

Tools of the Subclavian Trade

Equipment choices for subclavian arterial interventions.

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The majority of the supra-aortic atherosclerotic occlusive lesions involves the left subclavian artery.¹ Such disease results in a “subclavian steal,” which was first described in 1961 by Reivich et al.² By occluding the left subclavian artery, arterial flow is provided by the right subclavian artery with flow into the right vertebral artery and then retrograde flow into the left vertebral artery, and subsequently into the left subclavian artery (Figure 1). A very common cause of stenotic lesions in these vessels, similar to other vessels, is atherosclerotic disease. However, other causes such as dissection, fibromuscular disease, and various vasculitides are not infrequent.³

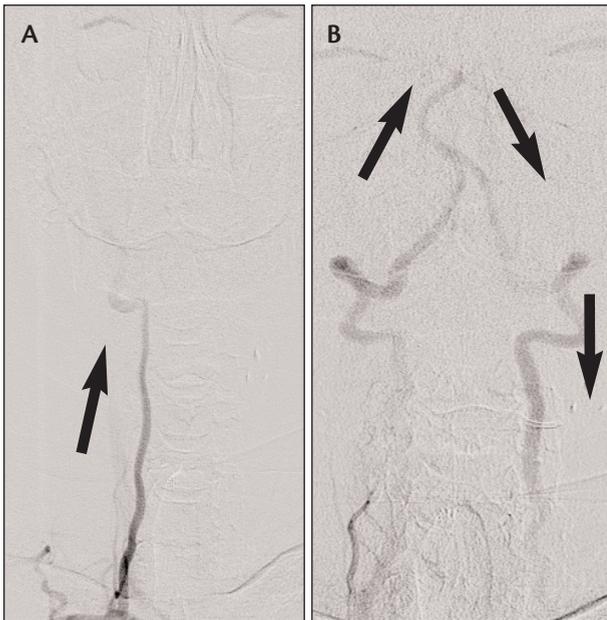


Figure 1. Total occlusion of the left subclavian artery with retrograde flow in the left vertebral reconstituting the subclavian artery (A). Selective injection of the right vertebral artery demonstrates the shunt (arrows) from the right to the left vertebral and retrograde flow to the left subclavian artery (B).

“... angioplasty and stent placement have been very successful with low complication rates and excellent technical and long-term results.”

The diagnosis of subclavian steal is based on having upper-extremity ischemia in which a pressure gradient of 20 mm Hg is noted and symptoms of arm claudication, paresis, and atheroembolic digital ischemia are seen. Less commonly, there is vertebrobasilar insufficiency, which includes symptoms of ataxia, diplopia, syncope, vertigo, dizziness, nausea, and vomiting. Another syndrome, which has been increasing in frequency, includes coronary steal syndrome in which a stenosis proximal to internal mammary-coronary artery bypass may cause ischemic symptoms. The more frequent use of the left internal mammary artery (LIMA) for coronary bypass procedures has resulted in greater surveillance and treatment of the left subclavian artery. Although debatable, high-grade, proximal subclavian arterial stenoses in relatively asymptomatic patients is now considered appropriate therapy to maintain the capacity to use the LIMA. Many cases of subclavian artery stenosis or occlusive disease are discovered by CT angiography and MRA, in addition to traditional angiographic means (Figure 2).

Innominate artery stenosis is relatively uncommon. When the atherosclerotic disease involves the innominate artery, the symptoms may be more severe and include cerebral symptoms. The occlusion in the innominate artery causes retrograde flow from the vertebral artery and into the right common carotid and the right subclavian artery. Symptoms generally include vertebrobasilar insufficiency with ataxia, diplopia, syncope, vertigo, dizziness, nausea and/or vomiting. It may also include upper-extremity ischemia and atheroembolic digital ischemia.

TABLE 1. EARLY ANGIOPLASTY RESULTS OF SUBCLAVIAN ARTERY STENOSES

Investigator	Patients	Technical Success	Restenosis Rate	Complication Rate	Follow-Up (months)
Erbstein et al ⁴	24	88%	16% (4/24)	4% (1/24)	18-26
Wilms et al ⁵	23	91%	13% (3/23)	4% (1/23)	25

Note: Results are prior to 1989.

ACCESS FOR DIAGNOSING AND TREATING SUBCLAVIAN DISEASE

Your first decision, whether to employ the femoral or brachial arterial approach, will determine which type of sheaths, wires, and stents should be deployed. We generally prefer to come from the common femoral route because of long-term experience and because of the lower risk of hematoma complications that can occur from brachial approaches (Figure 3). We will frequently start with a 5- to 6-F short sheath to perform our diagnostic studies from the femoral access.

The brachial approach is preferred in many subclavian and innominate artery occlusions, especially in lesions lacking a characteristic nipple in the proximal segment of the artery. We will also use this approach when the takeoff of the subclavian or innominate artery is at such a steep angle to the aorta that traditional femoral access is fore-

boding. Also, if severe aortoiliac disease is present, we will naturally choose the brachial approach (Figure 4).

When selected, we prefer the low brachial approach near the olecranon fossa because of the difficulty in holding pressure to the brachial artery in the upper arm. We will use the micropuncture set system to gain a clean access into the brachial artery and will then place a short 5-F sheath for our initial diagnostic and early intervention. We almost never use the axillary approach because of the brachial plexus injury that can result from an expanding hematoma.

DIAGNOSIS AND INTERVENTION IN THE LEFT SUBCLAVIAN ARTERY

Left Subclavian Stenoses

Once arterial access is obtained, we administer 5,000 units of heparin intravenously. A left anterior oblique projection with the 5-F pigtail catheter in the aortic arch is first performed. Using roadmapping with favorable image angles, we carefully cross the lesion (Figure 5).

Our guidewire selection depends on the lesion characteristic and the sheath/guide catheter that we plan to use. Traditionally, for a moderate stenosis of the left subclavian, a .035-inch Wholey wire (300 cm in length, Malinkrodt, St. Louis, MO) will work well and can be used to provide adequate strength throughout the procedure. The diagnostic catheter used for support is frequently a 5-F, 100-cm-long, hockey stick-shaped catheter. For higher-grade stenoses, we use a .035-inch, regular-angled Glidewire (Terumo, Tokyo, Japan) followed by our diagnostic catheter, which is then exchanged for a metal braided catheter. Equally well-tolerated are the .014-inch support coronary wires (Spartacore, Guidant Corporation, Indianapolis, IN).

With the guidewire past the lesion, we remove the diagnostic catheter and advance the long sheath (6-F to 7-F) or the guide catheter (7-F to 8-F) just proximal to the lesion. If the diagnostic catheter is extra long (125-cm to 135-cm), we can telescope the sheath or guide over the diagnostic catheter and save a step.

We frequently predilate lesions that are severely diseased



Figure 2. MRA with gadolinium injection in coronal projection revealing left subclavian artery occlusion with the left subclavian steel phenomenon.

TABLE 2. ANGIOPLASTY RESULTS OF SUBCLAVIAN ARTERY STENOSES

Investigator	Patients	Technical Success	Restenosis Rate	Complication Rate	Follow-Up (months)
Dorros ⁶	27	100%	5% (1/22)	0	28
Kachel ⁷	51	86%	4% (2/44)	2%	58
Hebrang ⁸	52	93%	22% (11/52)	0	6-48
Vitek ⁹	35	100%	—	0	36
Motarjeme ¹⁰	62	100%	8% (5/62)	0	60

Note: Results are after 1989.

and that pose a risk of stripping or impeding the passage of our balloon-mounted stents. Predilatation with a 4-mm X 2-cm PTA balloon catheter helps to reduce the risk of stent migration and allows for a quick reference of the vessel size and lesion length.

We recheck the images to see important vessel takeoffs and to assess possible dissections. For ostial lesions, we will occasionally use a right anterior oblique view to see the origin. Generally, a steep left anterior oblique projection works well. Biplane images are very useful, if available. We never advance the sheath over and past the lesion. We then advance the balloon-mounted stent to the lesion, being certain that important vessels such as the internal mammary and the vertebral arteries are not compromised. The balloon-mounted stent is frequently 7 mm to 8 mm in diameter and 15 mm to 20 mm in length. If the vertebral artery is at risk, we leave a .014-inch guidewire as a safety wire in the vertebral artery during subclavian stenting. We then hold the balloon carefully because of the aortic arch pulsations and then deploy the stent quickly to approximately 8 atm. We will then perform angiography after stent placement and assess the stent apposition to the vessel diameter. Unlike other major arteries, the origin of the subclavian artery is somewhat fragile, so we are always cautious not to overdilate this vessel for fear of rupture, which can have catastrophic results.

For lesions involving the proximal segments of the left subclavian, left common carotid, and especially the innominate artery, we always use a balloon-mounted stent. The chance for compression and deformation of the stent is low. Self-expandable stents are not chosen because of the inability to be exactly precise in a region where millimeters count. Furthermore, there is the possibility of stent migration with the self-expandable stents.

Since 1989, the equipment used to perform subclavian

interventions has advanced dramatically, improving technical success, which has been reflected in the high technical success rates, lower complication rates, and lower restenosis rates. Angioplasty alone had a restenosis rate ranging from 5% to 22% (Tables 1 and 2). With the development of endovascular stenting, there has been a reduction in the restenosis rate ranging from 0% to 16% (Table 3).

Intervention of Left Subclavian Occlusions

Gaining access through left subclavian total occlusions is somewhat more difficult and may require a femoral and/or a brachial approach to achieve. We will generally start from the femoral route and, with manipulations of a diagnostic catheter, such as a headhunter or vertebral-shaped catheter, and with a torquable guidewire (regular or stiff Glidewire or Wholey .035-inch guidewire), we will get through most lesions. Attention must be paid, especially with the stiff glide wire, to avoid perforation

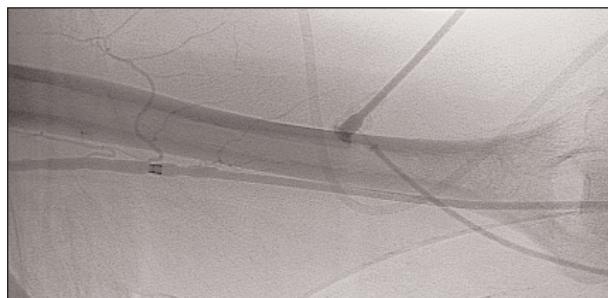
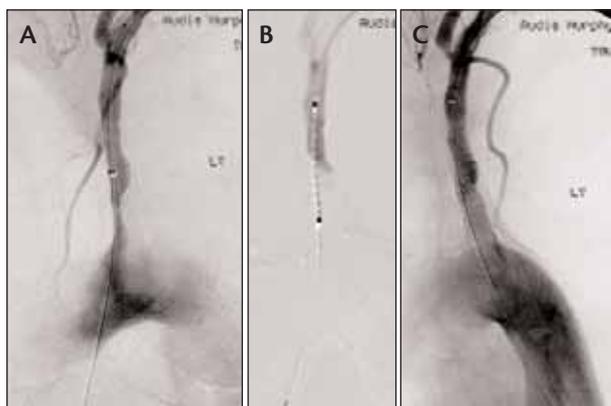


Figure 3. A long 6-F sheath from a low brachial approach demonstrating the small-caliber-diameter artery found in many patients, such as this elderly woman. Many such patients experience spasm, which further contributes to low or no flow. Intra-arterial nitroglycerin helps to reduce the spasm. Also, placing an oxygen sensor on the fingers of the patient's left arm with the brachial approach helps to keep us aware of potential problems.



Figures 4. Because of severe aortoiliac disease, a low brachial artery approach was performed. A 4-F catheter injection revealed a high-grade lesion of the left subclavian artery (not shown). Over a .035-inch wire, a balloon-mounted stent was placed at the lesion using a 6-F long sheath (A,B). Notice the difficulty in obtaining enough contrast through the 6-F sheath and the stent across the lesion. Injection reveals good deployment with the 8-mm X 20-mm stent (C).

or dissection of the subclavian artery. Also, care must be taken with the wire crossing the subclavian artery ostium, to be gentle with wire manipulations to avoid causing the wire to dissect across the ostium. If a dissection occurs, stop and have the patient return at a later date.

Once across the lesion, we may change the wire for one with more support. Predilation and balloon-mounted stent placement then proceeds in a manner similar to stenotic lesions.

CHOOSING BETWEEN GUIDING CATHETERS OR SHEATHS

Whether you chose a guiding catheter or a sheath, it is important never to compromise your ability to inject

contrast material to visualize the lesion in relation to the balloon catheter. Likewise, it is essential to obtain the best angle to see the takeoff of the vessel in relation to the aorta. It is also crucial to have the best angle to visualize the takeoff of key vessels (vertebral, common carotid, or internal mammary arteries). Because of respiration, roadmap images are not often helpful.

Another feature to be aware of is dramatic aortic pulsations when deploying a stent. If there is a large gap in diastolic and systolic blood pressures, there can be an excess of pulsations of the vessels. These pulsations can cause large motions (1 cm or more) in the position of the lesion relative to the balloon catheter or self-expanding stent when trying to deploy. Blood pressure control is essential in these patients, as well as the need for slightly longer stents.

Distal Subclavian/Axillary Lesions

We are encountering more patients, especially those on hemodialysis, who present with mid and distal subclavian stenosis. We frequently discuss these cases with our vascular surgery colleagues for possible surgical options on a case-by-case basis. When we intervene, we generally prefer to perform angioplasty along those lesions at crucial areas, such as between the first rib and clavicle, as well as at the subclavian/axillary junction where there is bending and compression. When the lesion does not respond to angioplasty, we use self-expanding stents, such as Wallstents (Boston Scientific Corporation, Natick, MA) and nitinol stents. We oversize the stent by 1 mm to 2 mm greater than the vessel diameter and deliver and deploy the stent through a long 7-F to 8-F sheath. Interestingly, there is a lot of slack that must be removed when deploying self-expandable nitinol stents. Furthermore, care must be taken to watch the proximal end of the stent, which tends to jump or shrink farther distally than planned (Figure 6).

TABLE 3. ENDOVASCULAR SUBCLAVIAN STENT RESULTS

Investigator	Patients	Technical Success	Restenosis Rate	Complication Rate	Follow-Up (months)
Henry ¹¹	46	91%	16%	3%	48
Sullivan ¹²	66	94%	15%	17%	36
Sueoka ¹³	7	100%	0	0	12
Kumar ¹⁴	27	100%	0	11%	



Figures 5. A shallow left anterior oblique projection of the thoracic arch was obtained, which revealed high-grade, focal proximal subclavian stenosis (A). The 7-F, long Brite-Tip sheath (Cordis Corporation, a Johnson & Johnson company, Miami, FL) is in position, and a .035-inch guidewire is moved past the lesion. We will frequently use a torqueable .035-inch wire such as a Terumo glidewire and then switch out for a metal braided guidewire once safely across. Poor flow is seen in the internal mammary artery. A balloon-mounted 8-mm X 27-mm stent was deployed successfully (B). There is improved flow in the vertebral and internal mammary artery, in addition to now-visible thyrocervical and ascending cervical branches (C). Arm claudication improved immediately.

Innominate Artery Lesions

The technique for innominate artery lesions is similar to stenting the left subclavian and the left common carotid arteries. Attention must be given to the bifurcation of the right common carotid and the right subclavian arteries (Figure 7). For disease that exists at the origin of the vessels, kissing stents may then be required. There has been some debate regarding the use of distal embolic protection in treating right subclavian artery disease, especially if the disease is close to the ostium of the subclavian artery. We have used distal protection with a filter placed in either the internal carotid artery or the common carotid, depending upon the carotid diameter and filter size available. The 7.5-mm Guidant Accunet (Guidant Corporation, Indianapolis, IN) is often large enough to protect patients with small common carotid arteries.

For more diseased subclavian arteries and for patients requiring a brachial approach, we generally use .014-inch

and .018-inch guidewires. There has been a long history of interventions in the subclavian great vessels with very favorable technical success and a relatively low rate of complications. The fortunate low rate of restenosis has also been experienced primarily due to the large size of the vessels.

CONCLUSION

Diagnosis and treatment of occlusive disease of the innominate and subclavian arteries varies depending upon the location of the disease and whether the lesions are highly stenotic or occlusive. Generally, angioplasty and stent placement have been very successful with low complication rates and excellent technical and long-term results. Much of the success depends on improved technology, patient selection, and operator skills. There will be further advances in the treatment of patients with atherosclerotic disease of the innominate and subclavian arteries, as these



Figure 6. A hemodialysis patient with high-grade stenosis of the subclavian artery between the first rib and the clavicle. The initial injection (A). The lesion did not respond to angioplasty and did not compress appreciably with abduction of the arm (consistent with thoracic outlet syndrome). A self-expandable nitinol stent (10 mm X 30 mm) was deployed and postdilated with a 9-mm PTA balloon for good results and increased flow to the left arm graft (B, C).

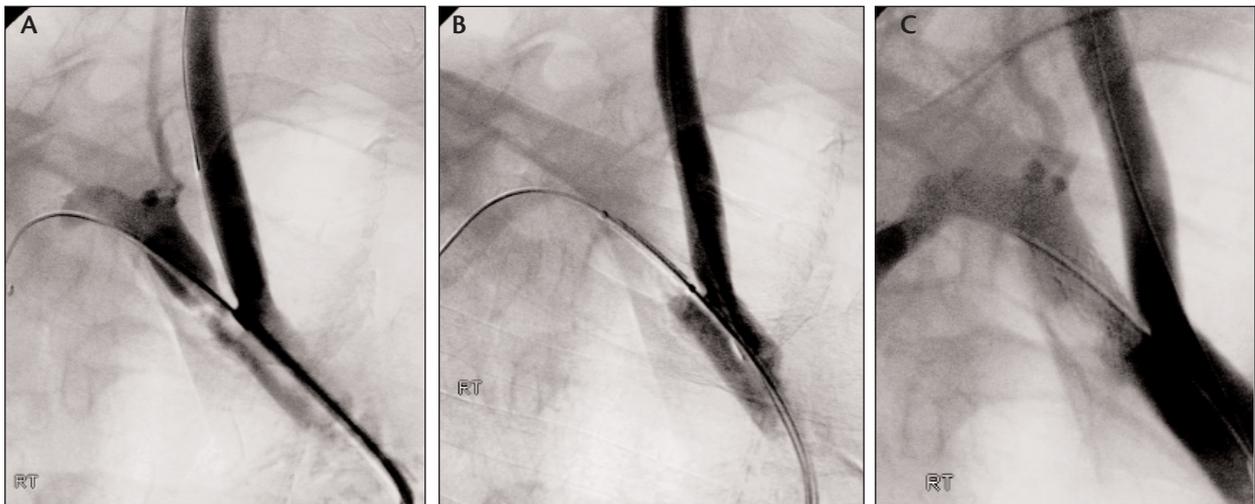


Figure 7. The patient has a high-grade, calcified stenosis of the right subclavian artery near the junction of the innominate and right common carotid arteries (A). A .014-inch safety wire was placed across the internal carotid artery, and an appropriate oblique angle was obtained of the subclavian artery. The stent across the lesion with flow diverted to the common carotid (B). The stent is in good position with the opening of the right common carotid intact. The distal end of the stent was then dilated further (C).

patients become identified earlier with the growing applications of CT angiography and MRA. ■

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Indications

The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- Adequate iliac/femoral access
- Infrarenal nonaneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10–20% smaller than the labeled device diameter
- Morphology suitable for endovascular repair
- One of the following:
 - (1) Aneurysm diameter of >5 cm
 - (2) Aneurysm diameter of 4–5 cm which has also increased in size by 0.5 cm in the last 6 months
 - (3) Aneurysm which is twice the diameter of the normal infrarenal aorta.

Contraindications

There are no known contraindications currently associated with this device.

Warnings and Precautions

The AneuRx Stent Graft is intended to prevent rupture of abdominal aortic aneurysms. However, this risk is not completely eliminated. Based on reports received for patients enrolled in all phases of the clinical study, through August 1, 2001, ruptures have occurred in 2/1193 patients (0.167%) during the operative period; in 3/1193 patients (0.251%) within 30 days of the treatment; and in 10/1193 patients (0.838%) greater than 30 days after treatment. The one-year freedom-from-rupture rate for patients enrolled in all phases of the clinical study is 99.5%; the two-year freedom-from-rupture rate is 98.6%; and the three-year freedom-from-rupture rate is 98.5%; and the four-year freedom-from-rupture rate is 98.5%.

The long-term safety and effectiveness of this implant have not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

Exercise care in the handling and delivery technique to aid in the prevention of vessel

rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of non-aneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle >45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle <45 degrees. The same data indicate that patients with an aortic seal length of <15 mm and an iliac seal length of <25 mm may also have a higher likelihood of suboptimal outcomes.

This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.

Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.

The results of the clinical studies indicated that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to surgical abdominal aortic aneurysm (AAA) repair, are likely to have increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues and mortality).

The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms have not been evaluated in patients:

- With aneurysms pending rupture
- With connective tissue disorder
- With hypercoagulability
- With mesenteric artery occlusive disease
- With ilio-femoral, thoracic, or inflammatory aneurysms
- With juxtarenal AAA
- With pararenal AAA
- With suprarenal or thoracoabdominal aneurysms
- Who are morbidly obese
- Pregnant or nursing
- Less than 18 years old
- With less than one-year life expectancy.

Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

Patient Selection, Treatment and Follow-up

Do not use this device in patients having an active systemic infection. Do not use this device in patients with sensitivities or allergies to the device materials. The materials include: polyethylene-terephthalate (PET), nickel, titanium, tantalum, stainless steel, polyetheresterblock-copolymer (Hytrel), polyetherblockamide (Pebax), polyetheretherketone (PEEK), platinum, ethyl cyanoacrylate, polymethylmethacrylate and hydroquinone.

The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.

The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively.

Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight exceeds 350 lbs (150 kg) or whose weight may impede accurate fluoroscopic imaging.

Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations). During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks and device integrity.

Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:

- Aneurysm growth >5 mm (with or without leak) since last follow-up
- Change in aneurysm pulsatility (with or without growth or leak)
- Persistent endoleak with or without aneurysm growth
- Stent graft migration resulting in an inadequate seal zone.

The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.

MRI may be used on the stent graft only under the following conditions:

- When used in shielded MRI

systems with static magnetic fields of 1.5T or less

- Spatial gradient of 450 gauss/cm or less,
- Gradient magnetic fields of 10 Tesla/second or less
- A maximum whole body averaged specific absorption rate (SAR) of 1.4 W/kg for 30 minutes of imaging.

Adverse Events

Death, AAA rupture, bleeding, cardiac failure/infarction, edema, wound healing complications, impotence, pulmonary complications, renal failure, gastrointestinal complications, arterial vascular occlusion and venous vascular occlusion.

Potential adverse events include: arterial and venous occlusion (includes thrombosis and thromboembolism), arterial trauma/dissection/perforation, bleeding, cardiac failure/infarction, central or peripheral nervous system impairment, coagulopathy, death, edema, endoleak, erosion with fistula or pseudo-aneurysm, gastrointestinal complications, graft dilatation, graft migration, graft occlusion, impotence, infection, loss of device integrity (stent fractures, graft wear holes and suture breaks), pulmonary/respiratory complications, renal insufficiency/failure, ruptured vessel/aneurysm, and wound healing complications.

Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



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