

## What to Expect at Your Implantation Surgery and Setting the Device

### About The ADvance Study

The ADvance Study is researching the use of deep brain stimulation of the fornix (known as DBS-f), a place in the brain that plays a central role in memory, in people with Alzheimer's disease. DBS-f uses a surgically implanted medical device, similar to a heart pacemaker, to deliver mild electrical pulses to precisely targeted areas of the brain.

FOR MORE INFORMATION,  
VISIT:

[www.ADvanceStudy4AD.com](http://www.ADvanceStudy4AD.com)



All subjects in the study will have a DBS-f system implanted, with the stimulation device turned on for half of the subjects, and off for half. If your device is left off at the start of the study, you will have it turned on after 12 months. Your physical health, psychological state and level of physical skills, memory and thinking patterns will be tested before and for 18 months following implantation of the system. The DBS-f system or certain components of the system are likely to remain in your body for the rest of your life.

## Implantation Surgery

### What is the Implant Procedure?

During this procedure, an experienced neurosurgeon will implant the DBS-f system in your body. The system includes an implantable neurostimulator that resembles a pacemaker and two attached wires that deliver electrical pulses directly to your brain.

### Should Someone Come With Me To the Hospital for Surgery?

Yes. You will need to bring the same family member or primary caregiver who accompanied you on your previous study appointments.

### What Will Happen to Me During the Implant Procedure?

The DBS-f system will be implanted under general anesthesia. The procedure involves placing a frame on your head that helps the surgeon identify the proper location to insert the wires. Your surgeon will implant the wires on both sides of the fornix area of your brain. These wires will be implanted beneath the skin in your neck and connected to the neurostimulator that is placed under the skin of the chest. The neurostimulator has a battery and electronics inside a strong metal shell.

### How Long Will I be in the Hospital?

Most subjects will be able to go home one to three days after surgery.

### **What is the Healing Process?**

Healing can take several weeks. Discomfort or pain at the incision sites can be managed with medication. For several weeks you should avoid strenuous activity, arm movements over your shoulder, and excessive stretching of your neck.

### **Setting the Device**

#### **When and How is the Device Activated?**

You will return to the clinic 2 to 4 weeks after the implant for a general assessment, including a physical exam and some questionnaires. After the assessment, your DBS device will be tested wirelessly through a computer, without needing to invade the body, to control the pacemaker. You will then be assigned by chance to one of two groups:

**Brain Stimulation On – the device will be activated by a technician**

**Brain Stimulation Off – the device will be left off by a technician**

You will have a 50-50 chance of being placed in either group. You will not be told if your device is turned on or left off. The physician will also be “blind” in the study and will not know whether the device is on or off for each subject.

If you are in the “On” group, your device will be turned on for the duration of the study. If you are in the “Off” group, your device will be left off for the first 12 months, and turned on after 12 months.

Your device will be tested during this visit and all future study visits. During this testing, you may have some side effects of the system like déjà vu (feeling as though you have previously experienced a situation) or other similar experiences.