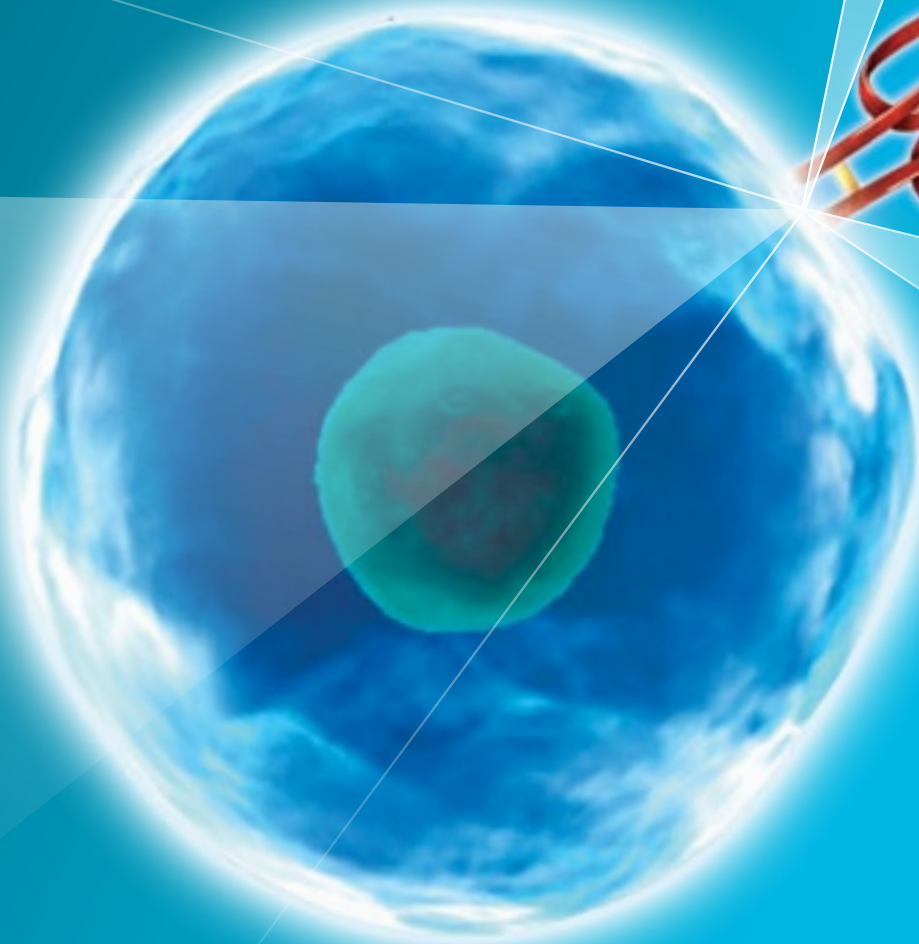
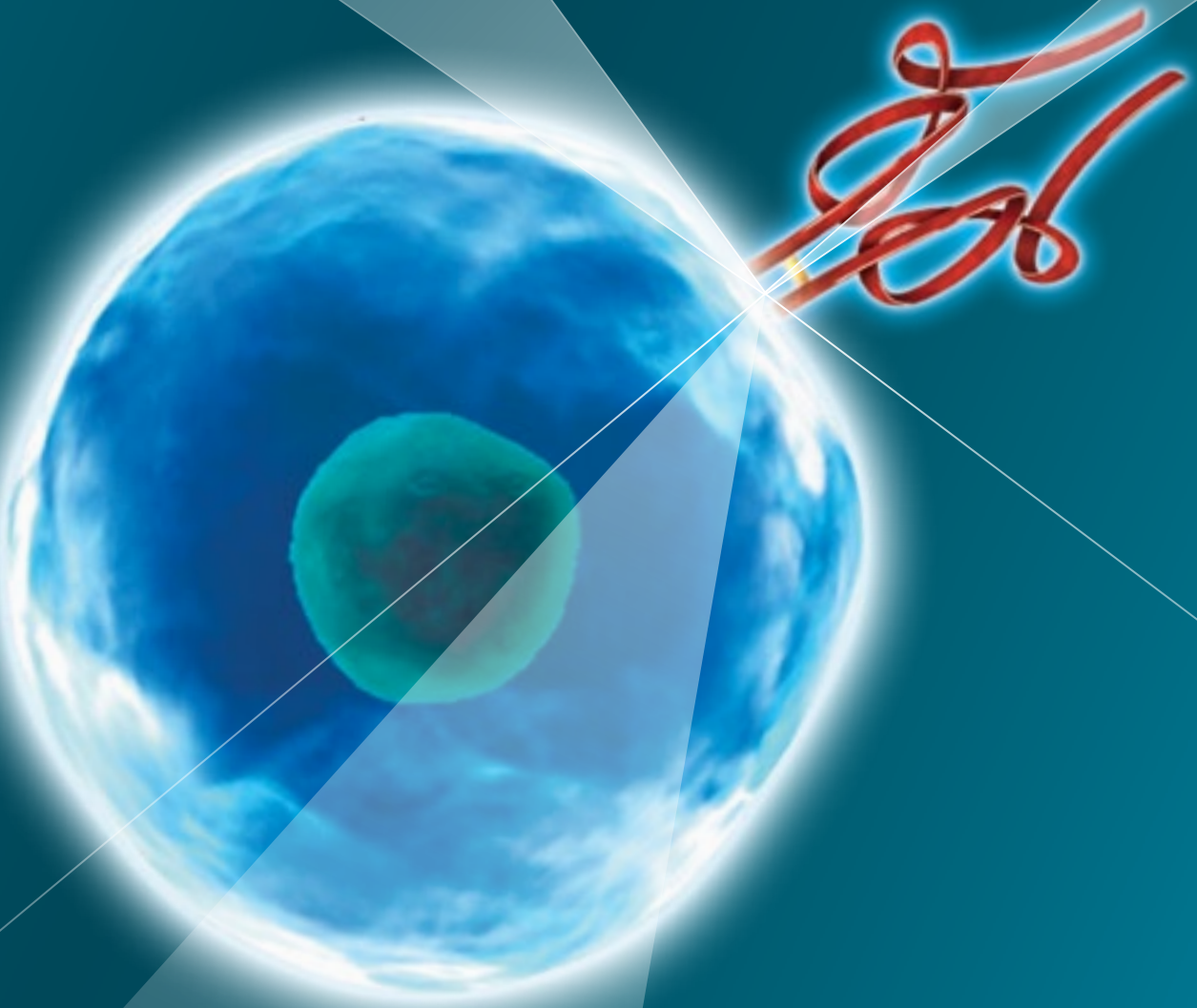




Medtronic

INFUSE[®] Bone Graft Reimbursement Guide





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INFUSE[®] Bone Graft

Reimbursement Guide

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INFUSE® Bone Graft: The Bone-Healing Power of rhBMP-2

The healing history of rhBMP-2 stretches back decades:

- » 1965: The discovery that demineralized bone matrix stimulates the formation of new bone tissue
- » 1988: A research team proves that the bone formation process caused by rhBMP-2 is similar to bone formation by osteoinduction
- » 2002: FDA approves INFUSE® Bone Graft/LT-CAGE® Device for use in spine fusion
- » 2004: INFUSE® Bone Graft gains approval for healing open tibial fractures
- » 2007: FDA approves INFUSE® Bone Graft for use in sinus augmentations and localized alveolar ridge augmentations for defects associated with extraction sockets

The rhBMP-2 unique mechanism of action* predictably leads to new bone formation**:

- » Application of rhBMP-2/ACS results in the induction of normal bone locally at the site of implantation
- » This process includes the migration of mesenchymal cells into the site, their proliferation and apparent differentiation into bone-forming cells
- » The bone induced by rhBMP-2/ACS remodels and assumes the structure appropriate to its location and function, as would be expected from host bone

* commonly accepted mechanism of action as determined by in-vitro and animal in-vivo studies.

** US Food and Drug Administration. Summary of Safety and Effectiveness—INFUSE® Bone Graft (P000054). <http://www.fda.gov/cdrh/pdf/P000054b.PDF>

INFUSE® Bone Graft:

- » Provides proven, predictable bone formation
- » Combines rhBMP-2 with an Absorbable Collagen Sponge carrier
- » Is supported by extensive research and clinical results, including a \$600 million investment in research and development in the past two decades

Coverage

Benefits

Benefits —

Covered benefits under commercial insurance plans can vary by health plan and by the group purchasing health plan coverage. It is important that you verify the specific benefits by group and plan of the patient being considered for surgery.

Predetermination —

Predetermination is a process established by health plans that allows a physician to submit a treatment plan prior to surgery. The health plan reviews the treatment plan as well as the patient's insurance benefit plan and medical policy to determine:

- » if the treatment is covered
- » if the patient is a covered member
- » the amount of copayments/coinsurance, deductibles, and the patient's maximum benefits.

This process is typically used to simply verify benefits, but it can be an effective tool to use with health plans for technologies for which you expect coverage to be an issue.

Predetermination Process

Planning Your Predetermination Benefit Strategy

Be Proactive: Determine if the surgical procedure and technology you plan to use are covered under your patient's benefit plan.

Predetermination reviews vary between insurance plans, with varying timelines and requirements. But in general the predetermination process, if available, allows the health plan to determine if the patient's plan covers the surgery and any spine implants required for the surgery. If the implants are considered "new technology," the predetermination process can provide a mechanism for the plan's Medical Director to review it and determine if the technology is covered. If the health plan or Medical Director reviews this information and decides the technology is covered and medically necessary, you should not encounter significant problems obtaining an authorization.

Here is a list of tasks to help you develop a predetermination packet:

- » Request the predetermination of benefits process or requirements from the patient's insurance plan
- » Obtain the name of a contact person
- » Verify the health plan's mailing address
- » Obtain the Medical Director's name, phone number and specifically ask the Medical Director to review your request. (See sample letter.) *[Note: A Medical Director's review may eliminate some of the difficulties you might encounter during the preauthorization process, especially if you are requesting use of a new technology. The Medical Director will often provide guidance about what additional information may be needed.]*
- » Obtain peer-reviewed and published studies from your Medtronic sales representative to support your request
- » Be an advocate for your patient: describe how the technology can benefit this specific patient
- » Include surgeon's availability, contact information and willingness to speak with the Medical Director about this matter

The Predetermination Request

Compose a **letter of medical necessity** addressed to the Medical Director

- » Patient information — name, date of birth, policy number
- » Details of the patient's medical history
 - Current diagnoses, billing codes, and reason for treatment
 - Duration and degree of illness and injury
 - Summary of past failed treatments (i.e., conservative care or other surgical interventions)
- » Description of the patient's current condition and treatment plan
 - Ability to work
 - Activities of daily living
 - Sleep
- » Proposed procedure(s), technology (medical device/implants if applicable) and rationale for treatment
- » Proposed location of service and dates planned
- » Summary of the clinical evidence supporting your treatment plan including comorbidities
- » Description of the spinal technology and rationale for its use in this patient's surgery

Additional Elements to Include with Your Predetermination Request

- » Copies of peer reviewed, published studies supporting your treatment plan and use of spinal technology
- » Product information
- » FDA approval letter(s) (helpful in certain situations; e.g., new technologies)
- » Copy of the patient's insurance card
- » Physician dictation regarding patient's history and current medical condition
- » Copies of previous surgical records
- » Results of diagnostic tests
- » Copies of prior authorization for use of the requested technology in other patients' surgeries that were approved by the health plan

Once the predetermination request is complete, submit it to the health plan. If you have not received a response within 30 days, follow up with the health plan by phone.

Medical Necessity

All health plans limit coverage to services that the health plan considers “medically necessary” and will exclude services or technologies that are deemed “experimental or investigational.” *[Note: Health plans have their own definitions of “medically necessary” and “experimental or investigational.” These definitions are documented in the patient’s health plan policy and generally reference the plan’s medical policy or technology assessment process.]*

A health plan’s medical policies and technology assessments are either developed internally within the health plan’s organization or are acquired from an external independent review firm. Many health plans provide these policies to the public through their websites. Contact the health plan and request a copy of its policy on medical necessity if you are unable to access it from the plan’s website.

Establishing Medical Necessity is Important to Determine if the Services/Procedures Requested:

- » Are in accordance with generally accepted standards of medical practice
- » Establish clinical appropriateness and effectiveness of the treatment
- » Establish that the procedure:
 - is not primarily for the convenience of the patient or surgeon
 - is not more costly than an alternative service or sequence of services
 - is likely to produce equivalent, or better results as other alternatives
- » Increase access to technology that may produce cost-effective equivalent/superior patient outcomes
- » Allow physician access to alternative treatment options based on medical judgment
- » Increase patient satisfaction
- » Minimize denials
- » Improve staff billing efficiency and productivity
- » Establish rapport and open communication with health plan representatives
- » Reduce cash flow issues

Plan a Communication Strategy

- » Outline: Prepare a comprehensive and organized outline based on the information the health plan needs to make an educated decision regarding medical necessity and coverage for your patient
- » Use the outline to discuss your request with the health plan: talk about key components of the patient’s care; describe the technology, rationale for use of the technology, patient benefits, and objectives of your request
- » Prepare for several scenarios: this helps you anticipate questions that may be asked about the requested surgery and/or proposed technology so you can formulate responses in advance
- » Clearly articulate the rationale for medical necessity and the need for the technology

Prior Authorization/ Precertification

While predetermination is an optional process offered by many plans, the prior authorization or precertification process is mandatory for most plans. The prior authorization/precertification requirements may vary, but health plans are often similar in scope and requirements. Request the plan's prior authorization/precertification policy if you are unfamiliar with its requirements.

Most plans require surgeons to:

- » Document medical necessity
- » Obtain approval within a specific timeframe
- » Verify coverage of proposed care
- » Establish covered length of stay and set a date for concurrent review
- » Receive advanced approval for elective inpatient medical and surgical admissions, and most outpatient surgeries

The following steps are necessary for prior authorization or precertification processes:

Step 1

- » Collect all necessary information listed below from the physician, patient and facility
- » Identify appropriate diagnostic and procedure codes
- » Provide supportive clinical documentation through history and physical (H&P), office notes, previous treatment and outcomes, diagnostics and related outcomes, medications (previous and current)
- » Compile the following information based on the proposed patient treatment plan and be able to discuss each of these areas during your conversation with the plan's medical management department:
 - Describe the technology and the applicability of its use in this patient's case
 - Identify the difference and benefits of the technology compared to the current standard of care
 - Discuss medical necessity rationale for use in this case
 - Supply FDA approval letter
 - Provide supportive peer review literature/product information for requested indication for this patient
 - Discuss and/or outline previously approved cases and related patient outcomes
 - Discuss surgeon's previous experience and outcomes with use of the technology

Step 2

- » Contact patient's health plan (member's services) and inquire about the following:
 - Verify that the patient is eligible for the service requested
 - Inquire about patient benefits and coverage for the intended procedure
 - Inquire about the health plan's authorization policy
 - Find out if the plan has a current medical coverage policy on the technology and definition of medical necessity
 - State what technology will be used for this procedure and inquire about the plan's policies. Ask if you can speak with the Medical Director to discuss the use of the technology
 - Assess the needs of the patient and determine if the treatment is consistent with medical necessity criteria before you call so your conversation with the medical management department is more constructive
 - Document the phone conversation including the date, time, and with whom you speak

Step 3

- » Contact the prior authorization provider. Prior authorization may not be the responsibility of the patient's health plan, so check the patient's insurance company or member identification card to determine whom to contact for prior authorization
- » Provide patient demographics and supporting clinical documentation
- » Obtain pertinent information concerning the plan's Medical Director and contact the director

Talking with the Medical Director

The Medical Director will want information about the technology, how it works, how it compares to current standard of care, how it benefits the patient, and how it improves outcomes. Provide supportive literature to help demonstrate safety and efficacy

- » Be prepared to provide additional documentation for the technology

Step 4**Obtaining Prior Authorization/Precertification**

It is important to have authorization prior to the surgical procedure to assure that benefits will be paid.

- » **Prior authorization approval** — Approval may be provided verbally or in writing
 - If approval is given verbally, note the name of the person who gives it, the date, and phone number and then **request a fax, letter, or e-mail verification**

- If the plan will not provide written prior authorization, request the individual's e-mail address and e-mail your understanding of the prior authorization/precertification to make sure you have written validation

- » **Conditional Approval** — You may receive a "conditional approval." The patient's health plan may issue a conditional approval pending review of literature and documentation of the patient's condition. In this case, you will want to document all communication with the health plan including date, contact, e-mail address, phone number, details of the conversation, action steps, and follow-up. Make sure you receive a defined timeframe for the decision to be made regarding this case

- » **Denial** — If the health plan's medical management department issues a denial or indicates a technology is investigational/experimental, you will need to inquire about the plan's appeal process so you can initiate it. Also, inquire about the plan's timeframes for a response at each appeal level. Ask what information is required and where to send the appeal (see sample appeal letter.)

- » **Urgent Cases** — Most health plans have policies for cases requiring an urgent review for sudden illness, injuries, or conditions that are not emergencies but do require immediate medical care. Contact the patient's health plan and inquire about the policy for urgent care claims

Step 5**Prior to Surgery**

- » Verify benefits and eligibility
- » Ensure the patient still has coverage
- » Check the patient's plan maximum
- » Include authorization information in the patient's chart in case future issues arise
- » Confirm the initial verbal approval for the surgical procedure

Documentation Requirements

The following medical record documentation is required to indicate the medical necessity for performing this service and to support that the service was performed:

- » History and physical
- » MD order/progress notes for services rendered
- » Pertinent test reports with written interpretation
- » Office/progress reports
- » Prior treatment(s) and patient response
- » Operative report
- » Itemization of charges

Handling Denials

Even with a comprehensive approach to prior approval, you may occasionally receive denials from health plans. The following guide is based on industry-standard appeals processes. Most health plans have a three-level documented appeals process. Refer to your provider manual and contact the health plan to obtain the appeals policy.

Step 1

Contact the Health Plan's Medical Director

— Many times the most effective way to get a denial overturned is through a conversation between you (the surgeon) and the health plan's Medical Director.

- » Ask for a peer-to-peer review (surgeon to Medical Director)
- » Schedule the peer-to-peer review at a time when you can give it full attention
- » Develop a strategy before the review
- » Compile the patient's information so you can effectively address all issues
- » Develop rapport with the plan's Medical Director
- » Provide information to demonstrate patient value:
 - Shorter recovery times
 - Faster return to work
 - Decreased length of stay, etc.
 - Failure of prior treatment options
- » Focus on the benefits of the technology and its medical necessity based on the patient's particular symptoms, diagnosis, and comorbidities

Step 2

File an Appeal

- » Obtain the correct address and phone number for appeals
- » Write the appeal letter, addressing the specifics of the denial
 - Justify the medical necessity and value to achieve a successful patient outcome
 - Include successful outcomes and patient experiences in similar or same surgeries
- » Give your reasons for filing an appeal (denial of coverage, medical necessity, etc.)
- » Date of denial/denial letter (if you need to reference it in the appeal letter)
- » Reference the denial reason and associated denial code if applicable
- » Discuss patient's diagnosis and course of treatment including adverse outcomes
- » Describe the surgery in detail including associated procedure codes
- » Describe any technology and its benefits as they relate to the patient's condition. Emphasize the advantages of the technology as compared to another device or approach
- » State the rationale and benefits of the technology and how its use can be expected to produce a superior clinical outcome for this particular patient
- » Discuss personal experiences and outcomes of surgical cases using the technology

- » Reference peer review literature in your letter to support your clinical decision and position regarding medical necessity. Attach a "white paper" referencing additional peer review literature to support your position

- » Provide a contact name and phone number and state your willingness to provide additional information and to answer questions

- » Request a specific timeframe for a response

- » Keep track of your appeal's status to ensure you comply with the health plan's requirements

Step 3

Peer-to-Peer Review

Request an outside peer-to-peer review from a board certified physician of the same specialty (e.g., neurosurgeon or orthopedic spine surgeon).

Sample Denial Appeal Letter

Date

Insurance Company

Attn: [Name], Medical Director

Address 1

Address 2

City, State, Zip

RE: Patient Name

Member Identification Number

Group Number

Dear [Name of Medical Director] :

Include the following major points in your appeal letter:

- » Give your reasons for filing an appeal (denial of coverage, medical necessity, etc.).
- » Date of denial/denial letter (if you need to reference it in the appeal letter).
- » Reference the denial reason and associated denial code if applicable.
- » Discuss patient's diagnosis and course of treatment including adverse outcomes or lack of improvement from prior therapies.
- » Describe the surgery in detail including associated procedure codes.
- » Describe any technology and its benefits as they relate to the patient's condition. Emphasize the advantages of the technology as compared to another device or approach.
- » State the rationale and benefits of the technology and how its use can be expected to produce a superior clinical outcome for this particular patient.
- » Discuss personal experiences and outcomes of surgical cases using the technology.
- » Reference peer review literature in your letter to support clinical decision and position regarding medical necessity. Attach a "white paper," referencing additional peer review literature to support your position.
- » Provide a contact name and phone number and state your willingness to provide additional information and to answer questions.
- » Request a specific timeframe for a response.

Given the advantages of the technology and the clinical status of [patient name], my opinion is that a [name of technology] is the best surgical option for this patient. It is my professional opinion that [name of technology] is warranted, appropriate, and medically necessary. Please call my office at [insert phone number] if I can provide you with peer reviewed literature demonstrating the positive effects of this technology or any other information you may need to make your decision. I look forward to your timely response and approval for the necessary treatment of this patient.

Sincerely,

[Physician's Signature]

Spinal Indication

INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device has been indicated by the U.S. Food and Drug Administration (FDA) for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level. Patients receiving the INFUSE® Bone Graft/ Medtronic Titanium Threaded Interbody Fusion Device should have had at least six months of nonoperative treatment prior to treatment with the INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device. INFUSE® Bone Graft with the LT-CAGE® Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach. INFUSE® Bone Graft with either the INTER FIX™ or the INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

Physician Coding and Payment

ICD-9-CM Diagnosis Codes

Each claim must be submitted with the ICD-9-CM codes that reflect the highest level of specificity of the condition of the patient. The following diagnosis codes may be appropriate to support medical necessity for lumbar spinal fusion procedures using INFUSE® Bone Graft:

Code	Description
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy, lumbar region
722.10	Displacement of lumbar intervertebral disc without myelopathy
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.73	Intervertebral lumbar disc disorder with myelopathy, lumbar region

Current Procedural Terminology Codes

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 flat payment amount to each CPT code. Under Medicare's RBRVS methodology for physician payment, each CPT code is assigned a point value, known as the Relative Value Unit or RVU, which is then multiplied by a flat 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 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 CMS, has become a national standard.

Medicare's 2010 RVUs and RBRVS payments are below:

CPT	Description	Total RVUs	Medicare Payment*
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	40.62	\$1,466
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), threaded bone dowel(s), methylmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)	11.07	\$399

* Calculated for 2010: RVU (no geographic adjustment) x Medicare Conversion Factor for 2010.

Source: CY 2010 Medicare Physician Fee Schedule, Final Rule. Federal Register, November 25, 2009.

Department of Defense Appropriations Act of 2010.

NOTE: No specific CPT code exists for the insertion/placement of INFUSE® Bone Graft. Medtronic believes that the placement of INFUSE® Bone Graft is covered in the placement of an intervertebral device, such as the LT-CAGE® Lumbar Tapered Fusion Device. If an individually identifiable code is needed to report its placement, report CPT code 22899, Unlisted procedure, spine.

Hospital Inpatient Coding and Payment

Payment Methodologies

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 pays hospital inpatient procedures under the Medicare-Severity DRG (MS-DRG) system, while most other insurers pay the hospital on a contractual basis (e.g., Case Rate or Per Diem rate) that has been negotiated between the hospital and insurance carrier.

Diagnosis-Related Groups

DRGs established a system of classification for inpatient hospital services based on principal diagnosis, secondary diagnosis, surgical procedures, and the presence of complications and/or co-morbidities. The system of classification is used as a financing mechanism to reimburse hospitals and selected other providers for services rendered. The cost of the equipment, supplies, operating room, patient room, nursing care and all other services the patient receives is covered in the DRG payment that the hospital receives.

Each DRG is assigned a relative weight that is representative of the amount of resources required for the patient's procedure/treatment. The relative weight is multiplied by the individual hospital's base rate (adjusted depending on labor costs, non-labor costs, capital payments, type of hospital [e.g., teaching hospital or hospital that provides a disproportionate amount of care to the disadvantaged], etc.) to determine the payable amount.

Case Rates

Using the Case Rate method, a payer pays the provider a fixed rate for a patient based on the diagnosis and/or presenting problem. For this rate, the provider covers all of the services the patient requires during an inpatient admission, observation stay, or specified outpatient procedure, if applicable. Case Rates are typically established on the basis of major diagnostic categories and may be classified by a DRG, Revenue Center Code, ICD-9 procedure code, or CPT code. The case rate may or may not include: 1) a specified number of days associated with the Case Rate, 2) outlier provisions if billed charges exceed a specific dollar amount, or 3) cost of instrumentation (implants). In this model, the provider is accepting some significant risk, but has considerable flexibility in how it meets the patient's needs. However, the provider must fully understand costs and volume potential when negotiating Case Rates. This type of financial arrangement is often used for high-cost or high volume procedures.

Per Diems

In the Per Diem billing system, the hospital and insurance carrier agree to a "per day" payment amount that will reimburse the hospital for all the services, supplies, etc. provided to the patient. Payments are usually limited to predetermined lengths of stay.

Line Item Payment (example: percentage of charges)

Under the line item system of payment, the hospital receives payment for each service performed and presented on the claim form.

ICD-9-CM Diagnosis Codes

Each claim must be submitted with the ICD-9-CM codes that reflect the highest level of specificity of the condition of the patient. The following diagnosis codes may be appropriate to support medical necessity for lumbar spinal fusion procedures using INFUSE® Bone Graft:

Code	Description
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy, lumbar region
722.10	Displacement of lumbar intervertebral disc without myelopathy
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.73	Intervertebral lumbar disc disorder with myelopathy, lumbar region

ICD-9-CM Procedure Codes

Hospitals use ICD-9-CM procedure codes to report inpatient services. INFUSE® Bone Graft (rhBMP-2) is separately reportable using ICD-9-CM procedure code 84.52. The following codes may be appropriate for the performance of a single-level Anterior Lumbar Interbody Fusion (ALIF) using INFUSE® Bone Graft and the LT-CAGE® Lumbar Tapered Fusion Devices:

Code	Description
81.06	Lumbar and lumbosacral fusion, anterior technique
80.51	Excision of intervertebral disc
81.62	Fusion or refusion of 2-3 vertebrae
84.52	Insertion of recombinant bone morphogenetic protein
84.51	Insertion of interbody spinal fusion device

Bill Type Code

011X Hospital: Inpatient (Part A)

Revenue Center Code

0360 Operating room services

0278 Medical/Surgical Supplies: Other Implants

Diagnosis-Related Groups (DRGs)

Medicare uses the Medicare Severity-DRG (MS-DRG) payment methodology to reimburse hospitals for inpatient services. Each inpatient stay is assigned to one of 745 payment groups, based on the ICD-9-CM codes assigned for the major diagnoses and procedures. Each DRG group has a flat payment rate which bundles the reimbursement for all services the patient received during the inpatient stay. The following chart shows the estimated Medicare payment amounts for the MS-DRGs to which an anterior lumbar interbody fusion (ALIF) using INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device may group.

MS-DRG	Description	MDC	Relative Weight	Medicare Payment*
028	Spinal Procedures with MCC	1	5.1090	\$28,878
029	Spinal Procedures with CC or Spinal Neurostimulator	1	2.7768	\$15,696
030	Spinal Procedures without CC/MCC	1	1.6019	\$9,055
459	Spinal Fusion Except Cervical with MCC	8	6.1506	\$34,766
460	Spinal Fusion Except Cervical without MCC	8	3.7097	\$20,969
907	Other O.R. Procedures for Injuries with MCC	21	3.8072	\$21,520
908	Other O.R. Procedures for Injuries with CC	21	1.8736	\$10,590
909	Other O.R. Procedures for Injuries without CC/MCC	21	1.1135	\$6,294
957	Other O.R. Procedures for Multiple Significant Trauma with MCC	24	6.2993	\$35,606
958	Other O.R. Procedures for Multiple Significant Trauma with CC	24	3.6544	\$20,656
959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC	24	2.2000	\$12,435

* Assumes payment for a hospital with wage index and geographic adjustment factor of 1.000.

Source: FY10 Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, August 27, 2009.

FY10 Updated Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, October 5, 2009.

CC – Complications and/or comorbidities, MCC – Major Complications and/or comorbidities

Hospital Outpatient Coding and Payment

HCPCS Codes and APC Assignment

Hospitals use the Healthcare Common Procedure Coding System (HCPCS) to report outpatient services. Under Medicare's Ambulatory Payment Classification (APC) methodology for hospital outpatient payment, each HCPCS code is assigned to one of about 879 payment classes. Each APC class has a relative weight which is multiplied by a flat 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.

HCPCS Code	Description	APC	Status Indicator	Relative Weight	Medicare Payment
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	—	C	—	—
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), threaded bone dowel(s), methylmethacrylate) to vertebral defect or interspace	0049	T	22.0149	\$1,484
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft/ Medtronic Titanium Threaded Interbody Fusion Device)	—	N	—	—

Source: Medicare Hospital Outpatient Prospective Payment System, Final Rule. Federal Register, November 20, 2009.

NOTE: No specific HCPCS Level II code exists for the use of INFUSE® Bone Graft. If an individually identifiable code is needed for billing by the facility, report HCPCS code L8699, Prosthetic implant, not otherwise specified.

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 indicators are applicable for this procedure:

- C Inpatient Procedure (Not paid under OPPS. Admit patient.)
- N Items and Services Packaged into APC Rates (No Separate APC Payment)
- T Significant Procedure, Multiple Procedure Reduction Applies

If a claim includes more than one HCPCS code with a status indicator of "T," full payment will be made for the highest paying procedure. All other services/procedures with a "T" status indicator will be discounted and paid at 50% of the amount allowed by Medicare.

Coverage of Spinal Fusion in the Hospital Outpatient Setting

Medicare does not cover instrumented spinal fusions in the outpatient setting. Commercial payers, however, may allow for the procedure to be performed in this 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 the outpatient setting.

Bill Type Code

013X Hospital Outpatient

Revenue Center Code

0360 Operating room services
0278 Medical/Surgical Supplies:
Other Implants

ASC Coding and Payment

Starting in 2008, Medicare began to base Ambulatory Surgery Center (ASC) payment groupings on the OPPS payment system. This change allows ASCs to be paid for any surgical procedure that CMS determines does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC and that is not expected to require an overnight stay. As a result, there are now approximately 3,300 covered surgical procedures under the revised ASC payment system.

The revised ASC payment rates are based on the APCs used to group procedures under the OPPS. Because procedures performed in ASCs are generally less costly than those performed in the hospital outpatient department, the ASC payment rates are targeted at 65% of the OPPS rates for the corresponding procedures, with a few exceptions, phased in over a four-year transition period.

HCPCS Code	Description	APC	Payment Indicator	Relative Weight	Medicare Payment
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	—	—	—	—
22851	Application of intervertebral biomechanical device(s) (e.g., synthetic cage(s), threaded bone dowel(s), methylmethacrylate) to vertebral defect or interspace	—	—	—	—
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device)	—	N1	—	—

Source: Medicare Program: Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule. Federal Register, November 20, 2009.

NOTE: No specific HCPCS Level II code exists for the use of INFUSE® Bone Graft. If an individually identifiable code is needed for billing by the facility, report HCPCS code L8699, Prosthetic implant, not otherwise specified.

ASC Payment Indicators:

Each HCPCS code in the ASC payment system is assigned a payment indicator to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The following payment indicator is applicable for this procedure:

N1 Packaged service/item; no separate payment made.

Coverage of Spinal Fusion in the ASC Setting

Spinal fusion is not listed on Medicare's Ambulatory Surgery Center List of Covered Procedures, meaning it is not covered in this setting. Commercial payers, however, may allow for the procedure to be performed in this 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 the outpatient setting.

Bill Type Code

083X Hospital Outpatient (ASC)

Revenue Center Code

0360 Operating room services
0278 Medical/Surgical Supplies:
Other Implants

Tibia Fracture Indication

INFUSE® Bone graft has been indicated by the U.S. Food and Drug Administration (FDA) for use in skeletally mature patients for treating acute, open tibial shaft fractures that have been stabilized with intramedullary (IM) nail fixation after appropriate wound management. INFUSE® Bone Graft must be applied within 14 days after the initial fracture.

Physician Coding and Payment

ICD-9-CM Diagnosis Codes

Each claim must be submitted with the ICD-9-CM codes that reflect the highest level of specificity of the condition of the patient. The following diagnosis codes may be appropriate to support medical necessity for treating open tibial shaft fractures using INFUSE® Bone Graft:

Code	Description
823.30	Open fracture of shaft of tibia
823.32	Open fracture of shaft of fibula with tibia

Current Procedural Terminology Codes

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 flat payment amount to each CPT code. Under Medicare’s RBRVS methodology for physician payment, each CPT code is assigned a point value, known as the Relative Value Unit or RVU, which is then multiplied by a flat 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 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 CMS, has become a national standard.

Medicare’s 2010 RVUs and RBRVS payments are below:

CPT	Description	Total RVUs	Medicare Payment*
<i>Select the most appropriate codes:</i>			
27759	Treatment of tibial shaft fracture (with or without fibular fracture) by intramedullary implant, with or without interlocking screws and/or cerclage	26.27	\$948
11010	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin and subcutaneous tissues	7.38	\$266
11011	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin, subcutaneous tissue, muscle fascia, and muscle	7.98	\$288
11012	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin, subcutaneous tissue, muscle fascia, muscle, and bone	11.42	\$412

* Calculated for 2010: RVU (no geographic adjustment) x Medicare Conversion Factor for 2010.

Source: CY 2010 Medicare Physician Fee Schedule, Final Rule. Federal Register, November 25, 2009.

Department of Defense Appropriations Act of 2010.

NOTE: No specific CPT code exists for the insertion/placement of INFUSE® Bone Graft. Regardless, per National Correct Coding Initiative guidelines, bone grafting is included within the treatment code 27759.

Hospital Inpatient Coding and Payment

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 of 745 payment groups, based on the ICD-9-CM codes assigned to the major diagnoses and procedures. Each DRG group 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-9-CM Diagnosis Codes

Each claim must be submitted with the ICD-9-CM codes that reflect the highest level of specificity of the condition of the patient. The following diagnosis codes may be appropriate to support medical necessity for treating open tibial shaft fractures using INFUSE® Bone Graft:

Code	Description
823.30	Open fracture of shaft of tibia
823.32	Open fracture of shaft of fibula with tibia

ICD-9-CM Procedure Codes

Hospitals use ICD-9-CM procedure codes to report inpatient services. INFUSE® Bone Graft (rhBMP-2) is separately reportable using ICD-9-CM procedure code 84.52. The following codes may be appropriate for the performance of an open tibial shaft fracture repair using an IM nail and INFUSE® Bone Graft:

Code	Description
79.36	Open reduction of fracture of tibia and fibula with internal fixation
79.66	Debridement of open fracture of tibia and fibula
84.52	Insertion of recombinant bone morphogenetic protein

Bill Type Code

011X Hospital: Inpatient (Part A)

Revenue Center Code

0360 Operating room services

0278 Medical/Surgical Supplies: Other Implants

Diagnosis-Related Groups

Medicare uses the Medicare Severity-DRG payment methodology to reimburse hospitals for inpatient services. The following chart shows the estimated Medicare payment amounts for the MS-DRGs to which a tibia fracture open reduction with internal fixation (ORIF) may group.

MS-DRG	Description	MDC	Relative Weight	Medicare Payment*
492	Lower Extremity and Humerus Procedures Except Hip, Foot, Femur with MCC	8	2.8500	\$16,109
493	Lower Extremity and Humerus Procedures Except Hip, Foot, Femur with CC	8	1.7806	\$10,065
494	Lower Extremity and Humerus Procedures Except Hip, Foot, Femur without CC/MCC	8	1.2619	\$7,133
907	Other O.R. Procedures for Injuries with MCC	21	3.0872	\$21,520
908	Other O.R. Procedures for Injuries with CC	21	1.8736	\$10,590
909	Other O.R. Procedures for Injuries without CC/MCC	21	1.1135	\$6,294
957	Other O.R. Procedures for Multiple Significant Trauma with MCC	24	6.2993	\$35,606
958	Other O.R. Procedures for Multiple Significant Trauma with CC	24	3.6544	\$20,656
959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC	24	2.2000	\$12,435

* Assumes payment for a hospital with wage index and geographic adjustment factor of 1.000.

Source: FY10 Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, August 27, 2009.

FY10 Updated Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, October 5, 2009.

CC – Complications and/or comorbidities, MCC – Major Complications and/or comorbidities

Hospital Outpatient Coding and Payment

HCPCS Codes and APC Assignment

Hospitals use the Healthcare Common Procedure Coding System (HCPCS) to report outpatient services. Under Medicare's Ambulatory Payment Classification (APC) methodology for hospital outpatient payment, each HCPCS code is assigned to one of about 879 payment classes. Each APC class has a relative weight which is multiplied by a flat 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 percent of charges mechanism, depending on their contract with the hospital.

HCPCS Code	Description	APC	Status Indicator	Relative Weight	Medicare Payment
<i>Select the most appropriate codes:</i>					
27759	Treatment of tibial shaft fracture (with or without fibular fracture) by intramedullary implant, with or without interlocking screws and/or cerclage	0064	T	65.4752	\$4,413
11010	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin and subcutaneous tissues	0019	T	4.3625	\$294
11011	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin, subcutaneous tissue, muscle fascia, and muscle	0019	T	4.3625	\$294
11012	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin, subcutaneous tissue, muscle fascia, muscle, and bone	0019	T	4.3625	\$294
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N	—	—

Source: Medicare Hospital Outpatient Prospective Payment System, Final Rule. Federal Register, November 20, 2009.

NOTE: No specific HCPCS Level II code exists for the use of INFUSE® Bone Graft. If an individually identifiable code is needed for billing by the facility, report HCPCS code L8699, Prosthetic implant, not otherwise specified.

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 indicators are applicable for this procedure:

- N Items and Services Packaged into APC Rates
- T Significant Procedure, Multiple Procedure Reduction Applies

If a claim includes more than one HCPCS code with a status indicator of "T," full payment will be made for the highest paying procedure. All other services/procedures with a "T" status indicator will be discounted and paid at 50% of the amount allowed by Medicare.

Bill Type Code

013X Hospital Outpatient

Revenue Center Code

0360 Operating room services
0278 Medical/Surgical Supplies:
Other Implants

ASC Coding and Payment

Starting in 2008, Medicare began to base Ambulatory Surgery Center (ASC) payment groupings on the OPPS payment system. This change allows ASCs to be paid for any surgical procedure that CMS determines does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC and that is not expected to require an overnight stay. As a result, there are now approximately 3,300 covered surgical procedures under the revised ASC payment system.

The revised ASC payment rates are based on the APCs used to group procedures under the OPPS. Because procedures performed in ASCs are generally less costly than those performed in the hospital outpatient department, the ASC payment rates are targeted at 65% of the OPPS rates for the corresponding procedures, with a few exceptions, phased in over a four-year transition period.

HCPCS Code	Description	APC	Payment Indicator	Relative Weight	Medicare Payment
<i>Select the most appropriate codes:</i>					
27759	Treatment of tibial shaft fracture (with or without fibular fracture) by intramedullary implant, with or without interlocking screws and/or cerclage	0064	A2	50.5787	\$2,118
11010	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin and subcutaneous tissues	0019	A2	4.5669	\$191
11011	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin, subcutaneous tissue, muscle fascia, and muscle	0019	A2	4.5669	\$191
11012	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s); skin, subcutaneous tissue, muscle fascia, muscle, and bone	0019	A2	4.5669	\$191
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N1	—	—

Source: Medicare Program: Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule. November 20, 2009.

NOTE: No specific HCPCS Level II code exists for the use of INFUSE® Bone Graft. If an individually identifiable code is needed for billing by the facility, report HCPCS code L8699, Prosthetic implant, not otherwise specified.

Payment Indicators:

Each HCPCS code in the ASC payment system is assigned a payment indicator to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The following payment indicator is applicable for this procedure:

A2 Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight

N1 Packaged service/item; no separate payment made

Bill Type Code

083X Hospital Outpatient (ASC)

Revenue Center Code

0360 Operating room services

0278 Medical/Surgical Supplies:
Other Implants

Oral Maxillofacial Indications

INFUSE® Bone graft has been indicated by the U.S. Food and Drug Administration (FDA) as an alternative to autogenous bone graft for sinus augmentations and for localized alveolar ridge augmentations for defects associated with extraction sockets.

Medical Necessity vs. Dental Necessity

A determination of whether the procedure/service will be covered under a dental or medical benefit must be determined prior to providing treatment. The decision of coverage is determined by the patient's plan benefits, diagnosis, and medical appropriateness of the services/treatment requested.

Medical Necessity

Coverage of medical benefits must be determined prior to providing service/treatment. The insurance company may require prior authorization of the procedure/service/treatment to determine medical necessity.

When the condition requires surgical correction, the medical necessity review of the surgery will examine whether or not the condition results in functional impairment (e.g., an impairment that affects the speech or the ability to eat or involves injury to the soft tissue of the mouth). In some cases, if the tooth was lost due to an accident or traumatic event, or tumor, the reconstruction may include implants in which the medical benefits may provide coverage.

Health plans *may cover* benefits for:

- » Accidental injury or the natural teeth, cheeks, lips, tongue, roof and floor of the mouth
- » Congenital deformity including cleft lip and palate
- » Disease due to infection or tumor, including tumor, cysts, and exostosis (abnormal bony growth on the surface of a bone or tooth)
- » Temporomandibular joint (TMJ) disease

Dental Necessity

Some dental plans will exclude congenital (hereditary) or developmental (following birth) malformations or cosmetic surgery or dentistry for purely cosmetic reasons, including but not limited to: cleft palate, maxillary and mandibular (upper and lower jaw) malformations, enamel hypoplasia (lack of development), fluorosis (a type of discoloration of the teeth), and anodontia (missing teeth). Dental plan exclusions may be covered under the patient's medical benefits.

Many dental insurance companies will require a pre-determination of benefits to be submitted to the dental plan prior to treatment. Submitting a pre-determination provides the provider and patient with information on benefits and associated financial responsibilities. Most dental insurance plans have an annual benefit maximum per covered person.

Dental plans may or may not cover the bone graft procedure. In most cases, dental implants are considered "non-covered." The pre-determination of benefits will provide benefit information on specific coverage.

Physician Coding and Payment

Current Procedural Terminology Codes

Current Procedural Terminology (CPT®) codes are used to report physician 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 flat payment amount to each CPT code. Under Medicare's RBRVS methodology for physician payment, each CPT code is assigned a point value, known as the Relative Value Unit or RVU, which is then multiplied by a flat 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 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 CMS, has become a national standard.

Medicare's 2010 RVUs and RBRVS payments are below:

CPT	Description	Total RVUs	Medicare Payment*
Alveolar Ridge Augmentation			
21210-52	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft) <i>(Report modifier -52, Reduced Services, because not performing part of surgery to obtain the bone graft)</i>	53.41	\$1,927**

NOTE: No specific CPT code exists for the insertion/placement of INFUSE® Bone Graft. If the practice needs to separately bill for the device, report L8699 (prosthetic implant, not otherwise specified) and the appropriate changes on the claim form.

CPT	Description	Total RVUs	Medicare Payment*
Sinus Augmentation			
21210-52	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft) <i>(Report modifier -52, Reduced Services, because not performing part of surgery to obtain the bone graft)</i>	53.41	\$1,927**

* Calculated for 2010: Non-facility RVU (no geographic adjustment) × Medicare Conversion Factor for 2010.

** Some payer policies implement payment reductions when modifier -52 is used. Consult with your payers and/or payer contracts for their specific payment policies.

Source: CY 2010 Medicare Physician Fee Schedule, Final Rule. Federal Register, November 25, 2009. Department of Defense Appropriations Act 2010.

Code on Dental Procedures and Nomenclature

The Code on Dental Procedures and Nomenclature (Code) is designated as the national terminology for reporting dental services, and is recognized by third-party payers nation wide. The Code is periodically reviewed and revised to reflect the dynamic changes in dental procedures that are recognized by organized dentistry and the dental community as a whole. Revisions to the Code are published and effective biennially, at the start of odd-numbered years.

CPT	Description	Total RVUs	Medicare Payment*
Alveolar Ridge Augmentation <i>[select most appropriate code(s)]</i>			
D7953	Bone replacement graft for ridge preservation — per site	0.00	\$N/A
Sinus Augmentation			
D7951	Sinus augmentation with bone or bone substitutes	0.00	\$N/A

* Calculated for 2010: Non-facility budget neutrality adjusted RVU (no geographic adjustment) × Medicare Conversion Factor for 2010.

Source: CY 2010 Medicare Physician Fee Schedule, Final Rule. Federal Register, November 25, 2009.

NOTE: If the practice needs to separately bill for the device, report L8699 (prosthetic implant, not otherwise specified) and the appropriate charges on the claim form.

Hospital Inpatient Coding and Payment

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 of 745 payment groups, based on the ICD-9-CM codes assigned to the major diagnoses and procedures. Each DRG group 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-9-CM Procedure Codes

Hospitals use ICD-9-CM procedure codes to report inpatient services. INFUSE® Bone Graft (rhBMP-2) is separately reportable using ICD-9-CM procedure code 84.52. The following codes may be appropriate for the performance of an alveolar ridge augmentation or a sinus augmentation using INFUSE® Bone Graft.

Code	Description
Alveolar Ridge Augmentation	
24.5	Alveoloplasty
84.52	Insertion of recombinant bone morphogenetic protein
Sinus Augmentation	
22.79	Other repair of nasal sinus
84.52	Insertion of recombinant bone morphogenetic protein

Diagnosis-Related Groups

Medicare uses the Medicare Severity-DRG payment methodology to reimburse hospitals for inpatient services. Each inpatient stay is assigned to one of 745 payment groups, based on the ICD-9-CM codes assigned for the major diagnoses and procedures. Each DRG group has a flat payment rate which bundles the reimbursement for all services the patient received during the inpatient stay. The following chart shows the estimated Medicare payment amounts for the MS-DRGs to which an alveolar ridge augmentation or a sinus augmentation using INFUSE® Bone Graft may group.

MS-DRG	Description	MDC	Relative Weight	Medicare Payment*
Alveolar Ridge Augmentation				
137	Mouth Procedures with CC/MCC	3	1.4004	\$7,916
138	Mouth Procedures without CC/MCC	3	0.7458	\$4,216
907	Other O.R. Procedures for Injuries with MCC	21	3.8072	\$21,520
908	Other O.R. Procedures for Injuries with CC	21	1.8736	\$10,590
909	Other O.R. Procedures for Injuries without CC/MCC	21	1.1135	\$6,294
957	Other O.R. Procedures for Multiple Significant Trauma with MCC	24	6.2993	\$35,606
958	Other O.R. Procedures for Multiple Significant Trauma with CC	24	3.6544	\$20,656
959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC	24	2.2000	\$12,435
987	Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC	ALL	3.4020	\$19,230
988	Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with CC	ALL	1.7836	\$10,082
989	Nonextensive O.R. Procedure Unrelated to Principal Diagnosis without CC/MCC	ALL	1.0358	\$5,855
Sinus Augmentation				
135	Sinus and Mastoid Procedures with CC/MCC	3	1.8520	\$10,468
136	Sinus and Mastoid Procedures without CC/MCC	3	0.9015	\$5,096

* Assumes payment for a hospital with wage index and geographic adjustment factor of 1.000.
 Source: FY10 Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, August 27, 2009.
 FY10 Updated Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, October 5, 2009.
 CC – Complications and/or comorbidities, MCC – Major Complications and/or comorbidities

Bill Type Code

011X Hospital: Inpatient (Part A)

Revenue Center Code

0360 Operating room services
 0278 Medical/Surgical Supplies:
 Other Implants

Hospital Outpatient Coding and Payment

HCPCS Codes and APC Assignment

Hospitals use the Healthcare Common Procedure Coding System (HCPCS) to report outpatient services. Under Medicare's Ambulatory Payment Classification (APC) methodology for hospital outpatient payment, each HCPCS code is assigned to one of about 879 payment classes. Each APC class has a relative weight which is multiplied by a flat 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.

HCPCS Code	Description	APC	Status Indicator	Relative Weight	Medicare Payment
Alveolar Ridge Augmentation					
21210-52	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft) <i>(Report modifier -52, Reduced Services, because not performing part of surgery to obtain the bone graft)</i>	0256	T	42.9827	\$2,897
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N	—	—
Sinus Augmentation					
21210-52	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft) <i>(Report modifier -52, Reduced Services, because not performing part of surgery to obtain the bone graft)</i>	0256	T	42.9827	\$2,897
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N	—	—

Source: Medicare Hospital Outpatient Prospective Payment System, Final Rule. Federal Register, November 20, 2009.

HCPCS Code	Description	APC	Status Indicator	Relative Weight	Medicare Payment
Alveolar Ridge Augmentation <i>[select most appropriate code(s)]</i>					
D7953	Bone replacement graft for ridge preservation — per site	—	E	—	—
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N	—	—
Sinus Augmentation					
D7951	Sinus augmentation with bone or bone substitutes	—	E	—	—
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N	—	—

Source: Medicare Hospital Outpatient Prospective Payment System, Final Rule. Federal Register, November 20, 2009.

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 indicators are applicable for these procedures:

- E Items, Codes, and Services:
 - » That are not covered by Medicare based on statutory exclusion
 - » That are not covered by Medicare for reasons other than statutory exclusion
 - » That are not recognized by Medicare but for which an alternate code for the same item or service may be available
 - » For which separate payment is not provided by Medicare
- N Items and Services Packaged into APC Rates
- T Significant Procedure, Multiple Procedure Reduction Applies

If a claim includes more than one HCPCS code with a status indicator of "T," full payment will be made for the highest paying procedure. All other services/procedures with a "T" status indicator will be discounted and paid at 50% of the amount allowed by Medicare.

Bill Type Code

013X Hospital Outpatient

Revenue Center Code

0360 Operating room services

0278 Medical/Surgical Supplies:
Other Implants

ASC Coding and Payment

Starting in 2008, Medicare began to base Ambulatory Surgery Center (ASC) payment groupings on the OPPS payment system. This change allows ASCs to be paid for any surgical procedure that CMS determines does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC and that is not expected to require an overnight stay. As a result, there are now approximately 3,300 covered surgical procedures under the revised ASC payment system.

The revised ASC payment rates are based on the APCs used to group procedures under the OPPS. Because procedures performed in ASCs are generally less costly than those performed in the hospital outpatient department, the ASC payment rates are targeted at 65% of the OPPS rates for the corresponding procedures, with a few exceptions, phased in over a four-year transition period.

HCPCS Code	Description	APC	Payment Indicator	Relative Weight	Medicare Payment
Alveolar Ridge Augmentation					
21210-52	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft) <i>(Report modifier -52, Reduced Services, because not performing part of surgery to obtain the bone graft)</i>	0256	A2	36.5245	\$1,529
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N1	—	—
Sinus Augmentation					
21210-52	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft) <i>(Report modifier -52, Reduced Services, because not performing part of surgery to obtain the bone graft)</i>	0256	A2	36.5245	\$1,529
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N1	—	—

Source: Medicare Program: Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule. Federal Register, November 20, 2009.

HCPCS Code	Description	APC	Payment Indicator	Relative Weight	Medicare Payment
Alveolar Ridge Augmentation [select most appropriate code(s)]					
D7953	Bone replacement graft for ridge preservation — per site	—	E	—	—
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N1	—	—
Sinus Augmentation					
D7951	Sinus augmentation with bone or bone substitutes	—	E	—	—
L8699	Prosthetic implant, not otherwise specified (Use this code to bill for the INFUSE® Bone Graft Device)	—	N1	—	—

Source: Medicare Program: Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Final Rule. Federal Register, November 20, 2009.

Payment Indicators:

Each HCPCS code in the ASC payment system is assigned a payment indicator to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The following payment indicators are applicable for these procedures:

- A2 Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight
- E Items, Codes, and Services:
 - » That are not covered by Medicare based on statutory exclusion
 - » That are not covered by Medicare for reasons other than statutory exclusion
 - » That are not recognized by Medicare but for which an alternate code for the same item or service may be available
 - » For which separate payment is not provided by Medicare
- N1 Packaged service/item; no separate payment made

Bill Type Code

083X Hospital Outpatient (ASC)

Revenue Center Code

0360 Operating room services

0278 Medical/Surgical Supplies:
Other Implants

Frequently Asked Questions

Does Medicare cover INFUSE® Bone Graft?

Medicare has not issued a national coverage policy for INFUSE® Bone Graft. Therefore, local Medicare contractors are free to make coverage determinations based on their own medical necessity and evidence criteria.

Will the hospital be reimbursed for this device? If not, the hospital will be resistant to use the product. Any suggestions?

In some cases hospitals have included contract terms that will allow for separate payment for devices. If there is no contract language that dictates the payment for devices some insurance companies will determine payment on a case by case basis while others will not allow payment. Our biggest suggestion to gain separate reimbursement for the device is to include a payment clause, commonly known as a “carve-out”, in future contract negotiations that will allow for payment.

Is there a code for the hospital to use for the insertion of INFUSE® Bone Graft?

For inpatient cases, hospitals should report the use of INFUSE® Bone Graft with ICD-9-CM procedure code 84.52 (insertion of recombinant Bone Morphogenetic Protein).

How will it effect the hospital’s reimbursement if a spinal fusion is performed in an outpatient setting?

Medicare does not cover instrumented spinal fusions in an outpatient setting. However, commercial payers may allow for the procedure to be performed in this setting. In these cases, hospitals will want to review their payer contracts to ensure they receive adequate reimbursement for this procedure in an outpatient setting.

What are HCPCS/C-codes and is there one for INFUSE® Bone Graft?

Level II of the Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician’s office. C-codes are a subset of HCPCS Level II codes used to report drugs, biologicals and devices eligible for transitional pass-through payments and for items classified in new technology ambulatory payment classifications (APCs) under the Outpatient Prospective Payment System (OPPS).

No specific Level II HCPCS code exists for INFUSE® Bone Graft. To report the use of this device in the outpatient setting, use L8699, Prosthetic implant, not otherwise specified.

Is there a CPT code for INFUSE® Bone Graft?

There is not a separate CPT code for the preparation or implantation of INFUSE® Bone Graft. For detailed coding, please refer to the appropriate physician coding and payment section within this guide for the indication and procedure being performed.

Coding and Reimbursement Assistance

SPINELINE®

Coding and Reimbursement Support

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

Phone:
877-690-5353

E-mail:
(Physician)
spinalcodingmd@medtronic.com

(Hospital)
spinalcodinghospital@medtronic.com

Internet:
www.medtronicsofamordanek.com/
spine

The Spine Academy Learning SeriesSM

It's no longer necessary to travel to a classroom in order to stay abreast of changes in the industry. Now it's possible to go online and learn about the latest developments in the business of spine care, coding changes, regulations and documentation requirements because Medtronic provides live interactive programs free of charge throughout the year.

Through the Spine Academy Learning SeriesSM, you can:

- » Ask questions and receive answers in real time
- » Get a basic overview of spine anatomy
- » View techniques, surgical procedures and medical devices
- » Learn spinal CPT and ICD-9 coding by reviewing actual operative reports
- » Clarify the correct use of CCI edits and modifiers
- » Identify new technologies and common documentation challenges
- » Learn coding and reimbursement changes
- » Discuss common challenges in spine practices

Register online for any of the programs at:
www.medtronicsofamordanek.com/
spine/registration

Healthcare Economic Strategies

Healthcare Economic Strategies (HES) works with physicians and hospital staffs to resolve issues and facilitate communication. This process may involve contract negotiations, the design and implementation of a Spine Center, education on the latest technologies and their clinical implications, or other physician and provider challenges. With our experience and access to business tools, every challenge becomes an opportunity.

HES provides:

- » Insights into successful spine service line management
- » Strategies for better communication with payers
- » Benchmark info for efficiencies at all levels, including clinical delivery, billing, coding and reimbursement
- » Measurement of both clinical and economic outcomes
- » Collaboration with you to understand your unique issues and market dynamics

Your Medtronic representative can schedule a convenient time for you to speak with a Healthcare Economic Strategies Regional Director, or call (800) 876-3133.

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR: INFUSE® BONE GRAFT

INFUSE® Bone Graft is indicated for treating acute, open tibial shaft fractures that have been stabilized with IM nail fixation after appropriate wound management. INFUSE® Bone Graft must be applied within 14 days after the initial fracture. Prospective patients should be skeletally mature.

INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 solution and a carrier/scaffold for the bone morphogenetic protein solution and resulting bone. **These components must be used as a system. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document.**

INFUSE® Bone Graft is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with an active malignancy or patients undergoing treatment for a malignancy. INFUSE® Bone Graft should also not be used in patients who are skeletally immature, in patients with an inadequate neurovascular status, in patients with compartment syndrome of the affected limb, in pregnant women, or in patients with an active infection at the operative site.

There are no adequate and well controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

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

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, WARNINGS, AND PRECAUTION FOR INFUSE® BONE GRAFT FOR CERTAIN ORAL MAXILLOFACIAL AND DENTAL REGENERATIVE USES

INFUSE® Bone Graft is indicated as an alternative to autogenous bone graft for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

The INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) placed on an absorbable collagen sponge (ACS). **These components must be used as a system for the prescribed indication. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in the package insert.**

INFUSE® Bone Graft is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy or patients undergoing treatment for a malignancy, in pregnant women, or patients with an active infection at the operative site.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible dental treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

INFUSE® Bone Graft has not been studied in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).

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

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR: INFUSE® BONE GRAFT/LT-CAGE® LUMBAR TAPERED FUSION DEVICE
INFUSE® BONE GRAFT/INTER FIX™ THREADED FUSION DEVICE
INFUSE® BONE GRAFT/INTER FIX™ RP THREADED FUSION DEVICE

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1, who may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level. The INFUSE® Bone Graft/ LT-CAGE® Lumbar Tapered Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach. INFUSE® Bone Graft with either the INTER FIX™ or INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device consists of two components containing three parts—a metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold for the bone morphogenetic protein and resulting bone. **These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The INFUSE® Bone Graft component must not be used without the Medtronic Titanium Threaded Interbody Fusion Device component.**

NOTE: The INTER FIX™ Threaded Fusion Device and the INTER FIX™ RP Threaded Fusion Device may be used together to treat a spinal level. LT-CAGE® Lumbar Tapered Fusion Device implants are not to be used in conjunction with either the INTER FIX™ or INTER FIX™ RP implants to treat a spinal level.

The INFUSE® Bone Graft/Medtronic Titanium Threaded Interbody Fusion Device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor; in patients with any active malignancy or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate INFUSE® Bone Graft kit.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

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