Table 3. Adverse Events

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| --- | --- | --- |
|  | EVICEL®  n=20 | SURGICEL®  n=20 |
| Total Number of Adverse Events | 87 | 101 |
| Total Number of Serious Adverse Events | 5 | 3 |
| Number (%) of Subjects with at Least 1 Event in the Category |  |  |
| AE \* | 19 (95.0%) | 20 (100.0%) |
| Serious AE | 4 (20.0%) # | 3 (15.0%) § |
| Severe AE | 2 (10.0%) | 1 (5.0%) |
| AE Related or possibly related to study product (investigator) | 2 (10.0%) | 2 (10.0%) |
| AE Related or possibly related to study product (sponsor) | 0 (0.0%) | 0 (0.0%) |
| SAE Related or possibly related to study product (investigator) | 0 (0.0%) | 0 (0.0%) |
| SAE Related or possibly related to study product (sponsor) | 0 (0.0%) | 0 (0.0%) |
| SAE Related or possibly related to Study Procedure | 16 (80.0%) | 18 (90.0%) |
| Subject Deaths/Ongoing (S)AE at death | 0 (0.0%) | 0 (0.0%) |
| Thrombotic events | 0 (0.0%) | 0 (0.0%) |
| AE related to re-bleeding at TBS † | 1 (5.0%) | 2 (10.0%) |
| \* AE that occurred in ≥5 subjects of either group were tachycardia, pyrexia, abdominal pain, vomiting and procedural pain.  # 5 SAE in 4 subjects: possible hypoxic brain injury, chickenpox, clostridium difficile infection, ureteric stent removal and urinary bladder leak  § 3 SAE in 3 subjects: Castleman’s disease, febrile neutropenia and central line leakage  † all 3 events were intraoperative re-bleedings and were captured as AE per protocol requirement | | |