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 |