FAQs Regarding Patient Suitability for Clearfast®

To address properly the question of which patients are suitable candidates to receive Clearfast® two hours prior to surgery, one must first review the original 1999 ASA® (American Society of Anesthesiologists®) Preoperative Fasting Guidelines for Elective Surgery on Healthy Patients. The ASA defined “healthy patients” as those qualifying as ASA Physical Status Classification I and II, out of a possible range of I to V. The following is a brief synopsis of that Classification System, wherein,

ASA I:
Patients are considered to be normal and healthy. They are able to walk up one flight of stairs or two level city blocks without distress. They have little or no anxiety and are virtually free of any systemic diseases, e.g., high blood pressure, diabetes, asthma, cancer, etc. They represent little to no risk for an anesthesia encounter.

ASA II:
Patients have mild to moderate systemic disease that is well controlled, e.g., non-insulin dependent diabetes, mild hypertension or pre-hypertension, epilepsy, asthma, thyroid conditions, etc. They are able to walk up one flight of stairs or two level city blocks, but may have to stop after completion of the exercise because of fatigue or mild distress. They represent minimal risk for an anesthesia encounter. They may or may not require a prior exam and medical clearance by their primary physician.

ASA III:
Patients have severe systemic disease that limits activity, but is not incapacitating, e.g., history of angina pectoris [angina], myocardial infarction [heart attack], cerebrovascular accident [stroke], congestive heart failure over six months ago, slight chronic obstructive pulmonary disease [COPD], controlled insulin dependent diabetes [Type I or II], hypertension, peripheral vascular disease, etc. [Patient would normally require a preoperative medical consultation.] Patients are often unable to walk up one flight of stairs or two level city blocks without pausing because of some distress. They represent a moderate risk for an anesthesia encounter and should have a prior exam and medical clearance by their primary physician.

ASA IV:
Patients have severe systemic disease that limits activity and is a constant threat to life, e.g., history of unstable angina pectoris, myocardial infarction or cerebrovascular accident in the last six months, moderate to severe chronic obstructive pulmonary disease, uncontrolled diabetes, malignant hypertension, poorly controlled epilepsy, thyroid condition, etc. They are usually unable to walk any distance at all, having distress or shortness of breath at rest. These patients pose a significant medical risk for an anesthesia encounter and are not usually considered candidates for elective surgery. A comprehensive pre-anesthesia medical consult is essential.

ASA V:
Patients are moribund and are not expected to survive more than 24 hours with or without an operation. They are considered terminally ill.

As the prevention of regurgitation and aspiration of stomach contents was the basis for 50 years of traditional pre-operative fasting, it remains the basis for possibly “disqualifying” patients from following the “liberalized” clear liquid fast. Therefore, any condition that potentially retards gastric emptying may present a contra-indication for Clearfast®. But, as the label on Clearfast® indicates, it must be used under the patient's medical supervision.
All that follows will be predicated on the above assumption. The purpose of this discussion is merely to cite the relevant literature and the ever-expanding body of “best evidence.” That said, here are some of the most Frequently Asked Questions (FAQs) about the use of Clearfast®. No doubt, others will emerge with time as some of these may become less relevant:

1. Can a diabetic drink Clearfast® like anyone else? Is it because he (she) has high blood sugars and carbohydrate-rich drinks like Clearfast® would make that worse?
   a. There are two classes or types of diabetes. In Type I, sometimes called Juvenile Diabetes because it commonly starts at a young age, patients do not have adequate levels of insulin and are dependent on injectable insulin to control their blood sugars. In Type II or “adult onset diabetes, insulin levels may be adequate but the patients act “insensitive” or “resistant” to it, or insulin resistant (IR). Treatment may involve exercise and weight management, oral anti-hyper-glycemics or insulin. When blood sugar control is optimal, both types of patients are called “euglycemic.”
   b. While glucose levels are important, the real concern about diabetics having clear liquids 2 hours prior to surgery is the notion that all diabetics have delayed gastric emptying. That would suggest that they are more likely to regurgitate and aspirate their stomach contents under anesthesia than non-diabetics.
   c. Two studies found that Type II diabetics or patients demonstrating insulin resistance (IR) could safely ingest 400 ml of a carbohydrate-rich beverage two hours before surgery. The first study concluded that Type II diabetics showed no signs of delayed gastric emptying:
   d. Our partners at Duke University are comfortable about giving Type I diabetics Clearfast® because, like most anesthesia professionals, they would be carefully managing the glucose levels of these patients who would likely receive a pre-Clearfast® dose of insulin to “match the calorie load” and have their blood sugar levels monitored pre-anesthesia induction as well as several times during the course of surgery. The assumption being that gastric emptying in a “euglycemic” patient should be no different from a non-diabetic.

2. Can ladies in labor have Clearfast?
   a. The archaic traditional pre-operative fast from midnight to whenever surgery starts began in 1946 when Obstetrician, Mendelson, described what happened when laboring women who had eaten and drunk during labor regurgitated and aspirated their stomach contents under anesthesia. They had no airway protection such as endotracheal (breathing) tubes and probably breathed a combination of oxygen and ether. The instances that involved aspiration of solids were often lethal.
   b. Over the last 22 years, there have been at least 6 review articles on the status of fasting during labor. Several comment on the incidence maternal mortality associated with aspiration at 7 in 10 million births. All criticize the lack of evidence for sustaining the policy both in the US and abroad (though facilities in Northern Europe and Switzerland apparently subscribe to a more liberalized fasting policy that includes carbohydrate-rich beverages). Finally, in 2011, researchers at the University of Pittsburg did such a study comparing, not a clear carbohydrate-rich beverage (which would seem like the logical first step), but a protein drink supplement containing 30 gms of protein in 11 ounces versus ice chips in the laboring population.
The conclusions of that trial were:

i. The ice chip group had lower mean satisfaction scores and higher nausea and emesis incidences;
ii. No patients required general anesthesia, all had epidural anesthesia;
iii. No patients aspirated.

Manasi B, Shah T, Rice J et al. Protein Drink Supplementation to Promote Parturient Satisfaction during Labor. 2011, Abstract Number 25 Presented at the Annual Meeting of the Society for Obstetric Anesthesia and Perinatology, Chicago, IL

3. Can other patients with possible delayed gastric emptying have Clearfast®? What about obese patients?
   a. While the assumption that obesity implies delayed gastric emptying is time-honored, a most recent study has concluded just the opposite [BMI≥40]: Buchholz V, Berkenstadt H, Goitein D et al. Gastric emptying is not prolonged in obese patients. Surg Obes Relat Dis. 2013 Sep-Oct;9(5):714-7.
   b. A more dated study concluded the opposite in obese women, but offered no good explanation [BMI not stated]: Jackson SJ, Leahy FE, McGowan AA et al. Diabetes Obes Metab. 2004 Jul;6(4):264-70

4. How about patients who have had gastric reduction procedures...gastric sleeves and gastric banding?
   a. Three articles in the last two years have described “De Novo” GERD following Sleeve Gastrectomy, Delayed Gastric Emptying (DGE) after paraesophageal hernia repairs and DGE following gastric banding:
      iv. Medical supervisor might consider adjusting Clearfast® back to 3 hours prior to surgery.

5. What about patients with a history of GERD?
   a. The first question is: Are they currently being treated?
   b. The second question is: Are their symptoms completely controlled with the current treatment?
   c. Medical supervisor might consider adding an a.m. dose of anti-GERD med on the morning of surgery plus pushing Clearfast® time back to 3 hours prior to surgery.

6. Will patients taking drugs that slow gastric emptying be able to have Clearfast®?
   a. Narcotics/pain medications including Demerol
   b. Antispasmodics for the bowel, including atropine, scopolamine
   c. Antispasmodics for the bladder, including Ditropan, Detrol, Vesicare, Flavoxate, Enablex
   d. Antimuscarinics or bronchodilators, including Artane, Cogentin, Atrovent, Spiriva
   e. Medical supervisor might consider pushing Clearfast® time back to 3 hours prior to surgery.

7. Will children be able to have Clearfast®?
   a. The ASA has stipulated the same 2 hour clear liquid fast for healthy children and adults. BevMD is working on an appropriate serving size for children.