OPTIMIZED PERFORMANCE

Spacemaker™ Pro
Access and Dissector System

*Compared to Spacemaker™ Plus device

Value Analysis Brief
# TABLE OF CONTENTS

- PRODUCT INTRODUCTION 4
- PRODUCT FEATURES & BENEFITS 6
- PRODUCT CODE REDUCTION 8
- PACKAGING & ORDER CODES 10
- PRODUCT REQUEST AND/OR STOCKING FORM 12
- 510(K) CLEARANCE 13
- REIMBURSEMENT INFORMATION 15
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\textsuperscript{1,3,†}
• Offers ability to operate in small spaces, with included low-profile 5 mm optical trocars\textsuperscript{1,5,†}
• Expands access to eligible patients, with balloons not made with natural rubber latex\textsuperscript{1,3,†}

OPTIMIZED DISSECTION

• Enhances visualization, with anatomic balloons and clear cannulas\textsuperscript{1,2,†}
• Creates the right space for each procedure, with new anatomic balloons\textsuperscript{1,2}
• Facilitates insertion and full balloon deployment, with tailored cannulas\textsuperscript{1,2}

Totally Extraperitoneal (TEP) Hernia Repair

Minimally Invasive Component Separation Technique (MICST)
OPTIMIZED EFFICIENCY

- Saves procedural steps with an integrated access and dissection solution\(^1,2,3\).
- Adapts to your technique, with the option to use as a system or separately\(^1,2\).
- Offers more choice in technique, while reducing product codes by up to 50 percent\(^1\).

\(^1\) 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
PRODUCT CODE REDUCTION

LEGACY CODES

Preperitoneal Distension Balloon
- OMSXB2
- OMSXB1
- OMSPDBS2
- OMSPDB1000
- OMST10BT
- OMSST10SB

Spacemaker™ Plus Dissection Balloon
- SMBTTOVL
- SMBTRND
- SMSBTOVL
- SMSBTRND
SPACEMAKER™ PRO
PRODUCT CODES

Reduced product codes by 50%

CURRENT CODES

Minimally Invasive Component Separation Technique (MICST)
  • SMCYLCST

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

**Totally Extraperitoneal Procedure (TEP) Hernia Repair**

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

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

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

4. **SMBSTRNDX**
   Spacemaker™ Pro Structural Balloon Trocar (SBT) with Round Dissection Balloon — 3 per box

**Minimally Invasive Component Separation Technique (MICST)**

5. **SMCYLCST**
   Spacemaker™ Pro Blunt Tip Trocar with Cylindrical Dissection Balloon for Component Separation Technique — 3 per box
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
- SMSBTOVLX Spacemaker™ Pro Structural Balloon Trocar (SBT) with Oval Dissection Balloon – 3 per box
- SMSBTRNDX Spacemaker™ Pro Structural Balloon Trocar (SBT) with Round Dissection Balloon – 3 per box
- SCYLCST 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 codes by up to 50%

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

Sincerely,
Covidien LLC  
Ms. Rebecca Magnanimo  
Regulatory Affairs Product Specialist  
60 Middletown Avenue  
North Haven, Connecticut 06473  

June 18, 2015  

Re: K151356  
Trade/Device Name: Spacemaker™ Pro Access and Dissector System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: GCJ  
Dated: May 18, 2015  
Received: May 20, 2015  

Dear Ms. Magnanimo:  

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.  

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.  

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set
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/ReportAProblem/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 Binita 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
HERNIA CARE

Our comprehensive product portfolio can enhance your hernia repair procedures.

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

Please visit http://medtronic.com/surgical-reimbursement for reimbursement information.

For more information, contact your Medtronic representative or visit medtronic.com/spacemakerpro

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.

© 2019 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further. Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.

555 Long Wharf Drive 800.722.8772
New Haven, CT 06511 508.261.8000