



3-Year UK PMCF Post Market Study Summary

Restorative Neurostimulation for Chronic Mechanical Low Back Pain – Three Year Results from the United Kingdom Post Market Clinical Follow-up Registry

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Key Takeaways

- **3-year** real-world data collected at 5 sites across the UK.
- 42 patients enrolled w/33 completing 3-year follow up.
- No formal inclusion or exclusion criteria enforced outside the IFU and indications of the CE Mark.
- **70%** of patients reached the remitter threshold reporting mild to negligible pain (NRS ≤ 3) and 55% improved by more than 15 points on ODI.
- **75%** of patients had a substantial or profound improvement in NRS ($>50\%$) and/or ODI (>20 point).
- Patients reported a mean EQ-5D approaching an age matched UK population normal value.
- No lead migrations.
- **Response to ReActiv8 consistent with the restorative mechanism of action and published pivotal trial data.**

% of Patients Showing Clinical Improvements at 3 Years

Outcome Measures	ReActiv8-B (N=133)	PMCF (N=33)
CLBP Remitter (VAS ≤ 2.5 /NRS ≤ 3)	64%	70%
$\geq 50\%$ reduction in low back pain	77%	67%
≥ 15 -point reduction in ODI	71%	55%
$\geq 50\%$ in VAS/NRS and/or ≥ 20 points in ODI	79%	75%
Completion Rate	76%	79%

Effective, Durable, and Generalizable

- Statistically significant, clinically meaningful, and durable response across pain, disability, and QOL **at 3 years.**
- Real world patients selected based on recommendations from the clinical trials rather than strict inclusion/exclusion criteria.
- The meaningful **3-year** clinical benefits suggest that published outcomes achieved in the clinical trial setting can also be achieved in routine clinical practice.

Graphs: Mean ratings over time for (top) low back pain NRS, (middle) Oswestry disability index, and (bottom). EQ-5D-5L index. Error bars represent the standard error of the mean.

