CONSUMER MEDICAL DEVICE INFORMATION

Commonly referred to as Patient Information Leaflet (PIL)

GYNECARE TVT™ FAMILY of PRODUCTS

Product Codes:
- TVTOML  GYNECARE TVT™ ABBREVO Continence System
- TVTRL  GYNECARE TVT™ EXACT Continence System
- 810081  GYNECARE TVT™ Obturator System Tension-free Support for incontinence
- 810041A  GYNECARE TVT™ DEVICE with ABDOMINAL GUIDES Tension-free Support for incontinence
- 810041B  GYNECARE TVT™ DEVICE

What is a Patient Information Leaflet?
This PIL answers some common questions about GYNECARE TVT™ FAMILY of PRODUCTS. It does not contain all the available information for GYNECARE TVT™ FAMILY of PRODUCTS.

All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using one of the GYNECARE TVT™ FAMILY of PRODUCTS against the benefits that are expected. Your surgeon has been provided additional information and can answer any questions you may have. Follow your surgeon's advice even if it differs from what is in this PIL.

This PIL is not intended to be medical advice or to substitute for a thorough discussion between you and your doctor or surgeon about the potential benefits and risks of the various treatment options. It does not take the place of talking to your surgeon.

Have you ever leaked urine when you laughed, coughed or sneezed? Many women suffer from a common condition called stress urinary incontinence, or SUI.

SUI is the most common type of urinary incontinence and can be the cause of some very embarrassing situations. There are treatments that could reduce urine leakage or stop it altogether. This PIL is intended to help you understand the causes, symptoms, and treatment options for SUI, and to encourage an in-depth consultation with your doctor or surgeon about your condition.

What is Urinary Incontinence?
Urinary incontinence occurs when you experience accidental urine leakage. Many women suffer from some type of urinary incontinence. There are 4 major types.

Stress Urinary Incontinence
Unintentional urine leakage during exertion, activity, or movements, such as coughing, sneezing, laughing and exercising. This is also referred to as stress incontinence.

Urge Incontinence
The sudden, intense urge to urinate, followed by urine leakage. You may feel like you can never get to the bathroom fast enough, or you may wake several times a night with the strong urge to urinate.

Mixed Incontinence
Occurs when women have symptoms of both stress and urge incontinence.

Incontinence associated with chronic retention urine (previously referred to as Overflow Incontinence)
Occurs when the bladder doesn’t completely empty. It may be caused by dysfunctional nerves or a blockage in the urethra that prevents the flow of urine.
Intended Purpose of the GYNECARE TVT™ FAMILY of PRODUCTS

The GYNECARE TVT™ Tension-free Support for Incontinence, GYNECARE TVT EXACT® Continence System and GYNECARE TVT™ with Abdominal Guides Tension-free Support for Incontinence, are intended to be used in women as pubourethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

GYNECARE TVT™ Obturator System Tension-free Support for Incontinence and GYNECARE TVT ABBREVO® Continence System are intended to be used in women as suburethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Be sure to speak with your doctor or surgeon about your treatment options and the best course of treatment for you.

More about Stress Urinary Incontinence (SUI)

SUI occurs when urine leaks involuntarily during exertion, activity, or movements. This can be caused by weakening of the pelvic muscles that support the bladder and urethra.

Normal Pelvic Anatomy

Effect of SUI

Common Symptoms

You may have SUI if you leak urine when you:

- Cough, sneeze or laugh
- Walk, exercise or lift
- Engage in intercourse
- Get up from a seated or lying position

Many women make gradual changes to their lifestyle to avoid embarrassment from accidental urine leakage. Take a moment to ask yourself:

- Do you wear sanitary pads to absorb urine?
- Do you avoid or limit some activities to prevent leakage?
- Do you limit the amount of fluids you drink to avoid leakage?
- Do you go to the bathroom frequently to avoid leakage?
- When planning a trip, outing or event, does the availability of restroom facilities affect your decision?

If you have any symptoms or answered “yes” to any of these questions, take the next step and talk with a doctor or surgeon that is specially trained to treat SUI, such as a urogynecologist, urologist, or gynecologist.
Common Causes

One of the myths about SUI is that it is a natural part of the aging process. In reality, it can affect women at any age. Although common, SUI is not a normal part of aging. Weakening of the muscles and supporting ligaments within the pelvis can occur as a result of:

- Pregnancy and childbirth
- Connective tissue disorders
- Chronic heavy lifting or straining
- Menopause
- Obesity
- Smoking
- Coexisting conditions such as pelvic organ prolapse

Diagnosis

SUI may be diagnosed based on the symptoms you describe to your doctor and a careful pelvic exam focused on your pelvic support. Your doctor may ask you to cough with a full bladder to observe leakage. Some doctors will want to conduct special bladder function tests (urodynamics) to evaluate your bladder and urethral function. These tests usually involve placing a small tube, called a catheter, into the bladder, which can measure bladder and urethral activity. Urodynamics may be useful in helping your doctor determine exactly what type of incontinence you have, as well as making a recommendation for treatment.

Treatments

Stress urinary incontinence is treatable at any age, but not all approaches work for every person. Your doctor may suggest one or more of the following:

**Behavioural/Muscle Therapy:** Therapy often starts with Kegel exercises, which help strengthen the pelvic floor muscles.

**Biofeedback:** While you exercise your pelvic floor muscles, you are connected to an electrical sensing device that provides “feedback”. Over time, biofeedback can help improve muscle control to prevent urine leakage.

**Electrical Stimulation:** This approach sends a mild electric current to the pelvic muscles or nerves that are involved in urination.

**Medication:** There is currently no medication approved to treat SUI. However, other types of urinary incontinence, like urge incontinence, can be treated with medications.

**Bulking Agents:** Injectable therapy that is used to thicken the wall of the urethra in order to help control urinary flow.

**Minimally Invasive Surgical Sling Procedure:** Typically, an outpatient procedure in which the surgeon places a thin piece of flexible, permanent surgical mesh under the urethra, like a sling, to prevent involuntary urine leakage. In some patients, an inpatient procedure may be required.

The most common surgical techniques used to treat SUI are mesh procedures which may be performed using the following approaches:
**Retropubic Approach**

Mesh is inserted through a small incision in the vagina and exits through two small incisions in the abdomen.

**Obturator Approach**

Mesh is inserted through a small incision in the vagina and exits through a small incision in each inner thigh.
A surgical sling procedure may be right for you

Many women suffer from SUI without getting treated. Women should know that SUI is, in many cases, a treatable condition, and there are surgical options that can usually be done as an outpatient procedure. In some patients, an inpatient procedure may be required.

One such procedure uses GYNECARE TVT™ family of products for Incontinence.

How is GYNECARE TVT™ Device used?

The GYNECARE TVT™ Device can only be implanted surgically, by a surgeon who is trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the GYNECARE TVT™ Device.

How GYNECARE TVT™ Tension-free Support for Incontinence works

GYNECARE TVT™ is designed to stop involuntary leakage the way your body normally should – by providing support for the urethra.

• Your surgeon will place a thin piece of flexible, permanent mesh underneath the urethra. The mesh acts like a supportive sling, which helps prevent urine leakage.
• The body then naturally incorporates the mesh into the surrounding tissue, thus helping to prevent future leakage.

What to expect during the procedure

• Typically a 30-minute procedure; in some patients, an inpatient procedure may be required.
• Performed under local, regional or general anesthesia.
• Depending on the type of procedure, the mesh is inserted through a small incision in the vagina and exits through two small incisions in the lower abdomen or inner thigh.

What to expect when you return home

• Most patients usually return home the same day of the procedure and are able to resume most daily activities.
• Most women see results immediately following the procedure, with significantly less or no leakage.
• You may have minimal scarring and should not feel the mesh once it has been placed.
• Your surgeon may advise you to rest for the first 24-48 hours.
• Your surgeon may advise you to avoid heavy lifting and sexual intercourse for approximately 4 to 6 weeks.

Who is a candidate for treatment?

The best way to determine if you are a candidate for a GYNECARE TVT™ procedure for Incontinence procedure is to consult with a surgeon that is specifically trained to perform sling procedures such as a urogynecologist, urologist, or gynecologist. GYNECARE TVT™ procedures may be appropriate for many women, even those who have undergone surgical treatments for incontinence in the past.

• The procedure should not be performed on women who are pregnant or who are planning future pregnancies. Pregnancy and child birth can cause the mesh to stretch and become ineffective against urine leakage.
• Women who smoke have a higher risk of mesh exposure. You should seriously consider smoking cessation before undergoing this surgery.
Questions for your doctor about Stress Urinary Incontinence

- What type of incontinence do I have?
- What are treatment options you would recommend for me?
- Will treatment affect my ability to have children?
- What are the risks for my situation with the recommended treatment options?
- How soon after treatment can I resume my normal activities?
- How is the procedure used to treat SUI different than the procedure used to treat pelvic organ prolapse with surgical mesh?

What are the risks?

Risks Common to All Pelvic Surgeries:
Risks for all pelvic surgeries include anesthesia risks, infection, inflammation, tissue contraction, vaginal scarring, pain (temporary or chronic), pain with intercourse, pelvic pain, development of urge urinary incontinence or voiding difficulties which were not present before the procedure (such as urinary retention or frequency), bleeding, including hemorrhage, hematoma (collections of blood in the pelvis), seroma, injury to vessels, nerves, and organs including the bladder, urethra or bowel, wound healing problems, urinary tract infection, fistula (holes between bladder or bowel and the vagina), injury to ureters (tubes bringing urine from kidneys to bladder), pelvic abscess formation, neuro-muscular problems (including pain in the groin, thigh, leg, pelvic or abdominal area), adhesion formation, abnormal vaginal discharge and recurrent incontinence. These complications may require additional medical treatment, hospitalization, or surgery. These complications may resolve over time or may be chronic.

Complications Associated with Synthetic Mesh to Treat SUI:
There is a risk of the mesh material becoming exposed into the vagina (mesh exposure). Mesh exposure can be associated with pain during intercourse for you and your partner. Mesh exposure is also associated with recurrent vaginal infection, abnormal vaginal discharge and light vaginal bleeding/spotting. Exposure may require treatment, such as vaginal medication, or removal of the exposed mesh, which may be performed in the office or may require a return to the operating room. There is also a risk that the mesh material may erode into another organ such as the bladder or urethra (mesh erosion) and cause pain and additional problems. Mesh erosion would likely require additional surgery (vaginal, laparoscopic or cystoscopic) to remove the mesh from the organ. Synthetic mesh is a permanent medical device implant. You should carefully discuss the decision to have surgery with your surgeon and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition.
The following information is an excerpt from the *GYNECARE TVT™ Family of Products Essential Product Information* provided with the device and will be useful for discussion with your doctor or surgeon.

**Contraindications**
- As with any suspension surgery, these procedures should not be performed in pregnant patients.
- Additionally, because the PROLENE Polypropylene Mesh will not stretch significantly, it should not be performed if in patients with future growth potential including plans for future pregnancy.

**Warnings & precautions**
- Do not use the GYNECARE TVT Family of Products in patients who are on anti-coagulation therapy
- Do not use the GYNECARE TVT Family of Products in patients who have a urinary tract infection
- Bleeding or infection may occur post-operatively
- Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics after a GYNECARE TVT Obturator System or GYNECARE TVT ABBREVO System procedure
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Family of Products, the patient should be counselled that future pregnancy may negate the effects of the surgical procedure and the patient may again become incontinent
- Since no clinical information is available about vaginal delivery following sub-urethral sling procedure with the GYNECARE TVT Family of Products, in case of pregnancy, delivery via cesarean section should be considered
- Post-operatively, refrain from heavy lifting and/or exercise (e.g. cycling, jogging) for at least three to four weeks and to refrain from intercourse for one month. The patients can usually return to other normal activity after one or two weeks
- Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems

**Patient factors**
Physicians should use their surgical experience and judgment to determine if PROLENE Mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions

**Adverse reactions**
- Punctures or lacerations or injury of vessels, nerves, structures or organs, including the bladder, urethra, or bowel, may occur and may require surgical repair
- Improper placement of the GYNECARE TVT Family of Products devices may result in incomplete or no relief from urinary incontinence or may cause temporary or permanent urinary tract obstruction
- Transitory local irritation at the wound site may occur
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection
- Pain – which may be severe and chronic
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur
- Recurrence of incontinence
- Bleeding including hemorrhage or hematoma
- One or more revision surgeries may be necessary to treat these adverse reactions
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required
Other adverse reactions

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient’s partner during intercourse
- Death

Consult your doctor to discuss the potential benefits and risks of your treatment options and whether PROLENE mesh is appropriate for you.

Reporting adverse effects

Report any adverse effects you believe are a result of GYNECARE TVT™ Device, to:

   or
2) Johnson & Johnson Medical Product Safety Department on: Email: productssafetyjjmanz@its.jnj.com
   or

Patient Information Card

A patient information card is available via your healthcare facility

For access to this PIL please visit: http://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets