MYO1®

The Continuous Perfusion Sensing Technology Platform

Value Analysis

Table of Contents

Company Overview

Founded in 2019

Based in Montreal, QC

About MY01

MY01 envisions a world where every disease is quantifiable, enabling precise, personalized care for all patients. Our breakthrough technology is designed to empower trauma teams with objective data to make faster, more informed decisions. Specializing in the management of acute compartment syndrome, MY01 enables proactive monitoring, early intervention, and improved communication across the care team.

The Value We Provide

While clinical judgment remains essential, the Continuous Perfusion Sensing Technology (CPST) Platform aims to transform trauma programs by converting complex biological signs into dynamic, actionable, real-time data to facilitate better decision-making. With our CPST Platform (*see-past*), clinicians can visualize objective and continuous disease progression, empowering healthcare facilities to match the needs of injured patients with appropriate levels of care.

Highest Quality of Outcomes

- 2,000 use cases
- Reduced time to diagnoses — 5 hours earlier than clinical signs
- 100% sensitivity and specificity

Optimized Clinical Workflow

- Seamless integration into hospital workflows
- Faster patient assessments
- Nerve block usage without compromise
- Scheduled OR time

Reducing Risk, Supporting Documentation

- Time-stamped compartment pressure data
- Objective record of care
- Mitigated medicolegal risks

OUR MISSION

To enhance the quality and outcomes of trauma care by utilizing advanced technology to minimize variation in care — delivering actionable insights driven by real-time, objective data.

> *"Fasciotomies are not benign procedures, so you want to be confident the patient absolutely needs one. The MY01 device gives objective data points to help you feel confident in making that decision."*

Charles Moon, MD
Cedar Sinai Hospital, Los Angeles

> *"Ultimately, the device aids in being able to understand where patients are on the spectrum of progression and whether or not they would benefit from a fasciotomy. In cases of high risk patients, it's really helpful to have consistent pressure readings and to be able to monitor trends when you don't have a full patient history."*

Hans Van Lancker, MD, FRCSC, FAAOS
Cambridge Health Alliance

Clinical Challenge

Compartment Syndrome is a Time Sensitive Problem

Compartment syndrome is a true orthopaedic emergency [1]. Compartment syndrome is a 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 [6-8].

The most important determinant of outcomes from acute compartment syndrome after an injury is time to diagnosis[8,9]. Muscle necrosis may occur within 2 hours of injury in as many as 35% of patients with acute compartment syndrome [3]. The difference between foot numbness (5.36h) and foot drop (7.25h) can be as little as 2-3 hours [9]. The severity of muscle necrosis and nerve injury worsens with the delay in performing

Missed diagnosis and treatment (late fasciotomy) can have catastrophic consequences for the patient with 5.7% of all cases leading to amputation [10]. Amputations carry a lifetime cost of over $500,000 and significant medicolegal liability risk to the surgeon and hospital [11].

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 [12-14].

Time is Muscle

Muscle Damage

Reversible Damage (EARLY)	Possible Irreversible Damage	⚠ Irreversible Damage (+12hrs)

Timing of Clinical Signs

Pain Out of Proportion (EARLY)	Pain on Passive Stretching	⚠ Pulselessness Paresthesia Pallor

Endorsements [15]

Recommended by an expert panel based on published peer-reviewed literature.

> *"Evidence supports the use of repeated/continuous intracompartmental pressure monitoring and a threshold of diastolic blood pressure minus intracompartmental pressure >30 mmHg to assist in ruling out acute compartment syndrome."*

> *"In the absence of reliable evidence, it is the opinion of the work group that without a dependable clinical examination (e.g. in the obtunded patient), repeated or continuous intracompartmental pressure measurements are recommended until acute compartment syndrome is diagnosed or ruled out."*

Published by METRC Major Extremity Trauma Research Consortium; AAOS American Academy of Orthopaedic Surgeons

Endorsed by AOFAS American Orthopaedic Foot & Ankle Society® Dynamic. Decisive. Dedicated.; SOMOS Society of Military Orthopaedic Surgeons; American College of Surgeons Inspiring Quality: Highest Standards, Better Outcomes 100+years

Patient Outcome is Determined by Time to Diagnosis

The Coordinated Research on Compartment Syndrome (CROCS) group developed a classification of the outcomes of acute compartment syndrome, validating 5 grades related to the timing of intervention, with each successive grade associated with increasing delay in diagnosis and increased morbidity[16]. The classification used data from previous compartment pressure studies to quantify the categories as follows:

Grade 1

Primary Closure or early delayed closure (within 1-2 days), without any evidence of acute compartment syndrome (prophylactic fasciotomy, no muscle necrosis)

Grade 2

Delayed Primary Closure - Acute Compartment Syndrome 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

Grade 5

Amputation

Fasciotomies Are Not Benign Procedures

To minimize the risk of missed or delayed diagnoses, many physicians err on the side of caution by performing prophylactic fasciotomies for patients suspected of having compartment syndrome. However, fasciotomies carry significant risks and complications. These include prolonged hospital stays, surgical site infections, the need for further surgical interventions for delayed wound closure, and an overall increase in healthcare costs [17, 18]. Patients who undergo fasciotomies for tibial fractures experience an average increase in hospital stay length from 6 to 14 days, doubling their hospitalization costs to approximately $79,000, compared to $34,000 for patients without fasciotomies [17, 18].

The complications of fasciotomies extend beyond cost, as surgical site infections occur in up to 25% of cases, resulting in an average additional cost of $23,466 per case [19]. Moreover, these infections and prolonged recovery times may lead to other long-term issues, such as delayed fracture union, non-union, or chronic functional deficits, which require further medical and surgical management. As such, while prophylactic fasciotomies aim to avoid catastrophic outcomes of missed compartment syndrome, they come at a high cost to both patients and healthcare systems.

History of Continuous Compartment Pressure Monitoring

The development of continuous compartment pressure monitoring (CCPM) has marked a significant advancement in the diagnosis and management of acute compartment syndrome (ACS). Early efforts to measure intracompartmental pressure were pioneered by groups like McQueen et al., who demonstrated that CCPM significantly improves diagnostic sensitivity and specificity for acute compartment syndrome [20]. Their work established the utility of continuous monitoring in differentiating true acute compartment syndrome cases from false positives, reducing unnecessary fasciotomies, and minimizing long-term complications like muscle necrosis and chronic pain [21].

History of Continuous Compartment Pressure Monitoring (CONT'D)

One of the key achievements of McQueen's research was documenting the sensitivity (94%) and specificity (98%) of CCPM, setting it apart as a gold standard for objective diagnosis in at-risk patients [20]. By reducing diagnostic ambiguity, their work highlighted how CCPM could prevent the overuse of fasciotomies, a common challenge when relying solely on clinical symptoms. However, despite these advancements, barriers remain to its widespread adoption. The limitations of CCPM include the perceived complexity of the monitoring equipment, the need for rigorous training of medical staff, and potential discomfort for patients undergoing prolonged monitoring.

Today, while CCPM remains the most reliable method for diagnosing acute compartment syndrome, its implementation is not as widespread as its clinical utility suggests. Reasons for this include clinician reliance on traditional diagnostic methods, a lack of standardized protocols for monitoring, and concerns about cost and resource allocation in certain healthcare settings. Overcoming these challenges will require targeted education on the benefits of CCPM, streamlined device usability, and integration into routine care protocols to fully realize its potential in improving outcomes for acute compartment syndrome patients.

MEMS vs Fluid-Based CCPM

MEMS-based (Micro-Electro-Mechanical Systems) continuous intracompartmental pressure monitors provide clear technical advantages over traditional fluid-based pressure monitors in the management of acute compartment syndrome. These devices achieve higher accuracy in pressure measurement due to advanced sensor technology and digital output [22]. Additionally, they maintain performance stability under varying physiological conditions, showing minimal sensitivity to body temperature fluctuations, position changes, and dielectric changes.

The design of MEMS-based monitors as self-contained units simplifies the setup process, reducing the risk of errors associated with assembly or component malfunction. Furthermore, the self-calibration feature of these devices ensures consistent and reliable readings over time, while also reducing the risk of user error during calibration—a common issue with manual calibration in fluid-based systems.

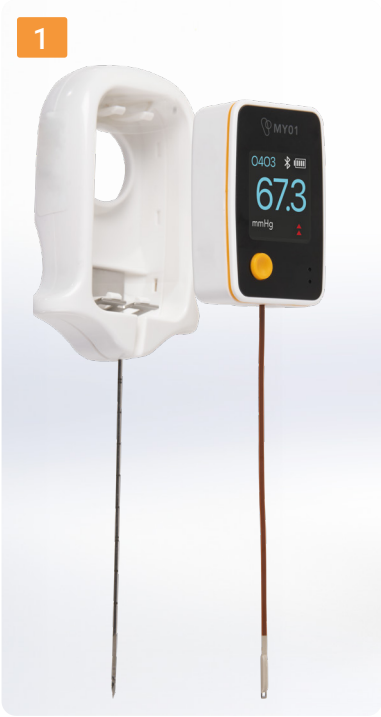
The inclusion of Bluetooth technology allows for easy connectivity to digital devices, enabling continuous monitoring, graphical representation of pressure data, and remote data display. This feature aids in tracking disease progression and adjusting treatment plans, while also improving data accessibility for healthcare providers. Overall, MEMS-based continuous intracompartmental pressure monitors offer a reliable, user-friendly, and technologically advanced solution for timely and reliable pressure monitoring in acute compartment syndrome management.

The CPST Platform

What is the CPST Platform?

MY01's Continuous Perfusion Sensing Technology is a platform intended to empower trauma teams to deliver faster, more consistent, and higher-quality care backed by objective data.
This platform consists of:

1



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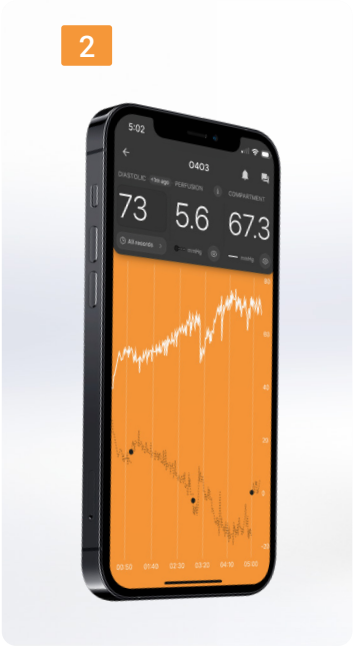

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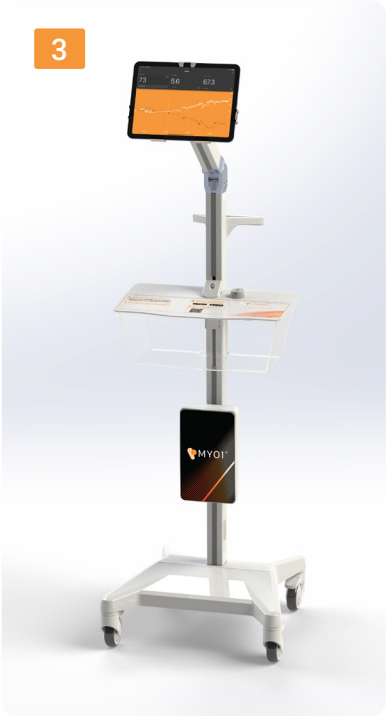


1 The MY01 Continuous Compartment Pressure Monitor

A microelectromechanical system-based sensor (MEMS) that continuously measures intramuscular pressure. Designed to support early and objective diagnosis of compartment syndrome, it provides up to 18 hours of real-time data.

2 The MY01 Mobile Application

Stores and displays identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculates critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician.

3 The MY01 Base Station

Streamlined bedside mobile cart system, set up for ease of use and optimized workflow in trauma settings.

Highest quality of outcomes

- 5-hour earlier diagnosis
- 100% sensitivity and specificity
- No missed cases or false positives
- Improved surgical outcomes
- Decrease for STSG from 50% to 15%

Optimizing clinical worflow

- 18-hour continuous monitoring
- 6x more accurate than other devices
- Real-time pressure data via app/cloud sync
- FDA cleared, CE and Health Canada licensed
- Easy-to-use

Financial optimization

- 2.8K$ savings per patient
- Shorter LOS by 2.73 days per patient
- Reduced unnecessary fasciotomies
- Net monetary benefit
- Improved resource allocation

Technology Overview

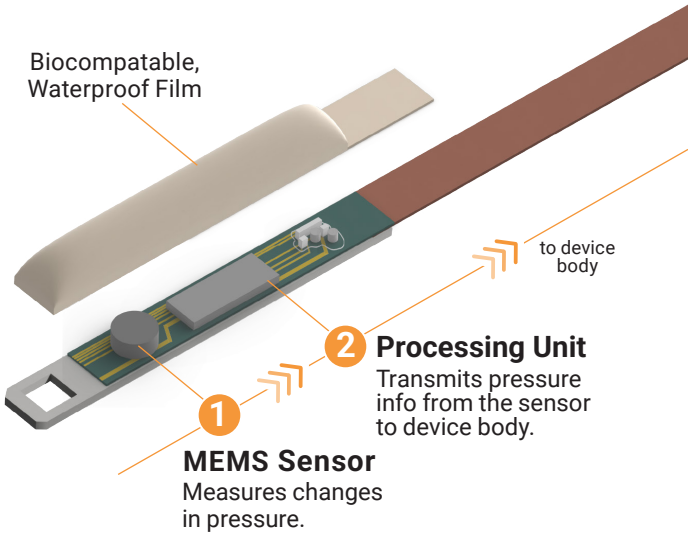
MEMS

The MY01 Continuous Compartment Pressure Monitor uses a patented intuitive insertion mechanism to deliver reliable MicroElectroMechanical Systems (MEMS) technology directly within the muscle.

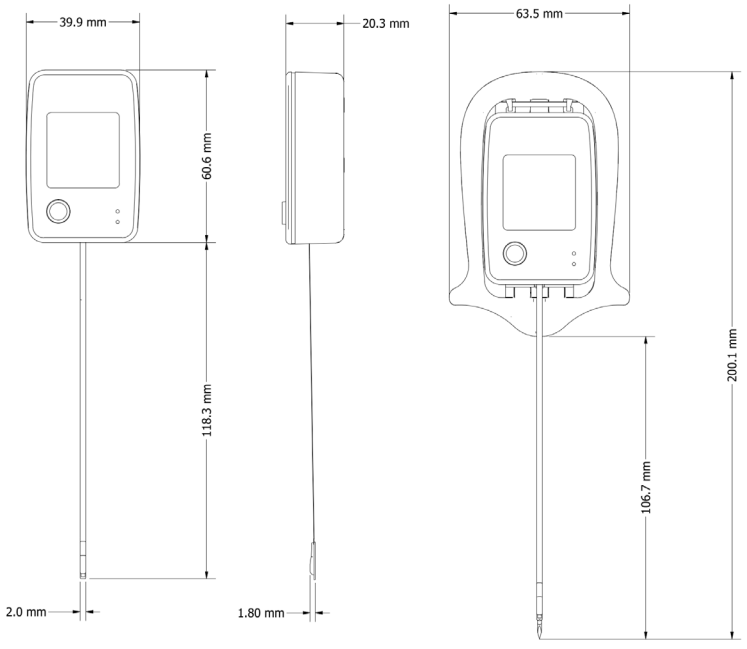
MEMS is a miniature machine that consists of:

- A central unit that processes data (integrated circuit such as microprocessor)
- Microsensors, MicroActuators, Microelectronics, MicroStructures
- Physical dimension ranging from several millimeters to less than 1µm.

Through the use of MEMS technology, the MY01 device is proven to be six times more accurate than fluid-based pressure monitors cleared by the FDA in the 1980s. [22]



Specs



Flex	Insertable length	118.3 mm
	Width	2 mm
Device size (incl. introducer)	Height	200 mm
	Width	63.5 mm
	Depth	30 mm
Pressure monitor	Height	178.9 mm
	Width	39.9 mm
	Depth	20.3 mm

Product Guide

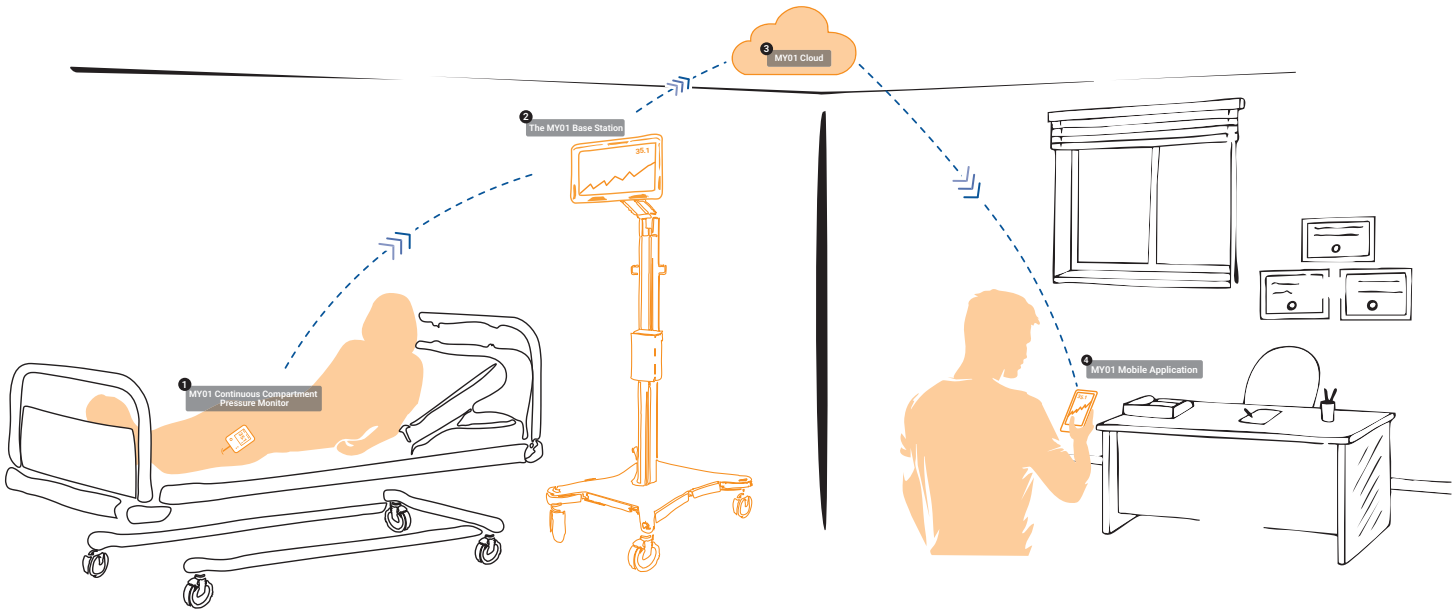
For a full set of instructions, follow this link or scan the QR code to read the user manual of your selected item.

ITEM	SKU
CPST Platform	MY01-CPST
Continuous Compartment Pressure Monitor	MY01-0001
MY01 Mobile Application	MY01-APP
MY01 Base Station	
Mobile Device Cart	MY01-CART
Companion Tablet	MY01-TBLT

At the heart of the CPST platform is the MY01 Continuous Compartment Pressure Monitor, a single-use, self-calibrating device inserted into the affected extremity. Data is generated by the embedded MEMS pressure sensor, capturing changes over time.

These readings are transmitted via Bluetooth to the MY01 Mobile Application, allowing visualization of a trend over time rather than relying on single pressure measurements, removing the need to manually record data.

To further streamline workflow and ensure immediate access to data, the MY01 Base Station combines the Mobile Device Cart and the Companion Tablet into a mobile bedside unit, including up to two MY01 Continuous Compartment Pressure Monitor boxes. The MY01 Base Station supports consistent access across shifts and staff, enhancing clinical adoption, and reducing variability in how the system is used.



Competitive Landscape

There are currently only a few devices that use compartment pressure measurements to manage compartment syndrome, such as the STIC Monitor (formerly made by Stryker and currently sold through C2Dx) and the A-line pressure transducer.

These devices have not been improved upon for more than 20 years, which has led to erroneous values in clinical settings.



	MY01	STIC	A-line
Single-use	✓	X	X
Quick to deploy	✓	X	X
Continuous	✓	X	✓
Accurate	✓	X	✓
Care-team collaboration	✓	X	X

Comparison of Three Devices to Measure Pressure for Acute Compartment Syndrome [22]

The study compared three devices—Synthes, Stryker, and MY01—for measuring intracompartmental pressures in a pre-clinical rat model of abdominal compartment syndrome. It assessed their precision, sensitivity, and accuracy relative to a high-precision reference gauge (METEK).

Key Findings

Accuracy and Precision

- The MY01 device was significantly more accurate and precise than Synthes and Stryker, showing a 670% superior precision in linear regression analysis.
- MY01 closely tracked reference pressures, while Synthes and Stryker exhibited significant deviations, drifts, and errors.

Device Performance

- Synthes and Stryker struggled with temperature variations, dielectric changes, and calibration errors.
- The Stryker device often failed at pressures > 30 mmHg, rendering it less reliable for continuous monitoring.
- MY01 demonstrated robust performance, maintaining accuracy and showing resistance to temperature or environmental changes.

Technological Advancements

- MY01 utilizes a Micro-Electrical-Mechanical System (MEMS) sensor capable of detecting minute pressure changes (±0.008 mmHg).
- It supports continuous real-time monitoring and provides wireless data transfer to healthcare providers.

Clinical Implications

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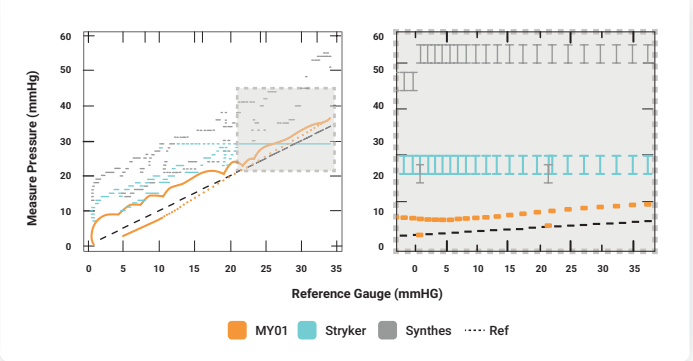
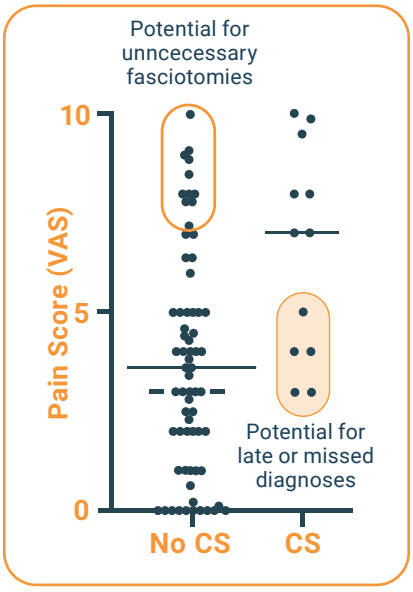
- It supports continuous real-time monitoring and provides wireless data transfer to healthcare providers.



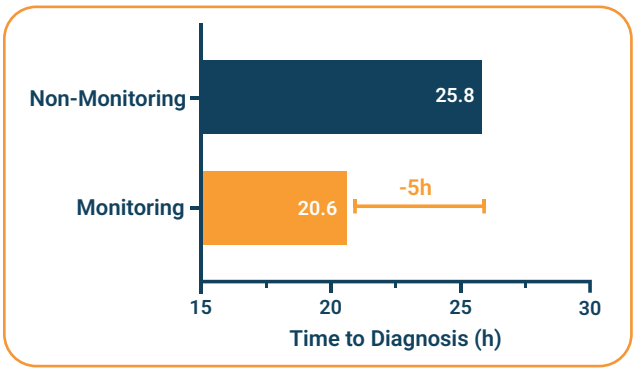
Clinical Benefits

Improved Clinical Decision Making

Clinical findings for Acute Compartment Syndrome (ACS) are inherently subjective, leading to variability and potential inaccuracies in diagnosis. In a single trauma hospital, the diagnosis rates for Acute Compartment Syndrome in patients with tibial fractures have been shown to vary widely, ranging from 2% to 24% [23]. This inconsistency highlights the challenges faced by clinicians relying solely on traditional diagnostic methods. The MY01 Continuous Perfusion Sensing Technology (CPST) Platform addresses these issues by providing objective, real-time data that enhances diagnostic accuracy and reduces reliance on subjective clinical assessments. Data from MY01 clinical trials further underscores the value of this innovative approach. Hypervariability in pain levels, which often complicates Acute Compartment Syndrome diagnosis, was confirmed across trials, demonstrating the need for a more reliable diagnostic parameter [24].



The MY01 device offers a clear perfusion pressure cutoff that distinguishes patients with Acute Compartment Syndrome from those without, ensuring timely and accurate diagnoses. Moreover, MY01 clinical studies have shown that the time to diagnosis is reduced by an average of five hours compared to standard care for patients not monitored for intracompartmental pressure. This earlier intervention can be critical in preventing complications and improving outcomes.



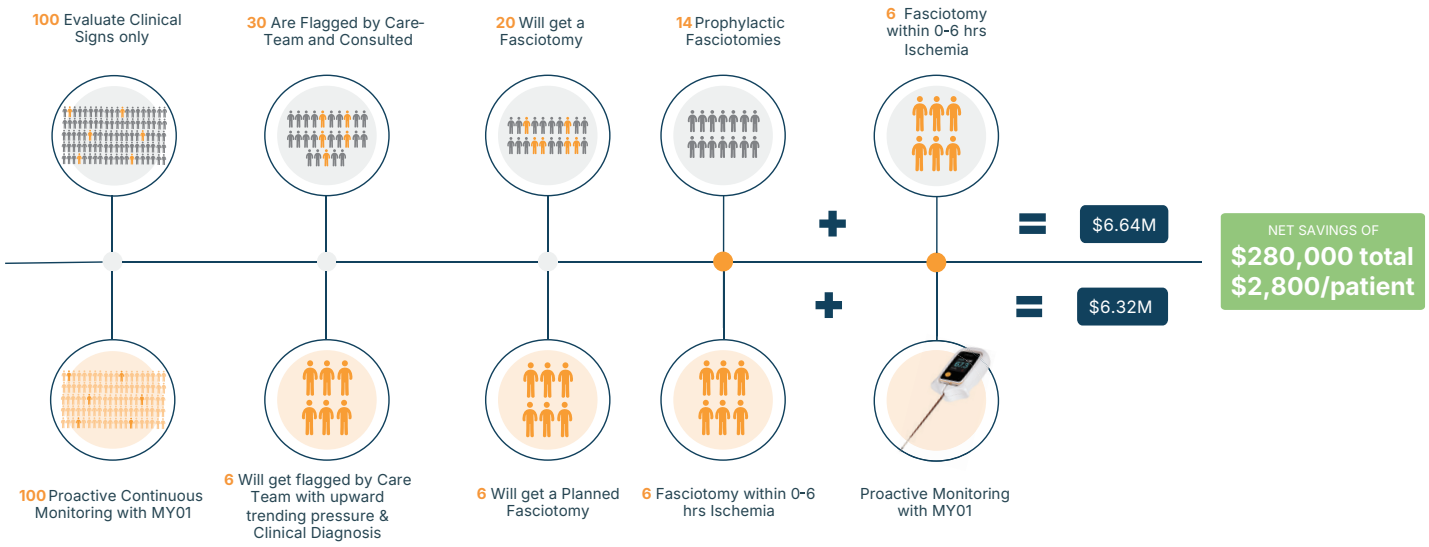
In addition to accelerating diagnosis, the MY01 CPST Platform has demonstrated a significant impact on patient management and outcomes. Continuous pressure measurements have been shown to reduce complications related to wound management, including the risks associated with delayed or unnecessary fasciotomies. By streamlining the diagnostic process and providing precise, actionable data, the MY01 CPST Platform empowers clinicians to make informed decisions quickly, improving both patient outcomes and healthcare efficiency.

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.

Continuous compartment pressure monitoring (CCPM) offers transformative economic and clinical advantages in the management of acute compartment syndrome (ACS). By enhancing diagnostic accuracy, CCPM significantly reduces unnecessary prophylactic fasciotomies, which add an average of $27,789 per procedure [25]. The use of CCPM also decreases hospital length of stay by 2.73 days per patient, creating substantial cost savings and optimizing healthcare resources. With a net monetary benefit (NMB) of $2,800 over 60 days and $4,086 over a lifetime, CCPM delivers measurable economic value while simultaneously improving patient care. [25]

In addition to its immediate cost-saving benefits, CCPM drives long-term improvements in patient outcomes by reducing complications and enabling better allocation of healthcare resources. Its high specificity in diagnosing acute compartment syndrome minimizes the risks of unnecessary interventions and associated morbidities, positioning it as a powerful tool for effective acute compartment syndrome management. The technology's ability to streamline treatment pathways and enhance care quality establishes it as a critical innovation for healthcare systems striving to balance cost-efficiency with exceptional patient outcomes.



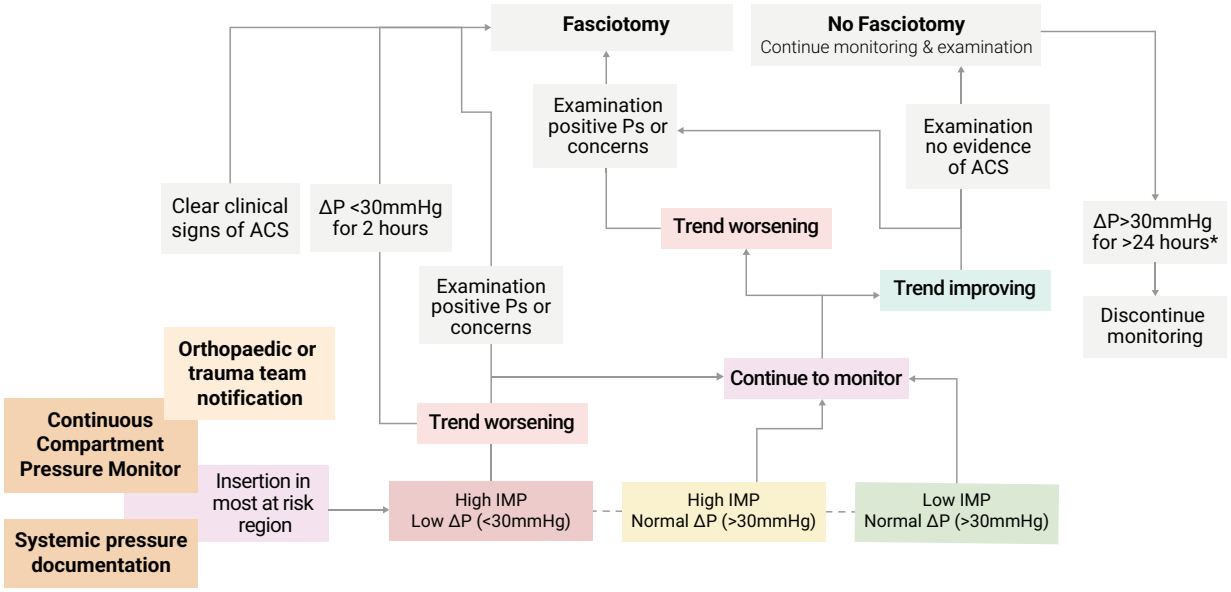
Protocol-based Management of Acute Compartment Syndrome

Rockwood and Green's Fractures in Adults is an essential reference for treating various fractures in adult patients. Volume 1 of the 10th Edition is designed to ensure healthcare professionals are fully equipped with modern techniques and technologies essential for effective fracture management in orthopaedics.

It includes recommendations for addressing patients at risk of developing Compartment Syndrome, highlighted in Chapter 17. The section on diagnosing Compartment Syndrome (pg. 580) highlights the importance of MY01's Continuous Compartment Pressure Monitoring in allowing earlier recognition of rising trends in pressure, often before irreversible tissue or nerve damage occurs.

The "Authors' Preferred Treatment" algorithm for Acute Compartment Syndrome (pg. 591) advocates the use of continuous pressure monitoring, based on a validated protocol established at McGill University and the Royal Infirmary of Edinburgh.

The McGill-Edinburgh Protocol



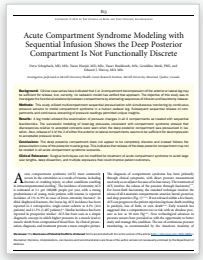
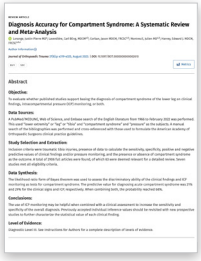
*Instructions about the use of the MY01 Continuous Compartment Pressure Monitor can be found at https://my01.io/my01-device-and-app-repository/

At-Risk Patient Profiles	High-energy injury	Obtunded patients with injury	Trauma + anticoagulants	Crush injury
	41, 42 B or C, 12, 22 C	Revascularization	Trauma + cirrhosis	

In conclusion, this evidence-based approach has been adopted by those leading institutions to complement their diagnostic framework, leveraging its ability to 1) identify rising intracompartmental pressures early, even before clinical signs manifest, and 2) provide continuous, reliable data that empowers clinicians to make informed decisions about the need for surgical intervention.

Clinical and Preclinical Evidence

Preclinical Data

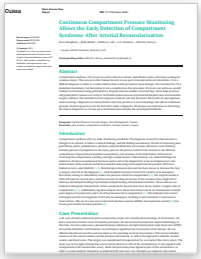
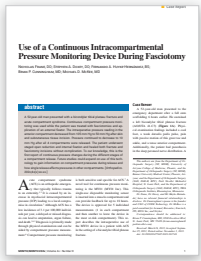
Paper	Description	
Comparison of Three Devices to Measure Pressure for Acute Compartment Syndrome., Merle, G., M. Comeau-Gauthier, V. Tayari, M. N. Kezzo, C. Kasem, F. Al-Kabraiti, C. Laverdiere, G. Xereas and E. J. Harvey (2020). "" Military Medicine 185(Supplement_1): 77-81. (As Presented at SICOT)	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 acute compartment syndrome model (over 600% more accurate).	
Honjol, Y., Monk, R., Schupbach, D., Merle, G., & Harvey, E. J. (2022). **Porcine Model of Acute Compartment Syndrome**. J Orthop Trauma. https://doi.org/10.1097/bot.0000000000002505	A pre-clinical model mimicking human compartment syndrome was developed using vascular occlusion plus crush or direct muscle crush maintained for over 5 hours. Intramuscular pressure was monitored continuously. After two hours of observation at elevated pressures (balloon catheter: avg. 25.1 mmHg; ischemia-reperfusion + direct crush: avg. 33.7 mmHg), fasciotomy reduced pressures to physiological levels (balloon catheter: avg. 2.4 mmHg; crush: avg. 4.9 mmHg). This model reliably replicates human response to injury and treatment, enabling testing of compartment syndrome therapies.	
Schupbach, D. E., Nasser Eddine, M., Honjol, Y., Merle, G., & Harvey, E. J. (2021). **Percutaneous Forefoot Decompression in a Foot Compartment Syndrome Model.** JBJS Open Access, 6(4), e21.00040. https://doi.org/10.2106/jbjs.Oa.21.00040	A cadaveric study demonstrated that a novel percutaneous decompression technique using two small dorsal incisions effectively and safely reduced pressures in foot compartments (from 43.8 mm Hg to 9.5 mm Hg, $p < 0.05$) without damaging critical structures. This less invasive and reproducible method offers a potential alternative to open fasciotomies, which have higher morbidity. The study validates the accuracy and utility of the MY01 continuous pressure monitoring system in improving compartment syndrome management and highlights the clinical relevance of MY01 technology for innovative treatment protocols.	
Schupbach, D., Honjol, Y., Bouklouch, Y., Merle, G., & Harvey, E. J. (2022). **Acute Compartment Syndrome Modeling with Sequential Infusion Shows the Deep Posterior Compartment Is Not Functionally Discrete.** J Bone Joint Surg Am, 104(9), 813-820. https://doi.org/10.2106/jbjs.21.00291	A cadaveric study using the MY01 sensor showed the deep posterior compartment doesn't function independently in acute compartment syndrome. Its pressure changes mirrored adjacent posterior compartments, suggesting decompression of anterior and lateral compartments alone may be enough. This indicates standard acute compartment syndrome surgery could be improved by skipping deep posterior release, reducing risks. The study also confirms the MY01 sensor's accuracy for continuous pressure monitoring, aiding in better acute compartment syndrome management.	
Lorange, J.-P., Laverdière, C., Corban, J., Montreuil, J., & Harvey, E. J. (2023). **Diagnosis Accuracy for Compartment Syndrome: A Systematic Review and Meta-Analysis.** Journal of Orthopaedic Trauma, 37(8), e319-e325. https://doi.org/10.1097/bot.0000000000002610	A meta-analysis of 7 studies (1,281 tibial fractures) evaluated ACS diagnosis using clinical findings and intracompartmental pressure (ICP) monitoring. ICP monitoring (90% sensitivity, 88% specificity) outperformed clinical findings alone (77% sensitivity, 86% specificity). Combining both increased diagnostic probability to 69%. The study emphasizes ICP monitoring's crucial role alongside clinical evaluation to improve diagnostic accuracy. Standardized protocols and validation of new technologies are needed.	

Paper	Description	
Bouklouch, Y., Bernstein, M., Bosse, M., Cota, A., Duckworth, A. D., Dunbar, R. P., Gamulin, A., Guy, P., Hak, D. J., Haller, J. M., Hayda, R., Jarragh, A., Johnstone, A. J., Karunakar, M., Lawendy, A. R., Leighton, R., Mavrogenis, A. F., Mauffrey, C., Miclau, T., . . . Harvey, E. J. (2023). **Postfasciotomy Classification System for Acute Compartment Syndrome of the Leg.** J Orthop Trauma, 37(11), 581-585. https://doi.org/10.1097/bot.0000000000002663	A new five-grade classification system for acute compartment syndrome severity post-fasciotomy was developed and validated by international experts using a modified Delphi method. The system, ranging from prophylactic fasciotomy (Grade 1) to amputation (Grade 5), showed strong inter-rater reliability (Fleiss' Kappa = 0.711) and high internal consistency (median Kendall coefficient = 0.855) in clinical scenario testing. This framework standardizes acute compartment syndrome severity evaluation, aiding prognostication, treatment, economic analysis, communication, and research by providing clear benchmarks for outcomes and costs. The classification improves acute compartment syndrome understanding and management, benefiting patient outcomes and healthcare burden assessment.	
Bouklouch, Y., Schmidt, A. H., Obremskey, W. T., Bernstein, M., Gamburg, N., & Harvey, E. J. (2022). **Big data insights into predictors of acute compartment syndrome.** Injury, 53(7), 2557-2561. https://doi.org/10.1016/j.injury.2022.02.041	A study of 203,500 tibial fractures identified key acute compartment syndrome predictors and outcomes. Proximal and midshaft fractures significantly increased acute compartment syndrome risk, with open fractures doubling the likelihood. Other risk factors included male sex, younger age, smoking, substance use, and cirrhosis. Muscle necrosis occurred in 16.9% of fasciotomies and was linked to complex fractures and comorbidities. The fasciotomy rate was 4.3%, varying by trauma center level. The study highlights the importance of soft tissue damage and fracture complexity in acute compartment syndrome, revealing new links to systemic conditions like cirrhosis and hypertension. This big-data analysis offers crucial insights for acute compartment syndrome risk assessment and clinical decision-making in trauma care.	

Published and Ongoing Data

MY01 is currently supporting 5 ongoing 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 consists 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.

Paper	Description	
Use of Novel Digital Continuous Pressure Sensor for Diagnosis Compartment Syndrome	The MY01 cICP device aided ACS diagnosis and management in three cases. In one case, early fasciotomy guided by cICP in a patient without typical symptoms prevented necrosis. In another, overnight cICP monitoring prompted timely decompression, preventing damage. In a third, stable cICP readings avoided unnecessary surgery. Continuous pressure data from MY01 enabled early ACS detection in two cases and ruled it out in another, improving management by supporting timely intervention and avoiding unnecessary procedures and complications. This highlights its potential in trauma centers and remote locations.	
Nasser Eddine, M., Schupbach, D. E., Honjol, Y., Merle, G., & Harvey, E. J. (2022). Minimal Percutaneous Release for Acute Compartment Syndrome of the Foot: A Case Report. JBJS Case Connect, 12(3). https://doi.org/10.2106/jbjs.Cc.21.00484	A 34-year-old male with a pilon fracture and acute compartment syndrome (ACS) of the forefoot was successfully treated with a novel minimally invasive percutaneous decompression using two 1-cm dorsal incisions. Compartment pressures were reduced from over 50 mm Hg to normal (5–12 mm Hg), resulting in immediate pain relief and full functional recovery without complications at 6 weeks, 6 months, and 1 year. This case demonstrates the effectiveness of a percutaneous approach for ACS of the foot, avoiding the morbidity of open fasciotomies and supporting broader use of minimally invasive techniques.	
Schupbach, D., Reindl, R., Gill, H. L., Liberman, A. S., & Harvey, E. J. (2024). Continuous Compartment Pressure Monitoring Allows the Early Detection of Compartment Syndrome After Arterial Revascularization. Cureus, 16(3), e55451. https://doi.org/10.7759/cureus.55451	A 28-year-old male undergoing pelvic exenteration developed an avascular right leg due to an iliac artery injury. Continuous intracompartmental pressure (ICP) monitoring, initiated despite absent clinical compartment syndrome (CS) signs, revealed a pressure rise necessitating surgical fasciotomy. Intraoperative findings confirmed Grade 2 CS with reversible muscle damage. The wounds were closed within 72 hours. This case highlights the value of continuous MEMS-based ICP monitoring for early CS detection in complex cases, improving diagnostic accuracy, treatment timing, and resource use.	
Frane, N., Doxey, S. A., Huyke-Hernández, F. A., Cunningham, B. P., & McKee, M. D. (2024). Use of a Continuous Intracompartmental Pressure Monitoring Device During Fasciotomy. Orthopedics, 47(2), e98-e101. https://doi.org/10.3928/01477447-20231027-03	A 52-year-old male with a bicondylar tibial plateau fracture and acute compartment syndrome underwent fasciotomy with continuous intracompartmental pressure monitoring using the MY01 device. Pressures decreased from a high of 105 mm Hg to 10 mm Hg after full release of all compartments. Postoperatively, the patient had restored sensation, no complications, full recovery at one year, and fracture union. This case highlights the value of real-time cICP monitoring during fasciotomy with the MY01 device to confirm adequate compartment release and potentially improve outcomes in ACS management. Future research could investigate postoperative use.	
Haidar, A., Pauyo, T., Harvey, E., & Drager, J. (2024). Resolution of Confusion Over Compartment Syndrome After Tibial Osteotomy With Continuous Pressure Measurements. Cureus, 16(5), e61114. https://doi.org/10.7759/cureus.61114	A 13-year-old female with autism and severe leg pain after a tibial tubercle osteotomy presented a challenging clinical assessment for compartment syndrome (CS). Continuous intracompartmental pressure (cICP) monitoring using the MY01 device showed decreasing pressures without critical elevations, ruling out CS and avoiding a fasciotomy. Optimized pain management with a nerve block resolved symptoms, leading to a smooth recovery. This case highlights the value of cICP monitoring in complex presentations where CS diagnosis is difficult, enabling objective data for clinical decisions, preventing unnecessary surgery, and improving patient outcomes.	
Al Nasser, A. M., Harvey, E. J., & Bunting, A. C. (2024). Early Detection of Compartment Syndrome With Minimal Symptoms: A Case Report on Continuous Pressure Monitoring. Cureus, 16(11), e74453. https://doi.org/10.7759/cureus.74453	A 53-year-old woman with a tibial fracture and minimal symptoms showed increasing intracompartmental pressure (cICP) (55-70 mmHg, delta P 10 mmHg) via MY01 monitoring. Despite no clear clinical signs of compartment syndrome (CS), early fasciotomy, guided by cICP trends, revealed and resolved early CS, leading to full recovery. This case highlights the importance of cICP monitoring for early CS diagnosis and intervention when clinical signs are unclear, preventing muscle damage and morbidity.	

Clinical Studies

Study	Sample Size	Principal Investigator	Treatment/ Intervention	Outcome of Interest	Follow Up Time	Status	Hospital /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	Completed	• 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	Completed	• Queen Elizabeth II Health Science Centre (Halifax), • St. Michael's Hospital (Toronto, • Foothills Hospital (Calgary) • Vancouver General Hospital (Vancouver) • 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	24	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	Completed	• 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 months	Recruiting	• Hennepin Medical Centre • University of Maryland • Carolinas Medical Centre • Vanderbilt 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	Completed	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	Completed	Surveying of experts from a variety of leading trauma centers across the US and Canada.

Reimbursement

MY01 is reimbursable under existing CPT codes used to monitor compartment pressure. This supports a smooth integration into clinical and billing workflows while helping hospitals recover costs associated with the procedure.

Physician CPT Codes

CPT 20950

Monitoring of interstitial fluid pressure (includes insertion of device, e.g., wick catheter technique, needle manometer technique) in detection of muscle compartment syndrome.
Physician Fee Schedule Payment: $88.45

CPT 76942

Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation.
Physician Fee Schedule Payment: $52.71 *(based on a 1.61 RVU - subject to insurer changes)*

Outpatient & ASC Facility Reimbursement

MY01 is also recognized under hospital outpatient and ambulatory surgery center (ASC) payment systems using the same CPT code.

Setting	Payment System	Code	Payment Rate
Hospital Outpatient	OPPS (APC 5071, Status Indicator T)	CPT 20950	$648.97
Ambulatory Surgery Center	ASC (Payment Indicator G2)	CPT 20950	$337.92

Inpatient Setting

When MY01 is used in an inpatient case, reimbursement is bundled into the hospital's MS-DRG based on diagnosis and procedures. MY01 aligns with DRGs such as:

- **DRG 480–482:** Hip and femur procedures
- **DRG 492–494:** Lower extremity and humerus procedures
- **DRG 500–502:** Soft tissue procedures
- **DRG 907–909:** Other O.R. procedures for injuries
- **DRG 957–959:** Multiple significant trauma

Regulatory Clearances

Device name: MY01 Continuous Compartment Pressure Monitor
510 (K) number: K242997
Device classification name: Monitor, pressure, intracompartmental.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210525

MY01 | FDA 510(k) Clearance

MY01 Breakthrough Device Designation

CE Mark (36359)

HC Approved (LN/NH 104256)

Manufacturing - ISO13485:2016 Certified (36360)

Audit - MDSAP (36361-1)

Training and Education

Medical Education

MY01 offers a myriad of education options for all levels of healthcare providers designed to increase competence and confidence in the MY01 device, aiding diagnosis of acute compartment syndrome. Included in these offerings are on-demand materials and virtual events, as well as in-person didactic and hands-on device training engagements provided by MY01 personnel.

Safe and effective utilization of the MY01 device is our highest priority, a theme present throughout the training. The clinical pathway is a continuum of learning starting with the basics and developing to more advanced material with an emphasis on evolving and current content to meet the needs of the health care provider to aid in patient care.

MY01 Self Training can be accessed at any time via the MY01 website, where you can instantly download the Device Instructions for Use Manual as well as engage in the MY01 onboarding training.

MY01 Clinical Pathway

Phase 1 Self-Led Onboarding Training

- MY01 device safe use video
- Review of MY01 device user manual
- Review MY01 App user manual
- MY01 compartment syndrome data

Phase 2 Live Didactic Training

- Schedule with local MY01 representative
- Tailored content delivered in-person or virtually
  - Patient assessment
  - Evaluation of pressures
  - At risk patient populations
  - Continuous monitoring leads to better outcomes
  - Closing the loop

Phase 3 Clinical Integration

- Schedule with local MY01 representative
- Medical Education and Account Manager led instruction
  - Performance Improvement Plan
  - Hands-On Training
  - App overview and user integration
  - Clinical Practice Guidelines, templates for PI auditing and reporting

Phase 4 Continuing Education

- On-demand videos and webinars
- Live Webinars
- Newly published data and abstracts
- Live Education Summits

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