Many patients considering sacral neuromodulation first undergo a therapy evaluation wherein stimulation is delivered to the sacral nerves via a temporary lead, enabling the patient to trial the therapy prior to receiving a permanent implant. Lead dislodgement during the trial period has been identified as a possible cause of inconclusive trial response [1-3].

To reduce the potential for dislodgement, the InterStim™ trialing lead (commonly known as the PNE lead or temporary stimulation lead) has been redesigned to better accommodate patient movement and stabilize the tip electrode during therapy evaluation. The hypothesis was that incremental tip electrode movement is lower during simulated activities of daily living in a cadaver when using the redesigned basic evaluation lead (new; Model 306001/306006) compared to the market-released lead (control; Model 205991/205996).

### Results

**Cadaver demographics.**
- **Age:** Mean age was 83 years and 5/10 were female.
- **BMI:** BMI ranged from 19.9 to 41.6 (average 25.5 ± 6.26).
- **Cadaver height:** Cadaver height was 67.3 ± 4.1 inches and weight was 163 ± 31.6 pounds.
- **Specimens and Implant:** The new basic evaluation lead was at or below 1 mm (red line).

**Summary statistics for both lead models and both cadaver cohorts are tabulated below (n = number of cadaver challenges).**

<table>
<thead>
<tr>
<th>Lead Type</th>
<th>Cohort</th>
<th>Incremental Tip Electrode Movement (mm)</th>
<th>Mean ± SD</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>n=5</td>
<td>1.74 ± 0.21 mm</td>
<td>0.34 ± 0.28</td>
<td>0.25 mm</td>
</tr>
<tr>
<td>New</td>
<td>n=10</td>
<td>0.21 mm</td>
<td>0.07 ± 0.19</td>
<td>0.20 mm</td>
</tr>
</tbody>
</table>

- **Tip movement after cadaver manipulation in the first cohort was 0.98 mm less for the new basic evaluation lead compared to the control lead [95% CI: -1.74 mm to -0.21 mm, p=0.015].
- **Across various positional changes in a cadaver model, the tip electrode of the new basic evaluation lead demonstrated statistically significantly less incremental movement compared to the tip electrode of the control lead.**

**Conclusions**

- **These results suggest**:
  - The new basic evaluation lead may improve tip electrode stability.
  - The biomechanics of basic evaluation lead movement serve as input to a computational model that will allow manufacturers to determine the impact of anatomic variation, implant procedure, and design on performance.

**References**

3. InterStim Temporary Lead Product Performance Summary (NDHF1534-161011); Medtronic data on file.