MY01 Continuous Compartmental Pressure Monitor granted Breakthrough Device Designation from the FDA

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MY01 Inc. receives their first-ever "Breakthrough Device" designation by the FDA in October, joining a select list of Orthopaedic companies to receive this designation since the program began in 2016.

MONTREAL, Oct. 27, 2021 /PRNewswire/ - The Breakthrough Device Designation is an FDA designation granted to devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Since the inception of the Breakthrough Devices Program in 2016, orthopaedics has accounted for only 6% of devices that have received this designation, making it an underrepresented group of technologies that have the potential to improve patient care.

The MY01 Continuous Compartmental Pressure Monitor provides reliable[1], real-time continuous pressure measurements to aid in the diagnosis of compartment syndrome. The receipt of Breakthrough Device Designation demonstrates that MY01 can offer significant advantages over existing alternatives for more effective and efficient management of Compartment Syndrome (CS).

While clinical assessment alone or single-point measurements can lead to delayed diagnosis or overtreatment, continuous IntraCompartmental Pressure (cICP) augments early decision-making in Acute Compartment Syndrome (ACS). Optimal management of ACS depends on early diagnosis and intervention, which significantly reduces a patient's chance of amputation, infection, and nerve damage; as well as minimizing the need for unnecessary fasciotomies.

Dr. Theodore Miclau, Professor of Orthopaedic Surgery at Zuckerberg San Francisco General Hospital, stated that "One of the benefits to MY01 is that the continued [pressure] data that you get from it is going to allow you to understand what the overall trend of the underlying condition is. If you have a single pressure measurement combined with clinical examination, it may not be enough. MY01 has the potential to change the way that we look at measuring compartment syndrome and when we decide to do surgery."

The MY01 Continuous Compartmental Pressure Monitor (and its companion mobile app) received 510(k) clearance from the FDA earlier this year and is being used in hospitals around the US to aid in the timely diagnosis of Compartment Syndrome. The simple, single-use device utilizes proprietary technology to deliver a microsensor directly to the at-risk muscle compartment to continuously measure pressure for up to 18 hours. Pressure readings are wirelessly transmitted to the MY01 app and stored on the Cloud, enabling true care team collaboration for more efficient patient care.

Charles Allan, CEO of MY01 Inc., commented, "MY01 has the potential to improve the standard of care for diagnosing CS and we will continue to innovate in this space based on surgeon feedback. This Breakthrough Device Designation affirms our commitment to improving patient care by providing clinicians better data to enhance their decision-making when addressing this serious condition."

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[1] Merle, G., M. Comeau-Gauthier, V. Tayari, M. N. Kezzo, C. Kasem, F. Al-Kabraiti, C. Laverdiere, G. Xereas and E. J. Harvey (2020). "Comparison of Three Devices to Measure Pressure for Acute Compartment Syndrome." Military Medicine 185(Supplement_1): 77-81.

About MY01 Inc.

MY01 Inc. is on a mission to empower healthcare professionals with the ability to pre-empt severe medical conditions thereby improving patient outcomes. MY01 believes that adding actionable quantitative data at the bedside can augment clinical assessments to provide more effective care collaboration that result in a more effective patient care. Headquartered in Montreal, Quebec since 2015, MY01 Inc. leverages its expertise in sensor technology to provide innovative diagnostic solutions.

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