The information provided herein reflects Cook Medical’s understanding of the procedure(s) and/or devices(s) from sources that may include, but are not limited to, the CPT® coding system; 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 third party payers is solely responsible for the accuracy of the codes assigned to the services and items in the medical record. Cook Medical does not, and should not, have access to medical records, and therefore cannot recommend codes for specific cases. We encourage you, when making coding decisions, to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you may submit claims. Cook Medical does not promote the off-label use of its devices.

If you have any questions, please contact our reimbursement team at 800.468.1379 or by e-mail at reimbursement@cookmedical.com

### Physician Coding and Reimbursement

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Procedure Description</th>
<th>Global RVUs (Facility)</th>
<th>Global RVUs (Office)</th>
<th>Global Period (Days)</th>
<th>Fee When Service Is Provided in Hospital or ASC (National Medicare Avg.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>46707</td>
<td>Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])</td>
<td>13.77</td>
<td>N/A</td>
<td>90</td>
<td>$493.35</td>
</tr>
</tbody>
</table>

The American Medical Association (AMA) identified several procedures for which code +15777, “Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk)” should and should not be reported. Repair of anorectal fistula with plug has been identified as a procedure that should be reported with CPT code 46707 only. CPT code 46707 describes the work of inserting the anal fistula plug. Therefore, code +15777 should **NOT** be reported for the repair of anal fistulas with a plug.

### Facility Coding and Reimbursement

The use of the Biodesign Fistula Plug to treat anal fistulas 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 vs. hospital inpatient), and **b)** the payer (Medicare, commercial insurance plans, Medicaid, etc.). Following is a brief discussion of the current (2016) facility reimbursement environment for the Biodesign Fistula Plug.

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1 2016 Medicare Physician Fee Schedule
Medicare

Medicare pays hospital outpatient departments under the hospital Outpatient Prospective Payment System (OPPS). Medicare updates its list of “approved” procedures annually. Each of these procedures is assigned to an Ambulatory Payment Classification (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.

CPT code 46707, “Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS]),” is assigned to APC 5314, “Level IV Lower GI Procedures.” The current (2016) national average Medicare payment to hospital facilities for APC 5314 is $2,326.64 (the actual fee schedule amount varies from hospital to hospital, based on local wage indices, geographic location, etc.).

The American Medical Association (AMA) identified several procedures for which code +15777, “Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk)” should and should not be reported. Repair of anorectal fistula with plug has been identified as a procedure that should be reported with CPT code 46707 only. CPT code 46707 describes the work of inserting the anal fistula plug. Therefore, code +15777 should NOT be reported for the repair of anal fistulas with a plug.

If applicable, Medicare requires hospitals to report devices by using the Level II Healthcare Common Procedure Coding System (HCPCS) “C-code”. The American Hospital Association’s Central Office on HCPCS suggests using C1763, “Connective tissue, nonhuman” to describe the Biodesign Fistula Plug.

Please note the importance of submitting appropriate charges for this procedure; 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 OPPS 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 rate-setting and encourage them to include all appropriate charges on their Medicare claims.”

Note: Inclusion of a procedure on Medicare’s OPPS payment schedule does not guarantee Medicare coverage of the procedure.

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 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 fistulas using the Biodesign Fistula Plug.

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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 departments. Each ASC-approved procedure is assigned a payment rate much like for the outpatient payment system; however, reimbursement for ASC procedures reflects the reduced costs for providing care in this surgical setting.

CPT code 46707, “Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS]),” is approved in the ASC setting and has been assigned a national average Medicare payment level of $1,301.02.4

The American Medical Association (AMA) identified several procedures for which code +15777, "Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk)" should and should not be reported. Repair of anorectal fistula with plug has been identified as a procedure that should be reported with CPT code 46707 only. CPT code 46707 describes the work of inserting the anal fistula plug. Therefore, code +15777 should NOT be reported for the repair of anal fistulas with a plug.

Note: Inclusion of a procedure on Medicare’s list of ASC-approved procedures does not guarantee Medicare coverage of that procedure.

Commercial Insurance

Unlike Medicare, commercial insurers have not established a consistent national payment methodology, so arrangements between insurers and ASCs vary considerably. Because of this, it is not possible for Cook Medical 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 using the Biodesign Fistula Plug.

4 2016 Medicare Ambulatory Surgery Center Fee Schedule