

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.

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1. DEVICE DESCRIPTION

The Guidant ANCURE™ ENDOGRAFT® System (ANCURE System) consists of the ANCURE™ ENDOGRAFT® Vascular Graft (Endograft) and the ANCURE™ Delivery Catheter. The ANCURE System is available in both tube and bifurcated configurations.

The ANCURE Endograft 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.

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 Endograft 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 aneurysms, in patients whose aneurysm etiology was other than degenerative/atherosclerosis, or in patients who have non-iatrogenic bleeding diatheses.

PATIENT SELECTION, TREATMENT, AND FOLLOW-UP

- 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.
- Conversion to standard surgical repair following endovascular repair should be considered for patients experiencing an increase in the size of their AAA.
- 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.
- 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.

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 resterilize the ANCURE System. Resterilization 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 Endograft 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

- Always use fluoroscopy for guidance and observation of the ANCURE System within the vasculature.
- DO NOT use excessive force to advance or withdraw the delivery catheter when resistance is encountered.
- Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels.
- DO NOT deploy the Endograft in a location that will occlude arteries necessary to supply blood flow to organs or extremities (e.g., a single, patent internal hypogastric (iliac) or mesenteric artery).
- Heparin flush should be avoided in patients with a history of sensitivity to heparin.
- After jacket retraction, the hooks on the superior attachment system and the superior capsule edge are exposed. The attachment system frame is not open at this point. Care must be exercised while advancing or retracting the delivery catheter after this point.
- After deployment of the superior attachment system hooks, the Endograft can only be removed in an open surgical procedure.
- DO NOT advance 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) attachment system has not been deployed.
- Inadequate anchoring of the Endograft may result in increased risk of perigraft flow or migration.

5. ADVERSE EVENTS

5.1. Observed Adverse Events

A total of 532 patients were enrolled in the EGS clinical study (153 tube, 268 bifurcated, and 111 control), and 89 patients were enrolled in the ANCURE clinical study (9 tube

and 80 bifurcated). Both trials provide the basis for the observed event rates. Adverse event data are summarized in alphabetical order in Tables 1 and 2.

In the EGS clinical study, the operative mortality rate was less than three percent in all treatment groups (0.0% tube, 2.6% bifurcated, 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. Three control patients died in the operative period.

In the ANCURE clinical study, the operative mortality rate was virtually identical in the ANCURE and bifurcated EGS subjects (2.2% and 2.6% respectively). Two ANCURE bifurcated subjects expired in the early postoperative period. One died from a myocardial infarction on post-operative day two. The other, who required an intraoperative conversion, died from cardiovascular collapse on the sixth postoperative day. There were no deaths among the ANCURE tube subjects.

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

Event	ANCURE (Tube & Bifurcated) ¹		Tube EGS		Bifurcated EGS		Control ²	
	%	(n/N)	%	(n/N)	%	(n/N)	%	(n/N)
Deaths – Operative	2.2%	(2/89)	0.0%	(0/153)	2.6%	(7/268)	2.7%	(3/111)
Other Adverse Events								
Arterial Trauma ³	13.5%	(12/89)	7.2%	(11/153)	16.0%	(43/268) ⁵	0.0%	(0/111)
Bleeding	12.4%	(11/89)	8.5%	(13/153)	15.7%	(42/268)	39.6%	(44/111)
Bowel	1.1%	(1/89)	5.2%	(8/153)	3.0%	(8/268)	8.1%	(9/111)
Cardiac	7.9%	(7/89)	10.5%	(16/153)	13.4%	(36/268)	20.7%	(23/111)
Coagulopathy	2.3%	(2/89)	0.7%	(1/153)	3.0%	(8/268)	4.5%	(5/111)
Conversions ⁴	3.4%	(3/89)	7.8%	(12/153)	9.7%	(26/268)	N/A	
Deep Vein Thrombosis	0.0%	(0/89)	0.7%	(1/153)	1.1%	(3/268)	0.9%	(1/111)
Embolism – Lower Extremity Ischemia	7.9%	(7/89)	3.9%	(6/153)	3.0%	(8/268)	0.9%	(1/111)
Hematoma	6.7%	(6/89)	10.5%	(16/153)	9.3%	(25/268)	1.8%	(2/111)
Impotence	0.0%	(0/89)	0.0%	(0/153)	0.0%	(0/268)	1.8%	(2/111)
Paraplegia/Paraparesis	0.0%	(0/89)	0.0%	(0/153)	0.4%	(1/268)	0.0%	(0/111)
Perigraft Flow, Discharge	19.3%	(16/83)	44.4%	(60/135)	48.4%	(106/219)	N/A	
Prosthetic Thrombosis	6.7%	(6/89)	0.0%	(0/153)	2.6%	(7/268)	0.0%	(0/111)
Reduced Limb Flow ⁵	37.7%	(29/77)	N/A		31.8%	(77/242)	N/A	
Renal Insufficiency	2.3%	(2/89)	3.3%	(5/153)	8.2%	(22/268)	1.8%	(2/111)
Respiratory	1.1%	(1/89)	7.2%	(11/153)	10.1%	(27/268)	22.5%	(25/111)
Stroke	3.4%	(3/89)	0.0%	(0/153)	0.7%	(2/268)	0.9%	(1/111)
TIA	0.0%	(0/89)	0.7%	(1/153)	0.7%	(2/268)	0.0%	(0/111)
Wound	3.4%	(3/89)	5.2%	(8/153)	3.4%	(9/268)	1.8%	(2/111)

1. Nine of the ANCURE subjects were tube subjects and 80 were bifurcated subjects.

2. 94 of the Control subjects were tube subjects and 17 were bifurcated subjects.

3. One bifurcated EGS arterial trauma resulted in limb amputation.

4. There were three conversions >30 days postoperative (1 tube and 2 bifurcated patients).

5. The analyses included only implanted patients. An additional 16 bifurcated subjects experienced reduced limb flow > 30 days postoperative.

Table 2. Adverse Event Rates at 12 months¹ (Listed Alphabetically)

Event	Tube EGS (%)	Bifurcated EGS (%)	Control ² (%)
Deaths	6.0%	7.1%	5.4%
Other Adverse Events			
Arterial Trauma	7.2%	16.1%	1.0%
Bleeding	8.5%	15.7%	39.6%
Bowel	5.9%	3.0%	11.0%
Cardiac	16.5%	22.3%	24.6%
Graft Migration ³	0.7%	0.4%	N/A
Perigraft Flow ³	25.0%	31.3%	N/A
Renal Insufficiency	4.7%	10.6%	1.8%
Respiratory	9.9%	16.3%	24.3%
Wound	5.9%	3.8%	1.9%

1. Event rates are based on Kaplan Meier methodology
2. 94 of the Control subjects were tube subjects and 17 were bifurcated subjects.
3. These events were assessed at discrete time points (discharge, 6 mos., 12 mos.) therefore Kaplan Meier estimates of the rates were not performed.

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

6. CLINICAL SUMMARY

Two clinical studies were conducted. The first study, referred to as the EGS clinical study, was conducted at 22 investigational sites using a first generation delivery catheter. This prospective, multi-center, non-randomized clinical study compared patients treated with the tube and bifurcated EGS Systems to a concurrent control group.

The second clinical study, referred to as the ANCURE clinical study, was conducted at 16 investigational sites to compare patients treated with the new ANCURE delivery system to patients previously treated in the EGS clinical study.

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	ANCURE (Tube & Bifurcated) (N=89) ¹		Tube EGS (N=153)		Bifurcated EGS (N=268)		Control (N=111) ²	
	n	%	n	%	n	%	n	%
Male	81	(91.0%)	131	(85.6%)	240	(89.6%)	85	(76.6%)
Age (yrs) Mean ±SD	72.8 ± 7.8		73.8 ± 7.1		72.7 ± 7.7		71.6 ± 7.0	
Race (Caucasian)	87	(97.8%)	145	(94.8%)	254	(94.8%)	108	(97.3%)
CAD	45	(50.6%)	85	(55.6%)	165	(61.6%)	68	(61.3%)
MI	25	(28.1%)	45	(29.4%)	105	(39.2%)	43	(38.7%)
Arrhythmia	38	(42.7%)	40	(26.1%)	89	(33.2%)	21	(18.9%)
Valvular Heart Disease	8	(9.0%)	20	(13.1%)	32	(11.9%)	10	(9.0%)
CHF	9	(10.1%)	18	(11.8%)	35	(13.1%)	8	(7.2%)
Stroke	12	(13.5%)	24	(15.7%)	34	(12.7%)	13	(11.7%)
Hypertension	58	(65.2%)	91	(59.5%)	166	(61.9%)	79	(71.2%)
PAOD	6	(6.7%)	16	(10.5%)	37	(13.8%)	12	(10.8%)
COPD	19	(21.3%)	43	(28.1%)	77	(28.7%)	33	(29.7%)
Smoking	66	(74.2%)	117	(76.5%)	217	(81.0%)	100	(90.1%)
Diabetes	13	(14.6%)	18	(11.8%)	32	(11.9%)	11	(9.9%)
Anesthesia Risk								
I	1	(1.1%)	0	(0.0%)	1	(0.4%)	1	(0.9%)
II	10	(11.2%)	27	(17.9%)	36	(13.5%)	14	(12.6%)
III	64	(71.9%)	103	(68.2%)	175	(65.8%)	79	(71.2%)
IV	14	(15.7%)	21	(13.9%)	54	(20.3%)	17	(15.3%)

1. Nine of the ANCURE subjects were tube subjects and 80 were bifurcated subjects.
2. 94 of the Control subjects were tube subjects and 17 were bifurcated subjects.

Table 5. Aneurysm Diameter Distribution

Diameter Range	ANCURE (Tube & Bifurcated) (N=88)		Tube EGS (N=152)		Bifurcated EGS (N=266)		Control (N=102)	
	n	%	n	%	n	%	n	%
< 30 mm	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
30 mm – 39 mm	1	(1.1%)	8	(5.3%)	7	(2.6%)	2	(2.0%)
40 mm – 49 mm	33	(37.5%)	60	(39.5%)	75	(28.2%)	28	(27.5%)
50 mm – 59 mm	41	(46.6%)	65	(42.8%)	116	(43.6%)	42	(41.2%)
60 mm – 69 mm	11	(12.5%)	13	(8.6%)	44	(16.5%)	21	(20.6%)
70 mm – 79 mm	2	(2.3%)	5	(3.3%)	19	(7.1%)	6	(5.9%)
80 mm – 89 mm	0	(0.0%)	1	(0.7%)	5	(1.9%)	3	(2.9%)
≥ 90 mm	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)

6.2. Summary of the EGS Studies

Purpose: This clinical study compared the rates of (proportions of patients with) major complications for patients treated with the Tube and Bifurcated 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 and Bifurcated EGS systems to a concurrent control group. All patients had a grade I (Tube) or II (Bifurcated) 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 and 6 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 268 Bifurcated, 153 Tube and 111 control patients.

Table 6. Principle 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]
	Control	2.7%	(3/111)	--
Major Complications ² (≤ 30 days)	Tube	19.6%	(30/153)	-24.5% ⁴ [-35.7, -13.4]
	Bifurcated	28.7%	(77/268)	-15.4% ⁴ [-26.1, -4.7]
	Control	44.1%	(49/111)	--
Need for ICU Stay (%)	Tube	35.5%	(54/152)	-60.8% ⁴ [-70.5, -50.9]
	Bifurcated	39.1%	(102/261)	-57.2% ⁴ [-66.0, -48.6]
	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]
	Control	0.0%	(0/111)	--
		Median	(N)	
Hospital Stay (days)	Tube	2	(152)	-4.0 ⁴ [-4.0, -3.0]
	Bifurcated	3	(262)	-3.0 ⁴ [-4.0, -3.0]
	Control	6	(108)	--
ICU Stay (hours) ³	Tube	24.0	(54)	-3.0 ⁵ [-10.0, 0.0]
	Bifurcated	24.0	(101)	-3.0 ⁴ [-8.0, -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 ⁴ [-42.0, 19.0]
	Control	167.0	(111)	--
Operative Blood Loss (cc)	Tube	200	(151)	-600 ⁴ [-675, -500]
	Bifurcated	300	(268)	-500 ⁴ [-550, -350]
	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. Major Complications = significant respiratory, cardiac, bleeding, bowel, wound, renal, arterial trauma, neurological and ischemic complications, and death.
3. ICU Stay duration includes only subjects who went to the ICU.
4. p<0.01
5. p<0.05

Table 7. Principle Safety and Effectiveness Results for EGS (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]
Postop Conversions	Tube	1/141	0.7% [0.2, 3.9]
	Bifurcated	2/235	0.9% [0.1, 3.0]
Aneurysm Rupture	Tube	0/141	0.0% [0, 1.9]
	Bifurcated	0/242	0.0% [0.1, 3.0]
Reduced Limb Flow ²	Tube	N/A	N/A
	Bifurcated	93/242	38.4% [32, 45]
Perigraft Flow, Discharge	Tube	60/135	44.4% [36, 53]
	Bifurcated	106/219	48.4% [42, 55]
Perigraft Flow, 12 mo	Tube	26/104	25.0% [17, 34]
	Bifurcated	40/128	31.3% [23, 40]
Increased Aneurysm Size (≥ 5 mm), 12 mo	Tube	6/103	5.8% [2.2, 12]
	Bifurcated	3/134	2.2% [0.5, 6.4]
Decreased Aneurysm Size, (≥ 5 mm), 12 mo	Tube	44/103	42.7% [33, 53]
	Bifurcated	64/134	47.8% [39, 57]
Graft Migration	Tube	1/141	0.7% [0.0, 3.9]
	Bifurcated	1/242	0.4% [0, 2.3]

1. Intraop Conversions = access failure or failure to deploy. Protocol required these subjects to undergo standard AAA repair.

2. Reduced Limb Flow = intraoperative or postoperative intervention during the first 12 mos. to treat reduced limb patency.

6.3. Summary of the ANCURE Study

Purpose: The ANCURE and EGS systems are different delivery systems that deploy the same Tube and Bifurcated endografts. 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. The primary endpoint was to establish that the rate of intraoperative conversion to standard surgery was equivalent for the two delivery catheter designs.

Study Design: This prospective, multi-center clinical study compared patients treated with the Tube and Bifurcated ANCURE 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 twelve months, however, only endpoints captured in the first 30 days were compared. Efficacy was evaluated using contrast enhanced CT scans, abdominal ultrasounds, and x-rays. Safety was assessed by physical exams. The study enrolled 80 Bifurcated and 9 Tube patients.

Table 8. Comparison of ANCURE™ and EGS® Delivery Systems

Outcome Measure		ANCURE % (n/N)	EGS % (n/N)	EGS-ANCURE ¹ Difference [95% CI]
Operative Mortality (≤ 30 days)	Tube	0.0% (0/9)	0.0% (0/153)	0.0% [-46, 5]
	Bifurcated	2.5% (2/80)	2.6% (7/268)	0.1% [-8, 8]
Major Complications ² (≤ 30 days)	Tube	22.2% (2/9)	19.6% (30/153)	-2.6% [-48, 22]
	Bifurcated	28.8% (23/80)	28.7% (77/268)	-0.1% [-11, 11]
Need for ICU Stay (%)	Tube	0.0% (0/9)	35.5% (54/152)	35.5% [1, 49]
	Bifurcated	23.1% (18/78)	39.1% (102/261)	16.0% [4.9, 27.1]
Thrombosis/Occlusion	Tube	0.0% (0/9)	0.0% (0/153)	0.0% [-46.4, -4.6]
	Bifurcated	7.5% (6/80)	2.6% (7/268)	-4.9% [-15.7, 1.6]
Intraop Conversions ³	Tube	0.0% (0/9)	7.8% (12/153)	7.8% [-27, 18]
	Bifurcated	3.8% (3/80)	9.7% (26/268)	6.0% [-3, 17]
Postop Conversions	Tube	0.0% (0/9)	0.7% (1/141)	0.7% [-34, 7]
	Bifurcated	1.3% (1/77)	0.9% (2/235)	-0.4% [-9.7, 3.7]
Aneurysm Rupture	Tube	0.0% (0/9)	0.0% (0/141)	0.0% [-46, 5]
	Bifurcated	0.0% (0/77)	0.0% (0/242)	0.0% [-7.8, 2.5]
Reduced Limb Flow ⁴	Tube	N/A	N/A	N/A
	Bifurcated	37.7% (29/77)	38.4% (93/242)	0.8% [-12, 14]
Perigraft Flow, Discharge	Tube	37.5% (3/8)	44.4% (60/135)	6.9% [-29.3, 44.1]
	Bifurcated	40.6% (28/69)	48.4% (106/219)	7.8% [-5.9, 21.8]
Perigraft Flow, 12 mo	Tube	N/A	25% (26/104)	N/A
	Bifurcated	N/A	31% (40/128)	N/A
Increased Aneurysm Size (≥ 5 mm), 12 mo	Tube	N/A	5.8% (6/103)	N/A
	Bifurcated	N/A	2.2% (3/134)	N/A
Decreased Aneurysm Size (≥ 5 mm), 12 mo	Tube	N/A	42.7% (44/103)	N/A
	Bifurcated	N/A	47.8% (64/134)	N/A
Graft Migration	Tube	N/A ⁵	0.7% (1/141)	N/A
	Bifurcated	N/A ⁵	0.4% (1/242)	N/A
		Median (N)	Median (N)	
Hospital Stay (days)	Tube	2 (9)	2 (152)	0 [0, 1]
	Bifurcated	2 (78)	3 (262)	1 [0, 1]
ICU Stay (hours) ⁶	Tube	0.0 (0)	24.0 (54)	N/A
	Bifurcated	21.8 (18)	24.0 (101)	2.2 [-2.0, 7.0]
Operative Time (min)	Tube	160 (9)	159.5 (152)	-0.5 [-40, 35]
	Bifurcated	184.0 (80)	130.0 (266)	-54.0 [-68.0, -37.0]
Operative Blood Loss (cc)	Tube	300 (9)	200 (151)	-100 [-200, 0]
	Bifurcated	400 (79)	300 (268)	-100 [-100, 0]

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. Protocols required these subjects to undergo standard AAA repair.
4. Reduced Limb Flow = intraoperative or postoperative intervention during the first 12 mos. to treat reduced limb patency.
5. Graft migration was not evaluated in the ANCURE study.
6. ICU Stay duration includes only subjects who went to the ICU.

6.4. Conversions for ANCURE and EGS

Table 9. Conversion to Standard Surgical Repair

Reason for Conversion	ANCURE ¹ Conversions (N=89)		Tube EGS Conversions (N=153)		Bifurcated EGS Conversions (N=268)	
	n	% [95% CI]	n	% [95% CI]	n	% [95% CI]
Conversion (Total)	3	3.4% [0.7, 9.5]	12	7.8% [4.1, 13.3]	26	9.7% [6.4, 13.9]
Failure to Access	1	1.1% [0, 6.1]	8	5.2% [2.3, 10]	11	4.1% [2.1, 7.2]
Failure to Accurately Place (Total)	2	2.2% [0.3, 7.9]	4	2.6% [0.7, 6.6]	15	5.6% [3.2, 9.1]
Arterial Trauma	0	0.0% [0, 3.3]	1	0.6% [0, 3.5]	4	1.5% [0.4, 3.8]
Failure to Retract Jacket	1	1.1% [0, 6.1]	0	0.0% [0, 1.9]	0	0.0% [0, 1.1]
Improper Graft Position	0	0.0% [0, 3.3]	3	2.0% [0.4, 5.6]	1	0.4% [0, 2.1]
Perigraft Flow	0	0.0% [0, 3.3]	0	0.0% [0, 1.9]	2	0.7% [0.1, 2.7]
Twist	1	1.1% [0, 6.1]	0	0.0% [0, 1.9]	3	1.1% [0.2, 3.2]
Unable to Remove Delivery Catheter	0	0.0% [0, 3.3]	0	0.0% [0, 1.9]	5	1.9% [0.6, 4.3]
Late Conversion (Total)	0	0.0% [0, 3.3]	1	0.6% [0, 3.5]	2	0.7% [0.1, 2.7]
Perigraft Flow and Aneurysm Enlargement	0	0.0% [0, 3.3]	1	0.6% [0, 3.5]	2	0.7% [0.1, 2.7]

1. Nine of the ANCURE subjects were tube subjects and 80 were bifurcated subjects.

6.5. Perigraft Flow for EGS

Table 10. Perigraft Flow for EGS[®] Subjects Over Time¹

	Discharge		6 Months		12 Months	
	n/N	% [95% CI]	n/N	% [95% CI]	n/N	% [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]
Endograft Permeability	0/135	0.0% [0, 2.2]	0/123	0.0% [0.0, 2.4]	0/104	0.0% [0, 2.8]
Indeterminate	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]
Endograft Permeability	0/219	0.0% [0, 1.4]	0/195	0.0% [0, 1.5]	0/128	0.0% [0, 2.3]
Indeterminate	17/219	7.8% [4.6, 12.1]	15/195	7.6% [4.4, 12.4]	3/128	2.3% [0.5, 6.7]

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

6.6. Aneurysm Size Change for EGS

Table 11. Change in Aneurysm Diameter Between Discharge and 12 months¹

	Tube EGS (N=103)			Bifurcated EGS (N=134)		
	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
No Change (± <5 mm)	53	51.5% [41.4, 61.4]	- 0.15	67 ²	50.0% [41.2, 58.8]	- 0.95
Decrease (- ≥5 mm)	44	42.7% [33, 52.8]	- 10.22	64	47.8% [39.1, 56.6]	- 10.04

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

2. One subject experienced a decrease from discharge to six months, and an increase from six months to 12 months.

6.7. Perigraft Flow Status versus Aneurysm Size Change for EGS

Table 12. Aneurysm Diameter by Perigraft Flow Status at 12 months

Perigraft Flow Status	Aneurysm Diameter Change					
	Decrease (≥ 5 mm)		No Change ($\pm < 5$ mm)		Increase (≥ 5 mm)	
	n/N	% [95% CI]	n/N	% [95% CI]	n/N	% [95% CI]
Tube EGS						
No Perigraft Flow at 12 months	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 at 12 months	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						
No Perigraft Flow at 12 months	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 at 12 months	13/40	32.5% [18.6, 49.1]	25/40	62.5% [45.8, 77.3]	2/40	5.0% [0.6, 16.9]

6.8. Reduced Limb Flow for Bifurcated ANCURE and Bifurcated EGS

Table 13. Types of Interventions to Optimize Bifurcated Graft Limb Flow

	Intraoperative		Postoperative		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	17/77	22.1% [13.4, 33]	0/77	0.0% [0, 3.8]	17/77	22.1% [13.4, 33]
PTA only	6/77	7.8% [2.9, 16.2]	0/77	0.0% [0, 3.8]	6/77	7.8% [2.9, 16.2]
Surgical ²	3/77	3.9% [0.8, 11]	1 ⁴ /77	1.3% [0, 7]	3/77	3.9% [1.4, 12.8]
Other ³	1/77	1.3% [0, 7]	1/77	1.3% [0, 7]	3/77	3.9% [0.3, 9.1]
(Total)	27/77	35.1%	2/77	2.6%	29/77	37.7%

1. Includes some subjects who had PTA or thrombolysis and stent.
2. Includes Femoral-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. Patient was converted to standard surgery.

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 (7.9 mm) device.
- Patients treated with the bifurcated Endograft must have a contralateral femoral artery or iliac artery permitting access by a 12 Fr (4.0 mm) device.
- The patient must have an aortic superior neck ≤ 26 mm in diameter and \geq approximately 15 mm in length.
- Patients treated with a bifurcated Endograft must have both iliac arteries with segments ≤ 13.4 mm in diameter and approximately ≥ 20 mm in length.
- Patients treated with a tube Endograft must have an aortic inferior neck ≤ 26 mm in diameter and approximately ≥ 12 mm in length.
- It is best if the superior neck does not contain an angle of greater than 60 degrees.

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 14 or 15, choose an appropriate ANCURE Endograft size based on the preoperative diagnostic tests. Over-sizing is not required for these devices.

Table 14. 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 15. ANCURE™ Bifurcated 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 19 (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) 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. The graft length on the contralateral limb is 0.74 cm shorter than the ipsilateral limb.

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 limb occlusion include pain in hips or limb during walking, discoloration of limb skin, and cool skin of limbs. Sign of aneurysm rupture include pain, numbness, weakness in 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 11.4.
- 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 packed in the ANCURE Delivery Catheter (see Figures 1 and 2). The ANCURE™ Bifurcated System consists of a bifurcated Endograft packed in the delivery catheter (see Figures 1 and 3). 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

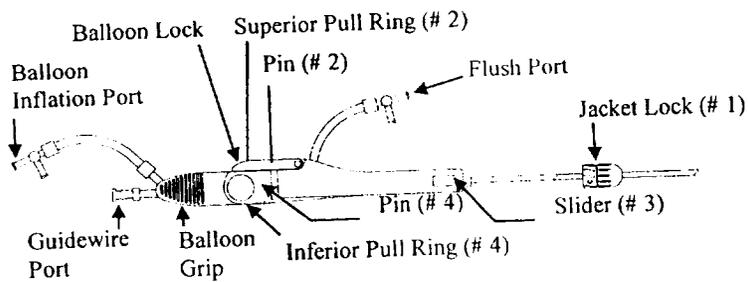


Figure 2. Other Components: ANCURE™ Tube System

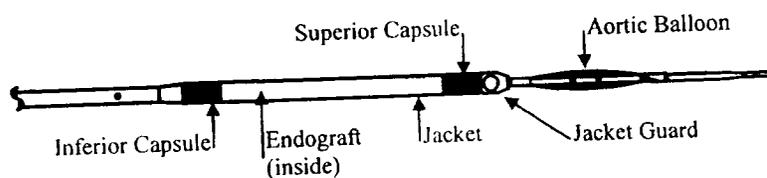


Figure 3. Other Components: ANCURE™ Bifurcated System

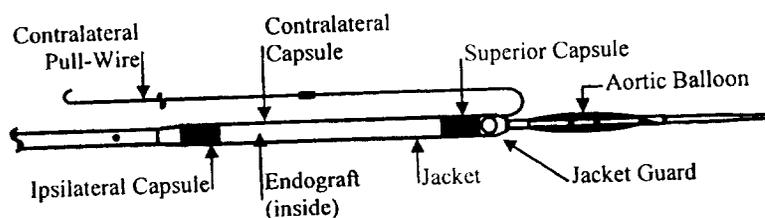


Figure 4. ANCURE™ Contralateral Torque Catheter

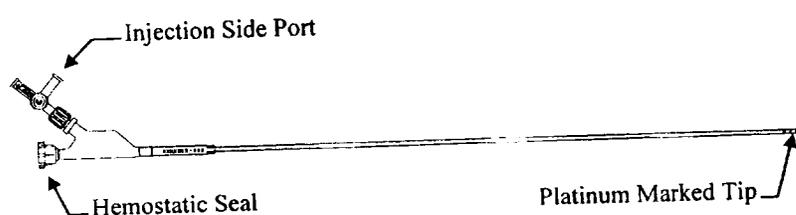
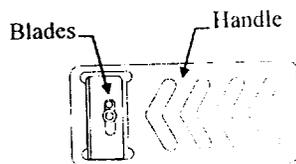


Figure 5. ANCURE™ Contralateral Cutter



10. HOW SUPPLIED

The ANCURE System is supplied STERILE and non-pyrogenic in a sealed pouch. The Endograft 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® Vascular Graft

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

11.2.1. Accessory Device Preparation

- Use of the ANCURE™ Marker Board is recommended. Position and adjust the marker board. (Refer to the Instructions for Use packaged with the device.)

- Use of the ANCURE™ Expandable Sheath and ANGIOSCALE™ Catheter are recommended. Prepare the expandable sheath and ANGIOSCALE 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

Caution: Always use fluoroscopy for guidance and observation of the ANCURE System within the vasculature.

Caution: The ANCURE System should be implanted in an operating room or similar sterile environment with appropriate personnel, and fluoroscopic imaging equipment.

Caution: The patient should be heparinized once the arterial vasculature has been accessed.

- The ipsilateral common femoral artery is exposed.
- Perform an angiogram of the abdominal aorta using the Angioscale 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 and at the aortic bifurcation.
- Return to live fluoroscopy and align the marker bars with the lines on the monitor screen indicating the renal arteries and the aortic bifurcation.
- Align the first or second radiopaque band of the Angioscale Catheter on the marker bar indicating the renal arteries.
- Use the markers on the ANGIOSCALE Catheter to measure the distance between the renal arteries and the aortic bifurcation. The distance between each marker equals one centimeter.
- Select an Endograft based on the infrarenal aortic length measurement.
- Remove the Angioscale Catheter over a 0.035" stiff exchange length guidewire.

11.2.2.2. Sheath(s)

- Introduce the ANCURE™ Expandable Sheath over the 0.035" exchange length stiff guidewire in the ipsilateral femoral artery.
- 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 back flow of blood through the flush port.

- 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 will relax to the open position.
- 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.
- An optional 6 Fr 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 ipsilateral to contralateral 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.
- Attach the balloon port tubing to the balloon grip.
- 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

- 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 the marker bar of the marker board identifying the renal arteries.

Warning: DO NOT use excessive force to advance or withdraw the delivery catheter when resistance is encountered.

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

- 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 expandable sheath, as appropriate to below the intended inferior attachment site. The radiopaque marker on the expandable sheath is used to confirm sheath location.

11.2.5. ANCURE™ Tube System Use

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

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

- 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 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 open at this point. Care must be exercised while advancing or retracting the delivery catheter after this point.

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 marker bar identifying the renal arteries.
- 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 marker bars should be performed for accurate placement of the attachment systems.
- Verify acceptable rotational alignment of the graft.
- 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

- 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 Endograft 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.
- A long radiopaque marker in the center of the aortic balloon identifies the working area of the balloon. Place this marker 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.

- Lock the aortic balloon into position.
- Prior to aortic balloon inflation compare the diameter of the superior aortic neck to the diameter of the superior attachment system. The aortic balloon diameter is equal to the diameter of the superior attachment system.

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

- 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.

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

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

- Perform 3 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.
- If the graft is too long, advance the delivery catheter slightly.
- If there is redundancy in the graft, **gently** pull the entire delivery catheter caudally.
- 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 secure the superior attachment system while the inferior attachment system is being deployed.

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.
- **Check the patient's mean arterial pressure prior to deflating the aortic balloon.** Deflating the aortic balloon after deployment of the inferior attachment system is similar to removing a cross clamp and re-establishing flow to the lower extremities. The patient may experience a significant drop in arterial pressure.
- 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.
- **Gently** inflate the aortic balloon under fluoroscopy to secure the hooks in the vessel wall.

Warning: DO NOT overinflate 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 Endograft may result in increased risk of perigraft flow or migration.

- Perform 3 one-minute inflations at the inferior attachment system.

11.2.6. Completion of the ANCURE Tube 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.

11.2.7. Post Implant Procedures

- Perform a final angiogram to assess the graft position and to document complete exclusion of the aneurysm.
- If no other interventions are required, remove the angiography catheter and introducer sheaths.
- Close arteriotomies and cutdowns according to standard practice.

Caution: Although the Endograft 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® Vascular Graft

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™ Marker Board is recommended. Position and adjust the marker board. (Refer to the Instructions for Use packaged with the device.)
- Use of the ANCURE™ Expandable Sheath and ANGIOSCALE™ Catheter are recommended. Prepare the expandable sheath and ANGIOSCALE 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 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: Always use fluoroscopy for guidance and observation of the ANCURE System within the vasculature.

Caution: The ANCURE System should be implanted in an operating room or similar sterile environment with appropriate personnel, and fluoroscopic imaging equipment.

Caution: The patient should be heparinized once the arterial vasculature has been accessed.

- The common femoral artery is exposed bilaterally.
- Perform an angiogram of the abdominal aorta using the Angioscale 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 and at the aortic bifurcation.
- Return to live fluoroscopy and align the marker bars with the lines on the monitor screen indicating the renal arteries and the aortic bifurcation.
- Align the first or second radiopaque band of the Angioscale Catheter on the marker bar indicating the renal arteries.
- Use the markers on the Angioscale Catheter to measure the distance between the renal arteries and the aortic bifurcation. The distance between each marker equals one centimeter.
- Select an Endograft based on the infrarenal aortic length measurement plus the length between the bifurcation and the predetermined iliac attachment zone.
- Remove the Angioscale Catheter over a 0.035" stiff exchange length guidewire.

11.3.2.2. Sheath(s)

- Introduce the ANCURE™ Expandable Sheath over the 0.035" exchange length stiff guidewire in the ipsilateral femoral artery.
- 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 back flow of blood through the flush port.

- 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 will relax to the open position.
- 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.
- Introduce a 12 Fr 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.
- Attach the balloon port tubing to the balloon grip.
- 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*

- Introduce a snare in the contralateral sheath and position it in the patient’s distal aorta.
- Introduce the delivery catheter’s contralateral pull-wire in the ipsilateral side.
- 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.
- 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.

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

- 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 inferior attachment systems are superior to the patient's native aortic bifurcation.
- 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 ipsilateral capsule recess as landmarks. Both the contralateral pull-wire and the ipsilateral capsule recess should face the contralateral side.
- 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 white 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.

Warning: DO NOT deploy the Endograft in a location that will occlude arteries necessary to supply blood flow to organs or extremities (e.g., a single, patent internal hypogastric (iliac) or mesenteric artery).

- Retract the contralateral pull-wire and the jacket simultaneously to uncover the graft. The superior attachment system hooks are now exposed, but not deployed.

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.

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 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 open at this point. Care must be exercised while advancing or retracting the delivery catheter after this point.

11.3.5.1. Superior Attachment System Deployment

11.3.5.1.1. Positioning

- 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 marker bars should be performed for accurate placement of the attachment systems.
- Retract the entire delivery catheter until the superior attachment system hooks are in alignment with the marker bar identifying the renal arteries.
- Verify acceptable rotational alignment of the graft.
- 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.
- Fill the inflation device with dilute contrast and attach it to the balloon inflation port prior to deployment of the superior attachment system.

11.3.5.1.2. Deployment

- Deployment of the superior attachment system is accomplished 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 Endograft 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.
- A long radiopaque marker in the center of the aortic balloon identifies the working area of the balloon. Place this marker 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.

- Lock the aortic balloon into position.
- Prior to aortic balloon inflation compare the diameter of the superior aortic neck to the diameter of the superior attachment system. The aortic balloon diameter is equal to the diameter of the superior attachment system.

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

- 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.

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

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

- Perform 3 one-minute inflations in the superior attachment system.

11.3.5.2. Contralateral Attachment System Deployment

11.3.5.2.1. Positioning

- Reinflate the aortic balloon 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.

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.
- Under fluoroscopic magnification, release the contralateral attachment system holding the contralateral pull-wire fixed while retracting the torque catheter.

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.** Deflating the aortic balloon after deployment of the contralateral attachment system is similar to removing a cross clamp and re-establishing flow to the lower extremities. The patient may experience a significant drop in arterial pressure.
- 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 (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 Endograft 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.

Warning: DO NOT advance the catheter while the aortic balloon is inflated.

- 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.
- 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 secure the superior attachment system, in preparation for ipsilateral limb deployment.

Warning: DO NOT over-inflate the aortic balloon.

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

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

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

- Perform 2 one-minute balloon inflations to vessel profile.

11.3.6. Completion of the ANCURE Bifurcated 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.
- Perform two one-minute balloon inflations.
- Perform balloon inflations along the entire length of the limb to fully expand the graft.
- 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.
- If no other interventions are required, remove the angiography catheter, contralateral pull-wire and introducer sheaths.
- Close arteriotomies and cutdowns.
- 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.

Caution: Although the Endograft 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. 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 aortoiliac 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 lateral views 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.

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

Table 16. 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

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

Diagnostic Test	Time Postoperative	
	0 – 7 Days	Every 6 months
Contrast CT	X	X
Duplex US	X ¹	X ¹
Abdominal X-rays	X	X ²

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

Note: Please return all explanted Endografts to Guidant for analysis.
Call Guidant C&VS Customer Service for explant kit.

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

12. Materials, Storage, and Handling

12.1. Storage and Handling

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

12.2. List of Materials

REQUIRED:

- ANCURE™ System with an appropriately sized ENDOGRAFT® Vascular Prosthesis
- ANGIOSCALE™ 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 .086" I.D.
- Intravascular snare
- Dilute contrast (10 – 20%) for balloon inflation
- Fluoroscopy

SPECIFICALLY REQUIRED FOR THE ANCURE BIFURCATED SYSTEM:

- Guidant ANCURE™ Iliac Balloon Catheter
- 20 cc capacity inflation device is required for ANCURE™ Iliac Balloon inflation
- 12 Fr (4 mm) introducer sheath for contralateral access

RECOMMENDED MATERIALS (OPTIONAL):

- ANCURE™ Marker Board
- ANCURE™ Expandable Sheath
- Introducer Sheath 6 or 7 Fr (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; 5,104,399; 5,275,622; 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.

Other U.S. and foreign patents pending.

10908 Rev. A 9/99

ANCURE™ Iliac Balloon Catheter

INSTRUCTIONS FOR USE

Caution: Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.

I. Device Name

ANCURE™ Iliac Balloon Catheter

II. Description

The ANCURE™ Iliac Balloon Catheter (refer to Figure 1) is a balloon dilatation catheter made up of a balloon at the distal end, catheter shaft, and an extension manifold at the proximal end. One lumen is used for inflation and deflation of the balloon. The other lumen accommodates a guidewire with a recommended diameter of 0.035" (0.89 mm).

The ANCURE™ Iliac Balloon Catheter has a maximum operating pressure of 2 ATM (30 psi, 200 kPa). The ANCURE™ Iliac Balloon Catheter shaft is 5.0 Fr (1.7 mm) in diameter. At a minimum, a 12 Fr (4.0 mm) introducer is recommended when using the ANCURE™ Iliac Balloon Catheter.

Note: The following information is provided as a guide.

Table 1. ANCURE™ Iliac Balloon Catheter Sizing Guide

Prosthesis Diameter ¹ (Trunk mm / Limb mm)	ANCURE Iliac Balloon Catheter Size (mm)
20 / 10	9.5*, 10.5
22 / 11	11.5
24 / 12	12.5
26 / 13	13.5

* may be useful when the native vessel is < 10 mm in diameter.

III. Indications

The ANCURE™ Iliac Balloon Catheter is indicated for use in securing the attachment systems in the iliac arteries and/or to expand vascular prosthesis limbs of the ANCURE™ ENDOGRAFT® System.

IV. Contraindications

There are no known contraindications for this device.

V. Warnings & Precautions

GENERAL

– Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.

- This device is designed for use by physicians trained in vascular interventional techniques.

HOW SUPPLIED

- The device is intended for single use only. Do not re-sterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate re-sterilization and cross contamination.
- Use the catheter prior to the "Use Before" date specified on the package.
- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use the device if damage has occurred or if the sterilization barrier has been damaged or broken. If this occurs, return the device to Guidant® Cardiac & Vascular Surgery Group.

IMPLANT PROCEDURE

- Patients will be exposed to radiation during the procedure.
- Do not inflate the balloon with pressures exceeding 2 ATM (30 psi, 200 kPa). Use of a pressure monitoring device is recommended to prevent over pressurization.
- Do not reinsert the ANCURE™ Iliac Balloon Catheter once it has been withdrawn from one introducer.
- Do not use for procedures other than those indicated in these instructions.

VI. Potential Adverse Events

- Air embolism
- Allergic reactions to contrast medium and heparin
- Arterial trauma/damage
- Embolization
- Hematoma
- Hemorrhage as a result of heparinization
- Hypotension
- Infection/sepsis
- Lower extremity ischemia
- Thrombosis

VII. How Supplied

The ANCURE™ Iliac Balloon Catheter is supplied STERILE and non-pyrogenic in a sealed pouch.

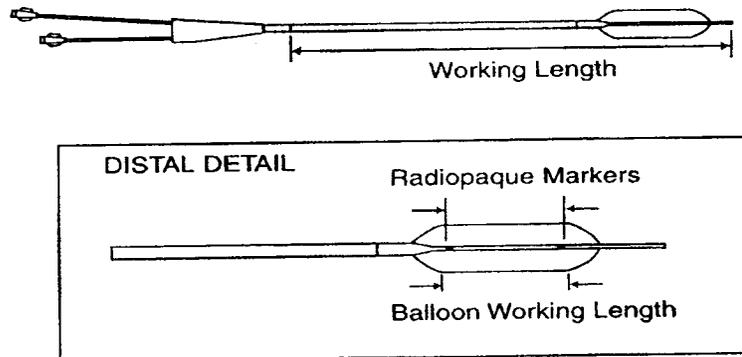
VIII. Storage and Handling

- Handle with care.
- Store in a cool, dry place.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.

IX. List of Materials

- ANCURE™ Iliac Balloon Catheter, appropriately sized
- Minimum 12 Fr (4.0 mm) introducer sheath
- Heparinized saline
- Dilute contrast (20%) for balloon inflation
- 20 cc capacity inflation device
- 20 cc syringe
- 0.035" (0.89 mm) guidewire

Figure 1. ANCURE™ Iliac Balloon Catheter



X. Use of the Ancure™ Iliac Balloon Catheter

Note: Refer to the instructions for use contained with the ANCURE™ System for specific information regarding graft implantation and use of the ANCURE™ Iliac Balloon Catheter within the iliac attachment systems.

1. ANCURE™ Iliac Balloon Catheter Selection:
 - Select an iliac balloon catheter that is appropriately sized to the limb diameter of the bifurcated endograft.
2. ANCURE™ Iliac Balloon Catheter Preparation:
 - Aspirate air from the balloon with a syringe.
 - Flush the guidewire lumen with heparinized saline.
3. Inflation Device Preparation:

Caution: Do not inflate the balloon with pressures exceeding 2 ATM (30 psi, 200 kPa). The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

- Using dilute contrast (20%), prepare the inflation device according to the manufacturer's instructions.

4. ANCURE™ Iliac Balloon Catheter Advancement:

- Advancement over a guidewire:
 - Insert the guidewire through the guidewire lumen
 - Advance the ANCURE™ Iliac Balloon Catheter, through the Introducer, into the iliac artery by tracking the ANCURE™ Iliac Balloon Catheter over the guidewire.
 - Position the ANCURE™ Iliac Balloon Catheter in the correct location with the aid of the radiopaque balloon marker.

5. Balloon Inflation:

Caution: Do not reinsert the ANCURE™ Iliac Balloon Catheter once it has been withdrawn from one introducer.
--

- When inflating the balloon, an inflation device should be used to monitor the balloon pressure.
- Inflate the balloon, and sustain the pressure for 1 minute.
- The maximum operating pressure is 2 ATM (30 psi, 200 kPa).
- Deflate, reposition the balloon, and re-inflate for 1 minute, as indicated.

6. Expansion of the Endograft Limb(s):

- The ANCURE™ Iliac Balloon Catheter may also be used to expand the limb(s) of the endograft to full diameter, if necessary.

7. Catheter Removal:

- Completely deflate the ANCURE™ Iliac Balloon Catheter prior to removal.
- Remove the ANCURE™ Iliac Balloon Catheter according to standard practice.

XI. References

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by the ACC/AHA.

XII. Patents

This product manufactured and sold under issued and pending U.S. and foreign patents and applications.

GUIDANT

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Graphical Symbols for Medical Device Labeling

STERILE	EO
Sterilized with ethylene oxide gas	
STERILE	R
Sterilized with electron beam radiation	
LOT	
Lot number	
	
For one (1) use only	
	
Read instructions prior to use	
	
Date of manufacture	
	
Expires	
REF	
Catalog number	
F	
French size	

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1. What is Abdominal Aortic Aneurysm (AAA)?



An abdominal aortic aneurysm (AAA) is a bulge in the **aorta** (the aorta is the main blood vessel coming from the heart that supplies blood to all organs) in your abdomen. Aneurysms may occur in any blood vessel in the body, but the most common place is in the abdomen below the **renal arteries** (blood vessels that provide blood to your kidneys). The aneurysm may continue to grow larger until, like a balloon, it bursts or "ruptures". The larger an aneurysm becomes, the easier it grows. Aneurysm rupture can be a life-threatening event. The goal of all aneurysm operations is to prevent the aorta from rupturing.

A normal aorta measures about 2.3 cm in diameter (1 inch) in men and 1.9 cm in diameter (3/4 inch) in women, but varies with age and body size. An aorta is considered aneurysmal when it grows more than double its normal size. Aneurysms are 4 times more common in men than women and occur most often after 55- 60 years of age.

Aneurysm rupture affects approximately 15,000 people per year making it the 13th leading cause of death in the US. The incidence of aortic aneurysm disease is increasing each 10 years as the population ages in general. Early detection and diagnosis is increasingly possible as more sophisticated medical screening methods become available.

a. Causes and Symptoms of Aneurysms

Aneurysms are caused by a weakening or damage in the wall of a blood vessel. There are many things known to contribute to the weakening of the artery wall such as:

- Atherosclerosis (hardening of the arteries)
- Cigarette smoking
- High blood pressure
- Inflammation or infection

Three out of four aneurysms show no symptoms at the time they are diagnosed. However, a rapid growth or rupture of an abdominal aortic aneurysm may cause intense back or abdominal pain and signs of shock such as shaking, dizziness, fainting, sweating, rapid heartbeat, and sudden weakness.

b. Diagnosis of Aneurysms

Aneurysms are most often found during a routine physical exam or when a doctor examines your heart, gall bladder, or kidneys. An abdominal aortic aneurysm can be felt as a pulsating mass at about the level of the belly button.

Tests used to evaluate aneurysms are:

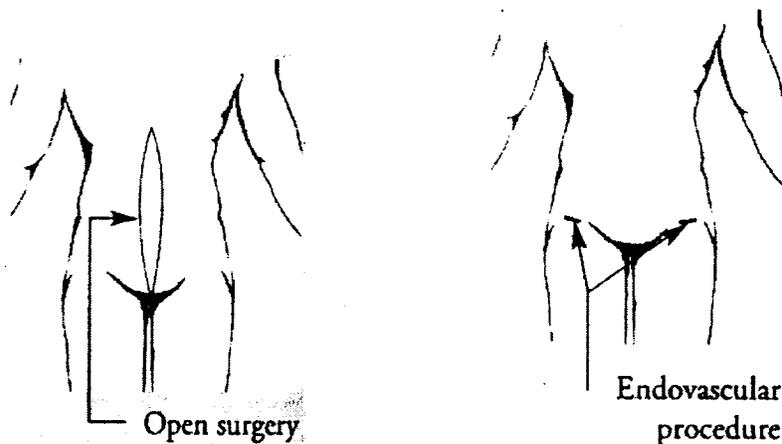
DRAFT - PATIENT LABELING

- Ultrasound, which uses sound waves read by a probe that moves along the top of your abdomen,
- CT (computerized tomography) scan, which uses special x-rays and contrast dye to show your blood vessels,
- MRI (magnetic resonance imaging), which uses radio waves and a strong magnet to show your blood vessels,
- Arteriogram, which uses x-rays and contrast dye to show blood flow through your blood vessels.

2. Treatment of Aortic Aneurysms

An aneurysm needs to be monitored regularly by your doctor for its growth and to evaluate the need for surgical repair. Your doctor will discuss the risk of rupture compared to the risks associated with surgery. In general, an aneurysm will require repair after reaching 5.0 cm (approximately 2 inches) in size, but this decision will be based on your overall medical condition. An aortic aneurysm normally grows 0.2 – 0.4 cm per year. Any rapidly growing aneurysm, or symptom which could indicate rupture, will require immediate attention. Whenever there is a question, seek prompt medical attention.

Abdominal aortic aneurysms can be surgically treated either with traditional open surgery or with a minimally invasive repair commonly known as an endovascular (within the blood vessels) procedure.

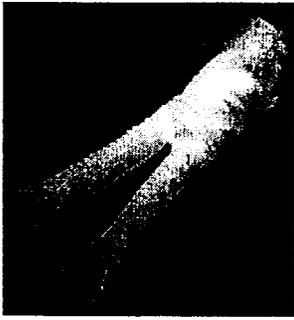


Traditional open surgery requires a large incision from just below your breastbone to the top of your pubic bone. Your surgeon opens the aneurysm and sews a vascular graft in place.

The endovascular procedure requires two small incisions in the groin. Using an x-ray imaging device, a delivery catheter (tube) containing a vascular graft is guided up through a blood vessel in your leg into your aorta and the graft is placed inside your aneurysm. The graft contains metal hooks at either end that are used to secure it inside your aorta.

3. Introduction of the ANCURE™ ENDOGRAFT® System

The ANCURE™ ENDOGRAFT® System is a new endovascular technology for repairing abdominal aortic aneurysms. The ANCURE™ ENDOGRAFT® Vascular Graft is similar to grafts used in traditional open surgery. The ANCURE™ ENDOGRAFT® Vascular Graft is made from polyester cloth and has specially designed metal attachment systems that act like the sutures used to sew a conventional graft.

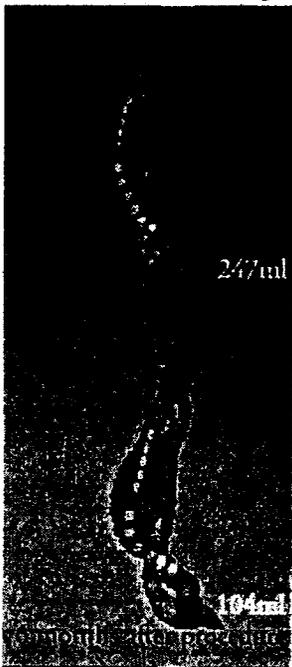


The main differences between traditional open surgery and the ANCURE™ ENDOGRAFT® System is in the way the graft is placed inside your aorta and the way it is attached to the walls of your aorta. Your blood vessels need to be of a certain size for the ANCURE™ ENDOGRAFT® Vascular Graft to be properly inserted and fit into place. Your doctor will measure the size of your blood vessels during the examination of the aneurysm. If your doctor has difficulty placing the graft, he or she may need to perform the regular surgery instead. Women may be more likely to have this happen than men, partly because their vessels are smaller. If you have to have the regular surgery performed, you may experience more complications.

4. Post Operative Follow Up

After having endovascular repair with the ANCURE™ ENDOGRAFT® System, you will remain in the hospital for 2-3 days. During your stay you will be under observation by the hospital staff. You may experience some of the following side effects:

Typical Results after Endovascular Grafting



- Groggy from medication
- Loss of appetite
- Soreness at the incision site

Typically the next day following your repair, you will be able to get up and walk the hallways. You will not be able to feel the graft in your abdomen, even though the hooks hold it in place. The aorta does not have any feeling to detect the hook or the sutures that hold a conventional graft in place.

Before you leave the hospital, the surgeon may perform a CT scan, ultrasound, or abdominal x-ray to evaluate your graft and ensure that it is in the right place and working properly. Once discharged, most people find themselves back to their normal activity level by 2 weeks. It usually takes 6-8 weeks after traditional open surgery.

a. Follow-up Visits

Your doctor will set up a schedule of follow-up visits to monitor your aneurysm repair. The initial follow-up visits may be frequent. Those visits will become yearly afterwards. Your doctor will determine the exact frequency of follow-up visits based on your individual situation.

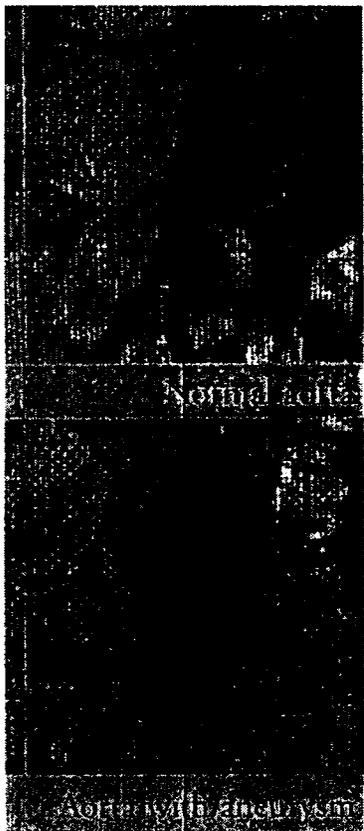
b. When should you call your doctor?

If you experience any of the following symptoms contact your doctor immediately:

- Pain, numbness, coldness, or weakness in your legs or buttocks
- Any back, chest, abdominal, or groin pain
- Dizziness, fainting, rapid heartbeat, or sudden weakness

c. Patient ID Card

Following surgery, the hospital staff will give you a plastic wallet size Patient Implant Card. It is important to keep this card with you and show it to future health care practitioners to inform them that you have an ANCURE™ ENDOGRAFT®. The Patient Implant Card also contains information to let health care practitioners know that it is safe for you to have an MRI.



5. Frequently asked questions:

What is an abdominal aortic aneurysm (AAA)?

The aorta is the largest blood vessel in the body. The aorta leads from the heart through the chest and abdomen where it divides into the major arteries to the legs. Along the way, the aorta supplies blood to all the organs of the body.

The part of the aorta that lies in the abdomen is about one inch wide. In some people, the aorta gradually swells (dilates) and may balloon to four or five times its normal size. This swelling is called an abdominal aortic aneurysm.

As the aorta swells, its walls weaken and it may eventually burst, or rupture. Sudden ruptures often end in death. Abdominal aortic aneurysm has become increasingly common, especially in people over the age of 60.

How does an aneurysm occur?

Atherosclerosis is the most common cause of abdominal aortic aneurysms. Atherosclerosis, “hardening of the arteries”, occurs when substances such as cholesterol, minerals, and blood cells build up in the walls of the artery, damaging it. The muscular wall of the aorta weakens and begins to bulge. High blood pressure may speed up the weakening, but it is not the cause. Aneurysms tend to run in families, so there is the

thought that genetics may play a role in who gets an aneurysm. There is a strong link between cigarette smoking and the occurrence of aneurysms. Smokers die four times more often from ruptured aneurysms than nonsmokers. Aneurysms in smokers expand and weaken faster than those in nonsmokers.

What are the symptoms of abdominal aortic aneurysm?

Abdominal aortic aneurysm may not cause any symptoms for a long period of time. You may feel a pulsation in your abdomen. There may be an occasional mild abdominal ache, back pain, or even groin pain. Most people have very few complaints related to the aneurysm. Sudden, very severe abdominal or back pain may suggest rupture of the aorta. When this happens, you need immediate medical attention.

How is an abdominal aortic aneurysm diagnosed?

Most abdominal aortic aneurysms are found during a routine medical examination of the abdomen. The doctor feels the aneurysm as a mass that pulses with each heartbeat. Once it is discovered, the aneurysm's size must be determined because the risk of aneurysm rupture is related to how large it is.

Abdominal ultrasound examination is an easy and accurate way to measure the size of an aneurysm. Abdominal x-rays can be used, but are not as accurate in measuring size. CT scans of the abdomen can be used to determine the size of the enlarging aorta. Aneurysms less than 2 inches in diameter are not dangerous but need checking from time to time. Those between 2 and 3 inches need to be carefully watched over time. They may need surgery if they are expanding. Those larger than 3 inches may need to be repaired, depending on the condition of the patient.

How is an abdominal aortic aneurysm treated?

If it is not an emergency, repair of abdominal aortic aneurysm has a low risk, few complications, and relatively quick recovery period. In traditional open surgery for repair of abdominal aortic aneurysm, the surgeon opens the abdomen, secures the aneurysm, and replaces it with a polyester cloth graft. The hospital stay is usually less than 10 days and recovery is usually complete in 4 to 6 weeks.

A newer method to repair abdominal aortic aneurysm has been used with success. This method, called endovascular grafting, involves inserting a catheter (tube) through a groin artery into the abdominal aorta. At the tip of the catheter are a deflated balloon and a tightly wrapped polyester cloth graft. When properly positioned, the graft is secured in place by inflating the balloon and opening the graft to the diameter needed to prevent blood flow into the aneurysm. The balloon is then deflated and removed along with the catheter. At each end of the graft are hooks that help secure it to the inner walls of the aorta. The graft allows blood flow to continue through the aorta to the arteries in the pelvis and legs, without filling the aneurysm. Hospital stay for this procedure is usually 2-3 days, with a return to normal activities in less time than traditional open surgery. This method is currently used only for non-emergency treatment. Your doctor will help you determine if this procedure is appropriate for you.

What happens after surgery for abdominal aortic aneurysm?

Successful treatment for abdominal aortic aneurysm usually results in full recovery, whether the procedure is done as a traditional open surgery or an endovascular repair. Your doctor will ask you to come back for periodic follow-up visits to ensure that no problems develop. Any new abdominal symptoms should be quickly reported to your doctor. Abdominal aortic aneurysms usually do not recur, and people with this type of aneurysm are not particularly at greater risk for developing aneurysms in other locations in their body. Your doctor will discuss with you any needed lifestyle changes such as stopping cigarette smoking.

6. Glossary

Aneurysm – A swelling or enlargement of a blood vessel.

Aorta – The main artery leaving the heart.

Arteriogram – A diagnostic test that uses x-rays and contrast dye to show blood flow through your blood vessels.

Atherosclerosis – Hardening of the arteries.

Computerized Tomography Scan (CT) – A diagnostic test that uses special x-rays and contrast dye to show your blood vessels.

Endovascular – Within the blood vessels.

Iliac Arteries – The two main arteries coming from the aorta, going into the legs.

Magnetic Resonance Imaging (MRI) – A diagnostic test that uses radio waves and a strong magnet to show your blood vessels.

Renal Arteries – Vessels that provide blood to your kidneys.

Ultrasound – A diagnostic test that uses sound waves read by a probe that moves along the top of your abdomen.