Case-Series Assessment of New Percutaneous Spinal Cord Stimulation Lead for Multi-Site and/or Evolutive Pain Patterns in Europe

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BACKGROUND

Advancements in Spinal Cord Stimulation (SCS) lead designs, when used in combination with new neural targeting technologies, are thought to be capable of supporting improved outcomes with SCS, including in patients with multi-site and/or evolutive (or changing) pain patterns over time.

In this study, SCS clinical outcomes are assessed in chronic pain patients using a newly available 16-contact percutaneous lead with increased span, tight contact spacing and direct connection to the IPG.

METHODS

Study Design	Multicenter, Consecutive, Observational, Case-Series
Study Device	Multiple waveform SCS system (Precision, Precision Spectra, Precision Plus, Novi, Montage and Spectra WaveWriter, Boston Scientific) with the following capabilities: <ul style="list-style-type: none">16-contact lead (Infinion CX, Boston Scientific)Multiple Independent Current Control (MICC)Anatomically-Guided (3D) Neural Targeting (Illumina 3D, Boston Scientific)Multiple available waveforms and/or field shapes
Subjects	45 subjects diagnosed with chronic pain
Key Inclusion	Implanted on-label with SCS

Baseline Characteristics (n = 45)

Gender - Females (%)	66.7% (30/45)
Age [Mean (SD)]	54.2 (11.6) yrs. n = 45
Pain Location (%)	Low Back and Legs (88.9%)
	Low Back (86.7%)
	Rt. Foot/Lt. Foot (11.1%)
	Rt. Knee/Lt. Knee (4.4%)
	Rt. Ankle/Lt. Ankle (4.4%)
	Pelvic/Groin Pain (6.7%)
Baseline NRS [Mean (SD)]	8.4 (0.9) n = 45
Follow-up Duration [Median (Range)]	13 months [1 – 155] n = 45

RESULTS

Distribution of Overall Pain Scores at Last Follow-up (n = 45)

CONCLUSIONS

- Results from this ongoing, multicenter, real-world cohort demonstrate significant improvement in overall pain with the use of a recently introduced SCS system with new leads capable of addressing multisite pain and/or changing pain locations.
- In this real-world cohort of 45 consecutive subjects:
 - A statistically significant improvement in overall pain (p < 0.0001) was reported at their last follow-up (58%; 8.4 → 3.5)
 - At 3 months (n = 21), a 69% improvement in overall pain was reported (p < 0.0001)
 - A similar trend for low back pain scores was also noted (at 3 months: Δ = 5.7, 7.9 → 2.3, p < 0.0001)
- These outcomes are consistent with other studies (Waghmarae R. et al. INS 2019)