Boston Scientific
Advancing science for life™

Tactra™ Malleable Penile Prosthesis

Offered in three size ranges:
9.5 mm diameter width x 14 cm – 23 cm length
11 mm diameter width x 16 cm – 25 cm length
13 mm diameter width x 18 cm – 27 cm length

General Information

Name of Product: Tactra Malleable Penile Prosthesis

Product Description: Malleable Penile Prosthesis

Manufacturer: Boston Scientific

Manufacturer Federal Tax ID: 04-269-5240

Supplement/Replace current in-house products: Yes

Clinical Improvements

Tactra Penile Prosthesis is the next-generation malleable prosthesis with enhanced ease of implant. It is designed for durability, offering both excellent rigidity and dependable concealment in a device that is natural to the touch.

Regulatory

Is this product FDA cleared for this intended use? FDA cleared

What Class of device under the FDA is this considered? IIB

Does the product/device have an FDA investigational device exemption (IDE)? No

Utilization

Is this item/technology on contract with GPOs and/or IDNs?
Please speak to your Boston Scientific Sales Representative for the contract status of specific GPOs and IDNs

Ship unit: Each

Mode of transportation: FedEx™ Delivery

Lead time in working days? 2 days

What are the dimensions of the package? 1.19 x 12.39 x 5.19" – Cardboard Box

Method of purchase: Direct purchase or bill upon use

Does this item require special storage considerations?
Per the DFU, store in a clean, dry, dark area at room temperature.

Is this a dated product? Product contains expiration date on package label.

What specific departments/clinical areas will use the product/procedure?
Urology Operating Room (OR)

What department(s) will use and/or be affected by this product?
Urology OR, and Purchasing

Is there a requirement for staff training? No

Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space? No

Does the product/procedure require a company representative to be present to operate equipment or to provide assistance to the physicians?
Per institution's penile implant procedure protocol

Is there any other equipment involved with the use of this product that will need to be leased, purchased, consigned or rented? No

What is the average length of procedure time to use this product/perform this procedure (surgery minutes)? 60 minutes

Will this equipment interface with any other equipment/supplies currently utilized at this facility? Yes, penile implant procedure instruments

Material/Environment

Does this product contain metal substances that may affect tests and or procedures performed on patients? No

If yes, is this product MRI safe? MRI conditional, refer to the DFU for further description.

Is this considered an implantable device? Yes

Does this item and its packaging contain latex? No

Is this a pharmaceutical or contain any pharmaceutical product? No

Does the product require a Material Safety Data Sheet? No

Is this product reusable? No

What additional waste or recycle costs are anticipated? After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

Does the product contain:
Mercury? No
PVC? No

Halogenated flame retardants/halogenated organic chemicals (HOCs)? No

UPN	720080-01	720081-01	720082-01
GTIN Number	08714729979340	08714729979357	08714729979364
Catalog Number	720080-01	720081-01	720082-01
Product Name	Tactra Malleable Penile Prosthesis	Tactra Malleable Penile Prosthesis	Tactra Malleable Penile Prosthesis
Product 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

Reimbursement

Is this product reimbursable by insurance? The procedures for which it is used are reimbursable when deemed medically necessary. For additional coding and reimbursement information, contact your local Territory Manager or the Urology and Pelvic Health Reimbursement Help Desk at 866-367-2796.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)? C-Codes are tracking codes established by the Centers for Medicare & Medicaid Services (CMS) to assist Medicare in establishing future APC payment rates. C-Codes only apply to Medicare hospital outpatient claims. They do not trigger additional payment to the facility. The C-code for this product is C2622.

Is this a patient-chargeable product? "Patient chargeable" is a colloquial term used to convey that a device/supply is appropriately charged to the patient's account (i.e., as a distinct line item on the patient's claim) in the hospital/facility's patient accounting or AR system. It does not mean that the patient is actually charged directly for the device/supply nor would an insured patient ever pay an additional amount "out of pocket" for the device/supply. The fact that a hospital/facility chooses to designate certain devices/supplies (e.g., single-use devices) as "patient chargeable" will not in and of itself result in immediate increased reimbursement for the hospital/facility. It will allow CMS to better factor the true cost of the procedure into future Medicare reimbursement rate setting. It may also help in negotiations with private payers by more clearly demonstrating novel device costs that have been introduced to a procedure.

The designation of a given device/supply as "patient chargeable" is entirely up to the discretion and policy of the individual hospital/facility. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g., operating room) does not specifically address which items are part of the basic (routine) charge and which are charged in addition to the basic charge (non-routine). Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific device/supply or alternatively incorporate it into overhead (e.g., via the OR charge).

However, Medicare does require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

The appropriate Revenue Code is 272 – Medical/Surgical Supplies and Devices-Sterile Supply.

Relevant Reimbursement Codes: Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

The coding information listed within this guide have been included solely for informational purposes only. It is not intended to imply, promote, or guarantee coverage and/or payment from a payer. The Health Care Provider (HCP) is solely responsible for selecting and accurately reporting coding based on the patient's medical condition and the treatment needs of that patient, and the independent medical judgment of the HCP.

Procedure Name	Malleable Penile Implant	Malleable Penile Implant Removal and Replacement
CPT Code	54400	54416
CPT Code Description	Insertion penile prosthesis; non-inflatable (semi-rigid)	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
ICD-10 Diagnosis Code	**F52.21** Male erectile disorder **N52.01** Erectile dysfunction due to arterial insufficiency **N52.02** Corporo-venous occlusive erectile dysfunction **N52.03** Combined arterial insufficiency and corporo-venous occlusive erectile dysfunction **N52.2** Drug-induced erectile dysfunction **N52.31** Erectile dysfunction following radical prostatectomy **N52.32** Erectile dysfunction following radical cystectomy **N52.33** Erectile dysfunction following urethral surgery **N52.34** Erectile dysfunction following simple prostatectomy **N52.35** Erectile dysfunction following radiation therapy **N52.36** Erectile dysfunction following interstitial seed therapy **N52.37** Erectile dysfunction following prostate ablative therapy **N52.39** Other and unspecified postprocedural erectile dysfunction **N52.8** Other male erectile dysfunction **N52.9** Male erectile dysfunction, unspecified **T83.410A** Breakdown (mechanical) of implanted penile prosthesis, initial encounter **T83.420A** Displacement of implanted penile prosthesis, initial encounter **T83.490A** Other mechanical complication of implanted penile prosthesis, initial encounter **T83.61** Infection and inflammatory reaction due to implanted penile prosthesis **T83.61XA** Infection and inflammatory reaction due to implanted penile prosthesis, initial encounter **T83.69** Infection and inflammatory reaction due to other prosthetic device, implant and graft in genital tract **T83.69XA** Infection and inflammatory reaction due to other prosthetic device, implant and graft in genital tract, initial encounter **T83.728A** Exposure of other implanted mesh into organ or tissue, initial encounter **T83.82XA** Fibrosis due to genitourinary prosthetic devices, implants and grafts, initial encounter **T83.83XA** Hemorrhage due to genitourinary prosthetic devices, implants and grafts, initial encounter **T83.84XA** Pain due to genitourinary prosthetic devices, implants and grafts, initial encounter **T83.85XA** Stenosis due to genitourinary prosthetic devices, implants and grafts, initial encounter **T83.86XA** Thrombosis due to genitourinary prosthetic devices, implants and grafts, initial encounter **T83.89XA** Other specified complication of genitourinary prosthetic devices, implants and grafts, initial encounter **T83.9XXA** Unspecified complication of genitourinary prosthetic device, implant and graft, initial encounter	
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	
Possible MS-DRG Assignment	**709** Penis procedures with CC/MCC **710** Penis procedures without CC/MCC	

April 16, 2019

Boston Scientific Corporation
Laura Kelly
Regulatory Affairs Specialist II
10700 Bren Road West
Minnetonka, MN 55343

Re: K183619
Trade/Device Name: Tactra™ Penile Prosthesis
Regulation Number: 21 CFR§ 876.3630
Regulation Name: Penile Rigidity Implant
Regulatory Class: II
Product Code: FAE
Dated: March 13, 2019
Received: March 14, 2019

Dear Laura Kelly:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

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

Products shown for informational purposes only – not meant as a promotion or offer for sale – certain components are pending CE Mark, not available for sale in the European Economic Area (EEA).

Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

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Boston Scientific does not promote the use of its products outside their FDA-approved label.

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