Q2 2018 Earnings Call

Company Participants

- Calvin Darling, Senior Director of Finance & Investor Relations
- Gary S. Guthart, President, Chief Executive Officer & Director
- Marshall L. Mohr, Senior Vice President & Chief Financial Officer

Other Participants

- Bob Hopkins, Analyst
- Brandon Henry, Analyst
- David Ryan Lewis, Analyst
- Isaac Ro, Analyst
- Larry Biegelsen, Analyst
- Lawrence Keusch, Analyst
- Richard Newitter, Analyst
- Tycho W. Peterson, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Intuitive Surgical Q2 2018 earnings release call. At this time, all participants are in a listen-only mode, and then later we'll conduct a question-and-answer session. Instructions will be given at that time. As a reminder, the conference is being recorded.

I'll now turn the meeting over to hour host, Calvin Darling, Senior Director of Finance, Investor Relations for Intuitive Surgical. Please go ahead.

Calvin Darling {BIO 17664656 <GO>}

Thank you. Good afternoon and welcome to Intuitive Surgical's second quarter earnings conference call. With me today, we have Gary Guthart, our President and CEO; and Marshall Mohr, our Chief Financial Officer.

Before we begin, I would like to inform you that comments mentioned on today's call may be deemed to contain forward-looking statements. Actual results may differ materially from those expressed or implied as a result of certain risks and uncertainties. These risks and uncertainties are described in detail in the company's Securities and Exchange Commission filings, including our most recent Form 10-K filed on February 2, 2018 and 10-Q filed on April 18, 2018. Our SEC filings can be found through our website or at the SEC's

EDGAR database. Investors are cautioned not to place undue reliance on such forward-looking statements.

Please note that this conference call will be available for audio replay on our website at intuitivesurgical.com on the audio archive section under our Investor Relations page. In addition today's press release and supplementary financial data tables have been posted to our website.

Today's format will consist of providing you with highlights of our second quarter results as described in our press release announced earlier today followed by a question-and-answer session. Gary will present the quarter's business and operational highlights. Marshall will provide a review of our second quarter financial results, then I will discuss procedures and clinical highlights and provide our updated financial outlook for 2018. And finally, we'll host a question-and-answer session.

With that, I'll turn it over to Gary.

Gary S. Guthart {BIO 3429541 <GO>}

Good afternoon and thank you for joining us on the call today. Our second quarter of 2018 was a strong one in pursuit of our mission to improve the availability and quality of minimally invasive surgery. Customer use of our systems and procedures exceeded our expectations in the quarter, with good performance in new system placements and increased system utilization at existing customer sites.

We believe acceptance of da Vinci in general surgery in the United States, growth internationally, and appreciation of our Generation 4 platform by surgeons underpins our recent growth. That said, we're neither satisfied nor comfortable. There is substantial opportunity for improvement in surgery and our customer base has demonstrated sustained interest in our new approaches to old problems.

Global procedure growth was approximately 18% in the second quarter of 2018 compared with the second quarter of 2017, accelerating from our Q1 growth rate. Regionally the United States showed particular strength with healthy growth in hernia repair and colorectal procedures. Mature procedure growth in the United States, including prostatectomy and hysterectomy continued to top our expectations.

Our first quarter aggregate procedure growth in Japan, after reimbursement listing, was in line with our expectations. European procedure growth was generally in line with our expectations with particular strength in the UK and mixed performance elsewhere. Calvin will review procedure trends in greater detail later in the call.

Our capital placement performance in the second quarter of 2018 accelerated relative to 2017 with growth in total placements rising 33% from 166 to 220. Net of trade-ins and retirements, our da Vinci installed base grew 12% over Q2 of 2017. The mix of system placements between our flagship Xi System, our value X System and refurbished Si

Systems aligned with our strategy regionally. Capital placements have historically been lumpy, and we anticipate volatility in placements for the remainder of 2018.

Turning to operating performance, our teams executed to plan, with manufacturing and quality costs meeting our goals and average selling prices within our expected ranges. On the investment front, we are building our organization and making targeted infrastructure investments to deepen both our technological and regional capabilities. Fixed cost spending in the quarter was slightly lower than we anticipated largely due to the timing issues that we anticipate will catch up in the back half of the year.

Highlights for our second quarter operating results are as follows. Procedures grew approximately 18% over the second quarter of last year. We placed 220 da Vinci Surgical Systems, up from 166 in the second quarter of 2017. Our installed base grew 12% from a year ago. Revenue for the quarter was $909 million, up 20%. Pro forma gross profit margin was 71.1% compared to 71.4% in the second quarter last year. Instrument and accessory revenue increased to $476 million, up 20%. Total recurring revenue in the quarter was $643 million, representing 71% of total revenue.

We generated a pro forma operating profit of $389 million in the quarter, up 23% from the second quarter of last year, and pro forma net income was $327 million, up 42%. Marshall will take you through our finances in greater detail shortly.

Delivery of substantive technology and service improvements are core to continued progress in surgery. We measure our innovations by their ability to positively impact outcomes in the hands of our customers, to be used efficiently while lowering the total cost of treatment per patient episode and for their positive impact on the experience with surgical patients. With increased interest in da Vinci from general surgeons, we have added our 60mm SureForm surgical stapler to our product portfolio with 510(k) clearance this month joining its prior CE mark. Our second-generation cut and seal instrument, Vessel Sealer Extend, is in its first quarter of U.S. launch with outstanding customer feedback, and we have submitted our 510(k) for an enhanced grasper for hernia repair.

As we've said in the past, we design our products, systems, instruments and software to work together seamlessly as an ecosystem to enable a holistic approach to a surgical procedure. These latest instruments and software releases are optimized for our Generation 4 platform in general surgery. We obtained FDA clearance for our da Vinci SP Surgical System for urologic surgical procedures in Q2 this year, and we are finalizing our transoral clinical IDE for SP this quarter.

We plan to launch the da Vinci SP Surgical System in the United States in phases, with first customer shipments expected to begin late Q3 or early Q4 this year. Our first access sites will focus on clinical data generation and customer feedback. Surgeon interest in SP is high and we believe SP to be a platform technology with potential application in a number of surgical specialties.

Consistent with our history, we will engage surgeons and regulators in clinical assessments for new applications of SP and anticipate filing additional 510(k) applications

over the next couple of years.

Our team is progressing to plan on our flexible robotics platform, initially targeted to address the acute need and diagnosis of lung cancer, one of the most commonly diagnosed forms of cancer in the world and for which early detection is important. Feedback from physicians evaluating our technology relative to existing and recently announced alternatives remains strongly supportive of our efforts. We anticipate submitting our 510(k) in this back half of 2018 and are working through final design validations and the bring-up of our supply chain.

As our approach to surgery has gained traction, organizations large and small are hurrying to participate in the market. Their entry is an inevitable reaction to positive change in the operating room. Customers appreciate options from Intuitive and others, and we anticipate customers will evaluate alternatives as they appear. At Intuitive, we are sharply focused on understanding our customers' world and providing them with products and services they value highly.

To take a simple example, our systems are available to start and able to complete cases with remarkable predictability, considering their use of a wide range of sophisticated technologies. This is a consequence of our holistic design and integration principles, the capability of our staff, and our deep commitment to understanding the surgical team's world. We believe it sets a high bar for new entrants in the eyes of the thousands of surgeons who use da Vinci weekly.

For the balance of 2018, our focus remains in completing the tasks we've set for ourselves. First, continued adoption of da Vinci in general surgery; second, continued development of European markets and access to customers in Asia; third, advancing our new platforms, imaging, advanced instruments, da Vinci SP, and our flexible catheter platform; and finally, support for additional clinical and economic validation by global region.

I'll now turn the call over to Marshall, who will review financial highlights.

Marshall L. Mohr {BIO 5782298 <GO>}

Good afternoon. I'll describe the highlights of our performance on a GAAP and non-GAAP or pro forma basis. Our results are also posted on our website.

Second quarter 2018 revenue of $909 million grew 20% compared with second quarter 2017 revenue of $759 million and increased 7% compared with first quarter revenue of $848 million. The year-over-year revenue growth benefited by approximately 100 basis points from a weaker dollar.

Second quarter 2018 procedures increased approximately 18% compared with second quarter 2017 and increased 8% compared with last quarter. Procedure growth continues to be driven by general surgery in the U.S., in urology worldwide. Calvin will review details of procedure growth later in this call. Instrument and accessory revenue of $476 million increased 20% compared with last year, which is higher than procedure growth reflecting

increased usage of our advanced instruments, partially offset by customer buying patterns.

Instrument and accessory revenue realized per procedure was approximately $1,850, an increase of 1% compared with the second quarter of 2017 and a decrease of approximately 4% compared with last quarter. The increase compared with last year reflects increased advanced instrument usage and the impact of the weaker dollar, partially offset by customer buying pattern. The decrease relative to last quarter primarily reflects customer buying patterns, partially offset by increased advanced instrument usage.

Systems revenue of $277 million increased 25% compared with the second quarter of 2017, primarily reflecting higher system placements, an increased lease-related revenue, partially offset by lower ASPs and an increased number of operating leases. We placed 220 systems in the second quarter of 2018 compared with 166 systems in the second quarter of 2017 and 185 systems last quarter.

44 operating lease transactions, representing 20% of total placements, were completed in the current quarter compared with 16% of total placements in the second quarter of 2017 and 23% last quarter. While the number of leases is difficult to predict in the short term, we expect the proportion of these types of arrangements to increase in the long term.

34% of current quarter system placements involve trade-ins, reflecting customer desire to access or standardize on our fourth-generation technology. This is an increase in the proportion of trade-in transactions compared to 20% in the second quarter of 2017 and 31% last quarter. However, trade-in activity can be lumpy and difficult to predict.

72% of the systems placed in the quarter were da Vinci Xis, and 21% were da Vinci X Systems compared with 76% da Vinci Xis and 16% da Vinci Xs last quarter. Our installed base of da Vinci Systems increased 12% year-over-year, and our average system utilization grew in the mid-single-digit range.

Globally, our average selling price, which excludes the impact of operating leases, lease buyouts and revenue deferrals, was approximately $1.42 million, which is lower than $1.46 million last year and $1.49 million in the first quarter. The decrease primarily reflects a higher mix of trade-in transactions.

Outside of the U.S., results were as follows. Second quarter revenue outside of the U.S. of $265 million increased 28% compared with the second quarter of 2017 and decreased 4% compared with last quarter. The increase compared with the prior year reflects increased systems revenue of $25 million or 32% growth and increased instruments and accessories revenue of $27 million or 31% growth. The increase in systems revenue was driven by an increase in the number of systems placed, partially offset by lower ASPs reflecting an increase in the number of trade-in transactions. The increase in instrument accessory revenue was primarily driven by procedure growth in customer buying patterns.

The decrease in OUS revenue relative to the previous quarter reflects a higher number of system lease transactions, lower system ASPs reflecting increased trade-in transactions and customer buying patterns related to INA. OUS procedures grew approximately 22% compared with the second quarter of 2017. OUS procedures were positively impacted by the timing of holidays in 2018 compared to 2017.

Outside the U.S. we placed 82 systems in the second quarter compared with 63 in the second quarter of 2017 and 73 in the first quarter. Current quarter system placements included 39 into Europe, 13 into Japan and 9 into Australia. 30 of the 82 systems placed in the second quarter were X Systems. Placements outside of the U.S. will continue to be lumpy as some of the OUS markets are in early stages of adoption, some markets are highly seasonal, reflecting budget cycles or vacation patterns and sales into some markets are constrained by government regulations.

Moving on to the remainder of the P&L. The pro forma gross margin for the second quarter of 2018 was 71.1% compared with 71.4% for the second quarter of 2017 and 71.6% last quarter. The decreases primarily reflect lower system ASPs and revenue mix. Future margins will fluctuate based on the mix of our newer products, the mix of systems and instrument and accessory revenue, system ASPs and our ability to further reduce product costs and improve manufacturing efficiency.

Pro forma operating expenses increased 14% compared with the second quarter of 2017 and decreased 1% compared with last quarter. The decrease relative to the first quarter primarily reflects the impact of payroll taxes. Overall, our spending was below our annual guidance reflecting the timing of expenditures. We expect spending to increase in the last half of 2018, consistent with our guidance.

Our pro forma effective tax rate for the second quarter was 19.7% compared with our expectations of 20% to 21%. Our tax rates will fluctuate with changes in the mix of U.S. and OUS income, changes in taxation made by local authorities and with the impact of onetime items.

Our second quarter 2018 pro forma net income was $327 million or $2.76 per share compared with $230 million or $2 per share for the second quarter of 2017 and $288 million or $2.44 per share for the first quarter of 2018.

I will now summarize our GAAP results. GAAP net income was $255 million or $2.15 per share for the second quarter of 2018 compared with GAAP net income of $223 million or $1.94 per share for the second quarter of 2017, and GAAP net income of $288 million or $2.44 per share for the first quarter of 2018. The adjustments between pro forma and GAAP net income are outlined and quantified on our website and they include excess tax benefits associated with employee stock awards, employee equity and IP charges and legal settlements, including the previously announced second quarter 2018 charge of $42.5 million.

Note that the IRS has not issued final tax regulations associated with the recent U.S. tax legislation. Therefore, impacts of the U.S. Tax Cuts and Jobs Act reflected in our results

and our projection of future tax rates represent our best estimates of the impact of the U.S. Tax Cuts and Jobs Act and could change as tax regulations are finalized and further interpreted.

We ended the quarter with cash and investments of $4.3 billion compared with $4.1 billion at March 31, 2018. The increase reflects cash generated from operations of $220 million. We did not repurchase any shares in the quarter and have approximately $718 million remaining under the board buyback authorization. In the quarter, we repatriated $1.4 billion of cash to the U.S. since the earnings have previously been taxed under the U.S. Tax Reform Act of 2017 and there were effectively no foreign taxes assessed on the repatriation. We've not changed our capital deployment strategy or plans.

And with that, I'd like to turn it over to Calvin who will go over procedure performance and our outlook for 2018.

Calvin Darling {BIO 17664656 <GO>}

Thank you, Marshall. Our overall second quarter procedure growth was 18% compared to 16% during the second quarter of 2017 and 15% last quarter. Our Q2 procedure growth was driven by a 17% growth in U.S. procedures and 22% growth in OUS markets. In the U.S., procedure performance across general surgery, gynecology and urology all exceeded our expectations, with Q2 year-over-year growth rates accelerating modestly across these largest categories. Q2 procedure performance was again driven by growth in general surgery. Hernia repair and colorectal procedures continued to lead the way as these categories again added the most incremental cases.

As usage of da Vinci in the U.S. general surgery expands, other general surgery procedures contributed larger numbers of incremental cases than previous quarters. In U.S. gynecology, second quarter 2018 growth was consistent with 2017 and Q1 2018 trends as procedures in this mature category grew modestly year-over-year with growth led by hysterectomy. We'd hypothesize our growth in gynecology to be driven by favorable surgical consolidation trends as our da Vinci surgery data indicate an increasing proportion of U.S. gynecology procedures are being performed by higher volume physicians that specialize in complex, benign and cancer surgery.

Q2 U.S. urology procedures also had growth rates consistent with 2017 and Q1 2018, driven by prostatectomy volumes. As a mature procedure category, we believe that our U.S. prostatectomy volumes have been tracking to the broader prostate market, which has benefited from recent macro trends. In U.S. other procedures, adoption of lobectomies and other thoracic procedures was again solid during the second quarter. Utilization of our da Vinci Xi Systems and surgical staplers, which helped to optimize robotic thoracic procedures, has been increasing.

Second quarter OUS procedure volume grew approximately 22%, compared with 22% for the second quarter of 2017 and 18% last quarter. Second quarter 2018 OUS procedure growth was driven by continued growth in dVP procedures and earlier stage growth in kidney cancer procedures, general surgery and gynecology. As expected, Q2 OUS

procedure growth was higher than Q1, benefiting from more operating days, resulting from the timing of holidays, including Easter.

Procedure growth in Japan accelerated as initial cases were performed within a set of 12 additional procedures approved for reimbursement effective April 1. Procedure growth in China again moderated in Q2 as da Vinci System capacity expansion is constrained by system quota requirements, the most recent of which expired at the end of 2015. In Europe, procedure results varied by country with particular strength in the UK.

Over the years, the discussion surrounding da Vinci surgery has been centered around the clinical patient benefits. In addition, we believe there is substantial opportunity to create surgeon value as well by improving the ergonomic characteristics of surgery. In 2017, in the Annals of Surgery, Dr. Chantal C.J. Alleblas et al. published an analysis entitled Prevalence of Musculoskeletal Disorders, MSDs, Among Surgeons Performing Minimally-Invasive Surgery: A Systemic Review. This metastudy reviewed 35 articles, including over 7,000 surgeons.

The authors characterized the risk factors associated with lap surgery to include "static body posture, repetitive upper extremity movements and forced exertion from adverse positions. Moreover, the workload is increased by the high level of task precision and time pressure. Physical demands differ between open and laparoscopic surgery and comparative studies have reported higher prevalences of physical complaints for laparoscopic surgeons. Recent studies report MSD prevalence rates of 73% to 88% among specialists in MIS. Relative to the general population, these numbers are excessively high."

In their study, the authors found, "a 74% prevalence of physical complaints among laparoscopic surgeons; however, the low response rates and the high inconsistency across studies leaves some uncertainty, suggesting an actual prevalence of between 22% and 74%. Fatigue and MSDs impact psychomotor performance; therefore, these results warrant further investigation."

While pain ratings are subjective, we think there's opportunity to improve ergonomics for surgeons. With our recent bariatric surgery indication and SureForm 60mm stapler 510(k) clearance, we are better positioned to serve bariatric surgeons.

I will now turn to our financial outlook for 2018. Starting with procedures. On our last call, we forecast full year 2018 procedure growth within a range of 12% to 15%. We are now increasing our forecast and estimate full-year 2018 procedure growth of 14.5% to 16.5%.

Turning to gross profit. We continue to expect our pro forma gross profit margin to be within a range of between 70% and 71.5% of net revenue. Our actual gross profit margin will vary quarter-to-quarter depending largely on product, regional and trade-in mix and the impact of new product introductions.

Turning to operating expenses. We continue to expect to grow pro forma 2018 operating expenses between 16% and 18% above 2017 levels as we follow through on investments in

several strategic areas intended to benefit the company over the long term. We continue to expect our non-cash stock compensation expense to range between $245 million and $255 million in 2018 as forecast on our last call. We expect other income, which is comprised mostly of interest income, to total between $70 million and $75 million in 2018, up from $55 million to $60 million forecast on our last call.

With regard to income tax, on our last call, we forecast our 2018 pro forma income tax rate to be between 20% and 21% of pre-tax income. We are now shifting our estimates slightly lower to a range of between 19.5% and 20.5% of pre-tax income.

That concludes our prepared remarks. We will now open the call to your questions.

Q&A

Operator

And our first question from Tycho Peterson with JPMorgan. Please go ahead.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Hey. Thanks. Great quarter. I want to just start with the U.S. procedure growth. You had about a 300-basis-point sequential acceleration. Can you maybe just talk a little bit more about that? I mean, hernia has obviously been doing well for a while, but you really seem to have an inflection here. So can you talk to maybe the sustainability of what you saw here in the quarter?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. We approach procedure enablement by designing system, instruments and imaging and software elements with surgeon feedback. And with the introduction of our Xi System and our next-generation advanced instruments and refinements imaging software, our customers are seeing real value in general surgery, particularly with the Gen 4 systems. And you mentioned hernia repair and colorectals, they've been leading adoption, and we've seen organic interest from bariatric surgeons as well. As our SureForm 60mm stapler comes to market and with the addition of the Gen 4 labeling in bariatrics, we look forward to serving those opportunities as well.

A - Gary S. Guthart {BIO 3429541 <GO>}

Tycho, it's Gary. One of the things we look at as you know is the stick rates or reorder rates, and just to see, are people trialing, are they staying with it. And in hernia repair and colorectal, we're seeing nice stick rates on those sides. So we feel like we're building momentum here.

A - Marshall L. Mohr {BIO 5782298 <GO>}

So you also asked about sustainability, and I think prostatectomy – urologic increases as well as gynecologic increases in the U.S. have surprised me. And I don't have as much confidence that those are sustainable.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Okay. And then thinking a little bit ahead on pipeline, can you talk a little bit about the data roadmap for flex cath? Obviously, you're doing a lot of the optimization work on the manufacturing side. But how should we think about incremental data coming out ahead of the launch?

A - Gary S. Guthart {BIO 3429541 <GO>}

Nothing new to report for you there. Certainly, as it starts coming into the market, you'll see early sites start to take a broader data collection and so on. With regard to what regulators want to see, we'll see what happens with regard to their feedback to our submission when that occurs. So I don't have anything to point you to at this time.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Okay. And the last one, Gary, you mentioned interest in SP beyond the initial opportunity set you've talked about. Are you willing to comment on some of those areas? It seems like there's some interest in cardiology based on checking what (28:22) others have done. How prevalent is that in some of your early discussions?

A - Gary S. Guthart {BIO 3429541 <GO>}

I have been pleased so far with the interest that SP is generating in our customers to explore where it can create real value. The things we've talked about with you earlier, clearly, some interest in urology. We think there'll be real interest in colorectal surgery and transoral surgery as well. We've had early discussions in several other specialties. I think it's very early to start pointing our investor base I think towards one or the other is probably too soon. That said, it provides access to the body that comes in fundamentally differently than an Xi brings instruments into the body. And we did that because we think it'll provoke interest in the value creation and other places. As we get more experience as these come out into the world, then we'll keep you up-to-date.

Q - Tycho W. Peterson {BIO 4279327 <GO>}

Okay. Thanks. Congrats on the quarter.

A - Gary S. Guthart {BIO 3429541 <GO>}

Thank you.

Operator

And we go next to Amit Hazan with Citi. Please go ahead.

Hey, guys. This is Jamie (29:35) on for Amit. Can you hear me okay?

A - Gary S. Guthart {BIO 3429541 <GO>}

Yes.

Q - Operator

Great. So first, a question just on system features. When you think about the benefits and challenges of an open console and also separately the benefits and challenges of the system with arms mounted on a table, how do you guys just think about those types of features that your competitors are starting to talk about?

A - Gary S. Guthart {BIO 3429541 <GO>}

Just zooming out for a minute, I think the way we think about it for our customers is what allows for smooth operations across a population of patients and a broad set of procedure types from urology to gynecology to general surgery to thoracic surgery and so on. And as we think about those things, we've been at this for a long time. The idea of mounting things to tables, the idea of mounting them to floors, of having them be modular, of using open consoles versus consoles that have immersive viewers, have been around quite a bit and we have evaluated and tried a lot of them.

We came to these decisions not based on whiteboard analysis, but on building things and talking to our customers and working through it. So it doesn't mean that we're right. Could absolutely mean that somebody else did something slightly different and they evaluated it differently. But we were not casual about this, and we did it with serving a population of patients, a population of surgeons across a procedure set in mind. With that, I'm comfortable where the company has made its investments.

Q - Operator

Okay. Thanks for that. And then, a question on the imaging side. With what you guys are working on for the first generation launch, is that basically going to be pre-op images only? Or is there a possibility to do real-time imaging in that first generation launch? Just help us understand the technology roadmap from here and timing expectation.

A - Gary S. Guthart {BIO 3429541 <GO>}

I'm not quite sure when you say first gen imaging – we have done a lot of things in imaging for a lot of years, so perhaps a little clarity on what...

Q - Operator

I'm sorry, for the imaging on-lay side of thing.

A - Gary S. Guthart {BIO 3429541 <GO>}

Overlays. With regard to this, I think, you're talking a little bit about image fusion, the idea of using pre-operative images like CT scans or MRI with endoscopic images and fusing those two together. Again, ideas, there have been around for many years. Today in existing shipping systems, customers can use something called Tile-Pro to bring up pre-operative images and compare them in real-time to what they're using. There are some other things in the works that allow for tighter integration of those images in fusion. We have not set expectations on timelines nor on future content yet.

We have a lot of technology capability there. We will bring something out when we feel like it really makes a difference in surgeons' lives and enables them to either create different outcomes or be more efficient. There's potential. Nothing to update you in terms of timing.

Q - Operator

Okay. Great. Thank you.

And we go to David Lewis with Morgan Stanley. Please go ahead.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Good afternoon. Gary or team, want to start with systems momentum in the first half of the year. So last quarter, we saw increased trade-outs and again this quarter. So I just wonder how are the dynamics in your mind different this quarter than last quarter? What are your thoughts to sustainability of the system trends? And any concerns on driving SP here in the back half of the year as you're also aggressively driving customers to the Gen 4 platform? And then I had a quick follow-up.

A - Marshall L. Mohr {BIO 5782298 <GO>}

I think we don't see a real change in terms of momentum from one quarter to another, at least first quarter or second, other than, as you indicated, you see a higher percentage of trade-ins. The fourth generation product has some features in it I think that we're seeing excitement from the general surgeons about utilizing for the procedures we talked about earlier; colorectal procedures, thoracic procedures. And I think hospitals and surgeons want to avail themselves to that technology. So we're seeing trade-outs.

We're also seeing some desire to have standardization within a hospital where they only have one set of instrumentation to manage rather than two. And so trade-ins are difficult to predict as to where we are in a particular cycle or how much will happen in any particular quarter, but what we have seen is a slight increase in those trade-ins.

A - Gary S. Guthart {BIO 3429541 <GO>}

Two things I'd add to that. One is customer use and efficiencies with Generation 4 platform is quite good. So we are pleased to see their interest. And, to the extent that we can be flexible and help them move into Gen 4, we will. With regard to SP, our initial thought here in Phase I of the launch is, is not to do an enormous capital placement of SP. It's really to establish clinical data centers and build out the value story as we go and to really begin the early collection for next indications.

Over time, as we build out that experience base, our interest in expanding the SP footprint will increase, but that's a multi-quarter conversation, not a really quick turn. SP long term – and I think we've talked about it – in beginning SP will go out as full systems. But as we build out the evidence base, it will be a part of the Gen 4 platform. It will be easy to upgrade and configure as part of Gen 4 and that's been part of our thought process for some time.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Okay. And then, Gary or team, just on Asia Pac strategy, broadly. Didn't hear much about Japan in this particular transcript. How are you encouraged by the early traction in Japan? Is that sort of on plan, ahead of plan, maybe comments there? And then, Gary, you've talked about before, I think, you made some statements at a certain point of the year, with the absence of the China quota obviously reduces the likelihood this year. Any updated thoughts on the likelihood of China this year and any impact on just tariff rhetoric on getting that deal done? Thanks so much.

A - Gary S. Guthart {BIO 3429541 <GO>}

Okay. On Japan, first quarter here after the listing, we're pleased with the interest of the customer base. Our training facilities are busy. We're pleased with that. We are really testing the capabilities now of our newly-formed or newly-grown team in Japan to really execute. So I think a little early to tell the ultimate performance there. First steps look fine.

I think there's real work to do. And so our team and we are focused on really execution. It's not a big strategy question. It's getting the training pathway to the proctoring pathway, to the follow-up pathway, to the support on-site really built and operating well. And that's what we've asked the team to focus on and we will be focused on. The first step of demand generation looks really good.

So moving to China, I'll speak briefly to the quota, I'll ask Marshall to speak briefly to the impact – the potential impact of tariffs. On the quota side, we have no real update to supply you with. We are awaiting an additional quota. No news there. Overall, I think the atmospherics that are going on globally do not help that conversation. I don't have anything specific to tell you there. But generally speaking, I think the atmospherics of those conversations are not helping the quota generation.

You do see, as we had told you in last calls, that a procedure upside is going to require additional capital if we think the demand is there. And so there's a problem we need to solve. China is important to us as a market and for our joint venture. We are committed to it. And we're going to have to work through current macro challenges that are out there. Marshall, you might speak to.

A - Marshall L. Mohr {BIO 5782298 <GO>}

Yeah. The tariff situation is, obviously, dynamic. The first round of tariffs that have been imposed do impact some of the components that our suppliers use to supply us. We're studying that as we speak. We think that the estimated impact will be modest in terms of the increase in product cost for our systems. That's not a cost or a level that we're going to pass any of those costs on to customers at this point in time.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Okay. Thanks so much. Nice quarter.

A - Gary S. Guthart {BIO 3429541 <GO>}

Thanks, David.

Operator

And we go to Bob Hopkins with Bank of America. Please go ahead.

Q - Bob Hopkins {BIO 2150525 <GO>}

Well, thanks for taking the questions. And, again, congrats on a great first half. I wanted to start with SP. Gary, you characterized interest in SP as high. I was wondering if you could just go into a little more detail and comment maybe on which types of accounts are expressing initial levels of interest. And will you restrict a center – if they're interested in SP, will you restrict them? So I just want to get a little more color on how you're thinking about SP.

A - Gary S. Guthart {BIO 3429541 <GO>}

In terms of accounts, there's a fair amount of interest that's I think broad across the segments. For us, first of all, we have a set of clearances that we have that will allow access to it to get started. And then, subsequent data collection to do for additional clearances, so that will determine the early access strategy there is really around what clearances we have and the ones we want to pursue in the future.

We will be supply-limited for the first few quarters here. So the answer there is there'll be a bit of a line to put these first set out as we go. Now, as we get the additional clearances and master the technologies, then I think that gets a lot easier, but it'll be a designed rollout to start.

Q - Bob Hopkins {BIO 2150525 <GO>}

Also, you made a comment in your prepared remarks about the potential for volatility in capital for the rest of 2018. Is that just because there could always be volatility in capital? Or is there something specific that you're referring to?

A - Marshall L. Mohr {BIO 5782298 <GO>}

No. There is nothing specific. It's really the – just in general, it's hard to predict capital given budget cycles, given government regulations in the case of China and just seasonality. So it's just hard to predict when hospitals will actually purchase and so you can see it be lumpy over time.

A - Calvin Darling {BIO 17664656 <GO>}

What happens also is the aggregate reporting, of course, averages a lot of lumpiness that happens underneath. So even if the aggregate looks smooth, the regional variances can be reasonably high. And so it's just as Marshall properly said, nothing specific, but the general dynamics that are out there.

Q - Bob Hopkins {BIO 2150525 <GO>}

Particularly on stapler and vessel sealing, if you're successful with those launches, shouldn't we start to see upward momentum in your revenue per procedure? I realize there's a lot of things that affect that line, but those are two pretty chunky products. And just curious if you're successful with those launches, should we expect that line item to start to move higher?

A - Calvin Darling {BIO 17664656 <GO>}

Yeah. When you look at revenue per procedure overall, there's clearly some variance quarter-to-quarter. We talked a lot about customer timing, order timing and things like that. So quarter-to-quarter, you see those things. But we are seeing an increasing contribution from advanced instruments, including our stapling products, which are getting more usage as well as the vessel sealing. We introduced a new version of our Vessel Sealer Extend in the last quarter.

And now the 60mm stapler that we'll be rolling out here in the third quarter with expanded access available in the fourth quarter, that just serves to expand this category further. Rounds out our product line a little further for stapling and provides a more optimized tool within the category of bariatrics. So the simple answer is yes that that will just be more on our advanced instruments side of things that that element will serve to be a tailwind for revenue per procedure.

A - Bob Hopkins {BIO 2150525 <GO>}

Great. Thank you.

Operator

And we go to Larry Biegelsen with Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good afternoon. Thanks for taking the question. You did I think 16.5% procedure growth in the first half of the year, if I'm doing the math right. Just my question is the second half, the guidance implies about 12.5% to 16.5% in the second half of the year, again, if I'm doing the math right. But the question is, Calvin, what gets you to the low end, what gets you to the high end? What are some of the assumptions that would get you to the high end, low end there? And I had one follow-up.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, sure. You're sitting six months into the year now. Year-to-date procedures are actually rounding up to 17%, but as you described, and so it's pretty straightforward. I think you look at it right now and at the high end of the range, we are talking about a continuity of the trends we saw in the first half across geographies and procedure sets.

Then at the lower end of the ranges, we are talking about moderation. Marshall talked a little bit about the mature procedures and we've continued to beat our expectations in these categories, urology and gynecology in the U.S., but some moderation in those

categories would be considered at the low end. And even in general surgery, we're performing very strong, just somewhat less robust growth in now our largest category in the U.S. would be contemplated at the lower end.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks. And then for my follow-up, I think bariatric has been tough to convert because of good lap outcomes. What's your strategy to penetrate this market? How meaningful is the 60mm stapler driving adoption? And what should we expect from an uptake standpoint? Thanks for taking the questions.

A - Gary S. Guthart {BIO 3429541 <GO>}

Thanks, Larry. It's a good question. On bariatrics, really, our customers have pointed us here. This is one where, as you've said, there's a fair amount of penetration of laparoscopy and outcomes are generally good. And so you can ask, why are they asking here? What's the organic interest? Like all things, we've said to you in earlier procedure adoptions, in the early days, there are clearly subsegments of a particular procedure.

In the case of bariatrics, sleeve gastrectomy, gastric bypass, revision procedures are all underlying segments. And where we find value as an entry point, I think, will have to develop over time. Clearly in revisional surgeries, in complex, comorbid cases, we see real interest on the part of surgeons. And so that appears to be a place that they're finding some entry point.

There's a wild card here, as Calvin alluded to, which is there's an ergonomic benefit for laparoscopists. And bariatric surgeons tend to be high-volume surgeons and it tends to be a challenging – physically a challenging procedure. And there may be some value there, too. So we're not ready yet to call what the market sizes are of those subsegments and where exactly all the value creation will be, but the organic interest is pretty high. And so we're going to engage our customers and follow their lead here, and short answer is stay tuned.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thank you very much.

Operator

We go to Rich Newitter with Leerink Partners. Please go ahead.

Q - Richard Newitter {BIO 16908179 <GO>}

Hi. Thanks for taking the questions and congrats on the quarter. The first one, Gary or team, we've picked up on a couple of institutions who have said that they're looking at new ways to get increased systems into their hospitals just given the demand from general surgeons that don't have enough time on their existing footprints.

And I'm just curious, what are some of the ways that we can think you might get creative on placing these systems beyond operating leases? Would you do minimum volume commitments for some upfront system placement model whereby, if the volumes aren't met over some predetermined time, you take the – you have the right to take the systems back? That was one model we had heard discussed. I was just curious, is this happening or are there other creative ways that you're potentially going to accelerate your footprint ahead of competition coming?

A - Marshall L. Mohr {BIO 5782298 <GO>}

First of all, the objective is to get systems out there, to get the productive and to provide improved surgery to patients. I think we've been flexible with leases. And when I say flexible, we've structured those very short-term leases, almost rentals that would get them past the budget cycle to what you would call plain vanilla leases that are five-year term with the piece of equipment staying with the customer at the end of the lease. We're willing to be flexible even further. And so although we have talked about different models, I don't think that we've rolled anything out that is important to the results at this point. But we will be flexible. We'll think about different models to get – to eliminate the barrier from a capital expenditure perspective.

A - Gary S. Guthart {BIO 3429541 <GO>}

The major things we're looking for when thinking about flexibility here really on the customer side is that they have a long-term commitment in terms of access to the system, that the access matters to them. We have confidence in our systems such that we're not too worried about a right of return and things like that. I think that if – this is a group that understands robotic surgery and understands the value of robotic system surgery relative to other forms of surgery, then we're willing to take some financial risk if they really are committed in terms of how they want to implement the program, how they want to train their surgeons and so on.

Q - Richard Newitter {BIO 16908179 <GO>}

Thank you. And then, just a quick follow-up. I think, Calvin, you had mentioned that SP and the phased rollout is initially only going to be sold as a standalone console, but then it will eventually be worked into your entire fourth generation package. How should we think about the ASP on SP as we model out maybe the initial placements? Is it like a 20%, 30% premium to what SP will be as we move out beyond 2019? How should we think about that?

A - Calvin Darling {BIO 17664656 <GO>}

So as the standalone systems, they should be at a slight premium to our Xi, less than 20% to 30%, more like in the 5% range.

Q - Richard Newitter {BIO 16908179 <GO>}

Thank you.

Operator

And we go Isaac Ro with Goldman Sachs. Please go ahead.

Q - Isaac Ro {BIO 15121543 <GO>}

Good afternoon, guys. Thank you. Just another question on Asia. Curious in Japan with the new coverage there. You talked about an acceleration. Wondering how you think that accelerating curve will play out over the balance of the year as it relates to your guidance. What's embedded in the Japan part of your outlook?

A - Gary S. Guthart {BIO 3429541 <GO>}

Let me do a...

A - Calvin Darling {BIO 17664656 <GO>}

From the guidance side...

A - Gary S. Guthart {BIO 3429541 <GO>}

Let me do a real – just a little bit of a qualitative, and you can speak to the quantitative. Qualitatively, while we had, I think, 12 additional procedures, some of which are sub-procedures of each other, added in terms of reimbursement listing, they will not all drive at the same rate concurrently. Some will take precedence over others in terms of priority for training and priority for development. The team is working through that now. So as we do our forecasting model, it's not a simultaneous event. It's a focus and deliver and really drive high value through our teams to the customer. Calvin, you can speak qualitatively.

A - Calvin Darling {BIO 17664656 <GO>}

Yeah, just quickly as we move beyond the urologic, DVPs, and partial nephrectomies into this broader set, as we described in the earlier comments, it's a foundational building period. We're very pleased and satisfied with one quarter's activities focused on training and new programs and all of the support that they require on the field. But in terms of the pure numbers, this is not a big factor in terms of the high end or low end of the guidance where we may traject overall.

The overall proportion of procedures in Japan relative to the worldwide is something in the 2%-ish range. So it's a phenomenal opportunity in the long run in Japan. But in the near term, it's really more about building programs and less of the impact it'll have on full-year procedure growth in the company.

Q - Isaac Ro {BIO 15121543 <GO>}

That's helpful context. Thanks. Follow-up is on the hernia market. I think that's a obviously huge potential opportunity for you guys and, I think, the thinking there has evolved over the years. And now that you've got, I think, a little bit of accelerated traction there, it would be helpful if you could maybe provide for us some kind of updated buckets or maybe chapters of market development that we can think through in terms of the types of procedures that you think are really driving the near-term adoption versus those that might be intermediate or longer-term opportunities. And just anything to help us

segment what is clearly a very heterogeneous and large opportunity for you guys. Thank you.

A - Gary S. Guthart {BIO 3429541 <GO>}

Yeah. I think it's a good question. It's not something we're prepared to do on this call, and it is true, just frankly that our view of these opportunities and markets evolves over time. As surgeons start to explore the capabilities of these systems, find value in different places, and as we get to understand really the subsegments of markets better, our view does progress. We'll think about it as to what has changed and where it is. I don't think here we're ready to tell you that we're ready to forecast something differently. But it is moving to a different phase, and it's worth thinking through that phase.

Q - Isaac Ro {BIO 15121543 <GO>}

Okay. Thanks, guys.

Operator

And we go to Larry Keusch with Raymond James.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Oh, thanks. Good afternoon. Gary, I couldn't help but notice that in the U.S. I think it's 87% of the systems place where Xi, which obviously suggests hospitals continue to go after the most capable system, despite the availability of the lower-priced X. So could you talk a little bit about the trends there between Xi and X in the U.S.?

A - Gary S. Guthart {BIO 3429541 <GO>}

Sure. I think in a sense, it comes down to how people think through this trade-off between clinical value and economic value and where they see value relative to the capital entry price. And in many, many places as you look at this deeply, the capital price, the capital component is not the driving determinant of cost. If you look at total cost to treat per patient episode, which is, in my opinion, the most relevant economic question here, the total costs of caring for that patient are absolutely dominated by outcomes and dominated by human labor.

And so the material costs that flow through is sort of a tiny fraction of all of it. And for those folks who have capital access and who see that, who have done that set of analyses, I think what they really ask themselves is what's going to give us the best outcomes and the highest efficiency and standardization and they make that sort of commitments. And so that's what we see. And I think that results in the acquisitions of Xis.

If folks are capital constrained and, by the way, that set of criteria can vary a little bit region-to-region. I do think total cost to treat per patient episode translates well across country boundaries, but different organizations have different approval processes and capital allocation processes, they may choose to get started with lower capital cost system. If they want to do that, we're happy to support them and that's the X. So in our

prepared remarks, we had talked about our allocation of these systems fitting our view of the world regionally and that's why.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Okay. Perfect. That's helpful. And then, I guess, the other question is, I know the Si is certainly around for a period of time. And there's an ability to offer refurbished systems at a discount for those that are really looking for less expensive capital equipment. But is there a place in the portfolio for a more de-featured system that would have even a lower capital cost? Do you think about that as also a potentially part of the portfolio at some point?

A - Gary S. Guthart {BIO 3429541 <GO>}

We will listen extremely carefully to our customers' needs and recognize that customer needs are three aim, right? Triple aim, that outcomes, efficiencies, workflow, standardization, and return on investment and high responsiveness to patient need, high patient centricity. Those three needs we're going to look for really carefully. If, in that set of analysis, a further de-featured system makes sense, of course, we will pursue that. And we're always looking. I don't think that it is obvious right off the bat that less capable systems at lower capital prices make those three aims a lot better. But we are constantly asking ourselves.

Q - Lawrence Keusch {BIO 1504587 <GO>}

Okay. Terrific. Thanks for the insights.

A - Gary S. Guthart {BIO 3429541 <GO>}

Operator, just one more questioner, please.

Operator

Thank you. Our last question will be from Brandon Henry with RBC Capital Markets. Please go ahead.

Q - Brandon Henry {BIO 18858621 <GO>}

Yeah. Thanks for taking my question. One of your robotic flex cath competitors recently partnered with a division of J&J for its ablative technology. Can you spend some time discussing how you see the future direction for the flex cath platform beyond lung biopsies? And specifically, what do you think is the right modality for ablative technology? And is this technology that Intuitive already has internally or something that Intuitive will need to acquire in the future?

A - Gary S. Guthart {BIO 3429541 <GO>}

First thing, as we've said before, we're excited about flex catheter technologies particularly in lung. I think it can make a big difference there but it's a platform and we think that it'll have applications beyond the lung. We are focused on creating value in the

lung to start, that does not say that our vision will not extend further. That's step one. Step two with regard to the idea of see and treat. If you can go do a detection and then be in a position to treat it, I think it's a very compelling vision. And it's a vision we share. We think that's interesting.

There are many different ablative technologies and approaches within technologies. Ablation has been around for quite some time. It's not a trivial or obvious therapeutic approach. It will take serious design and serious clinical validation to really understand where those things are. That's going to be a multiyear pathway for anybody. So we're not surprised to see others' interest in it. That is not new to us. It's not a new thought to us. We think there are opportunities there. We think there are multiple pathways to get to good solutions. We are investing in those. Some of that is organic. Some of it is partnered. As we evolve, we will share more of that with you.

Q - Brandon Henry {BIO 18858621 <GO>}

Okay. Thank you.

A - Gary S. Guthart {BIO 3429541 <GO>}

All right. Well, thank you very much. That was our last question. As we've said previously, while we focus on financial metrics such as revenues, profits, and cash flow during these conference calls, our organizational focus remains on increasing value by enabling surgeons to improve surgical outcomes and reduce surgical trauma.

We have built our company to take surgery beyond the limits of the human hand and I assure you we remain committed to driving the vital few things that truly make a difference. This concludes today's call. We thank you for your participation and support on this extraordinary journey to improve surgery and we look forward to talking with you again in three months.

Operator

Thank you, ladies and gentlemen. This concludes your teleconference. We thank you for using AT&T Executive Teleconference Service. You may disconnect.
