

Novel therapy for long-term pressure injury prevention: preliminary evaluation of a biomimetic implanted stimulator for automated regular weight shifting

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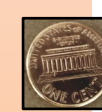
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IMPLANTED COMPONENTS:

Multilayer encapsulated flexSTIM IPG and electrodes. Inserted into a subcutaneous pocket through a 1" incision.

Packaged IPG footprint:

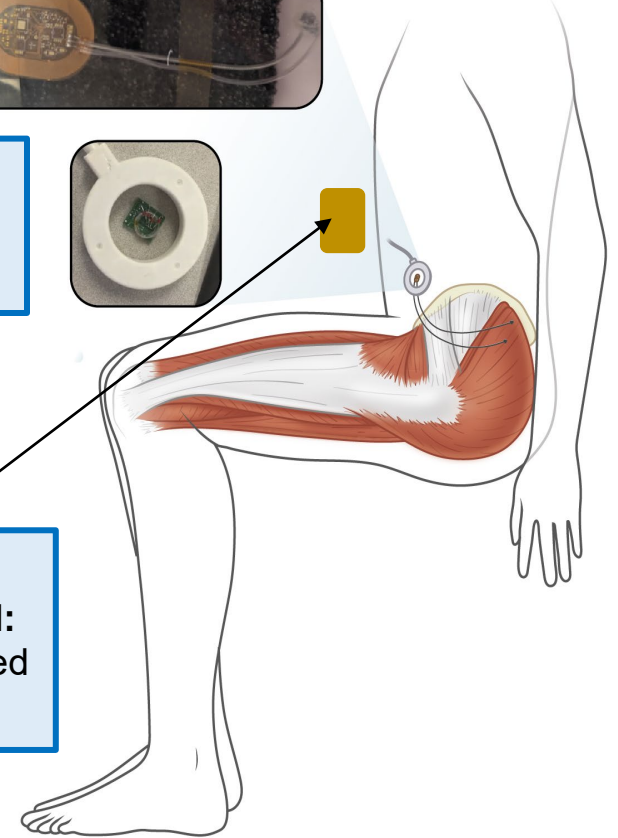
31.5 mm x 22mm x 4mm thick
(penny shows actual size)



EXTERNAL COMPONENTS I:
Secondary coil



EXTERNAL COMPONENTS II:
Battery powered controller unit



BACKGROUND: Pressure injury (PrI) prevention is a major challenge for many people with limited mobility, often leading to prolonged bedrest, hospitalization and even death. Weight-shifting every 20 minutes is difficult when busy with activities of daily living

Prevention thus remains a major challenge.

We have found that intermittent gluteal neuromuscular electrical stimulation (iGSTIM) can provide automated weight-shifting for up to 14 hours daily. iGSTIM using bilaterally implanted electrodes provides sustained and effective, regular and automatic weight-shifting, which increases muscle bulk, reduces intramuscular adipose tissue and maintains improved tissue health over many years.

A fully implanted iGSTIM system has been requested by many people desperate for a new alternative to PrI prevention. Newly emerged technologies have enabled us to build, *flexSTIM*, a 4-channel implanted stimulator which is both mechanically and functionally flexible and can provide clinically relevant weight-shifting.

Preliminary biocompatibility testing of *flexSTIM* has been completed in five New Zealand White rabbits.

RESULTS: Biocompatibility testing of system components implanted for a six month period found that *flexSTIM* and the intramuscular electrodes were well tolerated.



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U.S. Department of Veterans Affairs
Veterans Health Administration
VA Northeast Ohio Healthcare System