

# Tactra™ Malleable Penile Prosthesis

## Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

### Indications

The Tactra™ device is designed to provide penile rigidity and malleability, and the device can be placed in either an erect or a concealed position. Tactra is a sterile, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in adult males who are determined to be suitable candidates for implantation surgery.

### Contraindications

- The implantation of this device is contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery.
- The implantation of this device is contraindicated in patients whose total intracorporal length is not within the range of 14 cm to 27 cm.
- The implantation of this device is contraindicated in patients whom the physician determines to be poor candidates due to risks associated with open surgical procedures and /or the patient's medical history (physical and mental conditions), or with sensitivity to silicone materials.
- The implantation of this device is contraindicated in patients who require repeated endoscopic procedures.
- Patients who have compromised tissue and as a result cannot withstand constant intra-corpora pressure should not be implanted with a Tactra penile prosthesis.

### Warnings

The Tactra prosthesis is designed to be implanted as a pair of matched cylinders. A single implanted cylinder may not be adequate to achieve sexual intercourse and may have an adverse effect on the reliability of the device.

Known and potential complications include, but are not limited to infection, erosion, device migration, extrusion, mechanical malfunction (fracture of the prosthesis or breach of the outer silicone layer), device inadequate for sexual activity or concealed position, allergic reaction, inflammation, prolonged or intractable pain and discomfort, urinary obstruction, silicone particle migration, and other complications (e.g., post-operative hemorrhage, hematoma, ischemia, edema, dehiscence, fistula, necrosis/gangrene, perforation, urinary retention, and unintended tissue, muscle, vessel or nerve injury).

The complications listed above may necessitate surgical revision or removal of the prosthesis.

### *Product Life*

The Tactra Malleable Penile Prosthesis is intended as a prosthetic device which restores to the patient an important physiological function. As with any penile rigidity implant, this device is subject to wear

and eventual failure over time. It is not possible to predict how long an implanted prosthesis will function in a particular patient.

Patients should be advised that the implant is not considered a lifetime prosthesis and additional surgery for replacement and removal may be necessary.

Currently, there is no data on the revision rate for this device. However, in a study of the Dura II penile prosthesis (similar to this device), the revision rate was reported as 5.1% after two years post-implant for 196 patients. There were no mechanical failures reported.

### *Infection*

As with any surgical procedure, an infection may develop after surgery. Your doctor will take appropriate steps to reduce the likelihood of infection. These steps may include using antibiotics to rinse the surgical site during surgery, as well as appropriate antibiotics given before and after the surgery. Men with diabetes, spinal cord injuries, open sores, or existing skin infections in the area of the surgery, or existing urinary tract infections may have an increased risk of infection associated with the prosthesis. If the infection cannot be treated with antibiotics, it may be necessary to remove the prosthesis. In this case, it may not be possible to implant a new prosthesis. In addition, infection that causes the device to be removed may also cause scarring which may make implanting a new prosthesis difficult.

### *Erosion*

Erosion is a breakdown of the tissue next to the implanted cylinders. Erosion can be caused by infection, pressure on the tissue, improper sizing, tissue damage and cylinder misplacement. The most frequently reported sites of cylinder erosion are the glans (the tip of the penis), the urethra (the tube that carries the urine out of the body), and the skin. In any case of erosion, your doctor must evaluate and decide whether it is possible to repair the area by replacing the cylinders or if complete removal of the device is necessary.

### *Migration or Extrusion*

Migration is the movement or displacement of cylinders within the body space in which they were originally implanted. If a cylinder migrates, it can cause pain, psychological or medical complications and/or device malfunction, and may need to be corrected with surgery. Migration of cylinders may occur if the cylinders are improperly sized or they are not positioned properly. Extrusion is a specific type of migration that may occur when the prosthesis moves to a position outside of the body. Extrusion of the prosthesis is usually associated with an open wound at the incision site.

### *Silicone*

The Tactra Malleable Penile Prosthesis is made of materials including silicone elastomers (a type of rubber). Silicone elastomers have been commonly used in biomedical devices for more than forty years.

Scientific literature includes reports of adverse events in some patients with implantable silicone devices. These adverse events indicate allergic-like reactions or autoimmune-like symptoms (In an

autoimmune reaction, the body's own immune cells may attack some or many of the body's own tissues by mistake).

Silicone elastomers may lose very small particles from the device surface implantation. These particles may migrate to the lymph nodes where the particles may remain (lymph nodes are a normal part of the body's defense system against infection). Medical journals have indicated that particle migration has not resulted in any negative effects to a patient's health.<sup>1,2</sup>

### *Revision Surgery*

The risk of surgical revision or device removal is common to all devices. Generally, surgical revision or removal of penile prostheses is performed to address other complications.

However, the patient may elect to have the device removed due to patient dissatisfaction unrelated to safety or efficacy. Removal of an implanted prosthesis, for any reason, without timely re-implantation of a new prosthesis may substantially complicate re-implantation or make it inappropriate.

The patient must be informed that a penile prosthesis is subject to wear and that eventual failure is expected over time. It is not considered a lifetime prosthesis. The patient should be made fully aware that additional surgery for replacement and removal may be necessary.

### *Patient Expectations*

Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of a rigid penile prosthesis.

Implantation of a penile prosthesis may result in penile shortening, curvature, or scarring. The prosthetic erection may differ from the patient's original, natural erection in that it may be shorter, less firm, have less girth, and reduced sensations.

Realistic cosmetic expectations should be communicated to the patient and should include the potential for skin scarring and lack of concealability.

The implantation of a penile prosthesis will not provide rigidity to the glans, and may result in a floppy glans and lack of rigidity of the corpus spongiosum. Penile flaccidity will be less than prior to implantation.

### *Loss of Latent Erectile Capability*

Penile prosthesis implantation may result in the loss of any natural or latent spontaneous erectile capacity.

### *Device Sizing*

Proper sizing of the device is critical to a successful outcome. Improper measurement, inappropriate cylinder size selection, or malpositioning of the cylinders within the corpora cavernosa may result in migration or buckling of the cylinders or reduce cylinder life.

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<sup>1</sup> Barrett DM, O'Sullivan DC, Malizia AA, Reiman HM and Abell-Aleff PC. "Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices." J. Urol. 146: 319-322. (1991).

<sup>2</sup> Reinberg Y, J. Urol. 750: 694-696. (1993).

## *Pain*

You may have pain in your penis immediately after surgery and during the period when you first use your device. There have been cases of chronic or constant pain reported with the implantation of a penile prosthesis. If you have pain that is very severe or lasts longer than expected, it may be a symptom of medical complications. This may lead to medical or surgical correction. There have also been reports of patients who do not have any known medical complications who have chosen to have a penile prosthesis removed because of pain that would not go away.

## *Surgical technique*

Surgical technique is important to the success of the Tactra Malleable Penile Prosthesis. Improper sizing of the cylinders may occur. Inappropriate cylinder sizing may cause migration or erosion of the cylinders within the penis and may also reduce cylinder life.

## **Precautions**

### *Surgery Related*

- Direct contact of surgical instruments with the prosthesis may result in damage, rendering it unsuitable for implantation.
- During insertion, do not over bend cylinders beyond their natural U-shape as it may damage the prosthesis and shorten its product life.
- Do not trim the distal section of the cylinders beyond the lowest indicated graduation on the proximal section, or the RTEs. Doing so will compromise the device integrity.
- Trim the proximal section with a fresh scalpel blade to ensure a clean, straight cut.
- Careful intraoperative sizing is required to ensure proper device operation and to minimize the occurrence of sizing related complications such as migration and/or extrusion.
- Removal of an implanted prosthesis, for any reason, without timely re-implantation of a new prosthesis may substantially complicate reimplantation or make it impossible.
- Unsuccessful outcomes have been reported due to improper surgical technique, anatomical misplacement of the device, or improper sizing of cylinders.

### *Device Related*

- Implantation of a penile prosthesis that has been in previous contact with or contaminated by body tissue or fluid, regardless of cleaning, or sterilization, is prohibited.
- The "0" (zero) RTE is required to be attached to fulfill the indicated length on the cylinder. The physician may utilize the optional 0.5 cm and 1 cm RTEs to provide additional length as needed. Trimming should not take place beyond lowest indicated graduations to ensure optimal RTE fit and to avoid trimming too close to the internal cable.

### *Patient Related*

- A thorough preoperative consultation between patient and physician should include a discussion of all available treatment options and their risks and benefits.
- Adequate patient education is required to ensure safe, effective patient use.

- Uncircumcised patients may have an increased risk of postoperative complications with the sub-coronal approach. Surgeons may wish to discuss performing a circumcision to reduce the risks of postoperative complications associated with this approach.
- Patients must have sufficient strength and dexterity to position the device.
- The risk of surgical revision or device removal is common to all devices. Generally, surgical revision or removal of penile prostheses is performed to address other complications. However, the patient may elect to have the device removed due to patient dissatisfaction unrelated to safety or efficacy. Removal of an implanted prosthesis, for any reason, without timely re-implantation of a new prosthesis may substantially complicate re-implantation or make it inappropriate.

This is not a complete list of precautions. All precautions can be found in the product labeling supplied with each device.

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

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