

# ERECTILE DYSFUNCTION PROTOCOL

## *PRELIMINARIES*

### **Background:**

Erectile dysfunction (ED) is the inability to get and keep an erection firm enough for intercourse.

ED alters personal relationships and broadly every aspect in the quality of life of about 30 million men in the United States and more than 150 million men worldwide. ED is associated with hypertension, diabetes mellitus, obesity, metabolic syndrome, hyperlipidemia, smoking, alcohol, and sedentary behavior.

Frequently ED can be the first sign of endothelial dysfunction and potential cardiovascular disease.

### **Causes of Erectile Dysfunction:**

Often, the cause is multifactorial, but vascular causes are the most commonly implicated. Because the development and maintenance of a rigid erection depend on achieving a high intracavernosal pressure, it is not surprising that disorders affecting the peripheral arterial blood flow are strongly associated with erectile dysfunction. The vascular etiology of erectile dysfunction present in 60% of patients can be related to small vessel vascular diseases as in the case of diabetes and large vessel arteriosclerosis as in hypertension, which cause arterial insufficiency/erectile dysfunction.

## *TREATMENT OPTIONS:*

Many treatment options are available for men with ED. Any underlying condition should be treated.

- Phosphodiesterase (PDE) - 5 inhibitors: This drug class consists of sildenafil (Viagra), vardenafil (Levitra), tadalafil (Cialis), and avanafil (Stendra). Sildenafil was the first in this series of PDE inhibitors.
- Vasodilators: The most commonly used agents include alprostadil (prostaglandin E1 [PGE1]), papaverine, and phentolamine.
- Androgens: Treatment of ED in men with low levels of serum testosterone. Androgens may be administered via injections, cutaneous application via gel or skin patches, or oral administration.
- Other treatments: Include intra-urethral pellet therapy / Medicated Urethral System for Erections (MUSE), vacuum devices, placement of prosthetic devices within the corpora.
- Surgical placement of a penile implant.

## MONONUCLEAR LAYER CORD BLOOD PRODUCT TREATMENT OPTION :

Concentrated human stem cell product comprised of donated cord blood, that has been processed to remove excess plasma, red blood cells, vascular material and tissue solids leaving stem cells and other cellular components, which are then concentrated and banked through a validated process.

### **a. Objective:**

To provide the patient with a treatment that stimulates the nitric oxide pathway, promote cellular regeneration, angiogenesis and improve symptoms associated with Erectile Dysfunction. The direct injection in the corpus cavernosum with mononuclear layer cord blood product should serve to promote healing when current treatment is not responding.

### **b. Patient management:**

- *Initial patient evaluation:* Reviews the medical information, lab work, and diagnostic imaging provided by the patient in order to determine the stage of the medical condition and any other secondary conditions. Application of the International Index of Erectile Function questionnaire (IIEF).
- Patient consultation. Informed consent is obtained from all patients and medical records are updated, including patient's most recent physical exam, medication history, most up-to-date lab results and imaging studies. Evaluation of vascular function of the penis is performed by Doppler ultrasound.
- Treatment day:
  - Premedication infusion protocol is started one hour before product application.
  - Benadryl 25mg IM, Zantac 200mg IV, Solumedrol 125mg IV. Single Dose.
  - Attach certificate of analysis to patient's chart.
  - Place the bottle in the palm of your hand until product is in a complete liquid form which can take about 3-5 min.
  - Swab the outside of the vial with alcohol, then remove the sterile cover and draw the contents into a syringe using aseptic technique.

- Injection will performed using sterile technique, per specific protocol consistent with the condition to be treated. Sample should be injected within 2 hours of thawing.
  - ***Procedure for injection into Corpus Cavernosum:*** The corpus cavernosum is infiltrated with 2 cc of 1% Lidocaine, allowing 5 minutes for expansion. 5 cc of SVF / stem cell concentrate is injected using a 1", 27 G needle into the innermost part of the penis and each side of the corpus cavernosum.
  - Product should not be mixed with any other biologic compound.
- c. Risks:** There are possibilities for unwanted effects related to the injection of stem cells. Even with the most established protocol, adequate technique, and careful administration; a medical team may encounter uncontrollable events. Although there is no guarantee of perfect results, excellent results can be attained. The risks of complications with the administration of cord blood products are very low. Possible risks include but are not limited to:
- Pain at site of injections
  - Malaise
  - Fever
  - Allergic reaction
- d. Outcomes:**
- Clinical response evaluated by use of International Index of Erectile Function, review of response to treatment and number of sexual attempts. International standards for follow-up:
- Follow Up Plan:
- Pre-implant:*** Patient consult with his urologist. Clinical evaluation of symptoms.  
Use of International Index of Erectile Function questionnaire (IIEF)
- 3 months after implant:*** Patient follow-up with his urologist. Clinical evaluation of symptoms. Doppler US  
Use of International Index of Erectile Function questionnaire (IIEF)
- 6 months implant:*** Patient follow-up with his urologist.  
Clinical evaluation of symptoms Use of International Index of Erectile Function questionnaire (IIEF)

# ERECTILE DYSFUNCTION – IIEF-5 QUESTIONNAIRE

The International Index of Erectile Function (IIEF-5) Questionnaire

From Macmillan Publishers Ltd: Rosen RC, Cappelleri JC, Smith MD, et al. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. Int J Impot Res. 1999 Dec;11(6):319-26. © 1999.

Over the past 6 months:					
1. How do you rate your <b>confidence</b> that you could get and keep an erection?	Very low 1	Low 2	Moderate 3	High 4	Very high 5
2. When you had erections with sexual stimulation, <b>how often</b> were your erections hard enough for penetration?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
3. During sexual intercourse, <b>how often</b> were you able to maintain your erection after you had penetrated (entered) your partner?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5
4. During sexual intercourse, <b>how difficult</b> was it to maintain your erection to completion of intercourse?	Extremely difficult 1	Very difficult 2	Difficult 3	Slightly difficult 4	Not difficult 5
5. When you attempted sexual intercourse, <b>how often</b> was it satisfactory for you?	Almost never or never 1	A few times (much less than half the time) 2	Sometimes (about half the time) 3	Most times (much more than half the time) 4	Almost always or always 5

## *IIEF-5 scoring:*

The IIEF-5 score is the sum of the ordinal responses to the 5 items.

- 22-25: No erectile dysfunction
- 17-21: Mild erectile dysfunction
- 12-16: Mild to moderate erectile dysfunction
- 8-11: Moderate erectile dysfunction
- 5-7: Severe erectile dysfunction

- *The treatments described in this manual are considered experimental and have not been evaluated or approved by the FDA.*

## *REFERENCES*

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