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
810041B	GYNECARE TVT™ DEVICE

What is a Patient Information Leaflet?

This PIL answers some common questions about GYNECARE TVT™ FAMILY of PRODUCTS, which are medical devices used in the surgical treatment of Stress Urinary Incontinence as further explained below. It does not contain all the available information for the 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 your condition and the potential benefits and risks of the various treatment options. It does not take the place of your surgeon's evaluation of your condition or talking to your surgeon.

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 (stress). 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 incontinence and urge incontinence.

Incontinence associated with chronic retention of urine (previously referred to as Overflow Incontinence)

Occurs when the bladder doesn't completely empty. As a result, extra urine builds up and stays in the bladder until it overflows. It may be caused by nerves that don't work properly or a blockage in the urethra (small pipe shaped organ that is connected to the bladder and allows urine to flow out of the body) that prevents the flow of urine.

More about Stress Urinary Incontinence (SUI)

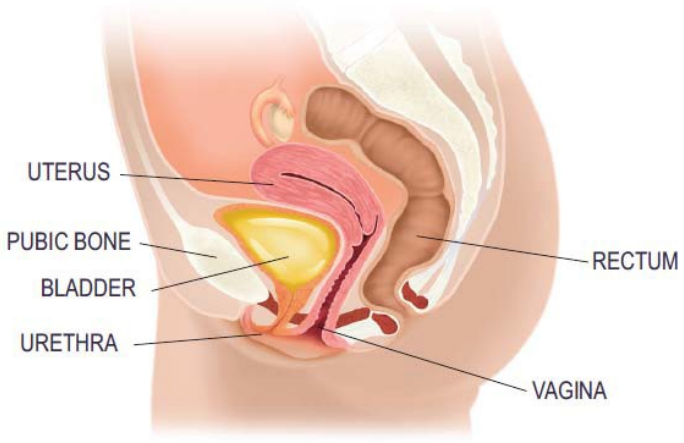
Common Causes

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. SUI is caused by weakening of the muscles and ligaments that support the bladder and urethra due to:

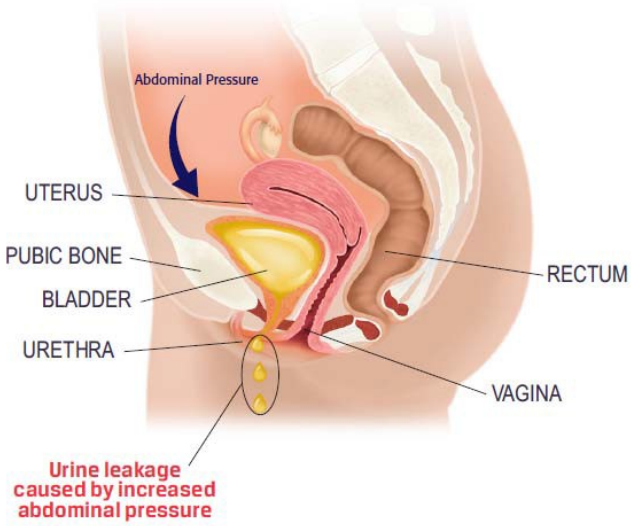
- Pregnancy and childbirth
- Connective tissue disorders
- Chronic heavy lifting or straining
- Menopause
- Obesity
- Smoking
- Other conditions such as pelvic organ prolapse (where the pelvic organs such as the bladder, rectum and uterus bulge into the vagina)

As shown in the pictures below, normally, the pelvic muscles and ligaments are able to support the bladder and urethra. A woman does not leak urine even if the bladder is full. SUI occurs when exertion, activity, or movement puts stress on the body and as a result pressure is increased in the belly (intraabdominal) area, but the body is not able to stop urine from leaking.

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 (sex)
- Get up from a seated or lying position

Effect of SUI

SUI can negatively affect a woman's personal, social, work and sexual relationships. It can decrease a woman's activities and quality of life. Many women make changes to their lifestyle to avoid embarrassment from accidental urine leakage. Examples include:

- Wearing sanitary pads to absorb urine
- Avoiding or limiting activities or exercise to prevent leakage
- Limiting the amount of fluids they drink to avoid leakage
- Going to the bathroom frequently to avoid leakage
- Planning a trip, outing or event, around the availability of restroom facilities
- Avoiding sexual intercourse due to a fear of leaking urine

Talk with a doctor or surgeon that is specially trained to treat SUI, such as a urogynecologist, urologist, or gynaecologist, if you have symptoms or if accidental urine leakage is bothering you or negatively affecting your life.

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:

No treatment: If SUI is not bothering you or if you are satisfied with the way you are coping with SUI, you may want to continue without any treatment.

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 (shock) 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.

Continence pessary: A removable device that is placed in the vagina to compress your urethra and lift the neck of your bladder so urine doesn't leak.

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

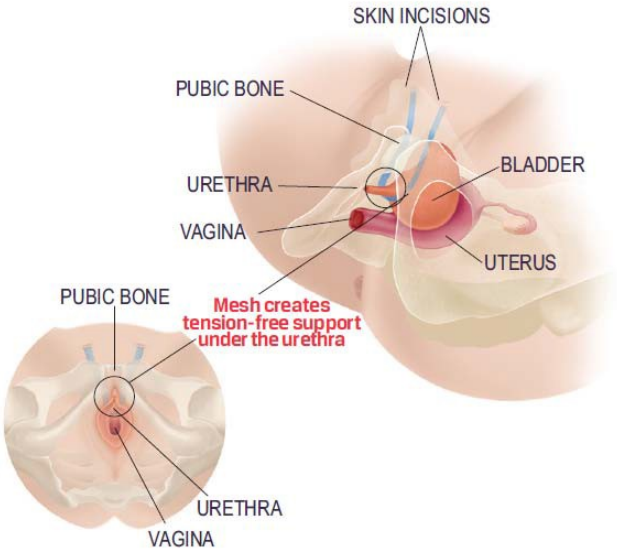
Colposuspension: Surgical procedure in which, through a traditional incision of the abdomen or through laparoscopy (introduction of special instruments and a scope through "ports" in small incisions on the abdomen), the tissues around the urethra are sutured up to a ligament behind the pubic bone to help lift the urethra and restrict the flow of urine.

Autologous fascial (native tissue) sling procedure: Surgical procedure where the surgeon harvests (cuts out and removes) a strip of the tough tissue from your own body covering the belly muscles (rectus fascia) or from the side of your leg (fascia lata) and uses the strip of tissue to make a sling. The sling is placed under the bladder neck (upper urethra) through a small incision in the vaginal wall and up through a lower abdominal incision where it is usually secured with sutures (stiches).

Minimally Invasive Synthetic Sling Procedure: Typically, an outpatient procedure in which the surgeon places a thin piece of flexible, permanent surgical mesh shaped like a sling under the urethra to prevent involuntary urine leakage. The sling is most commonly made of polypropylene mesh (non-absorbable suture material that is knitted together and is about 1 centimeter wide) and is placed between the middle portion of the urethra and the vagina. In some patients, an inpatient procedure may be required. They are referred to as minimally invasive because they do not involve larger abdominal incisions or harvesting tissue from the body, and more likely leads to shorter operating time, hospital stay, time to return to daily activities, and less voiding problems. They are the most common surgical techniques used to treat SUI and can be performed in two different ways:

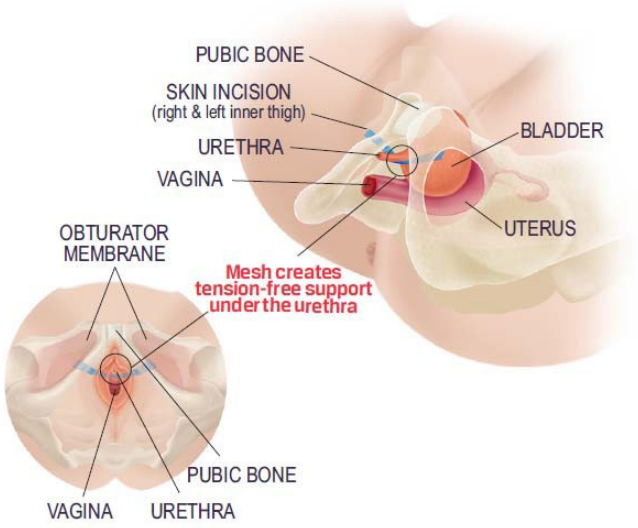
Retropubic Approach

A sling is inserted through a small incision in the vagina, sits under the urethra, and exits through two small incisions in the abdomen. The GYNECARE TVT™ Tension-free Support for Incontinence and GYNECARE TVT EXACT® Continence System use the retropubic approach.



Obturator Approach

A sling is inserted through a small incision in the vagina, sits under the urethra, and exits through a small incision in each inner thigh. The GYNECARE TVT™ Obturator System Tension-free Support for Incontinence and GYNECARE TVT ABBREVO® Continence System use the obturator approach.



Intended Purpose of the GYNECARE TVT™ FAMILY of PRODUCTS

The GYNECARE TVT™ Tension-free Support for Incontinence and GYNECARE TVT EXACT® Continence System are intended to be used in women as pubourethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility (i.e. due to loss of anatomical support of the urethra) and/or intrinsic sphincter deficiency (i.e. the functional structures responsible for keeping a pressure in the urethra are not functioning properly).

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, including no treatment, non-surgical treatment, surgical treatment, and which among these is the best course of treatment for you.

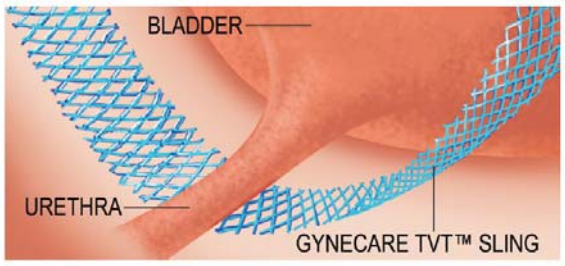
How is GYNECARE TVT™ Device used?

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 retropubic or transobturator slings as GYNECARE TVT™ Devices.

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 shaped like a sling underneath the urethra. The mesh acts like a supportive sling, which helps prevent urine leakage with stress.
- 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 overnight stay in the hospital may be required.
- Anesthesia can be local (injection of anesthetic agent in the sites of the vagina to be incised and where the mesh will exit), regional (also called “spinal” anesthesia, where the anesthetic agent will be injected through your back in the space between two vertebrae, the bone forming the spine, using a long needle), or general (where you are given a blend of injectable anesthetic in the blood circulation and inhaled gases).
- If local or regional anesthesia is used, you will be awake, but you will not feel pain. It is possible that you may feel pressure in the locations where the procedure is carried out. If general anesthesia is used, you will be unconscious and will wake up after surgery.
- Just before the procedure, a small tube (bladder catheter) may be inserted in your bladder through the urethra. This is to keep your bladder empty during the procedure and also to fill it if a cystoscopy (introduction of a scope inside the bladder to inspect it) has to be performed. The catheter is normally withdrawn at the end of the procedure, but may be left for some hours after the procedure.
- If a regional anesthesia is performed, your legs will feel extremely numb and cannot move for a couple of hours after the procedure.

What to expect when you return home

- Most patients usually return home the same day of the procedure and are able to shortly resume most daily activities.
- Most women see results immediately following the procedure, with significantly less or no leakage during exertion, activity, or movements (stress).
- You may have minimal vaginal scarring and should not feel the mesh once your body has healed.
- 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 or longer depending on your individual circumstances.
- It is extremely important that you follow your surgeon’s post-operative instructions.

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.

Questions for your doctor about Stress Urinary Incontinence

- What type of incontinence do I have?
- Do I have any other conditions that are related to or affecting my incontinence?
- What are the chances that my incontinence will worsen if I do not do anything?
- Are there any lifestyle changes that I should make and if so how do I make them?
- What non-surgical options are there to treat my incontinence?
- Will I be able to improve my incontinence by doing pelvic floor exercises or biofeedback? Are there any problems with these nonsurgical treatments?
- What are the benefits of an incontinence pessary?
- How often does a pessary need to be cleaned? Does it need to be taken out? How is it put back in and who puts it back in?
- Are there risks with an incontinence pessary?
- In which cases is surgery advised to treat my incontinence?
- What surgical options are there to treat my incontinence?
- How much have they been studied?
- What are the risks and benefits of the surgical options for me?
- What are the treatment options you would recommend for me?
- What are the chances that my incontinence will return after the surgery you would recommend for me, based on your experience?
- What is your recommendation based on?
- Will treatment affect my ability to have children?
- What are the risks for my situation with the recommended treatment options?
- Are you planning to use synthetic mesh in my surgery?
- Who will be there at the time of my surgery and will you do all of my surgery?
- Could I please have a copy of the synthetic mesh product information and the product number at the time of the surgery?
- What can I expect to feel after surgery?
- How soon after treatment can I resume my normal activities?
- What specific symptoms should I report to you after the surgery?
- Based on your experience, how long will I have pain after surgery?
- How long will you continue to see me as a patient?
- If I develop a complication while seeing you or later, what should I do?
- Will you be able to treat me, or will you refer me to another specialist?
- How is the procedure using the TVT sling to treat SUI different than the procedure used to treat pelvic organ prolapse with surgical mesh?

Risks and Essential Information

Risks Common to All Pelvic Surgeries including SUI Surgery:

- Risks related to the anesthesia
- Infection
- Inflammation (redness, swelling, hotness or tenderness to tissue)
- Tissue contraction (as a scar forms from surgery the tissues contract and become stronger)
- Vaginal and pelvic scarring
- Adhesion (scar bands between tissues and organs) formation
- Pain (temporary or chronic)
- Pain with intercourse (temporary or chronic)
- Pelvic pain (temporary or chronic)
- Neuro-muscular problems (including pain in the back, groin, thigh, leg, pelvic or abdominal area)
- Development of urge incontinence or voiding difficulties which were not present before the procedure (such as

urinary retention or frequency)

- Bleeding, including haemorrhage (larger amounts of blood lost due to a damaged blood vessel), hematoma (collections of blood in the pelvis), and the need for blood transfusion (a way to add blood to your body if you lose a lot of blood during surgery where you are given blood from another person)
- Seroma (pocket of clear serous fluid)
- Injury to vessels, nerves, and organs including the bladder, urethra or bowel
- Injury to ureters (tubes bringing urine from kidneys to bladder)
- Wound healing problems. These can be exacerbated by smoking and diabetes. You should strongly consider stopping smoking before any surgery and maintaining optimal levels of blood glucose and haemoglobin A1c.
- Suture exposure and erosion
- Urinary tract infection (infection most commonly in the bladder or urethra but can also be in the kidneys or ureters),
- Fistula (holes between bladder or bowel and the vagina)
- Pelvic abscess (pocket of infected fluid/pus) formation
- Abnormal/offensive vaginal discharge (unusual or bothersome color, smell, or discharge texture that may be associated with vaginal itching or burning)
- Recurrent incontinence.
- These complications may require additional medical treatment, hospitalization, or surgery.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- Revision surgeries may not resolve complications and are associated with a risk of adverse reactions.
- These complications may be difficult to treat and result in consequent pain.
- These complications may resolve over time or may be chronic.
- Adverse outcomes may occur notwithstanding the training and experience of the surgeon.
- Women who experience severe complications may experience significant personal and mental wellbeing effects.
- Death

Risks Associated with Synthetic Mesh Slings to Treat SUI:

Contraindications

- As with any suspension surgery, these procedures should not be performed in pregnant patients or on women who are planning future pregnancies. Pregnancy and child birth can cause the mesh to stretch and become ineffective against urine leakage.
- 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

- PROLENE mesh, being a polypropylene mesh, is designed to, and will elicit in all patients, an acute inflammatory reaction, followed by a chronic inflammatory response.
- The chronic inflammatory response will result in continuously regenerating scar tissue within and surrounding the implant for as long as the implant remains in the body. The scar tissue will cause the mesh to contract to some degree in all patients.
- It is not possible to predict the severity of the chronic inflammatory response in any individual patient. In some patients the chronic inflammatory response will have adverse effects. It is not possible to identify in advance the patients who will experience those effects, although some patients are at greater risk than others. Complications might also appear in patients without any known risk factors.
- The severity of a patient's chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor. It can also be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders. The mechanical forces in the pelvic floor may influence the compatibility and function of the implant.
- Synthetic mesh is a permanent medical device implant. Synthetic TVT slings have been studied more than non-mesh native tissue SUI surgeries. Based on the most reliable data, the life expectancy of the sling for the vast majority of patients is predictable and the device is expected to last during their lifetime. However, complications may be severe or chronic and the sling may need to be revised, or much more rarely, removed. Removal of the whole sling may be extremely difficult. The overall data show that the risk of the need to revise or reoperate on the sling due to a complication is less than or equal to 5% in studies that evaluate patients out to 17 years. As

compared to other non-mesh native tissue SUI surgeries, the device is as reliable or more reliable based on the studies.

- 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.
- 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.
- Smoking impairs wound healing for any type of surgery you may have. Women who smoke have a higher risk of mesh exposure. You should seriously consider smoking cessation before undergoing this surgery and in general for your overall health.
- 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, the patient is recommended to refrain from heavy lifting and/or exercise (e.g. cycling, jogging) for at least four to six weeks and intercourse for at least 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.
- As with any implant, a foreign body response will occur, the extent of which may differ. This response could result in extrusion, erosion, exposure, fistula formation and/or chronic inflammation, the severity of which is unpredictable, or other adverse reactions, which may be ongoing, difficult to treat and result in consequent pain.
- Mesh exposure can be associated with a prickly sensation and/or pain during intercourse for you and your partner.
- Mesh exposure can also be associated with recurrent vaginal infection, vaginal bleeding/spotting, and abnormal/offensive vaginal discharge (unusual or bothersome color, smell, or discharge texture that may be associated with vaginal itching or burning 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 a risk that the mesh material may be accidentally placed into or erode into another organ such as the bladder or urethra (mesh erosion) and cause damage to the organ, pain, blood in the urine, stone formation, and urinary tract infection.
- Erosion of the mesh into the vaginal canal resulting in infection which may be difficult to treat, cause offensive vaginal discharge and pain.
- Mesh erosion would likely require additional surgery (vaginal, laparoscopic or cystoscopic) to remove the mesh from the organ. Removal of the exposed or eroded mesh will not necessarily prevent further mesh exposure, mesh erosion or other adverse events.
- Local irritation at the wound site may occur
- Infection
- Seroma (pocket of clear fluid)
- 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

- Pain with sexual intercourse (dyspareunia), which may be severe and may become chronic
- Loss of sexual function (apareunia), which may be ongoing and may not resolve in some patients

- Excessive contraction or shrinkage of the tissue surrounding the mesh, and vaginal scarring from causes which include, but are not limited to, chronic inflammation and mesh exposure.
- Adhesion formation (fibrous bands that form between tissues and organs)
- Damage to nerves in the scar tissue surrounding the implant or elsewhere
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area, and leg weakness, may occur
- Recurrence of stress urinary incontinence
- De novo urge urinary incontinence
- Urinary frequency
- Urinary retention (difficulty urinating, poor urine stream)
- Temporary or chronic voiding dysfunction (or difficulty voiding) or urinary retention/obstruction independent from that caused by overcorrection or urethral hypermobility, i.e. too much tension applied to the tape, or from misplacement of the sling or placing the sling too tightly. This may also cause recurrent urinary tract infections.
- Bleeding including hemorrhage or hematoma
- Adverse events may occur years after implantation. The risk will endure for as long as the implant remains in the patient.
- One or more revision surgeries may be necessary to treat these adverse reactions. Revision surgeries may not resolve complications and are associated with a risk of 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.
- Removal of the implant in whole or in part will not necessarily alleviate the patient's symptoms. Removal of part of the implant can be difficult. Removal of the whole of the implant may be practically impossible. Surgery to remove the whole or part of an implant can result in further scarring and tissue damage which, in turn, may have adverse outcomes including severe chronic pain which may not be able to be satisfactorily treated. Surgery to remove the whole or part of the implant may also result in recurrence of stress urinary incontinence.
- Each of these events may occur regardless of the skill of the surgeon.
- While the true incidence of these complications is unknown, they are not rare.
- Women who experience severe complications may experience significant personal and mental wellbeing effects.
- Death

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

You may also direct questions related to the use of GYNECARE TVT™ FAMILY of PRODUCTS to Medical Affairs personnel at Johnson & Johnson Medical on RA-JNJAU-MIR_ANZ@ITS.JNJ.com, Please note that information provided by Medical Affairs personnel is not intended to be medical advice or to substitute for a thorough discussion between you and your doctor or surgeon about your condition and the potential benefits and risks of the various treatment options. It does not take the place of your surgeon's evaluation of your condition or talking to your surgeon.

Reporting adverse effects

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

1) Therapeutic Goods Administration via the website: http://www.tga.gov.au/reporting-problems

or

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

or

3) Manufacturer: Ethicon SARL: http://www.ethicon.com/global

Patient Information Card

A patient information card will be made available via your healthcare facility.

Front

GYNECARE TVT™ Device Tension Free Vaginal Tape

Product Code: **810041B**

Manufacturer: Ethicon SARL
Puits Godet 20, Neuchatel CH-2000 Switzerland
http://www.ethicon.com/global

Patient Information Leaflet:
https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets

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GYNECARE TVT™ Obturator System

Product Code: **810081**

Manufacturer: Ethicon SARL
Puits Godet 20, Neuchatel CH-2000 Switzerland
http://www.ethicon.com/global

Patient Information Leaflet:
https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets

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GYNECARE TVT™ EXACT™ Continence System

Product Code: **TVTRL**

Manufacturer: Ethicon SARL
Puits Godet 20, Neuchatel CH-2000 Switzerland
http://www.ethicon.com/global

Patient Information Leaflet:
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Batch Number:

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GYNECARE TVT™ ABBREVO™ Continence System

Product Code: **TVTOML**

Manufacturer: Ethicon SARL
Puits Godet 20, Neuchatel CH-2000 Switzerland
http://www.ethicon.com/global

Patient Information Leaflet:
https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets

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