OPTIMIZED PERFORMANCE

Spacemaker™ Pro
Access and Dissector System

*Compared to Spacemaker™ Plus device

Value Analysis Brief
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The Spacemaker™ Pro device from Medtronic is a next-generation, all-in-one access and dissector system for inguinal and abdominal wall repair. The system is optimized for access, dissection, and efficiency.

With a uniquely integrated solution that includes tailored cannulas and new anatomic balloons, the Spacemaker™ Pro device improves access, enhances visualization, and creates the desired space for each procedure. The device also saves steps in the OR, while offering more choice in technique.†,1,2

† Compared to Spacemaker™ Plus device or PDB distention balloons
**PRODUCT FEATURES & BENEFITS**

**OPTIMIZED ACCESS**
- Provides easier, one-time access to surgical space, with a uniquely integrated system†
- Offers ability to operate in small spaces, with included low-profile 5 mm optical trocars‡,§
- Expands access to eligible patients, with balloons not made with natural rubber latex†,§

**OPTIMIZED DISSECTION**
- Enhances visualization, with anatomic balloons and clear cannulas†,‡
- Creates the right space for each procedure, with new anatomic balloons
- Facilitates insertion and full balloon deployment, with tailored cannulas†,‡

**OPTIMIZED EFFICIENCY**
- Saves procedural steps with an integrated access and dissection solution†,‡
- Adapts to your technique, with the option to use as a system or separately†
- Offers more choice in technique, while reducing product codes by up to 50 percent†

† Compared to Spacemaker™ Plus device or PDB distention balloons
‡ Compared to Spacemaker™ Plus device
§ Compared to PDB distention balloons; trocar does not need to be reinserted or repositioned

Minimally Invasive Component Separation Technique (MICST)

Totally Extraperitoneal (TEP) Hernia Repair
PRODUCT CODE REDUCTION

SPACEMAKER™ PRO PRODUCT CODES

Reduced product codes by 50%

LEGACY CODES

Preperitoneal Distension Balloon
- OMSXB2
- OMSX81
- OMSPD852

Spacemaker™ Plus Dissection Balloon
- SMBTTOVL
- SMBTTRND

CURRENT CODES

Minimally Invasive Component Separation Technique (MICST)
- SMCYLCST

Totally Extraperitoneal (TEP) Hernia Repair
- SMBTTOVLX
- SMBTTRNDX
- SMSBTOVLX
- SMSBTRNDX
There are a total of five Spacemaker™ Pro device combinations:

Totally Extraperitoneal Procedure (TEP) Hernia Repair

SMBTTOVLX
Spacemaker™ Pro Blunt Tip Trocar (BTT) with Oval Dissection Balloon — 3 per box

SMSBTOVLX
Spacemaker™ Pro Structural Balloon Trocar (SBT) with Oval Dissection Balloon — 3 per box

SMBTTRNDX
Spacemaker™ Pro Blunt Tip Trocar (BTT) with Round Dissection Balloon — 3 per box

SMSBTRNDX
Spacemaker™ Pro Structural Balloon Trocar (SBT) with Round Dissection Balloon — 3 per box

SMCYLCST
Spacemaker™ Pro Blunt Tip Trocar with Cylindrical Dissection Balloon for Component Separation Technique — 3 per box

The package for each Spacemaker™ Pro product code contains:

- A dissection balloon
- A balloon trocar
- Two 5 mm low-profile optical trocars
- Endo-Lube™ solution
- Balloon inflation bulb
- Inflation syringe
- Accessory access cannula obturator*

* The extra access cannula obturator allows the balloon trocar and dissection balloon to be used separately, if such separate use is preferred by the surgeon due to patient structure or anatomy.

Minimally Invasive Component Separation Technique (MICST)
## Medicare National Average Rates and Allowables

### REIMBURSEMENT INFORMATION

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>PROCEDURE DESCRIPTION</th>
<th>PHYSICIAN **MPFS (CF=$35.887) FAC/ NON-FAC</th>
<th>APC CLASSIFICATION</th>
<th>APC DESCRIPTOR **APC RATE</th>
<th>AMBULATORY SURGICAL CENTER ***ASC</th>
</tr>
</thead>
<tbody>
<tr>
<td>15754</td>
<td>Muscle, myocutaneous, or fasciocutaneous flap, trunk</td>
<td>$1,562/$1,041</td>
<td>S005</td>
<td>Level 5 Skin &amp; Trunk</td>
<td>$2,505</td>
</tr>
<tr>
<td>39541</td>
<td>Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39543</td>
<td>Laparoscopy, surgical, repair, abdominal, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49550</td>
<td>Repair initial incisional or ventral hernia; reducible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49551</td>
<td>Repair initial incisional or ventral hernia; incarcerated or strangulated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49552</td>
<td>Repair recurrent incisional or ventral hernia; any</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49553</td>
<td>Repair initial incisional or ventral hernia; reducible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49554</td>
<td>Repair initial incisional or ventral hernia; incarcerated or strangulated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49555</td>
<td>Repair recurrent incisional or ventral hernia; reducible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>49556</td>
<td>Repair recurrent incisional or ventral hernia; incarcerated or strangulated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Codes supplied are for reference only, not intended as recommendation for use of this device. See IFU for device indications.
### Reimbursement Information

<table>
<thead>
<tr>
<th>CPT®/HCPCS Code</th>
<th>Procedure Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>49492</td>
<td>Repair, inguinal hernia, preterm infant younger than 37 weeks gestation at birth, not performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated</td>
<td>$994</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>Not reimbursed in ASC by Medicare</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT®/HCPCS Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>49495</td>
<td>Repair, inguinal hernia, full term infant younger than age 6 months, or preterm infant older than 50 weeks postconception age and younger than age 6 months at the time of surgery, with or without hydrocelectomy; reducible</td>
<td>$392</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>49496</td>
<td>Repair, inguinal hernia, full term infant younger than age 6 months, or preterm infant older than 50 weeks postconception age and younger than age 6 months at the time of surgery, with or without hydrocelectomy; incarcerated or strangulated</td>
<td>$522</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
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</thead>
<tbody>
<tr>
<td>49500</td>
<td>Repair, inguinal hernia, age 6 months to younger than 5 years, with or without hydrocelectomy; reducible</td>
<td>$406</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
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</thead>
<tbody>
<tr>
<td>49501</td>
<td>Repair, inguinal hernia, age 5 months to younger than 5 years, with or without hydrocelectomy; incarcerated or strangulated</td>
<td>$828</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
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</thead>
<tbody>
<tr>
<td>49505</td>
<td>Repair, inguinal hernia, age 5 months or older; reducible</td>
<td>$540</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
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</tr>
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<tbody>
<tr>
<td>49507</td>
<td>Repair, inguinal hernia, age 5 years or older; incarcerated or strangulated</td>
<td>$607</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
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<tbody>
<tr>
<td>49520</td>
<td>Repair, recurrent inguinal hernia, any age; reducible</td>
<td>$816</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
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<th><strong>APC Rate</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td>49521</td>
<td>Repair, recurrent inguinal hernia, any age; incarcerated or strangulated</td>
<td>$744</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
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</tr>
</thead>
<tbody>
<tr>
<td>49525</td>
<td>Repair, inguinal hernia, sliding, any age</td>
<td>$394</td>
<td>S34</td>
<td>Peritoneal &amp; Abdominal Procedures</td>
<td>$2,863</td>
<td>$1,455</td>
</tr>
</tbody>
</table>

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<th>AMBULATORY SURGICAL CENTER <em><strong>ASC</strong></em></th>
</tr>
</thead>
<tbody>
<tr>
<td>49530</td>
<td>Laparoscopy, surgical repair, initial inguinal hernia</td>
<td>$444</td>
<td>S36</td>
<td>Level 1 Laparoscopy</td>
<td>$4,199</td>
<td>$2,040</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>49531</td>
<td>Laparoscopy, surgical repair, recurrent inguinal hernia</td>
<td>$577</td>
<td>S36</td>
<td>Level 1 Laparoscopy</td>
<td>$4,199</td>
<td>$2,040</td>
</tr>
</tbody>
</table>

### Lumbar Hernia

<table>
<thead>
<tr>
<th>CPT®/HCPCS Code</th>
<th>Procedure Description</th>
<th><strong>MPFS (CF=535.887)</strong></th>
<th>APC Classification</th>
<th>APC Descriptor</th>
<th><strong>APC Rate</strong></th>
<th>AMBULATORY SURGICAL CENTER <em><strong>ASC</strong></em></th>
</tr>
</thead>
<tbody>
<tr>
<td>49540</td>
<td>Repair, lumbar hernia</td>
<td>$609</td>
<td>S36</td>
<td>Level 1 Laparoscopy</td>
<td>$4,199</td>
<td>$2,040</td>
</tr>
</tbody>
</table>

### MESH Implant Hernia

<table>
<thead>
<tr>
<th>CPT®/HCPCS Code</th>
<th>Procedure Description</th>
<th><strong>MPFS (CF=535.887)</strong></th>
<th>APC Classification</th>
<th>APC Descriptor</th>
<th><strong>APC Rate</strong></th>
<th>AMBULATORY SURGICAL CENTER <em><strong>ASC</strong></em></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;495581</td>
<td>Implantation of mesh or other prosthesis for open incisional or ventral hernia repair or mesh for closure of debridement for necrotizing soft tissue infection &amp; separately in addition to code for the incisional or ventral hernia repair)</td>
<td>$278</td>
<td>NA</td>
<td>NA</td>
<td>Packaged into Payment for Other Services</td>
<td>Package Service/Item</td>
</tr>
<tr>
<td>CPT®**/ ICD-10-CM</td>
<td>PROCEDURE DESCRIPTION</td>
<td>PHYSICIAN **MPFS (CF=$35.887)</td>
<td>APC CLASSIFICATION</td>
<td>APC DESCRIPTOR</td>
<td>APC RATE***ASC</td>
<td>AMBULATORY SURGICAL CENTER</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>43336</td>
<td>Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis</td>
<td>$1,570</td>
<td>Inpatient Procedures, not reimbursed in outpatient or ASC by Medicare</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43337</td>
<td>Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; with implantation of mesh or other prosthesis</td>
<td>$1,693</td>
<td>Inpatient Procedures, not reimbursed in outpatient or ASC by Medicare</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** NOTES: **

• Use 49568 in conjunction with 11004-11006, 49560-49566.

• S-Codes are not valid for Medicare payment

• Multiple Procedure Discounting – Multiple surgical procedures furnished during the same operative session are discounted. 50% is paid for any other surgical procedure(s) performed at the same time.

• MPFS Facility allowables and ASC rates include patient cost-sharing (coinsurance and deductibles). HCOPPS rates include patient cost-sharing (co-payments and deductibles). These amounts are national averages and are not adjusted for geography.

• All Medicare Physician Fee Schedules calculated using CF $35.887 effective January 1, 2017 - December 31, 2017. The new CF is reflected in the CY 2017 PFS Relative Value File (RVU17A) January 1, 2017. Update available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html

• The above National Average APC and ASC Rates represent the reimbursement amounts paid directly to the facility for the technical portion of the procedure. The Physician (surgeon) would separately receive the professional fee (MPFS Allowable) for the procedure performed.

** REFERENCES:**

• CMS 2016 Alpha Numeric HCPCS File Updated 11/5/2015

• PFS Relative Value Files - Centers for Medicare & Medicaid Services Value Files, RVU17A (1-1-17) effective January 2017

• CMS-1656-CN-FC Addendum A, B and C, January 3, 2017

• CMS-1656-FC ASC Addendum AA, BB, DD1, DD2 and EE, effective January 3, 2017

** REIMBURSEMENT INFORMATION:**

1. Codes are not valid for Medicare payment

2. Multiple Procedure Discounting – Multiple surgical procedures furnished during the same operative session are discounted. 50% is paid for any other surgical procedure(s) performed at the same time.

3. MPFS Facility allowables and ASC rates include patient cost-sharing (coinsurance and deductibles). HCOPPS rates include patient cost-sharing (co-payments and deductibles). These amounts are national averages and are not adjusted for geography.


5. The above National Average APC and ASC Rates represent the reimbursement amounts paid directly to the facility for the technical portion of the procedure. The Physician (surgeon) would separately receive the professional fee (MPFS Allowable) for the procedure performed.

6. NOTES:

   • Use 49568 in conjunction with 11004-11006, 49560-49566.
ICD-10 went into effect on October 1, 2015. ICD-10-PCS procedure codes are used by hospitals to report surgeries and procedures performed in the inpatient setting.

All ICD-10-PCS codes have seven digits, each digit representing a specific characteristic associated with procedures. Code assignment in ICD-10-PCS is a process of “constructing” the code by selecting values from a code table for each of the seven standard characters. The first three characters identify the code table that is used to complete the remaining four characters.

Hernia Repair

Note that different types of hernia may use the same ICD-10-PCS procedure code if the repair technique is the same. The type of hernia being repaired is determined by the ICD-10-CM diagnosis codes, not necessarily by the ICD-10-PCS procedure codes.

Abdominal Wall Repair

In general, abdominal wall repair uses the same coding principles and the same code values as hernia repair. An abdominal wall repair is differentiated from a hernia repair by the ICD-10-CM diagnosis codes, not necessarily by the ICD-10-PCS procedure codes.

Abdominal wall repair is not coded separately when an associated procedure is performed on an internal organ, because procedural steps differentiated from a hernia repair by the ICD-10-CM diagnosis codes, not necessarily by the ICD-10-PCS procedure codes.

Abdominal Wall Repair

<table>
<thead>
<tr>
<th>CHARACTER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>3: Section</td>
<td>Because hernia repair constitutes surgery, the appropriate section is D-Medical and Surgical.</td>
</tr>
<tr>
<td>2: Body System</td>
<td>Most hernias are assigned to the body system for Anatomical Regions, either W-Anatomical Regions, General (eg, umbilical hernia) or Y-Anatomical Regions, Lower Extremities (eg, inguinal hernia, femoral hernia). 2 Repair of diaphragmatic hernias is assigned to B-Respiratory System (eg, hiatal hernia) because the diaphragm is classified to this body system for coding purposes.</td>
</tr>
<tr>
<td>1: Root Operation</td>
<td>The two main root operations for hernia repair are Q-Repair; which is assigned when mesh is not used, and U-Substitute, which is assigned when mesh is used. Note that a code using root operation U-Substitute stands by itself as a hernia repair procedure and no additional code is required or assigned to capture the repair or use of mesh.</td>
</tr>
<tr>
<td>4: Body Part</td>
<td>On their given code tables, specific body part values are available for diaphragm, abdominal wall, inguinal region, femoral region, and other lower extremity areas.</td>
</tr>
<tr>
<td>5: Approach</td>
<td>Hernia repair performed by incising the tissue layers to expose the hernia sac uses O-Open. Laparoscopic hernia repair uses E-Peritoneal Endoscopic.</td>
</tr>
<tr>
<td>6: Device</td>
<td>For hernia repair without mesh, Z-No Device is used. For hernia repair with mesh, mesh is considered a device. There are three types of mesh: 1) Most mesh is made of synthetic materials such as polypropylene, polyester, and PTFE; 2) Some mesh is bioengineered from donated human tissue, such as from cadavers, and; 3) Some mesh is bioengineered from animal tissue such as bovine and porcine tissue (eg, PermacolTM Surgical Implant). Although there are three types of mesh, there are currently only two options for the device value. Synthetic meshes use J-Synthetic Substitute. Meshes made of other human and animal tissues currently use K-Nonauslogous Tissue.</td>
</tr>
<tr>
<td>7: Qualifier</td>
<td>Qualifiers add further information to the code but typically, Z-No Qualifier is used.</td>
</tr>
</tbody>
</table>

Abdominal Wall Repair

<table>
<thead>
<tr>
<th>CHARACTER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>2: Body System</td>
<td>Abdominal wound repair is coded to body system W-Anatomical Regions, General.</td>
</tr>
<tr>
<td>3: Section</td>
<td>The backbone root operations for abdominal wall repair are Q-Repair, which is assigned when mesh is not used, and U-Substitute, which is assigned when mesh is used.</td>
</tr>
<tr>
<td>5: Approach</td>
<td>Abdominal wall repair that involves closure of multiple layers below the skin uses O-Open.</td>
</tr>
<tr>
<td>6: Device</td>
<td>For abdominal wall repair without mesh, Z-No Device is used. For abdominal wall repair with mesh, either J-Synthetic Substitute or K-Nonauslogous Tissue is used.</td>
</tr>
</tbody>
</table>

NOTES
1. CMS ICD-10-PCS Official Guidelines for Coding and Reporting (Procedure), B3.1b
2. CMS ICD-10-PCS Reference Manual 2016, p. 69-70, 78. See also ICD-10-PCS Procedure Coding System (ICD-10-PCS) 2016 Tables and Index, ICD-10-PCS Definitions appendix II: 3-Medical and Surgical - Operation, Includes/Examples for root operation Supplement. 
5. Coding Clinic, 4th Q 2014, p. 37-58 
6. ICD-10-PCS Official Guidelines for Coding and Reporting (Procedure), B1.16. 
7. See AHIMA ICD-10-PCS: An Abridged Approach 2015, p. 150. Procedure Statement Coding Exercise 9. Also note that by definition, approach X-Exteranal is used for skin only. 

Component Separation

Component separation allows primary closure of large abdominal defects, by separating and releasing the fascial and muscle layers in the abdominal wall. When performed with hernia repair, it is coded separately. 

<table>
<thead>
<tr>
<th>CHARACTER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>2: Body System</td>
<td>Because component separation involves releasing muscles, the body system is K-Muscles.</td>
</tr>
<tr>
<td>3: Section</td>
<td>The root operation for component separation is N-Release.</td>
</tr>
<tr>
<td>4: Body Part</td>
<td>The body part is K-Abdomen Muscle, Right and L-Abdomen Muscle, Left. Release is performed on both sides of the abdomen so two codes are assigned, one with body part K and one with body part L.</td>
</tr>
</tbody>
</table>

NOTES
1. Coding Clinic, 4th Q 2014, p. 59-60. See also Coding Clinic, 4th Q 2013, p. 95-96 
2. Coding Clinic, 4th Q 2014, p. 59-60.

Adhesiolysis

Omental, intestinal and other abdominal adhesions may be found and/or released during hernia repair, particularly for incarcerated hernias. Lysis is typically not coded separately because it is considered an integral procedural step necessary to reach the operative site.10 As an exception, lysis of adhesions can be coded separately when the surgeon clearly documents its clinical significance in the operative report; for example if the adhesions are extensive and require tedious lysis.11 

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>2: Body System</td>
<td>For adhesiolysis in association with hernia repair, the body system is typically D-Gastrointestinal System.</td>
</tr>
<tr>
<td>3: Section</td>
<td>The root operation for adhesiolysis is N-Release.</td>
</tr>
<tr>
<td>4: Body Part</td>
<td>The body part value is coded according to the body part being cut, not the tissue being cut. For example, if adhesions are taken down to free the omentum from the abdominal wall, the body part is T-Greater Omentum. Similarly, if adhesions are taken down to free the jejunum, the body part is A-Jejunum.</td>
</tr>
</tbody>
</table>

NOTES
10. ICD-10-PCS Official Guidelines for Coding and Reporting (Procedure), B3.1b 
11. Coding Clinic, 1st Q 2014, p. 4-6 
12. ICD-10-PCS Procedure Coding System (ICD-10-PCS) 2016, p. 58. See also: Examples for root operation Release 

TRAM Flap

A transverse rectus abdominis myocutaneous flap is used to reconstruct the breast, typically after mastectomy for cancer or other disorders. A section of skin, fascia and muscle are harvested from the lower abdomen and, while maintaining an attachment to the lower abdomen for blood supply, advanced into place over the breast area to create a new breast mound. 

For reinforcement, mesh is often separately placed at the defect in the lower abdominal wall where the muscle was harvested. 

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>2: Body System</td>
<td>Because a TRAM flap involves abdominal muscles, the body system is K-Muscles.</td>
</tr>
<tr>
<td>3: Section</td>
<td>The root operation for TRAM flap is X-Transfer since the muscle is moved to another location and takes over function.</td>
</tr>
<tr>
<td>7: Qualifier</td>
<td>The qualifier E-Transverse Rectus Abdominis Myocutaneous Flap is defined specifically for TRAM and shows the tissue layers being transferred.</td>
</tr>
</tbody>
</table>

Notes:

19
PRODUCT REQUEST
AND/OR STOCKING FORM

I am requesting the following instruments be stocked in our facility so that I have consistent access to these devices for my cases:

- SMBTTOVLX Spacemaker™ Pro Blunt Tip Trocar (BTT) with Oval Dissection Balloon – 3 per box
- SMBTTRNDX Spacemaker™ Pro Blunt Tip Trocar (BTT) with Round Dissection Balloon – 3 per box
- SMBSTOVLX Spacemaker™ Pro Structural Baloou Trocar (SBT) with Oval Dissection Balloon – 3 per box
- SMBSTTRNDX Spacemaker™ Pro Structural Baloou Trocar (SBT) with Round Dissection Balloon – 3 per box
- SMCYLCST Spacemaker™ Pro Blunt Tip Trocar with Cylindrical Dissection Balloon for Component Separation Technique – 3 per box

The Spacemaker™ Pro device from Medtronic is a next-generation, all-in-one access and dissector system for inguinal and abdominal wall repair. The system is optimized for access, dissection, and efficiency.

Optimized Access
- Provides easier, one-time access to surgical space, with a uniquely integrated system
- Offers ability to operate in small spaces, with included low-profile 5 mm optical trocars
- Expands access to eligible patients, with balloons not made with natural rubber latex

Optimized Dissection
- Enhances visualization, with anatomic balloons and clear cannulas
- Creates the right space for each procedure, with new anatomic balloons
- Facilitates insertion and full balloon deployment, with tailored cannulas

Optimized Efficiency
- Saves procedural steps with an integrated access and dissection solution
- Adapts to your technique, with the option to use as a system or separately
- Offers more choice in technique, while reducing product costs by up to 50%

Thank you for reviewing this information. Please feel free to ask me if you have any questions.

Sincerely,

[1] Compared to Spacemaker™ Plus device or PDB distention balloons
[2] Compared to Spacemaker™ Plus device
[3] Compared to PDB distention balloons; trocar does not need to be reinserted or repositioned

INSTRUCTIONS FOR USE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION
The Spacemaker™ Pro access and dissection system consists of combinations of three dissectors and two balloon access devices integrated into a single, modular device. There are a total of five Spacemaker™ Pro device combinations:

1. Blunt tip trocar (BTT) with round dissection balloon
2. Blunt tip trocar (BTT) with oval dissection balloon
3. Structural balloon trocar (SBT) with cylindrical dissection balloon
4. Structural balloon trocar (SBT) with round dissection balloon
5. Structural balloon trocar (SBT) with oval dissection balloon

Each combination also includes two Hansaption trocars for use during the laparoscopic procedure. Please refer to the separate instructions for use for the Hansaption trocar device.

The access devices are available in two configurations: a blunt tip trocar with a round dissection balloon and a blunt tip trocar with an oval dissection balloon.

The access devices body assembly contains an internal 10/12 mm valve which prevents gas leakage when there is no instrument in place or in non-appropriately sized instruments are mounted into the trocar sleeve. There is unique attached to the body of the device allowing for insertion and full balloon deployment, with tailored cannulas.

CONTRAINDICATIONS
- The access device’s body assembly contains an internal 10/12 mm valve which prevents gas leakage when there is no instrument in place or in non-appropriately sized instruments are mounted into the trocar sleeve.
- The device is provided STERILE and is intended for use in a single procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.
- Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques.
- The Spacemaker™ Pro access and dissection system consists of combinations of three dissectors and two balloon access devices integrated into a single, modular device. There are a total of five Spacemaker™ Pro device combinations:

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INFORMATION

1. Apply Endo-Lube™ solution to access cannula seal, dissection balloon, or the accessory obturator.
2. Over inflation of the Spacemaker™ Pro structural balloon trocar may cause the balloon to rupture. Do not exceed 40 pumps.
3. Over inflation of the dissection balloon may cause the balloon to rupture. Do not exceed 40 pumps.
4. Over inflation of the Spacemaker™ Pro structural balloon trocar may result in balloon rupture. Do not exceed the recommended fill volume.

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WARRIORS AND PRECAUTIONS
- Comply with the manufacturer’s instructions for use when troubleshooting techniques are contraindicated.
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J) CO₂ INLET PORT – Stopcock in line with insufflation line to allow insufflation

CAUTION: Care must be exercised during manipulation of the balloon as it is advancing through the source of the procedure to avoid damaging the balloon with other instruments.

NOTE: The deflation nozzle of the bulb is in line with the dissection balloon when the stopcock lever on the inlet port faces the insufflation line. Gas leakage is prevented. When the stopcock lever on the inlet port faces the opposite side of the insufflation line, CO₂ desufflation is enabled. Insert the stopcock lever into the opposite side of the insufflation line, CO₂ desufflation is enabled. When the stopcock lever on the inlet port faces the insufflation line, CO₂ leakage is prevented. CO₂ inflation is initiated by turning the stopcock lever so that the CO₂ balloon is exposed to the air.

11. If necessary (depending on patient structure) squeeze the tabs (H) on the dissector to release the dissection balloon until it reaches a positive stop. When the incremental access cannula obturator balloon is inflated, the tissue down to the desired tissue plane.

12. Cannula balloon inflation

CAUTION: It is important to monitor the inflation and adjust based on patient anatomy.

13. While maintaining the position of the access cannula, squeeze the tabs to release the dissection balloon. Keep the handle connected (H) to the insufflation port. When the access cannula obturator balloon has inflated, remove the Spacemaker™ Pro obturator balloon from the incision until it reaches a positive stop.

14. Inversion of the secondary trocars should be avoided under direct vision. Care should be taken to avoid damaging the balloon with secondary trocars or other instruments.

NOTE: Inserting trocars into the Spacemaker™ Pro system may cause trauma to the patient. Do not insert trocars into the Spacemaker™ Pro system.

15. Insert the cannula balloon inflation valve (I) into the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.

16. Insertions of the secondary trocars should be avoided under direct vision. Care should be taken to avoid damaging the balloon with secondary trocars or other instruments.

NOTE: When the stopcock lever on the inlet port faces the insufflation line, CO₂ leakage is prevented. When the stopcock lever on the inlet port faces the opposite side of the insufflation line, CO₂ inflation is initiated. The stopcock lever is in line with the insufflation line, CO₂ leakage is prevented. CO₂ inflation is initiated by turning the stopcock lever so that the CO₂ balloon is exposed to the air.

CAUTION: Over inflation of the dissector balloon may cause tissue damage or may not be injurious to tissue.

10. Once the extraperitoneal space is adequately dissected, deflate the dissection balloon by removing the inflation bulb from the dissector.

9. Connect the inflation bulb to the dissection balloon inflation valve.

8. Insert the 10mm endoscope into the dissection balloon to visualize inflation and dissection. To use the 5mm scope, attach the 5mm reducer (K) by pushing the cap over the main seal on the dissection balloon until it reaches a positive stop.

7. With the inflation bulb attached to the dissection balloon inflation valve, squeeze the inflation bulb to elevate the balloon. Monitor the inflation and adjust based on patient anatomy.

6. Endoscope

5. OBTURATOR LOCKING LATCH ABS

4. Inserting trocars into the Spacemaker™ Pro system may cause trauma to the patient. Do not insert trocars into the Spacemaker™ Pro system.

3. Cannula balloon inflation valve

2. Insert the access cannula into the incision and advance until the distal portion, including the entire anchoring balloon, has advanced to the space.

1a. Remove the dissector cannula (C) from the incision.

1b. Insert the accessory access cannula obturator (D) into the access port.

1c. Attach the 5mm reducer (K) to the trocar sleeve.

1d. Insert the cannula balloon inflation valve (I) into the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.

H) DISSECTOR LOCKING LATCH ABS

G) DISSECTION BALLOON INFLATION VALVE

F) INFLATION BULB

E) ENDOSCOPE

D) OBTURATOR LOCKING LATCH ABS

B) ACCESS CANNULA (BTT or SBT )

I) CANNULA BALLOON INFLATION VALVE

a) Inflate the blunt tip trocar balloon by inserting the included syringe in the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.

3. Insert the cannula balloon inflation valve (I) into the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.

2. Insert the access cannula into the incision and advance until the distal portion, including the entire anchoring balloon, has advanced to the space.

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E) ENDOSCOPE

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B) ACCESS CANNULA (BTT or SBT )

I) CANNULA BALLOON INFLATION VALVE

a) Inflate the blunt tip trocar balloon by inserting the included syringe in the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.

With the access cannula and cannula balloon inflation valve, squeeze the inflation bulb to initiate balloon inflation. Monitor the dissection balloon via the endoscope.

NOTE: When the access cannula obturator balloon is inflated, the tissue down to the desired tissue plane.

1a. Remove the dissector cannula (C) from the incision.

1b. Insert the accessory access cannula obturator (D) into the access port.

1c. Attach the 5mm reducer (K) to the trocar sleeve.

1d. Insert the cannula balloon inflation valve (I) into the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.

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With the access cannula obturator balloon is inflated, the tissue down to the desired tissue plane.

1a. Remove the dissector cannula (C) from the incision.

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1d. Insert the cannula balloon inflation valve (I) into the cannula balloon inflation valve. The capacity of the structural balloon trocar is 120cc’s.
Page 2 – Ms. Rebecca Magannino

forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportProblems/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson – S

For Bunis S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
DRG Assignment FY2017 — effective January 1, 2017

Under Medicare’s MS-DRG methodology for hospital inpatient payment, each inpatient stay is assigned to one of about 750 diagnosis-related groups, based on the ICD-10 codes assigned to the diagnoses and procedures. Each MS-DRG has a relative weight that is then converted to a per diem rate of payment for each stay. The per diem rate is determined by the relative weight of the DRG and the wage index for the geographic locality where the hospital is located. The wage index is calculated based on the average labor costs in the hospital market. The wage index is used to adjust the per diem rate for each stay to reflect the average labor costs in the hospital market. The per diem rate is then adjusted by the Wage Index for specific geographic locations. Therefore, payment for a specific hospital will vary from the stated Medicare national average payment levels shown. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.

CPT is a registered trademark of the American Medical Association. This information is for educational purposes only and is not intended to serve as reimbursement advice. It is published in publications such as AMA HCPCS Level II, CPT publications or insurer policies for selecting codes based on the care rendered to an individual patient, and may wish to contact provider’s association for a list of other resources. Providers should refer to current, complete, and authoritative publications to select the appropriate codes for a procedure. Providers may wish to contact their local Medicare carrier to review their local payment policies to ensure that the codes selected are appropriate.

Notes:
16. WICC in MS-DRGs refers to secondary diagnosis codes that are major complications or comorbidities. MS-DRGs w/MCC have at least one major secondary complication or comorbidity. Similarly, W CC in MS-DRGs refers to secondary diagnosis codes that are major complications or comorbidities, and MS-DRGs W CC have at least one non-major (i.e., secondary) complication or comorbidity. MS-DRGs W/O CC/MCC have no secondary diagnoses that are complications or comorbidities, major or otherwise. Note that some secondary diagnoses are only designated as CCOs or MCCs when the conditions were present on admission and do not count as CCOs or MCCs when the conditions are acquired in the hospital during the stay.
17. Post-Acute Care Transfer (PACT) status refers to select DRGs in which payment to the hospital may be reduced when the patient is discharged to a post-acute care provider. The DRGs impacted are those marked “Yes” and the patient must be transferred out before the geometric mean length of stay to certain post-acute care providers, including rehabilitation hospitals, long-term care hospitals, skilled nursing facilities, or to homes under the care of a home health agency. When these conditions are met, the DRG payment is converted to a per diem and payment is made as double the per diem rate for the first day plus the per diem rate for each remaining day up to the full DRG payment.
18. Payment is based on the average standardized operating amount ($5,316.15) plus the capital standard amount ($649.79) for Medicare for End Stage Renal Disease (E SRD). Published August 22, 2016.
19. When lysis of adhesions is coded separately with hernia repair, e.g., when the surgeon documents its clinical significance, the code for adhesiolysis takes precedence over the code for hernia repair in DRG assignment logic. So the Adhesiolysis DRGs 335-337 are assigned, rather than the Hernia DRGs 350-355.
20. When placement of mesh at the abdominal wall defect is coded separately with TRAM flap, the code for TRAM flap takes precedence in DRG assignment logic and broad Hernia DRGs 350-355 are assigned.
21. The DRGs shown are assigned when repair of the abdominal wall injury is the most significant procedure. If other more significant procedures for injury are also performed, e.g., repair of hip fracture, those procedures will typically take precedence in DRG assignment logic.
22. Claims in the materials published by the Centers for Medicare and Medicaid Services and the American Medical Association may be helpful to providers in staying up to date on coding and billing of services. This information cannot guarantee coverage or reimbursement, and Medtronic does not make any other representations as to selecting codes for services rendered. This information is for educational purposes only and is not intended to serve as reimbursement advice. It is published in publications such as AMA HCPCS Level II, CPT publications or insurer policies for selecting codes based on the care rendered to an individual patient, and may wish to consult provider’s association for a list of other resources. Providers should refer to current, complete, and authoritative publications to select the appropriate codes for a procedure. Providers may wish to contact their local Medicare carrier to review their local payment policies to ensure that the codes selected are appropriate.
References
1. Based on internal test report #RE00010041, Spacemaker ™ Pro Design Verification Report. April 2015
2. Based on internal test report #RE00013395, Spacemaker ™ Pro Validation Report. April 7-9, 2015.