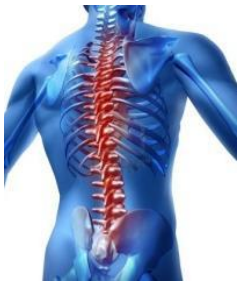

Clinical Trial Health Economics Results: Provant® Therapy

Patients in Pain After Back Surgery May Avoid Additional Procedures and Costs

- Pain that persists after spinal surgery is referred to as Failed Back Surgery Syndrome (FBSS).
- Persistent pain may lead to reduced physical function and sense of well-being, and increased consumption of healthcare resources.
- In a prospective study, Provant treatment twice daily for 45 days was associated with improved pain scores, improved overall well-being, improved physical function, reduced analgesic consumption, and avoidance of costly procedures, in a subset of patients.
- Provant accomplishes this by helping tissue move through, and out of, inflammation.

PROSPECTIVE STUDY

- Persistent pain after back surgery
- Average 16 months post-op
- 27 patients participated in the 6-month follow-up
- 13 patients were considering a total of 17 procedures prior to using Provant
- At 6-month follow-up, only 4 patients considering a procedure had one
- $13,616 average potential savings for these 13 patients

Persistent Pain After Back Surgery is Common and May Require Costly Procedures For Pain Relief

	Procedure Type	Persistent Pain %[1,2,3]
Decompression Surgery	Laminectomy Foraminotomy	20-30%
Fusion	Fusion	30%
Disc Material Removal	Discectomy Herniated Disc Removal	23% moderate, 9% severe

An Assessment of Costs Associated with Avoided Procedures Shows Provant May Be Cost Effective

- Prior to using Provant Therapy, 13 patients were considering 17 procedures; at 6-month follow-up only 4 patients considering a procedure had one.
- Averaging $13,616 potential savings for these 13 patients.
- Average patient savings = (Procedure Cost Savings – Provant Cost) / 13 patients.

Procedures Considered by the 13 Patients	Avoided at 6-Month Follow-Up	Cost Estimates[4,5]	Total Potential Procedure Cost Savings
Stimulator/Pump Implant	4/4	~$44,500	$178,000
Additional Surgery	4/5	$15,000+	$60,000
Injection/Ablation (series of 2)	5/8	$1,050	$5,250

Provant Case Report Summary

Relief of Failed Back Surgery Pain with Radiating Nerve Pain by Using Electromagnetic Energy

Abstract: Lumbar fusion patient with pain score of 10/10. Impaired quality of life, including difficulty working. Provant® Therapy was initiated almost one year after surgery. Provant was used a total of 4 months. Patient was able to decrease opioid medications, and reported a pain score of 2/10. She continues her demanding job and works out on an elliptical machine daily.

Conclusion: Provant is an alternative therapy for failed back surgery pain relief.

[Your Regenesis representative can provide you with the complete case report]

	Before Provant	After Provant
Interventions	• Lumbar selective nerve root blocks • Left piriformis muscle/sciatic nerve block	None
Pain Score 0-10	10/10	2/10
Pain Meds	• Taking more methadone than prescribed • Often asked to refill prescription early	• Never again asked for an early refill • Taking less than the prescribed amount • Increased time between refills
Quality of Life	• Difficulty driving • Difficulty working	• Continues her demanding job • Works out daily on her elliptical

The Provant System is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue. Provant received FDA clearance in 1997, 2010, and 2013. Molecular biology findings have not been reviewed by FDA. Prior to use, please see the Provant Instruction Manual for more information on indications, contraindications, precautions, warnings and operator's instructions. Regenesis, Provant, Energy Starburst logo, and the color yellow as applied to the Provant Therapy System are registered trademarks of Regenesis Biomedical, Inc., Scottsdale AZ.

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Assumptions:
These cost and savings estimates are based upon a prospective study. The trial population and survey responses are not necessarily representative of the general population of failed back surgery patients. Estimates are provided for illustrative purposes only. Actual costs, and extent of potential cost avoidance, will vary by facility and patient specifics, including underlying disease, surgical procedure, postoperative course and Provant outcomes. Not all patients respond to Provant Therapy.

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Provant® Therapy System

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