

Magnet Therapy/Implants

Surgically implanted magnets have been used for many years. Our team has been involved in a variety of FDA clinical trials with magnets since 2009.

Magnets have been successfully used in heart and brain stents as well as orthopedic applications. Our work and the work of others has shown that:

Implanted magnets are safe, and when encased in titanium cause no injury to humans.

Titanium encased magnets can remain in the body for years without any ill effects to the patients.

Magnetic movement of bone and tissue is almost imperceptible and painless to patients.

Implanted magnets cause minimal disruption to daily life.



The University Of California at San Francisco is a world leader in health care. The Department of Otolaryngology, Head and Neck Surgery and the Sleep Disorders Center have participated in a number of OSA clinical trials. These UCSF physicians and surgeons with years of experience are considered leaders in their field.

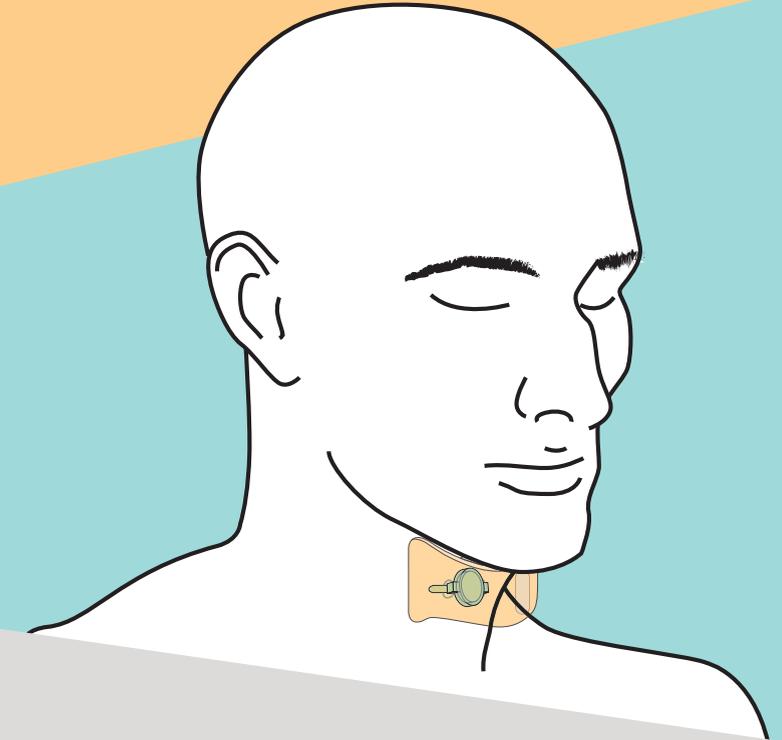
MagNap, Inc

MagNap, Inc. developed the OSA implant. We have worked with UCSF for the last 4 years testing the structure and function of the device. This intensive testing has lead to our FDA approved clinical trial.



MagNap Clinical Trial *for Obstructive Sleep Apnea*

The MagNap device was developed at the University of California San Francisco. All the surgeries and aftercare will take place at the UCSF Mt Zion Campus and treatment will be handled by Otolaryngology, Head and Neck Surgeons and Sleep Study Physicians.



MagNap Clinical Trail

For more information contact our trial coordinator, Jill Imamura-Ching

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Additional information is available at
magnapsleepapnea.net

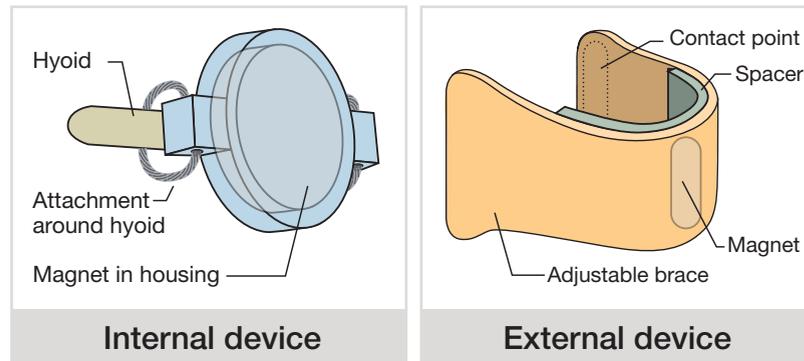
MagNap is a new sleep apnea treatment for patients who are unable to tolerate use of CPAP type devices.

Using magnetic attraction, the MagNap device keeps the airway open during the night, preventing sleep apnea episodes. The device makes absolutely no noise and is easy to wear.

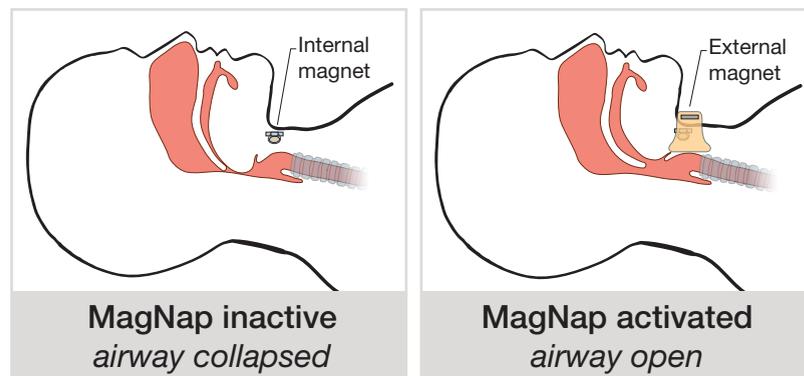
The MagNap Treatment for OSA

FDA Approved Trial

MagNap is a new surgical treatment for certain types of Obstructive Sleep Apnea or OSA. The device is composed of two rare earth magnets. The internal device, a little larger than a dime, is encased in titanium and implanted on the hyoid bone. This is a small free floating bone in your neck. The external device includes another magnet, which is attached to a small neck brace to be worn while sleeping.



Simply, the two magnets are attracted to each other and gently keep the airway open at night preventing bouts of OSA. The position of the external brace permits the magnet attached to the hyoid bone to be moved gently, allowing the airway to remain open throughout the night. During waking hours the magnet in the neck performs no function and does not inhibit any of the daily routines or activities.



This trial is sanctioned by the UCSF Committee for Human Research (CHR) and is approved by the FDA. You can obtain additional information at clinicaltrials.gov. Once there enter "magnap" in the search field.

How Will You Be Considered For the Trial?

In order to be considered for the trial, you must have OSA that is not adequately treated by a CPAP or similar device. You must be between 21–70 years of age and have tried other non-invasive therapies (weight loss, positional therapies, etc.). You will be required to provide the results from any sleep studies and undergo a series of interviews, exams and reviews by the study team. It may also be necessary to have an additional sleep study to confirm the diagnosis.

Your willingness to participate is also a factor in being accepted into this 13 month trial. We will require you to keep sleep journals and regularly correspond via email with the UCSF study coordinator. You will probably know that the device is working before we do and your cooperation is essential to the trial's success.

Cost for the Trial

There is no cost to the patient for the trial. All surgical and study expenses as well as a travel allowance will be covered by the trial's sponsor, MagNap, Inc.

Surgery

Once you have been accepted into the trial, a one hour surgery under general anesthesia will be scheduled. The MagNap will be attached to the hyoid bone through a small incision in your neck.



Recovery

Following the operation you will spend up to 23 hours overnight, first in recovery and then on a hospital ward, before you are examined and released. You may require over-the-counter pain medication for the first few days that you are at home. You should be able to return to normal activities within a few days.

We will provide you with a medical data necklace. This will tell others that you have an implanted magnet in your neck and you cannot have an MRI.

Bracing

You will be fitted with a small neck brace within a month of the surgery. The brace will be custom made to your neck and will be held in place by the proximity of the two magnets. We can adjust the distance between the magnets and the strength of the magnet inside the brace.



Monitoring and Treatment

There will be a number of fittings and adjustments made during the course of the trial. We will perform four additional sleep studies to evaluate the effectiveness of the MagNap system. Detailed sleep journal entries will be required as well as periodic conversations with the study coordinator. We will also schedule periodic examinations by the surgeons and sleep study physician.

Trial Completion

The trial will be completed within 13 months of implantation. At that time you may have the option to leave the device implanted or have it removed.