

**This document sets forth a brief description of the Infusion therapy that you will be receiving, and your consent to the procedures, which include being treated in a group setting unless you make other written arrangements. You may refuse treatment now, or at any time.**

**Metabolism Restoration:**

**Treatment:**

The patient must follow the pre-treatment therapy guidelines. The patient's blood glucose levels are maintained during the treatment so that the liver gets the two signals needed to generate proper metabolism.

1. Patient vital signs are recorded: weight, blood pressure, heart rate, temperature and capillary blood glucose. Oral glucose is given at the start of treatment. Normal saline and insulin are placed in the syringe attached to the pump.
2. An intravenous catheter is inserted in the right/left arm or hand.
3. Patient's capillary blood glucose is monitored frequently throughout the entire treatment. This measurement may be made more frequently if the blood sugars are lower or higher than what is optimal for the treatment.

For the initial treatment, the patient is scheduled for 2 days, back-to-back or with one day between treatment days, for two consecutive weeks. Thereafter, the treatment is usually once a week for 90 days or 3 months until further treatment decisions are made, based on the patient's individualized care plan.

**After Treatment:**

1. After the infusion is complete, the IV site is disconnected.
2. Patient must continue to monitor his or her blood sugar carefully, particularly if they engage in any exercise or physical activity.
3. It is normal to have somewhat elevated blood glucose after the treatment. Patients are advised to engage in some form of light physical activity during the post-activation period to decrease the amount of glucose stored in the muscles. This will help in keeping blood glucose levels in a more normal range. Patient should review any physical plans with the practitioner.

**The Patient must report any changes in his or her health or and medically related complications since the last treatment.**

**Exclusions:**

1. Medical disorders (HTN, Dialysis, ESRD), unstable psychiatric disorders
2. Pregnant
3. Patients who do not comply with the treatment recommendations will be counseled and/or dropped from the treatment program. This includes missed appointments.

**Risks, Discomforts, and Complications:**

Local complications of intravenous (IV) therapy rarely occur, but may present as adverse reactions or mild trauma to the surrounding venipuncture site. These complications can be recognized early by objective assessment. Proper venipuncture technique is the main factor related to the prevention of most local complications associated with IV therapy. Local complications can include bleeding, hematoma, thrombosis, phlebitis, post-infusion phlebitis, thrombophlebitis, infiltration, extravasation, local infection, venous spasm, and hypersensitivity reactions. Systemic complications may include hypoglycemia, hyperglycemia, nausea/vomiting, mild diarrhea, bloating, and muscle cramping, sometimes due to the ingestion of glucose. There is no known unusual or additional risk from the IV access other than any other IV therapy.

**Benefits:** The overall effect of metabolic reconditioning and recovery therapy is to treat the root cause of the metabolic disease or disorder and restore the patient’s ability to lead a normal, or near normal, lifestyle by mitigating or eliminating the chronic effects of the disease. The benefits demonstrated in the ongoing research program include:

1. More controlled and stable blood glucose levels.
2. Increased energy levels and a feeling of well-being.
3. The reduction of complications related to diabetes and other metabolic failures.
4. There is no absolute certainty you will react as other patients, or that you will receive the benefits suggested by clinic studies or prior patient outcomes. However, these outcomes are anticipated and normal with the great majority of other patients.

**Right to refuse or withdraw:** Your treatment is voluntary, and you may refuse any or all treatment, and you may discontinue treatment at any time.

**Anonymous and Confidential Data Collection:** Any information that specifically identifies you will be kept in a secure location and only the healthcare professionals and their authorized staff will have access to the data, or as otherwise agreed by you.

**Group Setting and Group Interface, including Visitors:** The treatment is usually provided in the presence of other patients, and perhaps their families, friends, and visitors. This implies that you will learn about other people in this

setting, and they may hear or see something about you. The fact that you are being treated suggests that you have diabetes or a related disease, and other facts of your medical, mental, and emotional condition may be disclosed, and those are confidential facts disclosed in a group setting. By group treatment, there are many other things that occur that normally would be private, such as psychological help, prayer, or other non-physical aspects of life. You hereby agree that privacy of treatment cannot be maintained in this setting. You may ask to talk in a private room at any time about these issues. However, Costus Medical personnel are not able to control what is said or seen by others, and it is not unusual for information of the most personal type to come out. Information about religious, political, sexual, or socioeconomic views will routinely be discussed in an open forum and if you are not able to be treated in this open forum manner, then private treatment arrangements must be made at a cost that is usually not paid for by insurance. Costus Medical personnel will attempt to keep loud obtrusive and offensive conduct to a minimum. If you want special private treatment settings, you must inform the Costus Medical representative at the first possible time.

**Group Instruction:** Some of the instructions to you will include information that is usually confidential, and you agree to be instructed in public, with the further agreement that your personal interviews, as well as any of your requests, will be conducted in a private room.

**Photographs, images of injured tissue, and graphic depictions:** In order to follow the treatment outcomes, photographs, images, and other recorded means may be used to exhibit progress. This information is used for both your treatment and to substantiate the results and outcomes, and can be shared with others not using your name.

**Whom to contact with questions:** If you have any questions about your treatment, please contact the Clinic Manager.

**Acceptance and signature:** I have read the information provided above, have been asked for any questions, and all my questions have been answered to my satisfaction. I can continue to ask questions at any time I request treatment and will reserve a copy of this consent form for my information.

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Patient’s or Patient’s Representative’s Signature

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Date

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Print Name of Patient and Representative