# Use of a Newly Developed Delivery Device for Percutaneous Introduction of Spinal Cord Stimulation Leads

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## INTRODUCTION

Paddle leads offer several advantages over cylindrical leads. For example, the electrodes lay closer to the spinal cord due to the dimensions and surgical placement of the paddle lead. This allows for increased stimulation while avoiding painful stimulation, enhancing the likelihood of capturing elusive back pain. Paddle leads also provide greater energy efficiency by unilaterally directing current towards the spinal cord, thereby reducing power requirements and the likelihood of painful dysesthesia caused by stimulating the ligamentum flavum.[1,2] In addition, cylindrical-type leads are more likely to migrate postoperatively due to postural changes. This movement within the epidural space can result in changes in the paresthesia coverage and in inadequate pain relief. Despite these advantages, paddle leads require a more invasive laminectomy procedure. In addition, placement of multiple cylindrical leads requires multiple needle sticks, increasing the probability of dural punctures and other complications. Thus, the ideal situation for lead insertion would be the percutaneous delivery of a paddle lead or placement of multiple cylindrical leads in which only one needle stick is required. A new delivery device called the Epiducer ™ lead delivery system (St. Jude Medical Neuromodulation Division; Plano, TX) has been developed to aid in these placement techniques.

1) North RB, Lanning A, Cutchis PN. Spinal cord stimulation with percutaneous and plate electrodes: side effects and quantitative comparisons. Neurosurg Focus. 1997;5:E3.
2) North RB, Kidd DH, Olin JC, Sieracki JM. Spinal cord stimulation electrode design: prospective, randomized, controlled trial comparing percutaneous and laminectomy electrodes—part 1; technical outcomes. Neurosurg. 2002;51:381-389.

## METHODS

- This new technology assessment (NTA) evaluated use patterns pertaining to the Epiducer lead delivery system. An NTA is a tool for assessing if a new or modified product meets the needs of the user in a pre-market release. The following procedural aspects of the surgery were recorded during the evaluation: procedure time, angle of entry, distance from entry to final lead placement, and physician feedback.
- The Epiducer lead delivery system NTA was conducted at 7 European sites consisting of 8 implanters.
- Patients were included in the NTA if they were candidates for percutaneous implantation of SCS system leads for chronic pain of the trunk and/or limbs and their implantation procedure involved the use of the Epiducer lead delivery system.

## RESULTS

### Implant Success

There were a total of 38 (82.6%) successful implants. Success was defined as the ability to place the lead in the epidural space using the Epiducer lead delivery system. The lead could not be placed in 8 patients due to various reasons, with the main reason being excessive scar tissue in the epidural space (13%). Other reasons included patient anxiety attack (2.2%) and too much pain experienced by the patient during implantation (2.2%).

### Epiducer Lead Delivery System Length Selection

| Length | Occurrence | Percent |
|---|---|---|
| 5-inch (13 cm) | 38 | 82.6% |
| 7.5-inch (19 cm) | 1 | 2.2% |
| Both | 7 | 15.2% |
| **Total** | **46** | |

Table 1. The type (length) of device used was captured. The 5-inch (13 cm) device was used most often (82.6%).

### Procedure Time (Minutes)

| | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|
| Epiducer Lead Delivery System Placement (n=45) | 1.0 | 35.0 | 10.2 | 7.5 |
| S-Series™ Paddle Lead Placement (N=41) | 1.0 | 52.0 | 19.1 | 14.2 |
| Total Procedure Time (N=45) | 12.0 | 72.0 | 32.2 | 15.4 |

Table 2. The time at which the following occurred was recorded: 1) first needle stick, 2) lead insertion 3) Epiducer lead delivery system removal and 4) final lead placement. Epiducer lead delivery system placement time was calculated from 1 and 3, S-Series paddle lead (St. Jude Medical Neuromodulation Division, Plano, TX) placement was calculated from 2 and 4, and total procedure time was calculated from 1 and 4.

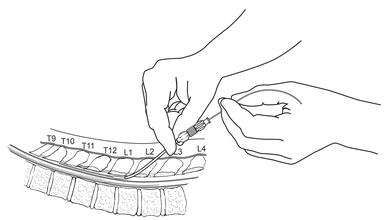
### Guide Wire Steering

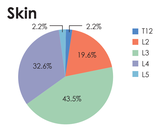
| Number of Vertebral Levels | Occurrence | Percent |
|---|---|---|
| 0–2 | 22 | 51.1% |
| 2.5–4 | 15 | 34.9% |
| Greater than 4 | 6 | 14.0% |
| **Total** | **43** | |

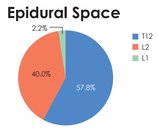
Table 3. Physicians were asked to indicate the number of vertebral levels the guide wire was steered for each case. The guide wire was steered a mean (± SD) of 2.9 (± 1.7) vertebral segments

## Epiducer Lead Delivery System Placement

### Insertion Location

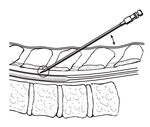


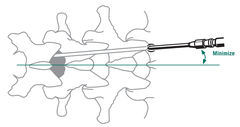



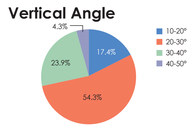



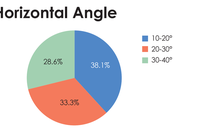

Figures 1 and 2. Physicians were asked to indicate at which vertebral level the device was initially inserted into the skin (Figure 1) and at which vertebral level the device entered the epidural space (Figure 2).

### Approach/Angles of Insertion





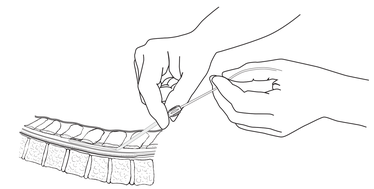

Figures 3 and 4. Physicians were also asked to indicate the angle of insertion (vertical in relation to the skin; Figure 3) of the Epiducer lead delivery system and the type of approach taken. If a paramedian approach was used, they were also asked to specify the horizontal angle used (Figure 4). A paramedian approach was used in 42 cases (91.3% ).

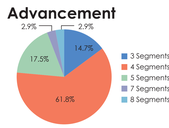
### Visualization

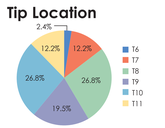
| Score | Occurrence | Percent |
|---|---|---|
| 5 | 1 | 2.2% |
| 6 | 1 | 2.2% |
| 8 | 14 | 30.4% |
| 9 | 26 | 56.5% |
| 10 | 4 | 8.7% |
| **Total** | **46** | |

Table 4. Physicians were asked to rate visualization of the device via fluoroscopy on an 11-point scale, where 0 = very poor and 10 = excellent. According to the physicians, the best indication that the outer gray sheath had entered the epidural space was lateral fluoroscopic guidance (50%), tactile feedback (37.5%), and A/P fluoroscopic guidance (12.5%).

## S-Series Paddle Lead Placement






Figures 5 and 6. The number of vertebral levels the lead was advanced (Figure 5) was calculated by subtracting the vertebral level at which the tip of the lead was implanted (Figure 6) from the vertebral level at which the Epiducer lead delivery system entered the epidural space.

## SUMMARY & CONCLUSIONS

- Data from a total of 46 patients was collected from 7 investigational sites
- A total of 38 (82.6%) implants were successful
- The average total procedure time was 32.2 minutes with placement of the Epiducer lead delivery system, requiring an average of 10.2 minutes
- The angle of entry was 20°–30° in 54.3% (25) of the cases, and the lead was advanced 5 or fewer vertebral segments in 82.9% of all cases
- All physicians indicated that they were satisfied with the device

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