APPENDIX 2 (ONLINE ONLY). DECEMBER 2002 CLINICAL UPDATE VOL I: THE ANEURX STENT GRAFT SYSTEM

This report was prepared by Medtronic AVE and approved by the FDA for distribution to physicians using the AneuRx Stent Graft System. It has been edited to comply with the format requirements of the Journal.

The report is divided into four sections. The first section contains clinical endpoint data from the entire Medtronic AVE US IDE cohort, which includes 1193 patients and data to 4 years. These data include safety endpoints (patient mortality, rupture, surgical conversion) as well as key endovascular measures (endoleak, aneurysm size, migration, patency, and device integrity). The second section summarizes information regarding aneurysm rupture, surgical conversion, and mortality from our combined global commercial experience. The third section summarizes the results from our explant analyses, and the fourth section provides summary comments. The data in this report include information collected and analyzed as of August 28, 2002.

Section I: Clinical trial data update

A total of 1193 patients were treated with the AneuRx Stent Graft System at 19 US investigational centers from 1996 to 1999. These patients were enrolled in three study phases. Phase I, consisting of 40 patients, enrolled patients from June 1996 to April 1997. Phase II began in April 1997 and ended in September 1998, with 424 patients enrolled and treated and one patient enrolled and not treated (the patient experienced a myocardial infarction after enrollment and prior to the procedure and did not receive the stent graft). Phase III enrolled 639 patients beginning in August 1998 and ending on September 30, 1999. Ninety additional patients not meeting the trial's inclusion criteria were enrolled in a high-risk arm of the trial. These patients are included in the long-term analysis. Sixty-six patients were also enrolled in the control arm of the study, receiving standard surgical treatment for abdominal aortic aneurysm (AAA). These patients were evaluated for morbidity and mortality and compared with 416 Phase II patients for premarket approval. Beyond the 1-year follow-up period for these 66 patients, we have only actively collected mortality status.

All patients in Phase I and 134 patients in Phase II (174 patients total) received a device design that incorporated a unibody "stiff" stent in the aortic body of the device. The remaining 1019 patients were implanted with a device design that incorporated a multisegmented "flexible" aortic body. This "flexible" device configuration is that which is currently marketed. The data below include all 1193 patients implanted with both stiff-body and flexible devices and include patient data through August 28, 2002.

One patient is not included in the rupture, survival, and aneurysm-related death analyses because this patient received a conversion device. The conversion device was approved as a treatment arm of the investigational device exemption (IDE) and is intended for use with the bifurcated device.

Table I provides a summary of clinical results relating to rates of rupture, conversion, aneurysm-related death, and all-cause mortality. Along with the "intraoperative", "less than or equal to 30 days", and "greater than 30 days" results, Kaplan-Meier summaries are provided for these endpoints for each year of follow-up, out to 4 years. A breakdown of the number of patients followed through each follow-up period for the clinical data presented in this report is provided in Table XII.

Tables II and III outline the primary causes of conversion and the primary categories of aneurysm-related death provided in Table I.

Table I. Rupture, conversion, and death

	Intraoperative n (%)	*≤30 days* n (%)*	*>30 days n†*	*Total† n*	*Kaplan-Meier summaries*	*1-year Kaplan-Meier*	*2-year Kaplan-Meier*	*3-year Kaplan-Meier*	*4-year Kaplan-Meier*
Aneurysm rupture	2/1193 (0.17%)	3/1193 (0.25%)	10/1193	15/1193	Freedom from aneurysm Rupture	99.5%	98.5%	98.4%	98.4%
Conversion to surgical repair	11/1193 (0.92%)	4/1193 (0.34%)	38/1193	53/1193	Freedom from conversion	98.5%	96.9%	94.2%	90.4%
Aneurysm-related death‡	0	22/1193 (1.8%)	8/1193	30/1193	Freedom from aneurysm-related death	98.2%	97.5%	96.9%	96.9%
Death (all-cause)	0	22/1193 (1.8%)	228/1193	250/1193	Probability of survival (based on all-cause mortality)	91.8%	83.1%	76.6%	62.4%

*Postoperative, but within 30 days.

†Patients within this group are currently at a variety of follow-up periods; therefore, rates are not given for these columns. Please refer to Kaplan-Meier estimates for specific projections for patients > 30 days postprocedure.

‡Aneurysm-related death is defined as any death occurring within 30 days of the initial treatment, a rupture, a conversion, or any other secondary stent graft procedure.

Table II. Primary causes of conversion

Cause	*n*
Endoleak w/AAA expansion	18
Rupture	11
Migration/displacement of modular component	11
Failure to access	7
AAA expansion	2
Endoleak	1
Other (pseudoaneurysm, aortic fistula, aneurysm pressing on colon)	3
Total	53

Table III. Primary categories of aneurysm-related death*

Category	*n*
Within 30 days of initial treatment	18
Within 30 days of rupture	4
Within 30 days of surgical conversion	7
Within 30 days of secondary stent graft procedure	1
Total	30

*Aneurysm-related death is defined as any death occurring within 30 days of the initial treatment, a rupture, a conversion, or any other secondary stent graft procedure.

Kaplan-Meier analyses of device performance during the US IDE trial are provided in Tables IV through VII. Kaplan-Meier curves for this data analysis are shown in Figs 1 through 4 (print). Please note that there are too few patients at this time to draw any valid statistical conclusions for the 5-year probability.

Ruptures: Kaplan-Meier analysis. As demonstrated in Table IV, patients treated with the AneuRx stent graft have a 4-year freedom from rupture rate of 98.4%.

Surgical conversion: Kaplan-Meier analysis. As demonstrated in Table V, patients treated with the AneuRx stent graft have a 4-year freedom from surgical conversion rate of 90.4%.

Aneurysm-related death: Kaplan-Meier analysis. Aneurysm-related death is defined as any death occurring within 30 days of the initial treatment, a rupture, a conversion, or any other secondary stent graft procedure. As demonstrated in Table VI, patients treated with the AneuRx stent graft have a 4-year freedom from aneurysm-related death rate of 96.9%.

Mortality (all cause): Kaplan-Meier analysis. As demonstrated in Table VII, patients treated with the AneuRx stent graft have a 4-year probability of survival (based on all-cause mortality) of 62.4%.

Other outcome measures. The data presented in Table VIII contain hospital data as defined by the investigating physician. The decrease in denominators over time is mostly attributed to patients not having reached that follow-up period. The decrease could also be attributed to the data point not having been collected at the visit or the patient missing the follow-up visit.

Core lab (Phase II patients)/hospital observations for device integrity. As part of the clinical study and routine follow-up, data were analyzed for "device integrity". This endpoint was based on core lab determination of the device displaying a stent fracture or (probable/possible) suture pop.

A total of 75 clinical trial patients had one or more device integrity reports. Forty-six Phase II patients had one or more device integrity reports as demonstrated by the core lab; seven patients did not have core lab reports but had noted hospital findings for possible stent graft integrity issues. Twenty-two Phase III patients had hospital reports only, as core lab evaluation was not required for Phase III. Core lab evaluations were based on review of plain abdominal radiographs for mostly Phase II patients (protocol requirement). The core lab device integrity report observations include the following: 39 unconfirmed or possible "suture pop" (also described as "step off"); 8 endoleaks (of questionable origin or existence); 3 appearances of migration of the stent graft; 1 note of separation of "cranial position" of the graft; 1 note of iliac limb separation; 4 possible stent graft fractures (with no fracture noted by hospital assessment); and 8 reports of "cannot determine" device integrity. Individual patients could have more than one observation.

Of the 46 patients with core lab evaluations, 40 patients had hospital reports of "no device integrity issue noted," and 6 patients had possible graft integrity issues recorded as "yes" on the hospital case report forms (3 reports of "graft wall defect, tear, or disruption"; 1 report of "attachment system fracture"; 1 report of "possible material defect in the right collateral limb"; and 1 report of suture pop). One patient with a report of graft wall defect underwent surgical conversion for endoleak and AAA expansion, and one patient had additional iliac limbs implanted to treat a persistent endoleak. None of the remaining four patients with both a core lab and hospital integrity concern had had an additional procedure of any kind.

Of the total patients with a device integrity report of any kind, six patients underwent successful surgical conversions. Two of these conversions were elective. Of the four remaining patients, two patients did not have confirmed loss of device integrity by either hospital or core lab findings.

During the successful surgical conversion procedure, one of the patients exhibited some blood flow through the stent graft, which had migrated due to lack of oversizing per the instructions for use. The aortic neck was observed to be thrombosed and calcified, which likely had a deleterious effect on the proximal seal. No stent ring fractures were observed. Some weave separation, minimal graft abrasion, and suture breaks were observed in the explanted device. This device did not contain the tighter fabric weave contained in the currently commercialized product.

The second patient was considered to have stent graft integrity issues as evidenced by hospital assessment and an endoleak of questionable origin as noted by the core lab report. At 2-year follow-up, this patient presented with

Table IV. Ruptures: Summary of Kaplan-Meier analysis*

	Treatment to 6 months	*6 months to 1 year*	*1 year to 2 years*	*2 years to 3 years*	*3 years to 4 years*
No. at risk†	1193¶	1116	1002	714	292
No. of events	5	1	8	1	0
No. of censored‡	72	113	280	421	251
Cumulative censored§	72	185	465	886	1137
Kaplan-Meier estimate‖	0.996	0.995	0.985	0.984	0.984
Standard error	0.0019	0.0021	0.0039	0.0044	0.0044

*For additional information on the number of patients followed at these time intervals, please refer to Table XII.
†Number of patients at risk at the beginning of interval (based on actual implantation duration).
‡Patients are censored because their last follow-up has not reached the end of the time interval, due to all-cause death, due to surgical conversion, or because they are lost to follow-up.
§The total censored for all time intervals up to and including that specific time interval.
‖Estimate made at end of time interval.
¶One patient is not included. This patient received a conversion device.

Table V. Surgical conversion: Summary of Kaplan-Meier analysis*

	Treatment to 6 months	*6 months to 1 year*	*1 year to 2 years*	*2 years to 3 years*	*3 years to 4 years*
No. at risk†	1193¶	1105	998	712	293
No. of events	16	2	14	14	6
No. censored‡	72	105	272	405	244
Cumulative censored§	72	177	449	854	1098
Kaplan-Meier estimate‖	0.987	0.985	0.969	0.942	0.904
Standard error	0.0034	0.0036	0.0056	0.0089	0.0177

*For additional information on the number of patients followed at these time intervals, please refer to Table XII.
†Number of patients at risk at the beginning of interval (based on actual implantation duration).
‡Patients are censored because their last follow-up has not reached the end of the time interval, due to all-cause death, due to surgical conversion, or because they are lost to follow-up.
§The total censored for all time intervals up to and including that specific time interval.
‖Estimate made at end of time interval.
¶One patient is not included. This patient received a conversion device.

Table VI. Aneurysm-related death: Summary of Kaplan-Meier analysis*

	Treatment to 6 months	*6 months to 1 year*	*1 year to 2 years*	*2 years to 3 years*	*3 years to 4 years*
No. at risk†	1193¶	1112	999	709	291
No. of events	22	0	5	3	0
No. censored‡	59	113	285	415	249
Cumulative censored§	59	172	457	872	1121
Kaplan-Meier estimate‖	0.982	0.982	0.975	0.969	0.969
Standard error	0.0039	0.0039	0.0047	0.0059	0.0059

*For additional information on the number of patients followed at these time intervals, please refer to Table XII.
†Number of patients at risk at the beginning of interval (based on actual implantation duration).
‡Patients are censored because their last follow-up has not reached the end of the time interval, due to all-cause death, due to surgical conversion, or because they are lost to follow-up.
§The total censored for all time intervals up to and including that specific time interval.
‖Estimate made at end of time interval.
¶One patient is not included. This patient received a conversion device.

abdominal pain radiating to the back. The aneurysm diameter had increased with evidence of a persistent endoleak. Type II endoleaks were noted at predischarge, 1-month CT scan, and 1-year CT scan, and coil embolization of the inferior mesenteric artery was performed during the follow-up period. During surgical conversion, a leak was noted in the contralateral limb. Upon explant, one fatigue fracture was noted which was not in the seal zone, and weave separation and suture breaks were also observed. The weave separation, noted on the contralateral limb of the explanted device, is likely related to the leak observed during surgical conversion. The patient was successfully

Table VII. Mortality (all cause): Summary of Kaplan-Meier analysis*

	Treatment to 6 months	*6 months to 1 year*	*1 year to 2 years*	*2 years to 3 years*	*3 years to 4 years*
No. at risk†	1193¶	1111	999	708	291
No. of events	61	35	87	38	24
No. censored‡	21	77	204	379	225
Cumulative censored§	21	98	303	681	906
Kaplan-Meier estimate‖	0.948	0.918	0.831	0.766	0.624
Standard error	0.0064	0.0080	0.0115	0.0147	0.0305

*For additional information on the number of patients followed at these time intervals, please refer to Table XII.
†Number of patients at risk at the beginning of interval (based on actual implantation duration).
‡Patients are censored because their last follow-up has not reached the end of the time interval, due to all-cause death, due to surgical conversion, or because they are lost to follow-up.
§The total censored for all time intervals up to and including that specific time interval.
‖Estimate made at end of time interval.
¶One patient is not included. This patient received a conversion device.

Table VIII. Other measures (or "efficacy outcomes")

	Predischarge n (%)	*1 month n (%)*	*6 months n (%)*	*1 year n (%)*	*2 years n (%)*	*3 years n (%)*	*4 years n (%)*
Endoleak	306/1103 (27.7%)	147/1056 (13.9%)	135/987 (13.7%)	132/951 (13.9%)	129/772 (16.7%)	63/451 (14.0%)	19/137 (13.9%)
Enlarged aneurysm*	N/A	48/523 (9.2%)	41/710 (5.8%)	48/689 (7.0%)	46/551 (8.3%)	39/346 (11.3%)	15/130 (11.5%)
Prosthesis migration	N/A	3/947 (0.3%)	10/920 (1.1%)	20/904 (2.2%)	39/732 (5.3%)	32/449 (7.1%)	13/137 (9.5%)
Patency	1105/1106 (99.9%)	1036/1041 (99.5%)	972/978 (99.4%)	945/953 (99.2%)	762/773 (98.6%)	443/451 (98.2%)	132/137 (96.4%)

*This endpoint is defined as any increase > 5mm as compared to pre-discharge measurement.

converted; however, he expired 10 days later due to respiratory failure.

The third patient had "modular disconnection" at 2 years by hospital assessment. At 28 months, the patient had a successful open repair because the proximal neck was too short to permit endovascular treatment. The explant analysis notes two fatigue fractures in the bifurcated segment and one fatigue fracture in the aortic cuff (none were in the seal zone, so they probably were not the cause of migration), an abrasion hole at the crown edge (totally obscured by tissue without evidence of leakage in the adjacent tissue), and consecutive suture breaks in the distal iliac cuff limb (not likely a cause of proximal endoleak).

The fourth patient had a successful surgical conversion at 25 months. The hospital assessment at 2 years was "modular disconnection". Angiogram revealed separation between the stent body and the cuff. There was evidence of a Type III endoleak, modular component disconnect, and evidence of separation of stent rings. Further assessment noted that the aortic extension cuff was implanted in an angled neck. This angle was also associated with the implant of the bifurcated segment. During explant analysis, stent fractures, graft abrasion, and suture breaks were observed.

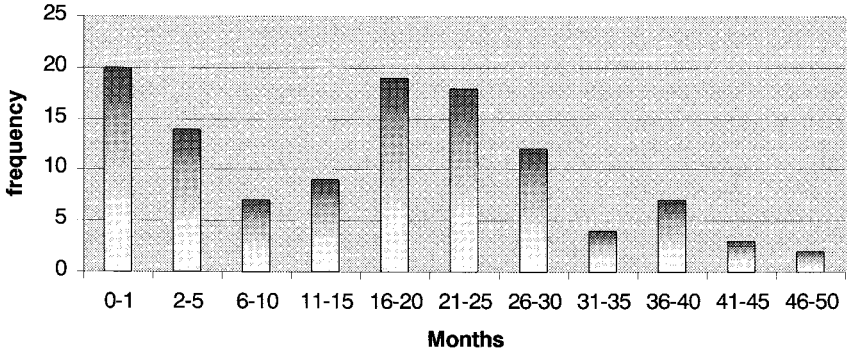
Of the remaining patients, 21 underwent an additional procedure (additional stent graft component placed, coil embolization or ligation of arteries for treatment of Type II endoleaks, or Dacron taping via aneurysmorrhaphy) for any reason. The remaining 48 patients did not require any additional procedure.

Careful patient selection and appropriate follow-up are important factors for success with endovascular stent grafting. The recently updated AneuRx Stent Graft Instructions for Use outlines the following critical factors for successful clinical outcomes:

- Appropriate patient selection, including a 15-mm aortic seal zone and 25-mm iliac seal zones and aortic neck angulation of <45 degrees;
- 10% to 20% oversizing;
- effective device deployment in accordance with the instructions for use;
- appropriate and timely patient follow-up.

Section II: Commercial experience/product performance update

As of August 30, 2002, more than 25,000 AneuRx devices have been distributed worldwide. From this commercial experience, Medtronic AVE gathered product performance information via field reports as well as from the active product and explant analysis programs. Table IX summarizes all reports received from commercial experience with the AneuRx Stent Graft through August 30, 2002.



Histogram of implant duration in months (N = 115).

Table IX. Commercial experience/product performance update

AE type	*US 9/28/99 to 8/30/02*	*International 11/97 to 8/30/02*
Rupture (total)	30	13
Preoperative*	6	
Perioperative	8	
Postimplant	16	13
Conversion	103	38
Aneurysm-related death (any death occurring within 30 days of the initial treatment, a rupture, a conversion, or any other secondary stent graft procedure)	78	11
Number of bifurcated devices distributed	20,694	4714

*The preoperative ruptures occurred in patients who had a rupture prior to inserting the AneuRx Stent Graft. The treating physician attempted rupture treatment with the endovascular stent graft rather than open surgical repair due to the patient's pre-existing comorbidities, surgical risk, and emergent circumstance.

Section III: Explant analyses

Medtronic AVE has analyzed AneuRx devices that were implanted and subsequently explanted either at surgery or at autopsy. As of August 30, 2002, Medtronic AVE has completed and submitted to the FDA individual case analyses (including summary reports and individual case reports) on 115 explants from patients implanted worldwide (Table X) from 1996 to 2002. A summary of these 115 explants is provided in the following pages.

Each explanted device received by Medtronic AVE is scientifically evaluated by Medtronic AVE personnel as well as outside technical experts where appropriate. The detailed findings are then evaluated in conjunction with the patient-specific clinical information to assess the potential clinical significance, if any, of the device findings. Patient anatomy and the procedural technique used by the physician are also assessed. Findings are presented to the implanting physician and appropriate regulatory bodies, including the FDA.

Explant summary of observations. The Figure shows the distribution of implant duration for these 115 explants. The explants had been implanted for an average of 16.9 months. Ninety-five of 115 explants (83%) had been implanted for more than 1 month.

Table XI shows the primary reasons for explant as determined by the treating or explanting physician. Perioperative implants (≤1 month) and longer-term explants (>1 month) are given separately.

Explant device observations. As part of an individual analysis of each explanted device, the integrity of the components of the stent graft is examined. This examination includes the stents, graft material, and sutures.

Stent observations. Nitinol stent strut fractures have been observed in devices that have been surgically explanted as well as removed at autopsy. Fractures can be categorized as due to single event overload or fatigue. It is likely that the majority of single event overload fractures occur during the explant procedure itself.

The AneuRx stent graft is designed to contain numerous and redundant stent strut elements. For example, bifurcated stent grafts contain between 728 and 1020 of these elements per device, and the observed rate of stent fractures has been very small. The rate of occurrence of stent element fractures as a percentage of available stent elements was 0.16% for the 115 explants, of which 0.13% are fatigue fractures. An average of 2.1 fatigue fractures per explant have been observed for the 115 explants. Fatigue fractures have been observed in 57 of the 115 explants, with a range of 1 to 29 fatigue fractures.

These fatigue fractures appear to be clustered in the midaortic stent rings, generally outside the seal zones of the bifurcated device. The majority of fatigue fractures observed during explant analysis do not appear to be related to adverse clinical outcomes; however, it appears that severe aortic neck angulation may be associated with the development of fatigue fractures. Patient selection and follow-up in accordance with the instructions for use is recommended.

Graft material and suture observations. The AneuRx stent graft includes a polyester graft material. A change in the material was implemented after December 1997 during the IDE clinical trial. This change to a tighter fabric weave reduced the porosity of the graft material. We denote this

Table X. Sources of explanted devices

	Number from surgical conversions	*Number from autopsies following rupture*	*Number from incidental autopsy*	*Total*
From IDE clinical study (of 1193 patients enrolled)	31	1	13	45
From US commercial sales (of 20,694 bifurcated devices distributed as of August 2002)	30	0	7	37
From commercial sales outside of the US (of 4714 bifurcated devices distributed as of August 2002)	27	0	6	33
Totals	88	1	26	115

newer version as the Reduced Porosity Material (RPM). The original version is referred to as pre-RPM. Eighteen of the 115 devices were made with the pre-RPM material, and 97 of the 115 devices were made with the RPM material.

Observations related to graft fabric include weave separation and abrasion. The RPM, with its tighter weave, exhibits less weave separation. Weave separation and abrasion occur predominantly in the ipsilateral and contralateral iliac legs. Both have also been observed, to a lesser extent, directly below the aortic seal zone. The presence of weave separation or abrasion is typically observed in areas of increased vessel tortuosity.

A portion of the RPM devices could not be evaluated for weave separation and abrasion, as they had been destructively analyzed when evaluated by an outside pathology laboratory. Eighty-one of the RPM devices were evaluated for weave separation and abrasion. Twenty-nine of the 81 RPM explants exhibited holes larger than 0.2 mm^2, which is the current manufacturing specification for this graft material. An average of 1.3 holes per RPM explant were observed. The holes in the RPM explants averaged 0.7mm^2 in size, with a median size of 0.5mm^2. The potential for transgraft endoleak as a result of these holes is unclear, because the process is influenced by many factors such as anticoagulation, tissue incorporation and healing, pressure gradients, and collateral flow. However, Medtronic AVE will continue to assess the potential for clinical impact as additional explants are received.

Broken sutures have also been observed in explanted AneuRx stent grafts. Abrasion of the suture against the nitinol stent appears to be the primary mode of the breakage. The breakage is typically seen at the junction (stent tip to stent tip connection) stitches. Suture breaks do not appear to be clustered around a specific area of the stent graft.

A sample of explanted devices was examined for suture breaks. Suture breaks have been observed in 12 of the 14 explants in this sample. An average of 24.6 breaks was observed, with a median of 22 breaks. The number of suture breaks ranged from 0 to 72 breaks. It should be noted that the AneuRx stent graft is designed to contain numerous and redundant suture attachment points. Bifurcated stent grafts contain between 1619 and 2079 sutures per device. The observed rate of suture breakage has been very small. For instance, in this sampling of 14 explanted devices the rate of suture breaks as a percentage of total sutures is less than 1.5%. Microleaks, typically through suture attachment sites, have been observed during a small number of explant procedures. These microleaks are typically observed during the surgical conversion when anticoagulation is administered, the aneurysmal sac is then opened, and finally the thrombus adhering to the sac is disturbed.

Table XI. Reasons for explant: Primary cause as determined by physician

Reason for explant	*Number of occurrences: Implant duration ≤1 month*	*Number of occurrences: Implant duration >1 month*	*Number of occurrences: Total*
Increase in AAA Size	0	32	32
Incidental Autopsy	8	18	26
Rupture	4	13	17
Postimplant	0	13	13
At time of implant	4	0	4
Endoleaks (Type I, Type II, Type III, including component separation)	0	14	14
Implantation difficulties	7	0	7
Limb occlusion	1	5	6
Aortoenteric fistula	0	3	3
Symptomatic AAA	0	2	2
Infection	0	2	2
Migration	0	3	3
Disease progression*	0	3	3

*As defined by localized dilatation of the aortic neck

Potential clinical consequences. Potential clinical implications associated with stent strut fatigue fracture include, but are not limited to, incomplete seal, endoleak, device migration, and/or vessel perforation. Potential clinical consequences of fabric wear and/or broken sutures include microleaks, loss of column strength, endoleaks, and aneurysm enlargement. These potential clinical consequences can often be detected and treated during regular patient follow-up. The presence of device anomalies such as stent fractures, graft wear, or suture breaks does not necessarily result in adverse clinical outcomes. Some anomalies may be the result of the device adapting to tortuous or remodeling patient anatomy.

Table XII. Patients followed and follow-up periods

	6 months	*1 year*	*2 years*	*3 years*	*4 years*	*5 years*
Phase I						
Patients followed	36	31	25	18	8	1
Deaths*	4	7	9	12	12	14
Patients censored*	0	2	6	10	20	25
Lost/terminated	0	2	6	6	7	7
Not reaching follow-up	0	0	0	4	13	18
Phase II						
Patients followed	445	412	351	230	34	0
Deaths*	19	33	66	84	103	106
Patients censored*	6	25	53	156	333	364
Lost/terminated	4	13	27	43	57	62
Not reaching follow-up	2	12	26	113	276	302
Phase III						
Patients followed	630	556	332	43	0	0
Deaths*	38	56	108	125	130	130
Patients censored*	15	71	243	515	553	553
Lost/terminated	7	18	31	46	51	51
Not reaching follow-up	8	53	212	469	502	502

*Number of deaths and patients censored are cumulative

Medtronic AVE is continuing to examine explanted devices and the environment of AAA disease to further the development of this important therapy option. If a physician has an explanted device available for analysis by Medtronic AVE, they should contact thier local Medtronic AVE representative for assistance with return of the device.

Section IV: Summary

The results of the US clinical trial, worldwide commercial experience, and explant analyses confirm that the AneuRx stent graft continues to be a safe and effective option for appropriately selected patients with infrarenal abdominal aortic aneurysms.

PATIENTS FOLLOWED AND FOLLOW-UP PERIODS

Table XII is intended to inform the reader of the number of patients in each phase of the IDE clinical study that have been followed at the various follow-up periods. The following definitions are included to enable interpretation.

- Patients followed: the number of patients reaching the end of the follow-up period with a study visit form.
- Deaths: the number of death forms received at the end of the follow-up period.
- Patients censored: the number of patients lost, terminated, or of unknown status.
- Patients lost/terminated: the number of patients with a study termination form.
- Patients not reaching follow-up: the number of patients in which a visit is not yet expected *and* the number of patients who should have a visit but don't have a visit or study termination form.