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REFINITIV

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PRESENTATION

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

All right. Good morning, everyone. My name is Danielle Antalffy, the medtech analyst here at UBS. And we are very lucky to have with us on this very exciting fireside chat the Johnson & Johnson Biosense Webster team. We are represented in full force here. Celine Martin, the company Group Chairman of CSS. Sorry, I guess, more than just Biosense Webster. We have Jasmina Brooks, the President of Biosense Webster; and Anthony Hong, VP Preclinical and Clinical Research and Medical Affairs. I know it's probably up there.

But anyway, thank you, guys, for joining. It's a very exciting time in electrophysiology and a lot is happening and a lot is going to happen over the next few months.

QUESTIONS AND ANSWERS

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

So maybe let's get a start, level setting. Biosense Webster is the very clear market leader today in electrophysiology. Can you talk, Celine, about how the EP market has evolved over the last decade? And how do you see it evolving over the next few years with pulsed field ablation, new technology coming online?

Celine Martin

Sure. Happy to. First, thank you for having us. It's a pleasure to be here. And I will say that having been in the space for 20 years, it's very rewarding to be talking today about how much we've come. We've come a long way in terms of the AF ablation established as a standard of care.

So maybe as a starting point, let me spend some time talking about AFib as a disease state, number one. So AFib is the most common cardiac arrhythmia. It's a disease that's impacting about 37.5 million patients around the world. It's an age-related disease. So that means that 1 patient out of 4 above the age of 40 will experience AFib in a lifetime. And the prevalence is on the rise. So we clearly see that by 2030, the prevalence will increase by 70%. And if we fast forward 2050, there will be 5 million patients more added to the pool of patients each and every year.

So you may ask, why does it matter? And it matters because AF is associated with a higher incidence of stroke and heart failure. The risk factor increases by a factor of 5x, and also mortality increases by a factor of 2x. So what we see today is that we've established ablation as a standard of care. If we look back in the last 10, 15 years, if I reflect on our latest product addition QDOT, the procedure is now well established. So the procedure is done in an hour with a success rate of 86% and practically almost no fluoroscopy.

In fact, we had great news in the last week. The FDA approved our portfolio of products that is essentially subject to workflow with - there's no need for fluoro, which is a big breakthrough. So the procedure is well established. The challenge is that only 5% of the AF population that should

get ablation, gets ablation today. So there's 95% of patients that essentially do not get access to therapy. So that's, I would say, the big challenge but also the big opportunity for us.

So as a company, we've been very, very focused on addressing unmet needs. And there's 4 areas we're looking for. One is locate where to ablate, deliver better lesions, simplifying the procedure and eliminate fluoroscopy. And as I said before, we've moved the needle in a huge way in terms of overall standard of care, but there's still much more to do.

So where I see the future is in 3 ways. Number one, a greater diagnosis of AF patients. No question about it. The smartwatches are helping in many ways, and there is greater awareness around AF and AF ablation. Number two, I am convinced that there will be much more innovation coming to the EP segment by virtue of the unmet need. Cadence of innovation will take the procedure time further down and hopefully enable better success rates. And last is greater access to care. So by virtue of the procedure time coming down, there will be many more patients being brought forward to the EP lab for procedure. And all that bodes really, really well for AF patients.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. One of the things -- as far as the 4 things that you've addressed as barriers to adoption, one of the things I noticed you didn't say was the referral funnel, and it sounds like that is something that has potential to improve significantly. What are you guys doing? Or what is the market doing, industry doing to improve that diagnosis of patients? And even if they are diagnosed, getting them referred and getting them to the EP?

Celine Martin

Yes. So I think, again, for over the last 10 years, we've been challenged to drive the market to broaden patient access. And for the longest time, we focused mostly on the technology and the techniques because until you reach a point where you have a high success rate in the hands of many, there's no point in creating further backlogs. And truthfully, we felt that the infrastructure was not ready and the technology was not ready.

So today, what we're doing is we're focusing on giving access to all the tools we have available today to the broader physician population. So we have more than 5,000 CARTO systems. And through our ASA programs, the advance service agreements, we're enabling physicians to access the latest and greatest innovation. So that's still, in my mind, a big enabler to cater to more patients.

Second is we're trying to accelerate the time from diagnosis to therapy. And what we've seen done a lot in the U.S. is this program called from ER to EP. We've seen a lot of patients essentially lose their way in the hospital referral process and being referred from one physician to the next and being kept on drugs forever. So what we're trying to do now is whenever a patient shows to the ER -- shows up to the ER, we're essentially giving them access to an EP early on so that the patient can be catered to ablation sooner in the disease state so that they don't have to progress to persistent or permanent. That's one aspect.

The second aspect, again, back to bottlenecks, is the procedure time and the fact that there's only so many cases that can be done in a day. So we're driving procedure time down, QDOT an hour and sometimes less. But second is we're working with hospitals to minimize the time wasted in between cases. So there is the procedure time and there's what's happening before the case and after the case. And we're enabling the single-day discharge to enable more patients to be catered to.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Okay. Got it. And is there some sort of education initiative that can be done at the referring physician level? Or how do we think about accessing the start of the referral funnel? And I appreciate that maybe some of it is like the EPs can't even handle it right now. So it's a moot point, I guess. But just thinking about the pathway that the patient goes through.

Celine Martin

We're definitely investing a lot in raising awareness around AFib. As I mentioned earlier, the connection between AFib and stroke, the connection between AFib and heart failure, we're raising awareness around that. We have this unique outlet called Get Smart About AFib that's garnered a lot of attention among patients and referring physicians, really raises the level of information and education around what AF is and how it can be treated.

We've also run studies. I think there's one that comes to mind, the ATTEST study, that has demonstrated that if you're essentially getting the ablation procedure done, you're 10x less likely to evolve from paroxysmal to persistent, again, with better outcomes in return.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. And just thinking about the cost -- so cost effectiveness is always the question in medical device therapy. And just thinking about the cost effectiveness here, I hear AFib and you can prevent recurrence, prevent progression. These patients are on drugs for their entire life. You've got to think this is a very cost -- much more a cost-effective modality than treating a patient medically. Is that well accepted?

Celine Martin

It is well accepted. And what I will say is that there is a quality-of-life benefit. There is the notion of readmissions that comes with AF. Again, when it evolves from paroxysmal to persistent to permanent. The cost of moving to heart failure that is now well understood. And nowadays, we're seeing, I want to say, close to 20% of AF patients being de novo patients, meaning that they go to ablation even without getting through the medication.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Okay, okay. Got it. Okay. And I don't know if this is still you, Celine, or whoever wants to take this question, but just the makeup of the overall ablation market today. Obviously, one of the things we're all trying to get our hands around is what this market looks like. From a growth perspective -- this has been a double-digit grower for a decade-plus, right, from a growth perspective but also from a market share perspective, thinking about RF and PFA.

So today, how many of these -- if you can answer this, how many of these are done for atrial fibrillation versus CT and SCT, RF versus cryo mapping versus catheters, paroxysmal versus persistent? However you slice and dice this market, maybe.

Jasmina Brooks

Well, I think we can slice and dice in many different ways. So maybe I'll start with just arrhythmias in general. Atrial fibrillation is the most common arrhythmia today. So majority of the cardiac ablation procedures are treating atrial fibrillation followed by flutter, SVTs and then VTs. So AF still continues to be the fastest growing as well as the largest arrhythmia population that's being treated today.

If you look at persistent versus paroxysmal or paroxysmal versus persistent, it's typically about a 60-40 is the number that we're looking at today, and that may shift. But right now, over the last 10 years, it has been that 60% to 40% split between paroxysmal and persistent AF.

When we look at the modalities of treatment that I use for cardiac ablation today, RF is still the cornerstone. Obviously, there is cryo that has certain percentage of cases. And PFA is the new entrant in the space that time will tell where and how that percentage split is going to look like 5, 10 years from now.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. Okay. And what about emerging markets and maybe first international, but I'm particularly curious about emerging markets. I mean this feels like it's probably very underpenetrated in emerging markets. Is that a real growth opportunity?

Jasmina Brooks

It is. Celine mentioned 5% of patients being treated globally versus those that are actually eligible for AF ablation. That's an average globally. If you look at the emerging market, that number is probably closer to 1% to 2%, maybe.

But what we're seeing the, you mentioned yourself double-digit growth in atrial fibrillation, we're seeing that across developed markets as well as the emerging markets. Our approach to emerging markets versus developed markets is very much the same from the Biosense Webster standpoint. We want to ensure that all of the physicians have access to the latest technologies and the techniques to provide the best patient care, improved safety, efficacy, efficiency.

So our technology, we equally go after regulatory approvals in those markets that we do in the developed markets as well. The same is true for the CARTO mappers and the support that we provide during those procedures. So in general, a very healthy market globally regardless if it's developed or emerging, double-digit growth in AF. And we're hoping that, that 1% to 2% of patients treated in emerging market is going to be moved more towards the 5% general area.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Do you ever envision a world in which we're at over 50% of the patients that should be treated or treated with -- I'm not even going to put a time frame on it ever that we get there, over 50% of the patients?

Celine Martin

I mean it's -- I want to go back to what I said earlier. I mean we have a desire to get to 100% technique success rates, done by 100% of physicians, eventually enabling 100% of patients who need ablation to get ablation. To get to 50%, not any time soon, just by virtue of the bottlenecks we talked about earlier, linked to number of physicians, number of labs and number of patients.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

I'd need to start doing ablations for that to happen. Okay. Well, let's -- maybe before -- I have on the list here PFA, but before we get there, you mentioned QDOT. And I actually, since we have Anthony here, wanted to talk about QDOT and what's going on from the J&J product portfolio specifically perspective. How -- what iteration is QDOT? What does it bring to -- you mentioned the fluoroscopy being a big piece of it and how that's doing in the marketplace?

Anthony Hong

Sure. QDOT is really our latest and greatest in terms of our RF technology. So as Celine mentioned and as Jass mentioned, there's a number of things that we're working on, obviously, on the PFA side, which we'll get into. But really, we see RF as still being an important cornerstone of patient treatment.

And with the IDE trial that we ran, we saw great overall effectiveness, very good safety rates. And with the product's ability to do what's called Q mode+ ablation, you actually have greater efficiency in terms of doing ablations, making the procedure very, very safe and very quick in terms of doing the pulmonary vein isolation. And that's recently going to -- recently approved and will be launched here in the United States.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Okay. Got it. And you mentioned PFA. So that's your fault that we're going to talk about that and not mine. But PFA, so maybe before we talk about what J&J is working on specifically, which you did highlight for the sell-side community at HRS, but how do you see PFA impacting the AF ablation market in the next few years from a growth perspective? I have my biases here, Celine. I think we spoke at the booth about this, but also the market share -- market split between RF, PFA and cryo.

Celine Martin

Yes. So I'll start by saying that I see PFA as the next inflection point in our AF market development by virtue of the benefits that are perceived coming from PFA, namely in terms of safety and in terms of efficiency.

Maybe a few words on the mechanism of action very, very briefly. So radio frequency is a thermal-based modality. PFA is as well, but the mechanism of action is different. So think of PFA that's also called IRE, irreversible electroporation, is essentially very, very short high-voltage bipolar pulses that are essentially delivered across a very, very small period of time, like fractions of a second.

And this mechanism being so quick, it essentially enables to discriminate between tissues. So think of it as -- the energy is going to go and deliver the lesion towards the myocardium but will not create the collateral damages that perhaps are known related to thermal energies like radio frequency. And I'm thinking here about phrenic nerve and esophagus. So there is a perceived notion of safety that makes it extremely compelling for clinicians.

And because the energy delivery is so fast, it's deemed to be efficient. So this, in theory, will enable potentially more patients having access to ablation by virtue of safety profile and obviously procedure time.

Now when we look at the body of clinical evidence, the PFA body of evidence really tells the 20 years' worth of experience we have with radio frequency. And I think there's still a lot we need to learn. We're already aware that even PFA has complications, especially the coronary spasm. So we are cautiously optimistic about the technology.

But what I will say is that our approach as a company, as a market leader is to leverage all the capabilities that we have existing today linked to radio frequency. And I'm thinking navigation, the CARTO system, the feedback related to algorithms and essentially enable a portfolio of technologies coming from J&J that's going to be a wide array of categories, but all powered by this CARTO ecosystem.

So we're going to have a multi-electrode catheter called VARIPULSE. We're going to have a focal tip dual energy, STSF, which is the most widely used catheter in the world. We want this platform to be dual-energy. Why? Because we want to give it the safety profile of PFA but also the proven durability of radio frequency. And we'll have next-gen single shot and we'll have a large tip focal technology called OMNYPULSE.

So we're really approaching it as a broad portfolio to cater to the procedural needs, namely paroxysmal but also, eventually, persistent.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. So actually, to that point, one of my questions here is what do you think are the most important features, characteristics that a PFA catheter has to bring to the market to really drive that inflection that you're talking about?

Anthony Hong

So maybe I'll take that. So I think, first and foremost, it has to be a technology that is usable. So Celine mentioned technology and technique. I often tell my team it's not just the technology itself, but how do we converge technology with technique to drive differentiated outcomes. And so really having a technology in the hands of many that could result in consistent and reproducible results, I think, is important.

We also need to recognize that not all technologies, even from a PFA perspective, are the same. So you have different waveforms, different recipes in terms of the pulse. And so that could vary from company to company. But even within the company, if we think about our portfolio of products, there are different waveforms and recipes that we're developing that will actually drive better outcomes depending on the type of catheter.

Certainly, from a safety and effectiveness perspective, the patient is our north star, and we're making products for the benefit of patients. So we have to drive products that are going to give continued high safety but also provide effectiveness and efficiency. But also, I think it's important for us to think about things that have really worked well on the RF side, contact force, for example.

Years ago when my team ran the SMARTTOUCH trial, we demonstrated the importance not only of the contact force but the stability of contact that results in better outcomes, and that actually helped to change guidelines. And so focusing on things like contact force even with PF. And then the integrated solutions in terms of mapping.

Last night, I was actually having a conversation with my son about this particular meeting. And he said, what is mapping and he's now learning to drive. And I said, well, you use Waze. Back in the old days, I used -- actually used to use a paper map. And he actually said, what's that? What's a paper map? All he knows is what's on the phone. And I said, it's mapping that really enables us to know where we're going, right? Are we going in the right direction?

Now that doesn't make him a better driver. I've got thousands of hours more than him. But I think it's things like integrated mapping and solutions that really enable the larger group of physicians to really work towards consistency, reproducibility, better outcomes for patients. So I think those are the things that we really need to think about going forward.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. Okay. That makes sense. And maybe we could talk about next steps for J&J and PFA. But actually, I just thought of something, if I could. You mentioned this being the -- an inflection. When was the last inflection? Like is there anything historically that you could point to that we could look at as a sort of proxy? Or is this like a totally new frontier for...

Celine Martin

So if I look at inflection point related to effectiveness and also share dynamics for J&J, I would say, the introduction of SMARTTOUCH.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. The contact force, yes.

Celine Martin

So contact force was truly a game changer. And in fact, in the last 6 years, we picked up 10 points of share. And to this day, we're still gaining share despite the fact we're market leaders.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. Okay. That's what I thought. Okay. So J&J's PFA portfolio and VARIPULSE. You presented data at -- I think it was the AF meeting in February. I don't even know if it's still called Boston AF because it's in Orlando, right? It's very confusing.

Anthony Hong

No, it's back in Boston.

Celine Martin

No. It's back...

Jasmina Brooks

Back in Boston, yes.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Okay. I can't keep track. So anyway, maybe talk about next steps for the J&J portfolio and how we should think about J&J entering the PFA field. And if you could, also maybe appreciating what you said about RF is still going to very much be a part of an EP's toolbox, how to think about J&J's EP business over the next year or so as a PFA -- 1 or 2 PFA product launch?

Jasmina Brooks

So maybe I'll start with that one. But the way that we look at PFA development and portfolio, it really is based on years -- 20-plus years of deep experience and expertise that we have developed in cardiac ablation. So Celine and Tony have mentioned some of these things already. Maybe I'll just try to pool it all together.

When we look at the PFA, we're not only looking at a single technology. We have portfolio of products that we'll be bringing to market. And the reason for that is we're looking at the -- truly at the unmet needs of electrophysiologists and go -- and trying to think what type of technology is going to help address specific workflow needs that they have, specific patient anatomies that they may be working with or even just the tailored procedures for different patients. So this is why the full portfolio of PFA products is extremely important.

However, we don't only look at it as one catheter, next catheter, next catheter. The importance of providing that ecosystem that helps them kind of create these procedures, recreate the procedure, standardize them. We think that mapping is the cornerstone on any cardiac ablation today in RF, and it will continue to be the cornerstone with PFA. Because in the end, you not only have the catheter technology, you need to know where the catheter is positioned within the heart. You need to be able to get unique information about that specific lesion.

As Tony mentioned, PFA, unlike RF, is not created equal. It's very different across companies. It's very different across catheters within the same company. So having the information on the lesion, having the information on the dosage that was delivered, showing the information where the lesion was delivered because PFA, unlike RF, you completely lose intracardiac signals as soon as you deliver the energy. So there need to be different opportunities to guide the physicians to know that they have delivered the transmural lesion that's going to have long-term durability, not just acute success.

So in addition to the integration with mapping for navigation, there is a multitude of algorithms that we're developing on the software side to kind of help physicians guide towards understanding that this was a good ablation that was completed, which again, is very similar to what we have done with RF over the years. So we're just kind of carrying the traditional lessons learned, understanding unmet needs into PFA portfolio.

So we're quite confident with the portfolio that we'll be bringing out on the PFA side of things. But at the same time, we understand over these 20 years how important RF energy is and will likely remain part of the cardiac ablation space. So Celine mentioned dual-energy STSF catheter. The way that we're looking at it that ultimately, physicians are going to have to decide what energy they want to use where, in which anatomical structures. And looking at the safety of PFA linked to the durability of RF is going to be also a nice transition for those that are not quite sure about PFA yet but want to be able to use both technologies in a single platform.

So that's the way that we're kind of looking at our PFA development, where we're taking it and the catheters that we'll be introducing, together with the mapping integration and the overall ecosystem that we're going to have.

Anthony Hong

Maybe I can just go a little bit more specifically into the timelines and where we are with the portfolio. I'm sure the audience here would be interested in knowing that. So as Jass mentioned, with a portfolio of products that we have, and you mentioned and asked about the inspIRE. So that's our VARIPULSE circular catheter really designed for pulmonary vein isolation, but we're also looking at ablation outside the PVs. That study has been completed in Europe. We've already submitted for CE Mark, and that's under review at this point.

The same catheter, VARIPULSE, the admIRE trial in the United States has been completed. We expect the last patient visit to occur actually in the November timeframe. And then obviously, from there, we'll have our final report, and ultimately, the submission for U.S. FDA review.

In Europe, we've also completed enrollment for our SmartfIRE trial for the STSF dual-energy catheter that both Celine and Jass have mentioned. And so that enrollment is finished and patients are in long-term follow-up at this point. And then for the United States, the SmartfIRE with STSF dual will be initiating enrollment shortly. So we've got a lot of things that are happening and coming up.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

You guys sound like your bored, probably. Okay. Well, that's great. And I think another thing that's important to point out is Biosense Webster has been delivering strong double-digit growth internationally still. While PFA -- I mean is there any reason to think that what happens in the U.S. wouldn't be similar to what happens internationally, which is RF is still growing double digits, PFA is growing well. Are they structurally different markets for some reason that we should think of the U.S. as being different?

Celine Martin

So I think, as Jass pointed out, our strategy is global in nature and the execution of our strategy is the same irrespective of where you are in the world. We have a pretty well organized go-to-market strategy with our CARTO mappers that you find everywhere around the world. So I don't expect differences. What I will even say is that we've picked up 10 points of share in the last 6 years. And this year, we're gaining share on the global basis.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Globally, yes. Okay. And then just thinking about PFA, we obviously have a big U.S. randomized controlled trial coming up here in the next few weeks, actually. And I'd love to hear what you guys think are -- not about that trial specifically, but just generally speaking, from a clinical data perspective, what is going -- what are going to be the most important metrics to, not necessarily get approval, but to actually really drive the type of adoption that everyone seems in an optimistic scenario? It's like a little blue sky here. I'm guilty of that.

Anthony Hong

Sure. I'll take that, and Celine and Jass can add to it. Look, at the end of the day, from a regulatory perspective, we still need to demonstrate appropriate safety and effectiveness. But I think from an adoption perspective, that also ties into the efficiency.

The PFA programs that we have seen thus far and the results that are available, I think, are very promising. Many people talk about the fact that safety is now already proven. I think we still have some additional work that needs to be done from a safety perspective. Certainly, the rates that we're seeing coming out of the gate, very, very low, which I think is really, really promising.

We are seeing some transient adverse events such as coronary spasms. There have been a few other instances that were reported in other trials. But I really think that from the perspective of collateral damage, certainly in the posterior wall and things like the esophagus and traumatic events like the atrial esophageal fistula, we haven't seen that. However, the sample size among the trials that have been done thus far, still relatively low when you think about it from the perspective of RF. So safety, very promising, really starting off well.

I think if we do an apples-to-apples comparison of effectiveness, this is where I believe most technologies are coming out of the gate around 70%. I mentioned this to a group of analysts at HRS. You have to consider standard-of-care monitoring in a registry versus the stringent monitoring. Advent, I think, is something that has been talked about quite a bit and in anticipation.

And so when you look at standard-of-care monitoring where patients may not be monitored very rigorously, for example, once or twice a year or not at all, versus a stringent monitored trial that is done for regulatory purposes, there is a big difference. And so when you apply the factor of stringent monitoring, most of these registries are -- when you apply that sort of discount factor, the registries are coming in at around 70%. Even our inspIRE trial with the stringent monitoring showed 70.9% primary effectiveness and 78.9% clinical success. And so I think we really need to take that into consideration.

But I think the fact that PFA is coming out very strong with safety, very good effectiveness, there's more work to be done to catch up to, I think, where RF is now where it's north of 85%. It's very promising. But I think it's the combination of those that we really need to demonstrate in order for the adoption to continue.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

And another point to make probably too, I think, correct me if I'm wrong, the initial PFA trials are being done in paroxysmal. And you mentioned 40% of these are being done in persistent patients.

Anthony Hong

Correct.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

And so presumably, those persistent patients if used on label will be still getting RF ablation.

Anthony Hong

Yes.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. Okay. Got it. And if we think about the operator dynamics, so from an EP perspective, are there still EPs that aren't doing ablations because they're not well trained, experienced, et cetera? Is PFA something that can get into the hands of a less experienced operator, and that helps drive market growth? And that wasn't a doc doing RF anyway. So is that something that is happening or could happen?

Jasmina Brooks

Of course, it's a possibility, right, especially if they're concerned with the complications rate. But I mean, complication rates with RF are not -- we're not talking double digit here. We're talking like lower single digits that we've seen. So there may be an opportunity for additional electrophysiologists that may not be doing left-sided procedures, which atrial fibrillation is the left side of the procedure. Knowing that there is the promise of safety with PFA, they may feel more comfortable doing PV isolation.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

And as PFA comes to market, Celine, you mentioned the mapping component navigation. And that's so important. I mean J&J is like the clear market leader in mapping. So how -- do you think PFA -- is the mapping any less important in PFA? Is it more important? Maybe talk about how that's going to help J&J to retain -- gain market share with your PFA portfolio.

Celine Martin

I think Jass touched on this earlier. We have more than 5,000 CARTO systems out there. And the workflow of the procedure, we believe, needs to remain the same. And what has enabled the success rate we have today link to the ablation index, link to knowing where the tip of the catheter is at any moment in time, we believe that those principles are here to stay.

So one commercial strategy we've implemented particularly here in the U.S. is this advanced service agreement concept, which is essentially hospitals invest in accessing a set of capabilities, software- or hardware-based. And a set amount of money every year. They have access to the latest and greatest technology essentially within the CARTO system itself. So we're essentially enabling the muscle memory to be maintained and not having to switch from one capital to the next one, which we know is a constraint at this point in time. So that's our approach to the market dynamics at this point in time.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

The one thing that I've been thinking about over the last few weeks as we get closer to Advent is J&J does not have the implantables that they sell to the EP, so think ICDs, CRTDs, things like that. And you are just selling not -- I mean it's a big product for the EPs, but AF ablation or ablation product. So is there a risk here in some way, shape or form of competitors bundling products and gaining share that way? I mean maybe talk about how sticky share is and whether that is a real risk or that's just me being...

Celine Martin

So I go back to the catheter equipment. I go back to giving monetary incentives for hospitals to access the latest and greatest from the CARTO system through the SA. I go back to the group of CARTO mappers we have to support cases each and every day. Those are very important switching costs that we believe cannot be dismissed when you think of the share dynamics. We index a lot on that as the reason why we believe that most of the customers are going to stick to the technology they are used to. They have it. It's readily available. And as I said earlier, with QDOT, with -- and our procedure time, they're already achieving amazing efficiency and clinical outcomes. So we believe that there is a tremendous stickiness linked to the technology and the people that are there to support.

Jasmina Brooks

If I may add something, this obviously, PFA -- introduction of PFA is not creating this new situation where other companies may have broader cardiovascular portfolio where they can offer this joint product offerings. So we have seen that play out over the last many years, right? In the end, the decision of what product they want to use for what procedure for their specific patient is down to an electrophysiologist, so they're planning their procedure.

One thing that I want to highlight here, we're Biosense Webster, but we're part of J&J MedTech. So this joint product offering doesn't necessarily need to be across the cardiovascular space. But if you look at the portfolio of products that we have as J&J MedTech, there is an opportunity for us to maybe start doing similar stuff across the wide range of the portfolio of products that we have outside of cardiovascular space.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

But my understanding, correct me I'm wrong, this is not -- I mean bundling is not huge thing in EP. Is that correct?

Celine Martin

There is a big physician preference. This is why I'm indexing a lot on the technology because it's not just a procedure. There's training, there's muscle memory, there's the connectivity with the CARTO mappers that gives physicians a desire to stick to what they know and that has been proven over many years for them.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes, yes. Okay. And then let's talk about if we could explore beyond PFA and what could be coming -- or maybe even if it's within PFA, how to continue to improve upon the system. So we -- the product offering, so we get to that 50%-plus share in 2300?

Celine Martin

So first, I would say, as a company, we're agnostic to the source of innovation. We're very fortunate to have a very, very strong R&D organization, a flagship center in Israel, a flagship center in California. So because we've been so focused on AF as our sole point of attention for 20 years, we have subject matter expertise and depth that gives us this edge in terms of innovation. And we always say it's the oxygen of the business.

But it's not just ablation. So when I think of AF, I mentioned earlier the connectivity to stroke and the connectivity to heart failure. So ablation does address the stroke risks, but there's other mechanisms of action to address stroke. And we're keenly interested in the left atrial appendage closure category as one adjacency that we believe is critical to play in. And you're familiar with our WaveCrest technology. That's one area that we're very committed to.

Second, imaging. We acquired NuVision as a company 2 years ago, and we believe that NuVision has the potential to expand within the sphere of EP AF, but also potentially other adjacencies in the IC category. Next to that, I'm thinking heart failure. And I'm thinking structural heart as natural adjacencies to leverage and capitalize on the CD presence we have as J&J.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. And you recently bought Abiomed, which is a big piece of that, yes. Okay. On the left atrial appendage closure, where are you guys with that?

Celine Martin

So we're now in the product development stage, and we'll share some news in the near future about how we're approaching this category. It's an exciting space. And I would say it's one that, from my standpoint, deserves multiple shots on goals.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes, and probably not something that doesn't necessarily -- tell me if I'm wrong, doesn't necessarily reduce the need for an ablation. It's more concomitant to an ablation...

Celine Martin

It is indeed. The trends in the future would suggest that it might be a concomitant procedure where you tackle the need for fixing the rhythm, so bring the patient back into sinus, but also managing the stroke risk.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

And then just you mentioned a lot about the navigation, imaging, things like that. AI is something that's been coming up a lot in conversations. You guys spent some time on it actually at your -- it was your Pharma Day, but -- and I'm curious about how AI is being integrated into ablation solutions and how you see that evolving over time. I imagine you're already starting to do it with CARTO.

Celine Martin

Yes, we have initiatives underway. And maybe, Tony, you can speak to CARTONET, which is a very critical program for us related to harnessing the power of AI in support of generating more clinical evidence.

Anthony Hong

Yes. So before I get to CARTONET, I think the topic of AI and machine learning is very, very important in this space. As we continue to understand the patient characteristics or other factors that drive outcomes, we have to really think about how do we tailor the treatment for the patient. Not every patient is created equal. And if all of us here on stage had AFib, we may be very, very different. Our anatomies are different, and how the physician needs to treat that patient is very different. So really understanding the various different factors that drive outcomes is important.

So as we start to aggregate data, and we're partnering with physicians around the world to really start to aggregate data, and that's where something like CARTONET comes in, where it's a cloud-based database where we now have, I think, over 75,000 procedures where we're now able to analyze the various factors that lead to better outcomes. And so when a patient presents him or herself in the clinic, we can sort of predict what is the appropriate procedure that should be used to drive better outcomes.

It goes back to the integrated solution and the mapping I talked about. When I bought my son his car, I didn't want just a car with 4 wheels. I wanted the lane change assist, the steering assist, the pedestrian alert, et cetera, et cetera, that makes his driving a little bit more safe. And so as we take all of the factors into consideration, it really allows the physician to make appropriate decisions from a treatment perspective on what may work best for that particular patient.

And so as we also gather data from all of our mapping that's been done in partnership with physicians, we can understand wave propagation. We can understand the various different maps that were created and how ablations were done that led to perhaps better outcomes. And so we can really start to take that into consideration and integrate that into our CARTO mapping solution, then becomes a marriage of technology with technique where physicians can really have differentiated outcomes.

Celine Martin

Yes. And I would say I was -- before rejoining Biosense Webster and CSS, for 3 years, I was a part of the surgical robotics program at J&J. And we talked a lot about making surgery smarter, less invasive, more personalized. And that promise rings very true for the space of EP AFib and this notion of making the procedure more personalized based on AI capabilities and making sure that we have the procedural technique that is suited for the type of AF patients we're dealing with is at the center of everything we do. And I would say CARTO is probably the most digitally advanced ecosystem there is at this point in time.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Okay. I was going to ask if CARTONET is there already or if that's -- yes. Okay.

Celine Martin

It is out already.

Anthony Hong

(inaudible).

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

And where to from here with CARTONET? I mean what more can be done?

Anthony Hong

Well, certainly, I think with CARTONET, as we continue the adoption and more and more centers get it, we're able to aggregate data. But even within centers, they're able to use CARTONET with all of the backup data from the ablation to actually understand how they're doing.

And so when physicians first start off in training -- and again, to use the driving analogy, when they start first learning how to drive, they improve over time. And so by having CARTONET, they can actually analyze their own procedures and say, in my first 50 patients, how did I do? What were the characteristics that drove outcomes? And in the next 100 or 1,000 cases, what am I doing as I learn from my past procedures? And that's where CARTONET can be very important.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Okay. Got it. I guess, in the last 2 minutes, is there any sort of message that you either think The Street investors are misunderstanding about the J&J Biosense Webster EP business or CSS broadly that you want to make sure we understand. So you go into these next few weeks, we see Advent make sure you leave an impression on folks, like this is how J&J is doing and will continue to do?

Celine Martin

I think the point that Tony made around the clinical standard of care and the success rates, understanding that is really, really critical. I would say, from a J&J standpoint, we're very bullish about the AF market. We're market leaders. We're gaining share. We have an amazing cadence of innovation

starting today. We have QDOT as the best-in-class RF technology that is out there with a very high success rate, short procedure time. And we're the only company with essentially the no fluoro label. So that's already a huge advancement for AF ablation in terms of standard of care.

And we're moving really fast to the next wave, which is PF-enabled, knowing that we're cautiously optimistic about it, we know that there's still a lot to learn, but you're going to see a cadence of innovation, as I mentioned earlier, of catheters that will be CARTO-powered. And we're very bullish about the clinical success we're going to get from those technologies. And we believe that by virtue of the CARTO installed base, more than 5,000 systems, we'll be able to reach the global patients as fast as possible.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Yes. And I think the installed base is something that's very important to pay attention to. And I mean hospital systems too are going to be wanting procedures to be done off of the CARTO systems. They've already invested in these systems, adding CARTONET on top of that. And once PFA comes, you have -- the learnings that you're talking about will be easily had with PFA.

Celine Martin

And it's technology, it's evidence, but it's also the support around it. We talk a lot about ecosystem, ecosystem of technologies, but ecosystem of people. The role that the CARTO mappers plays is critical to the outcome of the case. They are truly the physician partners in mapping the CARTO cases.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

All right. Well, with that, we're at time. So thank you so much, guys.

Celine Martin

Thank you for having us.

Anthony Hong

Thank you.

Jasmina Brooks

Thank you.