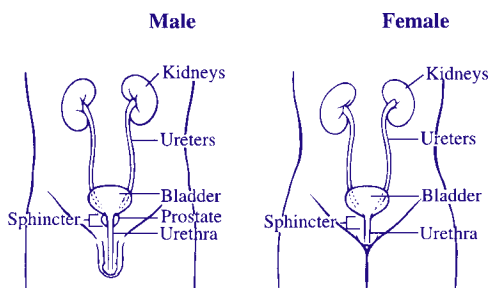


Injection Therapy

for the Treatment of Stress Urinary Incontinence

The failure to store urine can be simplified by considering whether the problem is located at the level of the bladder or the level of the urethra (the muscular tube that allows urine to flow from the bladder to the outside of the body). When the problem originates in the urethra, the difficulty is often related to poor function of the sphincter [SFINK-ter] mechanism at the neck of the bladder.



Although this may be the result of weakened pelvic muscle support, it may also be related to a problem in the sphincter mechanism itself as a result of a neurologic injury, surgical trauma, or congenital problems like spina bifida. In either of these situations, when the body experiences increased pressures on the abdomen from everyday activities such as coughing, sneezing, laughing, exercise, or even lifting, the bladder neck and the urethra function poorly and do not allow a water-tight seal. When urine leakage occurs, this condition is referred to as stress urinary incontinence, and more specifically, intrinsic sphincteric deficiency (ISD).

The treatment of urinary incontinence related to this condition has been a challenging problem and frequently involves difficult surgical procedures to improve the sphincter closure. Another technique to treat this type of incontinence is with the non-surgical injection of "bulking" material into the tissues around the urethra. This bulk results in a closing of

the sphincter and, therefore, protects against incontinence by increasing the resistance to the outflow of urine.

Attempts to treat urinary incontinence with injectables have been considered for decades with a variety of materials. Most doctors have concluded that the basic approach is effective, but they have been hindered by problems with the injectable bulking agents themselves. However, *Contigen® Bard® Collagen Implant* has been used routinely for these cases since 1993 as a safe and effective treatment for sphincter malfunction. Collagen is a natural protein found in the body. *Contigen® Implant* is a sterile, purified collagen taken from the skin of cows. It is chemically-treated to prevent any allergic reaction, but a skin test is still performed to be extra safe. A second injectable treatment called *Durasphere™* is a non-allergic man-made substance of small carbon-coated beads of zirconium, the same sand-like substance from which fake diamonds are made. This was determined to be a safe and effective treatment that does not require a skin test by the FDA in 1999.

Patient Selection

Recognizing that poor sphincter function may be due to either weakened pelvic muscle support or intrinsic sphincteric deficiency (ISD), a doctor will perform urodynamic pressure tests on the bladder and sphincter to make certain that the incontinent patient is a good candidate for this treatment. The best results occur when the patient's incontinence is a result of poor urethral function combined with good pelvic muscle support. The majority of patients with this type of urinary incontinence have had previous surgery.

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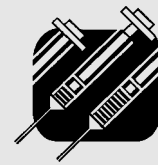
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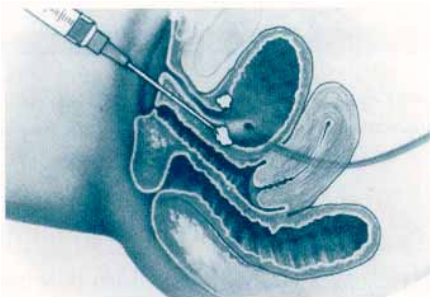


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In men, this is most commonly encountered following radical prostatectomy (surgical removal of a cancerous prostate). In women, the primary cause of ISD is multiple surgical bladder suspension procedures for stress incontinence which may interfere with nerve input to the sphincter and, ultimately, cause it to not function properly.

Injection Therapy

The injection treatment technique is not difficult but requires precision to ensure the most favorable result. The injection can be performed either through a needle placed directly through a cystoscope inserted through the urethra (transurethral injection) or periurethrally with a needle inserted through the skin next to the sphincter (see diagram).



The cause of the incontinence and the tissue condition at the injection site will affect treatment results. Repeated treatments with *Contigen® Implant* may be required to attain full continence since the implant loses some of its initial bulking due to the body's reabsorption of the implant's fluid content. Repeated treatments may also be required with *Durasphere™*. Nearly every patient can be injected under local anesthesia, which allows the procedure to be performed in a hospital outpatient setting, or simply in the physician's office.

Post-Injection Patient Care

After injection, most patients urinate with little difficulty. Catheters are typically not necessary. Antibiotics are administered for two days following the procedure to prevent infection. Additional *Contigen® Implant* and *Durasphere™* injections may be necessary to establish complete urinary continence. Once urinary continence has been achieved (usually after more than one injection), up to 80% of patients will not require further treatment.

Results of Treatment

Clinical practice at the Cleveland Clinic and multiple research studies have shown that up to eighty percent (80%) of women become dry or improved after three treatment sessions in properly selected patients. Seventy-seven percent (77%) will remain dry once dryness is initially attained. *Durasphere™* injections are currently approved for use in women only and the results appear to match those of *Contigen® Implant*. For incontinent men, *Contigen® Implant* injections following resection of the prostate through the urethra (TURP) offer equally strong results with 88% of patients achieving dryness. However, after radical prostatectomy – the removal of a diseased prostate – patients generally experience heavy internal scarring. In this instance, dryness with *Contigen® Implant* injections can be achieved in about 25% of patients. When a male patient has received radiation therapy for prostate cancer, the tissue is also much less receptive to the collagen injections and approximately 14% of patients can achieve dryness. Overall, approximately 40% of all male patients achieve dryness. The results in children are similar when related to gender.

The goal of treatment in patients with ISD is to allow for closing of the sphincter without obstructing it. Injections with *Contigen® Implant*, *Durasphere™*, and newer injectables to come have the potential to accomplish this need. It appears safe and produces the desired effect in the properly chosen patient. Since therapy with *Contigen® Implant* and *Durasphere™* can usually be performed with local anesthesia alone, a significant number of patients who are not candidates for surgical procedures may benefit from this treatment. Injectables are still in the developmental stages and *Contigen® Implant* has been very helpful for some patients. Work is still to be done to find even better injectable agents so that the success rate in treatment can continue to improve.

For Further Information

Becoming an educated consumer can empower you to expect proper diagnosis and treatment. Educational leaflets and booklets can be ordered from NAFC by calling **1-800-BLADDER** or visiting our website at www.nafc.org.

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National Association for Continence (NAFC) is a non-profit organization dedicated to improving the quality of life of people with incontinence. NAFC is a leading source of education, advocacy, and support to the public and to the health profession about the causes, prevention, diagnosis, treatments, and management alternatives for incontinence.

Always consult your doctor before trying anything recommended in this or any other publication that speaks to general health issues.

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