BULKAMID®

A Minimally Invasive Treatment For Stress Urinary Incontinence

Axonics

Contents

This brochure provides information about the Bulkamid Urethral Bulking System for the treatment of stress urinary incontinence. Please read this entire brochure and discuss it with your doctor.

BULKAMID®

Glossary

Adverse event
Complication or side effect that may result from a procedure or the device

Bladder
Balloon-like organ in the lower abdomen where urine is stored

Bulkamid
Bulkamid is an injectable soft-tissue urethral bulking agent

Bulkamid clinical studies
Clinical research studies of women with stress urinary incontinence where Bulkamid was used as a treatment

Catheter
A temporary flexible tube to drain urine from the bladder

Continence
The term continence is used when the individual has control of their bladder

Contraindication
A medical condition that indicates Bulkamid should not be used as it may cause harm

Pelvic floor muscles
The layer of muscles that supports the pelvic organs and spans the bottom of the pelvis

Precaution
A statement in the product information that alerts the doctor to take measures to avoid a problem

Stress urinary incontinence
The involuntary leakage of urine during physical activity or exertion such as laughing, coughing or jumping

Top-up injection
When an additional Bulkamid injection is required shortly after the initial procedure to improve patient satisfaction / continence

Urethra
The tube which transports urine from the bladder to the outside of the body

Urethral bulking
The injection of material (bulking agent) into the tissues surrounding the urethra to help the urethra close to avoid accidental urine leakage. Urethral bulking does not completely close the urethra; it can still open normally to allow for urination

Urethroscope
A small instrument with a viewing camera used by the doctor to view the urinary organs (urethra and bladder)

Urge urinary incontinence
Urge urinary incontinence happens when there is a sudden strong need to urinate and the toilet is not reached in time

Urinary incontinence
The unwanted and involuntary leakage of urine

What is stress urinary incontinence?

Stress urinary incontinence is the unintentional passing of urine during activity or exertion, such as coughing, laughing, or exercise. It is caused by a weakness of the ***pelvic floor muscles.***

Stress urinary incontinence is a common condition that affects 1 in 3 women.[1] This condition can have a significant impact on daily life, affecting activities, relationships and emotional well-being. It can occur at any stage of life, with pelvic disorders from childbirth, pelvic surgery and aging increasing the risk of incontinence.

1. National Institution for Health and Clinical Excellence guidelines

How is stress urinary incontinence normally treated?

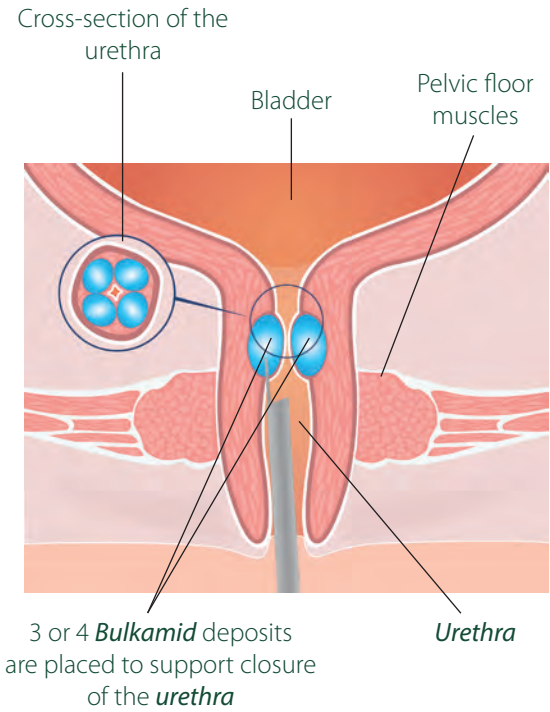
Stress urinary incontinence is a very treatable condition. Your doctor will advise you of the different options available and help you make the right treatment decision. These may include:

Pelvic Muscle Strengthening

Pelvic floor exercises, commonly referred to as Kegel exercises, will most likely be one of the first treatment options recommended by your doctor. These exercises help improve support of the ***bladder*** and ***urethra***.

Bulking Agents

Urethral bulking is the injection of a bulking agent, like ***Bulkamid***, into the wall of the ***urethra*** to add volume ("bulk") to the tissue. Bulking agents are intended for use in patients that have failed conservative treatment and are less invasive than surgery. A bulking agent supports the closing mechanism of the ***urethra*** and provides better control of urine when you cough, laugh, exercise or change position. ***Urethral bulking*** does not close the ***urethra*** totally; the ***urethra*** still opens normally to allow for urination.



What is Bulkamid?

Bulkamid is a urethral bulking agent, consisting of 97.5% water and 2.5% polyacrylamide. ***Bulkamid*** is injected into the soft tissue of your ***urethra***. ***Bulkamid*** achieves its bulking effect by the volume of the gel injected.

When should Bulkamid not be used?

Bulkamid Urethral Bulking System must not be used in patients suffering from acute urinary tract infection.

What are the risks of the Bulkamid procedure?

Over 70,000 women with ***stress urinary incontinence*** have been treated with ***Bulkamid*** across 25 countries over the last 15 years. During that time, a low number of complications or ***adverse events*** have been reported and there have been no reported long-term complications.

However, as with any procedure, complications may occur. These can include temporary pain during and shortly after the procedure (anaesthesia will help with this), a small amount of blood in the urine, delayed urination, painful urination, and/or urinary tract infection. These complications are usually temporary and normally resolve within a few days. In very rare cases patients may experience difficulties to pass urine normally and may require the temporary use of a disposable catheter to empty the bladder. This normally resolves within 24 hours but in very rare cases it may take days to weeks.

Side effects such as tissue hardening (fibrosis) loss of bulking agent (material leakage), bacterial infection (abscess), and tissue injury (necrosis) are possible, but rare. Migration of injected material is a theoretical risk which has not been observed for Bulkamid.

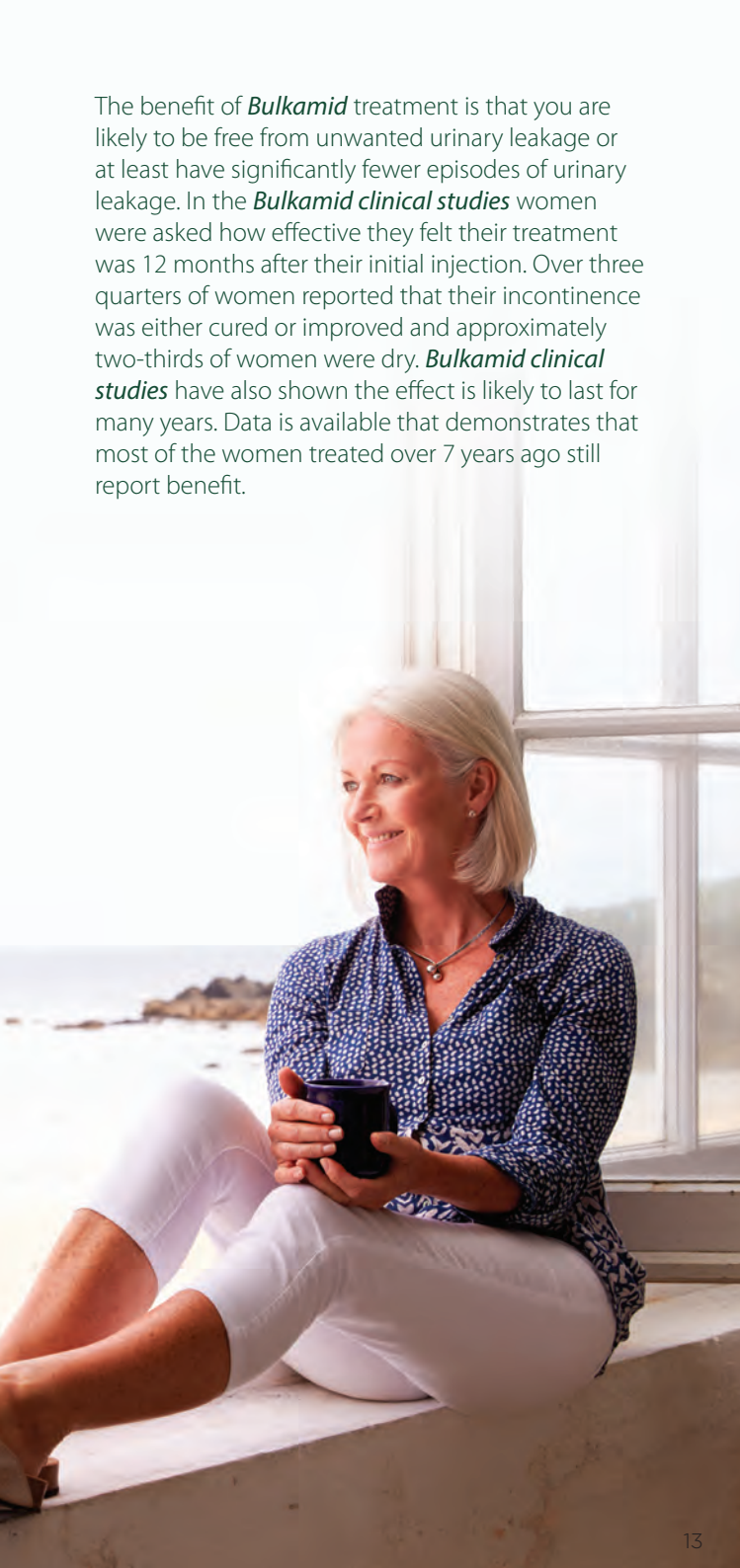
As with any treatment, there is a possibility that you may not experience any benefit from ***Bulkamid*** treatment, or the efficacy may diminish with time. Also, if you have a different type of incontinence, such as ***urge incontinence*** or if your incontinence condition worsens, ***Bulkamid*** may not be an effective treatment for you.

What are the benefits of the Bulkamid procedure?

The majority of women treated with ***Bulkamid*** report dryness or improvement in their symptoms, with many seeing that improvement as soon as they leave the doctor's office, hospital or clinic. Whilst experiencing no leakage at all is the most desired outcome of treatment, many women consider a successful treatment to be a meaningful decrease in the amount and frequency of urine leakage due to ***stress urinary incontinence*** such that they are able to go about most of their daily activities.

If relief from your symptoms is not sufficient following treatment with ***Bulkamid***, an additional injection ***(a "top-up" injection)*** can be given to help achieve your desired results. It is recommended that you wait at least 4 weeks after the initial treatment before an additional injection is given. Talk to your doctor about an additional treatment if you continue to experience urine leakage after the first treatment.

The benefit of ***Bulkamid*** treatment is that you are likely to be free from unwanted urinary leakage or at least have significantly fewer episodes of urinary leakage. In the ***Bulkamid clinical studies*** women were asked how effective they felt their treatment was 12 months after their initial injection. Over three quarters of women reported that their incontinence was either cured or improved and approximately two-thirds of women were dry. ***Bulkamid clinical studies*** have also shown the effect is likely to last for many years. Data is available that demonstrates that most of the women treated over 7 years ago still report benefit.



What can I expect on the day of my treatment?

The ***Bulkamid*** procedure is minimally invasive, with no cuts or incisions necessary, and typically takes about 10-15 minutes to perform. The procedure usually takes place in an outpatient clinic or day surgery unit and you will normally be able to go home on the same day.

Prior to the procedure, your doctor will discuss whether you should have a local or general anaesthetic to reduce any discomfort associated with the procedure. Most patients will undergo a ***Bulkamid*** procedure under local anaesthetic and will feel no more than a slight scratch as the needle enters the urethral wall.

During the procedure, a ***urethroscope*** will be inserted into the ***urethra***, allowing the procedure to be completed under constant visualisation. Three or four deposits of ***Bulkamid*** (1.5 – 2 mL total volume, equivalent to slightly less than half a teaspoon) will be placed into the urethral tissue to narrow the lumen of the ***urethra*** and allow for closure during activity or exertion, thus preventing the leakage of urine. The ***urethroscope*** is removed after the injection is complete and your treatment is finished.

What can I expect after the procedure?

After the procedure, your ability to empty your ***bladder*** will be checked prior to leaving the clinic.

If you cannot pass urine, a ***catheter*** may be required for a short period (normally less than 24 hours) to allow emptying of the ***bladder***. This is an uncommon complication. Once at home, the majority of patients return to normal activities within 24 hours, depending on their doctor's advice.

For more information about Bulkamid, please visit

www.bulkamid.com

Important Safety Information

Indications: Bulkamid® Hydrogel is intended to be used as a urethral bulking agent for the treatment of female urinary incontinence where the stress component is significant.

Contraindications: Bulkamid Urethral Bulking System is contraindicated in patients suffering from acute cystitis, urethritis, have active Herpes Genitalis, or have damaged tissue in the urethra.

Warnings: Patients receiving treatment interfering with blood coagulation have an increased risk of haematoma or urethral bleeding.

Precautions: If the patient has undergone major dental work or surgery, the Bulkamid Hydrogel should not be injected until the patient is fully recovered. Patients with acute or chronic infection in other sites of the body must be treated with caution. Only patients with well-controlled diabetes should be considered for Bulkamid Hydrogel injection. The procedure may cause urinary tract infections and scratches in urethra and bladder. Prophylactic antibiotic is recommended. Safety and effectiveness of device has not been established in patients: During pregnancy, delivery, or lactation; On immunosuppressive therapy or with autoimmune diseases; Under 18 years, Fragile urethral mucosal lining, Urethral hypermobility, Detrusor overactivity, Known polyuria, Unevaluated haematuria.

Side Effects: The following side effects may be associated with the use of the device system: General side effects normally associated with any surgical implantation procedure or local anaesthesia. Postoperatively, transient symptoms such as dysuria, stranguria, haematuria, urinary tract infection, and acute retention may occur; Scratching of the urethral mucosal may occur during the procedure; Long-term side effects such as non-acute retention, abscess formation, fibrosis (tissue hardening), de novo urgency, and necrosis are possible, but rare.

For a complete listing of indications, contraindications, warnings and precautions, go to **www.bulkamid.com/isi**.

Any serious incident that occurs in relation to the device should be reported to both Contura International at complaints@contura.com and to the Therapeutic Goods Administration at the TGA website www.tga.gov.au/reporting-problems.

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