**Table. Adverse Events Not Related to the Neuro-Spinal Scaffold™ or Its Implantation Procedure**

| **AE by MedDRA preferred term** | **0–6 months postimplantation**  **(n=19)** | | **6–24 months postimplantation**  **(n=16)a** | | **Overall**  **(n=19)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **n (%)** | **No. of events** | **n (%)** | **No. of events** | **n (%)** | **No. of events** |
| All AEs | 19 (100) | 353 | 13 (81) | 67 | 19 (100) | 420 |
| Most common AEs (>20% of patients overall) |  |  |  |  |  |  |
| Urinary tract infection | 13 (68) | 33 | 6 (38) | 10 | 14 (74) | 43 |
| Muscle spasms | 11 (58) | 15 | 0 | 0 | 11 (58) | 15 |
| Neuralgia | 9 (47) | 10 | 2 (13) | 2 | 10 (53) | 12 |
| Decubitus ulcer | 4 (21) | 5 | 2 (13) | 5 | 6 (32) | 10 |
| Pain in extremity | 5 (26) | 9 | 0 | 0 | 5 (26) | 9 |
| Depression | 4 (21) | 4 | 3 (19) | 4 | 5 (26) | 8 |
| Pleural effusion | 5 (26) | 8 | 0 | 0 | 5 (26) | 8 |
| Pyrexia | 8 (42) | 8 | 0 | 0 | 8 (42) | 8 |
| Back pain | 5 (26) | 6 | 1 (6) | 1 | 5 (26) | 7 |
| Leukocytosis | 6 (32) | 6 | 1 (6) | 1 | 6 (32) | 7 |
| Abdominal distension | 6 (32) | 6 | 0 | 0 | 6 (32) | 6 |
| Muscle spasticity | 3 (16) | 5 | 1 (6) | 1 | 4 (21) | 6 |
| Arthralgia | 4 (21) | 4 | 1 (6) | 1 | 5 (26) | 5 |
| Atelectasis | 4 (21) | 5 | 0 | 0 | 4 (21) | 5 |
| Headache | 3 (16) | 3 | 2 (13) | 2 | 5 (26) | 5 |
| Nausea | 3 (16) | 4 | 1 (6) | 1 | 4 (21) | 5 |
| Anxiety | 2 (11) | 2 | 2 (13) | 2 | 4 (21) | 4 |
| Constipation | 4 (21) | 4 | 0 | 0 | 4 (21) | 4 |
| Hypophosphatemia | 4 (21) | 4 | 0 | 0 | 4 (21) | 4 |
| Hypotension | 4 (21) | 4 | 0 | 0 | 4 (21) | 4 |
| Incision site pain | 4 (21) | 4 | 0 | 0 | 4 (21) | 4 |
| Urinary incontinence | 4 (21) | 4 | 0 | 0 | 4 (21) | 4 |
| Serious AEs | 12 (63) | 22 | 3 (19) | 4 | 12 (63) | 26 |
| Urinary tract infection | 2 (11) | 3 | 1 (6) | 1 | 2 (11) | 4 |
| Pleural effusion | 2 (11) | 2 | 0 | 0 | 2 (11) | 2 |
| Pulmonary embolism | 2 (11) | 2 | 0 | 0 | 2 (11) | 2 |
| Respiratory distress | 1 (5) | 2 | 0 | 0 | 1 (5) | 2 |
| Respiratory failure | 1 (5) | 2 | 0 | 0 | 1 (5) | 2 |
| Cellulitis | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Cerebrospinal fluid leakage | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Cerebrovascular accident | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| *Clostridium difficile* colitis | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Colitis | 0 | 0 | 1 (6) | 1 | 1 (5) | 1 |
| Deep vein thrombosis | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Dehydration | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Diarrhea | 0 | 0 | 1 (6) | 1 | 1 (5) | 1 |
| Epididymitis | 0 | 0 | 1 (6) | 1 | 1 (5) | 1 |
| Necrotizing myositis | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Traumatic pneumothorax | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Postoperative wound infection | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Sepsis | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |
| Spinal cord disorder | 1 (5) | 1 | 0 | 0 | 1 (5) | 1 |

AE, adverse event. MedDRA, Medical Dictionary for Regulatory Activities. NSS, Neuro-Spinal Scaffold™.

aOf the 19 patients who underwent NSS implantation, there were 3 early withdrawals due to death (cerebrovascular accident, pulmonary embolism, and sepsis, respectively) within 2 weeks of surgery; all were determined by investigators to be unrelated to the NSS or its implantation procedure.