ENCODE IDEAS

INITIATION REPORT

Encode Ideas

Titan Medical Inc.
(Nasdaq: TMDI, TSX: TMD)

October 28th, 2021

@encodeIp

FINANCIAL SUMMARY TABLE

Symbol	TMDI TMD
Exchange	Nasdaq TSX
Current Price	$1.65 USD $2.06 CAD
52 week Range	$0.65 - $3.47 $0.86 - $4.40
O/S	111mm*
Market Cap est. on 10/29/21	$183mm USD $229mm CAD
Average Volume (3M)	~400k
Cash	$55mm* USD
Debt	$2.1mm*

*6/30/21

KEY CATALYST DATES

4Q 2021	Medtronic Milestone
1H 2022	Approval of IDE by FDA
4Q 2022	IDE Study Completion
1H 2023	Submit FDA De Novo Request to FDA

KEY DISCLOSURES

Encode Ideas, L.P. owns stock in the covered company. Encode Ideas, L.P. has been engaged by Titan Medical to provide research coverage and awareness. Encode Ideas, L.P. intends to continue transacting in the securities covered therein, and we may be long, short, or neutral thereafter.

Catalyst Rich Titan Medical, Inching Towards Its David & Goliath Moment

Encode Ideas L.P. is initiating coverage on Titan Medical (Nasdaq: TMDI, TSX: TMD) as a high conviction idea. Titan is a development stage robotic-assisted surgery (RAS) company, focused on a single-port (single incision point) RAS medical device, Enos, for benign gynecological surgeries. Design lock for Enos is expected by YE21, after which Titan will apply to FDA for an Investigational Device Exemption (IDE). Once the IDE is approved, Titan should begin human testing with Enos in mid-22. The IDE study will enroll 30-40 women who will undergo total laparoscopic hysterectomy surgery with Enos and should be completed late-22. Assuming success in the IDE study, Titan should be in a position to submit a De Novo application to FDA in 1H23 and receive commercial authorization by 2H23. Assuming these timelines are met, Enos would enter the growing $3b U.S. RAS market, as one of the only single-port RAS systems available.

Of course, any conversation around RAS, and a potential new market entrant, like Titan's Enos, has to address the elephant in the room, Intuitive Surgical (Nasdaq: ISRG). Valued at $120b, it is estimated that Intuitive has 80% of the global RAS market, predominantly through its various generations of multi-port (multiple incision points) da Vinci systems. Intuitive also has an FDA-cleared single-port RAS product, Da Vinci SP, but since its launch in 2018, the company has been very measured in its commercial rollout with only 79 units installed in the U.S. as of 3Q21.

On the surface, this would appear to be one of those David vs Goliath situations, where Titan will face the daunting task of trying to fell the incumbent giant, Intuitive, never mind the other notable companies, like Medtronic (NYSE: MDT) and J&J (NYSE: JNJ), also making a concerted push into RAS. Although arguments can be made for how Titan can be successful, even when facing such formidable competition, by highlighting the scarcity of single-port competitors or that Enos will likely be the only single-port RAS system authorized by FDA for benign gynecological surgery, we think investors shouldn't be overly fixated on the commercial landscape Enos could face in 2024. Instead, investors should focus on the near-term clinical and regulatory milestones that, in our opinion, should unlock substantial value for Titan.

Over the next 24 months, Titan will be catalyst-rich. 2022 can be categorized as a clinical year for Titan, with an IDE approval and regular clinical trial updates throughout the year. 2023 will be a regulatory year, with a De Novo submission and potential FDA market authorization. We believe investors

should, and will, ascribe higher valuations to Titan as it progresses through its clinical and then regulatory milestones. Assuming Titan is able to successfully navigate through its clinical and regulatory milestones over the next 24 months, we believe the company should have a valuation of >$500mm as it prepares to launch Enos, offering an attractive return to investors from its current ~$185mm level. It is also worth highlighting the propensity for M&A in the robotics sector and Titan's existing collaboration with Medtronic, as reasons to suspect that, if given the opportunity, this David is unlikely to be taking on its Goliath on its own for long.

Robotic-Assisted Surgery & Intuitive Surgical

Robotic surgery may have existed before Intuitive, but it was the FDA clearance of Intuitive's first da Vinci system in 2000 that opened the door to making RAS part of the medical mainstream. Through its innovative technology, first-mover advantage, lack of viable competition, and aggressive marketing Intuitive has monopolized the RAS space for the better part of 20-years and made da Vinci synonymous with soft tissue RAS. Today Intuitive has over 6,500 da Vinci systems installed globally, representing ~80% of the RAS market, and is trending towards $5b in annual sales. The vast majority (>98%) of installed da Vinci systems are multi-port, with only 89 da Vinci SP systems installed globally as of 3Q21. There are over 1.2mm procedures done annually on da Vinci systems, primarily in general surgery, gynecologic surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. According to Intuitive, there are over 20mm soft tissue surgeries done globally per year of which 6mm fall within Intuitive's immediate addressable markets (i.e. geography and label).

What's amazing about Intuitive's success, is that it has been accomplished in the face of consistent scrutiny and questioning over the cost-effectiveness and long-term benefits of RAS versus traditional laparoscopic surgery. We will not wade into the debate, because in our opinion, the market (patients, surgeons, and hospitals) has by and large spoken, and that where possible it wants RAS. Therein lies the amazing part of Intuitive's success, they have made the da Vinci a coveted device, a shiny toy that hospitals and surgeons can use to draw patients in. The benefits of RAS, most notably, reduced blood loss, less pain, and shorter recovery time, clearly resonate with patients. The debate over the cost and long-term benefits of RAS vs laparoscopic surgery will continue, meanwhile, hospitals that have a da Vinci will continue to exploit them.

The purpose here isn't to extol the virtues of Intuitive, rather to paint a picture of the market that Titan aspires to enter. A market ready-made by Intuitive, where the merits, rightly or wrongly, of RAS are already widely embraced and accepted. Titan doesn't have to convince its future customers of the merits of RAS, Intuitive has already done that, it needs to convince them of the merits of single-port RAS (Intuitive is already helping with this), and most importantly the merits of Enos.

Titan's Enos

Titan is in the final stages of design-lock for its single-port Enos RAS system. Enos is a soft tissue surgery robot with two main components, a surgeon workstation, and a patient cart. Further details on Enos can be found in the scientific summary in the backend of this report, however, we would highlight these key differentiating features of the Enos system;

- Single-port access through 25mm cannula (insertion tube) with 2D high-definition camera for initial positioning and 3D high-definition camera for surgery
- Two multi-articulating instruments (arms)
- Eight end effectors (tips)

Titan has guided for Enos design lock by YE21, after which the company should be in a position to submit an IDE application to FDA to test Enos for benign gynecological surgery, specifically total laparoscopic hysterectomy.

In our opinion, IDE approval is a major de-risking event for Titan. Long-suffering Titan investors will recall that the company was once guiding towards an IDE submission in 2019, only to stall due to lack of funding. With $55mm on the balance sheet as of 06/30/21 and an $11mm final milestone payment due from Medtronic (a subject covered later) before year-end, Titan's treasury shouldn't be the cause of any further delays. We are optimistic Titan will achieve IDE approval for Enos in 1H22, and that the collective sigh of relief from investors should be positively reflected in the stock price.

Once the IDE is approved, Titan can begin to enroll its pivotal IDE study. In our interaction with Titan management, they have indicated that they are in discussions with FDA around the final details of the IDE study, but based on those discussions, here is what is known;

- Single study design (there have been suggestions of "studies" by others, but Titan has confirmed only a single study is needed for FDA clearance)
- 30-40 women from 3-4 clinical sites
- No control arm
- Safety is the primary endpoint (perioperative and postoperative)

- Efficacy endpoints - none specified at this point

An "efficacy" endpoint that may end up in the final study design is the rate of conversion to open hysterectomy. In essence, this would be an unsuccessful surgery with Enos, whereby the patient would need to be transitioned to a traditional open hysterectomy. This endpoint is highlighted because it was used in the IDE study for a transvaginal robotic competitor, Memic. Once the IDE is approved, we would expect the study details to be posted on clinicaltrials.gov.

Titan has guided that it anticipates starting the IDE study in mid-22 and be complete by YE22. Titan management confirmed that investors can expect announcements on first and last patients treated in the IDE study. Assuming these timelines are correct, investors should also expect a study update from the company in its 2Q22 (and/or 3Q22) press release. What kind of update Titan provides with the IDE study ongoing is unknown, but we assume it will be more qualitative in nature and light on actual data. Our assumption is that when the study is complete, late-22, that Titan will simultaneously announce whether it intends to proceed with an FDA De Novo submission. Again, without visibility as to what specific safety and efficacy endpoints will be tracked, we aren't able to opine on what clearly defines a successful or unsuccessful IDE study for Titan. These details will become apparent once the study design is finalized, in the meantime, we emphasize that success in the IDE study will position Titan for De Novo submission.

Titan announced in late-20 that FDA had given them written guidance that Enos should fall under the De Novo market authorization pathway. The De Novo pathway sits between the much quicker 510(k) route and the more arduous and time-consuming Premarket Approval (PMA). FDA recently authorized Memic's Hominis ® transvaginal robot for benign gynecological surgery via a De Novo path, so this regulatory path seems relatively assured for Titan. Within 15-days of a De Novo submission, FDA decides whether all the necessary information is present to move ahead with a substantive review. Assuming so, FDA endeavors to get back to the company within 150-days with a granted or declined market authorization decision. If the timing assumptions around the IDE study completion are correct, Titan should have a 1H23 De Novo submission and likely FDA market authorization decision sometime 2H23. FDA market authorization for Enos would position it as one of the few single-port RAS system available in the U.S. and potentially the only single-port system with market authorization for benign gynecological surgery.

How does Titan Compete?

As highlighted above, we believe Titan can generate meaningful incremental value over the next two years as it checks off the clinical and regulatory events we have outlined. However, assuming Titan progresses through these clinical and regulatory milestones, the presence of the elephant in the room, Intuitive, will become an increasing part of the investment narrative. How can a company the size of Titan compete with the giant Intuitive? Unquestionably a daunting task, but there are several reasons why investors should have optimism.

1. Make it Better & Make it More Affordable

Titan believes that their Enos single-port surgical system has some unique engineering advantages that can present an attractive alternative to the da Vinci SP system. A few of these include;

- Enos has a 25mm entry port (cannula) that is smaller than the 27mm for SP
- Enos has two instruments and a scope vs three instruments and a scope for SP, giving Enos a larger workspace in vivo (inside the patient)
- Enos has two components (surgeon workstation and patient cart) vs three for SP (surgeon console, patients cart, and vision cart), giving Enos a smaller footprint in the surgical suite

Regardless of any perceived technological advantages, Enos may have versus da Vinci SP, Titan as a new market entrant will certainly struggle against the inertia and allure of the da Vinci brand. However, technology advantages coupled with affordability (relative to da Vinci), could be the formula that will work for Titan. It is estimated that 30% of hospitals / surgical centers in the U.S. have at least one da Vinci robot, the 70% who don't, want one but just can't afford it or justify the cost. Titan is planning on pricing Enos 10-20% below da Vinci, this includes one-time capital cost, recurring instrument cost, and maintenance. By pricing Enos very competitively Titan is addressing the biggest barrier to RAS adoption head-on and giving itself a distinct competitive advantage.

	System Cost (M)	Instruments Per Procedure	Service Costs Per Year
Titan Medical Inc	**$1.25**	**$1,500**	**$125,000**
Competitive Systems[3]	$1.5 - 2.5	$1,800 - $2,000	$150,000 - 250,000

2. The Trend is Your Friend

Intuitive's business is predominantly focused on their multi-port da Vinci X/Xi systems. As noted earlier, Intuitive's current install base is >98% multi-port. They have openly stated they are taking a measured approach to their SP launch, but of the approximately 660 da Vinci installs over the past year (09/30/20 - 09/30/21) 31, a little over 5%, were SP systems, a small but improving trend. We would expect that by the time Titan is hopefully launching Enos in the U.S., that Intuitive's SP install base will be in the hundreds and the ratio of single-port to multi-port will continue to rise. This trend should play to Titan's benefit, for not only will Intuitive have convinced hospitals and surgeons of the merits of RAS, but they will also have increasingly convinced them of the merits of single-port RAS. As seen with da Vinci's multi-port systems, some of Intuitive's best marketing comes from their customers.

As the Lehigh Valley Health Network advocates above, the advantages of single-port vs multi-port RAS include less pain (less pain medicine), better cosmesis, and quicker recovery. These claims are supported by a Cleveland Clinic study comparing single-port surgery with da Vinci SP vs multi-port da Vinci surgery in radical prostatectomy.

	Single-port robotic prostatectomy	Multiport robotic prostatectomy
Hospital stay	4.3 hours	26.1 hours
Time in the operating room	195 minutes	190 minutes
Blood loss during surgery	190 mL	200 mL
Percentage of patients who use narcotics after surgery	32%	63.6%
Morphine equivalent	7.5 mg	15 mg

Lenfant L, Sawczyn G, Aminsharifi A, et al. Pure single-site robot-assisted radical prostatectomy using single-port versus multiport robotic radical prostatectomy: a single-institution comparative study [published online ahead of print, 2020 Nov 4]. *Eur Urol Focus*. 2020;S2405-4569(20)30290-X.

The science / clinical data, market awareness, and commercial footprint, for single-port RAS should be substantially greater by 2024 when Enos could be entering the market as one of the only single-port RAS systems available in the U.S.

3. Go Where They Aren't: Gynecology & Community Hospitals

Titan's first target market with Enos is benign gynecological surgery. According to Titan, there are approximately 700k benign gynecological surgeries annually in the U.S., making it a $1b annual addressable market for RAS (based on instrument & service revenue, not including upfront system revenue). Titan estimates that current RAS penetration in this market is 30-35% virtually all of which would derive from da Vinci multi-port systems. Intuitive's da Vinci SP is currently not cleared for any gynecological surgeries. Based on clinicaltrials.gov Intuitive has 9

studies completed, ongoing, or soon to start, with da Vinci SP, none of which are in gynecology. Without question, Intuitive has plans to enter gynecology with SP, but as it looks now, they are prioritizing other indications. This provides a unique opportunity for Titan, where they can potentially have the first single-port RAS system authorized by FDA for gynecological surgery.

If 30% of U.S. hospitals and surgical centers have RAS, the remaining 70% want them. It's a rather casual and flippant assessment of the demand dynamics for RAS, but there's no denying the appeal of RAS for patients, surgeons, and hospitals. Titan will certainly try to get Enos adopted into large, high-volume, hospital networks, but that will likely mean trying to displace a da Vinci system. The company has openly stated that they feel Enos could be a good fit for smaller hospitals, that have yet to adopt RAS. With 70% of hospitals in the U.S. still without a RAS system, there should be plenty of opportunity for a small company like Titan to find an initial niche for Enos, and smaller community-based centers would seem a viable one.

4. Bring in Help

Titan may have technological and cost advantages versus da Vinci, they may become the first single-port RAS system authorized for benign gynecological surgery, and single-port may have advantages over multi-port, but in the end, it is still a David vs Goliath story. In these scenarios, in healthcare, in particular, David rarely attempts to fell the giant on his own, and often seeks the support of another Goliath, to make it a fairer fight. In Titan's case, they already have a relationship with Medtronic, a $166b Medtech Goliath, that would seem a logical commercial partner for Titan in the future. In June 2020, Medtronic and Titan entered into a development and license agreement, whereby Titan would develop certain RAS technologies that could be used by Medtronic, and Titan, for their respective businesses. This development agreement had three milestones with associated payments totaling $31mm. Two milestones have already been met by Titan and they have received $20mm (2x$10mm) from Medtronic. One milestone remains outstanding and Titan has guided it should be completed by YE21, triggering the final $11mm payment. Medtronic also took a license to certain RAS technology already developed by Titan for an upfront fee of $10mm. Within RAS Medtronic is best known for its Mazor robotic systems for spinal surgery, but they have also been developing a soft-tissue RAS system, known as HUGO. A multi-port system, HUGO, has yet to be authorized by FDA, but just recently received its CE Mark in Europe for urological and gynecological surgeries. At this stage, Medtronic does not appear to be developing a single-port RAS system of its own.

As Titan draws closer to commercialization, as Enos becomes more de-risked from a clinical and regulatory perspective, the probability of a partnership or M&A should increase. Medtronic would appear to be the most logical candidate, given its existing relationship with Titan, expanding interest into soft-tissue RAS, and lack of single-port technology. Perhaps Medtronic follows a similar path in soft-tissue RAS with Titan as it did in spinal RAS with Mazor Robotics (Nasdaq: MZOR), where it started with a 2016 equity investment in Mazor before buying them for $1.6b two years later. If not Medtronic there are several other Medtech giants that may covet Enos, given the growing RAS market and scarcity of single-port technology.

Within the last ten years, Stryker, J&J, and Siemens have all made >$1b RAS acquisitions. Most of these deals were for spinal RAS technologies, but like Medtronic, many of these companies are also looking to enter the soft-tissue RAS market.

Enos as a Platform

Looking farther ahead, beyond benign gynecology, Titan's Enos would certainly have potential use in a variety of additional indications. Intuitive's da Vinci multi-port systems are used in general surgery, gynecologic surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. Whether all these surgical applications are suitable for single-port RAS is unknown, however, da Vinci SP is already cleared for use in urologic surgery and transoral oropharyngectomy (radical tonsillectomy). The transoral application of da Vinci SP demonstrates the additional potential for single-port systems to gravitate towards natural orifice RAS. Where Titan, or an acquirer, decides to take Enos after benign gynecology is anyone's guess, the point is, their technology has undeniable platform potential.

Financial Considerations

Titan reported a cash balance of $55mm at the end of 2Q21. As noted above, Titan is also expecting to receive a final $11mm milestone payment from Medtronic by YE21. Based on conversations with management we believe this should give the company financial runway into early-23. At the end of 2Q21, the company had 111mm shares and 28.8mm warrants outstanding. The vast majority of the warrants are out of the money. Titan has an equity line in place with a balance of 2.75mm shares at its discretion to sell before the line's expiration in June 2022. With a cash runway into early-23, we assume Titan will need to raise additional money next year. The most likely source of capital would be through an equity raise, but the company could also consider debt or possibly licensing / partnering as a source of capital. Throughout its history, Titan has been funded predominantly through retail investors. Its two largest institutional holders are Essex, LLC and Masters Capital Management, LLC, with 1.48mm and 1mm shares respectively.

Notable RIsks

Titan as a pre-revenue development stage company faces numerous risks, that we would categorize into the following areas; clinical, regulatory, commercial, and financial. Notable clinical risks include, but are not limited to, failure to achieve design-lock for Enos and an unsuccessful outcome in the IDE study. Notable regulatory risks include, but are not limited to, failure to receive IDE approval, declined De Novo authorization, and FDA asking for a PMA submission. Notable commercial risks include, but are not limited to, additional competition, beyond Intuitive, from the likes of Memic, and Vicarious among several others and lack of partnering / acquisition interest. Notable financial risks include, but are not limited to, an inability to access capital in a timely manner and failure to remain compliant with Nasdaq listing requirements.

Scientific Summary

Robotic assisted surgery is an advanced form of minimally invasive or laparoscopic surgery where surgeons use a computer-controlled robot to assist them in certain surgical procedures. The robotic systems allow delicate and precise movement in spaces too tight to accommodate hands. Advances in this technology have now enabled surgeons to use a minimally invasive approach for a multitude of complex surgeries that previously required a large incision.

Most modern robotic assisted surgery systems involve a camera and the use of very small surgical tools attached to robotic arms. A specially trained surgeon controls the robotic arms from a viewing screen, which is usually situated in the same room as the operating table. The screen is part of a console, which allows surgical procedures to be performed from a seated position, while the surgeon views a magnified three-dimensional view of the patient's surgical site.

There are many different types of surgery that can be performed using robotic assisted surgery technology, including general surgery head and neck surgery, colorectal surgery, urological surgery, gynecologic surgery, thoracic surgery, heart surgery and orthopedic surgery.

Robotic assisted surgery offers many benefits to patients compared to open surgery, including shorter hospitalization, reduced pain and discomfort, faster recovery time and return to normal activities, smaller incisions with a reduced risk of infection, reduced blood loss and transfusions and minimal scarring. In addition, there are some major advantages for surgeons using these systems including greater visualization, enhanced dexterity, and greater precision.

Despite these benefits, there are several barriers to the adoption of surgical robots including the overall expense of operating the robot and the efficiency of use, the learning curves required for both surgeons and the team, communication latency, difficulties of integrating this new technology into the existing systems of work within the organization, and potential for serious incidents.

In 2019 the FDA warned against the use of robotically assisted devices for mastectomies and other cancer surgeries, asserting the products may pose safety risks and result in poor outcomes for patients. In addition, a study of all types of robotic surgery concluded that despite widespread adoption of robotic systems for minimally invasive surgery in the US, a non-negligible number of technical difficulties and complications are still being experienced. However, it is expected that with the right expertise and technology, the benefits and advantages of RAS will eventually overcome the risks and barriers to adoption.

Robotic assisted surgery has been around for many years. However, in 2000 the da Vinci Surgery System (Intuitive Surgery) became the first robotic assisted surgery approved by the FDA for general laparoscopic surgery. This system remains the workhorse and most widely used robotic device. Intuitive Surgery has progressively improved on the da Vinci device through the development of five generations of devices, however, all of these devices were multi-port access systems. More recently Intuitive Surgery has developed a single-port version of the robot, called the da Vinci SP. Single-port systems use only one incision point, conferring additional potential advantages for scarring, blood-loss and pain versus multi-port systems.

Titan Medical Inc. is a medical device company headquartered in Toronto, Ontario, with research and development facilities in Chapel Hill, North Carolina. Titan Medical is focused on enhancing robotic assisted surgery using innovative technology through a single access point. The company is in the final stages of designing the EnosTM surgical system, a single-port soft tissue surgery robot.

The Enos surgical system is a unique single-port robotic surgery system that is differentiated by its patented multi-articulating instruments, user interface and ergonomic features. Currently Titan holds more than 180 patents and/or patent applications. Titan has also leveraged some of the value of its intellectual property) portfolio by entering into a development and license agreement with Medtronic to further the development of its robotic assisted surgical technologies, as well as a separate license agreement with Medtronic in respect of certain IP. The development and license agreement provides for the development of technologies for use by both Titan and Medtronic in their respective businesses.

Titan believes that their Enos single-port surgical system has some unique engineering advantages that can present an attractive alternative to the da Vinci SP system. For example, the Enos surgical system entry port is ~25 mm in diameter compared to 27 mm for the da Vinci SP system, the Enos surgical system has two instruments and an endoscope whereas the da Vinci SP system has three instruments and a scope, all of which is believed to lead to a larger workspace in vivo for the Enos surgical system versus the da Vinci SP system, the Enos surgical system has two components (patient cart and workstation) and the da Vinci SP system has three (patient cart, surgeon console and vision cart). Another key differentiating factor on the Enos surgical system verses the da Vinci SP system include a different end effector actuation system.

In addition to the advantages listed above, Titan plans to target relatively overlooked community hospitals by providing proper training especially in procedures such as endometriosis/ benign hysterectomy. Titan plans to offer competitive pricing with the aim of lowering systems costs, lowering the cost per procedure, and lowering service costs.

Titan initially intends to pursue benign gynecologic surgical related indications for the Enos surgical system. Titan has estimated that the US market size for benign gynecological surgery is approximately one billion dollars per year with 30-35% robotic assisted surgery penetration.

Currently the Enos system has not been cleared by the FDA or any other regulatory authority in any jurisdiction and is not yet commercially available. Titan expects to complete Enos surgical system product development, tooling for manufacturing and preclinical system performance verification in Q4-2021. Titan is then expected to submit an Investigational Device Exemption application to FDA to begin human clinical studies in mid-2022. Upon completion of the Investigational Device Exemption studies, Titan plans to submit a De Novo regulatory request to the FDA in 2023 followed by submissions to additional regulatory agencies in other major markets.

In conclusion, Titan is focused on enhancing robotic assisted surgery using innovative technology through a single access point. The company is in the final stages of designing the Enos

surgical system, a soft tissue surgery robot. Titan has integrated significant technology into the Enos surgical system for the purpose of improving the robotic assisted surgical experience for surgeons, which they believe will bring important benefits to patients, including less trauma, less scarring and faster recovery times. In addition, the Enos surgical system is designed to benefit hospitals through its smaller footprint, easy mobility and lower operating costs with the intent of improving clinical capabilities, operating room efficiency and hospital economics.

Detailed Scientific Summary

Robotic assisted surgery (RAS) is one of the most cutting-edge medical technologies of modern times. RAS is an advanced form of minimally invasive or laparoscopic (small incision) surgery where surgeons use a computer-controlled robot to assist them in certain surgical procedures. The robotic systems allow delicate and precise movement in spaces too tight to accommodate hands. Advances in this technology have now enabled surgeons to use a minimally invasive approach for a multitude of complex surgeries that previously required a large incision.

Most modern RAS systems involve a camera and the use of very small surgical tools attached to robotic arms. A specially trained surgeon controls the robotic arms from a viewing screen, which is usually situated in the same room as the operating table. However, the viewing screen can also be located far away, allowing surgeons to perform telesurgery from remote locations. The screen is part of what is referred to as a console, which allows surgical procedures to be performed from a seated position, while the surgeon views a magnified three-dimensional (3D) view of the patient's surgical site (Christiansen, 2020). Contrary to what many people believe RAS is not actually performed by robots. Rather, the surgeon is continuously in complete control of robotic arms. The robot serves as a tool that assists the surgeon.

There are many different types of surgery that can be performed using RAS technology, including:

- General surgery such as gallbladder removal, severe gastroesophageal reflux disease (GERD), gastric bypass surgery and gastric banding, pancreatic surgery, liver tumors, and more
- Head and neck surgery such as tumors of the throat or tongue, thyroid cancer, and more
- Colorectal surgery such as surgery for colon cancer, treatment for Crohn's disease, and more
- Urological surgery such as prostatectomy, kidney stones or other kidney disorders, urinary incontinence, kidney or bladder surgery, and total or partial kidney removal
- Gynecologic surgery such as tubal ligation, ovarian or cervical cancer, ovarian cysts, uterine fibroids, hysterectomy, and more
- Thoracic surgery for conditions affecting the lungs, such as lung tumors, or esophagus

- Heart surgery such as coronary artery bypass, mitral valve prolapse, atrial fibrillation and more
- Cancer surgery to remove tumors, particularly those near vital body parts such as blood vessels and nerves
- Orthopedic surgery such as a total hip replacement

(Christiansen, 2020)

RAS offers many benefits to patients compared to open surgery, including:

- Shorter hospitalization,
- Reduced pain and discomfort,
- Faster recovery times and return to normal activities,
- Smaller incisions, resulting in reduced risk of infection,
- Reduced blood loss and transfusions, and
- Minimal scarring.

In addition, there are some major advantages for surgeons using RAS, including:

- Greater visualization,
- Enhanced dexterity, and
- Greater precision.

Despite these benefits, there are several risks and barriers to the widespread adoption of surgical robots including:

- Overall expense of operating the robot and the efficiency of use,
- Learning curves required for both surgeons and the surgical team,
- Communication latency,
- Difficulties of integrating this new technology into the existing systems of work within the organization, and
- Potential for serious incidents.

In 2019 the food and Drug Administration (FDA) warned against the use of robotically assisted devices for mastectomies and other cancer surgeries, asserting the products may pose safety risks and result in poor outcomes for patients (FDA in Brief, 2019). In addition, a study of all types of robotic surgery, not only for cancer, concluded that despite widespread adoption of robotic systems for minimally invasive surgery in the United States (US), a non-negligible number of technical difficulties and complications are still being experienced (Alemzadeh et al., 2016).

It is expected that with the right expertise and technology, the benefits and advantages of RAS will eventually overcome the disadvantages, risks and barriers to adoption. Communication latency is currently one of the biggest hurdles to overcome to allow this technology to hold a more prominent place in the medical community. Even if the cost of these procedures slows down the integration of these systems into hospitals, surgeries with robotic systems will likely continue to become more commonplace, allowing for more precise microsurgeries with improved accuracy.

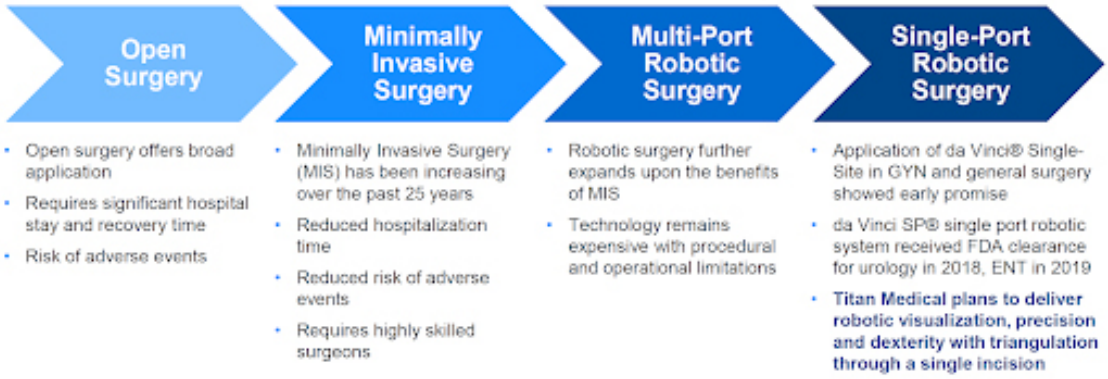
Multi-port and Single-port Robotic Assisted Systems

Robotic assisted surgery has been around for many years. The first surgical robot, the PUMA 560 robotic surgical arm (Westinghouse Electronics), was first used to perform a brain biopsy procedure in 1985 (Shah et al., 2014). In 1990, the Automated Endoscopic System for Optical Positioning (AESOP® System; Computer Motion) was the first system to obtain clearance from the FDA. It consisted of only a robotized arm to control and direct the laparoscope. The Zeus Surgical System® (Computer Motion) was an evolution of the AESOP® System and consisted of two robotized arms fixed to the sides of the operative table in association with the robotic endoscopic arm; all directed from a remote console.

In 2000, the da Vinci Surgery System broke new ground by becoming the first RAS cleared by the FDA for general laparoscopic surgery. This was the first time the FDA cleared an all-encompassing system of surgical instruments and camera/scopic utensils. Although a variety of surgical robotic systems are now available, the da Vinci Surgery System remains the workhorse and most widely used robotic device.

For almost 20 years, Intuitive Surgery has progressively improved on the da Vinci device through five models – the Standard, S, Si, Xi, and the recent hybrid X models. All of these devices have followed the usual pattern of multi-port access to the abdominal and thoracic cavities, allowing surgeons to triangulate on the tissue of interest. However, Intuitive Surgery has more recently developed a single-port version of the robot, called the da Vinci SP (Figure 1).

Figure 1 Evolution of Surgical Care (Titan Medical Overview Presentation, 2020)



Initially, the da Vinci SP was cleared by the FDA for use in urologic procedures such as prostatectomies and nephrectomies. Early trials of the device were conducted in 2010 by a combined surgical team from Cleveland Clinic and the University of Lille France (Kaouk et al., 2014). More recently, trials have explored the use of the device for both transoral (Chan et al., 2017; Chan et al., 2019) and transanal (Marks et al., 2021) procedures. In 2019, the company announced it had received clearance for the use of the da Vinci SP system in certain transoral otolayngology procedures in adults.

Single-port access systems are advantageous for all the same reasons that have previously been cited for other forms of minimally invasive surgery (MIS) including smaller incisions, less trauma to the body, reduced opportunity for infection, and more rapid recovery by the patient. However, in a study published by Lenfant et al. (2020), they also found a reduction in the duration of hospital stay, a decrease in blood loss during surgery and a reduction in the percentage of patients using narcotics after surgery (Table 1).

Table 1 Comparison between Single-Port and Multi-port Robotic Prostatectomy

	Single-port Robotic Prostatectomy	Multi-port Robotic Prostatectomy
Hospital Stay	4.3 hours	26.1 hours
Time in Operating Room	195 minutes	190 minutes
Blood Loss during Surgery	190 mL	200 mL
% Patients Using Narcotics After Surgery	32%	63.6%
Morphine Equivalent	7.5 mg	15 mg
mg = Milligram; mL = Millilitre		

(Lenfant et al., 2020)

Garbens et al. (2021) pointed out in a recent review of the literature, there are currently no high-quality published studies with the da Vinci SP robotic system. All the studies identified were case series, many with ten or fewer patients. However, Garbens et al. (2021) also found that all the identified studies found the da Vinci SP system to be safe and feasible in performing most urological procedures. Renal and pelvic surgery using the SP robotic system was also found to be safe and feasible in the hands of expert robotic surgeons, but long-term, high-quality data is generally lacking.

Titan Medical

Titan Medical Inc. (Titan) is a medical device company headquartered in Toronto, Ontario, with research and development (R&D) facilities in Chapel Hill, North Carolina. Titan is focused on enhancing robotic assisted surgery using innovative technology through a single access point. The company is in the final stages of designing the Enos surgical system, a soft tissue surgery robot.

Titan is applying robotic technology to replicate natural movement so that surgeons can be

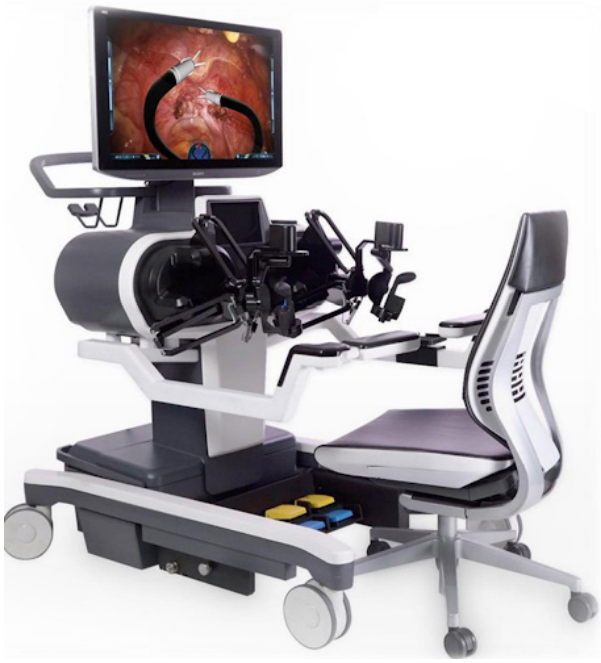
more comfortable using their surgical system to deliver precise surgical end effector movement with forces appropriate for the essential tasks of surgery. Titan have developed input and motion control systems with an ergonomic focus and that seek to mimic the real-life movements associated with tissue grasping, blunt dissection, cutting, approximation, suturing, coagulation, and ligation that surgeons regularly execute during minimally invasive surgery.

Enos Surgical System

The Enos surgical system combines minimally invasive single-port access with robotic instruments providing an increased range of motion, precision and dexterity compared to other single-port laparoscopic instruments. The system is comprised of two primary components, the Surgeon Workstation (Figure 2) and the Patient Cart (Figure 3).

The Enos Surgeon Workstation includes a 3D high-definition display to provide a crucial balance of surgical immersion and situational awareness in the operating room. The display is mounted to the ergonomic workstation with a natural handle interface designed to deliver and support comfortable surgical posture, even during long procedures. In addition, Titan has designed the workstation to be highly mobile and to cover a smaller footprint.

Figure 2 Enos System Workstation



(Titan Medical Corporate Presentation, 2021)

The Enos Patient Cart is designed with mobility in mind and is easy to maneuver. The Enos Patient Cart features swift docking and multi-quadrant positioning with easy-to-load instruments and endoscope. It has a single cable and a single boom with no external movement which unencumbers bedside operating staff. The Patient Cart is easily repositioned in the operating

room and to maneuver around the hospital facilities.

Figure 3 Enos System Patient Cart

(Titan Medical Corporate Presentation, 2021)

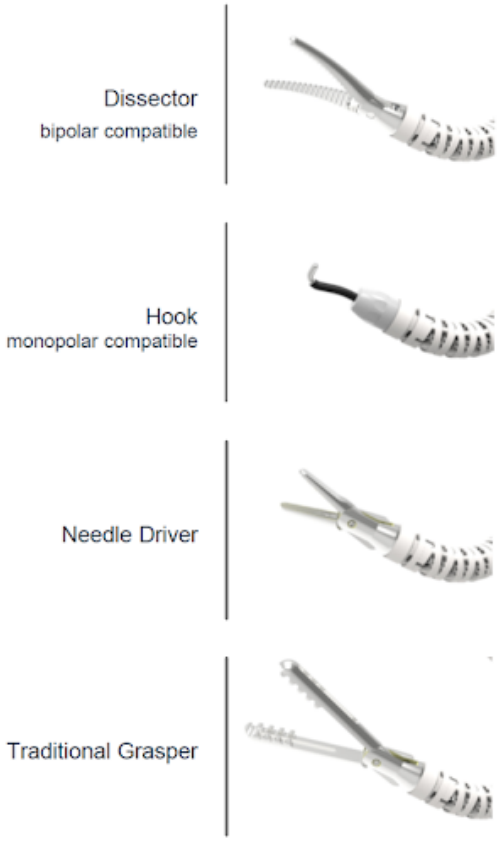
The Enos surgical system utilizes a 25 mm insertion tube, which contains two lighted camera systems. The first camera system contains a two-dimensional (2D) high-definition camera with light source to facilitate insertion tube positioning. The second camera system is a steerable 3D high-definition camera that elevates, tilts, and pans under surgeon control to ensure visibility of the surgical site at all times.

The 25 mm insertion tube also delivers two re-usable "snake-like" multi-articulated instruments (seven axes of movement) to the surgery site (Figure 4). Attached to the ends of the multi-articulated instruments, the surgeon has the choice of an assortment of end effectors (Figure 5). Initially, Titan plans to commercialize eight end effector tip types. However, Titan anticipates developing new end effectors for future adaptability and additional functionality.

Figure 4 Enos System Insertion Tube with Cameras and Multi-articulated Instruments

(Titan Medical Corporate Presentation, 2021)

Figure 5 Examples of End Effectors for the Enos System



(Titan Medical Investor Presentation, 2019)

The Enos surgical system is a unique single-port robotic surgery system that is differentiated by its patented multi-articulating instruments, user interface and ergonomic features. Currently Titan holds more than 180 patents and/or patent applications and plans to continue to work aggressively to pursue patent protection on their inventions in innovative areas including camera and vision systems, ergonomic design, motion control and more.

Titan has also leveraged some of the value of its intellectual property (IP) portfolio by entering

into a development and license agreement with Medtronic to further the development of its robotic assisted surgical technologies, as well as a separate license agreement with Medtronic in respect of certain IP of Titan (Table 2). The development and license agreement provides for the development of technologies for use by both Titan and Medtronic in their respective businesses.

Table 2 Development and License Agreement between Titan and Medtronic

	Titan Medical	Medtronic
Instruments	•	•
Input Device/Controllers	•	
Interoperative Overlays	•	
SW Control	•	
Access	•	
Camera Systems	•	•
Workstation	•	
Patient Cart	•	
Draping System	•	

(Titan Medical Investor Presentation, 2021)

ENOS Verses da Vinci SP

As mentioned previously, although multiple surgical robotic systems are currently available, the da Vinci Surgery System remains the workhorse and most widely used robotic device in US hospitals. Titan believes that their Enos single-port surgical system has some unique engineering advantages that can present an attractive alternative to the da Vinci SP system. For example, the Enos surgical system entry port is ~25 mm in diameter compared to 27 mm for the da Vinci SP system, the Enos surgical system has two instruments and an endoscope whereas the da Vinci SP system has three instruments and a scope, all of which is believed to lead to a larger workspace in vivo for the Enos surgical system versus the da Vinci SP system, the Enos surgical system has two components (patient cart and workstation) and the da Vinci SP system has three (patient cart, surgeon console and vision cart) (Table 3). Another key differentiating factor on the Enos surgical system verses the da Vinci SP system includes a different end effector actuation system.

Table 3 Comparison of the Single-port Enos and da Vinci SP RAS Systems

	Enos	Da Vinci SP
Number of Ports	Sinlge-Port	Single-Port
Entry Port Diameter	25mm	27mm
Cameras	2D Camera 3D Camera	3D Camera

Instruments	2 Arms	3 Arms
End Effectors	8	12
Footprint		
Patient Cart	+	+
Workstation	+	+
Vision Cast	-	+
Projected Cost Comparison		
System (M)	$1.25	$1.5-2.5
Instruments per Procedure	$1,500	$1,800-2,000
Services Costs/Year	$125,000	$150,000-250,000
M = Million; mm = millimeter; SP = Single-port		

In addition to the advantages listed above, Titan plans to target relatively overlooked community hospitals by providing proper training especially in procedures such as endometriosis/benign hysterectomy, an indication(s) where da Vinci SP is not currently FDA cleared Titan plans to offer competitive pricing with the aim of lowering systems costs, lowering the cost per procedure, and lowering service costs.

(Table 3; Titan Medical Investor Presentation, 2021)

ENOS Supporting Data

The Enos surgical system has been tested on live pigs and human cadavers, at a number of different institutions, by various laparoscopic surgeons. A brief summary of the types of surgeries and where they were performed have been provided below:

GYN and GYN-ONC (8 procedures at Columbia University and Florida Hospital)

- Radical hysterectomy with bilateral salpingo oophorectomy and bilateral pelvic/para-aortic node dissection
- Simple hysterectomy with bilateral salpingo oophorectomy and bilateral pelvic node dissection
- Simple hysterectomy with bilateral salpingo oophorectomy

Urology (19 procedures at IHU Strasbourg and Florida Hospital)

- Hemi-nephrectomy and partial nephrectomy
- Prostatectomy (human cadaver)
- Pyeloplasty
- Ureteral-bladder anastomosis

General Surgery (14 procedures at IHU Strasbourg and Florida Hospital)

- Cholecystectomy (1 human cadaver, 5 live Porcine)

- Nissen fundoplication (1 human cadaver, 3 live porcine)
- Esophagectomy (human cadaver)
- Gastrectomy
- Splenectomy

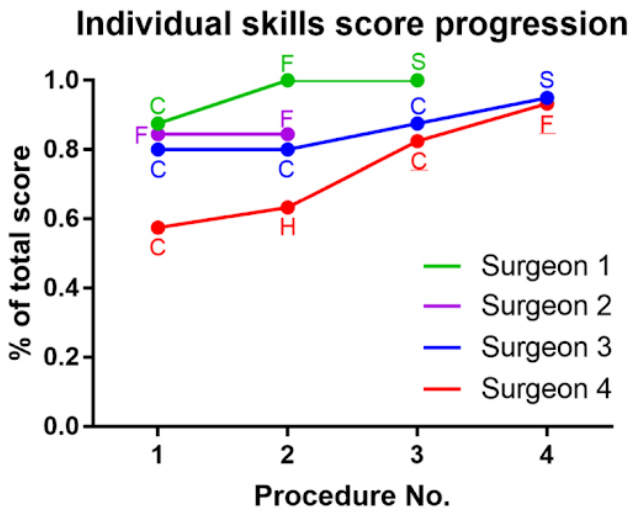
Colorectal (4 procedures at Florida Hospital)

- Colectomy
- Low anterior resection

In addition, Seeliger et al. (2019) published a study assessing the safety and feasibility of single-port and reduced port robotic abdominal surgery using a prototype Enos surgical system in a preclinical setting. A total of 12 minimally invasive procedures were performed on six pigs (5 cholecystectomies, 3 Nissen fundoplication, 1 splenectomy and 1 hepatic pedicle dissection) and on one human cadaver (1 cholecystectomy and 1 Nissen fundoplication), by four laparoscopic surgeons. The usability of the device was assessed by means of the modified objective structured assessment of technical skills (OSATS) score that was calculated and analyzed by two independent observers on recorded videos. Surgeon feedback and recommendations were systematically recorded.

Individual analysis of modified OSATS score revealed an overall learning curve effect represented by an increasing percentage of total score with every performed procedure. Figure 6 shows the individual OSATS score progression of four surgeons where C represents cholecystectomy, F represents fundoplication, H represents hepatic pedicle dissection, and S represents half splenectomy.

Figure 6 Analysis of Modified OSATS Score



(Seeliger et al., 2019)

All procedures were successfully completed with the prototype Enos system. In general, the surgeons were reported to have appreciated the intuitive interface and controls, the high-resolution 3D imaging, the dexterity of the end-effectors, and the ergonomic open control platform. Some features requiring optimization were also identified.

Seeliger et al. (2019) also compared the benefits of the prototype Enos surgical system with conventional laparoscopic single-port surgery. The results of this comparison can be found in Table 4.

Table 4 Potential Benefits of the Enos Protype Surgical System Compared to Conventional Laparoscopic Single-port Surgery

		Conventional Laparoscopic Single-Port Surgery	Enos Prototype Single-Port Surgery
Ergonomy	Surgeon	-	+
	Assistant	-	+
Image Quality	5 mm laparoscope vs 3D imaging system	-	+
	Camera inseration towards target zone	+	-
	Camera exchange (0, 30)	+	-
Instruments	Multi-articulated instruments	-	+
	Specialized (vessel sealing, stapling)	+	-
Conflicts	Instrument clashing	-	+
	Instrument / camera conflict	-	+
	Operating room footprint	+	-
Disadvantage (-); Advantage (+)			

(Seeliger et al., 2019)

A list of peer reviewed articles and presentations involving the Enos surgical system developed by Titan can be found in the Addendum to this report.

ENOS Clinical Indication

Hysterectomy is the surgical removal of the uterus and is the most frequently performed major gynaecological surgical procedure, with millions of procedures performed annually throughout the world (Garry 2005). Approximately 90% of hysterectomies are performed for benign conditions, such as fibroids causing abnormal uterine bleeding (Flory 2005). Other indications include endometriosis/adenomyosis, dysmenorrhoea, dyspareunia and prolapse.

The use of robotic surgery in gynecologic procedures first dates back to 2005, when the FDA cleared the da Vinci Surgical System for use in the US. After FDA clearance the number of minimally invasive gynecologic procedures increased dramatically, with the number of robotically assisted hysterectomies surpassing the number of hysterectomies performed with conventional laparoscopy. In fact, until 2014 benign hysterectomy, was the fastest growth segment in terms of robotic surgery procedures. However, when the American College of Obstetricians and Gynecologists (ACOG) published a letter authored by Dr. James Breeden which questioned the clinical utility of robotic surgery in benign hysterectomy this growth temporarily stalled.

Titan initially intends to pursue benign gynecologic surgical related indications for the Enos surgical system. Titan has estimated that the US market size for benign gynecological surgery is approximately one billion dollars per year with 30-35% RAS penetration.

Enos Development Timelines

Currently the Enos system has not been cleared by the FDA or any other regulatory authority in any jurisdiction and is not yet commercially available. Titan expects to complete Enos surgical system product development (software verification and validation), tooling for manufacturing (initial instruments and camera systems will be manufactured in-house; workstations and patient carts by third party vendors) and preclinical system performance verification in Q4-2021. Titan is then expected to submit an Investigational Device Exemption (IDE) application to FDA to begin human clinical studies in mid-2022. Upon completion of the IDE studies, Titan plans to submit a De Novo regulatory request to the FDA in 1H-2023 followed by submissions to additional regulatory agencies in other major markets (Figure 7).

Figure 7 Titan Medical/Enos Development Timeline

(Titan Medical Investor Presenation, 2021)

Conclusions

Titan is focused on enhancing robotic assisted surgery using innovative technology through a single access point. The company is in the final stages of designing the Enos surgical system, a soft tissue surgery robot. Titan has integrated significant technology into the Enos surgical system for the purpose of improving the robotic assisted surgical experience for surgeons, which they believe will bring important benefits to patients, including less trauma, less scarring and faster recovery times. In addition, the Enos surgical system is designed to benefit hospitals through its smaller footprint, easy mobility and lower operating costs with the intent of improving clinical capabilities, operating room efficiency and hospital economics.

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