Tactra™ Malleable Penile Prosthesis
Tactra™ Penile Prosthesis

The next generation malleable prosthesis with enhanced ease of implant and designed for durability, offering both excellent rigidity and dependable concealment in a device that is natural to the touch.
Customer Insights Drive Design Requirements

Natural Feeling
Proprietary dual-layer silicone construction for an authentic, natural feel

Patient Comfort & Concealability
Soft, rounded silicone distal tips designed to provide maximum patient comfort and satisfaction
Articulating flex zone for concealability

Rigidity & Durability
Dynamic Nitinol core provides optimal rigidity and durability

Simplicity & Ease of Implantation
Cut to length sizing, single box configuration containing implants and RTEs
Ease of implantation through multiple surgical approaches
Natural Feeling & Patient Comfort

- Proprietary dual-layer silicone construction for authentic, natural feel
- Soft, rounded silicone distal tips designed to provide maximum patient comfort and satisfaction
- Articulating flex zone for concealability when the device is not in use
Optimal Rigidity, Durability & Concealability

- Dynamic Nitinol core for optimal rigidity and durability
- 4X the required axial rigidity for intercourse$^{1,2}$
- Articulating flex zone for concealability
- Device cycling test requirements:$^1$
  - Cylinders must cycle from 0 to 90° bend under the following conditions:
    - Normal: 50,000 cycles, equivalent to 10-year life
    - Challenge: 100,000 cycles, equivalent to 2X 10-year life
  - Tactra™ Penile Prosthesis met and exceeded the required cycling requirements
  - Device was X-rayed to confirm no material fatigue

DEVICE ANGLE 0° - 90° STATIC
(DYNAMIC 100,000 CYCLES WET)
Simplicity & Ease of Implantation

Simplicity:
• Simplified sizing to address the widest spectrum of patient anatomy
• Consolidated device packaging configuration to minimize shelf space and allow greater accessibility for emergent cases

Ease of Implantation:
• Laser etched markings to aid in appropriate device measuring
• Insertion-fit Rear Tip Extenders (RTEs) for a secure connection and stable foundation¹
Effectively Treat Appropriate Penile Implant Patients with Tactra™ Penile Prosthesis

Patients with Erectile Dysfunction (Impotence) Suitable for Tactra™ Penile Prosthesis

- **Dexterity concerns**
  - Arthritis
  - Peripheral neuropathy
  - Amputated digits
- **Patients with hostile abdomen**
  - Prior pelvic surgery
  - Bilateral hernia mesh
- **Radical pelvic surgery**
  - Radical Prostatectomy
  - Cystectomy
- **Emergent cases (ED due to priapism)**
- **Interim treatment to an IPP**

- **Neurological conditions**
  - Spinal cord injury patients
  - Younger patients with neuromuscular disease such as ALS, Multiple Sclerosis
  - Stroke patients
- **Patients who want simplicity and ease of use**
  - Patients who are adverse to having IPP

“I never really thought about malleables, but talking about Tactra I can see some patients in my practice that want to be sexually active and could benefit from this device”
- D. Tortorelis, MD, at SMSNA 2018
Delivers Potential Economic Benefits to Institutions

The Tactra Penile Prosthesis enhancements help improve the “ease of implantation” and efficiency of the procedure by reducing OR time and intended to improve patient outcomes.

Delivers Potential Clinical Benefits for Physicians and Patients

The Tactra Penile Prosthesis offers the opportunity to treat more men who are candidates for a penile implant.

Delivers Potential Operational Benefits to Institutions

By simplifying the size offerings and device packaging configuration, the Tactra Penile Prosthesis offers operational and inventory management efficiencies.
<table>
<thead>
<tr>
<th>Is this product FDA cleared for intended use:</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device classification name:</td>
<td>Malleable Penile Implant</td>
</tr>
<tr>
<td>Trade/device name:</td>
<td>Tactra™ Malleable Penile Prosthesis</td>
</tr>
<tr>
<td>Intended use:</td>
<td>The Tactra Penile Prosthesis is intended for use in the treatment of erectile dysfunction (impotence) by subcoronal or penoscrotal device placement.</td>
</tr>
<tr>
<td>Regulation number:</td>
<td>21 CFR 876.3630</td>
</tr>
<tr>
<td>FDA classification:</td>
<td>II</td>
</tr>
<tr>
<td>Clearance date:</td>
<td>April 16, 2019</td>
</tr>
</tbody>
</table>
# Procedural Codes for Tactra™ Penile Prosthesis

<table>
<thead>
<tr>
<th>Procedural Codes</th>
<th>Tactra Penile Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT® Code:</strong></td>
<td></td>
</tr>
<tr>
<td>S4400</td>
<td>Insertion penile prosthesis; non-inflatable (semi-rigid)</td>
</tr>
<tr>
<td>S4416</td>
<td>Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session</td>
</tr>
<tr>
<td><strong>ICD-10 Procedure Code:</strong></td>
<td></td>
</tr>
<tr>
<td>0VUS0JZ</td>
<td>Supplement Penis with Synthetic Substitute, Open Approach</td>
</tr>
<tr>
<td>0VPS0JZ</td>
<td>Removal of Synthetic Substitute from Penis, Open Approach</td>
</tr>
<tr>
<td>0VUS0JZ</td>
<td>Supplement Penis with Synthetic Substitute, Open Approach</td>
</tr>
</tbody>
</table>

*Please refer to the Tactra Penile Prosthesis Product VAC Guide for the full list of ICD-10 Diagnosis Codes*
## Tactra™ Penile Prosthesis Ordering Information

<table>
<thead>
<tr>
<th></th>
<th>UPN</th>
<th>GTIN Number</th>
<th>Description</th>
<th>Size (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>720080-01</td>
<td>08714729979340</td>
<td>Malleable Penile Prosthesis</td>
<td>9.5mm x 14cm – 23cm</td>
</tr>
<tr>
<td></td>
<td>720081-01</td>
<td>08714729979357</td>
<td>Malleable Penile Prosthesis</td>
<td>11mm x 16cm – 25cm</td>
</tr>
<tr>
<td></td>
<td>720082-01</td>
<td>08714729979364</td>
<td>Malleable Penile Prosthesis</td>
<td>13mm x 18cm – 27cm</td>
</tr>
</tbody>
</table>

**NOTE:** no orders shall be taken until after FDA clearance.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

The Tactra™ Malleable Penile Prosthesis is intended for use in the treatment of erectile dysfunction (impotence) in adult males. Implanting a penile prosthesis will damage or destroy any remaining natural ability to have a spontaneous erection, as well as make other treatment options impossible. Men with diabetes, spinal cord injuries, or skin infections may have an increased risk of infection. Implantation may result in penile shortening, curvature or scarring.

Potential adverse events may include device malfunction/failure leading to additional surgery, device/tissue erosion, infection, and pain/soreness. MH-611819-AA

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider’s responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider’s responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD) and any other coverage requirements established by relevant payers which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters.

All images are the property of Boston Scientific.
All trademarks are the property of their respective owners.
©2019 by Boston Scientific Corporation or its affiliates. All rights reserved. MH618708-AA APR 2019