

True You Weight Loss is seeking volunteers to participate in a randomized validation research study:

## HYBRID ARGON PLASMA COAGULATION & ENDOSCOPIC SLEEVE GASTROPLASTY TRIAL (HAPCET 2.0)

**THE PURPOSE** of this investigational research study is to assess whether we can further enhance the durability of the Endoscopic Sleeve Gastroplasty with an advanced Endoscopic technique called HAPC (Hybrid Argon Plasma Coagulation). We will be comparing two groups, those with HAPC+ ESG vs. those with ESG alone. We will also be assessing weight loss outcomes and improvement of obesity related co-morbidities between the two groups.

## WHAT IS THE HAPC + ESG APPROACH & WHY ARE WE USING IT?

This is a weight loss procedure performed to reduce the size of your stomach (via ESG) in combination with a Hybrid Argon Plasma Coagulation (HAPC) technique to aid in tissue repair. It is thought that a hybrid ESG with the addition of APC may aid in durability of sutures which can potentially lead to a safer procedures & greater weight loss outcomes and gastroplasty healing along with other metabolic benefits.

FOR MORE INFORMATION, CONTACT A MEMBER OF THE STUDY TEAM!

RESEARCH@TRUEYOUWEIGHTLOSS.COM

## **CAN I PARTICIPATE?**

- 21-65 Years Old
- BMI 30-40
- Willing to make lifelong diet changes
- Struggled with past non-surgical weight loss
- Commitment to monthly virtual and on-site follow-up appointments for one year
- Agree to use birth control methods if of childbearing potential
- Residing within a reasonable driving distance from the True
   You Weight loss Cary, NC location
- Approved to undergo the ESG procedure at True You Weight Loss

## WHAT TO EXPECT?

- If you agree to participate in the trial, you will be randomly assigned (like a flip of a coin) to one of two groups: HAPC and ESG vs ESG alone. You will not know which group you are in. This is to assess the safety and effectiveness of the HAPC technique systematically.
- From the time of study enrollment, your participation would last up 1 year.
- Monthly virtual provider & dietician visits
- Monthly Questionnaires
- 3 Lab draws at Baseline, Month 6, & 12
- 1 Endoscopy at Month 6