

Patient Information to be retained by patient

Periurethral bulking agent for stress urinary incontinence

 affix patient label

Who is this leaflet for?

This leaflet provides information about having an injection of agent to treat stress urinary incontinence. It explains what is involved, the benefits and possible risks.

What is Stress Urinary Incontinence (SUI)?

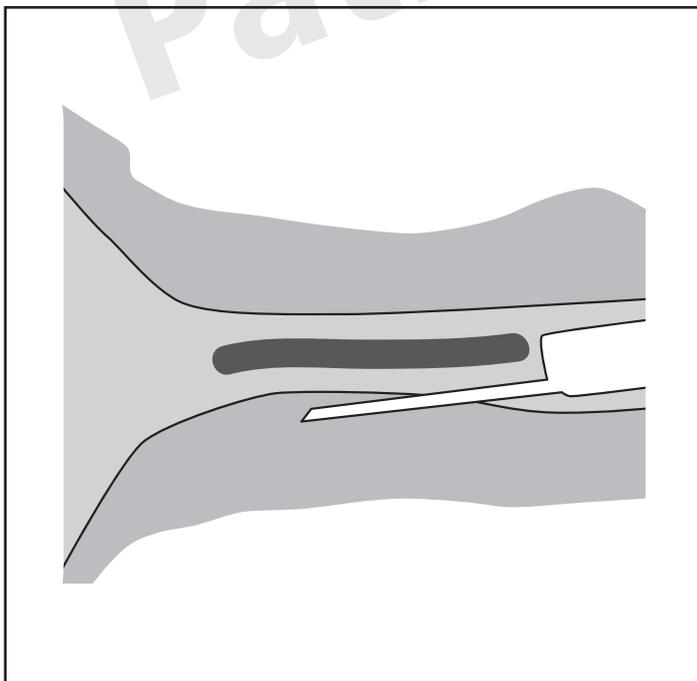
This is a condition in which you leak urine on exertion, for example when you cough, sneeze, jump, run or perform exercises.

What is a bulking agent?

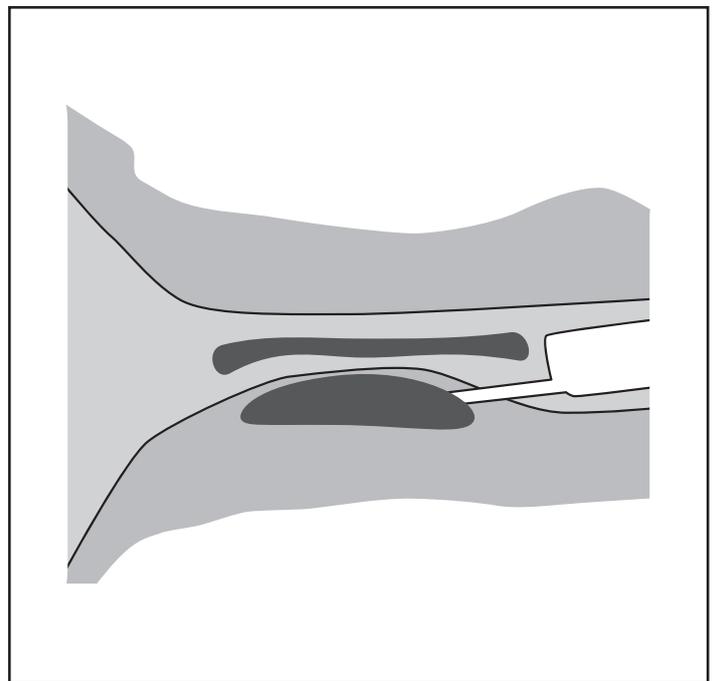
This is an injectable soft-tissue agent, which creates a bulk around the urethra (tube that brings urine out of the bladder). This treats female SUI that is primarily due to deficiency of the muscle that controls urinary leakage.

What are the benefits of this treatment?

This bulking agent is uniquely designed to create an open matrix or scaffolding to deposit collagen, one of our body's natural support tissues, thereby helping with symptoms of urinary leakage. There is no evidence of migration of this agent in clinical studies.



A tunnelling technique is used to inject bulking agent at the mid-urethral position



The cystoscopy ensures a controlled and precise procedure

What are the benefits?

The benefits of this treatment are:

- can be done in outpatient settings
- no overnight stay in hospital
- you will recover quickly
- you will be able to return to normal activities and work soon after
- overall improvement in stress incontinence (50-60%)
- suitable if your family is not complete or if you are overweight or medically unfit
- does not rule out the possibility of another surgical treatment at a later date
- it can be performed without a general anaesthetic if you prefer.

What are the risks associated with this procedure?

Common risks:

- Bleeding – vaginal bleeding and discharge may take a couple of weeks to settle
- Pain – usually controlled with simple painkillers such as paracetamol
- Infection – requiring treatment with antibiotics
- Urinary retention – you may need to go home with a catheter for a few days / weeks. For about 1-5 in 100 women this may be a long term problem, requiring intermittent self catheterisation)
- Urgency of urine - especially if you had this problem before
- Failure of operation to cure stress incontinence - 40-50% chance.

Uncommon risks:

- It can become less effective (20%) with time and you may need a repeat procedure after nine months to one year.

Are there any alternatives?

- **Pelvic floor exercises** – these are usually the first step in managing mild symptoms of SUI. They can also be effective in preventing incontinence from worsening. The exercises have to be performed daily and a cure rate of up to 70% may be expected in mild SUI. If exercises do not work or cannot be done, surgery will be the next option.
- **Colposuspension** – stitches are placed around your bladder neck in order to raise the bladder neck and urethra. These will support the neck of your bladder within your pelvis and hold it securely in this new position. This procedure has an 85-90% success rate. However, it needs a general anaesthetic, there is usually a 2-3 day stay in hospital, and risks include pain, infection, bleeding and damage to bladder.
- **Autologous fascial sling** – this creates a sling underneath the urethra (water-pipe from the bladder to the outside) using a strip of your own tissue (fascia) taken from the wall of your abdomen. A referral will need to be made to a unit out of county as this surgery is not performed in Cornwall.

The pre-operative assessment

Before your visit, we will invite you to a pre-operative clinic where you will be assessed for surgery. This may be a telephone or face to face interview. A member of the nursing staff will ask questions about your previous medical history and will arrange for some tests, such as a blood test. You may also have a chest X-ray and ECG. You will be given advice on whether or not you need to stop taking your medications on the day of the operation, and when to stop eating and drinking before your operation.

How do I prepare for the procedure?

To exclude urinary tract infection, take a urine sample to the GP 7-10 days before the procedure. Your GP will prescribe antibiotics, if needed.

To prevent cancellation on the day, if you suffer from frequent water infections, please see your GP for a prescription of prophylactic antibiotics (antibiotics you take in advance to stop infection) for the three days before your procedure. You will be asked to take either two ibuprofen or paracetamol tablets at home on the morning of your treatment and then come to clinic.

When will I be admitted to hospital?

For day case admissions to the ward

You will come in on the day of your procedure. You need to have a bath or shower before you attend the hospital. Please bring into hospital any tablets or medicines you may be taking. Please leave any jewellery at home. If you are unable to remove any piece of jewellery, a protective tape will be placed over it.

If your procedure is in the morning, you must have nothing to eat or drink after midnight. If you are having your operation in the afternoon, please follow the instructions provided at your pre-operative assessment.

What happens before the operation?

When you arrive on the ward, you will be asked to sit in the waiting room. The nurse will call you through, check your details, help you to change into a gown and give you an identity wristband. Please remove nail varnish at home and do not wear makeup. If you wear acrylic nails please remove from both index fingers. We will do some basic checks such as pulse, temperature, blood pressure and a urine sample. You will also need to remove contact lenses, glasses and false teeth prior to going to theatre.

Visit by the surgical team:

A doctor will come and see you and confirm the operation with you. If you have not already signed a consent form in the clinic, we will ask you to sign one, which gives us permission to perform the operation. If you have any questions, please ask.

Visit by the anaesthetic team:

One of the anaesthetists who will be giving you your anaesthetic will come and see you. Please tell the anaesthetist about any allergies, chest problems, dental treatment and any previous anaesthetics you have had, and also any anaesthetic problems within the family. The procedure can be performed under local anaesthesia, sedation and in occasional circumstances a general anaesthetic.

For outpatient procedures

When you arrive in the Gynaecology outpatient department, check in at the reception. You will be then called through by a nurse who will check your details, the urine sample and prepare you for the procedure.

For improving patient care, the team will also ask you to complete a questionnaire about your symptoms. This information and procedure-related data will be entered onto our local and a national database. All personal information is confidential and not shared outside of the hospital.

What happens during the procedure?

The procedure usually takes about 20-30 minutes, then you will stay in recovery for monitoring. If you are awake for the procedure, you may experience some discomfort and your bladder may feel rather full. Women often describe a sensation of stinging as the bulking agent is injected but this soon wears off.

What happens afterwards?

Following the procedure, you will recover on a ward or in the recovery area until you pass urine. An ultrasound scan will then be performed to check that you are able to empty your bladder. If you are unable to successfully empty your bladder, you may go home with a fine catheter for a few days. A small valve may be attached to the catheter for you to open every 3-4 hours (or before, if you have the sensation to void). You will be instructed on how and when to remove the catheter. You will be given an appointment in EGU for a bladder scan to make sure your bladder is emptying properly.

Will I have any pain or discomfort?

Following the procedure, you may have some pain during the first few hours. This can be controlled by simple over the counter painkillers such as paracetamol and ibuprofen (if you are able to take them).

When can I eat and drink again?

When you are on the ward after the procedure, the nurse will give you something to eat and drink.

How long will I be in hospital?

You will be able to go home after you have passed urine and had an ultrasound to check that you have fully emptied your bladder. You should have eaten before you leave and had a walk in the department. You must arrange for an adult to take you home in a private car or taxi. You will not be able to travel on public transport, as it can be painful and uncomfortable.

When can I resume intercourse?

You can resume sexual intercourse when you feel comfortable, usually after a week.

How will the operation affect my sex life?

In the long term there is no evidence that the operation will make any difference to your sex life. However if you previously leaked urine during intercourse, the operation often makes this better.

When can I drive?

You can drive as soon as you have recovered from the anaesthetic, usually around 48 hours. However, if you have had a general anaesthetic we advise that you check with your insurance company regarding any restrictions. If you had local anaesthetic, you can drive on the same day.

How can I help myself?

Do's:

- Taking regular baths or showers is safe after the operation.
- Tampons are safe to use for menstrual protection after any pain and bleeding from the operation has stopped; until this has settled you should use sanitary towels.
- Exercise is good for you and will speed up your recovery.
- Drink lots of fluids and eat fresh fruit and vegetables to avoid constipation and straining to open your bowels.

Don'ts:

- Avoid vaginal douches.
- Avoid heavy lifting or any sport that involves straining your pelvic muscles.
- Any constant cough is to be treated promptly. Please see your GP as soon as possible.

When can I resume work?

Usually after two weeks. A sick note can be provided upon request. However, if there are ongoing problems, contact your GP who will consider an extension of your sick leave.

Will I have any follow up?

You will be telephoned 10-12 weeks afterwards by the team who performed your surgery.

What should I look out for?

Following your discharge from hospital, if you are unable to pass urine or have severe vaginal bleeding, high fever, or pain when passing urine or blood in the urine in the first week after surgery, contact the gynaecology ward immediately on 01872 252090 or via switchboard on 01872 250000.

Contact us

If you have any questions or need any further information, please contact the RCHT switchboard on 01872 250000 and ask for your consultant's secretary.

Urogynaecology nurse specialist

Mobile: 07824 836818

Office: 01872 252299

Further information

For further detailed information of recovery after this operation see:

www.rcog.org.uk/recoveringwell

www.bsug.org.uk/pages/information-for-patients/111

Comments or concerns

If you have a problem when in hospital that the nurses and doctors are unable to resolve, you can contact the Patient and Family Experience team who will be happy to help you.

The Patient and Family Experience team offers assistance, advice and support for patients and their families. The service can help if you have concerns or worries about treatment or care, and may also be able to provide further information about tests and procedures. They also have a library of voluntary and support agencies. Their number is 01872 253545.

Data Protection

During your visit you will be asked for some personal details. This is kept confidential and used to plan your care. It will only be used by staff who need to see it because they are involved in your care and we may send details to your GP. Information about you may be used for audit purposes and shared within the NHS. Your consent is required for this which you have a legal right to refuse.

Smoking

RCHT is a no smoking hospital. If you would like help to stop smoking before you come into the hospital, there is a smoking cessation help line that you can call. Visitors must not smoke at all in the hospital or in hospital grounds.

If you would like this leaflet in large print, Braille, audio version or in another language,
please contact the General Office on 01872 252690

CONSENT FORM 1
PROCEDURE SPECIFIC PATIENT AGREEMENT

Periurethral bulking agent for stress urinary incontinence

NHS number:

Name of patient:

Address:

Date of birth:

CR number:

AFFIX PATIENT LABEL

STATEMENT OF HEALTH PROFESSIONAL (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained the intended benefits and summarised the risks, as below:

- To relieve your symptoms of urinary stress incontinence

Significant, unavoidable or frequently occurring risks:

- *Failure (50-60%), urinary retention needing catheterisation (long term rate is 1-5%), pain, swelling in vagina*

Uncommon possible later issues:

- *It can become less effective (20%) with time and you may need a repeat procedure after nine months to one year.*

Any extra procedures which may become necessary during the procedure:

- *For example - Blood transfusion*
- *Other (please specify):*

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

I have given and discussed the Trust's approved patient information leaflet for this procedure: Periurethral bulking agent for stress urinary incontinence (CHA3545) which forms part of this document.

I am satisfied that this patient has the capacity to consent to the procedure.

This procedure will involve: General and/or regional anaesthesia Local anaesthesia Sedation

Health Professional signature: Date:

Name (PRINT): Job title:

STATEMENT OF INTERPRETER (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe he/she can understand.

Interpreter signature: Name (PRINT): Date:

affix patient label

STATEMENT OF PATIENT

Please read this form carefully. If your treatment has been planned in advance, you should already have a copy of the patient information leaflet which describes the benefits and risks of the proposed treatment. If not, you will be given a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I understand that tissue samples will only be taken in relation to the procedure explained to me. No samples will be taken for quality control, clinical education or research purposes.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion.

I have received a copy of the Consent Form and Patient Information leaflet: Periurethral bulking agent for stress urinary incontinence (RCHT1470) which forms part of this document.

Patient signature: _____ Name (PRINT): _____ Date: _____

A **witness** should sign below if this patient is unable to sign but has indicated his or her consent. Young people / children may also like a parent to sign here (see guidance notes).

Witness signature: _____ Name (PRINT): _____ Date: _____

CONFIRMATION OF CONSENT (to be completed by health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.

Health Professional signature: _____ Date: _____

Name (PRINT): _____ Job title: _____

Important notes (tick if applicable):

See advance decision to refuse treatment Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: _____ Name (PRINT): _____ Date: _____

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