Minimal adverse effects profile following implantation of periauricular percutaneous electrical nerve field stimulators: a retrospective cohort study.

Roberts A, Sithole A, Sedghi M, Walker CA, Quinn TM. Med Devices (Auckl). 2016;9:389-393.

The periauricular percutaneous implantation of the Neuro-Stim System™ family of devices EAD, MFS, and BRIDGE is a procedure involving the use of a non-opiate, neuromodulation analgesic for relieving acute and chronic pain. It has been approved as a minimal-risk procedure by multiple governmental and institutional facilities. This retrospective report of findings will help quantify the incidence of clinically observed bleeding, localized dermatitis, and infections at the implantation sites of the electrode/needle arrays, dermatitis at the site of the generator, and patient syncope. A total of 1,207 devices, each producing up to 16 percutaneous punctures, for a total of 19,312 punctures were monitored for adverse effects, based on retrospective chart audits conducted at six clinical facilities over a 1-year period.