#### INFORMATION SHEET AND INFORMED CONSENT IV HYDRATION THERAPY

# TREATMENT

Intravenous ("IV") hydration therapy is the administration of intravenous fluids, vitamins, minerals and other nutrients. It is a <u>therapy</u> that delivers liquid substances directly into a <u>vein by inserting a needle and infusing over a period of time</u>. The intravenous route is the fastest way to deliver <u>medications</u> and <u>fluid</u> replacement throughout the body, because the <u>circulation</u> carries them. Intravenous therapy may be used for fluid replacement (such as correcting <u>dehydration</u>), to correct <u>electrolyte imbalances</u>, to deliver medications, and for <u>blood transfusions</u>. The role of IV hydration therapy is to replace the essential nutrients, correction of deficiencies, and for other reported therapeutic effects such as improving immune function, improving antioxidant status, combating fatigue, hangovers, minor colds and flu-like symptoms, treating headaches and improving athletic performance.

## **ALTERNATIVE TREATMENTS**

This procedure may be considered medically unnecessary. It may or may not mitigate, alleviate or cure the condition for which it has been reported to treat. Alternative forms of management include oral consumption of liquids, medications or nutrients depending on the condition being treated and/or dietary and lifestyle changes.

#### **RISKS OF IV HYDRATION THERAPY**

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your health care practitioner to make sure you understand the risks, potential complications, limitations, and consequences of IV hydration therapy. Other complications and risks can occur but are even more uncommon. Should complications occur, additional treatments may be necessary. The practice of medicine and IV hydration therapy is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The possibility of additional risk factors or complications attributable to the use of IV hydration therapy may be discovered. Uncommon and dangerous side effects include:

- headache
- nausea
- Diarrhea
- gastrointestinal hyperactivity
- flushed face
- chills
- upset stomach
- Restlessness
- dizziness

**Pain, Swelling and Redness:** Swelling is a normal occurrence following the injections. It decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary. Discomfort associated with injections is normal and usually of short duration. Redness may occur after injection and be present for a few days.

**Needle Marks:** Visible needle marks from the injections occur normally and resolve in a few days.

**<u>Skin Sensitivity</u>**: Burning and stinging at the site of infusion or if IV infiltrates into the surrounding tissue. Skin rash, itching, and tenderness may occur following injections.

Infection and Allergic Reaction Although infection and allergic reaction following IV hydration is unusual, bacterial, fungal, or anaphylaxis can occur. I should immediately consult my primary health

care Physician and discontinue further use of the product. Signs of allergic reactions include, but not limited to:

- Itching of skin
- Hives
- Rashes
- Wheezing
- Difficulty breathing
- Swelling of mouth or throat

**Phlebitis.** Complications of phlebitis may include local infection and abscess formation, clot formation, and progression to a deep venous thrombosis and pulmonary embolism. When pronounced deep venous thrombophlebitis has seriously damaged the leg veins, this can lead to post-phlebitic syndrome.

**Infiltration** / extravasation Infiltration occurs when an IV fluid or medication accidentally enters the surrounding tissue rather than the vein. **Extravasation** occurs when vesicant solution (medication) is administered and inadvertently leaks into surrounding tissue, causing damage to surrounding tissue. Characterized by the same signs and symptoms as infiltration but also includes burning, stinging, redness, blistering, or necrosis of the tissue.

**Fluid overload.** This occurs when fluids are given at a higher rate or in a larger volume than the system can absorb or excrete. Possible serious consequences include hypertension, heart failure, and pulmonary edema.

<u>Unsatisfactory Result</u>: IV hydration therapy alone may not produce an outcome that meets your expectations. There is the possibility of a poor or inadequate response. Additional IV hydration therapy or other treatments may be necessary.

**Unknown Risks:** The long term effect of IV hydration is unknown. The possibility of additional risk factors or complications attributable to the use of IV hydration may be discovered.

**Pregnancy and Nursing Mothers:** Animal reproduction studies have not been performed to determine if IV hydration therapy could produce fetal harm. It is not known if the particular formula used or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive IV hydration therapy. I will make sure to tell my Physician if I am pregnant, lactating or have any of the following conditions:

- Leber's Disease
- Kidney disease
- History of Kidney stones
- Liver disease
- Hormonal disease
- Cardiovascular disease
- History of ulcers
- History of gastrointestinal problems
- Bipolar disorder (manic depression)
- Attention Deficit Hyperactivity Disorder (ADHD)
- Muscular Dystrophy
- Elliptic seizures
- Hypoglycemia
- Schizophrenia
- Benign prostatic hypertrophy (BPH)

- Acetaminophen poisoning
  - Hypertension (high blood pressure)
- History of seizures
- Under-active thyroid (hypothyroidism)
- Osteoporosis
- Receiving treatment or taking any medication that might "thin" the blood
- Receiving treatment or taking medication that has an effect on bone marrow
- An infection
- Iron deficiency
- Folic acid deficiency
- Dependent on intravenous nutrition (TPN) or liquid nutrition products for food
- Diabetes, mellitus, or high blood sugar levels
- An unusual or allergic reaction other medicines, foods, dyes, or preservatives

**Drug Interactions:** It is not known if IV hydration therapy reacts with other drugs within the body. Some of the medications that may cause drug interactions include, but are not limited to:

- Heparin (Fragmin, Lovenox, Innohep...ect.)
- Antithrombin (A Tryn, Thrombate III)
- Argatroban
- Aspirin
- Ibuprofen
- Dipyridamole (Persantine)
- Bivalirudin (Angiomax)
- Clopidogrel (Plavix)
- Warfarin (Coumadin, Jantoven)
- Nonsteroidal anti-inflammatory drugs (Ibuprofen,...etc.)

**DISCLAIMER** Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed-consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your medical provider may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the current state of medical knowledge. Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

# It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

## INFORMED CONSENT FOR IV HYDRATION THERAPY

- 1. I \_\_\_\_\_\_am over the age of 18 years or older and am of sound legal mind to authorize and consent to the use of IV hydration therapy.
- 2. I have read the 2 page information sheet and hereby authorize my medical provider and/or such assistants as may be selected by my medical provider to perform the IV hydration therapy.
- 3. I understand what my medical provider can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered.
- 4. I understand the specific risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- 5. I understand that multiple treatments may be necessary to achieve desired results.
- 6. I understand that clinical results will vary per patient. I agree to adhere to all safety precautions and regulations during the treatment.
- 7. I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and /or court cost and reasonable legal fees, should this be required. No refunds will be given for treatments received. I understand that if complications arise, I will be responsible for the cost of any treatment.
- 8. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
- 9. For purposes of advancing medical education, or staff training, I consent to the admittance of observers to the treatment room.
- 10. I have informed the clinical staff of any known allergies to drugs or other substances that may be included in the ingredients of my solutions, or of any past reactions to anesthetics. I have noted all of these on the patient history form.
- 11. I have informed the clinical staff of any history or current/recent use of recreational/illicit drugs, understanding this could affect my outcome or reactions.
- 12. I have informed the clinical staff of all current medications and supplements and documented on the patient history form.
- 13. I have informed the clinical staff of my prior medical history and documented in the patient history form.
- 14. To my knowledge, I am not pregnant and I am not breast feeding. I understand it is not recommended to receive IV hydration therapy in pregnancy or with breast feeding.
- 15. I understand that I may suspend or terminate my treatment at any time by informing my medical provider.
- 16. I understand that I am experiencing any adverse effects or symptoms after I receive IV hydration therapy, I will seek medical evaluation.
- 17. I fully understand and confirm that the nature and purpose of the aforementioned treatment to be provided may be considered unproven by scientific testing and

peer-reviewed publications and therefore may be considered medically unnecessary or not currently indicated.

18. I understand that I can withdraw my consent at any time.

Patient Signature	9	Date:
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Witness Signature \_\_\_\_\_ Date: