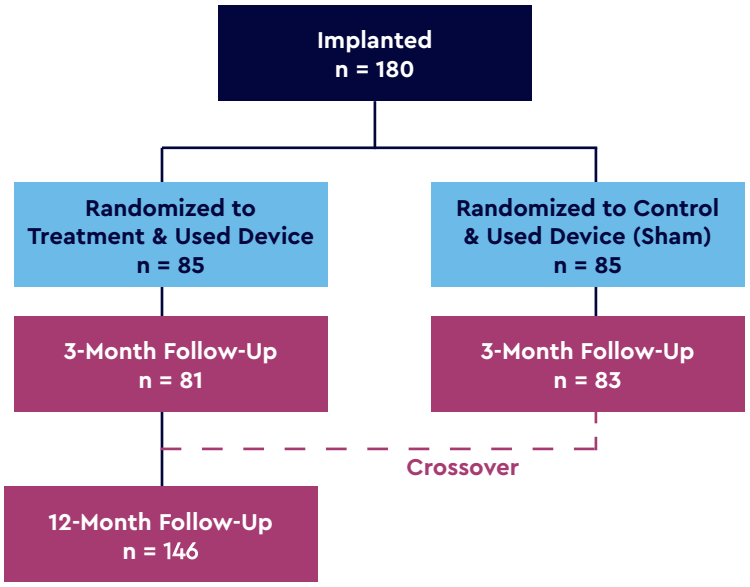
QUEST STUDY 12-MONTH DATA SUMMARY[1]

Study Design[2]

- Multicenter, randomized, double-blinded, active-sham controlled pivotal study.
- Designed to assess the effectiveness and safety of the Altius® System in lower limb amputees with chronic post-amputation pain.
- Study subjects suffered from substantial post-amputation pain (PAP) refractory to previous therapy.
  - » 87% regularly experienced both phantom limb and residual limb pain.
  - » 88% ranked worst daily pain as 7-10.
  - » 52% ranked least daily pain as 4-10.
- Pain was measured and reported at least daily throughout the study with use of eDiary.

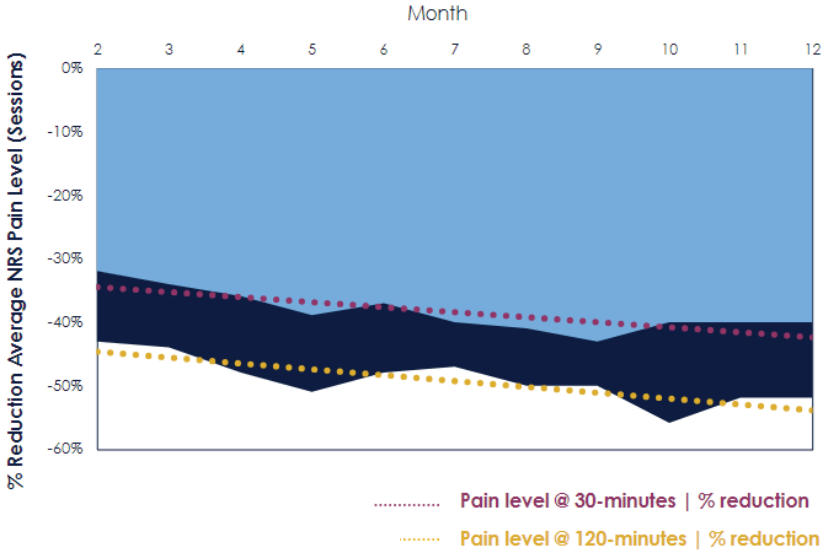


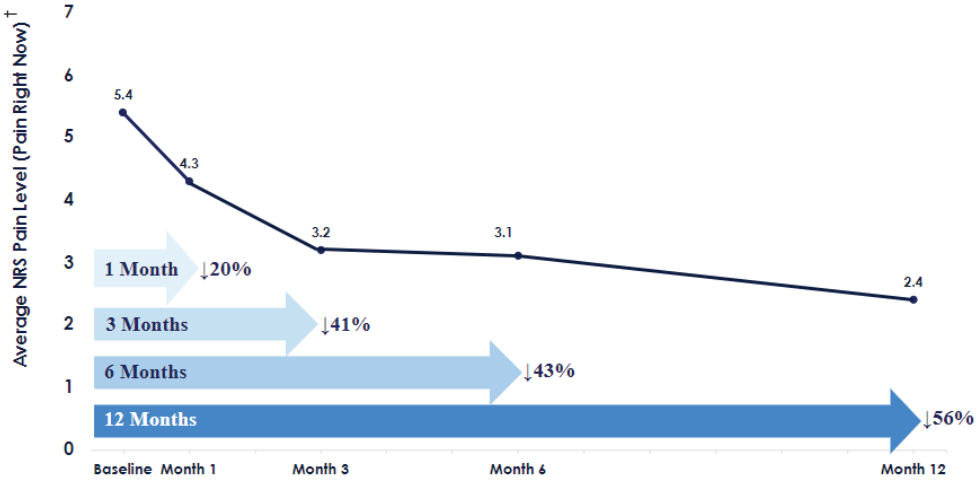
Results

QUEST Outcome*	Benefit
Met primary effectiveness and safety endpoints[3]	**Safe and effective for use in chronic post-amputation pain**
30% ↓ in pain by 30 min on average **50%** ↓ in pain by 2 hours on average	**Rapid, on-demand acute pain reduction**
Acute pain reduction maintained over 12 months	**Lasting relief from pain without observable therapeutic fatigue**
44% ↓ in average pain levels over 12 months **50%** ↓ in days with pain felt over 12 months	**Improvement in chronic pain over time**
81% of subjects taking opioids decreased or eliminated opioid use by 12 months	**Dramatic and sustained opioid reduction**
90% of subjects reported Quality of Life improvement at 12 months** **45%** ↑ in overall Quality of Life including walking, working, and relationships	**Rapid and sustained quality of life improvement**

*Primary endpoints compared results between treatment and control arms. All subsequent table data reflect outcomes of combined cohorts at 12 months. Average pain level, days of pain felt (pain≥4), and QOL data obtained from BPI survey.
** based on Patient Global Impression of Change (PGIC)

- 30% average pain reduction 30 minutes after initiating treatment
- 50% average pain reduction 120 minutes after initiating treatment
- No observable therapy fatigue at 12 months
- Per IMMPACT criteria, 30% pain reduction (>2 points NRS scale) is classified as clinically meaningful, and 50% pain reduction is classified as clinically significant.[4]





- After 12 months of therapy, basal pain levels reduced by >50%
- Normal pain modulation re-established as pain signals are repeatedly prevented over time

† Data from subjects initially randomized to the treatment arm, as control arm did not receive a full 12 months of treatment.

Authors' Conclusion[1]

Altius therapy delivered directly to the damaged peripheral nerve provided sustained, on-demand relief of acute PAP exacerbations, reduced opioid utilization, and improved QOL for lower limb amputees with chronic PAP.

1 Kapural L, Kim B, Eidt J, et al. Long-term treatment of chronic post-amputation pain with bioelectric nerve block: 12-month results of the randomized, double-blinded, cross-over QUEST study. Neuromodulation. 2024. *In Press.* FDA Trial NCT02221934.

2 Kapural L, Syed Shah N, Fang Z-P, Mekhail N. Multicenter, double-blinded, randomized, active-sham controlled clinical study design to assess the safety and effectiveness of a novel high frequency electric nerve block system in the treatment of post-amputation pain (the QUEST study). J Pain Res. 2022. FDA Trial NCT02221934.

3 Kapural L, Melton J, Kim B, et al. Primary 3-Month outcomes of a double-blind randomized prospective study (the QUEST study) assessing effectiveness and safety of novel high-frequency electric nerve block system for treatment of post-amputation pain. J Pain Res. 2024. FDA Trial NCT02221934.

4 Dworkin R, Turk D, Wyrwich K, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. The Journal of Pain. 2008.

Indications for Use: The Altius® Direct Electrical Nerve Stimulation System is indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. **Contraindications:** The Altius System is contraindicated for patients who are: Unable to operate the system or Unsuitable for the Altius implant surgery. **Warnings/Precautions:** Use as indicated and instructed. Diathermy should not be used on patients with the Altius System, or any of its components, either as a treatment for a medical condition or as part of a surgical procedure. Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with Altius System function. The electrical pulses from the Altius System may interact with the sensing operation from a cardiac device and could result in an inappropriate response of the cardiac device; physicians involved should discuss the possible interactions between the devices before surgery. Safety and Effectiveness of Altius System for pediatric use and for pregnant patients has not been established. Surgical complications and adverse events may be more frequent and severe in diabetic patients. Safety of MRI/NMRI with an implanted Altius System has not been evaluated. Patients implanted with the Altius System, or any of its components, should not be subject to MRI/NMRI. See Instructions for Use for detailed information regarding the procedure(s), indications, contraindications, warnings, precautions, and potential adverse events before performing the Altius procedure. For more information and to view full Instructions for Use, visit www.neurosmedical.com.

Although FDA has determined that the probable benefits outweigh the probable risks, there remains some uncertainty regarding the manufacturer's human factors engineering (HFE) and usability engineering (UE) analysis and validation testing. As a condition of approval, FDA is requiring the manufacturer to provide an HFE/UE analysis and validation testing and recommending that this analysis and testing is designed using the FDA's 2016 guidance document "Applying Human Factors and Usability Engineering to Medical Devices" (https://www.fda.gov/media/80481/download).

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Rx only

LB-0222 Rev A