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ELGX - Endologix Inc Conference Call to Discuss the Positive Clinical Data from the Nellix EVAS FORWARD-IDE Study

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## PRESENTATION

**Operator**

Greetings and welcome to the Endologix, Inc. EVAS FORWARD-IDE Study Conference Call. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. (Operator Instructions) It is now my pleasure to introduce your host, Zack Kubow. Thank you. You may begin.

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**Zack Kubow** - *Endologix, Inc. - IR*

Thanks, operator, and thanks everyone for participating in today's conference call. Joining me from the Company are John McDermott, Chief Executive Officer; and Dr. Jeffrey Carpenter, Professor and Chairman of surgery for Cooper Medical School and Chief of Surgery for Cooper Health System in New Jersey and National Principal Investigator of the EVAS FORWARD-IDE Clinical Study. This call is also being broadcast live over the Internet at www.endologix.com and a replay of the call will be available on the Company's website for one year. The webcast of the call includes presentation slides and if you are dialed into the call by phone, I encourage you to also open the webcast at this time in order to view the accompanying slides.

Before we begin, I would like to caution listeners that comments made during this conference call will include forward-looking statements within the meaning of Federal Securities Laws. These forward-looking statements involve material risks and uncertainties. For a discussion of risk factors, I encourage you to review the Endologix Annual Report on Form 10-K and subsequent reports as filed with the Securities and Exchange Commission. Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, June 11, 2016. Endologix undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this call.

With that said, I'd like to turn the call over to John McDermott.

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Thank you, Zack, and good afternoon everyone. I'm pleased to be joining you today with Dr. Carpenter live from the 2016 Vascular Annual Meeting of the Society for Vascular Surgery. Earlier this morning, Dr. Carpenter presented detailed results from the EVAS FORWARD IDE Study. The results from the EVAS FORWARD IDE Study were submitted to the US Food and Drug Administration as a part of the Company's pre-market approval at the end of March of this year. With the submission complete, we remain on track to potentially receive FDA approval for Nellix at the end of 2016 or early 2017.

For the call today, Dr. Carpenter will present the same slides he reviewed this morning at the SVS and then we'll open up the call for questions. Turning to slide 2. This is our Safe Harbor statements for this conference call and presentation. We encourage you to review this information along with the risk factor discussions contained in our Form 10-K for the fiscal year ended December 31, 2015 and our other filings with the Securities and Exchange Commission. I'll now turn the call over to Dr. Carpenter.

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

Greetings, everyone. I'm going to be discussing this morning the results of the IDE clinical trial safety and efficacy results of the Nellix System for the IDE pivotal trial for endovascular aneurysm sealing. Endovascular aneurysm sealing or EVAS is a novel approach to repair abdominal aortic aneurysms whereby polymer is placed into the aneurysm sac to completely obliterate the aneurysm. This is accomplished by injecting endobags which are attached to balloon expandable stents which span the length of the aneurysm. The injected polymer provides the fixation and seal and obliterates the aneurysm sac. We conducted a multicenter prospective trial at 29 sites inside and outside the United States and enrolled 150 patients between February and November of 2014.

There was a core imaging laboratory that reviewed all of our CAT scans, there was a Data Safety Monitoring Board that reviewed safety, and a Clinical Events Committee that adjudicated all of the adverse events. Inclusion criteria for the trial required that the patient have an aneurysm greater than 5 centimeters or we also included aneurysms 4.5 centimeters or larger that were demonstrating rapid growth. This was a good neck trial that is to say necks were required to be between 18 millimeters and 32 millimeters diameter, at least 10 millimeters in length, and not highly angulated. Of note, we were able to treat large common iliac artery aneurysms in this trial, something which is unique to EVAS IDE compared to EVAR IDEs, with no minimum requirement for an iliac landing zone distillate.

There were both safety and effectiveness endpoints. The safety endpoint was the rate of major adverse events at 30 days and you can see those eight MAEs listed here on the slide. The effectiveness endpoint was defined as treatment success at one year. Treatment success includes procedural technical success and also the absence of aneurysm rupture, conversion, clinically significant migration, Type I or III endoleak at one year, aneurysm expansion, or device related secondary interventions. This slide shows the baseline characteristics of patients treated. You'll see that they were overwhelmingly male and of course aneurysm is a predominantly male disease and the ASA Class indicates that this was a sick population with high ASA Class III, IV, or V.

The average diameter of the aneurysm sac was 57.5 millimeters so these were not small aneurysms, these were large aneurysms. Of note, and there's a red box around it on the slide, the right and left common iliac diameters, you'll see that the range goes up to 50 and 53 millimeters; quite large iliac aneurysms included in this trial, which is somewhat unusual for a traditional EVAR trial. How did the patients do? Our procedural in-hospital outcomes showed that the device was implanted very quickly compared to other devices with an average device implant time of only 30 minutes. At the bottom of the slide, you'll see the time to hospital discharge was on average only one day. There was 100% technical success. All the patients in whom we intended to place the device, it was placed successfully.

Safety is the rate of major adverse events and the safety standpoint was measured at 30 days. The MAE rate at 30 days, you see at the bottom of the slide, was 2.7%. That is compared with the SVS open surgery control group and is significantly less as an MAE rate thus achieving the safety endpoint at 30 days. The effectiveness endpoint is assessed at one year. It's the treatment success rate at one year and that was 94%. The comparative group is 80%. So, the 94% is highly significant compared with the comparative of 84% achieving the effectiveness endpoint at one year. I'll describe for you in a little detail the treatment failures. Those were seen in these eight subjects or 5% and related to one patient who sustained aneurysm rupture resulting in conversion to open repair. So, those two events occurred in the same patient.

That patient's story is that they had a Type IA endoleak, which was unsuccessfully or inadequately treated with simple coil embolization, subsequently returned and was retreated with both coils and glue. But then presented later with abdominal pain, had a CAT scan which showed stranding which is a sign of rupture around the aneurysm, was taken to the operating room, and underwent open conversion and explantation of the graft at that time. There were five secondary interventions, there were two sac expansions. Sac expansion is defined as growth greater than 5 millimeters, one of those was 5.3 millimeters and one was 8.4 millimeters. Neither one of the sac expansion patients had an associated endoleak or had any ill effect that required any secondary intervention.

There was a Type IB endoleak detected at one year and the next slide will show us the full story on endoleaks. Starting with Type IA, there was one Type IA endoleak at one month. There is not shown on this slide a second Type IA endoleak that appeared at six months. The Type IA endoleaks were treated, one successfully with coils and glue and one unsuccessfully that I described previously that underwent open conversion. There was a single Type IB endoleak noted at one year and that was treated with extension of the [distelim] with a covered stent graft as per usual. Type II endoleaks are very low in this trial. The rate at 30 days was 5.6% or 8 patients. We did observe at one year that that rate had decreased to 2.3%.

The eight original Type II endoleaks spontaneously thrombosed in all but one case which persisted so this number three includes the one persistent and two new Type II endoleaks. The Type II endoleaks in addition to being a very small rate compared to other trials were also a very small size. The total volume of these leaks, each one was less than 1 cc which is much less than a typical endoleak and they involved exclusively lumbar arteries and a single pair of lumbar arteries, no inferior mesenteric or middle sacral arteries, which tend to be the more troublesome Type II. There were no sac expansions and no secondary interventions related to any of these Type II endoleaks. There were no Type III or Type IV endoleaks.

This is an example of how a Type IA endoleak results and typically we see inaccurate or low placement of the device not up to the renal artery level allowing blood to pass beyond the first stent which is uncovered and allow entry into the aneurysm. The best way to prevent a Type IA endoleak is accurate placement at the index procedure with the bare metal stents up over the renal artery level and the endobags beginning just below the renal arteries. Something that we've learned over and over in endovascular repair and open repair is the necessity of repairing the aorta all the way to the level of the renal arteries for renal segment between the renals and the top of the aneurysm is indeed a very fickle segment of the aorta. Device performance, other parameters.

There were two limb occlusions for a rate of 1.3%, which is in keeping with other trials; a migration rate of 2.3%, also typical of other trials. These migrations did not result in any secondary procedures or any endoleaks. The sac growth, I've described to you previously those two patients. Next I'll show you a series of Kaplan-Meier survival curves, which are freedom from events. So freedom from all-cause mortality in the blue and freedom from aneurysm related mortality in the red excellent at one year, 96% and 98.7% respectively. Freedom from conversion and freedom from rupture both relate to that one single patient who had both events yielding a one-year result of 99.3% freedom. Freedom from device related secondary interventions, a remarkable 96.6% at one year.

This slide compares the Nellix IDE results with those of several competitive devices. These data have been thoroughly scrubbed to make sure that the methodology for each of the endpoints reported was identical in the report of the Nellix IDE and those of the other IDEs. You can see that the results are comparable on almost all characteristics with dramatic differences however between Nellix performance and those of competitive devices in the categories of secondary interventions and endoleaks. The endoleak rate is a half or a third of that reported in other trials. The secondary intervention rate at one year is at least a half or a third of that reported in other trials. So by comparison with other one-year data in FDA IDEs, the Nellix device stands out particularly in the categories of low endoleaks and low secondary interventions.

The conclusions then are that the primary safety and effectiveness endpoints have been achieved for the Nellix device with 100% technical success. This is the lowest overall endoleak and secondary intervention rate reported at one year compared to other FDA approved EVAR devices. The one-year IDE results demonstrate that EVAS with Nellix is successful at treating a broad range of infrarenal aneurysms and common iliac artery aneurysms as well. And as with all new devices and technology, longer follow-up is necessary to ensure durability of the EVAS procedure and device. These are the many investigators that we wish to thank for their participation and recruitment and follow-up to the trial.

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Thank you very much, Dr. Carpenter. Operator, we'll now transition and open the call up for questions.

## QUESTIONS AND ANSWERS

**Operator**

Thank you. Ladies and gentlemen, we will now be conducting our question-and-answer session. (Operator Instructions) Brooks West, Piper Jaffray.

**Brooks West** - *Piper Jaffray - Analyst*

Dr. Carpenter, congratulations on a good study. I'm curious if you would go over for people that weren't able to attend SVS the questions you received after your presentation whether it was from the discussion or [audio peers]?

**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

Yes, I'll be happy to do that. We do have the questions in front of us that we received at the end of the presentation from the surgeons in the audience. The first one was what is the learning curve for Nellix. The procedure as reflected by our data, you saw that the implant time was only 30 minutes, which is quite brief compared with other devices. So while the procedure is quick, it does differ from standard EVAR and there are some unique things to learn. The essence of it however is a kissing balloon and stent technique followed by the injection of polymer, which are familiar steps to surgeons. So, I would say it's somewhere between 5 and 10 cases to really gain familiarity with the device and its use. But I like to say that I learn something from every case so the learning curve is never over.

The next question is what is the exclusion limit for flow lumen diameter. That's an interesting question and it's a question that's unique to EVAS and to Nellix. The way EVAS works is by filling the flow lumen with polymer filled endobags so if the flow lumen diameter exceeds the size of the endobag, it can't be completely filled. So, the exclusion limit for the flow lumen diameter is 6 centimeters. That doesn't mean you can't fix a 10 centimeter aneurysm, it just means that you can't fix a 10 centimeter aneurysm if its flow lumen diameter is greater than 6 centimeters. That in practice turns out to be an extremely small group of patients, not very many excluded at all. The next question was what was the minimum saccular diameter if you used 1.5x aortic diameter.

I think that related to the minimum size aneurysm in the trial. Remember the average was 57.5 millimeters, the smallest aneurysm that was treated in the trial was 4.4 centimeters because we did include that 1.5x aortic diameter is a way to enter the trial. But this was not in any way a small aneurysm trial. The next question how do you explain the lack of IMA endoleaks. One of the most dramatic and interesting and promising aspects of Nellix and EVAS in general is the potential to eliminate Type II endoleaks, which can be very troublesome and have been associated in large registry studies with increased aneurysm related mortality, later secondary interventions, and lead to Type I endoleaks a very malignant behavior. And the inferior mesenteric artery is the biggest bad actor of the Type II endoleaks.

We saw zero inferior mesenteric artery related endoleaks in the study and I believe in the global registry of Nellix, there are no Type II endoleaks at all and no IMA related endoleaks. All of our endoleaks were small lumbar endoleaks. Now if you ask, the data that I presented to you were endoleaks rates detected by our Core Laboratory. If you asked our site investigators, they rejected the Core Laboratory analysis of those endoleaks. In the majority of cases, the Core Laboratory would identify contrast inside of lumbar artery going up to the aneurysm shell and extrapolating from that that therefore it must be entering the aneurysm shell. Vascular surgeons are used to not calling an endoleak unless they can see an actual puddle within the aneurysm so there is some disagreement between Core Lab and investigators.

The technology seems to be very effective at, I use the word spackling the endoleaks shut, closing the orifice of the IMA and the lumbar arteries which is a great advantage. Does the device allow us to ignore Type II endoleaks? I think time will tell. I don't think anyone at present can ignore a Type II endoleak, it needs further study. We have some evidence that behavior of Type II endoleaks in Nellix may in fact be far less malignant than in traditional EVAR because the endoleaks are butting up against the solid polymer rather than a liquid, blood or thrombus, which allows the leak pressure to be transmitted throughout the aneurysm shell. But time will tell and we'll study it and we haven't seen any sac expansions with the very few Type II endoleaks we have.

In fact what we've noticed about the Type II endoleaks is that all but one of our original was thrombosed by the one-year endpoint. Is Nellix used in rupture? There have been mixed opinions about the use of Nellix in rupture. Some advocate it as a good rupture device because of how quickly it can be put in and how quickly the bags can be inflated to achieve a seal. Others advise caution that raising the pressure in the endobags can propagate the tear in the aneurysm and cause the endobag to herniate out through the sac destabilizing. So, the jury is out on that and that is a subject of further study whether it's good, bad, or otherwise. How did you do a proximal cuff extension? I believe that question related to how to treat a proximal endoleak.

And there are a number of safety nets for you built into the Nellix device for use at the index initial procedure and then a number of bailout strategies. At the time of the original procedure, you have the opportunity before you ever put the polymer in to fill the endobags with saline and then perform arteriography to test the seal whether or not you've eliminated any blood from entering the aneurysm sac and you do multiple angiographic views to make sure that you've accomplished that. You then evacuate the saline and only then do you cast the Nellix procedure in concrete as it were by injecting the polymer. If you proceed that far and find that after the polymer injection is complete and the polymer has cured, you do your final arteriogram and low and behold there is a Type IA endoleak.

Then you have the opportunity to remove what's called the primary fill line that you used for the original endobag filling and access the secondary fill line. In other words, it's like having your second ripcord for your parachute when you parachute. You have another chance with the secondary chute to get it right and add more polymer and you may be able to take care of the endoleak right then and there that way. Third, if you develop the leak late and you see it on a CAT scan and want to bring the patient back. We found that we can very successfully treat endoleaks by placing coils as a scaffold like a rebar and then adding glue like concrete to rebar and particularly if we use the Onyx glue, that glue makes a chemical bond with our endobag so it becomes one and the same really an extension of the initial procedure to fill in the endoleak cavity and obliterate the leak.

The final strategy would be to move the operation more proximally by placing chimneys or snorkels into the renal arteries and adding additional Nellix pieces up above to create a seal higher and allow visceral blood flow to be achieved through the snorkels. So, those are the multiple approaches that we've taken to Type IA endoleaks with success. And then the last question I was asked at the meeting was how is the Nellix procedure affected by thrombus burden. As we've discussed already, the procedure relies upon the injection of polymer to achieve fixation and seal so the more polymer we are able to deliver into the aneurysm sac, the more effective we can create the sealing and the fixation.

So with extensive thrombus and a small flow lumen, we have less opportunity; with large flow lumens, we have more opportunity and that's how thrombus affects the operation. Those were all the questions that we had time for in the brief discussion following the presentation.

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**Brooks West** - *Piper Jaffray - Analyst*

It sounds like a lot of technique in patient selection. As my one follow-up question, was there anything controversial in the data or was there anything that might cause hesitation by your peers in terms of adopting this technology (inaudible)?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

I don't think so, in fact quite the opposite. There's a real buzz around this device and this technology at this meeting as there was last year and people's reaction mostly is when can I get this in my hands, I'm anxious to try it. I can't believe the decreased secondary procedures, I can't believe the low endoleak rate, this is great. And the first question I was asked was about the learning curve and that was prompted by a surgeon who is anxious to have it and wonders how long it's going to take him to learn it once he has access to it.

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**Brooks West** - *Piper Jaffray - Analyst*

Great. Thanks so much.

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**Operator**

Rick Wise, Stifel.

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**Matt Blackman** - *Stifel, Nicolaus & Company - Analyst*

It's Matt Blackman in for Rick Wise. A couple questions for Dr. Carpenter. The first question on migration, I'm wondering is there any predictor or anything anatomically or procedurally similar amongst the migrating Nellix grafts?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

The first answer to that is we're only talking about three patients so it's very difficult to draw any conclusions from three patients. As I've said a number of times, the fixation and the seal is related to the amount of polymer that's injected and we're looking at that and trying to figure out what anatomies, what volumes of polymer, what volumes of thrombus if any can be identified that would help us understand what cases are migration prone and which ones are better cases. A remarkable aspect is that despite seeing three patients with migration, none of them has produced an endoleak or required a secondary procedure. So, it remains a subject of interest and study and a mandate for long-term follow-up of these patients.

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**Matt Blackman** - *Stifel, Nicolaus & Company - Analyst*

Okay. Again I know we're dealing with small numbers here, but you mentioned the learning curve and I was just curious if there's a way to parse the data at all as we look at again the low rate of endoleaks. Did these occur predominantly in sort of the early enrolled cases versus the later cases? Is there any difference in some of the outcomes given the learning curve in the beginning of the trial versus closer to the end of the trial?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

No, we couldn't identify that. That may be an artifact of extremely small numbers of secondary procedures and a very low adverse event rate so it's hard to say. I know in the global registry, that also was examined and it's only when extremely challenging anatomies were taken on that they found slightly higher incidence of complications, things that are way off of the IFU that we're attempting in this trial.

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**Matt Blackman** - *Stifel, Nicolaus & Company - Analyst*

Okay. And then I'm going to slip one last one. John, this is probably for you. Just curious on the limb occlusion rate, I know you guys have rolled out enhancements in Europe. Any sense of whether again small number, 1% and change, but any sense of whether those enhancements may have addressed or resolved some of these occlusions that you saw in the IDE trials?

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Matt, the enhancement to the implant that's going to be ultimately the device gets approved in the US was recall we extended the endobag and fixed it at the distal end of the device. So, that enhancement was not designed for limb occlusions. It was designed to get a precise seal at the distal edge of the device. So the benefit there is not limb occlusions, it's more so a doctor can take the end of the device right down to the hypogastric artery and get a good seal without needing a branch or some other adjunctive procedure. So, there's two different things.

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**Matt Blackman** - *Stifel, Nicolaus & Company - Analyst*

Got it, okay. That's all from me. Thanks so much.

**Operator**

Mike Weinstein, JPMorgan.

**Andrew Hanover** - *JPMorgan - Analyst*

This is Andrew Hanover in for Mike. I just wanted to start out just really high level. Dr. Carpenter, I wanted to get your thoughts on given the strong data, any thoughts around why there would actually need to be an FDA panel at this point?

**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

I'm not sure that I can answer that. I'm unaware of the need for a panel for this device and I wouldn't anticipate that.

**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Andrew, at this point you've seen the data now and it all falls either within similar experience with EVAR and then in some cases much better than EVAR. So, there doesn't appear to us to be anything about these results that would suggest a panel. But we'll know that more definitively when we have our 100-day interaction with the agency, which will be in the middle of July. So, our plan is to provide everyone with an update on our Q2 call which will be in early August. By then we should have had our interactions with the agency and if they have a reason for a panel, we would know it at that time and that's when we'll talk about it.

**Andrew Hanover** - *JPMorgan - Analyst*

And then I wanted to go back to migration, I know it was a small number of 2.3%, which is extremely impressive and comparable to other studies. But in the small Liverpool study just wanted to get your thoughts, Dr. Carpenter, around whether or not the group of patients though small 18, there was a higher thrombus burden of small flow lumen in those patients and that was the reason for a higher migration rate?

**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

That's one of the areas that's being examined right now. The essence of fixation and seal is the need for polymer and the more thrombus and the smaller the flow lumen, the less polymer is able to be delivered. So, that's a topic of intense study and scrutiny by clinicians and the Company alike to try to understand what the contributors to migration are.

**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Andrew, one point about the Liverpool paper as a reminder is they chose to define migration as 4 millimeters which is less than half of the SVS definition and also found the same that we found so far in the IDE at one year, they had no reinterventions or endoleaks or events related to those imaging findings.

**Andrew Hanover** - *JPMorgan - Analyst*

So, there is obviously chatter from the competition ahead of Nellix launch approval around trying to convince surgeons that Nellix doesn't have long-term data and obviously with new technology, there's always a group of early adopters but then there's a large majority of docs that want to see data and proof. So, just wanted to get your thoughts around how effective the competitive message is at this point versus the extremely robust

data set that was presented today. Any thoughts around what you anticipate, Dr. Carpenter, what the adoption rate of Nellix could be once approved? And thanks for taking our questions.

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

I'm not hearing that from my surgeon colleagues. My surgeon colleagues are extremely excited about Nellix. They get the concept of EVAS, they're very attracted to the idea of eliminating the aneurysm sac which is something that we do in the open aneurysm repair that heretofore we've never been able to do with any endovascular technique. And eliminating the sac means eliminating the risk of future problems for the patient permanently, something we do with open repair and something that we do with varying success with EVAR right now. So, there's a lot of excitement around that I have not heard people worried about waiting for longer-term data because there has been an OUS experience that's longer than one year in the form of the global registry and that seems to support our findings with the IDE.

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Operator, I know we've got other folks in the queue for questions. We should keep quick along here.

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**Operator**

Glenn Novarro, RBC Capital Markets.

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**Glenn Novarro** - *RBC Capital Markets - Analyst*

Just a follow-up to Andrew's question. Dr. Carpenter, I wonder if you can talk a little bit about how you expect to use Nellix in your practice. Is this going to be a workhorse stent or graft just going to be 80% of your cases or get used for more complex? So, maybe talk a little bit about how you're going to use it in your practice. And then as a follow-up, if this is going to be a major share gain or based on your commentary and how excited your colleagues are, what grafts are you seeing are going to be the share losers? Thank you.

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

My goal as the vascular surgeon is to provide the best possible procedure for my patients that I believe is going to be durable and keep them safe. I think our data to date and data worldwide suggests that Nellix and EVAS is a procedure that can eliminate endoleaks and secondary interventions in a way superior to EVAR. In addition, we find that more patients are eligible for EVAS than are currently eligible for EVAR, patients for whom we would reach for some very complicated branch and other solutions that require a lot more finagling can be handled relatively simply and on-label with Nellix. So for me, it will become the default device.

I'll pick up a CAT scan and I'll be thinking this is an EVAS case until I see something about that patient that tells me that it's not. I think again there's a lot of enthusiasm in the vascular surgical community for it. I think almost everyone's going to want to try it and gain experience with it and everyone will figure out for themselves how it fits into their own practice. But we're excited about the platform for infrarenal, we're fascinated by the possibilities of marching up the aorta with ChEVAS as is being done outside the US currently to handle more complicated juxtarenal, pararenal, visceral segment aneurysms. So we think there's a large market for this, much larger than the current EVAR market.

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**Glenn Novarro** - *RBC Capital Markets - Analyst*

Okay. Thank you for taking my questions.

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**Operator**

Chris Pasquale, Guggenheim.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Dr. Carpenter, can you just clarify on the reintervention data, were there five patients who had a reintervention procedure or five reintervention procedures? It sounded like that one Type IA patient who went on to have a conversion actually got retreated three times just by themselves.

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

There were five patients that had secondary interventions.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Okay. In the past when we've talked to physicians who were not big fans of this technology, they've often downplayed the significance of reducing Type II leaks because of how infrequently those lead to complications. Now we have data suggesting an actual reduction in reinterventions relative to conventional grafts. How important a data point do you think that is for your colleagues? Where does that fall in the spectrum related to some of the other things you have to worry about with these patients?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

I think that's a very big deal. If you look at the results of EVAR currently versus open aneurysm repair, the place where EVAR fails is not in any way other than they need to continually reintervene on the patients for long-term issues and the root cause that's been shown for most of the reinterventions is an endoleak of some sort. So, Nellix really speaks to the source of the reintervention problem and it's no surprise that the reinterventions are reduced as the endoleak rate is reduced.

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**Chris Pasquale** - *Guggenheim Securities - Analyst*

Thanks. That's helpful.

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**Operator**

Chris Cooley, Stephens.

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**Chris Cooley** - *Stephens Inc. - Analyst*

Dr. Carpenter, congratulations on a very successful study. When we look at the reintervention rate particularly in the Type IA, I realize it's a very small number. But would the changes to the Nellix device (inaudible) how do we saw a chain cross address that as it would [prevent] fluid device from migrating back at the time of the seal of the polymer bag. I'm just kind of wondering if that could further enhance what are already very impressive results? And I have one quick follow-up.

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

First of all, I agree with you. The rate of Type IA endoleaks is very small so it's hard to say anything about it. But if there has been a learning curve not for individuals, there certainly has been a learning curve for the entire EVAS community as to what happens or what conspires to create a Type

IA endoleak. At the very earliest state, remember EVAS is a completely new concept, some of us thought that maybe all you needed to do was to fill with polymer the aneurysmal portion and you didn't need any neck or any buffer from the aneurysm whatsoever; just fill what's aneurysmal now with polymer. What we've learned is a lesson that we learned in open vascular surgery very early and that is if you don't place a background graft all the way up to the renal arteries, you're going to be back in a number of years doing that because you've developed an aneurysm.

Sadly we had to learn it again with EVAR and tried only replacing the aneurysmal segment of the aorta and found that we developed Type IA endoleaks when the segment below the renals but above the aneurysm that was good at the time had degenerated later. That's a very fickle segment of the aorta. So, we're now learning with EVAS that once again we need to repair all the way up to the renal arteries. I don't know if there have so much been changes in the device or the delivery system as there have been changes in the disposition of the operators to learn various techniques to make sure that they accurately place the device, accurately hold and maintain control of the device so that it does not move while the polymer is curing or while the polymer is being introduced to assure that we do place the device right at the renal arteries and assure a success.

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Chris, sorry to interrupt you. I've still got a good bit of people in the queue behind you so I'm going to try to take it down to one and then if you don't mind dropping back in, that way we'd try to get everybody through here. So I apologize, but we're going to have to take the next question.

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**Operator**

Steven Lichtman, Oppenheimer.

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**Steven Lichtman** - *Oppenheimer & Co. - Analyst*

Dr. Carpenter, just wanted to follow-up on the strong procedural outcomes that you mentioned. Could you may be further discuss the comparators out there particularly on the implant time and time to discharge? What are we seeing in the field today, how does this compare? And relative to implant time being low, what would you attribute that to (inaudible)? What keeps it or makes it a pretty quick procedure?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

I would back up to the procedural in-house outcomes; the implant time, the [floret] time, the total procedure time, the anesthesia time; all of those things that measure how complicated and how quick the procedure is are low compared to other devices. I think there isn't that much more to this than a basic stent technique, which is put a wire up the right side, put a wire up the left side, thread the balloon expandable stent over the wire on each side, and simultaneously deploy them and that just doesn't take very long. The final step is the polymer step and that's where we encourage everyone to slow down, take their time, do their imaging, do their test fill, evacuate that, and then do the final polymer fill to cast the whole thing in polymer permanently. So, all of these steps are familiar to surgeons up to the point of the polymer step; there are standard procedures and interventional radiology and interventional vascular surgery for treatment of Occlusive Disease. So, every vascular surgeon perhaps the very first thing they learnt how to do is how to do a balloon angioplasty with a stent. So, that's all quick and easy and very familiar and all that needs to be learned is the nuances of the polymer steps.

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**Operator**

Matt Keeler, Credit Suisse.

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**Matt Keeler** - *Credit Suisse - Analyst*

Dr. Carpenter, I wondered if you could just maybe characterize for us how technically challenging it is to place the stent to the height that you want and should that be achievable 100% of the time if you're really paying attention or are there anatomies where that is made more difficult?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

Of course if everything's nice and straight, everything is much easier. The more tortuous and angulated the anatomy, the more challenging the cases become. Usually it's not difficult at all to deliver the stent to the location that you want at the renal arteries. If there are challenges introduced by tortuousity, it's at the step of polymer filling as those bags expand in tortuous anatomy they expand asymmetrically and they can cause the stents to move as the bags begin to fill and it's important to be very vigilant at that point not to allow the device to fall down. One of the tricks that we've learned is to keep the balloons that are inside the stents inflated and that adds rigidity to the system and pushability so that you can accurately keep the device aligned with the renal arteries and land where you intend.

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**Operator**

Joanne Wuensch, BMO Capital Markets.

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**Joanne Wuensch** - *BMO Capital Markets - Analyst*

Big picture question, a year from now how do you think that this Nellix procedures are going to be performed versus traditional EVAR procedures? In other words does this open up the market in a bigger way to MIS procedures versus surgery and does it change the way that doctors are thinking about patients returning for follow-up?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

As I said earlier, I believe that there are a lot of cases that we can do on label with the Nellix device that currently would be off label for EVAR or perhaps only be achievable by open surgery. So I do believe that it doesn't merely cannibalize business from other competitive devices, it actually enlarges the market. And what was the second part of the question?

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**Joanne Wuensch** - *BMO Capital Markets - Analyst*

How to do more with patients management in terms of (multiple speakers)?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

The surveillance question. So certainly if we can reduce the endoleak and secondary reintervention rates, it may be possible in the future to decrease surveillance. But I for one, I don't think anyone at this point would advocate doing that for a brand new device. A revolutionary technology needs to be studied. So, we intend to continue to survey these patients aggressively and intend to learn a lot from the surveillance that we do.

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**Joanne Wuensch** - *BMO Capital Markets - Analyst*

Terrific. Thank you so much.

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**Operator**

Sean Lavin, BTIG Capital.

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**Unidentified Participant**

This is actually Paul on for Sean. Dr. Carpenter, just one question for you. In your experience, what has kind of been the post procedure follow-up and has it changed at all and is it going to be different than any other stent graft? Thanks.

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

So, our experience in the US of course is in the context of US IDE trial and the follow-up that we do is mandated by the surveillance protocol that's designed in the IDE. So, I have no intention of deviating from that necessitates CAT scans at 30 days, six months, and a year and then annually thereafter and that's exactly what we'll do. With standard EVAR, follow-up is very diverse amongst the vascular surgical community. I think most of us will obtain an initial CAT scan at least and if that initial CAT scan looks good, some of us will continue to get annual CAT scans, others of us will switch to ultrasound surveillance of those patients. We do know that you can very nicely interrogate a Nellix graft with ultrasound so it's not necessary to adopt a CAT scan only surveillance protocol. You can do it non-invasively and hopefully we'll reach the day and time and confidence level that we can do that.

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**Unidentified Participant**

Perfect. Thank you.

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Operator, we probably have time for one more call if there is any others remaining.

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**Operator**

(Operator instructions) Matt Keeler, Credit Suisse.

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**Matt Keeler** - *Credit Suisse - Analyst*

Dr. Carpenter, just one if I can about an earlier question. You mentioned that Nellix will likely be the default choice for you once approved unless you reason not to use it. Can you give us some color on the types of patients where you might prefer another device?

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**Jeffrey Carpenter** - *Cooper Health System - Chief of Surgery*

I think that would chiefly be in the category of patients who had access requirements that didn't accommodate the 17-French sheaths, requires bilateral 17-French sheath placement, and if someone has a disadvantage to access route on one or both sides; I might reach for another graft where I can deliver the stent graft through a smaller access route. And also there is that exclusion we talked about at the beginning of the call. If someone has a flow lumen that happens to be greater than 6 centimeters that is off-label for Nellix and perhaps that would be a situation where we think about another device.

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**Matt Keeler** - *Credit Suisse - Analyst*

Thanks very much.

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**Operator**

Thank you. Ladies and gentlemen, we have no further questions in queue at this time. I'd like to turn the floor back over to management for closing comments.

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**John McDermott** - *Endologix, Inc. - Chairman of the Board & CEO*

Thank you for calling in today and for your questions. We look forward to providing another update on our second quarter earnings call in early August. Thanks again and have a great weekend.

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**Operator**

Thank you. Ladies and gentlemen, this does conclude our teleconference for today. You may now disconnect your lines at this time. Thank you for your participation and have a wonderful day.

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