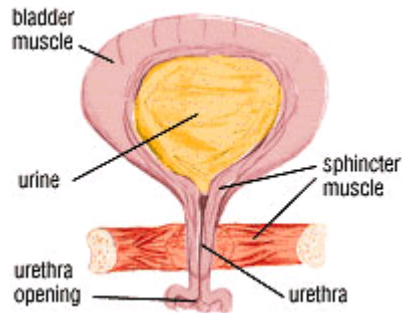
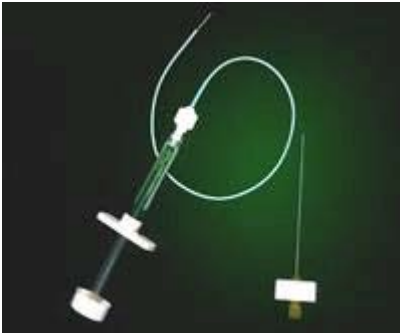




COLLAGEN IMPLANTS



INTRODUCTION

We have given you this pamphlet to make sure that you understand as much as possible about the treatment that is being recommended to help correct your urinary incontinence.

This pamphlet contains brief explanations of the different methods of treatment which are presently used to treat your type of incontinence. You will also learn important facts about collagen implants: what it is; how it works; and what you might expect during and after treatment. In addition, you will be given information about what side effects may occur as a result of treatment with the implant.

After you have read this pamphlet, your doctor will review its contents with you to ensure that you understand the information you have been given.

IS MY INCONTINENCE TREATABLE?

There is no single solution to the problem of incontinence, just as there is no one type of incontinence. Unfortunately, many thousands of people feel they must resort to absorbent or sanitary products to avoid situations where embarrassing leakage may occur. Contrary to popular opinion, however, most incontinence is treatable and manageable. After tests have shown what type of incontinence you are experiencing, your doctor will be able to tell you if it is treatable and which treatment option is appropriate for you.

WHAT IS A COLLAGEN IMPLANT?

Collagen implants are used to treat incontinence when leakage is caused by lack of control or poor control of urine flow from the bladder. Collagen implant is made from collagen obtained from cows and then highly purified. Collagen is a natural protein that provides texture and shape to tissues under the skin.

HOW DO COLLAGEN IMPLANTS WORK?

Collagen implants are injected with a syringe into the tissues around your urethra. Once injected, the

Collagen implant adds "bulk" to the tissues surrounding the urethra so that it can close tightly enough to prevent urine from leaking out. The result is very similar to the way your body functions naturally - the opening of the bladder into the urethra is closed off, but then expands normally when you intentionally empty your bladder.

ARE THERE OTHER TREATMENTS WHICH CAN HELP CURE MY INCONTINENCE?

There are ways other than collagen implants for treating incontinence. Not all of these are right for every person. Your doctor will help you decide what is right for you. It will depend on your medical history, your general health, and the results of the tests.

There are two types of surgery that are intended as long-term treatments: one creates a sling and is a procedure for female patients only. This surgical procedure is successful in about 80-95% of the cases, and approximately 20-30% of patients experience complications. The other procedure implants an artificial sphincter prosthesis. Implantation of an artificial sphincter improves incontinence in approximately 90% of men and 95% of women. Serious complications are experienced in approximately 30% of patients.

Your doctor can explain these surgical procedures to you in more detail if you wish to know more about them.

WHEN SHOULD COLLAGEN IMPLANTS NOT BE USED?

Collagen implant treatment should not be started in any person who: -has been incontinent for less than one year; -has shown improvement in their incontinence in the last year.

In addition, Collagen implant treatment is contraindicated (cannot be used) in any person who: -has a positive reaction to the skin test; -ever had an allergic reaction to a material made with collagen from cows. Some materials used in surgery, such as sutures, are made with collagen from cows. -is getting injections ("shots") to lessen allergy to meat or who will soon get these injections; -had a severe allergic reaction that was a threat to life; -is severely allergic to many substances; -has an acute irritation or infection of the kidney, bladder or the urethra (the urine outlet path from the bladder).

WHAT ARE SOME OF THE THINGS I SHOULD CONSIDER BEFORE CHOOSING COLLAGEN IMPLANTS AS A TREATMENT FOR MY INCONTINENCE?

There are some things you should be aware of before having collagen implant treatment.

If there is a question regarding your skin test reaction, your doctor may have to place another skin test on the other forearm. This, too, must be watched for four weeks before collagen implant treatment is started.

A small number of patients who have received collagen injections for correction of scars and wrinkles have been found to have connective tissue diseases (such as rheumatoid arthritis, scleroderma, dermatomyositis, polymyositis, and systemic lupus erythematosus) after the injections. Experts have not determined whether the collagen injections caused the diseases. They have reported that the number of people with polymyositis / dermatomyositis in the group who had collagen treatments may be higher than should be expected, when compared to the general population of untreated people.

One to two percent of patients treated with implants in skin became sensitive to collagen and had redness, swelling, hardness, and or hives where collagen was implanted.

Side effects seen with skin implants of collagen may develop with collagen implants. These include: rare abscesses; hardening of tissues; scars; allergic reactions; flu-like symptoms; fever; rashes; itching; blurred vision; tingling; and aches and pains.

People who have rheumatoid arthritis, juvenile rheumatoid arthritis or scleroderma, especially, may be sensitive to collagen.



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Persons who are allergic to beef may be allergic to collagen.

If the outlet from your bladder is very small or your urethra is very narrow (called a stricture), you may need to have this corrected before you are treated with collagen implants.

WHAT SHOULD I BE CAUTIOUS ABOUT BEFORE UNDERGOING COLLAGEN TREATMENT?

There are some cautions you should know about before undergoing collagen implant treatment. There is a chance that infections such as urinary tract infection (UTI) or blood in the urine will develop after collagen implant treatment. Because no pregnant women and only a small number of children were included in the clinical studies, it has not been established whether collagen implant may be used safely and effectively in pregnant women, or in children less than 18 years old.

Collagen implant must be used with caution in a person:

- who is receiving treatment that lowers the body's immunity (including steroid medication)
- who has experienced allergic reactions.

The safety of injected collagen implants for dermal (skin) applications has been studied only since 1976, and for urethral injection only since 1985. Long-term safety and effectiveness for urological use has not yet been established.

WHAT ARE SOME OF THE SIDE EFFECTS THAT MAY BE CAUSED BY COLLAGEN TREATMENT?

Almost any medical treatment has some risks. Side effects and complications related to collagen implants treatment that were experienced by patients in the clinical study included:

- urinary retention (inability to pass urine). This was experienced by approximately 8% of the patients and generally was treated with catheterization.
- worsening of incontinence. Approximately 7% of treated patients experienced worsened incontinence lasting one to six months, which was improved with further treatment. Approximately 3% of patients experienced worsened incontinence which did not improve at all during their study participation.
- infection in the bladder or urine pathways. This was experienced by approximately 4% of the patients and was treated with medication.
- blood in the urine for a short time after treatment This occurred in approximately 2% of the patients.
- pain or discomfort at the collagen implant injection site. This occurred in approximately 1% of the patients treated.
- too tight a closure (or obstruction) of the opening from the bladder. This occurred in approximately 1% of the patients.
- sensitivity reaction (such as abscess) in the tissues where the collagen implant was injected. This

was experienced by approximately 1% of the patients and was treated with medication.

WHAT TESTS WILL I NEED BEFORE THE PROCEDURE?

Tests must be done to help ensure that the collagen implant will be a proper and safe treatment for you. These will include a physical exam, a medical history, tests of urine flow (called urodynamics), and a skin test.

The skin test is done to make sure that you do not have an allergy to collagen implants. For this test, a small amount of collagen material is injected under the skin of your forearm. The skin test site is watched for four weeks. Pay special attention to your skin test site during the first three days, since most reactions occur during this time period. If the skin there turns red, swells or itches, notify your doctor.

HOW IS THE COLLAGEN IMPLANT PROCEDURE PERFORMED?

Using a syringe and needle, your doctor injects the collagen implant into the tissues around your urethra. The area is first anesthetized (deadened to pain). A cystoscope (a hollow tube used for seeing into the urethra and bladder) is inserted into the urethra. Then, collagen implant is injected into the tissues surrounding the urethra either from inside the urethra (by inserting the needle through the scope) or from outside the body through the skin and tissues. All the while, the doctor observes the area through the scope to make sure the proper amount of collagen is being injected to allow the bladder opening to close and keep urine from leaking out.

IS MORE THAN ONE TREATMENT NEEDED?

You should understand that collagen implant therapy is not a one-time or permanent therapy and that most patients will need additional treatment sessions to achieve and maintain improvement or dryness.

In general, women need fewer treatments than men do.

WHAT RESULTS CAN I EXPECT AFTER TREATMENT?

Based on clinical studies, women tend to do better than men following treatment with collagen implants. If you are a woman, there is a greater than 80% chance that you will experience some type of improvement (having less leakage or even becoming dry) following treatment. If you do improve, the chance that you will do so after only one or two treatments is greater than 90%. All the women in the clinical study began to improve with from one to four treatments. There is about an 80% chance that you will remain improved for one year after having from one to four treatments with, perhaps, some retreatments and a better than 75% chance that you will remain improved for two years after having one to four treatments with, perhaps, some retreatments. Women treated with collagen implants have about a 70% chance of becoming completely dry after treatment. If you do become dry, the chance that you will do so after only one or two treatments is about 80%. If you do become dry after only one or two treatments, the chance that you will maintain without additional treatments is about 70%. This means that, for a woman, the chance of becoming dry with only one or two treatments and not needing additional treatments is about 40%. For women, the chance that you will remain dry for one year after having one to seven treatments (no retreatments) is about 50%, and the chance that you will remain dry for two years after one to seven treatments (no retreatments) is about 40%.

SUGGESTED POINTS FOR REVIEW OF PATIENT INFORMATION

The following may be of assistance in reviewing with treatment candidates important information from the Collagen Implant Patient Booklet:

1. Before you can be treated with collagen implants, you must have a skin test done to make sure you don't have a reaction to the material.



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- Do you have any allergies?
 - Have you ever had a severe allergic reaction?
 - Have you ever had an allergy to beef or to cow's milk?
 - If you ever had surgery, did you experience a reaction to any of the materials or medicines used during that surgery?
 - If you ever had plastic surgery, did you experience any reactions or side effects after the surgery?
 - Have you ever had a serious infection of the bladder or urinary tract?
2. Do you understand that the collagen implant is injected with a syringe, and that the area around the urethra must be anesthetized before treatment?
 3. Is it clear to you that one or more side effects are possible with collagen implant treatment?
 4. Did the collagen implant pamphlet make it clear to you that you may need more than one treatment to correct your incontinence?
 5. Do you understand that while your incontinence may be improved, it is possible that you may not be completely dry after Collagen implant treatment?
 6. Do you understand that even after improvement or dryness is achieved, you may have occasional regressions that require treatment?
 7. Do you have any questions about the other forms of incontinence treatment and why they may or may not be appropriate for you?