MY01

Monitoring of Muscle Compartment Pressure

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Speaker

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Presentation Flow

- Regulatory Clearance
- Disease Condition: Compartment Syndrome
- Device description
- MY01 device use
- Questions

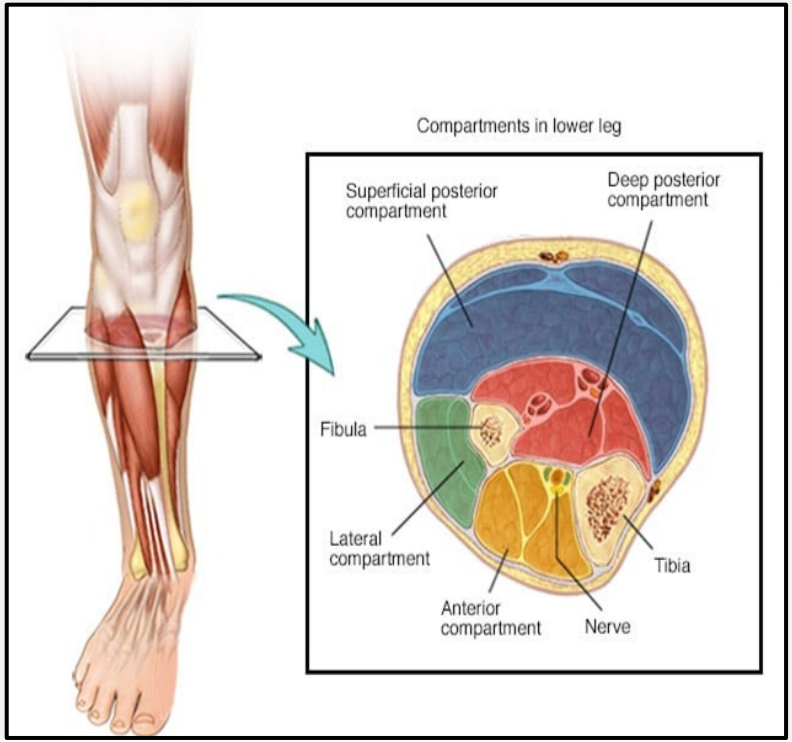
Regulatory Clearance

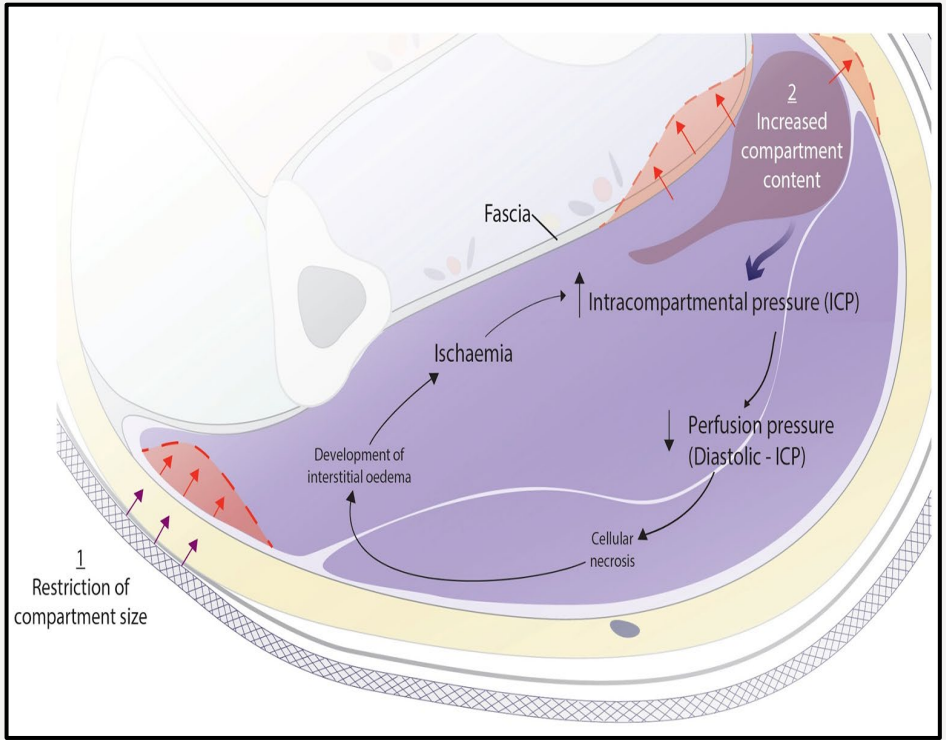
- MY01 Continuous Compartmental Pressure received FDA Breakthrough Device Designation (Q211914) in October 2021

- MY01 Continuous Compartmental Pressure received FDA clearance (K220952) in May 2022.

- MY01 Inc. submitted NTAP submission for consideration in FY 2024.

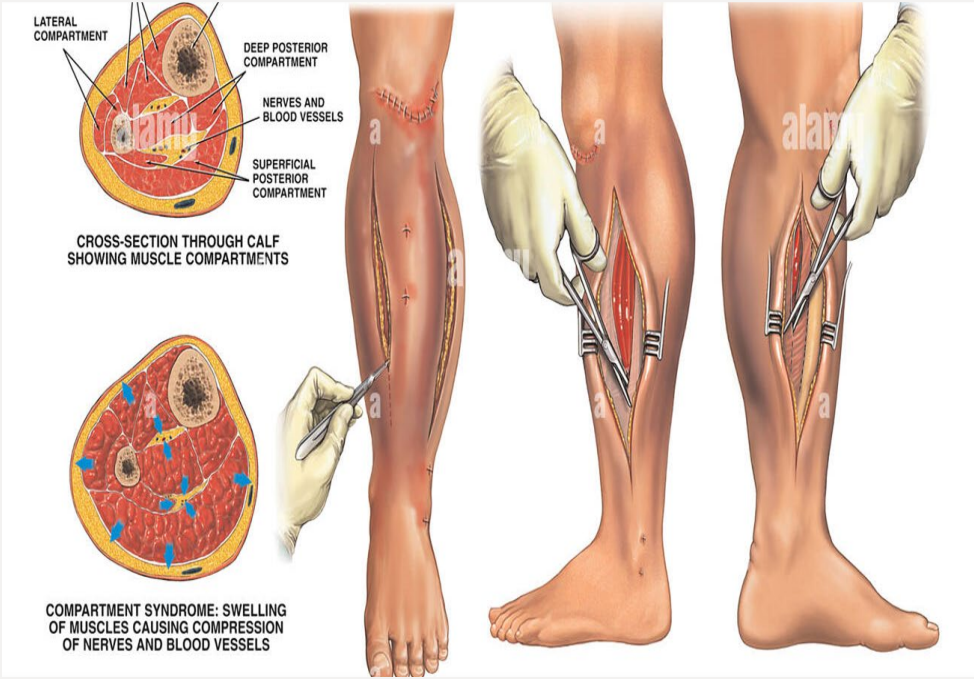
What is Compartment Syndrome ?





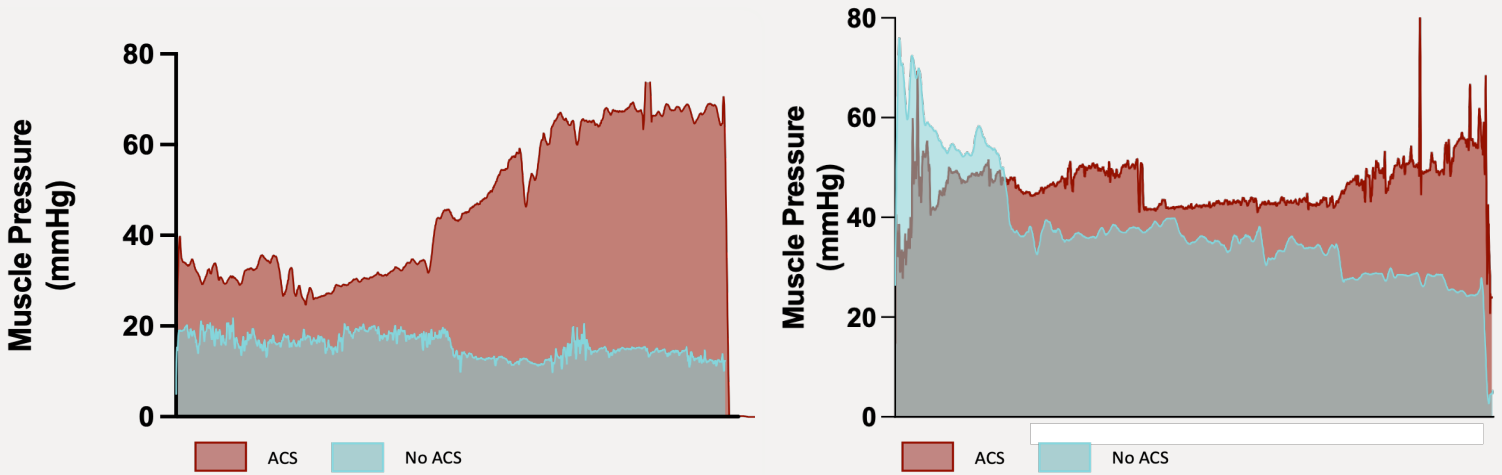
Compartment Syndrome: Current Diagnosis and treatment

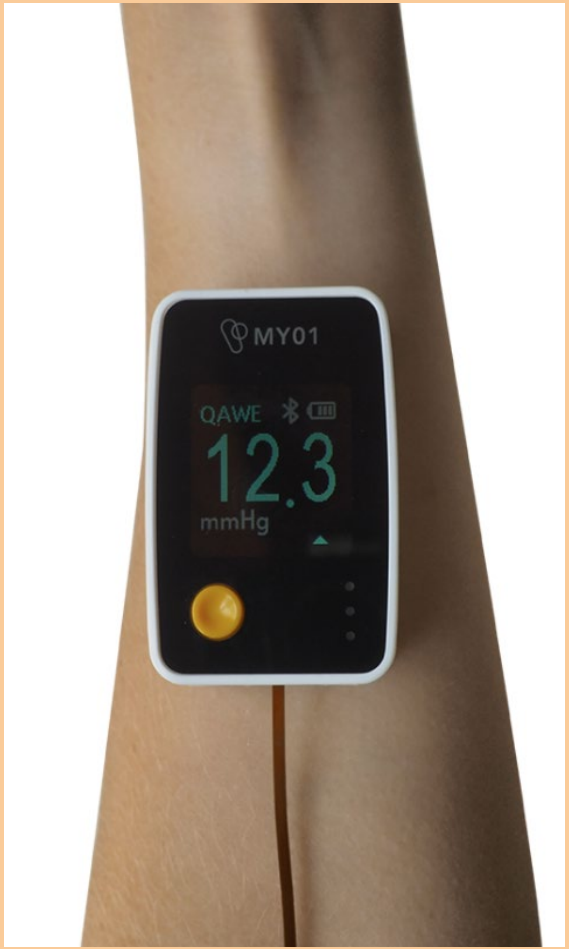
- 6 P's (Pain, Pallor, Pulselessness, Paresthesia, paralysis, poikilothermia) are used to diagnose Compartment Syndrome
- These are subjective findings. Reliance on these usually leads to delayed diagnosis.
- MY01 device can be used to measure Intracompartmental muscle Pressure as an aid in diagnosis of Compartment Syndrome.
- MY01 device is intended to be used in muscle compartments of the extremities.
- Fasciotomy is performed to relieve pressure



Why Continuous monitoring is important

New Clinical Data shows early information is important





Device Description

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic processes).

The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device. It also calculates critical muscle perfusion pressure utilizing the diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

MY01 Device

Device Features

1.0 Introducer

Allows for easy placement of the pressure sensor into muscle compartment.

1.1 17-gauge needle

Allows for up to five single-point insertions into various compartments before disengaging the device if desired.

2.0 Device Body

Once the device body is ejected from the introducer, its adhesive backing is available for aiding device to the patient.

2.1 Push-button

Initially ctivates the device and begins self-calibration. Also used for display rotation and dimming of screen.

2.2 MEMS sensor

Microelectricomechanical system (MEMS) sensor measures only compartmental or intra-compartmental pressure without use of fluid.

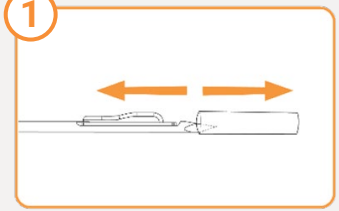
3.0 Device Display

LCD monitor displays real-time measurements for up to 18 hours.

3.1 Muscle compartment pressure measurement

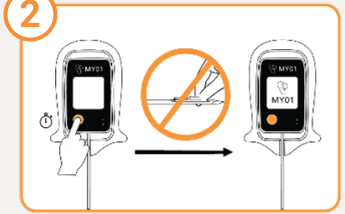
Insertion of MY01 Device
Deployment for Continuous Monitoring

1



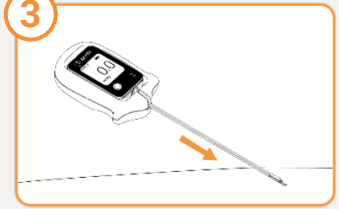
Remove the protective needle cap prior to turning on the device.

2



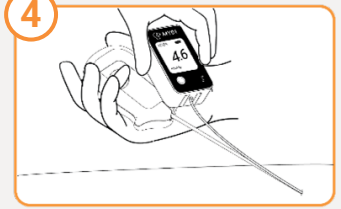
Press and hold the orange push button until the MY01 logo and a pressure value of 0 mmHg appears on display.

3



Insert the needle into the muscle compartment in a controlled linear motion.

4

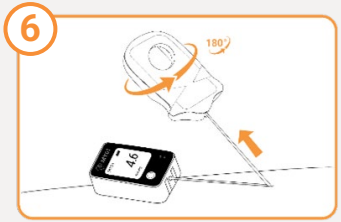


Once inserted into the desired compartment, separate the monitor from the device by pressing through the hole at the back of the device.

5

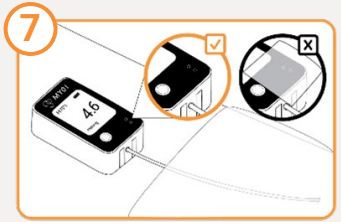
Adhere the device to the patient's skin using the exposed adhesive strip on the back of the device.

6



Rotate the introducer 180° to disengage the sensor from the needle introducer. Slowly remove the introducer from the patient and dispose.

7



Apply a medical dressing on the insertion site.

Monitoring with the MY01 Device

- MY01 can be used for continuous monitoring of Intracompartmental muscle pressure for up to 18 hours.
- The device can be used for up to 5 discrete single-point insertions before detaching the device.
- MY01 device connects wirelessly to the MY01 App. This allows users to view real-time pressure trends and enable care-team collaboration.

MY01 Device

- Only one device is routinely used per episode of care. (Pre-surgery versus post surgery)
- Based on the nature of injury and physician's discretion multiple devices may be used.
- MY01 is a sterile, single-use device that can stay inside the patient for up to 18 hours. It is not considered permanent.
- MY01 is a stand-alone technology and does not depend on the app for usage.
- MY01 device use provides objective data that can be documented in OR reports, patient files or notes.
- MY01 device is used in both Inpatient and Outpatient setting.

Device Naming convention

- MY01 Continuous Compartmental Pressure Monitor
- MY01 Device
- MY01 Pressure Monitor
- Muscle Pressure Monitor
- Intra-Compartmental Muscle Pressure Monitor
- Intramuscular Pressure Monitor

Adverse events

- Since 2019
  - 1 AE has been reported
    - unrelated to device malfunction or user-error

Questions?