

## For Those Who Snore Heavily, Implants May Help

By DONALD G. McNEIL Jr.

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Gerard O'Donnell is a firefighter, so his snoring - which sounds like a chain saw fighting its way through 500 pounds of toffee - is a problem at work as well as at home.



Dr. Charles P. Kimmelman treating Gerard O'Donnell.

His girlfriend frequently gets up to sleep in her son's bed "just so she can get a few hours," he said.

At his Brooklyn firehouse, he stays up late, trying to be the last one into the bunkroom, "but they still bust my chops." His crew mates even added a box of nasal strips to one of their grocery runs. It didn't help.

So last month, Mr. O'Donnell tried something new. Dr. Charles P. Kimmelman, a Manhattan otolaryngologist, injected three braids into the back of his throat.

The treatment, known as the pillar palatal implant system and patented by the Restore Medical Company of St. Paul, has been performed on about 9,000 Americans and 1,000 patients in Europe and Hong Kong. It has received publicity because it is faster, cheaper and far less painful than traditional snoring surgery.



[A New Treatment for Sleep Apnea](#)

How well it works, however, is still an open question, and most insurance companies do not pay for the operation, which costs \$1,500 to \$3,000.

The braids, like the battens sewn into yacht sails to stiffen them, reduce the flapping of the soft palate, which makes most of the noise in snoring and helps close off the airway, causing sleep apnea.

Mr. O'Donnell has relatively severe apnea; a night in a sleep lab showed that he woke up momentarily as many as 67 times an hour.

"I don't get real rest," he said. "I never reach that REM sleep."

For a year, he tried to use a continuous positive airway pressure machine, generally regarded as the most effective apnea treatment, but like many patients, he hated it. A habitually fidgety person, he could not stand being tethered by the nose to a tube blowing cool air into his lungs, and he often tore it off as he slept.

His girlfriend saw the pillar implant on television and made an appointment at Dr. Kimmelman's Upper East Side office. "I thought it was worth a shot," Mr. O'Donnell said.

Dr. Kimmelman said he gave Mr. O'Donnell the implant, even though it is not approved for treating severe apnea, because the sleep test showed that Mr. O'Donnell's blood still had high oxygen levels. Apnea that radically lowers blood oxygen is associated with strokes and heart disease.

The whole procedure took about half an hour, and the only pain was the initial Novocaine shot, Mr. O'Donnell said. The braids, each nearly an inch long, were injected through a curved needle on a handle resembling a toy gun.

Afterward, the doctor pushed a fiber optic scope up his nose to check that the inserts did not protrude above the palate and sent him home with a prescription for mild painkillers.

Dr. Kimmelman, who said he had no financial interest in Restore Medical and was not part of its clinical trials, is one of the device's most enthusiastic backers.

"I kick myself that I didn't think of it," he said. "It's so simple: if you look at the flags on Fifth Avenue, you can see metal rods that keep them from flapping around. It's the same idea: you stiffen the apparatus, but still allow it to function normally."

Of the many treatments for snoring and apnea, none are routinely successful. The most popular home remedies - kicking one's partner and pinching the nose shut - are short-term solutions with the risk of serious domestic side effects. Separate bedrooms can be costly.

Traditional operations, which Dr. Kimmelman has performed, involve cutting away the uvula and soft palate, removing tonsils, trimming the back of the tongue or sawing the jaw apart to move the tongue forward.

Uvulopalatopharyngoplasty (or palate-trimming), the most common, requires hospitalization, often leaves patients in pain for weeks and works less than half the time, sleep experts say. In some cases, patients end up talking with cleft-palate nasality, or regurgitate beverages into their noses.

The pillar implant's other advantage is that the inserts can be removed if they don't work.

But it is still controversial. The company's tests show that up to 75 percent of patients and 90 percent of their bed partners report decreases in snoring and recommend the procedure.

The Food and Drug Administration approved it for snoring in 2003 and for mild to moderate apnea last year. In March, the American Academy of Sleep Medicine complained that those approvals, especially for apnea, were premature.

The four clinical trials on it were done overseas, and two involved fewer than 20 patients, said Dr. Michael J. Sateia, the academy's president. Also, instead of using sleep studies to measure effectiveness, the investigators asked patients about their daytime sleepiness and their partners about their snoring.

A spokesman for the F.D.A. said the implant had been approved because of a combination of that data and an agency ruling that it was similar to two previously approved measures: a procedure that stiffens the palate by bombarding it with radio waves and another that involves putting a screw inside the chin to hold down the tongue.

Dr. Stuart F. Quan, a former president of the sleep medicine academy, said he considered the implants experimental and did not recommend them to patients.

"It may work, but I don't think it's been appropriately studied," he said. "Apnea is a complex thing, and it's not just anatomic. The idea that you'd be able to apply this to all patients is naïve."

J. Robert Paulson Jr., president of Restore Medical, said he considered the implant a "minimally invasive, clinically effective alternative" to airway pressure machines, which prevent apnea if used correctly.

The company is conducting three more clinical trials now, involving 236 patients, he said.

They will be double-blind, with neither the patient nor the doctor knowing whether the needle gun has inserted the implants or is what he called "a sham stick."

Mr. O'Donnell is not participating in a trial, but five weeks after the implant, he could be forgiven for wondering whether he had had a sham stick.

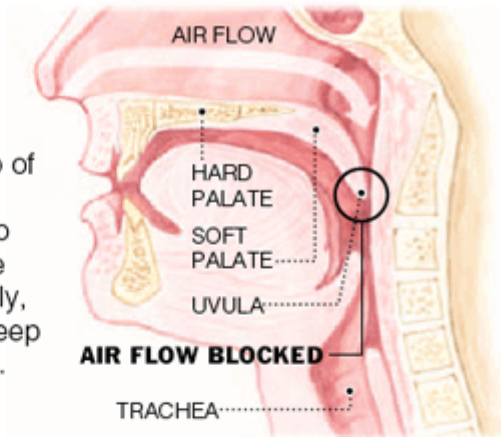
"I'm still the same guy who still snores," he said. "My girlfriend still gets up and goes in the other room."

Dr. Kimmelman has told him to be patient and remember that it can take some weeks for scar tissue to form, stiffening the palate further.

He is being patient, he said, "but I'm a divorced father of three, and springing for \$2,500 isn't easy. I was hoping for a little more." ■

# A New Treatment For Sleep Apnea

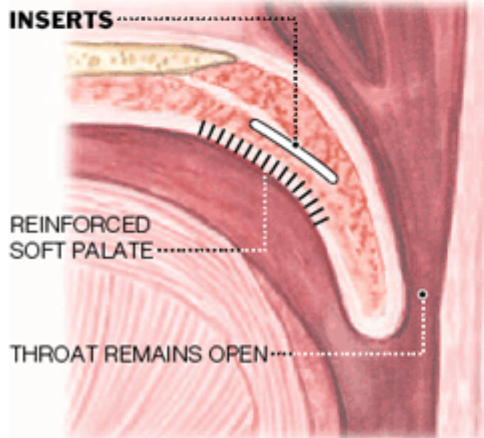
Obstructive sleep apnea, is caused when tissue, like the uvula, at the tip of the flexible soft palate, momentarily closes the throat, blocking air flow to the trachea. Lacking enough air, the sleeper struggles to breathe normally, often choking. The resulting poor sleep quality may lead to health problems.



## A Possible Answer

A recently tested technique has been developed, in which inserts are implanted into the soft palate. The inserts reinforce and stiffen the soft palate, limiting its movement and its ability to block the throat.

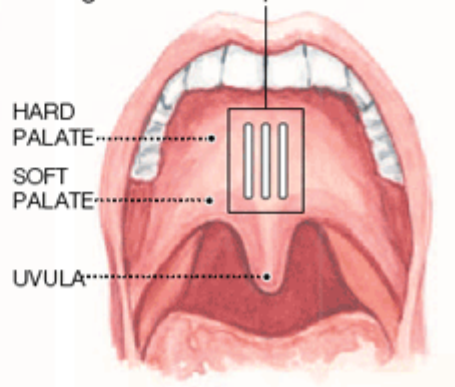
### SIDE VIEW



Source: *Restore Medical Inc.*

### FRONT VIEW

The inserts are spaced close together so that tissue growth after implantation adds even more strength to the soft palate.



Visit Dr. Kimmelman's website for more information: [www.stopsnoringnewyork.com](http://www.stopsnoringnewyork.com)