Continuous Compartmental Pressure Monitor

VALUE ANALYSIS 2021

MY01

MRKT-PRMA-010 Ver.0

MY01 CONTINUOUS COMPARTMENT PRESSURE MONITOR DRIVES VALUE AS AN AID IN DIAGNOSIS OF COMPARTMENT SYNDROME.

MY01 Inc. is on a mission to empower healthcare professionals with the ability to pre-empt severe medical conditions, improving patient outcomes.

The MY01 Continuous Compartmental Pressure Monitor is a sterile, single-use device. The easy-to-use nature of the MY01 device allows organizations to allocate their healthcare resources to focus on more important activities. Only the MY01 device provides quick, reliable and continuous pressure measurements to aid in diagnosis of Compartment syndrome.[2]

Acute Compartment Syndrome (ACS) is a true orthopaedic emergency. [3] Trauma is the most common cause of ACS.[4] Following trauma, swelling may build up causing an increase in muscle pressure leading to ACS.[5] Rapid diagnosis followed by prompt surgical decompression via a fasciotomy is critical to achieving favorable patient outcomes.[6] In the US, it is estimated that there is a prevalence of 500,000 cases per year that could be at-risk of Compartment Syndrome.

> **"I am so excited to be involved with the design of the MY01 device because it's easy to use and meets a need identified by almost all orthopaedic surgeons. I'm really enjoying using it in my hospital,"** said Ed Harvey, M.D., an orthopedic surgeon based in Montreal (Canada) and the Co-Founder of MY01.

Dr. Mitchell Bernstein, MD FRCSC - Principle Investigator of MY01 - An aid for diagnosing acute compartment syndrome in real time said, **"The MY01 device has been extremely easy to use, it is extremely reliable and integrates very well with users technology and hospital systems. It appears to be a timely adjunct to helping us diagnose and find safe dispositions for patients with suspected compartment syndrome."**

Some Important Considerations Related to Acute Compartment Syndrome:

1. Compartment syndrome is a potentially devastating and relatively common complication of fractures about the knee and tibial shaft (OTA 33,41,42).[7]
2. Delayed diagnosis and treatment (late fasciotomy) can have catastrophic consequences for the patient with 5.7% of all cases leading to amputation.[8] Amputations carry a lifetime cost of $500,000 and significant legal liability risk.[9]
3. In some cases, because of current deficiencies with diagnosis, the physician will conduct prophylactic fasciotomies. These prophylactic fasciotomies leave patients with large scars that carry their own set of complications, adding unnecessary costs due to added length of stay.[10]
    - On average, performing a fasciotomy on a tibia fracture patient will increase their length of stay by 8 days and over $50,000 in additional Charges[11]
    - Fasciotomies can result in risk of surgical site infection to 25%.[12] Surgical site infection is the third most costly type of healthcare-acquired infection (HAI) with an estimated added cost of $20 785 per case.[13]
    - Fasciotomies are associated with long-term pain in 10% of patients [14]. Roughly 30% will not return to work [15]
4. On average, an Acute Compartment Syndrome lawsuit rules in favor of the patient 33-55% of the time with damages awarded for litigation averaging over $1,550,000.[16-18]

As clinicians and hospitals evaluate options for cost-effective management of Acute Compartment Syndrome, it is important to employ new methods to detect Acute Compartment Syndrome or to rule it out in a timely fashion.[1] MY01 Continuous Compartmental Pressure Monitor provides the necessary immediate and timely information to aid physicians to monitor at-risk patients.[1] Treatment delays and misdiagnosis are preventable with the Continuous Pressure Monitoring. The American Academy of Orthopaedic Surgeons (AAOS) recognizes the use of continuous intra-compartmental pressure monitoring (Perfusion > 30mmHg) to assist in ruling out ACS.[4]

Sources

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MY01

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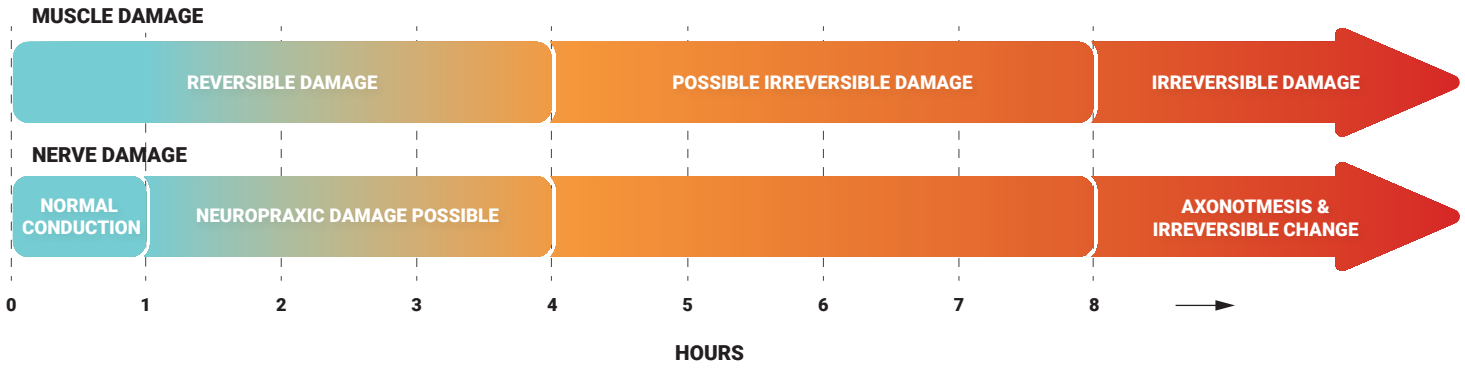
CLINICAL CHALLENGE

Compartment Syndrome is a Time Sensitive Problem

Compartment syndrome is a **true orthopaedic emergency**[1]. Compartment syndrome is relatively common but potentially devastating complication of fractures about the knee and tibial shaft (OTA 33,41,42)[2,3]. Compartment Syndrome develops progressively after trauma - requiring close monitoring and serial physical exams. Serial physical exams have proven to have poor specificity and sensitivity. The physical signs can be missed or attributed to other aspects of injury[4,5]. Rapid diagnosis followed by prompt surgical decompression via a fasciotomy is critical to achieving a favorable outcome[6,7].

The most important determinant of outcomes from acute compartment syndrome after injury is time to diagnosis[8,9]. Muscle necrosis may occur within 2 hours of injury in as many as 35% of patients with ACS[10]. The difference between foot numbness (5.36h) and foot drop (7.25h) can be as little as 2 hours[11]. The severity of muscle necrosis and nerve injury worsens with the delay in performing fasciotomy[11].



Missed diagnosis and treatment (late fasciotomy) can have catastrophic consequences for the patient with 5.7% of all cases leading to amputation[12]. **Amputations carry a lifetime cost of over $500,000 and significant medicolegal liability risk to the surgeon and hospital[13]. An acute compartment syndrome lawsuit rules in favor of the patient 33-55% of the time with damages awarded for litigation averaging over $1,550,000[14-16].**

Patient Outcome is determined by time to diagnosis

The Research on Extremity Acute Compartment Syndrome (REACtS) developed a classification of the outcomes of acute compartment syndrome, describing 5 grades related to the timing of diagnosis, with each successive grade associated with increasing delay in diagnosis and increased morbidity[17]. The classification used data from previous compartment pressure studies[18] to quantify the categories as follows:

- **GRADE 1:** Primary Closure or early delayed closure (within 1-2 days), without any evidence of ACS (prophylactic fasciotomy, no muscle necrosis)
- **GRADE 2:** Delayed Primary Closure- ACS with post-ischemic swelling, none to minimal necrotic muscle
- **GRADE 3:** Delayed primary closure needing advance wound closure techniques - some muscle necrosis in 1 or 2 compartments (split thickness skin graft or flap, local rotation flap, extended VAC coverage to minimize swelling)
- **GRADE 4:** Limb Salvage or Significant Necrosis in greater than 2 compartments (non-functional muscles)
- **GRADE 5:** Amputation

To limit the risk of missed or late diagnosis, it is widely considered among physicians that performing early fasciotomy is critical to achieving the best possible outcomes. In general, performing unnecessary/prophylactic fasciotomy is better than missing a true case of compartment syndrome[19-22] Trauma cases may be overtreated with fasciotomy to avoid ACS. Furthermore, unnecessary/prophylactic fasciotomies are associated with poor outcomes when compared to patients who did not receive the procedure[23].

Fasciotomy increases the risk of surgical site infection

A Surgical Fasciotomy is the only effective treatment, offering an immediate decrease in compartment pressure by increasing the volume of the affected muscle through the release of the skin and muscle fascia[24,25]. Nonetheless, fasciotomy carries its own risk and complications, including long hospital stay, surgical site infection, a need for further surgery for delayed wound closure[9], and an overall increased cost of care[26-28].

Liberal use of prophylactic fasciotomies leave patients with large scars that carry their own documented set of complications[23]. On average, performing a fasciotomy on a tibia fracture patient will increase their length of stay by 8 days[30] and triple their risk of surgical site infection to 25%[11]. **Surgical site infection is the third most costly type of healthcare-acquired infection (HAI) with an estimated added cost of $20,785 per case[31].**

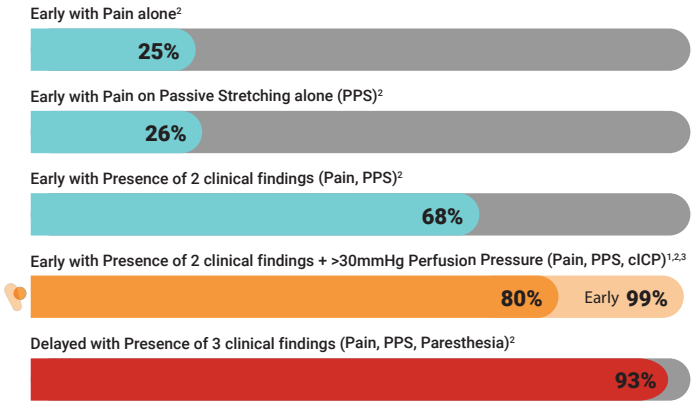
Improved outcomes through state of the art diagnosis that provides reliable timely information

While single point pressure measurements can lead to overtreatment[32], continuous pressure monitoring can enhance decision making where clinical assessments alone fail to indicate the early signs of ACS[9] and has been shown to not increase the instances of false positives. The AAOS recommends continuous ICP (cICP) monitoring in obtunded and unconscious patients. Continuous intracompartmental pressure monitoring provides healthcare professionals with a reliable diagnostic aid, increasing the chances of making the right call[33,34]. **In a recently published study, continuous pressure measurement decreased the time to fasciotomy by 6 hours, drastically reducing the necessity of split thickness skin grafts (from 50 to 15%)[9]**. The American Academy of Orthopaedic Surgeons (AAOS) recognizes the use of continuous intra-compartmental pressure monitoring (Perfusion > 30mmHg) to assist in ruling out ACS[4].

Diastolic Pressure
– Compartment Pressure
= Perfusion Pressure / Δp

Continuous Pressure Readings can correlate to change in Clinical Findings increasing the odds of making the right call.

- The American Academy of Orthopaedic Surgeons (AAOS) recognizes the use of continuous intra-compartmental pressure monitoring (Perfusion > 30mmHg) to assist in ruling out ACS.[4]
- AAOS recommends cICP to aid in diagnosis of unconscious or obtunded patients.[4]
- Helps streamline when clinical assessments are necessary
- Monitoring limits risk of ruling out ACS too early



Recommendation for Use

8 of 10 physicians recommend using the MY01 Device for all at-risk patients* as well as unconscious patients with orthopedic injuries

*OTA 31, 42 & 43

Only MY01 can provide quick reliable digital continuous pressure monitoring required to aid physicians in making a timely diagnosis.[35]

TECHNOLOGY OVERVIEW

MY01's Continuous Compartment Pressure Monitor uses a patented intuitive insertion mechanism to deliver reliable MicroElectroMechanical Systems (MEMS) technology[35] directly within the muscle -enabling reliable, continuous pressure measurements. The Continuous Compartment Pressure Monitor is specifically designed to minimize common use errors[36] in order to provide quick, reliable continuous pressure readings over time. In multiple preclinical models, MY01 was the only device that could reliably measure continuous pressure readings under clinical conditions.

The MY01 Continuous Compartmental Pressure Monitor is a sterile, single-use device. The easy-to-use nature of the MY01 device allows organizations to allocate their healthcare resources to focus on more important activities. Only the MY01 device provides quick, reliable and continuous pressure measurements to aid in diagnosis of Compartment syndrome.[35]

Key Characteristics

1. Quickly delivering proven MEMS technology in situ providing reliable continuous pressure measurements, relative to current methods [35].
2. Enables single point measurements for survey and placing sensor in most at-risk muscle compartment.
3. Specifically designed for continuous pressure monitoring while minimizing use errors by design.
4. Wireless capabilities enable visualization of data over time enabling physicians to augment clinical findings.

COMPETITIVE LANDSCAPE

Currently, the main 3 competitors addressing compartment pressure measurement are devices made by C2Dx, Compass, and makers of arterial lines. In all three cases, there has been little to no innovation for over 20 years.

MY01 represents a significant improvement over current competition in the following areas:

- Superior accuracy [35] and resolution which is the result of an innovative and intuitive insertion mechanism and micro sensor technology
- Single use with no re-usable parts
- Continuous monitoring
- Mobile app that enables ongoing care team collaboration
- Simple easy to use with all components in one sterile package
- Auto Replenishment Available

	 MY01	 A-Line	 STIC Monitor (C2Dx)
Single Use	✔	✔	✔
Simple Setup	✔	✗	✔
Continuous	✔	✔	✗
Superior Accuracy [35]	✔	✗	✗
Connected	✔	✗	✗

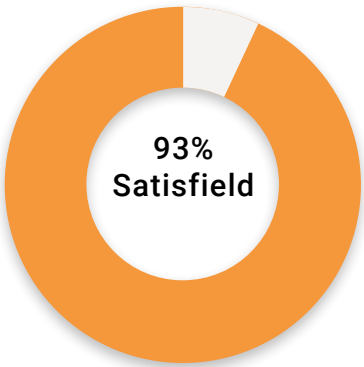
CASE STUDY

Continuous Pressure Monitoring Leads to Improved Patient Care

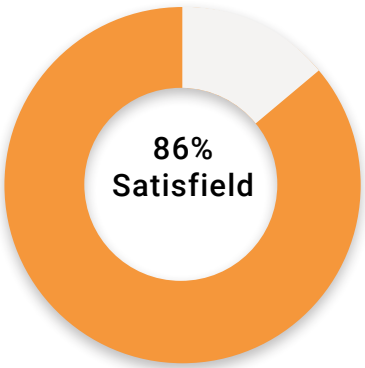
Since implementing the MY01 on at-risk patients at a busy Level 1 Trauma Teaching Center with 427 beds. The center used 20 devices on 18 trauma patients and detected 3 true ACS early and avoided 1 unnecessary fasciotomy. Driving significant savings to the hospital. 90% of the physicians found the device **much easier to use and better** than incumbent technologies. The physicians had confidence in function and placement of the device which is a significant improvement over the performance of incumbent devices.

Ease of Use

Confidence in Placement



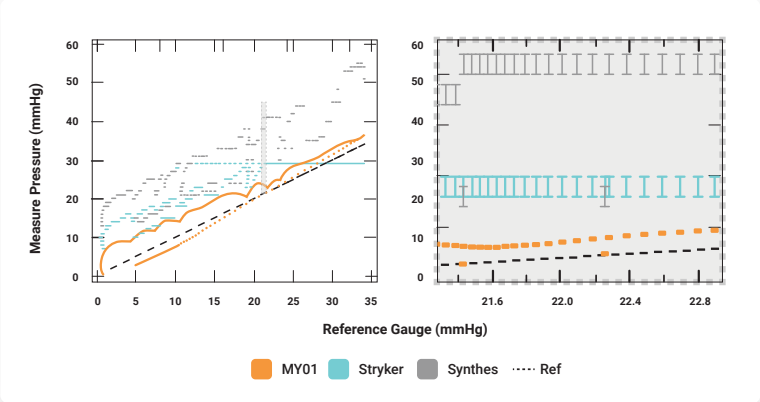
Confidence in Function



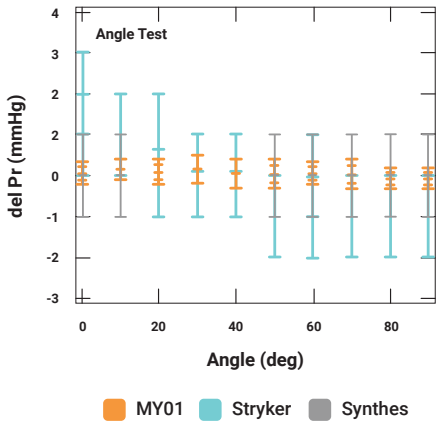
HEAD TO HEAD COMPARISON SHOWS MY01 IS SIGNIFICANTLY MORE RELIABLE THAN INCUMBENT PRESSURE MONITORING TOOLS. [35]

Compartment pressure monitoring devices were compared under real world condition changes. Stryker, Synthes, and MY01 devices were tested under strict laboratory conditions.

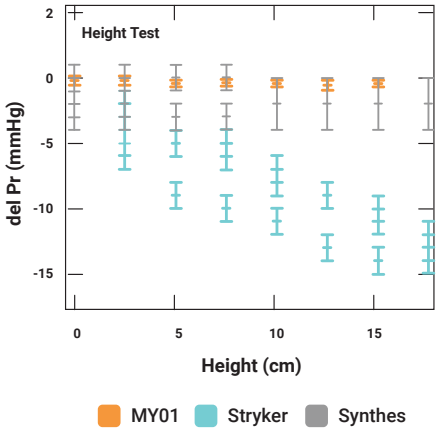
First comparisons were performed under ideal conditions with the devices measuring pressure inside a controlled pressure chamber in order to test the accuracy of measurements of each device. Measurements were performed under constant angle and height. The Synthes device showed an offset of 20 mmHg +/-1 compared to the reference gauge. The MY01 and Stryker device showed accurate measurements of pressure when compared to the reference. However, the Stryker device had a 10 fold higher variability (1mmHg) compared to the MY01 device (0.1mmHg)



Comparison of angle impact on ICP devices measurement accuracy



Comparison of height impact on ICP devices measurement accuracy



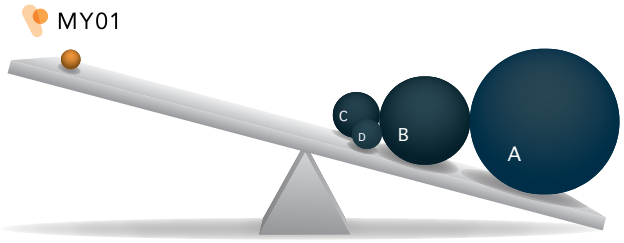
The measurement conditions were then modified to reflect real work conditions of motion and position changes. The modifications reflected realistic movement vectors in slower than expected vector changes. While under constant pressure, the angle of each device was changed from 0 to 90 degree to determine effect on the measured pressure. The measurements provided by the Stryker device were greatly affected by angular changes with up to 3 mmHg +/-1 of unwanted variance. The MY01 and Synthes readings remained unchanged. The differences between the three devices were marked and statistically significant. The second parameters that was tested is the impact of height on pressure measurements. While under constant pressure, the height at which each device was placed was modulated (0 - 18cm from the rat). Similar to the previous test, the Stryker device exhibited the most variation with up to 15 mmHg +/-1 false deviation while the MY01 and Synthes readings remained similar.

Patient care is affected by a variety of environmental factors that may alter the accuracy of pressure readouts such as angular and height placements. It is not surprising that use of currently available pressure sensors has significant limitations and is not yet recommended because of their unreliable accuracy. This has been confirmed in the present study, accuracy of the Stryker device was significantly affected by height and angle changes while the accuracy of the MY01 device remained relatively unchanged.

Both Synthes and Stryker are unable to accurately monitor pressure continuously. Multiple needle insertions increase the level of pain for the patient and the chance of introduction of bacteria into deep tissues, as well as potentially causing more tissue damage. The method needs to be set-and-forget so that busy personnel do not need to constantly monitor the injured patient. The lack of necessary technology causes musculoskeletal injuries with ACS to be more disabling and a costly burden. MY01 is the only device that can reliably and continuously monitor Intracompartmental pressure, without being affected by environmental factors.

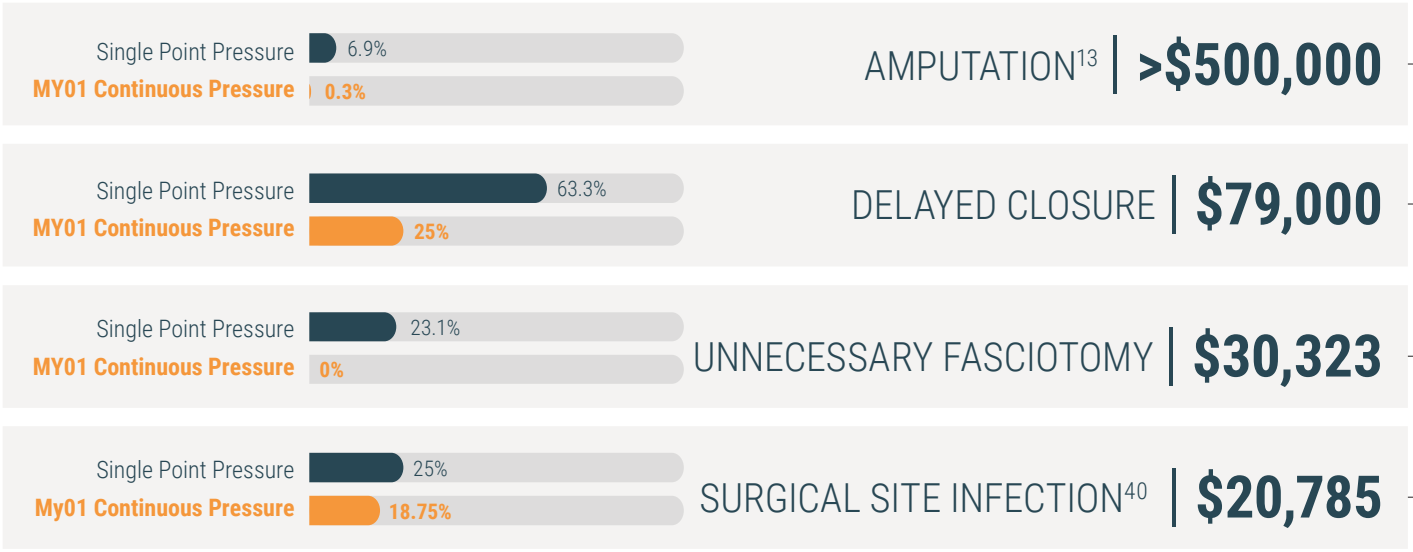
COST-EFFECTIVE SOLUTION

Early, Reliable, Continuous compartment pressure monitoring in at-risk patients can drive significant savings when compared to Single Point Measurements with Clinical Findings. Only Continuous pressure measurements enable a stable reference which can be used to correlate the changes in clinical findings in order to reduce unnecessary fasciotomies while de-risking delayed diagnosis. Catching compartment syndrome early and reducing unnecessary fasciotomies contribute to decreasing the cost of care for patients at-risk of developing compartment syndrome. [9, 11, 13, 17, 18, 22, 29, 31, 37-39]



LONG TERM COSTS

A. AMPUTATION
B. DELAYED CLOSURE
C. UNNECESSARY FASCIOTOMY
D. SURGICAL SITE INFECTION



Some Important Considerations Related to Acute Compartment Syndrome:

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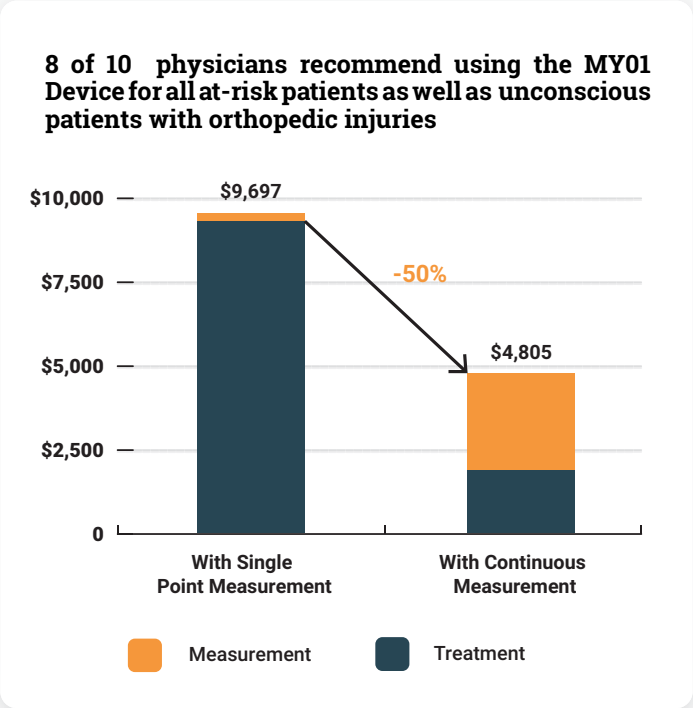
3. In some cases, because of current deficiencies with diagnosis, the physician will conduct prophylactic fasciotomies. These prophylactic fasciotomies leave patients with large scars that carry their own set of complications, adding unnecessary costs due to added length of stay.[23]
    - On average, performing a fasciotomy on a tibia fracture patient will increase their length of stay by 8 days and over $50,000 in additional Charges[29]
    - Fasciotomies can result in risk of surgical site infection to 25%.[30] Surgical site infection is the third most costly type of healthcare-acquired infection (HAI) with an estimated added cost of $23,466 per case.[40]
    - Fasciotomies are associated with long-term pain in 10% of patients [41]. Roughly 30% will not return to work [42]
4. On average, an Acute Compartment Syndrome lawsuit rules in favor of the patient 33-55% of the time with damages awarded for litigation averaging over $1,550,000.[14-16]

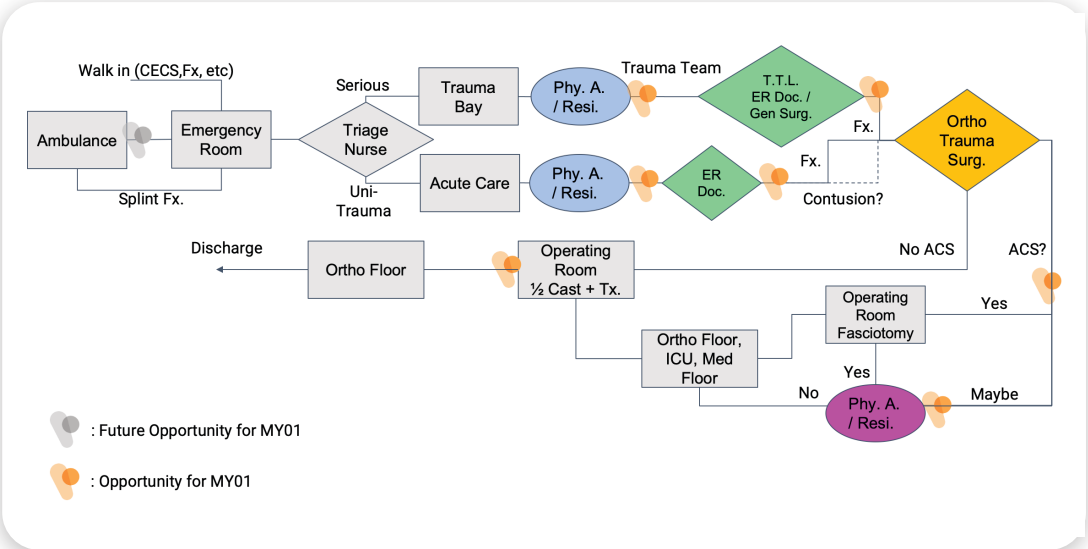
SCREENING ALL AT-RISK PATIENTS TO DRIVE COST SAVINGS

While single point pressure measurements can lead to overtreatment[32], continuous pressure monitoring can enhance decision making where clinical assessments alone fail to indicate the early signs of ACS[9] and has been shown to not increase the instances of false positives. The AAOS recommends continuous ICP (cICP) monitoring in obtunded and unconscious patients. Continuous intracompartmental pressure monitoring provides healthcare professionals with a reliable diagnostic aid, increasing the chances of making the right call[33,34]. **In a recently published study, continuous pressure measurement decreased the time to fasciotomy by 6 hours, drastically reducing the necessity of split thickness skin grafts (from 50 to 15%) without increasing the risk of false positives[9]**. Screening of all at-risk patients will ensure cost savings for the healthcare system by reducing both the time to diagnosis and the number of unnecessary costly interventions.



INTERACTING WITH THE FULL PATIENT FLOW

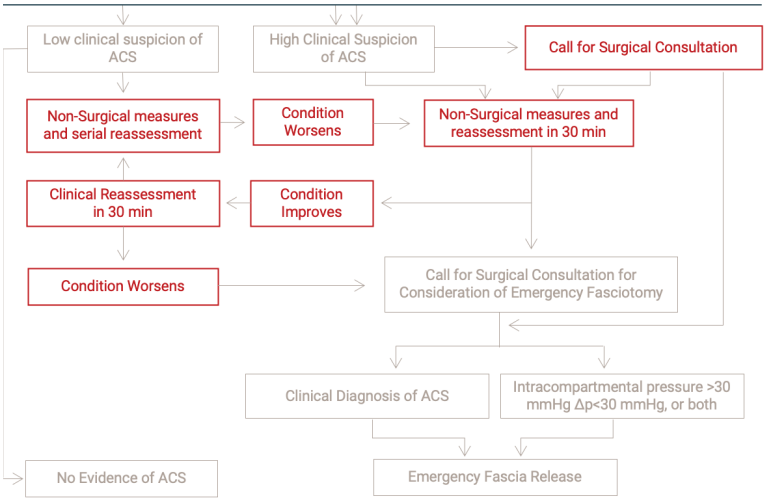
As clinicians and hospitals evaluate options for cost-effective management of Acute Compartment Syndrome, it is important to employ new methods to detect Acute Compartment Syndrome or to rule it out in a timely fashion.MY01 Continuous Compartmental Pressure Monitor provides the necessary immediate and timely information to aid physicians to monitor at-risk patients. Treatment delays and misdiagnosis are preventable with the use of Continuous Presure Monitoring.



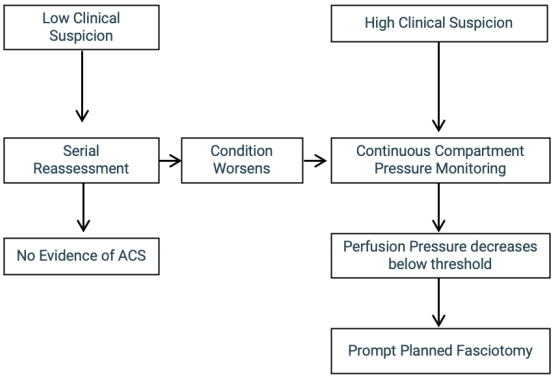
IMPROVING THE DECISION FLOW

Operating room (OR) time occupied by fasciotomy procedures are low value and cannibalize other higher value elective surgeries. By eliminating unnecessary procedures, MY01 will help decrease operating room utilization so that more elective surgeries can be performed without delay. Lower unnecessary OR utilization further improves hospital operating efficiency, leading to reduce waitlist times and higher patient satisfaction.

Current



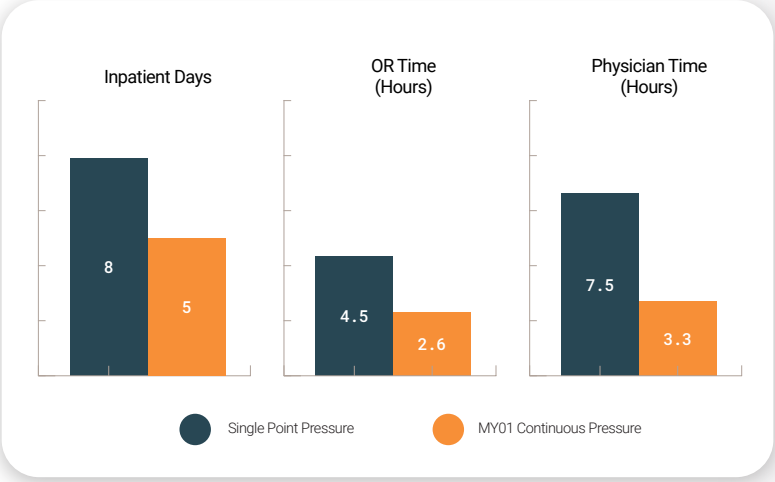
Proposed



Faster Diagnosis with Less Patient Contact Time

IMPACT ON HEALTHCARE FACILITIES

Liberal use of prophylactic fasciotomies leave patients with large scars that carry their own documented set of complications[23]. On average, performing a fasciotomy on a tibia fracture patient will increase their length of stay by 8 days[30] and triple their risk of surgical site infection to 25%[11]. Continuous pressure monitoring can drive hospital cost savings[9] by assisting in the elimination of unnecessary fasciotomy procedures, reducing inpatient days, mitigating follow up procedures, and diminishing infection risk. **In a recently published study, continuous pressure measurement decreased the time to fasciotomy by 6 hours, drastically reducing the necessity of split thickness skin grafts (from 50 to 15%) without increasing the odds of false positives. [9]**



PRODUCT INFORMATION

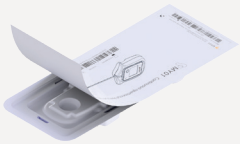
Product Composition

The MY01 Continuous Compartment Pressure Monitor is sterile, single use and comes ready to measure with minimal training and minimal effort. Only MY01 enables reliable digital pressure readings continuously over time.[35] The MY01 monitor comes equipped with an intuitively designed introducing mechanism that provides up to 5 single point measurements for determining the most at-risk compartment. After which, the introducer can be removed to allow the MY01 to continuously measure the most at-risk compartment for up to 18 hours. The MY01 device measures one compartment at a time.

When monitoring around the tibial shaft (OTA 41,42), literature recommends continuous monitoring of the anterior compartment, including the other compartments only as clinically indicated. [19,36] Depth markings located on the introducer needle aid with placement of the sensor within the muscle compartment.

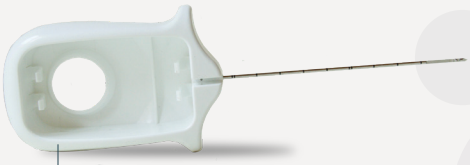
MY01 can be used for up to 18 hours. Data is stored and displayed on the device's LCD screen. MY01 has wireless capabilities enabling pressure data to be visualized over time through our accompanying Mobile Application. MY01 is the only device which enables these features to promote care team collaboration, ultimately improving patient care.

Packaged MY01 Device



MY01 Device

Introducer



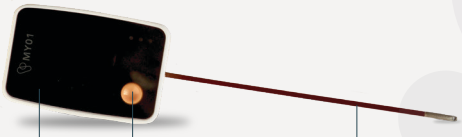
Housing

Needle

Pressure Monitor (Applied Apart)

Sensor

Device Body



Push-Button

Display

Lead-Wire

PRODUCT LIST

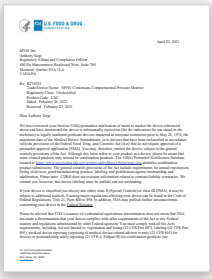
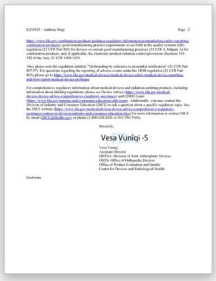
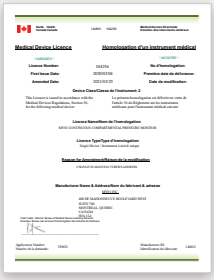
ITEM	SKU
Continuous Compartmental Pressure Monitor (6 devices)	MY01-0001
Continuous Compartmental Pressure Monitor (1 device) *	MY01-0001
MY01 Mobile Application	MY01-APP
	*Auto Replenishment Option Available

INDICATION FOR USE STATEMENTS

The MY01 Continuous Compartmental Pressure Monitor is intended for real-time and continuous measurement of compartmental pressures. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome. The trend arrows displayed are meant for qualitative purposes only and are not intended to have any clinical significance.

The MY01 Mobile Application is an optional application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. The data is for informational purposes only and is not intended to be used for diagnosis of any nature or active patient monitoring

REGULATORY CLEARANCES

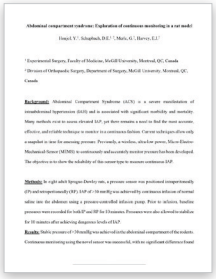
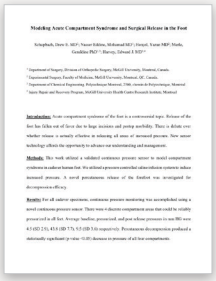
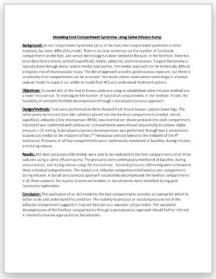
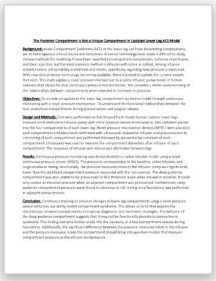
CLEARANCE TYPE	
510(k) Clearance (K210525)	 
CE Mark (36359)	
HC Approved (LN/NH 104256)	
Manufacturing - ISO13485:2016 Certified (36360)	
Audit - MDSAP (36361-1)	

CLINICAL & PRECLINICAL EVIDENCE

MY01 has a considerable pipeline of research supporting its clinical value. The MY01 Continuous Compartment Pressure Monitor is supported by 10 pre-clinical studies and 5 on-going multisite post market clinical studies which will combine for over 400 patients. The clinical research and historical analysis is being overseen by the 11 member Compartment Syndrome Research Collaboration Steering Committee (Steering Committee), which is a collaborative effort between members of the Major Extremity Trauma and Rehabilitation Consortium (METRC) along with members of ongoing MY01 affiliated research. The MY01 Continuous Compartment Pressure Monitor is enabling this collaborative research to be undertaken on Compartment Syndrome.

Pre-Clinical Data Review

STUDY TITLE	DESCRIPTION	
Comparison of Three Devices to Measure Pressure for Acute Compartment Syndrome., Merle, G., M. Comeau-Gauthier, V. Tayari, M. N. Kezzo, C. Kasem, F. Al-Kabraiti, C. Laverdiere, G. Xereas and E. J. Harvey (2020). "" Military Medicine 185(Supplement_1): 77-81. (As Presented at SICOT)	Three devices (Synthes, Stryker, and MY01) were compared in a pre-clinical rat compartment syndrome simulation. Simultaneous measurements of intracompartmental pressures allowed concurrent comparison among all devices. Results: Large variations from the reference values are seen with the Synthes and Stryker devices. Variances are large in these two devices even under ideal conditions. The MY01 device was the truest indicator of reference pressure in this ACS model (over 600% more accurate).	
Pre-Clinical Acute Compartment Syndrome with a Porcine Continuous Measurement Model (OTA 2021)	Continuous monitoring of compartment pressure was successfully performed in vivo using novel pressure sensing technology. The ischemia-reperfusion with superimposed direct crush injury model was found to consistently yield higher compartment pressures than the balloon catheter model during the observation period. The use of a fasciotome was able to release compartment pressures back to baseline in >50% of hind limbs. Gross inspection after open fasciotomy of the anterior compartment revealed a thick fascia as compared to humans.	
Validation of a Human Model of Compartment Syndrome (EWI SOMOS)	Fresh frozen cadaver legs were used to determine if a new device that permits continuous pressure monitoring would allow evaluation of high pressure changes in the leg. The goal was to evaluate the ability to isolate and pressurize compartments without loss of fluid to other compartments or the external environment. Increase in saline volume correlated with an increase in compartmental pressure. The posterior compartment required significantly more fluid to increase the pressure. Once fasciotomies were performed all four intracompartmental pressures decreased to levels less than ACS threshold. Deep posterior pressures tracked behind posterior pressures during isolated posterior infusion. Significantly less fluid inflow was needed in the lateral and anterior compartments once another compartment had elevated pressures.	

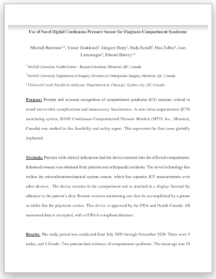
STUDY TITLE	DESCRIPTION	
Comparison of Three Devices to Measure Pressure for Acute Compartment Syndrome., Merle, G., M. Comeau-Gauthier, V. Tayari, M. N. Kezzo, C. Kasem, F. Al-Kabraiti, C. Laverdiere, G. Xereas and E. J. Harvey (2020). "" Military Medicine 185(Supplement_1): 77-81. (As Presented at SICOT)	Three devices (Synthes, Stryker, and MY01) were compared in a pre-clinical rat compartment syndrome simulation. Simultaneous measurements of intracompartmental pressures allowed concurrent comparison among all devices. Results: Large variations from the reference values are seen with the Synthes and Stryker devices. Variances are large in these two devices even under ideal conditions. The MY01 device was the truest indicator of reference pressure in this ACS model (over 600% more accurate).	
Abdominal compartment syndrome: Exploration of continuous monitoring in a rat model Honjol, Y.1, Schupbach, D.E.1, 2, Merle, G.2, Harvey, E.J.2	In adult Sprague-Dawley rats, a pressure sensor was positioned intraperitoneally (IP) and retroperitoneally (RP). IAP of >30 mmHg was achieved by continuous infusion of normal saline into the abdomen using a pressure-controlled infusion pump. Prior to infusion, baseline pressures were recorded for both IP and RP for 10 minutes. Pressures were also allowed to stabilize for 10 minutes after achieving dangerous levels of IAP. Results: Stable pressure of >30 mmHg was achieved in the abdominal compartment of the rodents. Continuous monitoring using the novel sensor was successful, with no significant difference found between IP and RP values at baseline, throughout infusion, or during stabilization. Furthermore, the position of the animal had no significant effect on pressure readings.	
Modeling Acute Compartment Syndrome and Surgical Release in the Foot Schupbach, Drew E. MD2; Nasser Eddine, Mohamad MD1; Honjol, Yazan MD2; Merle, Geraldine PhD1,3; Harvey, Edward J. MD1,4	This work utilized the MY01 Continuous Compartmental Pressure Monitor to model compartment syndrome in cadaver human feet. We utilized a pressure controlled saline infusion system to induce increased pressure. A novel percutaneous release of the forefoot was investigated for decompression efficacy. Results: For all cadaver specimens, continuous pressure monitoring was accomplished using a novel continuous pressure sensor. There were 4 discrete compartment areas that could be reliably pressurized in all feet.	
Modeling Foot Compartment Syndrome Using Saline Infusion Pump. (#2825 EFORT 2020) Drew Schupbach1, Yazan Honjol1, Geraldine Merle1, Edward Harvey1, Cooper Jefferson2, Animesh Saha2, Charles Allan2	ACS level pressures (>30 mmHg) were able to be replicated in the foot compartments of all three cadavers using a saline infusion pump. The pressures were continuously monitored at baseline, during pressurization, and during release using the microsensor. Isolated pressures >30 mmHg were achieved in three individual compartments. The medial and adductor compartment behaved as one compartment during infusion. A dorsal percutaneous approach successfully decompressed the forefoot compartments in all three cadavers. No injuries to extensor tendons or dorsal nerves were identified during post-fasciotomy exploration.	
Does The Deep Posterior Compartment Exist? An Updated Lower Leg ACS (#2813 EFORT 2020) Drew Schupbach1, Yazan Honjol1, Edward Harvey1, Geraldine Merle1, Charles Allan2, Animesh Saha 2, Cooper Jefferson2	Infusion tests were performed on five thawed fresh frozen human cadaver lower legs. The pressure was modulated using a saline infusion pump with inline pressure sensor terminated as 14G catheters placed. The deep posterior compartment was unable to be pressurized to ACS threshold levels when infused in isolation. It could only sustain an elevated pressure when an adjacent compartment was pressurized. Furthermore, deep posterior compartment pressures were found to decrease to <10 mmHg once fasciotomy was performed in adjacent compartments.	

Clinical Data Review & Ongoing Clinical Studies

STUDY	SAMPLE SIZE	PRINCIPAL INVESTIGATOR	TREATMENT/ INTERVENTION	OUTCOME OF INTEREST	FOLLOW UP TIME	TIMING OF DATA AVAIL.	HOSPITALS/ RESEARCH ORG.
Quebec Study: MY01 - An Aid for diagnosing ACS in real time	50	Dr. Mitchell Bernstein	Pressure monitoring with MY01 device (pressure, clinical monitoring with 7 Ps)	Development of ACS based on clinical signs and continuous pressure measurement	6 weeks	Recruiting	• Montreal General Hospital • Sacre-Coeur Hospital • Hôpital Enfant Jésus
COTS Study: Clinical Trial of a New Device for Real-Time Muscle Pressure Measurements in Patients with an Upper or Lower Extremity Fracture at Risk for Acute Compartment Syndrome (Leighton)	100	Dr. Ross Leighton	Pressure monitoring with MY01 device (pressure, clinical monitoring with 7 Ps)	Safety and functionality of MY01 (the device) in patients at risk for developing acute compartment syndrome	2 weeks	Recruiting	Queen Elizabeth II Health Science Centre (Halifax), • St. Michael's Hospital (Toronto, • Foothills Hospital (Calgary) • Vancouver General Hospital (Vancouuver) • London Health Science Centre (London)
DoD Sponsored Study: Real-Time Muscle Pressure Measurements in Patients at Risk for ACS: A Prospective Cohort Study with Historical Control	50	Dr. Mitchell Bernstein	Pressure monitoring with MY01 device (pressure, clinical monitoring with 7 Ps)	Development of ACS based on clinical signs and continuous pressure measurement	2 weeks	Seeking IRB approval	Recruitment: VUMC, Hennepin (Dr Obremskey, Dr Schmidt) Coordination: MUHC
RESTORE - Evaluation of the diagnostic and therapeutic value of tissue ultrafiltration in patients at risk of acute compartment syndrome	200	Dr. Andrew Schmidt	Tissue Ultrafiltration (TUF) and continuous compartment pressure monitoring	Efficacy of TUF in reducing the incidence of ACS and fasciotomy, lowering IMP, and improving functional outcomes among lower extremity injury patients.	6 month	Planning Phase	• Hennepin Medical Centre • University of Maryland • Carolinas Medical Centre • Vanderbilt Medical Centre • San Antonio Military Medical Centre
Retrospective Study on Tibial Fractures and Dislocations Resulting in Acute Compartment Syndrome" (Bernstein)	133	Dr. Mitchell Bernstein	Clinical exam, surgical assessment	Validation of new classification. 6-7p's validation	6 weeks	Ongoing	MUHC/VUMC/Hennepin
Expert panel survey - REACtS. REsearch on Acute CompartmenT Syndrome Working Group	24	Dr. Edward J. Harvey	Continuous monitoring of IMP	Validation of the new HOPS ACS classification classification	6 weeks	On-going	Surveying of experts from a a variety of leading trauma centers across the US and Canada.

Published and On-going Clinical Data

MY01 is currently supporting 5 on-going multisite post market clinical studies which will combine for over 400 patients. These studies are being overseen by the 11 member Compartment Syndrome Research Collaboration Steering Committee (Steering Committee). The Steering Committee is made of members of the Major Extremity Trauma and Rehabilitation Consortium (METRC) along with members of ongoing MY01 affiliated research. The steering committee is intended to ensure the continuity of compartment syndrome study research goals, streamlining the sharing of data, and effectively allocating inter-organizational resources. Augmented by historic data accumulated during past METRC projects, committee members will also have access to a common database of cases to drive important insights in the management of Compartment Syndrome.

STUDY TITLE	DESCRIPTION	
Use of Novel Digital Continuous Pressure Sensor for Diagnosis Compartment Syndrome	The MY01 Continuous Compartmental Pressure Monitor (MY01 inc., Montreal, Canada) was studied in this feasibility and safety report. Patients with clinical indications had the device inserted into the affected compartment. Informed consent was obtained from patients and orthopaedic residents. The novel technology lies within the microelectromechanical system sensor, which has superior ICP measurements over other devices. The study period was conducted from July 2020 through November 2020. There were 5 males, and 1 female. Two patients had evidence of compartment syndrome. The mean age was 38 (range, 22-57). Fractures were classified according to the AO/OTA classification. The device was in place for an average of 8hrs 38min. There were no complications with the device pressure readings, usability, or data-transfer.	

REIMBURSEMENT

Procedure Coding

MY01 Continuous Compartmental Pressure Monitor

		HOSPITAL OUTPATIENT	INPATIENT PROSPECTIVE PAYMENT SYSTEM (PPS)4
CPT CODE[1]	DESCRIPTON	AMBULATORY PAYMENT CLASIFICATION (APC)	ICD-10 DIAGNOSIS CODE[4]
20950	Interstitial Fluid Pressure Monitoring	5071	Packaged into Primary Procedure. Typically T.79.A Traumatic Compartment Syndrome

Hospital Outpatient[3]

AMBULATORY PAYMENT CLASIFICATION (APC)	DESCRIPTON
5112	Level 2 Musculoskeletal Procedures
5113	Level 3 Musculoskeletal Procedures
5114	Level 4 Musculoskeletal Procedures
5115	Level 5 Musculoskeletal Procedures

Inpatient Prospective Payment System (IPPS)[4]

MS-DRG	DESCRIPTON
474	Amputation for Musculoskeletal Sys & Conn Tissue Dis w/ MCC
963	Other Multiple Significant Trauma w/ MCC
501	Soft Tissue Procedures w/ CC
965	Other Multiple Significant Trauma w/o CC/ MCC
923	Other injury, Poisoning, & Toxic Effect Dlag. without MCC

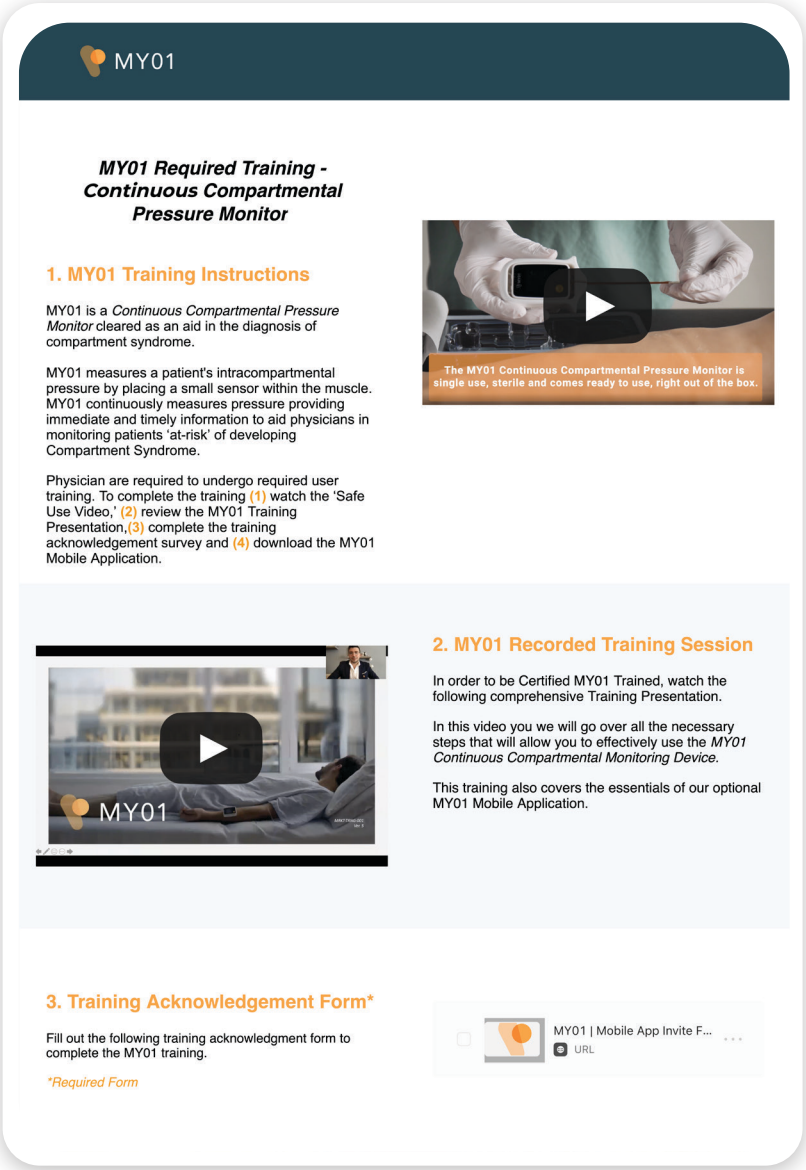
TRAINING AND EDUCATION

In addition to online resources, MY01 offers training sessions and events (in person and virtual) for healthcare professionals throughout the year. These educational resources provide opportunities for clinicians to learn about the safe and effective use of the MY01 Continuous Compartment Pressure Monitor.

Under the direction of course faculty, program attendees may participate in didactic sessions and muscle model labs highlighting the use of MY01 for continuous intracompartmental pressure monitoring. Upon completion of these courses, attendees will be able to:

- Identify patient selection criteria when using MY01
- Confidently handle and introduce the MY01 device.

MY01 is committed to providing physicians and care teams with as many educational resources as possible, including a team of knowledgeable clinical specialists, videos, and guides, to ensure the entire care team has the latest knowledge around Compartment Syndrome and feels confident while using the MY01 Continuous Compartment Pressure Monitor.
and analysis of all incidents included in this report.



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MY01

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