



VitalStim/DINES

CONTRAINDICATIONS, WARNINGS AND CONSIDERATIONS FOR USING NMES (VITALSTIM) ON A PATIENT WITH AN INSPIRE IMPLANTED DEVICE

Per Inspire Medical Systems, Inc. (August 2024)

Regarding VitalStim therapy usage on Inspire patients, implanted devices are not contraindicated for VitalStim by the FDA, but due to the location of the stimulation therapy it should be avoided for Inspire patients. **Our guidance on stimulation therapies requires the device to be 6 inches away from any implanted components. VitalStim would be in direct contact with the implanted components.**

Per the Clinical Authors of the VitalStim Specialty Certificate Course (August 2024)

(see [Inspire Upper Airway Stimulation - P130008/S089 | FDA](#))

Inspire Medical Systems has said they feel the current could affect the implanted circuit (implanted electrode is on CN XII) even when the device is turned off. As a general rule, always check the user manual of the implanted device for cautions and contraindications specific to that device. Some devices (e.g., Inspire) consider the anterior neck to be contraindicated in the use of NMES as they believe the current would flow through the implanted circuit.”

