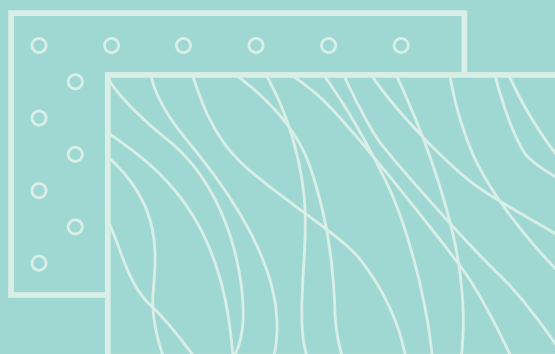
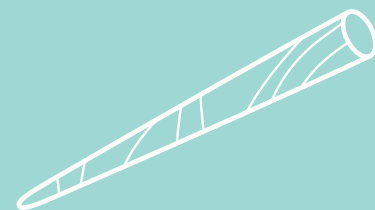
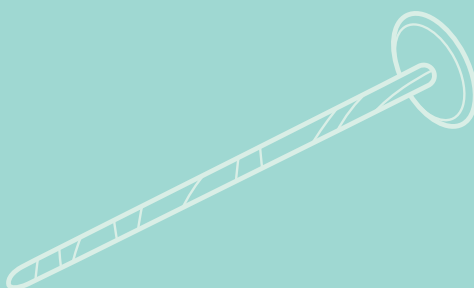




# Surgisis® Biodesign™

FISTULA PLUG



Anal Fistula

## 2008 Coding and Reimbursement Guide

Surgisis® Biodesign™

COOK® MEDICAL

## Coding and Reimbursement Guide

### January 2008

The information provided herein reflects Cook Medical's understanding of anal fistula repairs utilizing the Surgisis Biodesign Fistula Plug; the CPT, ICD-9, and MS-DRG coding systems; Medicare payment systems; commercially available coding guides; professional societies; and research conducted by independent coding and reimbursement consultants. This information should not be construed as authoritative. The entity billing Medicare and/or other third-party payers is solely responsible for the accuracy of the codes assigned to the services and items in the medical record. Cook does not, and should not, have access to medical records, and therefore cannot recommend codes for specific cases. When making coding decisions, we encourage you to seek input from the AMA, AHA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Cook does not promote the off-label use of its devices.

If you have any questions please contact our Reimbursement Team at 1.800.339.2235 and request:

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## Table of Contents

Introduction .....	4
Physician Coding and Reimbursement .....	4
Establishing Value for a Category III Service .....	5
Table A - Digestive system reference service and anal fistula treatment codes	
Contesting Non-coverage .....	6
Influencing Payer Decision-Making .....	6
Facility Coding and Reimbursement .....	6
Hospital Outpatient Department .....	7
Medicare	
Commercial Insurance	
Ambulatory Surgery Center (ASC) .....	8
Medicare	
Commercial Insurance	
Hospital Inpatient .....	9, 10
Medicare	
Commercial Insurance	
Attachment 1 .....	11, 12
Attachment 2 .....	13

## Introduction

This guide is for those involved with the coding and reporting of provider services. Two letters are provided at the end of this guide (**Attachments 1 & 2**) that may be customized for your practice and submitted to your patients' health plans.

**Attachment 1** is to request pre-authorization (non-Medicare payers) and may also be submitted with your claim and operative note to support reimbursement.

**Attachment 2** may be used to contest non-coverage.

The FDA clearance of the Cook Surgisis Biodesign Fistula Plug offers physicians a minimally invasive, clinically effective procedure for treating anal fistulae.\* However, as with many new procedures in medicine, adequate reimbursement sometimes lags medical innovation and the Fistula Plug is no exception. The use of this device has created a new surgical procedure that as of January 1, 2007, is assigned an emerging technology Category III CPT code (a "T" code). The cost of the new device may not be adequately recognized yet in all facility payment systems and rates but progress continues to be made to rectify this. Until then, Cook Medical has produced this guide to assist in obtaining adequate reimbursement for this beneficial new procedure. However, as with all coverage, coding and payment related issues, we encourage you to contact your patients' insurance plans for guidance.

## Physician Coding & Reimbursement

Many questions have arisen regarding the correct CPT code to use in reporting an anal fistula repair utilizing the Fistula Plug. CPT coding convention requires that you "Select the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided. If no such procedure or service exists, then report the service using the appropriate unlisted procedure or service code."<sup>1</sup> Effective January 1, 2007, a new Category III CPT code was created by the AMA's CPT Editorial Panel to describe and report anal fistula repair using the Fistula Plug:

*0170T - Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS])*

Submission of claims with Category III codes typically requires: **(a)** a paper claim; **(b)** the operative note attached to the claim; and **(c)** a cover letter to the health plan/payer which contains the following information: **1)** identification of comparable procedure(s) to assist the insurer in establishing a payment level; and **2)** an explanation of the procedure, the patient selection, the medical necessity and clinical benefits (**see Attachment 1**). Category III codes are not universally accepted by all insurance carriers. To avoid unnecessary claim denials, we encourage you to contact the payer for their coding recommendations prior to claim submission.

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<sup>1</sup>CPT 2007 Professional Edition, American Medical Association, page xiv, "Instructions for Use of the CPT Codebook."

\*510 (K) K050337 SIS Fistula Plug, March 9, 2005.

## Establishing a Value for a Category III Service

Common questions physicians ask when starting to perform a new service are “How much do I charge for the procedure?” and “How much should I expect to be reimbursed for the procedure?” Obviously, setting fees is a business decision that must be addressed by the physician and/or designated personnel. However, Medicare law requires that payments under the Medicare fee schedule be based on national uniform relative value units (RVU) determined by the resources used in furnishing a service.<sup>2</sup> CMS’ reasoning behind the law is that the relative value of the work in a physician’s service exists only in comparison with the physician’s work in another service; therefore, CMS established a set of reference services. The criteria for the reference services were that they must be commonly performed with established work RVUs and be fairly well understood outside of their own specialty.<sup>3</sup> The work RVUs assigned to the reference services represent benchmarks for comparison with the work represented by other codes.

To aid the reader with a value determination, the reference code for digestive system services (CPT code 46600<sup>4</sup>) and CPT codes representing anal fistula services are provided in Table A. When establishing the value for treatment of anal fistulae with the Surgisis Biodesign Fistula Plug, consider the amount of time, skill, risk and intensity of work. Referencing the information in the table below may aid your decision making and provide a defensible rationale for your value determination.

**Table A Digestive system reference service and anal fistula treatment codes**

CPT	Description	2008 Work RVU	Global RVU <sup>5</sup>	Global Period (Days)
46600	Diagnostic anoscopy [CMS designated reference service for digestive system services]	0.55	2.07	00
46020	Placement of seton	2.94	6.05	10
46270	Surgical treatment of anal fistula, subcutaneous	4.81	10.96	90
46280	Surgical treatment of anal fistula, complex or multiple, with or without placement of seton	6.28	10.70	90
46288	Closure of anal fistula with rectal advancement flap	7.68	12.64	90

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<sup>2</sup>Section 1848 of the Social Security Act, “Payment for Physicians’ Services.”

<sup>3</sup>Federal Register Vol. 64, No. 211, November 2, 1999, p. 59428.

<sup>4</sup>Federal Register Vol. 64, No. 211, November 2, 1999, Addendum E, pp. 59585-59590.

<sup>5</sup>2008 Medicare physician fee schedule out-of-office, i.e., facility global RVU, Federal Register Vol. 72, No. 227, November 27, 2007, Addendum B.

## Contesting Non-Coverage

If the procedure is still denied by Medicare or another payer after following this process, you may need to further educate the payer regarding medical necessity, FDA clearance and/or the efficacy of the procedure. If reimbursement is denied, the reason should be listed under the Explanation of Benefits (EOB). If the denial indicates the procedure is not medically necessary or is considered “experimental,” see **Attachment 2** for a sample letter that can be sent to the payer along with the notification of FDA clearance and articles supporting clinical efficacy. (Request reprints of clinical literature at the following e-mail address: reimbursement@cookmedical.com).

## Influencing Payer Decision-Making

If Medicare is a dominant payer and you plan to do the procedure on a regular basis, you may want to go directly to the Carrier Advisory Committee (CAC) member or Carrier Medical Director (CMD) for your state Medicare Carrier (The Medical Director contact directory may be accessed through the following link: [www.cms.hhs.gov/contacts](http://www.cms.hhs.gov/contacts)).

Private payer coverage determinations are usually made by the payer’s technology or medical device group. You may need to modify the included letter slightly (**Attachment 2**) if you are asking for overall approval of the Surgisis Biodesign Fistula Plug rather than reconsideration on a specific case. However, the supporting information included in the request should be the same as or similar to what is outlined.

As noted in the Introduction, we have included two letters that can be customized to your practice and may be helpful with payer correspondence. **Attachment 1** may be submitted to request pre-authorization (non-Medicare payers) or submitted along with your claim and operative note to support reimbursement. **Attachment 2** may be submitted to health plans to contest non-coverage.

For electronic copies (Word documents) of either of these letters, please contact the following e-mail address: reimbursement@cookmedical.com.

## Facility Coding and Reimbursement

The use of the Fistula Plug to treat anal fistulae is a minimally invasive procedure. Based on feedback from physicians performing the procedure, it will most often be performed in hospital outpatient surgery departments or free-standing ambulatory surgery centers.

The method and amount of facility reimbursement for medical services is dependent on a number of factors, including: **a**) the site of service (ambulatory surgery center vs. hospital outpatient dept. vs. hospital inpatient) and **b**) the payer (Medicare, commercial insurance plans, Medicaid, etc.). Following is a brief discussion of the current (2008) facility reimbursement environment for the Fistula Plug.

## Hospital Outpatient Department

### Medicare

Medicare pays hospital outpatient facilities under the Hospital Outpatient Prospective Payment System (HOPPS). Medicare updates its list of “approved” procedures annually. Each of these procedures is assigned to an Ambulatory Payment Classification, or “APC” created by Medicare. Although there are several hundred APCs, a CPT code is assigned to only one APC. The facility is reimbursed the APC amount that the CPT code is assigned to. Presently (as of 1-1-2008), the CPT code 0170T - Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS]) is assigned to APC “0150 Level IV **Anal/Rectal Procedures.**” The current (2008) national average Medicare payment to hospital facilities for **APC 0150** is \$1921.05<sup>6</sup> (the actual fee schedule amount varies from hospital to hospital, based on local wage indices, geographic location, etc.).

Medicare also requires that pass-through or C-code devices used in the hospital outpatient setting be included on the claim. Recognized coding authorities suggest using **C1781 Mesh (implantable)** to describe the Surgisis Biodesign Fistula Plug.

Please note the importance of submitting appropriate charges for this procedure, as Medicare uses charge data to ensure equitable payment in the future. According to CMS:

*“Our goal is to establish payment rates that provide appropriate relative payment for all services paid under the OPSS without creating payment disincentives that may reduce access to care. As a matter of policy, we do not tell hospitals how to set their charges for their services. However, we will continue to inform hospitals of the importance of their charge data in future ratesetting and encourage them to include all appropriate charges on their Medicare claims.”<sup>6</sup>*

Also note that revenue codes are to be assigned at the providers’ discretion.

### Commercial Insurance

Unlike Medicare, commercial insurers have not established a consistent national payment methodology so arrangements between insurers and hospitals vary considerably. Because of this, it’s not possible for Cook Medical to offer guidance to hospitals regarding an individual plan. We encourage you to work closely with your local hospital management and insurance plans to understand their contracted payment arrangements. A coordinated effort between the physician and hospital can be effective in obtaining appropriate reimbursement for innovative procedures such as treatment of anal fistulae utilizing the Fistula Plug.

When submitting claims it may be helpful to provide the documents listed under **Item 1** at the end of this guide.

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<sup>6</sup>Medicare Program; Changes to the HOPPS and Calendar Year 2008 Payment Rates; Final Rule, Federal Register, Vol. 72, No. 227, November 27, 2007.

## Ambulatory Surgery Center (ASC)

### Medicare

Medicare's payment system for ASCs is also based on a list of "approved" procedures identified by CPT codes, but is not identical to the list used for hospital outpatient facilities. Each ASC approved procedure is assigned a payment rate much like the outpatient payment system; however, reimbursement for ASC procedures reflects the reduced costs for providing care in this surgical setting.

0170T - Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS]) is now approved in the ASC setting and has been assigned a payment level of \$1,248.68.<sup>7</sup> When submitting claims it may be helpful to provide the documents listed under **Item 1** at the end of this guide.

### Commercial Insurance

Unlike Medicare, commercial insurers have not established a consistent national payment methodology so arrangements between insurers and hospitals vary considerably. Because of this, it is not possible for Cook to offer guidance to ASCs regarding any individual plan. We encourage you to work closely with your local ASC management and insurance plans to understand their contracted payment arrangements. A coordinated effort between the physician and ambulatory surgery center can be effective in obtaining appropriate reimbursement for innovative procedures such as anal fistula repair utilizing the Surgisis Biodesign Fistula Plug.

When submitting claims it may be helpful to provide the documents listed under **Item 1** at the end of this guide.

*Current Procedural Terminology CPT is a registered trademark of the American Medical Association.*

<sup>7</sup>*Medicare Program; Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Final Rule, Federal Register, Vol. 72, No. 227, November 27, 2007.*

# Hospital Inpatient

## Medicare

Medicare pays for inpatient hospital services based on the MS-DRG (Medicare-Severity Diagnosis-Related Group) system. Within this system, Medicare assigns patients to a MS-DRG based primarily on their diagnosis (coded with ICD-9 diagnosis codes) and any procedures (coded with ICD-9 procedure codes) performed during their hospital stay. Medicare has established hospital-specific MS-DRG fee schedules which determine how much the hospital will get paid for a given admission. These amounts vary from hospital to hospital based on the hospital’s location, whether it’s a teaching hospital and whether it sees a disproportionate share of low-income patients.

<b>The ICD-9 diagnosis code for anal fistula is:</b>		<b>565.1 Anal Fistula</b>
	Fistula:	anorectal rectal rectum to skin
	Excludes:	fistula of rectum to internal organs ischioanal fistula rectovaginal fistula
<b>The ICD-9 procedure code for anal fistula repair utilizing the Surgisis AFP plug is:</b>		<b>49.73 Closure of anal fistula</b>
	Excludes:	excision of anal fistula

Patients admitted with 565.1 as their primary diagnosis and who receive this procedure as their primary procedure will typically fall into one of three MS-DRGs:

DRG 347	Anal and Stomal Procedures with Major Comorbidity or Complication
DRG 348	Anal and Stomal Procedures with Comorbidity or Complication
DRG 349	Anal and Stomal Procedures without Comorbidity or Complication or Major Comorbidity or Complication

This is dependent on the presence or absence of certain comorbid or complicating diagnoses documented in the patient’s medical record and captured on the claim form submitted to Medicare.

The current (2008) average Medicare hospital reimbursement rates for these three MS-DRGs are:<sup>8</sup>

DRG 347	\$8,640.06
DRG 348	\$6,253.74
DRG 349	\$4,222.17

Actual hospital payment rates will vary based, among other things, on the hospital's geographic location, its status as a teaching hospital and whether it sees a disproportionate share of low-income patients.

**Note:** As mentioned under the hospital outpatient section, charges play an important role in future CMS rate setting; therefore, it is important to capture all appropriate service charges.

Also note that revenue codes are to be assigned at the provider's discretion.

### Commercial Insurance

Unlike Medicare, commercial insurers have not established a consistent national payment methodology so arrangements between insurers and hospitals vary considerably. Because of this, it's not possible for Cook Medical to offer guidance to hospitals regarding any individual plan. We encourage you to work closely with your local hospital management and insurance plans to understand the contracted payment arrangements between them. A coordinated effort between the physician and hospital can be quite effective in obtaining appropriate reimbursement for innovative procedures such as anal fistula repair utilizing the Surgisis Biodesign Fistula Plug.

When submitting claims it may be helpful to provide the documents listed under

**Item 1:** (1) the patient's medical record documenting the need for this procedure; (2) the operative note describing the procedure; and (3) an invoice documenting the cost of the Surgisis Biodesign Fistula Plug.

<sup>8</sup>2008 DRG Expert - Ingenix.

## Attachment 1

Today's date

Your letterhead

Dear (Health Plan/Medical Director):

On [date] I performed the procedure described on the attached operative note. This is a surgical procedure utilizing an FDA-cleared device (Surgisis® Biodesign™ Fistula Plug)\* that is proving effective in treating anal fistulae. Reported clinical results indicate that it is as or more effective than more traditional means of fistula repair (fistulotomy, setons, fibrin glue, etc.) and it is very well tolerated by patients.<sup>1, 2, 3, 4, 5, 6</sup>

[Optional insertion: it is generally beneficial to add in something as to the medical necessity and the clinical benefits and patient selection regarding use of the new technology rather than an existing technology/procedure.]

(Consider comments made in body of guide)

Beginning January 1, 2007 CPT code 0170T - Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS]), is the correct code to report this service but, as a Category III CPT code, it has not been assigned a value for payment. Outlined in the table below are other procedures commonly performed to treat anal fistulae, along with their Relative Value Units (RVUs). In regard to time, effort and skills needed to perform this procedure, I suggest fistula repair using the Fistula Plug most closely compares to CPT code [insert CPT code, descriptor and total RVU or payment amount the physician feels most closely represents the anal fistula procedure].

CPT	Description	Global RVU
46706	Repair of anal fistula with fibrin glue	4.06
46020	Placement of seton	6.05
46060	I&D of ischiorectal or intramural abscess, with fistulectomy or fistulotomy, submuscular, with or without placement of seton	10.74
46270	Surgical treatment of anal fistula, subcutaneous	10.96
46275	Surgical treatment of anal fistula, submuscular	11.46
46280	Surgical treatment of anal fistula, complex or multiple, with or without placement of seton	10.70
46285	... second stage	10.90
46288	Closure of anal fistula with rectal advancement	12.64

\* 510 (K) K050337 SIS Fistula Plug, March 9, 2005.

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Please contact me if you have any additional questions about this procedure or its application to this particular patient.

Sincerely,

Your name

Your contact information

1. Johnson EK, Gaw JU, Armstrong DN. Efficacy of anal fistula plug vs. fibrin glue in closure of anorectal fistulas. *Dis Colon Rectum*. 2006;49(3):371-6.
2. O'Connor L, Champagne BJ, Ferguson MA, et al. Efficacy of anal fistula plug in closure of Crohn's anorectal fistulas. *Dis Colon Rectum*. 2006;49(10):1569-73.
3. Champagne BJ, O'Connor LM, Ferguson M, et al. Efficacy of anal fistula plug in closure of cryptoglandular fistulas: long-term follow-up. *Dis Colon Rectum*. 2006;49(12):1817-21.
4. Ellis CN. Bioprosthetic plugs for complex anal fistulas: an early experience. *J Surg Educ*. 2007;64(1):36-40.
5. van Koperen PJ, D'Hoore A, Wolthuis AM, et al. Anal fistula plug for closure of difficult anorectal fistula: a prospective study. *Dis Colon Rectum*. 2007;50(12):2168-72.
6. Schwandner O, Stadler F, Dietl O, et al. Initial experience on efficacy in closure of cryptoglandular and Crohn's transsphincteric fistulas by the use of the anal fistula plug. *Int J Colorectal Dis*. 2008;23(3):319-24.

## Attachment 2

(PHYSICIAN LETTERHEAD)

(Date)

(Name Payer/Person Contacting)

(Business Name)

(Address)

(City, State, Zip)

RE: Insertion of the Surgisis® Biodesign™ Fistula Plug for anal fistula treatment

Dear <<title>> <<name>>:

The insertion of the Fistula Plug was recently denied for <<insert patient name and identifying information for the carrier>> for treatment of an anal fistula. The procedure was denied on the basis of <<insert denial reason>>.

I am writing to provide you with further information supporting the safe and effective treatment of anal fistulae with the Fistula Plug. The plug has received FDA clearance for the repair of anal, rectal and enterocutaneous fistulae; its 510(K) clearance number is K050337. The device is supplied sterile and is intended for one-time use.

<<insert patient's name>> was a candidate for this type of anal fistula repair as opposed to another type of anal fistula repair for the following reasons <<outline patient condition and medical reasons for using the Fistula Plug as to other existing procedures>>.

I have included a packet of literature supporting the efficacy of this procedure. (Request reprints of clinical literature at the following e-mail address: reimbursement@cookmedical.com

Please reconsider your coverage policy and/or denial of this procedure taking into account the information provided in this letter and the supporting literature supplements.

Sincerely,

<<insert physician's name>>







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SUR-BE-AFPCRG-EN-200805

