Boston Scientific

Advancing science for life™

# Tactra™ Malleable Penile Prosthesis

# Contents



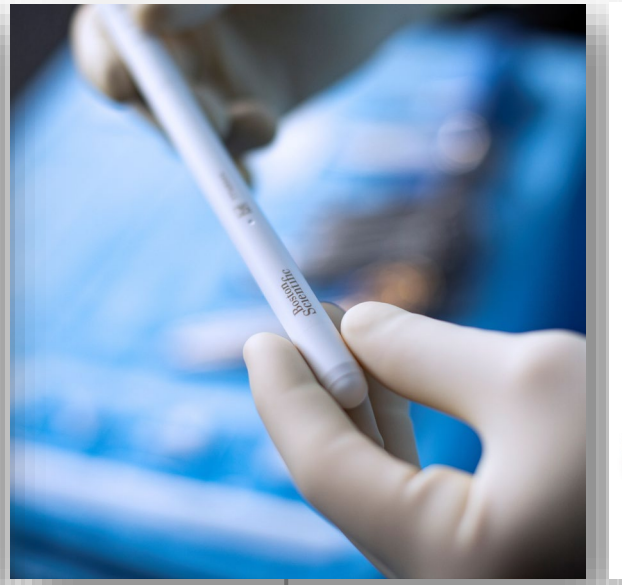
# Tactra™ Penile Prosthesis

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

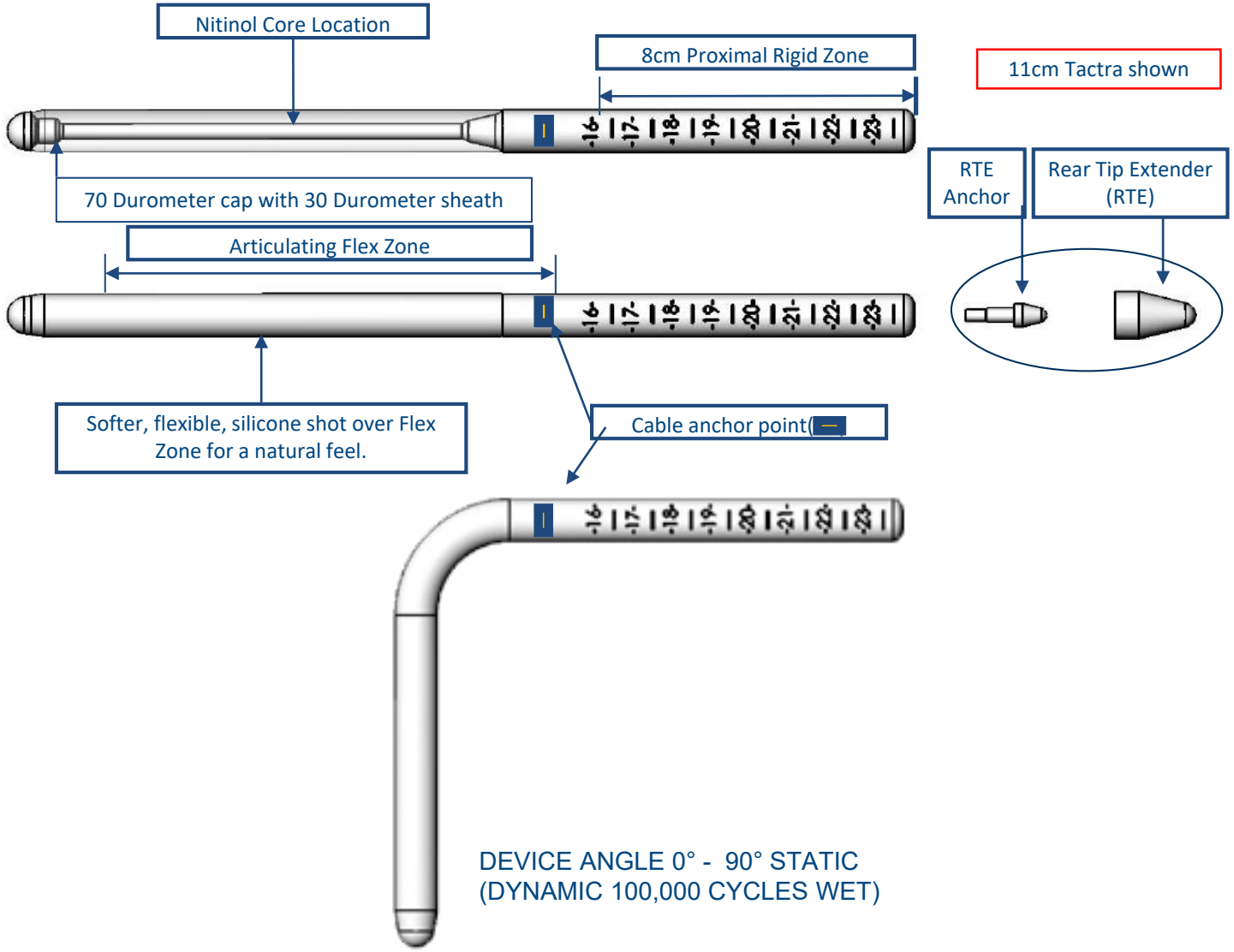
Ease of implantation through multiple surgical approaches

# 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



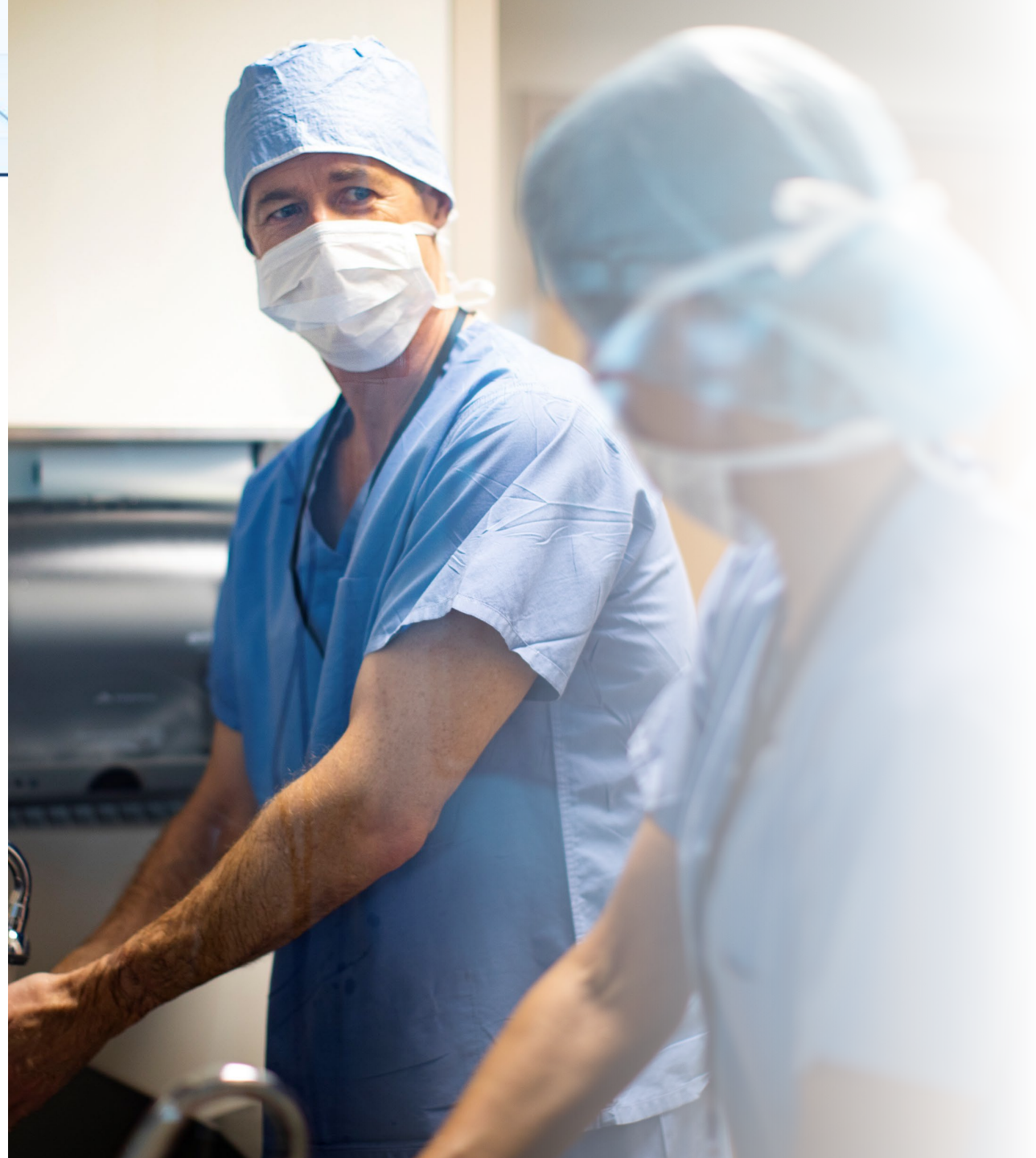
# Simplicity & Ease of Implantation

**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 foundation[1]

# 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

# Tactra™ Malleable Penile Prosthesis – The Natural Choice

## 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

# Tactra™ Penile Prosthesis Regulatory Information

| | |
|---|---|
| Is this product FDA cleared for intended use: | Yes |
| Device classification name: | Malleable Penile Implant |
| Trade/device name: | Tactra™ Malleable Penile Prosthesis |
| Intended use: | The Tactra Penile Prosthesis is intended for use in the treatment of erectile dysfunction (impotence) by subcoronal or penoscrotal device placement. |
| Regulation number: | 21 CFR 876.3630 |
| FDA classification: | II |
| Clearance date: | April 16, 2019 |

# Tactra™ Penile Prosthesis Reimbursement

| Procedural Codes | Tactra Penile Prosthesis |
|---|---|
| CPT® Code: | |
| 54400 | Insertion penile prosthesis; non-inflatable (semi-rigid) |
| 54416 | Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session |
| | |
| ICD-10 Procedure Code: | |
| 0VUS0JZ | Supplement Penis with Synthetic Substitute, Open Approach |
| 0VPS0JZ | Removal of Synthetic Substitute from Penis, Open Approach |
| 0VUS0JZ | Supplement Penis with Synthetic Substitute, Open Approach |

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

# Tactra™ Penile Prosthesis Ordering Information

| UPN | 720080-01 | 720081-01 | 720082-01 |
|---|---|---|---|
| GTIN Number | 08714729979340 | 08714729979357 | 08714729979364 |
| Description | Malleable Penile Prosthesis | Malleable Penile Prosthesis | Malleable Penile Prosthesis |
| Size (cm) | 9.5mm x 14cm – 23cm | 11mm x 16cm – 25cm | 13mm x 18cm – 27cm |

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

1. Data on file with Boston Scientific.
2. Al Ansari, A, Talib RA, Canguven O, et al. Axial penile rigidity influences patient and partner satisfaction after penile prosthesis implantation. *Arch Ital Urol Androl*. 2013 Sep 26;85(3):138-42

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

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