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ELGX - Endologix Inc AFX Update Conference Call

EVENT DATE/TIME: DECEMBER 27, 2016 / 2:00PM GMT

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PRESENTATION

Operator

Good day everyone, and welcome to the Endologix update conference call. Today's call is being recorded.

(Operator Instructions)

Now, your host for today's conference, Mr. Zack Kubow of The Ruth Group. Mr. Kubow, please go ahead sir.

Zack Kubow - *Endologix Inc. - IR - The Ruth Group*

Thanks, Operator and thanks everyone for participating in today's call. Joining me from the Company are John McDermott, Chief Executive Officer, and Vaseem Mahboob, Chief Financial Officer. 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.

Before we begin, I would like to caution listeners that comments made by management 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, December 27, 2016. Endologix undertakes no obligation to revise or update any statement to reflect events or circumstances after the date of this call. With that said, I'd now like to turn the call over to John.

John McDermott - *Endologix Inc. - CEO*

Thanks, Zack, and good morning everyone and thank you for joining us today on short notice for an update on the AFX system.

This morning we issued a press release announcing a temporary hold on shipments of AFX in order to resolve a manufacturing issue that was just identified. During our ongoing product testing, we identified damage to the graft material in some sizes of the AFX device. We believe this is related to the manufacturing process where the graft is loaded into the delivery system and are confident this issue can be resolved.

Although we are not aware of any reported clinical events related to this issue, we want to conduct a thorough investigation and run additional tests to make sure we are providing physicians and their patients with the highest possible quality devices. This temporary hold has no impact on Ovation or Nellix, as both products have separate manufacturing lines and processes.

Based upon our evaluation so far, we expect the temporary hold to be lifted for some sizes in the near future and plan to provide an update with additional details by the end of this week. At this point it is too early to predict the impact that this will have on the Company, but we felt it was important to share the information quickly while we work diligently to complete the investigation, implement corrective actions and release the hold.

Before we open the call to questions, I just want to emphasize a few points. First is, this temporary hold on AFX is not related to any reported events from physicians or the recently announced CE suspension. We continue to see very good commercial clinical results with the latest versions of AFX and AFX2.

Next, this manufacturing issue was identified through our ongoing internal product testing. We are proactively implementing this temporary hold to ensure we always provide the safest possible products for patients.

And lastly, Ovation and Nellix are unaffected by this temporary hold on AFX. We will continue -- they will continue to be available in the approved markets, both Ovation and Nellix.

We realize you need additional information and plan to provide an update by the end of this week. When we know the exact timing of the next conference call, we will announce it via press release. And in the meantime, we do not expect to provide additional updates so we can focus our energy and resources on solving the problem and growing the business.

With that, we will now open up the call for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Rick Wise, Stifel

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Good morning everyone, it's Matt Blackman in for Rick. I've got a few questions. First of all, maybe the team -- can you remind us if you are there -- can you remind us what AFX represents today as a percent of your total top line? And then if you are willing to, you mentioned some sizes could be back on the market relatively quickly?

I don't know if you feel willing to share what percent of procedures those sizes represent? And what percent of procedures the other sizes which may take a little bit longer to resolve represent?

Vaseem Mahboob - *Endologix Inc. - CFO*

Matt, good morning. At this point, the only piece of information I can share is that AFX represents about 55% of our total global sales. And the rest of the analysis here is a work in process and we just got to continue to work through the whole issue and then come back to you guys in the next couple of days. But if I give you any numbers at this point, it will be just misleading and we might have [wall] back from that.

So my sense is, it is a pretty significant portion of the business. I think we are just making the right call here. To John's point, we don't have any clinical evidence of these issues and we think we can make the product, so it should be very temporary hold and we will continue to monitor it, investigate it, and come back to you guys.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay, I appreciate that. Then John, maybe -- I know there's no direct link between what you're announcing today and the CE Mark suspension, but what's the impact on that process? Which I believe you hope to have resolved sometime in early January? Is there an impact on the timing of resolution of the CE Mark suspension from this announcement?

John McDermott - *Endologix Inc. - CEO*

Matt, there should not be an impact. They are very unrelated. The CE suspension was more a function of looking at reported events for older generation AFX. So this is just a new, hopefully very short term effort.

We will interact with our Notified Body, certainly make them aware of what this is and what it isn't, and -- but we don't really see any connection between this and the evaluation that they've already started related to the CE recertification.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay, and is that process, fair to say, tracking on plan with the timelines you've talked about in the last couple of weeks?

John McDermott - *Endologix Inc. - CEO*

Yes. The process really was, we gathered up additional information and analysis and supplied that on schedule and they are reviewing that as we speak.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay, then the last question here, and I apologize in advance for this, but I think we all understand the merits of having a broad, if not the broadest portfolio in AAA -- but with this announcement and recent updates on Nellix and AFX in Europe -- we have to wonder whether this portfolio may be too broad for you? I'm just curious if you have any thoughts on that and how we should think about that?

John McDermott - *Endologix Inc. - CEO*

Yes, that is a fair question or comment, Matt. I don't think that's the case. I think this is just an unusual situation. I would not read too much into it about our capability of managing a broader portfolio.

These particular devices that we identified are historically more challenging to load, and we've put in some very good process improvements over the years, but occasionally see excursions. The good news is we caught this internally, this didn't lead to any outside event. So that's why we are confident we can turn it around and fix it.

Wish it didn't happen of course, but we felt once we identified it we needed to put the product on hold and it just be very proactive. So that's what we're doing.

Matt Blackman - *Stifel Nicolaus & Company - Analyst*

Okay, understood, thank you.

Operator

Brooks West, Piper Jaffray

Brooks West - *Piper Jaffray & Co. - Analyst*

Hi, thanks. Can you hear me?

John McDermott - *Endologix Inc. - CEO*

Yes, good morning, Brooks.

Brooks West - *Piper Jaffray & Co. - Analyst*

Morning. So John, just out of curiosity, you said that you're seeing damage to the graft material, where the graft is loaded into the delivery system in some devices? Is there inventory of devices in the field that might have this issue? Or is this -- I'm trying to understand when this problem might have started.

John McDermott - *Endologix Inc. - CEO*

Potentially, there could be product in the hospital inventories. We don't provide a lot of inventory -- there's not a lot of shelf inventory. Most of the inventory we supply is taken in by our reps for the procedures, so there isn't likely to be a lot of inventory -- but there is potentially some. So we want to put that on hold and assess that.

As I mentioned earlier, the reported rates of this -- for AFX2, for example, is zero. So we've done over 4,000 cases with AFX2 and have not had a single report of a type IIIB endoleak.

And then with AFX, with the DuraPly graft material, the reported rate of a graft defect, or a type IIIB endoleak is 0.19%. So these are very, very rare. We are just taking a proactive approach to nip it in the bud. But we have not gotten any reports from the field about this.

Brooks West - *Piper Jaffray & Co. - Analyst*

Okay, but do you think this is a result of the recent change to the manufacturing line? I'm trying to get an understanding -- and maybe you're not there yet -- but I'm trying to get understanding of how long this issue might have been in place?

John McDermott - *Endologix Inc. - CEO*

Yes, we did another process qualification activity in the summer of this year, and that all went very successfully as well. Of course all of the design verification, validation work that was done with the development of the product and the release of the product earlier in 2016 -- so there's been a lot of testing and validation.

We must have just had an excursion and that's what we are trying to investigate here. At this point it seems to be related to certain sizes, but we're doing additional testing to confirm that. And also looking for any other trends within lots to see if we can further isolate these devices.

Brooks West - *Piper Jaffray & Co. - Analyst*

Okay. It sounds like Ovation might get a little bit more focused? Can you just remind us where -- is the salesforce fully trained on Ovation now? And do you have manufacturing capacity that could satisfy increased demand there?

John McDermott - *Endologix Inc. - CEO*

Yes, sales force in the US is trained and we have manufacturing capacity, we also have a pretty healthy inventory situation for Ovation. So, not how we planned it, but there will be an opportunity here for the team to accelerate their learning and capability with Ovation.

Brooks West - *Piper Jaffray & Co. - Analyst*

Okay, thanks for taking the questions, John.

John McDermott - *Endologix Inc. - CEO*

Of course.

Operator

Chris Pasquale, Guggenheim

Christopher Pasquale - *Guggenheim Partners - Analyst*

Thanks, good morning, John, Vaseem. John, you say this is unrelated to the CE Mark suspension? You don't believe that this impacts the timing there, but we are talking about the same type of issue that the notified body there called out -- type III leaks. So what drives your confidence that they won't look at this and now feel like there's additional information that needs to be considered prior to the CE Mark being reinstated?

John McDermott - *Endologix Inc. - CEO*

Again, I think they are unrelated. So the information we've already given them for reconsideration of their decision to temporarily suspend the CE -- they're processing that. That is not the same issue as this, what we view as a temporary internally identified manufacturing issue, they are looking at reported complaints from the field, based on longer-term implants of the original AFX system.

We have not manufactured that device for a couple of years, and what we are talking about here is AFX2 and what we see as a temporary manufacturing glitch. So I do think they are independent.

We will have to supply them with all the information when we release the holds. We will provide them and FDA and our other regulatory agencies with the data and the rationale for what we saw when we put on the hold, and why we're taking it off -- but that's pretty straightforward. I'm not saying we're not going to need to have a conversation, but I am saying that these are unrelated.

Christopher Pasquale - *Guggenheim Partners - Analyst*

Okay. I'm just trying to keep straight here -- what is actually impacted? So before, you said you had not had any reports of issues with AFX2, but that's reported events from the field of type III leaks. This suspension does impact AFX2, and the issue here is related to the graft loading for AFX2? Can you just clarify that?

John McDermott - *Endologix Inc. - CEO*

Yes, that's exactly correct, what you said. This is loading -- we believe loading-related -- we are doing that confirmatory work today and tomorrow. We just discovered this really over the weekend, and did as much work as we could and made the determination late yesterday afternoon to put the product on hold.

We've also, as a precautionary measure, put AFX on hold because they do share similar loading processes, and we want to have a chance today to dig into that and see if there are any overlapping relationships. So the hold applies to AFX 2 and AFX, although what started this was some of our internal testing on AFX2. And again the plan is to complete this testing and evaluation here as quickly as we can, and provide the physicians and you guys with an update later this week.

Christopher Pasquale - *Guggenheim Partners - Analyst*

Okay, that was going to be my final question. It is an little unusual to preannounce a call that you don't actually have a set time or topic for -- the idea there is get back to us in a couple of days with the update on this specific issue? Or is there something else that you guys want to talk about later this week?

John McDermott - *Endologix Inc. - CEO*

This is the primary reason. We know we just need a little more time to process this investigation. We did not want to come out and make an announcement about certain sizes, and then have to take any steps back. So we thought it would be better to let you know that we expect to have clarity around this here in the next few days.

Concurrently, we have been in dialogue over the past several weeks with FDA on an updated physician communication that may parallel along the same timeline, but that's nothing that we have not already talked about in the past. So we will see how everything comes together and what kind of communication we will have on this and any other issues by the end of the week.

Christopher Pasquale - *Guggenheim Partners - Analyst*

That's a physician communication related to Nellix and the revised IFU, or is it related to AFX and these issues?

John McDermott - *Endologix Inc. - CEO*

AFX. We communicated that previously, that we've been working on an update. We've been doing that annually for a while so we will provide another physician update here shortly.

Christopher Pasquale - *Guggenheim Partners - Analyst*

Okay, thanks, that's helpful.

Operator

Joanne Wuensch, BMO Capital Markets

Joanne Wuensch - *BMO Capital Markets - Analyst*

Can you hear me okay?

John McDermott - *Endologix Inc. - CEO*

Yes, good morning, Joanne.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Good morning. Just to clarify something, the problem with AFX2, is that related to the type III endoleaks or not?

John McDermott - *Endologix Inc. - CEO*

It can be -- it could result in a type IIIB endoleak. We have not had reports of type IIIB endoleaks that are related to this manufacturing issue, but this is -- this does manifest itself as damage to the graft.

Which, if it was noticed clinically would be a reported type IIIB endoleak. That hasn't happened clinically, but that's how it would be reported if was, clinically.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Physicians will be updated today, in a couple of days? I'm just trying to work through the process. I know there's probably not of surgeries booked this week, but the process of communicating with sales force and physicians?

John McDermott - *Endologix Inc. - CEO*

The communication to our teams and to the physicians is happening in parallel with the call. So our folks are out interacting with physicians as we speak, providing them with the information and having a dialogue around anything that is scheduled and the physician's preference. We believe the most appropriate course of action here is to not use the devices until we can complete our investigation.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Okay, these devices have been manufactured for years, can you help us understand what now has created this moment where you need to hit pause on it? How exactly did this become identified?

John McDermott - *Endologix Inc. - CEO*

It became identified in our ongoing routine testing. So we are always putting the product through testing, and sometimes, particularly with a the more challenging sizes to manufacture, you can see excursions. Which is why you monitor all the testing results and to try to identify anything before it gets to the field.

And this particular case we saw an excursion, we think related to the loading, and we are currently assessing to what extent has any of the product made its way into the field.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Okay, my last question -- and forgive me for this, there have been a number of -- shall we call them hiccups -- over the last couple of months? Do you need to shore up -- and whether it is manufacturing or regulatory or human oversight -- on certain aspects? Or do you feel at this stage you have the right people in place?

John McDermott - *Endologix Inc. - CEO*

I do think that we have the right people. There is certainly some settling in post- the merger. I don't believe that has really driven this issue.

As I said, we think this is related to the loading of certain sizes. That's not related to the merger or any recent activities, that's kind of a common issue with endovascular stent grafts, trying to put big things into small catheters and particularly the bigger the size, the more challenging it can be. So this isn't a unique issue to us or others.

They pop up from time to time, and when they do there's small variations. You try to grab them as quickly as you can and not have it make its way to the field. I am certainly not making excuses, but I don't think this is anything more than just an unfortunate set of circumstances and timing, and we will get it fixed as quickly as we can.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Okay, thank you very much for hosting the call.

Operator

Michael Weinstein, JPMorgan

Unknown Participant - - *Analyst*

Thanks for taking our question, this actually Andrew in for Mike. John, I want to return to a question that was asked before, but what was the process you all went through to make a determination to put AFX on hold? Was there any -- I don't know if you answered this directly, but was there any specific event that drove it?

And I get there's an increasing number of excursions, but is that because there are new people in manufacturing, and they found this? Is it something that the sales reps found in the field? Can you give us some clarity around that?

John McDermott - *Endologix Inc. - CEO*

Yes, it wasn't found in the field, wasn't found by doctors. As we mentioned this wasn't driven by any kind of external findings. We do routine internal testing of the products. One of the things that is difficult with these and other devices is once they're loaded, they're difficult to inspect.

We test them periodically just to make sure that through the loading processes everything is okay, and this test uncovered a deviation. An internal test uncovered a deviation. So once that happens, you explore that -- the lots, the operators, the time frames, the sizes, there's a whole variety of areas that we investigate. We've got a good bit of that done over the holiday weekend but could not get it all completed in time for today, frankly.

So that's why we are not able to be as explicit as we would like to be in terms of the sizes and exact timing, because we still have a little bit more work to do to finish off. But hope to provide that clarity here by the end of the week.

Unknown Participant - - *Analyst*

All right, and then I just want to understand some of the unintended consequences of putting this on hold? I understand this is an independent event between CE Mark, and whatever the FDA headlines were following CE Mark suspension. But one could push out a CE Mark approval, again, and then are there any risks in the US at all whereby the FDA is asking for more information? I don't know, any clarity there would be helpful.

John McDermott - *Endologix Inc. - CEO*

Again, these are not related, these issues -- what we are announcing this morning and the CE suspension are really unrelated. That said, it is hard for me to answer the question with absolute confidence, will it create any pause in the mind of the Notified Body. I'm sure we're going to have a conversation and share some more information.

We will be very transparent with them, like we are you and the physicians, about this is what we found, here's the product that's affected and this is the corrective action and here are the products that we're going to be able to release hopefully here in the near-term and here's the products that will release in the future based upon this new testing activity that we will put in place.

So I cannot really predict the Notified Body's reaction. We believe they are unrelated and will provide them with supporting information to that effect. (multiple speakers)

Then you also asked about the FDA, and really although we don't have the same situation with FDA we don't have -- the product has not been suspended in the US. In this particular case, my experience with the FDA is that they appreciate when companies take a proactive stance. Oftentimes companies may take more time to process it, and in some and some cases these things get bigger.

I feel like we are being very proactive under the circumstances. And even though we don't have the information putting a hold on while we gather the additional information and conduct the analysis, we feel it is just the best and most appropriate move for the patients.

Unknown Participant - - *Analyst*

Then my last question, just in regards to sales reps? Has there been any incremental amount of turnover over the past couple weeks? What are you seeing on the sales front? Appreciate taking the question. Thank you.

John McDermott - *Endologix Inc. - CEO*

Sure. We have not seen any increased turnover in the fields over the last few weeks. The teams been holding together nicely.

Operator

Chris Cooley, Stephens

Chris Cooley - *Stephens Inc. - Analyst*

Good morning, gentlemen. Can you hear me okay?

John McDermott - *Endologix Inc. - CEO*

Yes, good morning.

Chris Cooley - *Stephens Inc. - Analyst*

Just two quick questions for me at this point. First, can you remind us -- I'm assuming this is an issue with the graft materials when you are loading the grafts, but the defect would not be discernible by the implanting clinician?

So if that assumption is correct, can you remind us when, generally speaking, we might see this manifest itself if we were to see a type IIIB endoleak start to occur clinically? I'm trying to think about if there could be any kind of contingent issue that is already out on the field? And I have one quick follow-up.

John McDermott - *Endologix Inc. - CEO*

Yes, Chris, generally if there was any defect in the graft that made it to the field, that would typically be picked up acutely. So any time they do these procedures, they always do at least one if not a series of a angiographic follow-up runs to confirm that they've got seals. So if there was a defect in the graft at that time, that was at all pressurizing or leaking into the aneurysm sac, they would see that.

And if that did occur, it is a very simple procedure to add another component over wherever the defect is. Again, that has not been reported, but that's what would be the scenario if in fact it occurred. So it would be much more of an acute finding.

Chris Cooley - *Stephens Inc. - Analyst*

But I guess just to clarify that, and I agree with you (inaudible) this morning, but the point being that the defect that you are alluding to here is in fact acute. It is not much more subtle than that, if it could maybe manifest itself over time in vivo?

John McDermott - *Endologix Inc. - CEO*

Yes. The only way it can manifest itself over time in vivo is if there was a lot of potential movement, I guess in the anatomy, not likely. There's always some lateral displacement of these devices. Kind of depends on the aneurysm and the patient.

So the graft materials in particular, this new Duraply material was designed specifically to mitigate any kind of hole propagation. So I don't believe that this would be a situation that necessarily worsens over time. I think that if there was a defect in the graft they would see it acutely, if was going to be a defect that was pressurized in the aneurysm sac.

We have done quite a bit of work on this and what we call -- medical device manufacturers call health hazard evaluation, and if you had one of these defects we believe you would see it acutely.

Chris Cooley - *Stephens Inc. - Analyst*

Understood. Just finally from you, maybe it is premature on this front but, unfortunately the Company has had a couple of product-related issues here to close out the calendar year?

Any thoughts on ways to counter detail going forward into the new year to reassure clinicians about the overall quality of the portfolio and maintain some excitement associated with the upcoming Nellix panel and some (inaudible) hopefully approvable at the end of next calendar year? Just thinking about how you're thinking about strategic positioning here in the marketplace that impacts the fourth quarter? Thanks.

John McDermott - *Endologix Inc. - CEO*

Sure, Chris, of course we want to work through this AFX hold issue as quickly as we can. So that will be a priority, but we've already got our sales meetings planned, both in Europe and in the US and in Asia in early part of 2017, with a lot of great information. As we've talked about recently with the Ovation platform in particular, the life data that was announced at VIVA, followed by the five-year data that was announced at the VEITH Symposium, gives us some great clinical evidence to take into the marketplace here in the first part of the year.

We continue to get very good feedback on our early cases with Ovation Alto. A lot of excitement about that, particularly in Europe since that's planned for launch in the first half so the team is going to be getting up to speed and trained with that. There continues to be a lot of positive energy.

There's clearly been some setbacks but there's tremendous growth potential & the Company still exists. We see this as an unfortunate and hopefully very short term situation, but it doesn't really change the long-term outlook for the business, which we think is very positive.

Chris Cooley - *Stephens Inc. - Analyst*

Thank you.

Operator

Jason Mills, Canaccord

Jason Mills - *Canaccord Genuity - Analyst*

Hi, thanks, John, can you hear me okay?

John McDermott - *Endologix Inc. - CEO*

Yes, good morning, Jason.

Jason Mills - *Canaccord Genuity - Analyst*

Good morning. Thanks for taking the question and squeezing me in. Going back to the question about the FDA? I understand this is a Company-driven decision, but when and at what level would FDA get involved here?

I'm sure you're in communication with them, but this is an issue that you've identified a product that they've got responsibility for. So could you walk us through what their responsibility matrix looks like in cases like these? And at what point in time they may get involved?

John McDermott - *Endologix Inc. - CEO*

Yes, so we will be talking with them today and providing them with the information, what we discovered and the purpose for the hold. I think they will appreciate that. I think some folks would view this as a conservative move, based upon the information we have so far, but that's appropriate.

And then we will also supply them with our analysis as we go to start releasing codes -- what is the data and the rationale behind the release of those codes. That will be an interactive process so we will share them our plans and our approach and that will be the nature of the communications and the process moving forward.

Jason Mills - *Canaccord Genuity - Analyst*

So as you share with them, if you're planning to release certain lots within the next couple of weeks, would they want time to -- how long will it take them, do you think, to understand the issue -- to feel comfortable with you releasing lots after this temporary hold within that short period of time? Is that something they could push back on?

John McDermott - *Endologix Inc. - CEO*

I guess it is possible they could push back, but if we've got an approved product with approved specification. If we've put a temporary hold on product because we've seen an excursion, but we have evidence that we've got good product that meets specification, it wouldn't really be a good reason to push back on releasing the product.

So just based on our knowledge of the work we've done over the weekend, we think we will have a very compelling rationale to start releasing product here. I cannot think of a reason they would resist making the product available, if it was meeting specification and we had the evidence to support it

Jason Mills - *Canaccord Genuity - Analyst*

Okay. That's helpful. I appreciate it is a little bit early in the process to provide quantitative guidance for us, whether it be to 2016 or any thoughts on 2017. But I guess -- can you speak on relative terms, maybe help us understand -- in this week between Christmas and New Year's, typically it would seem like it would be a light week which is alluded to earlier in the call in terms of AAA procedures?

But maybe you can provide this a little bit more granularity to confirm that presumption? And would therefore be presumed impact of this be more weighted towards the early part of 2017, insofar as there would be a financial impact from this?

John McDermott - *Endologix Inc. - CEO*

Yes, Vaseem, you want to take that?

Vaseem Mahboob - *Endologix Inc. - CFO*

Sure. Jason, it is just not the cases that are on the books here, in the last week here. There's a lot of distributor shipments that happen in Q4, and typically in the last two weeks of the quarter. So I think depending on how quickly we can lift this hold will determine the impact on Q4 as well.

But could be a bigger number than you would think, just based on the number of cases on the books in the last week of the quarter. So we will give you an update on that on Friday as we get a sense on what we can and cannot share in Q4.

Jason Mills - *Canaccord Genuity - Analyst*

I appreciate that. Just follow-up on that, could you explain that again? Just terms of your distributor, when you are booking those cases, those sales, you're booking that in the fourth quarter? And that's product that will be implanted, presumably in the first quarter? But you're booking that revenue in the fourth quarter when you ship it pre-end of the year?

Vaseem Mahboob - *Endologix Inc. - CFO*

That's correct. Particularly in some of the capital markets, where we do tend to ship some stuff in the last two weeks of the quarter.

Jason Mills - *Canaccord Genuity - Analyst*

Okay. What you are saying is the impact could actually be more acute here in the fourth quarter than the first quarter?

Vaseem Mahboob - *Endologix Inc. - CFO*

That's right.

Jason Mills - *Canaccord Genuity - Analyst*

Okay. I suppose will get more information on Friday. I will leave it at that. Thank you, guys.

Vaseem Mahboob - *Endologix Inc. - CFO*

Thanks.

Operator

Ravi Misra, Leerink Partners

Ravi Misra - *Leerink Partners - Analyst*

Good morning, John and Vaseem. Thanks for the transparency, guys. Just one quick technical question -- sounds like you are still going to the root cause analysis for the product, but seems like, if I heard you right you said you did a similar type of test earlier in the year and nothing was showing up?

Is there any change in the tests that you've done? Or is this completely product-related?

And second, Vaseem, did you say it was 55% or 65% of worldwide sales?

John McDermott - *Endologix Inc. - CEO*

Vaseem, why don't you go first and I will jump in on the testing question.

Vaseem Mahboob - *Endologix Inc. - CFO*

The AFX business is about two-thirds of the total portfolio, so that should be in the 60% 65% range.

John McDermott - *Endologix Inc. - CEO*

Nothing's changed with the testing methodology. We do these periodic tests to confirm all of the design and development and verification work that we've done from the beginning, and then we monitor those test results over time. Occasionally you see an excursion and that's what we've encountered here and you try to catch it as quickly as you can.

Like I said, unfortunately you cannot inspect the graft after it is loaded. So what you do is develop procedures and processes and validate those to make sure that the devices that come out are always defect free. But sometimes you see changes, particularly in certain sizes. So that's what bubbled up, and that's what we will fix quickly.

We've seen it, just like as I mentioned earlier the other companies have also. It comes up occasionally and you just try to overwhelm it with testing and great processes, but it sometimes happens.

So what we can do in the very near-term is mitigate it with lot-release kind of testing which is a whole other level of testing. It is a little tougher on inventory but it is a good way to make sure everything passes clearly, while we are continuing to improve the processes to just make sure this never happens again.

Ravi Misra - *Leerink Partners - Analyst*

Great, thanks and just wanted a clarification on the whole CE Mark and now this news over the last two weeks. Has there been any sort of increased exposure over that time to FDA or FDA investigations? Or plant checks that would say, let's do another test and see what we need to do here?

Can you just bridge the last couple weeks between us? Was wondering if you had a planned review or anything like that? Or if this is just part of the normal process? Thanks.

John McDermott - *Endologix Inc. - CEO*

We have not had any inspections or any inspections announced to us. We have been in regular communication with FDA on a variety of fronts. As I mentioned earlier, we have been collaborating on an updated physician communication related to AFX, that will go out here in the near-term.

But we are working with them on the Nellix, the IDE and the submission of the two year data. We've been working with them on the approval for the Ovation Altos. We have a lot of interaction with the agency, and I would characterize that interaction to be collaborative.

Ravi Misra - *Leerink Partners - Analyst*

Great, thanks, John.

Operator

And with that, ladies and gentlemen, we have no further questions on our roster. Therefore, I will turn the conference back over to Endologix's management for closing remarks.

John McDermott - *Endologix Inc. - CEO*

Thanks everyone for joining us on this call this morning, and your interest in Endologix. We will, as we mentioned earlier, schedule a follow-up call for later in the week after we get some more work done here and provide you with an update. Have a great day. Thank you.

Operator

And again ladies and gentlemen, this will conclude today's conference. Thank you for your participation. You may now disconnect.