

# CEM-Plate and CEM-Cage First-In-Human Use Efficacy Study

NCT04883411

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Status	RECRUITING
Phase	Not Applicable
Sponsor	ReVivo Medical, Corp.
Enrollment	50 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Males and females aged 22-79 years.
- Documented diagnosis of cervical spine radiculopathy or myelopathy.
- Symptomatic cervical degenerative disc disease at 2 contiguous levels between C2 through T1.
- Baseline NDI score  $\leq 30$  and/or baseline mJOA score  $\leq 16$ .
- Pathology at the level to be treated correlating to the primary symptoms confirmed by imaging (computed tomography (CT), CT myelography, magnetic resonance imaging (MRI), or plain radiography).

... and 3 more (see full listing online)

### Exclusion (30)

- Any prior cervical surgeries at the symptomatic levels; prior surgery or cervical fusion procedure at any level.
- Fewer than 2 or more than 2 vertebral levels requiring treatment.
- Anatomy that is non-conductive to receiving investigational device.
- More than one immobile vertebral level between C-1 to C-7 from any cause, including but not limited to congenital abnormalities and osteoarthritic "spontaneous" fusions.
- Known diagnosis of osteoporosis, current pharmacological treatment for osteoporosis or bone density which in the medical opinion of the surgeon precludes operation or contraindicates instrumentation.

... and 25 more (see full listing online)

## Locations (4 total)

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IGEA, Union, New Jersey, United States  
Albany Medical College, Albany, New York, United States  
University at Buffalo Neurosurgery, Williamsville, New York, United States  
... and 1 more locations