FDA Approval Gives Spectranetics a Window for Moderate Sales Growth

Companies: ABT, BCR, COV, JNJ, SPNC, VOLC

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Research Question:

Will Spectranetics’ laser atherectomy and PTA become the new standard of treatment for femoropopliteal ISR and be the catalyst for a significant revenue boost?

Summary of Findings

- Spectranetics Corp. (SPNC) can expect a moderate sales increase as a direct result of its successful EXCITE ISR trial and the FDA’s approval of the use of the company’s laser atherectomy and percutaneous transluminal angioplasty (PTA) procedure for the treatment of femoropopliteal in-stent restenosis (ISR), according to 14 of 20 sources.
- Spectranetics has a window of opportunity to capture additional sales. Treatment options for peripheral ISR are limited, and the company has the only FDA-approved laser atherectomy devices. It also will benefit from strong trial data, a substantial yet underserved peripheral vascular disease (PVD) patient population, an expanded, knowledgable sales force from its recent AngioScore acquisition, and quality company management.
- Sources were divided regarding Spectranetics’ laser atherectomy and PTA procedure becoming the standard of care for the treatment of peripheral ISR.
- Challenges facing Spectranetics include receiving FDA approval and positive trial data earlier than expected and prior to launch plans, marketing a procedure and device that have been used off-label for some time, the high cost and cumbersome nature of the laser equipment, the difficulty of performing laser atherectomy, and what could become a crowded market.
- Noteworthy emerging treatments include drug-coated technologies for balloons and stents, bioabsorbable stents, noninvasive pharmacological options, radiation-induced brachytherapy, ACI Medical’s ArtAssist, and new modes of arterial access.

Silo Summaries

1) Interventional Cardiologists and Vascular Specialists
These five physicians expect Spectranetics to experience a revenue boost as a result of its superior EXCITE ISR trial results and the FDA indication for treating peripheral ISR with its laser and laser catheters. However, sources said the procedure has been performed off-label for some time and that sales gains may be limited as a result. Laser atherectomy is likely to become the standard of care, particularly for difficult-to-treat in-stent lesions, according to three of the five sources. The remaining two did not comment. One source said laser atherectomy has become his “go-to therapy.”

2) Medical Professionals
These four sources with management and clinical PAD therapy experience think the new FDA indication is unlikely to make Spectranetics’ laser, laser catheters and PTA the standard of care for peripheral ISR or to provide a significant revenue boost for the company. The procedure is not considered new and has been an off-label option for as long as 10 years.

3) Medical Sales Executives and Professionals
Five of six sources think Spectranetics will experience some market share and revenue gains as a result of its successful EXCITE ISR trial results and the FDA indication for use of its laser, laser catheters and PTA for the treatment of peripheral ISR. Sales forecasts ranged from a short-term boost, to gobbling up the atherectomy market, to 10% to 20% growth. A dissenting source said the FDA indication will not help Spectranetics place more lasers as its procedure is just another therapy option. Only one source thinks laser atherectomy will become the new standard of care.

4) Industry Specialists
Four of five sources commented on Spectranetics, and three of these four think the company will experience a revenue boost from the EXCITE ISR trial results and the FDA indication for use of its laser, laser catheters and PTA for the treatment of peripheral ISR. One was especially positive about Spectranetics’ future given its acquisition of AngioScore, the significant peripheral ISR patient population, the ability to perform laser atherectomy on an inpatient or outpatient basis, quality management, and the company’s monopolistic position. The dissenting source said Spectranetics has refined its lasers over the years but that these remain cumbersome, difficult to use and expensive.
Background

Spectranetics, a developer, manufacturer, marketer and distributor of single-use medical devices for minimally invasive procedures within the cardiovascular system, saw revenue from its Vascular Intervention business increase 19% quarter to quarter and U.S. revenue from peripheral atherectomies rise 22% compared with the prior quarter. Continued growth is expected as the company received FDA 510(K) approval of its peripheral atherectomy products Turbo-Tandem and Turbo Elite for the treatment of femoropopliteal in-stent restenosis (ISR). Management has highlighted that Spectranetics is the only company with devices indicated for ISR treatment, with approval received from the FDA in July. The market opportunity is estimated to be $750 million worldwide. In the recent EXCITE ISR trial, this procedure showed a 93.5% success rate with laser atherectomy plus PTA (also known as balloon angioplasty) for the treatment of ISR, versus 82.7% with PTA alone.

Peripheral arterial disease (PAD) affects roughly 10 million Americans and is more prevalent, 1 in 20, in men and women over the age of 60. Stenting is a minimally invasive surgery that props open clogged arteries with a circular metal cylinder and has become the first line of treatment for PAD. Over time these stents can become clogged and lead to femoropopliteal ISR, which occurs in 20% to 35% of patients within the first year after femoropopliteal artery stenting. That rate increases to as much as 65% when a standard angioplasty balloon is used to treat restenosis in arteries. These high rates of plaque buildup are aiding the rise in demand for longer-lasting treatments or methods to unclog stents.

New treatments are evolving, posing competition for Spectranetics’ laser atherectomy and PTA procedure. C.R. Bard Inc.’s (BCR) Lutonix drug-coated balloon PTA catheter elutes paclitaxel during the balloon inflation and received a unanimous “yes” vote from the FDA’s Circulatory System Devices panel of advisors. The FDA usually follows the panel’s advice, which would make Lutonix the first drug-coated balloon on the U.S. market for the treatment of femoropopliteal ISR. New methods of preventing a second surgery also are emerging. Earlier this year a study showed that sanding off calcium in the coronary arteries before the deployment of a stent lessened the need for a repeat procedure.

Current Research

Blueshift Research assessed whether the new FDA indication would increase the likelihood of Spectranetics’ laser atherectomy and PTA procedure becoming the new standard of treatment for peripheral ISR and provide a significant revenue boost for the company. We employed our pattern mining approach to establish five independent silos, comprising 20 primary sources (including two repeat sources) and four relevant secondary sources focused on Spectranetics’ EXCITE ISR trial offering better treatment of femoropopliteal ISR than angioplasty alone, the procedure’s FDA approval, Spectranetics furthering its laser research with the U.S. Air Force Academy, and how the AngloScore acquisition will improve Spectranetics’ distribution and diversify its products:

1) Interventional cardiologists and vascular specialists (5)
2) Medical professionals (4)
3) Medical sales executives and professionals (6)
4) Industry specialists (5)
5) Secondary sources (4)

Next Steps

Blueshift Research will monitor Spectranetics’ marketing and sales efforts for its laser atherectomy and PTA procedure. We will determine if the procedure is becoming the standard of care for patients with peripheral ISR. Finally, we will research emerging technologies for the treatment of peripheral ISR patients and how they affect Spectranetics’ sales.
Spectranetics Corp.

**Silos**

1) Interventional Cardiologists and Vascular Specialists

These five physicians expect Spectranetics to experience a revenue boost as a result of its superior EXCITE ISR trial results and the FDA indication for treating peripheral ISR with its laser and laser catheters. However, sources said the procedure has been performed off-label for some time and that sales gains may be limited as a result. Laser atherectomy is likely to become the standard of care, particularly for difficult-to-treat in-stent lesions, according to three of the five sources. The remaining two did not comment. One source said laser atherectomy has become his “go-to therapy.” Sources do expect new treatment options to emerge, including drug-eluting balloons, drug-eluting stents, bioabsorbable/bioresorbable/biodegradable stents, noninvasive pharmacological treatments, radiation-induced brachytherapy, ArtAssist, and new modes of arterial access. Sources’ patient cases ranged from one to 60 per month; about 30% of those patients have experienced peripheral ISR, and a smaller percentage are appropriate for laser atherectomy.

**KEY SILO FINDINGS**

Spectranetics Laser Atherectomy and PTA Economics
- All 5 expect some sales growth for Spectranetics as a result of the positive EXCITE ISR trial data and the recent FDA approval. Sales increase forecasts ranged from “not much” to 10% to 20%.

Spectranetics Laser Atherectomy and PTA in General
- Spectranetics’ procedure is likely to become the standard of care for difficult-to-treat in-stent lesions.
- 1 said laser atherectomy has become his “go-to therapy.”

ISR Treatment and Patient Population
- Patient populations served by these sources varied, but ISR was cited common and reoccurring.

Miscellaneous
- New therapies of interest include drug-eluting balloons, drug-eluting stents, biodegradable stents, noninvasive pharmacological treatments, radiation-induced brachytherapy, ArtAssist and new modes of arterial access.

1) Interventional cardiologist

The EXCITE ISR trial findings convinced this cardiologist to adopt laser atherectomy as his “go-to therapy.” Still, laser atherectomy should be tested against other promising interventions. In the short term, Spectranetics’ revenue probably will rise in and outside of the United States.

Spectranetics Laser Atherectomy and PTA Economics
- “It is likely that [Spectranetics] U.S. and international revenues will continue to increase in the short term, and may do so by as much as 10% and 20%, respectively.”

Spectranetics Laser Atherectomy and PTA in General
- “Few interventions have been tested for the treatment of femoropopliteal in-stent restenosis in randomized trials, the gold standard for addressing questions of efficacy. The EXCITE ISR data demonstrated that atherectomy using the Spectranetics laser was superior to balloon angioplasty alone, the standard therapy until now. Based on these findings, I suspect that Spectranetics’ laser atherectomy [plus] PTA has already become the standard of care at those institutions that have access to the technology.”
- “There remains a need to test the relative safety and efficacy of other promising technologies, such as drug-coated balloons, drug-eluting stents and brachytherapy [compared] to laser atherectomy.”

ISR Treatment and Patient Population
- “[I treat] about one patient [with ISR] per month.”
- “When the EXCITE ISR trial data were presented/published, I began to alter my treatment strategy such that laser atherectomy has now become my ‘go-to’ therapy.”
Miscellaneous
- “Beyond prevention, the most promising interventions include drug-coated balloons, drug-eluting stents and new modes of arterial access, such as tibiopedal [from the foot] that enable more complex procedures to be performed in a minimally invasive fashion.”

2) Cardiologist who participated in the EXCITE ISR trial
This physician currently uses Spectranetics’ laser atherectomy and PTA to treat ISR. He predicts that the FDA-approved treatment will become the standard of care once word spreads. Spectranetics’ sales will “absolutely” get a boost.

Spectranetics Laser Atherectomy and PTA Economics
- “Having an FDA indication and giving physicians the comfort to know that the procedure they are performing has not only been proven efficacious but also has the blessing of the FDA and isn’t off-label will absolutely boost [Spectranetics’] sales.”
- “It’s exciting that we finally have something that does have FDA approval for in-stent restenosis. ... Quite frankly, as we move forward with healthcare, I think there is going to be a push to where it’s really going to be looked at as to whether the procedure you are doing has an FDA indication or it’s an off-label use. I think at some point, that may be an issue that we are going to have to think a little bit harder about.”

Spectranetics Laser Atherectomy and PTA in General
- “Now that they have the FDA indication, more physicians will come on board with using the technique.”
- “It very well may [become the standard of care for femoropopliteal ISR]. [As for when] it depends. Of course, it’s a matter of getting the word out to the various physicians. To my knowledge, to date Spectranetics is the only company that has an FDA indication for the atherectomy treatment of in-stent restenosis, and that should definitely carry some weight.”

ISR Treatment and Patient Population
- “I probably treat 20 to 30 patients [with peripheral ISR per month].”
- “Almost all [peripheral ISR occurs] above the knee. Probably 90% to 95% of all peripheral leg stenting is above the knee.”

Miscellaneous
- “There are all kinds of devices that are coming out [for peripheral arterial disease, or PAD]. There are different access devices to make it easier to access the disease from the pedal access or coming from a foot. There’s the advent of drug-eluting balloons ... that could in the future possibly be used for in-stent restenosis. There are possible biodegradable stents that may be on the market, and, of course, we are always looking for new atherectomy devices. ... There may even be some pharmacological medication ... or even some gene therapy.”

3) Director of cardiovascular cath laboratory at a Midwest health facility
Spectranetics may experience some gains in the near future, as recent clinical trial data has encouraged some nonusers to adopt the company’s laser. Although using all treatments available to avoid amputation is important, less-invasive alternatives are needed and eventually may compete in this market.

Spectranetics Laser Atherectomy and PTA Economics
- “The company may see some gains in the near future.”

Spectranetics Laser Atherectomy and PTA in General
- “Lasers are already widely adopted.”
- “Lasers may become standard treatment for hard-to-treat lesions now. But in the future there will be other, less-invasive alternatives.”

ISR Treatment and Patient Population

Having an FDA indication and giving physicians the comfort to know that the procedure they are performing has not only been proven efficacious but also has the blessing of the FDA and isn’t off-label will absolutely boost [Spectranetics’] sales.

Cardiologist, Participated in the EXCITE ISR trial

Lasers may become standard treatment for hard-to-treat lesions now. But in the future there will be other, less-invasive alternatives.

Director of Cardiovascular Midwest Health Facility
“Recent data may encourage some centers to adopt lasers. Many centers use them already.”
“We try to avoid amputation with early revascularization. We use what it takes—balloons, lasers—to avoid amputation. It is important to maintain good communication with our referable doctors and to act on a case quickly.”

4) Vascular surgeon at an East Coast medical center
Spectranetics will experience some gains as laser usage increases to some extent, following positive clinical trials results compounded by FDA approval. Long-term results will be important for continued laser usage for PVD. This center treats 50 to 60 patients with PVD a month, and may use the laser on 10% to 15% of all lesions.

Spectranetics Laser Atherectomy and PTA Economics
“The company will see some gains but probably not much.”

Spectranetics Laser Atherectomy and PTA in General
“Lasers are used in many centers now, and it will increase some with the new trial results out. It is hard to say by how much. Some people are cautious because the laser was not FDA-approved, but now with a seal of approval, some nonusers may join in.”
“Lasers may become a standard for hard-to-treat stenoses. But it will be important to see how long the lesions remain patent.”

ISR Treatment and Patient Population
“We do four procedures a day, four days a week, and have clinic one day a week. Most of these patients have vascular problems of the legs. We may see 50 to 60 patients a month with peripheral vascular disease, and maybe 30% have in-stent restenosis.”
“Fewer of the lesions are calcified and require a laser, so less than half. I use the laser on about 10% of patients, maybe 15%.”
 “[Most of the patients have problems] below the knee, without a doubt.”

5) Vascular surgeon at a Northeast medical center
A laser and PTA success rate of above 90%, as well as the FDA approval, will encourage some laser usage. Spectranetics will experience a bump in sales; however, total laser sales will depend on the capital outlay required by healthcare institutions. The source has used lasers in the past but not at this current facility. Eventually, the laser may work synergistically with drug-eluting balloons, but permanent plaque removal would be more beneficial. Treatments in the offering include possible pharmacology products, radiation-induced brachytherapy, and external flow-assist devices.

Spectranetics Laser Atherectomy and PTA Economics
“The FDA approval will help increase usage a little bit, and Spectranetics may see a bump in sales.”
“Do you know what kind of capital outlay is required to use Spectranetics’ laser? What is the upfront investment? Does it require a special outlet? The answer to these questions would probably determine what kind of sales they will have. You need a console, and that may be expensive. I haven’t gone through the process of looking into what else you need besides a laser or how many lasers you need to buy. For example, to get Bard’s Crosser wire atherectomy, to get the machine, you needed to commit to 10 catheters. Coviden [plc’s/COV] SilverHawk Plaque Excision catheter was also very expensive.”
“I’m not sure about the Spectranetics trials. The numbers, either 83% improvement or 93% improvement, are both good and durable as a selling point. If you have improvement north of 90%, you will have people who want to buy.”
Spectranetics Laser Atherectomy and PTA in General
- “There is a lot of off-label use in vascular; it doesn’t scare them too much. But an approved indication never hurts.”
- “The laser may eventually work synergistically with drug-eluting balloons. The problem is, they won’t reduce the amount of disease that is there; they just reduce the plaque. You want to keep it from coming back.”
- “There is more fuss with lasers, but conceptually they are more attractive. Drug-eluting balloons are interesting.”
- “Vascular surgeons are really about bypasses. We have an obligation to do bypasses.”

ISR Treatment and Patient Population
- “I have used lasers in the past, even Spectranetics’ lasers in Europe, but we do not use it in our current facility. Lasers are emerging in Europe, but they use them selectively.”
- “I see lasers as a last-ditch treatment for patients who are not surgical candidates. I used it as a backup; I have not used a lot of lasers. Lasers may save the limb, but they are not used with great effect. However, they may have more potential as a plaque remover.”
- “Some folks really like lasers ... but I don’t believe a ton of people are using them.”
- “The laser is better suited for tibial. Spectranetics Quick-Cross Support Catheter, designed around the wire, is an awesome support catheter. It is the dominant one used, and the cheaper [nonbrand] ones are not as good.”

Miscellaneous
- “I hear of more and more treatments out there every day. People are looking at pharmacological and immunological treatments that would be noninvasive. There was a trial of a drug that might reduce stenosis, and an autoimmune drug did not go well. There is also 1) radiation-induced brachytherapy, which some people are excited about, and 2) Art Assist, an external counter-pulsation that would drive circulatory changes from the outside, from ACI Medical.”
- “The SSA [stent-supported angioplasty], most of what we originally had, are the biliary stents that just got bigger and bigger. They were eventually made into purposefully built stents for specific body anatomy.”

2) Medical Professionals
These four sources with management and clinical PAD therapy experience think the new FDA indication is unlikely to make Spectranetics’ laser, laser catheters and PTA the standard of care for peripheral ISR or to provide a significant revenue boost for the company. The procedure is not considered new and has been an off-label option for as long as 10 years. One source whose hospital does not use the Spectranetics laser as a result of its high cost does not expect to get the device, because balloon therapy already is successful. Another source said the procedure would gain wider adoption if endorsed by medical thought leaders, but price still would be a limiting factor. The peripheral ISR population at three sources’ institutions ranged from six to 60 patients per month; of those, 5% to 30% might be candidates for laser atherectomy and PTA.

KEY SILO FINDINGS
Spectranetics Laser Atherectomy and PTA Economics
- All 4 do not expect the newly approved indication for use of Spectranetics’ laser, laser catheters and PTA in treating peripheral ISR to provide a significant revenue boost.

Spectranetics Laser Atherectomy and PTA in General
- The 4 do not anticipate laser atherectomy and PTA to become the standard of care for treating peripheral ISR.
- Laser atherectomy has been used off-label for 10 years.

ISR Treatment and Patient Population
- Candidates for laser atherectomy ranged from 5% to 30% of the PVD patients served by sources’ institutions.

Miscellaneous
- Medical thought leaders could boost laser atherectomy adoption, but the high cost still will be a challenge.

1) Cardiac cath lab manager at a Northern regional medical center
The FDA is just confirming what everyone already knows, and the source doubts Spectranetics will experience much near-term growth from the new indication. Her facility treats up to 10 patients with femoropopliteal ISR a week; it is very selective regarding its use of the laser and applies it in only 5% of all patients with ISR. The laser is most often used for
other procedures. She cited no need to prep an area with a laser, and said using multiple drug-eluting balloons is common. New techniques include a different balloon configuration that causes less trauma to the affected area.

Spectranetics Laser Atherectomy and PTA Economics
- “I’m not involved with reimbursements, but because the laser is always used in combination with stents or balloons, payment must be arranged with the other equipment used. People are getting paid for these procedures.”
- “If this procedure was something new, yes, people would be excited. But I can’t imagine that the company’s sales will change much.”

Spectranetics Laser Atherectomy and PTA in General
- “I would say the laser therapy is already widely adopted. Our procedures will stay the same despite FDA approval. The FDA is just confirming what we already know. This will not affect our use of the device.”
- “We already use multiple drug-eluting balloons for difficult cases.”
- “There is really no need to prep an area with a laser before using a balloon.”

ISR Treatment and Patient Population
- “We have been using the laser off-label for several years now. We never use it alone but always in combination with PTA, when we feel that the stenosis is difficult and the patient would benefit.”
- “Restenosis is fairly common, and we see one to two patients each week. We are selective with the use of the laser, and only use it in a very small percentage of patients, maybe 5%.”
- “Most of the problems we see are below the knee.”

Miscellaneous
- “I have heard that a different-shaped balloon will be coming out sometime, which is supposed to lessen trauma and restenosis. I don’t know who is making this balloon. Other than that, I don’t think there is anything new.”
- “We use the laser more often for lead extraction in the operating room, when you need to remove catheter leads.”

2) Clinical coordinator of the special procedures room for a West Coast community hospital

Despite the new FDA-approved indication, Spectranetics will not experience greater laser sales. Smaller community hospitals find the laser to be cost-prohibitive, so they rely solely on multiple balloon therapy to treat femoropopliteal ISR. In addition, many larger hospitals already are using the laser therapy and probably will not need another device. The source’s facility has a large diabetic population, with the resulting circulatory complications. The hospital treats up to 45 patients with peripheral vascular disease each month, and a laser could be used on 20% of those patients. However, physicians have not expressed interest in the laser but are intrigued by new drug-eluting balloons.

Spectranetics Laser Atherectomy and PTA Economics
- “I couldn’t tell you about the economics of the laser or how people get reimbursed. I just don’t know.”
- “I can’t imagine that the company will sell more lasers because people have already been using what they need.”

Spectranetics Laser Atherectomy and PTA in General
- “I hear that other hospitals that can afford the laser have been using it for a while, so they have already bought what they needed. The smaller ones, like ours, just can’t afford it.”
- “The standard treatment is balloon therapy, and that will continue. Laser treatment is just a complement to treat a harder stenosis. Most lesions don’t need the laser, especially not to be prepped prior to the balloon. I doubt if the laser will ever be used as a prep.”
- “Drug-eluting balloons seem to work, and we sometimes use several balloons at a time.”

ISR Treatment and Patient Population
- “We are not using the laser because we can’t afford the $300,000 price tag. That is too much money for a small community hospital; it is cost-prohibitive. I don’t know of one doctor who has expressed interest in the laser. There is no way, even with FDA approval, that we can afford a laser.”

Other hospitals that can afford the laser have been using it for a while, so they have already bought what they needed. The smaller ones, like ours, just can’t afford it.

Clinical Coordinator
West Coast Community Hospital
“We treat about three cases per day with leg blockages or about 45 cases per month. My guess, we could use a laser on 20% of those 45 cases or up to 10 a month.”

“We have a big Latino population, and a lot of our patients have diabetes and resulting circulatory complications. Sixty percent have problems below the knee. We see gangrene toes due to diabetes.”

“I don’t know how many people in the United States have this problem, but it must be on the rise as adult-onset diabetes climbs. This is really a treatable problem that doesn’t get treated at the onset.”

**Miscellaneous**

“[One of the medical centers in this area] will be sponsoring a study on peripheral vascular disease and restenosis. Several of us are going to it, and we hope to learn about the new techniques for treatment. I know that there are newer drug-eluting balloons coming out on the market, and this is what we are interested in. There may be other new treatments as well.”

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**3) Assistant coordinator of a large West Coast medical center’s cath lab**

Laser atherectomy with PTA is not a new treatment for femoropopliteal ISR, and Spectranetics will not experience a significant revenue boost with its newly approved procedure. This facility has been using lasers for ISR on an off-label basis for at least 10 years. It treats up to 60 patients with ISR a month. Approximately 25% to 30% of patients would be laser candidates, but the facility uses lasers irregularly because of doctor preference. The source does not foresee any changes to laser usage despite FDA approval. The center’s balloon usage also varies case by case.

**Spectranetics Laser Atherectomy and PTA Economics**

“Given that we aren’t seeing any changes, I don’t think this will have a change on the economics one way or the other. The FDA approval really didn’t matter, and doctors defend the use of balloons or laser on a case-by-case approval. They have been using lasers all along for off-label usage.”

“I doubt if the company will experience much change in the number of lasers used for femoropopliteal ISR.”

**Spectranetics Laser Atherectomy and PTA in General**

“Even before FDA approval, we were already using the new laser. We use it only when necessary and always appropriately. It is hard to say if we are using it more or less since the approval.”

“I don’t know what other hospitals are doing, so I can’t say it the treatment will be widely adopted. But it really isn’t a new treatment.”

“Usage of the laser all depends on the comfort of the doctors. Some are more comfortable with the laser than others. Some prefer just to use the balloons. This really varies. I don’t think laser will become the standard treatment, and I don’t think you will see a wide adoption. There may not be any change.”

“We already do use multiple balloons for some cases. Again, this depends on the doctor’s comfort level and what he or she prefers to do. We usually use one balloon, but sometimes the doctors use two or maybe more.”

“Some doctors prefer to balloon first, while others prefer to use a laser first.”

**ISR Treatment and Patient Population**

“We are using the laser now. We’ve been using it for a while now, for more than 10 years.”

“We treat at least one to two peripheral ISR cases a day, but the use of the laser is very sporadic. In 10 years we’ve only used it sporadically. In general we treat a lot more cardiac cases each day, and we have used the laser for cardiac on occasion.”

“We see a lot of femoropopliteal cases, and probably 25% to 30% of them would be candidates for a laser. That is just my opinion.”

“I’m not sure of specific numbers, but I don’t think our use of the laser has changed since the [Spectranetics laser received] FDA approval. That hasn’t really affected what we do. We were using the laser as off-label before approval. I don’t expect to see any changes in usage.”

“The majority of our ISR cases occur below the knee.”
4) Cardiac cath lab nurse from the Southwest

This source recently became familiar with the Spectranetics EXCITE IST trial data. The therapy looks promising, but adoption will depend on the price difference between it and established procedures. The institution treats fewer than 10 ISR patients each month, and most of those are treated with a balloon. An additional 15% to 20% of patients require mechanical atherectomy. The physicians are adept at these procedures, resulting in a very high success rate at costs in line with current reimbursement (roughly $600 per balloon and $3,250 per mechanical device). An institutional change in procedure is unlikely unless the cost is comparable and the procedure shows clear benefits. More institutions will adopt Spectranetics’ system if it appears to be becoming the standard for care.

Spectranetics Laser Atherectomy and PTA Economics

- “Price is a limiting factor. Balloon cost is about $600 and mechanical atherectomy costs about $3,250 per device. These costs are in line with current reimbursement, and we enjoy high patient success rates. Willingness to adopt will depend on the cost of the new procedure and the added benefits it offers.”

Spectranetics Laser Atherectomy and PTA in General

- “If the Spectranetics procedure become the standard of care with the most well-respected leaders, other institutions are likely to adopt it.”

ISR Treatment and Patient Population

- “Most of our patients are treated with balloons. Mechanical atherectomy is employed for another 15% to 20%. Our physicians are very proficient with these techniques, so we enjoy a high success level.”

3) Medical Sales Executives and Professionals

Five of six sources think Spectranetics will experience some market share and revenue gains as a result of its successful EXCITE ISR trial results and the FDA indication for use of its laser, laser catheters and PTA for the treatment of peripheral ISR. Sales forecasts ranged from a short-term boost, to gobbling up the atherectomy market, to 10% to 20% growth. A dissenting source said the FDA indication will not help Spectranetics place more lasers as its procedure is just another therapy option. Only one source thinks laser atherectomy will become the new standard of care. Promising treatments include drug-coated technology for stents and balloons and bioabsorbable stents. One source said drug-coated stents will reduce ISR and curtail the need for laser atherectomy. Spectranetics could face such headwinds as extensive off-label use of laser atherectomy, the limited new and novel information provided by the EXCITE trial, the high cost of the laser, and poor results in reducing calcified blockage.

KEY SILO FINDINGS

Spectranetics Laser Atherectomy and PTA Economics

- 5 of 6 think the EXCITE ISR trial results and FDA approval will provide some sales increases for Spectranetics.
- 1 thinks laser atherectomy is just another treatment tool and will not result in the more laser sales for Spectranetics.

Spectranetics Laser Atherectomy and PTA in General

- 1 thinks laser atherectomy will become the standard of care for peripheral ISR.
- 5 consider laser atherectomy to be another treatment option for peripheral ISR.

ISR Treatment and Patient Population

- Patients with PVD are an underserved population.

Miscellaneous

- New technologies of interest included drug-coated technology for stents and balloons and bioabsorbable stents.
- Headwinds facing Spectranetics include the extensive off-label use of laser atherectomy, the limited new and novel information provided by the EXCITE Trial, the high cost of the laser, and poor results in reducing calcified blockage.
1) Vascular device sales vice president for a global provider of devices for treating peripheral vascular disease

Considering how difficult in-stent restenosis is to treat, the improvements shown with the laser plus PTA method represent a significant leap forward and should be widely adopted.

**Spectranetics Laser Atherectomy and PTA Economics**

- “Because of the fact that the peripheral ISR was given that FDA approval, I really think that Spectranetics is going to gobble up a lot of the atherectomy market.”
- “Spectranetics hired a lot of folks this year when they acquired AngioScore, and they’re poised to attack the market. I think that we’re going to see the adoption happen, but I couldn’t say at what pace.”

**Spectranetics Laser Atherectomy and PTA in General**

- “I think we will see an atherectomy industry shift toward the laser method.”
- “Spectranetics’ laser for peripheral ISR is a game changer, I really do. But obviously we have to wait to see what the real results in the field will be.”
- “When it comes to manual atherectomy—[Covidien’s] Fox Hollow, CSI ... essentially those devices have been around in one form or another for a long time. And I think that every once in a while, because we’re in an area where nothing really works, you’re always digging in the past and bringing stuff forward to see if it will work. But I do think the Spectranetics laser is actually an improvement upon past treatments.”
- “Physicians who already have the laser are going to go ahead and jump in to using it right away.”
- “You’ll always get earlier adopters, but the procedure has to work and be a dramatic improvement.”

**ISR Treatment and Patient Population**

- “The laser does add time to the procedure. There’s a small percentage of physcials who will always be attracted to the fastest method; sometimes it’s for the patient’s sake to keep them under anesthesia for as short of a time as possible, and sometimes it just economics.”

2) Sales manager at a company in the vascular intervention space

Spectranetics’ ability to market its laser on-label and to tout the EXCITE ISR results will increase its sales. Many companies are trying to discover the “Holy Grail” intervention that preempts the need for retreatment. Drug-coated balloons or biodegradable stents are possible alternatives to current treatments, but they have yet to be proven.

**Spectranetics Laser Atherectomy and PTA Economics**

- “Physicians ... are starting to separate from the hospitals for a significant portion of their outpatient procedures, and they are going toward physician-based catheterization labs. That allows them to basically get the entire fee.”
- “I think any company will look at having their product on-label as an opportunity to boost their revenue and market share. ... Hence, the thought process is that yes, it will drive more revenue.”
- “Companies out there [that have doctors] using their product off-label and haven’t invested in these types of clinical trials do run a risk of being liable for anything they may or may not say. So it’s always a fine line that they have to walk.”
- “Generally speaking [however], 99% of the physicians—the cardiologists, the vascular surgeons, the interventional radiologists—are going to do the right thing. They are not going to try something so risky that it’s not proven. ... There are lots of off-label medical articles and things of that nature that lead physicians to want to try some things. It’s just that the companies can’t really go out and promote it.”
- “There are strengths and weaknesses I think to every technology, and
nobody has it figured out yet. That leads to what will be the future of drug-coated balloons or the future of possibly biodegradable stents where nothing is left behind. Nobody has the Holy Grail yet.”

**Spectranetics Laser Atherectomy and PTA in General**

- “Sometimes when you have in-stent restenosis, historically you don’t have to use the laser to regain blood flow through that stent. Sometimes an angioplasty balloon works pretty well. However ... I do think any time you can go out with a strong message and collectively execute on your strategic plan, there can be some early adoption. Whether or not that stays consistent, a lot of that will depend on reimbursement rates and long-term outcomes.”
- “[Laser atherectomy] takes a little bit longer but not that much longer, and an angioplasty balloon doesn’t do the same thing.”
- “Everyone is getting excited about drug-coated balloons. I think the European experience right now [with those] is saying that it’s OK, but it’s still yet to be determined if it’s really a viable alternative to what’s currently out there. The fact of the matter is nothing really is ideal and perfect yet. Everyone is searching for the [treatment with] the best long-term outcomes so patients don’t have to keep coming back and be retreated.”
- “Apparently ... a company or two [will make drug-eluting balloons] available in the U.S. in the early part of 2015. I do think that the doctors will want to ... test and try them to see what the healthcare outcomes are.”
- “Will laser atherectomy or atherectomy in general be used as a preparatory device before a paclitaxel drug-coated balloon is used? Right now I have reason to believe that’s the thought process because I think you will have to debulk lesions and prep the vessel before you do an angioplasty [with a balloon] that has a drug on it.”

**ISR Treatment and Patient Population**

- “For years physicians have being using laser [atherectomy] at their discretion off-label ... because it’s a meaningful solution to kind of restore blood flow to the leg of a patient with a stent who came back in a certain period of time [with ISR].”
- “I don’t think that what they found out [in the EXCITE ISR trial] is what I would call novel and substantially different than what physicians have recognized who have been using it off-label. I think it’s about a strategically developmental company trying to work within the parameters of what the FDA allows them to talk about and to grow. Now they can go out and talk about their positive results for this therapeutic use of their device.”
- “Any company that can get an on-label indication, that’s a big deal because it allows them to actually market the product and talk about it at the physicians’ medical tradeshows. ... There are enough of those in the course of a year that you can really make some headway, and the physicians can start changing the way they treat some of these patients when they come back.”
- “The PVD market is a very underserved market. ... You can say there’s an ... opportunity [to treat many more patients] if physicians screen, and there is PVD awareness on the street so people understand that when they become symptomatic, it might not necessarily be arthritis. It may actually be that they may have pain in the legs because the blood isn’t flowing.”
- “Peripheral vascular disease is a kind of silent killer, unlike coronary disease where you have chest pain and get scared to death ... and go to the hospital.”

3) **Sales executive at a cardiovascular device company; repeat source**

As a result of Spectranetics’ FDA clearance, physicians “on the fence” about laser atherectomy may adopt it, but the naysayers will remain unconvinced. Spectranetics will have a 10% to 20% increase in laser revenue.

**Spectranetics Laser Atherectomy and PTA Economics**

- “If ‘significant’ [revenue boost] is defined as a 10% to 20% increase over their current laser business, then yes, I think [the increase] will be significant.”
- “I also believe that laser use may, or will, increase in physician-owned peripheral [vascular] labs.”

**Spectranetics Laser Atherectomy and PTA in General**
“If they show that [the patients] don’t [have recurrent restenosis] in a year to two years, yes, I think the usage would increase.”

“[With] a drug-eluting stent, the drug stays on the stent long enough so you have vascular remodeling. The drug on the stent inhibits tissue regrowth in the stent while the artery is healing itself after the procedure. In a peripheral procedure with a drug-eluting balloon, I am not convinced that the drug that’s on the balloon for however long you inflate it for... is permeating into the tissues. I’m not sure that’s exactly going to make a big difference long term.”

**ISR Treatment and Patient Population**

- “ISR” treatment technology compared to the restenosis. What happened in the devices that reduce the restenosis. It’s going to prove itself in the lower extremities with stenting, whether it is bioabsorbable or the drug-eluting.”

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**4) Sales manager for a vascular device company**

Because physicians already have been using Spectranetics’ device for ISR off-label, the new approval is not going to sell more lasers for the company. New technology in stents is the future.

**Spectranetics Laser Atherectomy and PTA Economics**

- “I’m still working with cardiologists and vascular surgeons, and a lot of them are gravitating toward other devices. I don’t think the ISR is going to be a game changer for Spectranetics.”

**Spectranetics Laser Atherectomy and PTA in General**

- “Spectranetics’ laser for ISR is going to be just another option on the menu. I don’t think it’s going to be a blockbuster.”

- “The FDA approval is going to give Spectranetics the opportunity to market their products more effectively in the devices that reduce the restenosis. It’s not like now that Spectranetics has the approval it will suddenly flood gates and everyone will start using this.”

- “Spectranetics’ ability to place more lasers into facilities just based on the ISR indication is a stretch.”

- “One of the problems Spectranetics has with the laser is that inherently it’s such a big piece of equipment and it is technology that’s been around forever, compared to a lot more nimble devices that are out there on the marketplace.”

**ISR Treatment and Patient Population**

- “The future of ISR treatment is in the devices that reduce the restenosis. What happened with the drug-eluting stents in the coronary marketplace compared to bare barrel stents made a big impact. I think the same type of technology is going to prove itself in the lower extremities with stenting, whether it is bioabsorbable or the drug-eluting.”

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The future of ISR treatment is in the devices that reduce the restenosis. What happened with the drug-eluting stents in the coronary marketplace compared to bare barrel stents made a big impact. I think the same type of technology is going to prove itself in the lower extremities with stenting, whether it is bioabsorbable or the drug-eluting.

*Sales Manager*

*Vascular Device Company*
5) Vascular device marketing manager for a major international manufacturer

Because new stent design will reduce the overall market for ISR, the laser procedure will experience less demand over time. However, for existing in-stent restenosis, the Spectranetics laser is the most effective treatment.

**Spectranetics Laser Atherectomy and PTA Economics**

- “Before the study for EXCITE was even started, the laser was already the choice for restenosis for many of our users of Spectranetics. There was already a big chunk of ISR cases that were going to Spectranetics because it really is the only solution to remove the material effectively.”
- “I come from a standpoint that Spectranetics’ laser already had roughly 40% of the ISR market. With the EXCITE trial data coming out, it certainly won’t hurt them because now they can talk about ISR more freely and promote. I think it will help in the near term, and it’s obviously driving a lot of their current growth. But in my opinion it’s somewhat short-lived for several reasons. First, new stent designs like the Supera stent, with Abbott Lab’s [Abbott Laboratories/ABT] sales force power behind it, will have a very large impact on the market because it will lower overall stenosis rates. Likewise, with the bioabsorbable stents that Abbott has in Europe, now coming to the U.S., will make a big impact. Next is the growing trend of patients not wanting to put in a stent in all. That also pushes off the potential for ISR.”
- “The new stent technology will soon make an impact in the market. The SurePath stent, which was approved earlier this year just before IDEV was acquired by Abbot, won, without indication, 6% market share. Now with Abbott’s sales force behind it, they have the horsepower to drive large-scale and rapid adoption of this new stent design, thus reducing the market for ISR.”
- “The new SurePath shows a 20% improvement over current stents in keeping arteries open after one year. There’s another new stent called the FlexStent from Johnson & Johnson [JNJ]. I think that will have some impact just because it’s J&J, but it won’t be that huge because it’s a hybrid design.”
- “Another new stent that should be a player is [W.L. Gore & Associates Inc.’s] Gore Tigris. And then, of course, the bioabsorbable stents, which are showing very good results below the knee as well as coronary, but it will take several years to get to the United States.”

**Spectranetics Laser Atherectomy and PTA in General**

- “Another limit to the laser’s adoption is the device itself. Spectranetics’ Turbo Booster, when it first came out was not accepted very well by existing customers, let alone people who didn’t already use lasers. It is cumbersome, bulky. It took more time than necessary. ... [Physicians] preferred to use the laser catheter without the Turbo Booster, but that limited its effectiveness. The Turbo Booster can get up to 4 or 4.5 mm diameters with multiple passes; the laser itself does up to 2 mm to 2.5 mm. That limits you in terms of your overall market penetration because the most common size of a stent is 5 or 6 mm. Doctors using just the laser catheter along might get at best a 3 mm channel in a restenosis. Is that good enough to restore blood flow? Maybe, maybe not.”
- “The Spectranetics laser does make the most sense because there’s no moving parts. It does a great job of vaporizing the material. But it can’t make large holes.”

**ISR Treatment and Patient Population**

- “Balooning and the stent don’t really make sense with ISR, but people still do it quite a bit because it’s easy and they don’t believe in a laser. Stenting inside of a stent ... people do that too, but they know it’s simply staving off the inevitable of a bypass.”
6) Medical device marker devoted to treating peripheral and coronary vascular disease

Laser technology is ineffective against ISR involving calcium, which is a large percentage of the patient population. Interventionists are looking for technology that offers longer-term solutions than laser.

**Spectranetics Laser Atherectomy and PTA Economics**
- “Everybody that’s been using it in ISR will probably continue. Will they pick up some more market share from that? Possibly. You may have some naysayers who don’t want to pick up a device until it gets some sort of approval or a seal of approval, but that’s a small number.”

**Spectranetics Laser Atherectomy and PTA in General**
- “I don’t think that the Spectranetics laser is going to cause a lot of excitement. For the last three or four years they’ve had a lot of centers involved in the trial, and I think it had an impact on other physicians who decided to try it as well.”
- “It’s getting to be a crowded space in ISR. There are other items out there that could be used for ISR, most of them off-label.”
- “Quite recently Gore received ISR approval with their Viabahn Endoprosthesis.”
- “There’s also drug-eluting technology that’s coming out pretty quickly that could reduce the occurrence of ISR. Bard is probably going to be the first one to market with this in a few months. Their drug-eluting balloon, they say, will be the answer to restenosis.”
- “I don’t know that the drug-eluting technologies will be effective in ISR. They will probably be more effective in your native vessels that are occlusive [blocked]. There are studies out there now on the drug-eluting technologies, but they all exclude calcium. You’re going to need to debulk the calcium first so the drug can reach the arterial wall.”

**ISR Treatment and Patient Population**
- “Spectranetics has been able to treat moderate stenosis. But when it comes to calcified lesions—which you’re going to find in all of your diabetic and dialysis patients and probably 70% of the peripheral patients out there—the laser is very ineffective because the device’s method of action requires some sort of fluid base to react. When you have calcium present it is dry.”
- “Restenosis in the stent comes back very hard, and it’s difficult to deal with. You’re never going to get rid of a lot of it. Your atherectomy devices and balloons will chip at some of it, but at best you’ll get rid of 50% of it. And it just comes back very, very quickly.”

4) Industry Specialists

Four of five sources commented on Spectranetics, and three of these four think the company will experience a revenue boost from the EXCITE ISR trial results and the FDA Indication for use of its laser, laser catheters and PTA for the treatment of peripheral ISR. One was especially positive about Spectranetics’ future given its acquisition of AngloScore, the significant peripheral ISR patient population, the ability to perform laser atherectomy on an inpatient or outpatient basis, quality management, and the company’s monopolistic position. The dissenting source said Spectranetics has refined its lasers over the years but that these remain cumbersome, difficult to use and expensive. One source thinks laser atherectomy is now the standard of care, while another said post-label studies and long-term outcomes are needed to make that determination. A medical coding expert does not expect physicians’ fees to be increased by Medicare for laser atherectomy.

**KEY SILO FINDINGS**

Spectranetics Laser Atherectomy and PTA Economics
- 3 of 4 who commented think Spectranetics will experience a revenue boost thanks to the EXCITE ISR trial results and the new FDA indication for treating peripheral ISR with laser atherectomy and PTA.
Spectranetics Corp.

- 1 said sales of Spectranetics will be limited because its laser is cumbersome, hard to use and expensive.

**Spectranetics Laser Atherectomy and PTA in General**
- Spectranetics’ advantages include its acquisition of AngioScore, the significant peripheral ISR patient population, the ability to perform laser atherectomy on an inpatient or outpatient basis, quality management, and its monopolistic position as the only FDA-approved laser catheter.

**ISR Treatment and Patient Population**
- 1 said the United States’ significant peripheral ISR patient population is a positive for Spectranetics.

**Miscellaneous**
- Medicare is unlikely to increase the allowable reimbursement for laser atherectomy.
- PQ Bypass Inc. and InterVene Inc. were cited as innovative companies working in the PVD space.

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1) Mike Vintges, president of **MJV & Associates**, a consulting firm in Flower Mound, TX; repeat source

TCT conference attendees appeared to be quite enthused about the EXCITE trial data presentation at the September meeting. Thanks to its AngioScore acquisition, Spectranetics has a “cutting balloon” to complement its laser product. Demand for Spectranetics’ laser will continue to grow in light of the EXCITE ISR trial, the FDA-approved indication, “fairly good” reimbursement for PVD, among other factors. Spectranetics will unquestionably realize a significant revenue hike. The new FDA indication will encourage more physicians to offer laser atherectomy in-house. Prepping the lesion with a laser before using drug-eluting balloons will not become the standard of care.

**Spectranetics Laser Atherectomy and PTA Economics**
- “You have a learning curve with all new technology. ... As [physicians] get more experience with [laser atherectomy, it may take less time].”
- “If it takes [longer] but the patient doesn’t come back [for retreatment], that’s good for the patient and the payer.”
- “It’s always challenging to look at a technology and say there is or isn’t reimbursement or [to ask if] reimbursement [will] change The answer to the third is that reimbursement always changes every year, not only in terms of how and what payers pay but also in terms of how hospitals figure out what to code so they can even get paid to begin with.”
- “Hospitals that are smart will look at [laser atherectomy] as a continuum versus as a silo [based on] reimbursement. As an example, when I was a hospital administrator, when we put robotics in, we didn’t get reimbursed extra for doing [surgical] cases with a robot and cases took longer but ... it had a positive marketing halo effect.”
- “Vascular surgeons are offering a continuum of care in an outpatient setting [including diagnostic, interventional procedures, and cosmetic work]. By the nature of the lower acuity [of vascular procedures compared with cardiovascular], these things have become more outpatient-based. As a result, the physician will create his/her own physician-owned entity. ... A lot of cardiologists have expanded [their] practices where they begin to do peripheral and renal work.”

**Spectranetics Laser Atherectomy and PTA in General**
- “Demand will continue to increase for several reasons: You have FDA approval, you have a clinical study, you have high demand and different operators who can do the procedure: radiologists, cardiologists and vascular surgeons. You also have fairly good reimbursement for PVD, both for diagnostic and interventional procedures. ... And you can [do the procedure] in the inpatient or outpatient setting.”
- “The challenge facing Spectranetics is that they got the good news [about the FDA approval] before they were prepared. ... I don’t have a sense for what their inventory levels are or how fast they can deliver to the market. I do know they have been fairly collaborative, however, with customers in terms of being innovative in helping people get access to the laser if they can’t afford to purchase the capital equipment component [laser console].”
- “What they are still for is using the excimer laser for lead extractions. And that same capital hardware is what you can now use for this vascular procedure as well. Hospitals don’t have to buy another new widget.”

I think [the indication] will be kind of the marquee that drives them for a period of time. ... Obviously company financial growth ... is not just revenue associated with one particular product, but this is a good one because I think they have a monopolistic position in [the vascular] space.

President
Consulting Firm, Flower Mound, TX
“Physician adoption is completely different than what it was even as recent as two years ago; that’s because physicians are now more employed than ever. I think 75% to 80% of cardiologists are employed. Now you have more people in the process [of deciding whether to get the technology], which is going to slow down the decision and which can ultimately slow down the adoption. … Also, if [employed] physicians have a choice of getting the latest stent, the latest laser, a new cath lab, extra nurses, more education time, they might weigh all of those things and not put as much weight on the new laser.”

“[The revenue boost from the new indication] will be significant. … I think [the indication] will be kind of the marquee that drives them for a period of time. … Obviously company financial growth … is not just revenue associated with one particular product, but this is a good one because I think they have a monopolistic position in [the vascular] space.”

“Spectranetics will make more selling laser catheters than they will selling laser consoles.”

“In ISR [laser atherectomy and PTA will become the standard of care], but who knows what the future holds relative to advances? There may be new pharmaceuticals that do the same physical process of plaque removal or other things to where you don’t have to do it mechanically [including by laser]. … But I don’t think those are on the short-term horizon.”

“A drug-eluting balloon is kind of an interesting concept, but I personally think you are better off if you want to put the drug in the lesion to just infuse the drug systemically during the procedure. I don’t know what the benefit of eluting from a balloon is when it’s only in contact with the artery for seconds or maybe a minute in a long inflation.”

“If you are using [drug-eluting] balloons … [you would have to use multiple balloons for long and hard to treat lesions] which I think would add enormous cost, time and risk.”

**ISR Treatment and Patient Population**

“I was at TCT when the EXCITE trial data was presented on Tuesday, which was near the end of the meeting. It seemed that there was a significant amount of excitement amongst the attendees about this data presentation.

“The trial was laser with balloon vs. PTA alone. The reason the FDA gave Spectranetics clearance is they allowed them to end the trial early, due to the fact that they hit their desired clinical endpoint much earlier than anticipated. That’s why Spectranetics was kind of frantically scrambling to present their trial results.”

“As you have successful clinical trials, then you have a lot of interest relative to customers currently adopting your technology and then customers who want to. Things look fairly positive, I would say, for Spectranetics in the short term and also in the long term relative to some of the things that they have done in addition to getting the EXCITE data out to the market.”

“A couple of years ago [Spectranetics implemented] a whole new leadership team that created a different culture … which resulted in their ability to essentially recruit and retain a lot of good people.”

“Earlier this year they acquired AngioScore. … Through that acquisition, they then have the ability to pick up that additional sales force and put more feet on the street. It just gives them another tool in their belt that they can use to be more effective in the [peripheral vascular] space.”

“The patient population [with femoropopliteal ISR] is huge. [I think] it’s somewhere in the range of 120,000-plus cases that are done in the U.S. on an annual basis.”

“If you look at the potential population of PVD patients and correlate that to cardiovascular population, it’s a huge underserved market. … The family practice internal medicine physicians who could identify PVD don’t do it because there aren’t financial incentives. It’s a fairly simple test. You can do an ABI.”

“For patients who have been treated [with a stent] and then need to be retreated … probably 95%-plus are going to be candidates for [the FDA-approved Spectranetics] laser. … For patients that have a de novo lesion, that is, one without treatment yet, I think further clinical studies will have to prove what is the best treatment.”

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President Consulting Firm, Flower Mound, TX

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2) Managing editor of a trade digest

Spectranetics will need to market the laser to increase sales. The company cannot rely solely on FDA approval to sway nonusers, who have been hesitant because of the lack of efficacy and long-term data regarding the benefits of laser atherectomy and PTA for femoropopliteal ISR.

**Spectranetics Laser Atherectomy and PTA Economics**
- “FDA approval may or may not increase sales [for the company]. But if [Spectranetics] markets the catheter, it will increase sales.”

**Spectranetics Laser Atherectomy and PTA in General**
- “The EXCITE ISR trial data [to date] released at the 2014 TCT conference in September will be influential. This was a good trial, well received, and news releases are out.”

**ISR Treatment and Patient Population**
- “Hesitation by nonusers was due to lack of data.”

3) President of a medical consulting company

The FDA’s approval of the Spectranetics laser will not drive sales, but long-term data will. Spectranetics has refined its laser significantly over the years, but the product is still “cumbersome and expensive,” making it difficult to use for a chronic disorder such as peripheral vascular disease. A number of competitive products focused on the venous system will be emerge in the near future.

**Spectranetics Laser Atherectomy and PTA Economics**
- “The FDA approval won’t bring in a whole lot of sales [for the company]. The Spectranetics laser is cumbersome and expensive. Patients with [peripheral vascular] problems have a chronic disease; it is not going away. They need repeat procedures, and the Spectranetics laser doesn’t have great value. [Users] will need to look elsewhere for an easier-to-use, less expensive catheter.”

**Spectranetics Laser Atherectomy and PTA in General**
- “Long-term data drives usage. A lot of institutions will not use a medical device unless a lot of papers have been written on it. This is a tough one. Institutions have a hard time justifying the expense unless the [device’s efficacy] is proven.”
- “Over the course of time, Spectranetics has shifted applications to different procedures. They have refined their laser significantly. It has been through lots of hills and valleys in how useful the laser has been in the cath lab.”

**ISR Treatment and Patient Population**
- “This patient population is chronic. Their problems continue. This is not just a ‘one-and-done’ procedure.”

**Miscellaneous**
- “There are a number of new, competitive medical device application PMAs [premarket approvals] coming up. A lot are focused on the venous system right now. ... Most are based in the Bay Area. I’d check into the Fogarty Institute for Innovation, Dr. [James] Joye, and PQ Bypass. The VIVA Conference in October is where you can hear about the first human experiences.”
- “Spectranetics has been around a long time. I worked with them 15 years ago, when they were working with Italian hospitals.”

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**Managing Editor, Trade Digest**

**President, Medical Consulting Company**
4) Physician researcher involved in the EXCITE ISR trial; and a hospital business vice president

This hospital has not yet decided to use laser atherectomy with PTA. Whether it becomes the standard of care hinges on post-label studies and future outcomes. Usually technology becomes the standard of care when it is proven and the cost declines. The FDA approval will certainly increase Spectranetics’ revenue.

Physician Researcher
- “We treat one to three patients [with peripheral ISR] per physician per month. There are five to six doctors who are active [in treating patients with peripheral ISR].”
- “We don’t know if we will [do the laser atherectomy with PTA for ISR]. Now that the trial is over, we aren’t using it. It’s not the standard of care for the patients.”
- “The evidence [for using the laser with PTA] is good based on the EXCITE trial, and many physicians may take a look at the evidence. [It is the biggest randomized, multicenter trial [looking at treating ISR that] I’ve seen.”
- “You may need to do more than one laser pass if the lesion is very hard. [Whether it takes the physician more time] will be on a case-by-case basis.”
- “Unfortunately, for ISR there aren’t many options because the stent is already in. You can put another stent over the stent. But sometimes the stent can’t expand, and you can actually perforate or damage the vessel, which is something you don’t want to happen.”
- “We don’t know [whether the new treatment will become the standard of care]. This is just an indication for using the device. It all depends on the post-marketing or post-label studies. We also need to know more about what is the outcome [a few years] down the road.”

Hospital Business Vice President
- “You have hospital systems that do not cover a loss leader, which could be a hurdle for [Spectranetics’ laser atherectomy and PTA] to overcome. If this turns out to be a loss leader ... where the reimbursement isn’t to the point that it can cover costs, that’s a hurdle that has to be overcome for this to be widely adopted.”
- “It’s typically an issue with any new technology. ... If the science is proven and the results are proven and the cost continues to come down, then it becomes the standard of care.”
- “The [FDA] approval will increase revenues for Spectranetics, for sure.”
- “I can’t really speak to how many times or how often Medicare raises payment for new technologies because it’s a rare occurrence, but it does happen.”
- “I can’t really speak to [Spectranetics’] technology, but I think in a perfect world we would hope the best resulting technology would be fairly compensated.”
- “Physicians’ time can be affected [by having to do a longer procedure], especially when they have five or 10 more cases that morning or day. I’m not a physician, but I’m sure the thought crosses their mind that they are not going to use a technology that in some cases takes [much more time] than the older technology.”

5) Vascular coding and reimbursement specialist who consults with physicians

This consultant said her clients are receiving Medicare and private payer reimbursement for femoropopliteal laser atherectomy/PTA. Laser atherectomy and PTA performed together are reported as a single CPT code. She predicts that Medicare will not increase physician fees for the procedure.

Laser Atherectomy and PTA Reimbursement
- “The CPT code for [femoropopliteal] atherectomy with angioplasty is 37225. It assumes that angioplasty is inclusive. There’s no code for atherectomy alone. If you do atherectomy with PTA, it’s exactly the same code and exactly the...
same payment if you’re in the same vessel/vascular territory. Per CPT rules, the fem-pop area is a single territory, so even if an atherectomy is done in the femoral and a separate one done in the popliteal vessel, a single 37225 is reported.

- “Before 2011, if you did an angioplasty PTA and atherectomy, you would bill for both. Nationwide, there were certainly people doing both so they could get paid for both, and they did get paid for both.”
- “It is now very clear in the CPT book that atherectomy codes include laser, directional and rotational devices.”
- “Medicare and private payers are paying for laser atherectomy [in the femoropopliteal area]; it’s an acceptable CPT code with or without angioplasty. Our clients are being paid for it by Medicare and private payers. I don’t know what every private payer says. I can’t ever make that blanket statement because every private payer is different.”
- “Medicare sets the payment for atherectomy, [which] was newly reviewed [for the femoropopliteal area] in 2011. After much debate and discussion with specialty groups [at that time], Medicare arrived at the payment for atherectomy and PTA in the femoropopliteal area. They review codes every five years, and the chance of any code being increased in value is slim to none—and slim just left. Even if they show that it’s a wonderful procedure or if more doctors perform it, won’t increase the [Medicare] payment.”
- “There are various physician impressions about atherectomy vs. stent vs. PTA. It’s quite a debatable and controversial area among physicians who do these procedures.”

6) Additional comments from industry specialists

Prominent Angiologist and Participant in Spectranetics’ Laser Research
- “The EXCITE data will not affect the lack of adoption of laser angioplasty in Germany. The outcome is not superior to the already published PATENT data [Schmidt et al., JETV], and more importantly [Spectranetics’ laser] is significantly inferior as compared to DEB [drug-eluting balloons], DES [drug-eluting stents] and [Gore’s] Viabahn Endoprosthesis.”

Prominent Vascular Device Engineer Who Said Cost of Laser Is Prohibitive to Its Expansion
- “Given that [Spectranetics has] a very expensive piece of capital equipment attached to their catheter, whereas companies like CSI, Covidien and Volcano [Corp./VOLC] do not, I think they will have to come up with a very creative business model to compete.”

Chief Operating Officer for a Medical Innovation Institute
- “There are several companies working on problems with leg vascularity. We have an in-house company ... for veins that are not functioning in the legs. If the valve doesn’t work, this percutaneous approach is used in situ to create a new valve. It’s a new approach to avoid chronic care.”
- “Dr. Jim Joye is the cofounder of PQ Bypass. ... They are working on peripheral vascular disease and long-segment blockages [in clinical trials in 2014 for European introduction in 2015].”

Secondary Sources

These four secondary sources discussed Spectranetics’ EXCITE trial showing better treatment of femoropopliteal ISR than via angioplasty alone in terms of efficiency and safeness. Also highlighted were the FDA’s indication approval, Spectranetics furthering its laser research with the U.S. Air Force Academy, and how the AngioScore acquisition will improve Spectranetics’ distribution and diversify its products.
Spectranetics Corp.

Sept. 26 Healio Cardiology Today article
The EXCITE ISR trial showed that the use of Spectranetics’ excimer laser atherectomy with adjuvant percutaneous transluminal angioplasty better treated femoropopliteal ISR than angioplasty alone.

- “At TCT 2014, Eric J. Dippel, MD, from the Genesis Heart Center in Davenport, Iowa, presented initial results from EXCITE ISR, the first large, prospective study to evaluate the use of excimer laser atherectomy (Spectranetics) in femoropopliteal in-stent restenosis. ‘This remains a considerable challenge in our daily practice,’ he said during a press conference.”
- “The multicenter, prospective, randomized controlled trial enrolled 250 patients at 40 US sites from June 2011 to February 2014. The study initially sought to enroll 335 patients, but was terminated early after researchers were able to achieve statistical significance with 250 patients. Eligible patients had in-stent restenosis target lesions ≥40 mm, vessel diameter of 5 mm to 7 mm and peripheral arterial disease classified as Rutherford grade 1 to 4. The average lesion length was 19 cm and more than 30% of patients presented with total occlusion.”
- “All patients were randomly assigned in a 2:1 ratio to excimer laser atherectomy plus percutaneous transluminal angioplasty (ELA + PTA; n=169) or PTA alone (n=81). The two groups had comparable demographics and lesion characteristics at baseline.”
- “The primary safety endpoint was major adverse events at 30 days, defined as death, unplanned major amputation and target lesion revascularization. The primary efficacy endpoint was freedom from clinically driven TLR at 6 months.”
- “According to results presented, patients assigned ELA + PTA had a lower rate of major adverse events at 30 days compared with patients assigned PTA alone (5.8% vs. 20.5%; P<.001). In addition, freedom from TLR at 6 months was 73.5% in the ELA + PTA group compared with 51.8% in the PTA alone group (P<.005). Excimer laser atherectomy with adjunctive PTA was associated with a 52% reduction in TLR (HR=0.48; 95% CI, 0.31-0.74).”
- “The procedural success rate was 93.5% in the ELA + PTA group compared with 82.7% in the PTA alone group (P=.01).”
- “The dissection rate was 7.7% with ELA + PTA vs. 17.2% with PTA alone (P=.03) and the rate of bailout stenting was 4.1% vs. 11.1% (P=.02). There was no procedurally related stent damage observed in either cohort.”
- “This is an area that does not have any previously well-defined treatment strategies,’ Dippel said. ‘I believe now we are beginning to have level 1 evidence that would support the use of laser atherectomy as standard of care for treating femoropopliteal in-stent restenosis.”
- “In July, Spectranetics received an FDA 510(k) indication for its Turbo-Tandem and Turbo-Elite peripheral atherectomy products to treat in-stent restenosis, according to a company press release.”

Sept. 16 BioOptics World article
Spectranetics’ excimer laser received FDA approval for treating patients with peripheral artery disease. It is now the new standard of care in ISR treatment after being proven to be safer and more efficient than other treatment options. Spectranetics is well positioned to capitalize on the 115,000 ISR procedures performed annually in the United States, and could realize $350 million domestically and $750 million worldwide.

- “Biophotonics-based systems earning recent regulatory approval include a welcome advance in colorectal cancer screening that gives patients a pass on the usual dietary restrictions and bowel prep. Also included is a laser-based adjunct to balloon angioplasty for peripheral artery disease, and a system for tattoo removal and treatment of pigmented lesions on all skin types.”
- “Excimer laser maker Spectranetics (Colorado Springs, CO) has received FDA approval for its laser atherectomy products to treat in-stent restenosis (ISR; that is, return of blockage following stent placement) for patients with peripheral artery disease (PAD).”
- “The development prompts a new standard of care in ISR treatment with improved clinical outcomes, and it follows clinical findings of the EXCimer Laser Randomized Controlled Study for Treatment of Femoropopliteal (the arteries above and behind the knee) In-Stent Restenosis (EXCITE ISR).”
- “The study, reportedly the first multi-center, randomized prospective trial ever conducted for ISR treatment, demonstrated highly superior and efficacy of laser atherectomy with adjunctive percutaneous transluminal angioplasty (PTA, or ‘balloon angioplasty’) compared with PTA alone. The trial shows a 94-percent procedural success rate using laser atherectomy with PTA vs. 83 percent with PTA alone.”
- “Additionally, a high number of complex or advanced disease-state patients were enrolled in the trial, a fact that indicates success in treating all types of ISR lesions, including the most complex.”
“While stents deliver improved overall outcomes compared to PTA treatment, restenosis is common and stent re-obstruction or ISR remains therapeutically challenging. Once ISR develops, there is a 65-percent chance of recurrence after PTA, which is considered the standard of care. With over 115,000 ISR procedures performed annually in the U.S., Spectranetics says it is positioned to capitalize on potential market opportunities of $350 million domestically and up to $750 million worldwide.”

Sept. 15 U.S. Air Force Academy article
Spectranetics will continue to partner with the Air Force Academy to develop next-generation lasers for use in removing artery blockages.

“One of those projects is an 18-month study between the Aeronautics Department and NASA. Two cadets spent the summer at the Johnson Space Center, working to determine if NASA can save money on experiments requiring zero gravity for short periods, while another project led to a cooperative research agreement with Spectranetics, an international medical device company based in Colorado Springs founded by a former Academy physics professor.”

“Spectranetics has a long history with the Academy, a history that will most likely continue thanks to Magday, who conducted absorption studies to determine the best lasers for calcified deposits in the arms and legs. Essentially, she helped characterize the difference in laser strength and effects on both biological and non-biological samples, assisting the company in creating a wider knowledge base of the types of tissue available for laboratory testing.”

“This is Spectranetics main line of work; as the company makes lasers and the fiber optics doctors use to remove blockages and infected leads from pacemakers from patients’ appendages.”

“Magday’s research serves as the start of the future of medical lasers, and Spectranetics officials were pleased.”

“Getting to work with the brightest students—that’s an incredible help,” said Greg Ebbets, Magday’s adviser at Spectranetics. “[Magday’s] work advanced what we do, but it was a project we couldn’t find the time for. And when we looked for a partner, what we discovered was that the best laser laboratory in the nation was just across the highway. We’re fortunate to partner with the Academy.”

“The cooperation between the Academy and Spectranetics continues during this fall; Spectranetics is using the biology labs and the Laser and Optics Research Center to develop next-generation lasers to use to remove blockages from arteries.”

“This is one of our technology division projects,” Ebbets said. “We test pretty far out for commercial products. We need to know about the physics of how the laser works in different settings so we test things like hot dogs, potatoes, some synthetics, plastics. The better we understand how the laser works in the laboratory, the better we can determine what strength to use moving forward.”

“Magday’s work served as the basis for the ongoing partnership—an experience every cadet should have, she said.”

“It was a huge help to me,” she says. “I’m hoping to go on to nursing school after I graduate. Having this hands-on experience—finding solutions that you aren’t sure are there—that’s going to be a big help in my future career in the Air Force.”

June 30 Medical Design Technology article
Spectranetics completed its acquisition of AngioScore, which will expand its market opportunity and allow it to diversify its product offerings.

“The Spectranetics Corporation has announced that it has completed the acquisition of AngioScore Inc., a leading developer, manufacturer and marketer of cardiovascular, specialty balloons, for $230 million in cash, along with additional contingent commercial and regulatory milestone payments.”

“AngioScore, based in Fremont, Calif., develops and markets the AngioSculpt scoring balloon technology platform, which is a differentiated, comprehensive portfolio to treat blockages in the coronary and peripheral vasculature. AngioScore’s product and distribution platforms diversify Spectranetics’ portfolio while expanding physicians’ options to treat critical limb ischemia (CLI), in-stent restenosis (ISR), calcified lesions and chronic total occlusions (CTO).”

Additional research by Karen Lusky, Pam Conboy, Renee Euchner and Carolyn Schwaar
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