuse the saline at a controlled rate to prevent back flow of blood from the delivery catheter.
- Retract the sheath, as appropriate to below the intended inferior attachment site.

11.4.6. ANCURE® Aortoiliac System Use

- Unlock the Jacket Lock #1 (see Figure 1) by turning the blue knob one rotation counterclockwise.

Warning: DO NOT deploy the graft in a location that will occlude arteries necessary to supply blood flow to organs or extremities; perfusion through at least one internal iliac artery should be maintained.

- To facilitate jacket retraction, a vigorous flush with 30 – 60 cc of heparinized saline is recommended.
- Retract the jacket.

Warning: Failure to completely retract the jacket will result in the inability to deploy the graft. If this occurs, it is recommended that the ANCURE System be removed via standard AAA surgery due to exposed superior attachment system hooks.

- Keep the delivery catheter stationary while retracting the jacket.
- Snap the jacket lock into the delivery catheter handle.

Caution: DO NOT re-lock the jacket lock to the main catheter. This will prohibit slider movement.

Caution: After jacket retraction, the hooks on the superior attachment system and the superior capsule edge are exposed. The attachment system frame is not deployed. At this point, care must be exercised while advancing or retracting the delivery catheter to avoid arterial trauma.

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11.4.6.1. Superior Attachment System Deployment

11.4.6.1.1. Positioning

- Ensure that the superior attachment system hooks are in alignment with the radiopaque markers identifying the renal arteries.

Caution: Retracting the jacket results in loss of column strength; therefore, it may be difficult to advance the delivery catheter after jacket retraction. Take care not to retract the superior attachment system below the target zone.

Caution: If any changes are made in C-arm settings (i.e., longitudinal movement, angulation of, or raising or lowering of the image intensifier), another angiogram and realignment of the radiopaque markers should be performed for accurate placement of the attachment systems.

- Verify acceptable rotational alignment of the graft.

Caution: There is a hole in the jacket guard used during assembly which may be visualized under fluoroscopy. This should not be used for orientation of the graft during deployment.

Caution: Another angiogram and realignment of the radiopaque markers should be performed for accurate placement of the attachment systems if any changes are made in C-arm settings, i.e. longitudinal movement, angulation of, or raising or lowering of the image intensifier.

- Fill the inflation device with dilute contrast and attach it to the balloon inflation port prior to deployment of the superior attachment system.

11.4.6.1.2. Deployment

- Deploy the superior attachment system by removing Pin #2 and retracting the Superior Pull Ring #2 (see Figure 1). The superior pull ring and its release wire should be completely removed.

Warning: DO NOT retract the delivery catheter handle after deployment of the superior attachment system. Retraction of the delivery catheter could dislodge the superior attachment system hooks.

Warning: After deployment of the superior attachment system hooks, the graft can only be removed in an open surgical procedure.

11.4.6.1.3. Securing

- Unlock the aortic balloon lock.
- Secure the position of the delivery catheter and retract the balloon handle until the working area of the balloon is centered within the superior attachment system.
- Two radiopaque bands in the center of the aortic balloon identify the working area of the balloon. Place these bands in the center of the attachment system to ensure balloon contact on the hooks. Take care not to place the working area of the balloon above the attachment system as this may displace the attachment system downward.

Caution: DO NOT continue to pull the balloon grip if resistance is felt and the inferior attachment system has not been deployed. This may prevent deployment of the inferior attachment system.

Caution: Inflating/deflating the aortic balloon is similar to placing/removing a cross clamp. The patient may experience a significant change in arterial pressure.

- Lock the aortic balloon into position.
- Compare the diameter of the superior aortic neck to the diameter of the superior attachment system prior to aortic balloon inflation.

Warning: DO NOT inflate the aortic balloon without using a pressure measurement gauge such as that included on a balloon inflation device.

Warning: DO NOT over-inflate the aortic balloon, as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

- Inflate the aortic balloon to vessel profile under fluoroscopic monitoring using a standard inflation device. Do not exceed 2 atm (30 psi, 200 kPa). Decrease balloon inflation pressure to less than 2 atmospheres if aortic balloon diameter exceeds diameter of the native artery. Deflate the balloon.

Warning: DO NOT rotate, advance, or retract the catheter while the aortic balloon is inflated as damage to the aorta or aortic balloon may occur. DO NOT over-inflate the aortic balloon.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

- Perform three one-minute inflations in the superior attachment system.

11.4.6.2. Ipsilateral Attachment System Deployment

11.4.6.2.1. Positioning

- Check the aortic balloon under fluoroscopy to ensure that the balloon has completely deflated.

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Warning: DO NOT rotate, advance, or retract the catheter while the aortic balloon is inflated as damage to the aorta or aortic balloon may occur. DO NOT over-inflate the aortic balloon.

- Assess the graft for twist and overall length. Twist resolution is achieved by rotating the entire delivery catheter.
- Actuate the spring valve of the sheath while rotating the delivery catheter to prevent damage to the hemostatic valve.
- Reconfirm location of the internal iliac artery prior to deployment of the inferior attachment system.
- A hand injection of contrast medium through the sheath may be administered to identify the internal iliac artery for accurate placement of the ipsilateral limb.
- Reposition the aortic balloon if necessary. (The working area of the balloon may no longer be adjacent to the superior attachment system.)
- Inflate the aortic balloon to vessel profile to secure the superior attachment system while the ipsilateral attachment system is being deployed.

Warning: DO NOT over inflate the aortic balloon as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

Warning: DO NOT rotate, advance, or retract the delivery catheter while the aortic balloon is inflated as damage to the aorta or aortic balloon may occur.

Warning: Acute occlusion of both internal iliac arteries could cause ischemic complications in the pelvis.

- Retract the ANCURE Expandable Sheath, if necessary, to avoid deployment of the iliac attachment system in the sheath.

11.4.6.2.2. Deployment

Warning: DO NOT move the delivery catheter handle during slider retraction. Retraction of the delivery catheter could displace the superior attachment hooks.

- Retract the Slider #3 (see Figure 1) to expose the ipsilateral attachment system.
- Deploy the ipsilateral attachment system by removing Pin #4 and retracting the Inferior Pull Ring #4 (see Figure 1). The inferior pull ring and its release wire should be completely removed.

Warning: If resistance is felt, STOP. DO NOT continue to retract the inferior release wire. This may lead to wire breakage and may result in patient conversion to standard care.

- If resistance is felt when retracting the inferior release wire,
  - verify that pin #4 has been removed,
  - deflate and advance the aortic balloon 5 mm, while maintaining the position of the delivery catheter,
  - re-inflate the aortic balloon to secure the superior attachment system,
  - continue retraction with inferior release pull wire #4.
- **Check the patient's mean arterial pressure prior to deflating the aortic balloon.**
- Deflate the aortic balloon.

11.4.6.2.3. Securing

- Check the aortic balloon under fluoroscopy to ensure that the balloon has completely deflated.
- Retract the entire delivery catheter to align the aortic balloon in the ipsilateral iliac attachment. If resistance is felt when retracting the delivery catheter, ensure that the aortic balloon is completely deflated and re-attempt removal of the delivery catheter. If unsuccessful, the jacket guard may have encountered an area of local stenosis in the limb. Refer to Section 12.A, Delivery Catheter Removal.

Warning: DO NOT apply excessive force when retracting the delivery catheter. This may cause displacement of the superior attachment system hooks or damage to the delivery catheter resulting in separation of components.

- **Gently** inflate the aortic balloon for one minute under fluoroscopy to secure the hooks in the vessel wall.

Warning: DO NOT over-inflate the aortic balloon in the iliac attachment system. Rupture of the iliac artery could result.

Warning: Inadequate anchoring of the graft may result in increased risk of perigraft flow or migration.

- Perform two one-minute balloon inflations to vessel profile.

11.4.7. Completion of the ANCURE® Aortoiliac System Procedure

11.4.7.1. Removal of the ANCURE® Delivery Catheter

- Deflate the aortic balloon.
- Remove the delivery catheter, taking care to maintain access of the stiff guidewire within the graft.
- Advance the ANCURE Iliac Balloon Catheter over the stiff guidewire until the active area of the balloon is within the iliac attachment system.
- Inflate the balloon to secure the hooks to the vessel wall. If the iliac balloon extends into the external iliac artery, limit inflation pressure and inflate to vessel profile.

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Warning: DO NOT over-inflate the iliac balloon. Over inflation of the iliac balloon could result in arterial trauma.

- Perform two one-minute balloon inflations to vessel profile.
- Advance the balloon into the graft limb under fluoroscopic magnification to avoid dislodging the attachment system.
- Perform balloon inflations along the entire length of the limb to fully expand the graft.
- Remove the iliac balloon leaving the stiff guidewire in place.

11.4.8. Adjunctive Procedures

- Perform the femorofemoral bypass procedure according to standard practice, restoring flow to the ipsilateral and contralateral limbs at the appropriate times. Perform one of the following procedures to prevent backflow into the aneurysm sac and to maintain adequate pelvic circulation:
  - if the ipsilateral internal iliac artery remains patent, occlude either the contralateral common iliac artery or the contralateral external and internal iliac arteries.
    OR
  - if the ipsilateral internal iliac artery is no longer patent, occlude the contralateral common iliac artery.

11.4.9. Post Implant Procedures

- Perform a final angiogram to assess the graft position and to document complete exclusion of the aneurysm. Assess patency of the femorofemoral bypass.

Caution: A completion angiogram using a power injector must be performed allowing for sufficient time to detect Type II Endoleaks.

- If no other interventions are required, remove the angiography catheter and introducer sheath(s).
- Following implantation of the graft, the following can be performed to assess graft limb patency: angiography or Intravascular Ultrasound (IVUS) as well as pressure gradient measurements.
- Maintain wire access until closure.
- Close arteriotomies and cutdowns according to standard practice.

Caution: Although the graft is MRI safe up to 1.5 Tesla static magnetic field at 540 G/cm field gradient, it may cause minimal artifacts in MRI scans due to distortion of the magnetic field.

11.5. Suggested Patient Follow-up

Note: This is a suggested follow-up protocol. Actual follow-up should be based on the condition of the individual patient.

The following diagnostic radiological evaluations should be used to assess the efficacy of endovascular AAA repair:

- Contrast enhanced Computed Tomography Scan (CT) should be used to assess the diameter of the aneurysm sac, the presence of perigraft flow, and graft migration.
- Duplex Ultrasound (US) of the aorto-iliac vessels may also be used to assess the presence of perigraft flow and the diameter of the aneurysm sac. US may be more technician dependent and, therefore, less reproducible than CT for measuring the diameter of the aneurysm sac. US should only be used exclusively in patients for whom iodinated contrast enhanced CT is contraindicated.
- Abdominal X-ray should be used to assess the integrity of the attachment system and any movement of the graft relative to bony landmarks. It is recommended to acquire both a frontal (AP) view and both obliques (LPO and RPO at 30 degrees) as well as a lateral view centered on the iliac crest with the patient lying in the supine position. (Care must be taken to avoid parallax by centering all films at the same position.
- Compare follow-up X-ray and CTs to films obtained at discharge to assess for the movement of the graft relative to bony landmarks or within the vasculature.
- Angiography is not part of standard follow-up, but may be useful based on patient condition.
- If a contrast CT is contraindicated, an MRI or MRI Angiography may be useful.
- Use US to assess the patency of any femoro-femoral bypass graft used in conjunction with the Aortoiliac graft.

The following follow-up schedule is suggested for patients without evidence of perigraft flow:

Table 21. Suggested Follow-up Schedule for Patients Without Evidence of Perigraft Flow

Diagnostic Test	Time Postoperative		
	0 – 7 Days	6 Months	Annually
Contrast CT	X	X	X
Duplex US	X[1]	X[1]	X[1]
Abdominal X-rays	X	X	X
Fem-fem US (Aortoiliac only)			X

1. US required only when contrast enhanced CT is contraindicated

The following follow-up schedule is suggested for patients with evidence of perigraft flow and should be continued for at least 6 months after the flow resolves, at which time the schedule for patients without perigraft flow can be followed.

Table 22. Suggested Follow-up Schedule for Patients With Evidence of Perigraft Flow

Diagnostic Test	Time Postoperative		
	6 – 7 Days	Every 6 months	Annually
Contrast CT	X	X	
Duplex US	X[1]	X[1]	
Abdominal X-rays	X	X[2]	
Fem-fem US (Aortoiliac only)			X

1. US required only when contrast enhanced CT is contraindicated
2. After 6 month visit, only required annually thereafter

Note: Please return all explanted grafts to Guidant for analysis. Call Guidant Customer Service for an explant kit.

- Describe the fixative
- Include patient history and summary
- Include full shipping address

12. TROUBLESHOOTING SUGGESTIONS

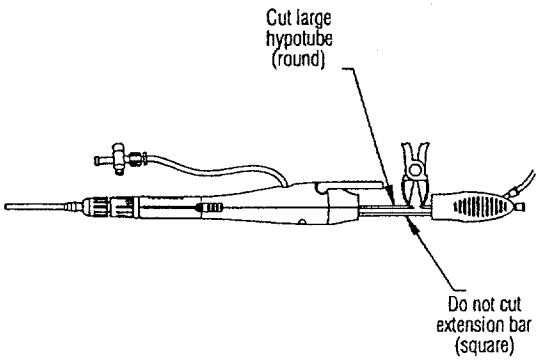
CONTENTS:

A. Delivery Catheter Removal Issues

Materials required:
- Sterile Wire Cutter: Heavy wire cutters or equivalent, such as bone snips.
- Sheath Introducer: 11F minimum ID sheath introducer, minimum 45 cm length.
- Floppy tip 0.035" (0.89 mm) guidewire.

Steps:
- Deflate the ANCURE aortic balloon.
- Withdraw the 0.035" (0.89 mm) stiff exchange length guidewire from the ANCURE delivery catheter.
- Use sterile wire cutters to cut the ANCURE large hypotube close to the balloon grip (see Figure 6). Remove the delivery catheter, leaving the quadlumen in place. Grasp and secure the quadlumen as soon as it is exposed. All that remains *in vivo* is the quadlumen with jacket guard and aortic balloon (See Figure 7).

Figure 6



- Reinsert the 0.035" (0.89 mm) stiff guidewire in the quadlumen.

Caution: Maintain control of the quadlumen during all manipulations to avoid cephalad migration.

- Advance the sheath introducer over the quadlumen and position the sheath introducer tip inside the ipsilateral graft limb as close to the jacket guard as possible, while observing the position of the ipsilateral attachment system under fluoroscopy. Magnification is recommended for best observation.

Caution: Take care not to dislodge the ipsilateral attachment system. This could result in damage to the attachment system, inability to achieve seal or inability to gain access.

- The sheath introducer may be used to push the jacket guard cephalad to allow room for a floppy tip 0.035" (0.89 mm) guidewire.
- Insert a floppy tip 0.035" (0.89 mm) guidewire into the sheath introducer, beside the quadlumen and inside the ipsilateral graft limb. Verify that the floppy tip guidewire is inside the ipsilateral graft limb.

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- Withdraw the sheath introducer.
- Advance an appropriately sized balloon catheter, such as the ANCURE Iliac Balloon Catheter, over the guidewire next to the quadlumen while observing the position of the ipsilateral attachment system under fluoroscopy. Magnification is recommended for best observation.

Caution: Take care not to dislodge the ipsilateral attachment system. This could result in damage to the attachment system, inability to achieve a seal or inability to gain access.

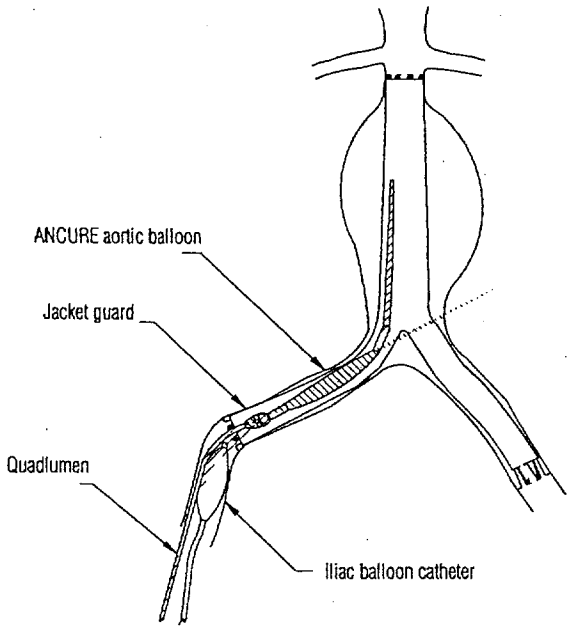
- Position the iliac balloon below and as close to the jacket guard as possible, inside the ipsilateral graft limb. Inflate the iliac balloon to vessel profile to create space for the jacket guard. Do not exceed 2 atm (30 psi, 200 kPa).

Warning: DO NOT over-inflate the iliac balloon. Over-inflation of the iliac balloon could result in arterial trauma.

Warning: DO NOT inflate the iliac balloon in a position alongside the jacket guard as this could result in arterial trauma.

- Alternate jacket guard retraction with ballooning the ipsilateral limb as needed until the jacket guard is fully withdrawn. Remove the floppy tip 0.035" (0.89 mm) guidewire; leave the 0.035" (0.89 mm) stiff guidewire in place.

Figure 7



- Resume ANCURE procedure within Section 11.3.6.1, at the step, "Advance the ANCURE Iliac Balloon Catheter over the stiff guidewire."

B. Type I Endoleaks (Attachment Site)

- Re-balloon the superior attachment system using a balloon appropriately sized to the superior neck diameter.

Warning: DO NOT over-inflate the aortic balloon as this may result in rupture of the proximal aortic neck. The aortic balloon and attachment system may be larger than the aortic neck.

- Use two iliac balloons to perform the kissing balloon technique in the tube inferior attachment system to increase the potential for balloon contact on all hooks.
- Center the balloon(s) within the attachment frame as well as at the hooks.
- Reversal of systemic anticoagulation may promote thrombus formation at the site of the leak.

Warning: DO NOT over-inflate the iliac balloon. Over-inflation of the iliac balloon could result in arterial trauma.

- Clinical investigators have placed a stent(s) into the graft limb to aide in graft limb to vessel apposition.

Warning: The safety and effectiveness of a stent within a graft has not been established.

C. Reduced Limb Flow

Warning: The safety and effectiveness of a stent within a graft has not been established.

C.1 Focal limb twist
- Inflate iliac balloon in the area of restricted flow.
- Clinical investigators have used stents in graft limbs to treat restricted flow.

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C.2 Redundant graft material
- Inflate iliac balloon in area of restricted flow to "iron" redundant graft material.
- Clinical Investigators have used stents in graft limbs to treat restricted flow.

C.3 Kinked graft limb
- Inflate iliac balloon in area of restricted flow.
- Clinical Investigators have used stents in graft limbs to treat restricted flow.

C.4 Limb occlusion
- Limb occlusions, although rare, were successfully treated in the clinical study with the usual interventional techniques including administration of a thrombolytic agent, thrombectomy, angioplasty, and stents.

13. MATERIALS, STORAGE, AND HANDLING

13.1. Storage and Handling

- Handle with care.
- Store at room temperature.
- Avoid extremes of humidity.

13.2. List of Materials

REQUIRED:
- ANCURE ENDOGRAFT System with an appropriately sized ENDOGRAFT® Vascular Prosthesis.
- Marker Catheter.
- ANCURE Iliac Balloon Catheter, or equivalent.
- Heparinized saline.
- IV Heparin.
- Pressure bags.
- 0.035" (0.89 mm) stiff, exchange-length guidewire.
- 0.035" (0.89 mm) standard guidewire.
- Inflation device:
  Approximately 20 – 30 ml of inflation volume is required for aortic balloon inflation, depending upon diameter.
- Guiding catheter, fully braided 0.086" (2.18 mm) I.D.
- Intravascular snare.
- Dilute contrast (10 – 20%) for balloon inflation.
- Fluoroscopy.
- Torquable guidewire.
- Standard surgical instrumentation in the event open AAA procedure is required.

SPECIFICALLY REQUIRED FOR THE ANCURE BIFURCATED SYSTEM:
- 20 cc capacity inflation device is required for iliac balloon inflation.
- 12 Fr (4 mm) introducer sheath for contralateral access.

RECOMMENDED MATERIALS (OPTIONAL):
- ANCURE Expandable Sheath.
- DualPASS™ Tear-Away Sheath Introducer (bifurcated only).
- Introducer Sheath 6 Fr (2.0 mm) or 7 Fr (2.3 mm) (tube only).

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This product may be manufactured under one or more of the following U.S. patents:
5,397,345; 4,787,899; 5,489,295; 5,562,728; 5,609,625;
5,628,783; 5,662,700; 5,669,936; 5,782,909; 5,749,920;
5,769,885; 5,693,083; 5,800,518; 5,824,039; 5,957,973; 6,017,364; 6,030,413; 6,039,758;
6,132,459; 6,197,046; 6,210,435; 6,214,038; 6,221,102; 6,235,050; 6,241,759; 5,104,399;
6,322,587 and 6,287,330.
Other U.S. and foreign patents pending.