

## Time to get a new handle on your Diabetes

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Laparoscopic Implantation of an Electrical Stimulator of the Stomach is a new, investigational surgical treatment for patients with Diabetes Mellitus Type 2.

If you think you might qualify for this study and are interested, please contact us for further information.

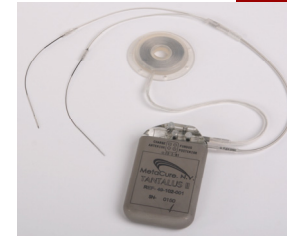


**Caution:  
Investigational Device.  
Limited by Federal (US) law to  
investigational use.**

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## Surgical Treatment of Type 2 Diabetes



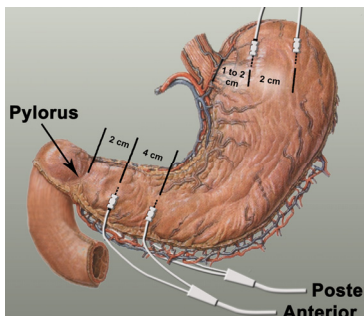
## What is the TANTALUS® System?

The TANTALUS II is an **investigational** device very similar to a heart pacemaker that is **designed** to sense when you are eating and deliver a small electrical current to the stomach. The TANTALUS must be charged once a week by placing the charging device over the TANTALUS which is underneath the skin for about a 1 hour period.

This technology is **intended** to treat Type 2 diabetes with obesity by reducing blood sugar levels and weight.

### How is the surgery done?

This operation is done laparoscopically through several small incisions using special cameras and instruments. The TANTALUS is placed under the skin of the abdomen much like a heart pacemaker and the wire electrodes are sutured to the stomach. The benefits of doing this surgery laparoscopically are less pain, quicker time to recovery and it can be done as same day surgery. Risks of the surgery include (but are not limited to) bleeding, infection and injury to other organs.



## Do you qualify for this study?

We are starting a study here at Vanderbilt Hospital called “The TANTALUS II for the Treatment of Type 2 Diabetes: A Randomized Study.” The purpose of the study is to help determine if this **investigational** device can improve diabetes in certain patients.

To be a potential candidate for this study, one must meet certain inclusion criteria, including:

- Have type 2 diabetes
- Between the ages of 18 to 70
- Have a body mass index (BMI) between 28 and 45 kg/m<sup>2</sup>. BMI is calculated by dividing a person’s weight by his or her height.
- Be medically treated for diabetes with stable, oral medication over the last 3 months
- Have stable weight with no significant changes in the prior three months

### Those not eligible for this study include individuals who:

- Receive insulin or BYETTA therapy
- Have a systolic blood pressure above 150
- Take medications known to affect gastric motility
- Are experiencing severe and progressing diabetes complications
- Have had prior bariatric surgery
- Use an active medical device such as an ICD, pacemaker or neurostimulator

Other criteria will be explained to candidates by the investigators.



## What can I expect if I sign up for this study?

If you sign up for this study you will be agreeing to have blood drawn for research studies and to undergo a surgical procedure to implant the TANTALUS pulse generator and electrodes into your stomach. You will return frequently (17 times during the first year) to check any improvements in your diabetes.

You will be compensated for your participation in the study. All costs of the study including the surgery will be paid by the sponsor of the trial. Neither you nor your insurance company will be charged.

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