Supplemental Content: Evaluation of Intervertebral Body Implant Performance using Active Surveillance of Electronic Health Records

Tables

Table S1: Clinical characteristics of the patients receiving intervertebral body implant devices, by type of device implanted.

Covariate	Concorde Bullet (n=136)	Alternative IVBI (n=98)	No Device Identified (n=214)	Mixed (n=158)	Total (n=606)
Female	72 (52.9%)	51 (52.0%)	107 (50.0%)	80 (50.6%)	310 (51.2%)
Age - Median (Interquartile Range)	64 (72-54)	61 (52 - 70)	59 (48 - 70)	66 (55 - 72)	62 (51 - 71)
BMI - Median (Interquartile Range)	29.0 (33-26)	28.5 (23 - 33)	28.0 (25 - 32)	28.0 (25 - 33)	29.0 (25 - 33)
Diabetes	19 (14.0%)	10 (10.2%)	21 (9.8%)	30 (19.0%)	80 (13.2%)
Heart Failure	1 (0.7%)	1 (1.0%)	2 (0.9%)	1 (0.6%)	5 (0.8%)
Coronary Artery Disease (CAD)	6 (4.4%)	4 (4.1%)	10 (4.7%)	11 (7.0%)	31 (5.1%)
Smoker (active)	18 (13.2%)	8 (8.2%)	11 (5.1%)	6 (3.8%)	43 (7.1%)
Pre-operative Opioid Rx	26 (19.1%)	27 (27.6%)	76 (35.5%)	27 (17.1%)	156 (25.7%)
ASA Class 1-2: Healthy or Mild Disease	93 (68.4%)	71 (72.5%)	108 (50.5%)	104 (65.8%)	376 (62.1%)
ASA Class 3-5: Severe, Incapacitated, Moribund	43 (31.6%)	27 (27.6%)	106 (49.5%)	54 (34.2%)	230 (38.0%)
Prior Spine Surgery	1 (0.7%)	0	8 (3.7%)	1 (0.6%)	10 (1.7%)
Single Level	55 (40.4%)	44 (44.9%)	39 (18.2%)	98 (62.0%)	236 (38.9%)
Two-level	0	1 (1.0%)	23 (10.8%)	0	24 (4.0%)
Complex Repair (>2)	55 (40.4%)	6 (6.1%)	96 (44.9%)	57 (36.1%)	214 (35.3%)
No level identified	26 (19.1%)	47 (48.0%)	56 (26.2%)	3 (1.9%)	132 (21.8%)
Surgeon Annual Spine Volume (IQR)	57 (55-132)	35 (18 - 37)	43 (0 - 68)	60 (50 - 264)	55.0 (35 - 132)

Abbreviations: NDI - No Device Identified; IVBI - Intervertebral Body Implant; ASA - American Society of Anesthesiologists

Table S2: Unadjusted clinical outcomes of patients receiving intervertebral body implant devices, by type of device implanted.

Clinical Endpoints	**Concorde Bullet** (n=136)	**Alternative IVBI** (n=98)	**No Device Identified** (n=214)	**Mixed** (n=158)	**Total** (n=606)
Primary Endpoint: Re-operation at 1 year	2 (1.5%)	0	4 (1.9%)	4 (2.5%)	10 (1.7%)
Secondary Endpoints:					
Mortality at 1 year	1 (0.7%)	0	2 (0.9%)	0	3 (0.5%)
Surgical Site Infection Hospitalization	0	0	2 (0.9%)	1 (0.6%)	3 (0.5%)
Any Hospitalization at 1 year	22 (16.2%)	11 (11.2%)	45 (21.0%)	27 (17.1%)	105 (17.3%)
Blood Transfusion during Index Hospitalization	16 (11.8%)	4 (4.1%)	33 (15.4%)	13 (8.2%)	66 (10.9%)

Table S3: Covariate distributions for the expanded patient population used in the sensitivity analysis, prior to the propensity score match, after the match, as well as in the remaining unmatched CB treated patients.

Covariate	Total Study Population			After Propensity Match			Unmatched Exposures	
	Concorde Bullet (N=136)	Alternate IVBI / NDI (N=312)	Std. Diff	Concorde Bullet (N=124)	Alternate IVBI / NDI (N=124)	Std. Diff	Concorde Bullet (N=12)	Std. Diff
Female	52.94%	50.64%	0.046	54.84%	53.23%	0.032	33.33%	0.444
Age - Median (IQR)	61.84 ± 12.43	58.22 ± 14.73	0.266	62.04 ± 12.60	62.03 ± 13.93	0.001	59.75 ± 10.80	0.195
BMI - Median (IQR)	30.034 ± 5.69	29 ± 6.06	0.175	29.73 ± 5.61	30.06 ± 6.15	0.056	33.08 ± 5.81	0.587
Diabetes	13.97%	9.94%	0.125	12.90%	13.71%	0.024	25.00%	0.312
Heart Failure	0.74%	0.96%	0.025	0.81%	0.00%	-	0.00%	-
Coronary Artery Disease (CAD)	4.41%	4.49%	0.004	4.84%	4.03%	0.039	0.00%	-
Smoker (active)	13.24%	6.09%	0.244	11.29%	9.68%	0.053	33.33%	0.549
Pre-operative Opioid Rx	19.12%	33.01%	0.321	20.16%	22.58%	0.059	8.33%	0.343
ASA Class 1-2	68.38%	57.37%	0.229	66.13%	60.48%	0.117	91.67%	0.659
ASA Class 3-5	31.62%	42.63%	0.229	33.87%	39.52%	0.117	8.33%	0.659
Prior Spine Surgery	0.74%	2.56%	0.144	0.81%	0.00%	-	0.00%	-
Single Level	40.44%	26.60%	0.296	41.13%	31.45%	0.202	33.33%	0.162
Two-level	0.00%	7.69%	-	0.00%	0.00%	-	0.00%	-
Complex Repair (>2 Levels)	40.44%	32.69%	0.161	37.90%	45.16%	0.148	66.67%	0.601
No level identified	19.12%	33.01%	0.321	20.97%	23.39%	0.058	0.00%	-
Surgeon Volume Low (≤25/yr)	5.15%	32.69%	0.751	5.65%	3.23%	0.118	0.00%	-
Surgeon Volume Medium (26-150/yr)	72.79%	52.56%	0.428	74.19%	74.19%	0.000	58.33%	0.340
Surgeon Volume High (>150/yr)	22.06%	14.74%	0.190	20.16%	22.58%	0.059	41.67%	0.479

Table S4: Clinical outcomes of the propensity match extended sensitivity analysis, comparing patients treated with the CB with matched patients treated with pre-defined or no alternative IVBI.

Outcomes: Propensity Match Expanded Analysis	Concorde Bullet (%) (n=69)		Alternative IVBI or No IVBI (%) (n=69)		Relative Risk	95% CI	p-value
Primary Endpoint: Re-operation at 1 year	2	1.6%	1	0.8%	2.00	(0.18-21.77)	0.561
Secondary Endpoints:							
Mortality at 1 year	1	0.8%	0	0.0%	n/a	n/a	0.316
Any Hospitalization at 1year	20	16.1%	13	10.5%	1.54	(0.80-2.95)	0.191
Blood Transfusion (post-op)	14	11.3%	15	12.1%	0.93	(0.47-1.85)	0.843
Surgical Site Infection	0	0.0%	0	0.0%	n/a	n/a	n/a

Table S5: Estimated odds-ratios, calculated via IPTW, for the risk of adverse outcomes with treatment using the CB as compared to using a pre-defined or no alternative IVBI.

Outcomes: IPTW Expanded Analysis	Odds Ratio	Lower CI	Upper CI	Standard Error	p-value
Primary Endpoint: Re-operation at 1 year	1.00	0.98	1.01	0.01	0.63
Secondary Endpoints:					
Mortality at 1 year	1.00	0.99	1.01	0.01	1.00
Any Hospitalization at 1 year	0.97	0.91	1.03	0.03	0.34
Blood Transfusion (post-operative)	1.23	1.14	1.32	0.04	0.00
Surgical Site Infection	0.99	0.99	1.00	0.00	0.28

Table S6: Clinical covariate and clinical endpoint definitions.

Covariate Definitions:

Covariate	Definition
Diabetes	An occurrence of an HBA1c laboratory result value greater than 6.5 within 180 days prior to the surgery date through the a day after the surgery date.
Heart Failure	Any occurrence of heart failure any time prior to the surgery date. The ICD10 codeset included; I11.0, I13.0, I13.2, I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89, I50.9
Coronary Artery Disease (CAD)	Any occurrence of CAD any time prior to the surgery date. The ICD10 codeset included; I20.0, I20.1, I20.8, I20.9, I24.0, I24.1, I24.8, I24.9, I25.10, I25.110, I25.111, I25.118, I25.119, I25.5, I25.6, I25.700, I25.701, I25.708, I25.709, I25.710, I25.711, I25.718, I25.719, I25.720, I25.721, I25.728, I25.729, I25.730, I25.731, I25.738, I25.739, I25.750, I25.751, I25.758, I25.759, I25.760, I25.761, I25.768, I25.769, I25.790, I25.791, I25.798, I25.799, I25.810, I25.811, I25.812, I25.82, I25.83, I25.89, I25.9, Z95.1, Z95.5, Z98.61
Smoker (active)	An occurrence of a nicotine laboratory result with a value greater than 2.0 within 90 days prior to the surgery date.
Pre-operative Opioid Rx	An occurrence of a complete order for an opioid medication in the DEA schedule II class within 90 days prior to the surgery date.
ASA Class 1-2	American Association of Anesthesiologists (ASA) classification healthy and mild disease categories.
ASA Class 3-5	American Association of Anesthesiologists (ASA) classification incapacitating, moribund and severe disease categories.
Prior Spine Surgery	Any occurrence of a spine surgery procedure in the 12 months prior to the surgery date. The CPT codeset included; 0164T, 22206, 22207, 22208, 22212, 22214, 22216, 22222, 22224, 22226, 22533, 22534, 22558, 22585, 22610, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22818, 22819, 22830, 22840, 22841, 22842, 22843, 22844, 22845, 22846, 22847, 22848, 22849, 22865, 63085, 63086, 63087, 63088, 63090, 63091, 63101, 63102, 63103, 63301, 63302, 63303, 63305, 63306, 63307, 63308
Single Level	Designation was based on the surgical procedure including CPT codes-22630, 22558, 22853 (with one level) and excluding-22632, 22845, 22585, 22842.
Two-level	Designation was based on the surgical procedure including CPT codes-22632 (with one level), 22585 (with one level), 22853 (with two levels) and excluding-22632 (with greater than one level), 22842, 22846, 22847, 22632 (with greater than one level)
Complex Repair (>2 Levels)	Designation was based on the surgical procedure including CPT codes-22842, 22632(with greater than one level), 22846, 22847, 22853 (with greater than two levels).
No level identified	Designated when surgical procedure was not identified as single, two-level or complex repair.
Surgeon Volume Low	Annual Surgeon spine surgery volume of 25 or fewer procedures
Surgeon Volume Medium	Annual Surgeon spine surgery volume of 26 to 150 procedures
Surgeon Volume High	Annual Surgeon spine surgery volume of 151 or greater procedures

Clinical Outcome Definitions:

Clinical Outcome	Definition
Primary Endpoint	
Any Cause Re-operation within 12 months	Any occurrence of any arthrodesis-related procedure within a day through 12 months after surgery. Arthrodesis procedures were defined by 24 CPT codes that included anterior, posterior, lateral and combined techniques with all vertebral segments. CPT codeset included; 0195T, 0196T, 0309T, 0334T, 22532, 22533, 22534, 22556, 22558, 22585, 22586, 22610, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812.
Secondary Endpoints	
Mortality at 12 months	Any occurrence of any type of encounter with a discharge disposition designated as "expired" within one day through 12 months after surgery.
Any Hospitalization within 12 months	Any occurrence of an inpatient encounter with a length of stay of at least one day within one day through 12 months after surgery.
Blood Transfusion (intra-operative)	Any occurrence of a completed blood transfusion order between the admission and discharge dates for the encounter under which the surgery was performed. Local Epic nursing procedure codeset included; NUR619, NUR620, NUR621, NUR622, NUR628, NUR638, NUR631, NUR632, NUR1042.
Surgical Site Infection requiring hospitalization	Any occurrence of an inpatient encounter with a diagnosis of infection following a procedure. ICD10 Codeset included; T81.4, T81.4XXA, T81.4XXD, T81.4XXS.
Falsification Hypothesis Endpoint	
New Renal Dysfunction	Any occurrence of serum creatinine greater than 2.0mg/dl >30 days post-operatively, in patients with no pre-procedure history of renal dysfunction and in whom serum creatinine was not >1.5mg/dl within 30 days of surgery

Table S7: Qualifying surgical CPT4 procedure codes.

Code	Description
20930	ALLOGRAFT, MORSELIZED, OR PLACEMENT OF OSTEOPROMOTIVE MATERIAL, FOR SPINE SURGERY ONLY (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
20931	ALLOGRAFT, STRUCTURAL, FOR SPINE SURGERY ONLY (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22845	ANTERIOR INSTRUMENTATION; 2 TO 3 VERTEBRAL SEGMENTS (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22846	ANTERIOR INSTRUMENTATION; 4 TO 7 VERTEBRAL SEGMENTS (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22851	APPLICATION OF INTERVERTEBRAL BIOMECHANICAL DEVICE(S) (EG, SYNTHETIC CAGE(S), METHYLMETHACRYLATE) TO VERTEBRAL DEFECT OR INTERSPACE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22585	ARTHRODESIS, ANTERIOR INTERBODY TECHNIQUE, INCLUDING MINIMAL DISCECTOMY TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION); EACH ADDITIONAL INTERSPACE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22558	ARTHRODESIS, ANTERIOR INTERBODY TECHNIQUE, INCLUDING MINIMAL DISCECTOMY TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION); LUMBAR
22634	ARTHRODESIS, COMBINED POSTERIOR OR POSTEROLATERAL TECHNIQUE WITH POSTERIOR INTERBODY TECHNIQUE INCLUDING LAMINECTOMY AND/OR DISCECTOMY SUFFICIENT TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION), SINGLE INTERSPACE AND SEGMENT; EACH ADDITIONAL INTERSPACE AND SEGMENT (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22633	ARTHRODESIS, COMBINED POSTERIOR OR POSTEROLATERAL TECHNIQUE WITH POSTERIOR INTERBODY TECHNIQUE INCLUDING LAMINECTOMY AND/OR DISCECTOMY SUFFICIENT TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION), SINGLE INTERSPACE AND SEGMENT; LUMBAR
22632	ARTHRODESIS, POSTERIOR INTERBODY TECHNIQUE, INCLUDING LAMINECTOMY AND/OR DISCECTOMY TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION), SINGLE INTERSPACE; EACH ADDITIONAL INTERSPACE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22630	ARTHRODESIS, POSTERIOR INTERBODY TECHNIQUE, INCLUDING LAMINECTOMY AND/OR DISCECTOMY TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION), SINGLE INTERSPACE; LUMBAR
22614	ARTHRODESIS, POSTERIOR OR POSTEROLATERAL TECHNIQUE, SINGLE LEVEL; EACH ADDITIONAL VERTEBRAL SEGMENT (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22612	ARTHRODESIS, POSTERIOR OR POSTEROLATERAL TECHNIQUE, SINGLE LEVEL; LUMBAR (WITH LATERAL TRANSVERSE TECHNIQUE, WHEN PERFORMED)
22610	ARTHRODESIS, POSTERIOR OR POSTEROLATERAL TECHNIQUE, SINGLE LEVEL; THORACIC (WITH LATERAL TRANSVERSE TECHNIQUE, WHEN PERFORMED)
22802	ARTHRODESIS, POSTERIOR, FOR SPINAL DEFORMITY, WITH OR WITHOUT CAST; 7 TO 12 VERTEBRAL SEGMENTS
22800	ARTHRODESIS, POSTERIOR, FOR SPINAL DEFORMITY, WITH OR WITHOUT CAST; UP TO 6 VERTEBRAL SEGMENTS
22586	ARTHRODESIS, PRE-SACRAL INTERBODY TECHNIQUE, INCLUDING DISC SPACE PREPARATION, DISCECTOMY, WITH POSTERIOR INSTRUMENTATION, WITH IMAGE GUIDANCE, INCLUDES BONE GRAFT WHEN PERFORMED, L5-S1 INTERSPACE
20936	AUTOGRAFT FOR SPINE SURGERY ONLY (INCLUDES HARVESTING THE GRAFT); LOCAL (EG, RIBS, SPINOUS PROCESS, OR LAMINAR FRAGMENTS) OBTAINED FROM SAME INCISION (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
20937	AUTOGRAFT FOR SPINE SURGERY ONLY (INCLUDES HARVESTING THE GRAFT); MORSELIZED (THROUGH SEPARATE SKIN OR FASCIAL INCISION) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
20938	AUTOGRAFT FOR SPINE SURGERY ONLY (INCLUDES HARVESTING THE GRAFT); STRUCTURAL, BICORTICAL OR TRICORTICAL (THROUGH SEPARATE SKIN OR FASCIAL INCISION) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22315	CLOSED TREATMENT OF VERTEBRAL FRACTURE(S) AND/OR DISLOCATION(S) REQUIRING CASTING OR BRACING, WITH AND INCLUDING CASTING AND/OR BRACING BY MANIPULATION OR TRACTION
22830	EXPLORATION OF SPINAL FUSION
22853	INSERTION OF INTERBODY BIOMECHANICAL DEVICE(S) (EG, SYNTHETIC CAGE, MESH) WITH INTEGRAL ANTERIOR INSTRUMENTATION FOR DEVICE ANCHORING (EG, SCREWS, FLANGES), WHEN PERFORMED, TO INTERVERTEBRAL DISC SPACE IN CONJUNCTION WITH INTERBODY ARTHRODESIS, EACH INTERSPACE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

63267	LAMINECTOMY FOR EXCISION OR EVACUATION OF INTRASPINAL LESION OTHER THAN NEOPLASM, EXTRADURAL; LUMBAR
63005	LAMINECTOMY WITH EXPLORATION AND/OR DECOMPRESSION OF SPINAL CORD AND/OR CAUDA EQUINA, WITHOUT FACETECTOMY, FORAMINOTOMY OR DISCECTOMY (EG, SPINAL STENOSIS), 1 OR 2 VERTEBRAL SEGMENTS; LUMBAR, EXCEPT FOR SPONDYLOLISTHESIS
63003	LAMINECTOMY WITH EXPLORATION AND/OR DECOMPRESSION OF SPINAL CORD AND/OR CAUDA EQUINA, WITHOUT FACETECTOMY, FORAMINOTOMY OR DISCECTOMY (EG, SPINAL STENOSIS), 1 OR 2 VERTEBRAL SEGMENTS; THORACIC
63017	LAMINECTOMY WITH EXPLORATION AND/OR DECOMPRESSION OF SPINAL CORD AND/OR CAUDA EQUINA, WITHOUT FACETECTOMY, FORAMINOTOMY OR DISCECTOMY (EG, SPINAL STENOSIS), MORE THAN 2 VERTEBRAL SEGMENTS; LUMBAR
63012	LAMINECTOMY WITH REMOVAL OF ABNORMAL FACETS AND/OR PARS INTER-ARTICULARIS WITH DECOMPRESSION OF CAUDA EQUINA AND NERVE ROOTS FOR SPONDYLOLISTHESIS, LUMBAR (GILL TYPE PROCEDURE)
63047	LAMINECTOMY, FACETECTOMY AND FORAMINOTOMY (UNILATERAL OR BILATERAL WITH DECOMPRESSION OF SPINAL CORD, CAUDA EQUINA AND/OR NERVE ROOT[S], [EG, SPINAL OR LATERAL RECESS STENOSIS]), SINGLE VERTEBRAL SEGMENT; LUMBAR
63046	LAMINECTOMY, FACETECTOMY AND FORAMINOTOMY (UNILATERAL OR BILATERAL WITH DECOMPRESSION OF SPINAL CORD, CAUDA EQUINA AND/OR NERVE ROOT[S], [EG, SPINAL OR LATERAL RECESS STENOSIS]), SINGLE VERTEBRAL SEGMENT; THORACIC
63044	LAMINOTOMY (HEMILAMINECTOMY), WITH DECOMPRESSION OF NERVE ROOT(S), INCLUDING PARTIAL FACETECTOMY, FORAMINOTOMY AND/OR EXCISION OF HERNIATED INTERVERTEBRAL DISC, REEXPLORATION, SINGLE INTERSPACE; EACH ADDITIONAL LUMBAR INTERSPACE (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
63042	LAMINOTOMY (HEMILAMINECTOMY), WITH DECOMPRESSION OF NERVE ROOT(S), INCLUDING PARTIAL FACETECTOMY, FORAMINOTOMY AND/OR EXCISION OF HERNIATED INTERVERTEBRAL DISC, REEXPLORATION, SINGLE INTERSPACE; LUMBAR
63030	LAMINOTOMY (HEMILAMINECTOMY), WITH DECOMPRESSION OF NERVE ROOT(S), INCLUDING PARTIAL FACETECTOMY, FORAMINOTOMY AND/OR EXCISION OF HERNIATED INTERVERTEBRAL DISC; 1 INTERSPACE, LUMBAR
22216	OSTEOTOMY OF SPINE, POSTERIOR OR POSTEROLATERAL APPROACH, 1 VERTEBRAL SEGMENT; EACH ADDITIONAL VERTEBRAL SEGMENT (LIST SEPARATELY IN ADDITION TO PRIMARY PROCEDURE)
22214	OSTEOTOMY OF SPINE, POSTERIOR OR POSTEROLATERAL APPROACH, 1 VERTEBRAL SEGMENT; LUMBAR
22842	POSTERIOR SEGMENTAL INSTRUMENTATION (EG, PEDICLE FIXATION, DUAL RODS WITH MULTIPLE HOOKS AND SUBLAMINAR WIRES); 3 TO 6 VERTEBRAL SEGMENTS (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22843	POSTERIOR SEGMENTAL INSTRUMENTATION (EG, PEDICLE FIXATION, DUAL RODS WITH MULTIPLE HOOKS AND SUBLAMINAR WIRES); 7 TO 12 VERTEBRAL SEGMENTS (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
22849	REINSERTION OF SPINAL FIXATION DEVICE
22855	REMOVAL OF ANTERIOR INSTRUMENTATION
22850	REMOVAL OF POSTERIOR NONSEGMENTAL INSTRUMENTATION (EG, HARRINGTON ROD)
22852	REMOVAL OF POSTERIOR SEGMENTAL INSTRUMENTATION
63056	TRANSPEDICULAR APPROACH WITH DECOMPRESSION OF SPINAL CORD, EQUINA AND/OR NERVE ROOT(S) (EG, HERNIATED INTERVERTEBRAL DISC), SINGLE SEGMENT; LUMBAR (INCLUDING TRANSFACET, OR LATERAL EXTRAFORAMINAL APPROACH) (EG, FAR LATERAL HERNIATED INTERVERTEBRAL DISC)
29999	UNLISTED PROCEDURE, ARTHROSCOPY
63101	VERTEBRAL CORPECTOMY (VERTEBRAL BODY RESECTION), PARTIAL OR COMPLETE, LATERAL EXTRACAVITARY APPROACH WITH DECOMPRESSION OF SPINAL CORD AND/OR NERVE ROOT(S) (EG, FOR TUMOR OR RETROPULSED BONE FRAGMENTS); THORACIC, SINGLE SEGMENT

Table S8: Excluded surgical CPT4 procedure codes.

Code	Description
600	ANESTHESIA FOR PROCEDURES ON CERVICAL SPINE AND CORD; NOT OTHERWISE SPECIFIED
22554	ARTHRODESIS, ANTERIOR INTERBODY TECHNIQUE, INCLUDING MINIMAL DISCECTOMY TO PREPARE INTERSPACE (OTHER THAN FOR DECOMPRESSION); CERVICAL BELOW C2
63075	DISCECTOMY, ANTERIOR, WITH DECOMPRESSION OF SPINAL CORD AND/OR NERVE ROOT(S), INCLUDING OSTEOPHYTECTOMY; CERVICAL, SINGLE INTERSPACE
63265	LAMINECTOMY FOR EXCISION OR EVACUATION OF INTRASPINAL LESION OTHER THAN NEOPLASM, EXTRADURAL; CERVICAL

63001	LAMINECTOMY WITH EXPLORATION AND/OR DECOMPRESSION OF SPINAL CORD AND/OR CAUDA EQUINA, WITHOUT FACETECTOMY, FORAMINOTOMY OR DISCECTOMY (EG, SPINAL STENOSIS), 1 OR 2 VERTEBRAL SEGMENTS; CERVICAL
63015	LAMINECTOMY WITH EXPLORATION AND/OR DECOMPRESSION OF SPINAL CORD AND/OR CAUDA EQUINA, WITHOUT FACETECTOMY, FORAMINOTOMY OR DISCECTOMY (EG, SPINAL STENOSIS), MORE THAN 2 VERTEBRAL SEGMENTS; CERVICAL
63045	LAMINECTOMY, FACETECTOMY AND FORAMINOTOMY (UNILATERAL OR BILATERAL WITH DECOMPRESSION OF SPINAL CORD, CAUDA EQUINA AND/OR NERVE ROOT[S], [EG, SPINAL OR LATERAL RECESS STENOSIS]), SINGLE VERTEBRAL SEGMENT; CERVICAL
63020	LAMINOTOMY (HEMILAMINECTOMY), WITH DECOMPRESSION OF NERVE ROOT(S), INCLUDING PARTIAL FACETECTOMY, FORAMINOTOMY AND/OR EXCISION OF HERNIATED INTERVERTEBRAL DISC; 1 INTERSPACE, CERVICAL
22326	OPEN TREATMENT AND/OR REDUCTION OF VERTEBRAL FRACTURE(S) AND/OR DISLOCATION(S), POSTERIOR APPROACH, 1 FRACTURED VERTEBRA OR DISLOCATED SEGMENT; CERVICAL
22864	REMOVAL OF TOTAL DISC ARTHROPLASTY (ARTIFICIAL DISC), ANTERIOR APPROACH, SINGLE INTERSPACE; CERVICAL
63082	VERTEBRAL CORPECTOMY (VERTEBRAL BODY RESECTION), PARTIAL OR COMPLETE, ANTERIOR APPROACH WITH DECOMPRESSION OF SPINAL CORD AND/OR NERVE ROOT(S); CERVICAL, EACH ADDITIONAL SEGMENT (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
63081	VERTEBRAL CORPECTOMY (VERTEBRAL BODY RESECTION), PARTIAL OR COMPLETE, ANTERIOR APPROACH WITH DECOMPRESSION OF SPINAL CORD AND/OR NERVE ROOT(S); CERVICAL, SINGLE SEGMENT

Figures

Figure S1: Cohort inclusion flow diagram. The study included patients identified through two separate searches of the electronic health record (EHR) system. The first was a search based on identification of patients by device of interest (panel A). This query identified those patients receiving exclusively the Concorde Bullet IVBI (highlighted in pink), those receiving exclusively an pre-specified alternative IVBI (highlighted in blue), and excluded those patients who had received both Concorde Bullet and a pre-specified alternative device. Panel B details the EHR query based on the procedure performed, thereby capturing patients treated with alternative, but not pre-specified IVBI, as well as those treated with fusion who did not receive an IVBI (included patients highlighted in green panel).

Figure S2: Cumulative incidence of re-operation within 12 months of treatment with Concorde Bullet IVBI versus a propensity-matched alternative device. The circles indicate observed event rates among the Concorde Bullet (CB) treated patients, and the black squares indicate the observed event rates in the matched alternative device group. Black vertical lines indicate the 95% confidence interval of adverse event rates in the alternative device group, and the green sloped line indicates cumulative sample size (with sample size shown on the right vertical axis). No significant difference in the rate of reoperation within 12 months is observed between treatment groups as the event rate for CB treated patients consistently falls within the confidence interval of adverse events for patients in the alternative device group.

Figure S1: Cohort Flow Diagram

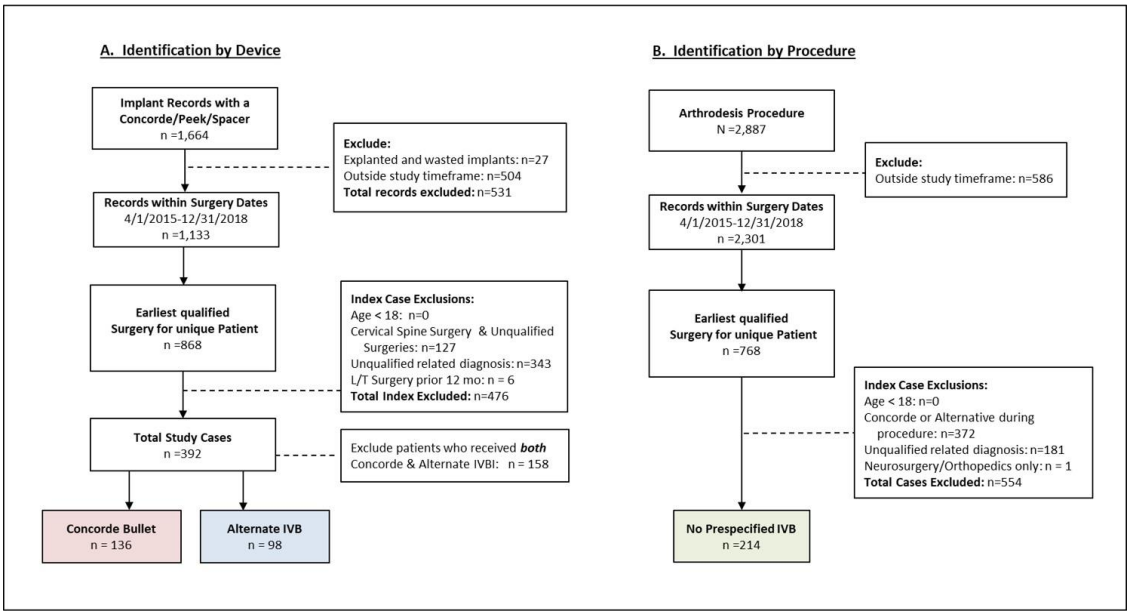

Figure S2: Propensity Matched Results for Re-Operation within 12-months of implant.