

# Summary of a Multicenter, Randomized, Sham-Controlled, Double-Blind Study of Provant Therapy in the Treatment of Persistent Post-Operative Pain Following Lumbar Surgery

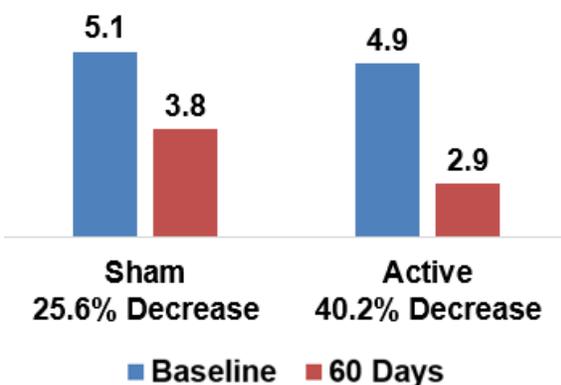
## Subjects Treated with Provant® Therapy had a Clinically Meaningful Reduction in Average Low Back Pain and Leg Pain



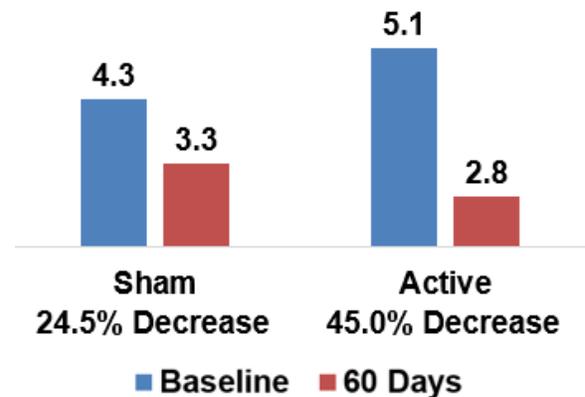
- Up to 30% of back surgery patients experience pain beyond the acute postoperative period, which may lead to reduced physical function, increased use of opioids, and expensive ancillary procedures.
- Provant is an alternative treatment for persistent postoperative pain.
- Subjects completed a multicenter, randomized, sham-controlled trial. Subjects treated twice a day for 60 days. Two groups are reported on here: Active (current commercial device) and Sham.
- Subjects between 3 and 36 months after their most recent lumbar surgery.
- Provant use resulted in a clinically meaningful reduction in average pain.
- This pilot trial was intended to inform future trial design.

**Results** Pain reduction was the primary endpoint; clinically meaningful change was defined as a 30% reduction for pain intensity (11-point numeric pain rating scale used)

**Back Pain: Active Provant Achieved Clinically Meaningful Pain Reduction**



**Leg Pain: Active Provant Achieved Clinically Meaningful Pain Reduction**



### SUMMARY Pain Following Lumbar Surgery Randomized Controlled Trial

- Completed a multicenter, randomized, sham-controlled trial.
- Active and Sham groups treated for 60 days.
- Provant Therapy was associated with a clinically meaningful reduction in average pain.
- Provant Therapy is an alternative treatment for persistent postoperative pain.

## Sources

1. Manchikanti, L. et al. Contribution of Facet Joints to Chronic Low Back Pain in Postlumbar Laminectomy Syndrome: A Controlled Comparative Prevalence Evaluation. *Pain Physician*, Volume 4, Number 2, pp 175-180, 2001.
2. Chan and Peng. Review article: Failed back surgery syndrome. *Pain Medicine* 2011; 12: 577–606.
3. Parker, S. et al. Long-term back pain after a single-level discectomy for radiculopathy: incidence and health care cost analysis. *J Neurosurg Spine* 12:178–182, 2010.

The Provant System is indicated for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue. Provant received FDA clearance in 1997, 2010, and 2013. Prior to use, please see the Provant Instruction Manual for more information on indications, contraindications, precautions, warnings and operator's instructions. Regenesi, Provant, Energy Starburst logo, and the color yellow as applied to the Provant Therapy System are registered trademarks of Regenesi Biomedical, Inc., Scottsdale AZ.

**Provant**<sup>®</sup>  
Therapy System



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