

# Titan™

## Spinal System



The Endoskeleton™ TA interbody system devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The Endoskeleton™ TA interbody system implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The device is to be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Endoskeleton™ TA interbody system is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

The Endoskeleton™ TAS interbody system device including those with macro-, micro-, and nano-roughened surface textured features are indicated for use in skeletally mature patients with symptomatic Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices. The device is a standalone system intended to be used with the bone screws provided and requires no additional supplementary fixation. The Endoskeleton™ TAS Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. However, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis and spinal stenosis at one or two adjacent levels, the Endoskeleton™

TAS interbody system must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

The Endoskeleton™ TAS hyperlordotic interbody system ( $\geq 16^\circ$ ) devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use in skeletally mature patients with DDD, degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The Endoskeleton™ TAS hyperlordotic interbody system must be used with a posterior supplemental internal spinal fixation cleared by the FDA for use in the lumbar spine.

The Endoskeleton™ TC interbody system devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The Endoskeleton™ TC interbody system is indicated to be used with supplemental fixation cleared by the FDA for use in the cervical spine and autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

The Endoskeleton™ TCS interbody system devices

including those with macro-, micro-, and nano-roughened surface textured features are intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 to T1. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The device is a stand-alone system when used with Endoskeleton™ TCS interbody system integrated screws. When used without the integrated screws, the Endoskeleton™ TCS interbody system requires additional supplemental fixation cleared by the FDA for the cervical spine.

The Endoskeleton™ TL hyperlordotic interbody system ( $\geq 16^\circ$ ) devices with macro-, micro-, and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. Patients should have received 6 months of non-operative treatment prior to treatment with the Endoskeleton™ TL hyperlordotic interbody system. Patients with previous non-fusion spinal surgery at the involved levels may be treated with the device. The Endoskeleton™ TL hyperlordotic Interbody System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The interbody device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. The Endoskeleton™ TL hyperlordotic interbody system must be used with an integrated lateral plate and bone screw and additionally must be used with posterior supplemental internal spinal fixation cleared by the FDA for use in the lumbar spine.

The Endoskeleton™ TL interbody system devices including those with macro-, micro-, and nano roughened surface textured features are indicated for use in spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the

lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TL interbody system implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. Patients with previous non-fusion spinal surgery at the involved levels may be treated with the device. It is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

The Endoskeleton™ TO interbody system devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TO interbody system implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. The device is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

The Endoskeleton™ TT interbody system devices including those with macro-, micro-, and nano-roughened surface textured features are indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD, defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), degenerative spondylolisthesis, and/or spinal stenosis at one or two contiguous levels from L2-S1 whose condition requires the use of interbody fusion. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation cleared by the FDA for use in the lumbar spine. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. The Endoskeleton™ TT interbody system implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. It is indicated to be used with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof.

## Risks

Possible adverse effects include, but are not limited to, bending, loosening, or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral fluid leakage; gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium; pain or discomfort; bone loss due to resorption or stress shielding, or bone fracture at, above, or below the level of surgery (fracture of the vertebra); hemorrhage of blood vessels and/or hematomas; malalignment of anatomical structures, including loss of proper spine curvature, correction, reduction, and/or height; bursitis; bone graft donor site pain; inability to resume activities of normal daily living; reoperation or death.

## 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 Titan™ 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 interbody fusion device with integral screw fixation. 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 bio-mechanical device and are coded separately." - AMA CPT Changes 2017. Therefore, there may be circumstances where additional non-integral fixation is coded separately. Payers may require the use of NCCI associated modifiers with anterior instrumentation unrelated to anchoring the interbody device.

# 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. Typically 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.

Spinal fusion procedures including the implantation of Titan Endoskeleton interbody fusion devices are coded from the Medical and Surgical section ICD-10-PCS. The typical ORG and OSG codes tables for fusion of the upper and lower joints are appropriate. **The New Technology ICD-10-PCS X codes for Nanotextured Surfaces are no longer in use.**

### Diagnosis-Related Groups (DRGs)

Spinal fusion procedures are typically grouped to the following MS-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
471	Cervical Spinal Fusion W MCC	08	4.919	\$34,441
472	Cervical Spinal Fusion W CC	08	2.9554	\$20,693
473	Cervical Spinal Fusion W/O CC/MCC	08	2.4606	\$17,228

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's ASC payment methodology is based on the hospital outpatient APCs, but using payments unique to ASCs.

HCPCS Code	Description	APC	Status/ Payment 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/N1	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

Outpatient APC 5115: \$12,539.82

Outpatient APC 5116: \$17,756.28

Each HCPCS code in the ASC Payment System is assigned a payment indicator to signify certain payment rules. The following status indicator is represented in this procedure:

N1 Packaged Service/Item, no separate payment made

ASC CPT 22551: \$8,864.37

ASC CPT 22554: \$8,683.78

# Coding and reimbursement assistance

## SpineLine™

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

**Email:** [RS.CSTreimbursementssupport@medtronic.com](mailto:RS.CSTreimbursementssupport@medtronic.com)

**Web:** [medtronic.com/SpineLine](https://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.

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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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