

**The Issue:** Withdrawal is part of the necessary detox process that people with opioid addiction must go through to transition to medication assisted therapies (“MAT”) that will get and keep them clean. It also is well known that withdrawal is often so severe that people relapse before successfully transitioning to MAT, and continue down the path of destructive addiction.

**The Role Our Medical Device Plays:** The **NSS-2 BRIDGE** is the first and only FDA-cleared device to aid in reduction of opioid withdrawal symptoms. The device stimulates branches of certain cranial nerves to reduce opioid withdrawal symptoms, such as gastrointestinal upset, agitation, insomnia, and joint pain.

**The Research:** There are several completed, published, and ongoing studies evaluating the role of the NSS-2 BRIDGE in treating opioid withdrawal symptoms and associated conditions, such as functional gastrointestinal pain. Most notably, an FDA- and peer-reviewed clinical study of 73 patients undergoing opioid physical withdrawal demonstrated the efficacy of the NSS-2 BRIDGE in reducing patients’ clinical opiate withdrawal scale (COWS) score. Prior to using the device, the average COWS score for all patients was 20.1. Study results showed that all patients had a reduction in COWS of at least 31 percent within 30 minutes of using the device. Overall, 64 of the 73 patients (**88 percent**) transitioned to MAT after five days of using the device.

**The Real Life Use:** There are programs that have been successful using BRIDGE technology as part of treatment protocols to help patients get clean. For example, a small program in Union County, Indiana has used over 200 BRIDGE devices to help patients get clean. However, state and local programs often don’t have the money to pay for devices, and must rely on donations from Innovative Health Solutions. For example, each of the 200+ devices used by Union County was donated by us because we wanted to help our local Indiana community.

**The Value:** The United States loses well over \$500 billion per year to the opioid crisis. People die, families are torn apart, and the fabric of our society is being damaged daily by this scourge. A tool that can aid in reduction of opioid withdrawal, and thereby may help people transition and stay clean with MAT, could have a tremendous impact and for a relatively low cost, with each NSS-2 BRIDGE costing about \$600.

**The Problem:** While \$600/unit is negligible compared to the cost of the opioid crisis, many individuals and programs (such as the one in Union County) simply can’t afford these devices, and as a small business, we cannot simply donate devices to everyone in need. So we are trying to get coverage for the device from both government and private payors, and are looking for government programs that would group purchase products. However, this is an arduous journey, and payor systems are not equipped or conditioned to be responsive to the opioid epidemic.

**The Solutions:** There are many potential solutions. The solutions could be related to the Medicaid program and facilitating reimbursement; providing funds for purchases by government programs that are directly treating patients, such as the Department of Veterans Affairs; including the NSS-2 BRIDGE in special evaluation programs; etc.

**The Ask:** We would like to work with your office to help identify the best opportunities to expand access to our important technology, and develop legislative solutions to the problem we all face.