BULKAMID®

Urethral Bulking System

A Minimally Invasive Treatment For Stress Urinary Incontinence

contura

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.

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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.

Contents

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
Catheter	A temporary flexible tube to drain urine from the bladder
Bulkamid clinical study	Contura's research study of women with stress urinary incontinence and treated with Bulkamid or another bulking agent
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
Cystoscope	A small instrument with a viewing camera used by the doctor to view the urinary organs (urethra and bladder)
Pelvic floor muscles	The layer of muscles that support the pelvic organs and span the bottom of the pelvis
Polyacrylamide	A highly water-absorbent gel. It is the primary component of Bulkamid
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
Urge urinary incontinence	Urge incontinence happens when you have a strong need to urinate but can't reach the toilet 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 during coughing, laughing, or exercise. It is caused by a weakness of the ***pelvic floor muscles***.

Stress urinary incontinence is a common condition that affects over 13 million adults in the United States, 85% of which are women. 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.

How is *stress urinary incontinence* normally treated?

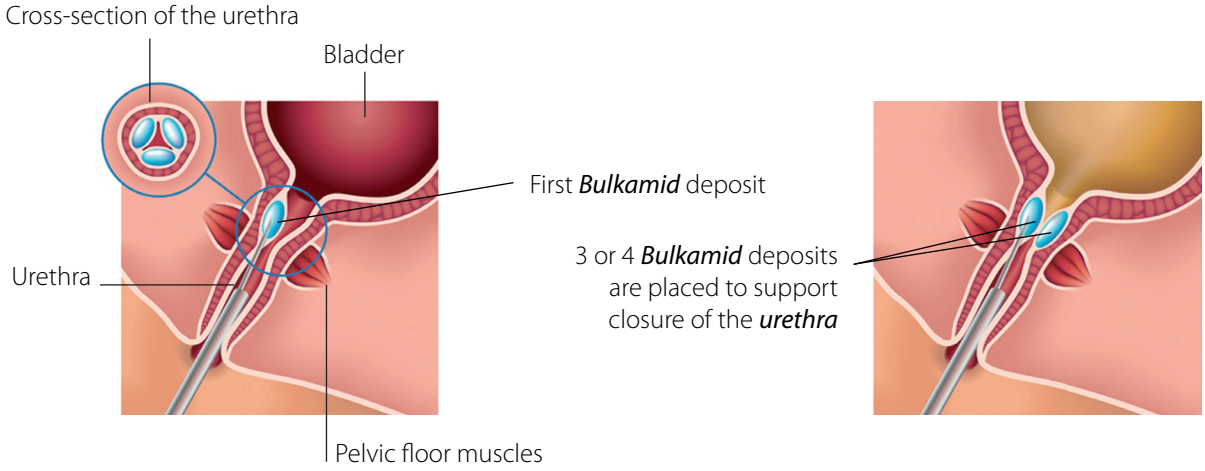
Stress urinary incontinence is a very treatable condition. Your doctor will advise you of the different options available and help you make the right treatment decision. These may include:

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 ***urethra*** to add volume ("bulk") to the tissue. It is 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.



Surgery
Surgery is often used to treat ***stress urinary incontinence***, especially when the cause is a weakened pelvic floor. A common surgery to provide support for the ***urethra*** is a sling or mesh procedure. During this surgery, a narrow strip of a permanent material is placed below the ***urethra*** to support it and to maintain its seal.

All treatment options have ***contraindications, precautions*** and ***adverse events*** (side effects) associated with their use. You should discuss the different treatment options available with your doctor.

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*** using a syringe. ***Bulkamid*** achieves its bulking effect by the volume of the gel injected; other bulking agents achieve their bulking effect by a combination of the micro particles themselves and the body's own reaction to the particles.

Bulkamid is indicated for use as a ***urethral bulking*** agent for the treatment of female ***urinary incontinence,*** where stress incontinence is the primary type of incontinence (as some people have ***urge incontinence***).

When should *Bulkamid* not be used?

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

Bulkamid should not be used in male patients.

What were the results of the *Bulkamid Clinical Study*?

Contura conducted a ***Bulkamid clinical study*** at 33 medical centers in the United States and Canada. Two hundred and twenty eight (228) women with ***stress urinary incontinence*** received ***Bulkamid*** and were followed for 12 months after the initial treatment; 46.9% (107 of 228) of these women reported their symptoms to have improved by at least half (50%), whilst three quarters (75%) of women reported dryness or improvement in their symptoms after ***Bulkamid*** treatment. The level of improvement was similar to another FDA-approved bulking agent that was also used in the study, specifically the Allergan Inc. Contigen Bard Collagen Implant.

In the ***clinical study***, once women had received the initial injection of ***Bulkamid***, they were offered up to two additional injections if their symptoms were still present. Seventy-seven (77) percent (176 of 228) of women treated with ***Bulkamid*** had additional injections of ***Bulkamid.***

The most common side effects (***adverse events***) reported by ***Bulkamid clinical study*** patients are listed in the table below. Most of these ***adverse events*** were temporary. One patient treated with ***Bulkamid*** experienced a serious ***adverse event*** (blood in urine) that was thought to be related to the bulking procedure but not to the ***Bulkamid*** gel.

Most Common Side Effects Reported in the *Bulkamid Clinical Study*

Side Effect	**Occurrence**
Pain at implantation	13 in 100
Acute urinary retention	6 in 100
Urinary tract/***bladder*** infection	4 in 100
Blood in urine (hematuria/transient hematuria)	2 in 100
Painful urination (dysuria)	1 in 100
Strong desire to urinate, but no incontinence episodes (urgency)	1 in 100
Urge incontinence	1 in 100
Worsening ***urinary incontinence***	1 in 100
Vaginal infection	1 in 100

What are the risks of the *Bulkamid* procedure?

Over 70,000 women with ***stress urinary incontinence*** in 25 countries over 10 years have been treated with ***Bulkamid.*** During that time, a low number of complications have been reported and there have been no reported long-term complications. However, as with any invasive procedure, complications may occur.

Complications can include pain related to the procedure, 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 normally pass urine and may require the use of a disposable catheter to catheterize themselves to empty the bladder a few times each day until the bladder starts to empty on its own again.

Although not seen in the ***Bulkamid*** Clinical Study, following side effects have occurred in women who received other urethral bulking agents: blood vessel blockage (embolism/vascular occlusion), skin redness (erythema), loss of bulking agent material through the injection site (excreted material), movement of bulking agent material to a different location inside the body (migration), inflammation causing a growth of tissue (granuloma), inability to completely empty the bladder (outlet obstruction), loss of urethral tissue over the implant site (erosion), and frequent urination.

There is a possibility that you may not experience any benefit from ***Bulkamid*** treatment. This could happen if ***Bulkamid*** is placed too deeply in the tissue, thereby creating poor bulking around the ***urethra.*** 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. While being free from unwanted leakage is the most desired

outcome of treatment, many women consider a successful treatment to be a decrease in the amount and frequency of urine leakage due to ***stress urinary incontinence.***

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 satisfactory results. Contura recommends that you wait at least 4 weeks between treatments to realize the full benefit of the first treatment. 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 could be free from unwanted urinary leakage or have fewer episodes of urinary leakage. In the ***Bulkamid clinical study*** 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 "dry, much improved or improved" and approximately half of women reported zero stress urinary incontinence episodes.

What can I expect on the day of my treatment?

The ***Bulkamid*** procedure is minimally invasive and typically takes about 10-15 minutes to perform. The procedure usually takes place in an outpatient clinic 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 anesthetic to reduce any discomfort associated with the procedure. Most patients will undergo a ***Bulkamid*** procedure under local anesthetic and will feel no more than a slight scratch as the needle enters the urethral wall.

Your doctor may prescribe an antibiotic to reduce the risk of infection.

During the procedure a ***cystoscope*** (a small instrument with a viewing camera used by the doctor) will be inserted into the ***urethra,*** which allows the procedure to be completed under constant visualization. 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 until the opposite walls are gently touching in the center of the urethral opening. The ***cystoscope*** 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 to ensure no further assistance is required.

If you cannot pass urine, a ***catheter*** may be required for a short period (normally less than 24 hours but in very rare cases it may take days to weeks) to allow emptying of the ***bladder.*** This is an uncommon complication occurring in only 6 out of every 100 patients. Once at home, the majority of patients return to normal activities within 24 hours, depending on their doctor's advice.

If you need to undergo a surgical procedure in the future, especially a dental procedure, there is a risk of infection developing near where the Bulkamid was placed. This is due to the possibility of bacteria moving and settling in to the implant, which is the case with many other medical implants. So if you require a surgical or dental procedure in the future, please tell the treating physician that you have a permanent implant and discuss the need for possible antibiotic therapy with them.

For more information about Bulkamid, please visit

www.bulkamid.com

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