

# ReActiv8®

## ReActiv8-B Trial 5-Year Follow up - Study Summary First neurostimulation trial to report 5-year outcomes for Mechanical CLBP

### Five-Year Longitudinal Follow-up of Restorative Neurostimulation Demonstrates Durability of Effectiveness in Patients with Refractory Chronic Low Back Pain associated with Multifidus Muscle Dysfunction

Neuromodulation. Accepted for Publication: January 2024. Chris Gilligan, MD et al.



#### Key Takeaways

- 204 participants implanted with ReActiv8 system
- Randomized, sham-controlled, double-blinded
- Completer analysis on 62% patients at 5 years (n=126)
- Intent-to-Treat analysis accounting for 100% of patients (n=204) provided with Mixed Model of Repeated Measures imputation
- Patient improvements accumulate over time, consistent with restorative mechanism of action
- Explants for success demonstrate increasing number of patients no longer need treatment to maintain clinical benefit
- **ONLY** restorative therapy for patients suffering from non-surgical, mechanical CLBP evidenced by multifidus dysfunction

#### Compelling long-term effectiveness\*

- Average VAS improved from 7.3 to 2.4
- Average ODI improved from 39 to 16
- **72%** with  $\geq 50\%$  improvement in LBP VAS
- **61%** with  $\geq 20$ -point improvement in ODI
- **78%** with  $\geq 50\%$  improvement in VAS and/or ODI
- **88%** were “Definitely satisfied” with the treatment

#### Opioid reduction

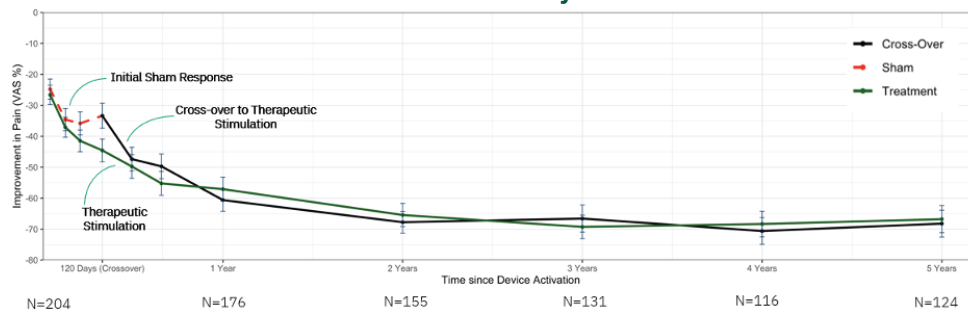
- **69%** of patients on opioids at baseline have eliminated (46%) or reduced (23%) opioid consumption

#### Safety

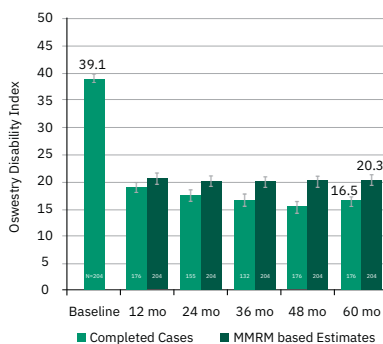
- No lead migrations

\*Completers, n=125/126

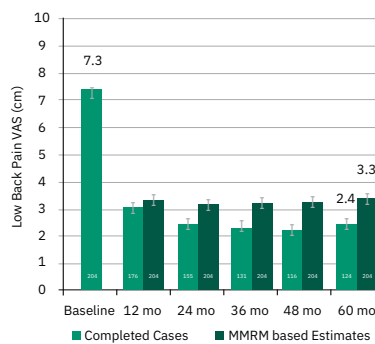
#### Demonstrated Durability Over 5 Years



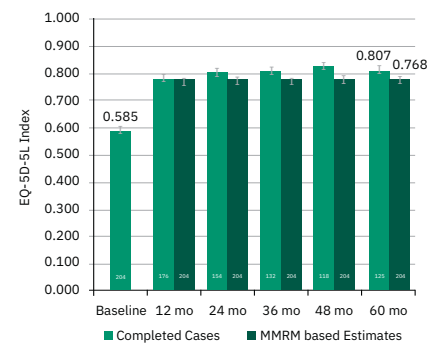
Oswestry Disability Index (ODI)



Visual Analog Score (VAS)



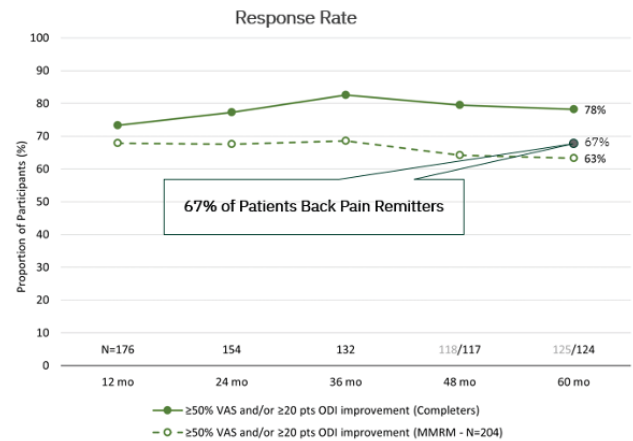
Healthcare Related Quality of Life (EQ-5D-5L)



# ReActiv8®

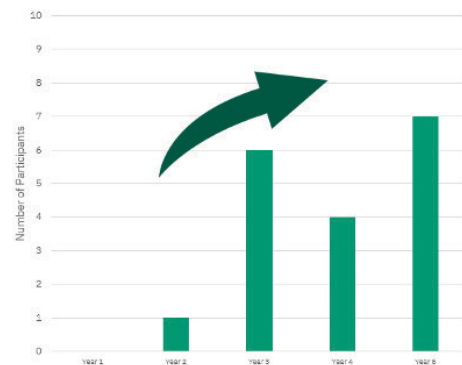
## Substantial Response to Therapy Over 5 Years

- **50% VAS reduction** = Substantial Clinical Improvement
- **20 pt ODI reduction** = Substantial Clinical Improvement
- **~8 out of 10** completers (78%) showed substantial improvement in pain and/or function
- **~7 out of 10** patients (67%) were back pain remitters (VAS ≤ 2.5 cm)



## Systems Removed for Resolution of Pain

- Restorative mechanism **accrues benefit** over time
- Increasing number of patients **no longer need treatment** to maintain clinical benefit
- **9% of patients explanted for resolution of pain (n=18)**



## Established Therapy for Mechanical CLBP w/Multifidus Dysfunction

- **ONLY** neurostimulation device with proven long-term effectiveness, durability, and safety data out to **5 years** for mechanical CLBP
- **ONLY** neurostimulation device with consistent, long-term clinical trial and real-world outcomes for mechanical CLBP
- **ONLY** restorative therapy for patients suffering from non-surgical, mechanical CLBP evidenced by multifidus dysfunction
- **ReActiv8** removals for success suggest restorative mechanism and therapy shows no evidence of loss of efficacy commonly observed with palliative treatments
- **ReActiv8** is a first line interventional treatment option that can significantly impact the clinical and economic burden of mechanical CLBP by reducing the need for repeated palliative treatments

