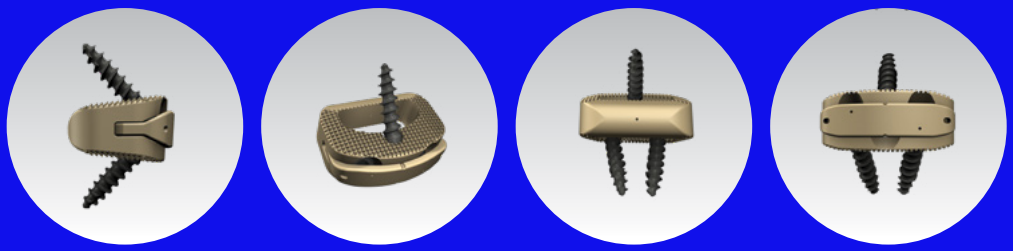
Medtronic

Billing and coding guide

Sovereign™

Spinal System



The Sovereign™ spinal system is indicated for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the Sovereign™ spinal system is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The Sovereign™ interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign™ interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g., facet screws or posterior fixation).

Physician reimbursement

Physicians use Current Procedural Terminology (CPT®) codes to report all of their services. These codes are uniformly accepted by all payers. Medicare and most indemnity insurers use a fee schedule to pay physicians for their professional services, assigning a payment amount to each CPT code. Under Medicare's Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as the Relative Value Unit (RVU), which is then multiplied by a conversion factor to determine the physician payment. Many other payers use Medicare's RBRVS fee schedule or a variation of it. Industrial or work-related injury cases are usually reimbursed according to the official fee schedule for each state.

Use of CPT codes is governed by various coding guidelines published by the American Medical Association (AMA) and other major sources such as physician specialty societies. In addition, the National Correct Coding Initiative (NCCI), a set of CPT coding edits created and maintained by the Centers for Medicare and Medicaid Services (CMS), has become a national standard.

The following CPT code may be appropriate for the implantation of the Sovereign™ spinal system:

CPT Code	Description	RVUs	Medicare Payment
+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)	7.70	$252.10

Source: See references

Coding of Anterior Instrumentation

A separate anterior instrumentation CPT code is not recommended for the insertion of Sovereign™, as the screws are integral to the interbody device. However, guidance indicates that "Additional fixation not integral to the device, other provision for arthrodesis, or bone grafting are coordinated with the placement of the biomechanical device and are coded separately." -AMA CPT Changes 2017. Therefore, there may be circumstances where additional non-integral fixation is coded separately.

Facility reimbursement

Inpatient Reimbursement

Hospital payment for inpatient services/procedures is usually based on Diagnosis-Related Groups (DRGs), Case Rates, Per Diem rates or a line item payment methodology. Medicare uses the Medicare Severity-DRG (MS-DRG) payment methodology to reimburse hospitals for inpatient services. Each inpatient stay is assigned to one payment group, based on the ICD-10 codes assigned to the major diagnoses and procedures. Each DRG has a flat payment rate which bundles the reimbursement for all services the patient received during the inpatient stay. Most insurers usually pay the hospital on a contractual basis (i.e., Case Rate or Per Diem rate) that has been negotiated between the hospital and insurance carrier.

ICD-10-PCS Procedure Codes

Hospitals use ICD-10-PCS procedure codes to report inpatient services. In ICD-10-PCS insertion of interbody devices is included in the 6th character device value of the primary procedure code, and not coded separately. The following ICD-10-PCS code may be appropriate for a lumbar fusion including the implantation of the Sovereign™ spinal system:

Code	Description
0SG00A0	Fusion of Lumbar Vertebral Joint with Interbody Fusion Device, Anterior Approach, Anterior Column, Open Approach
0SG10A0	Fusion of 2 or more Lumbar Vertebral Joints with Interbody Fusion Device, Anterior Approach, Anterior Column, Open Approach
0SG30A0	Fusion of Lumbosacral Joint with Interbody Fusion Device, Anterior Approach, Anterior Column, Open Approach
0SG04A0	Fusion of Lumbar Vertebral Joint with Interbody Fusion Device, Anterior Approach, Anterior Column, Percutaneous Endoscopic Approach
0SG14A0	Fusion of 2 or more Lumbar Vertebral Joints with Interbody Fusion Device, Anterior Approach, Anterior Column, Percutaneous Endoscopic Approach
0SG34A0	Fusion of Lumbosacral Joint with Interbody Fusion Device, Anterior Approach Column, Percutaneous Endoscopic Approach

Diagnosis-Related Groups (DRGs)

The Sovereign™ spinal system is indicated as an adjunct to fusion of the lumbar spine. Lumbar spinal fusions are typically grouped to the following DRGs:

Medicare Severity–Diagnosis Related Group (MS-DRG) Assignment

MS-DRG	Description*	MDC	Relative Weight†	Medicare Payment†
028	Spinal Procedures with MCC	01	6.0261	$42,192
029	Spinal Procedures with CC or Spinal Neurostimulator	01	3.4282	$24,003
030	Spinal Procedures without CC/MCC	01	2.319	$16,237
453	Combined Anterior/Posterior Spinal Fusion with MCC	08	8.8614	$62,044
454	Combined Anterior/Posterior Spinal Fusion with CC	08	6.1163	$42,824
455	Combined Anterior/Posterior Spinal Fusion without CC/MCC	08	4.6056	$32,247
456	Spinal Fusion except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusions with MCC	08	8.4294	$59,019
457	Spinal Fusion except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusions with CC	08	6.0753	$42,537
458	Spinal Fusion except Cervical with Spinal Curvature/Malignancy/Infection or Extensive Fusions without CC/MCC	08	4.531	$31,724
459	Spinal Fusion Except Cervical with MCC	08	6.6323	$46,437
460	Spinal Fusion Except Cervical without MCC	08	3.6579	$25,611

Under the MS-DRG system, cases may be assigned to a number of other MS-DRGs, based on individual patient diagnosis and presence or absence of additional surgical procedures performed. Additional MS-DRGs include but are not limited to: MS-DRGs 907, 908, 909; MS-DRGs 957, 958, 959; and MS-DRGs 981, 982, 983.

* MCC – Major Complication and/or Comorbidity. CC – Complication and/or Comorbidity.

†Source: See references.

Outpatient Reimbursement

Hospitals use the Healthcare Common Procedure Coding System (HCPCS) to report outpatient services. Under Medicare's methodology for hospital outpatient payment, each HCPCS code is assigned to one Ambulatory Payment Classification (APC). Each APC has a relative weight which is multiplied by a conversion factor to determine the hospital payment. An APC and payment amount are assigned to each significant service. Although some services are bundled and not separately payable, total payment to the hospital is the sum of the APC amounts for the services provided during the outpatient encounter.

Many payers use Medicare's APC methodology or a similar type of fee schedule to reimburse hospitals for outpatient services. Other payers use a percentage of charges mechanism, depending on their contract with the hospital.

Medicare does not cover anterior approach lumbar interbody fusion CPT 22558 in the outpatient setting per the CY2022 Outpatient Fee Schedule. However, commercial payers may allow for the procedures to be performed in the outpatient setting. In these cases, hospitals will want to contact the payer and review their payer contracts to ensure that they provide adequate payment for this procedure in an outpatient setting. However, commercial payers may allow for the procedures to be performed in the outpatient setting. In these cases, hospitals will want to contact the payer and review their payer contracts to ensure that they provide adequate payment for this procedure in an outpatient setting.

HCPCS Code	Description	APC	Status Indicator	Relative Weight	Medicare Payment
+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)	N/A	N	N/A	N/A

Source: See references.

Status Indicators:
Each HCPCS code in the Outpatient Prospective Payment System (OPPS) is assigned a status indicator to signify whether a discount (payment reduction) applies to the respective APC payment. The following status indicator is represented in this procedure:

N Items and Services Packaged into APC Rates, no separate payment

Coding and reimbursement assistance

SpineLine

Provides coding, billing and reimbursement assistance for procedures performed using Medtronic products.

E-mail: RS.CSTreimbursementsupport@medtronic.com

Web: medtronic.com/SpineLine

References

Source: 2024 Medicare Fee Schedule and Prospective Payment Systems, Final Rule, Federal Register. No geographic adjustments. 2/24

Check bundling edits before applying and submitting codes for payment.

CPT Changes 2017, AMA.

Important information on the Sovereign™ spinal system

PURPOSE

The Sovereign™ spinal system is a fusion system intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant's material and surgical aspects and instructed as to its mechanical and material applications and limitations. This system may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

DESCRIPTION

The Sovereign™ spinal system is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with 3 holes for placement of titanium screws using an anterior or oblique approach. The Sovereign™ spinal system contains both a fixed and a variable angle screw option. The fixed angle screw option provides an interference fit with the PEEK interbody implant. The variable angle screw option provides a slight clearance between the PEEK interbody implant and the screw which allows for a small amount of variable screw angulation. This system is intended to be radiolucent and the interior space of the product is to be used with autogenous bone graft. The accompanying cover plate is designed to resist screw backout and must be used when the variable angle screws are implanted.

The Sovereign™ spinal system interbody device is manufactured from PEEK (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

INDICATIONS

The Sovereign™ spinal system is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the Sovereign™ spinal system is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. The Sovereign™ spinal system is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The Sovereign™ interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign interbody device is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g., facet screws or posterior fixation).

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include:

- Any case where there is translational instability (spondylolisthesis of any grade or retrolisthesis) at the level treated unless posterior supplemental fixation is used to augment stability.
- Any case where posterior elements were removed such that it introduces instability at the level(s) treated unless posterior supplemental fixation is used to augment stability.
- Severe osteoporosis.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Any case where the implants would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from 2 different components or systems.
- Any patient in which implant use would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- **Osteoporosis unless posterior supplemental fixation is used to augment stability.**
- **Severe bone resorption.**
- **Osteomalacia.**

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation. The risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include, but are not limited to:

- Implant migration.
- Breakage of the device.
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Autogenous bone graft donor site complication.
- Inability to resume activities of normal daily living.

- Early or late loosening or movement of the device.
- Urinary retention, loss of bladder control, or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or autogenous bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

WARNINGS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Supplemental fixation systems which may be used with this device include: the CD Horizon™ spinal system, the TSRH™ spinal system, the Dynalok™ Classic spinal system, the Z-plate II™ anterior fixation system, the Pyramid™ anterior plate fixation system, and/or their successors. When additional support instrumentation is used, refer to the package insert for requirements and limitations related to those devices.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous spinal surgery.

Use of this product without autogenous bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.

Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

Do not re-use or re-process devices labeled as single use devices. Re-use or re-processing of a single use devices may compromise the structural integrity and the intended function of the device which could result in patient injury.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

For additional reimbursement information contact the SpineLine™ Reimbursement Support Center at (877) 690-5353.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

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Medical necessity will dictate site of service for each individual patient. Physicians should confirm inpatient or outpatient admission criteria before selecting site of service.

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