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New Implant Offers Hope for Easing Rheumatoid Arthritis

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The Food and Drug Administration on Wednesday approved a medical device that offers new hope to patients incapacitated by rheumatoid arthritis, a chronic condition that afflicts 1.5 million Americans and is often resistant to treatment.

The condition is usually managed with medications. The device represents a radical departure from standard care, tapping the power of the brain and nervous system to tamp down the uncontrolled inflammation that leads to the debilitating autoimmune disease.

The SetPoint System is an inch-long device that is surgically implanted into the neck, where it sits in a pod wrapped around the vagus nerve, which some scientists believe is the longest nerve in the body. The device electrically stimulates the nerve for one minute each day.

The stimulation can turn off crippling inflammation and “reset” the immune system, research has shown. Most drugs used to treat rheumatoid arthritis suppress the immune system, leaving patients vulnerable to serious infections.

On a recent episode of the [American College of Rheumatology](#) podcast, the SetPoint implant was described as representing a “true paradigm shift” in treatment of the disease, which until now has relied almost entirely on an evolving set of pharmaceutical interventions, from gold salts to powerful agents called biologics.

The F.D.A. designated the implant as a breakthrough last year in order to expedite its development and approval. It represents an early test of the promise of so-called bioelectronic medicine to modulate inflammation, which plays a key role in diseases including diabetes, heart disease and cancer.

Clinical trials are already underway testing vagus nerve stimulation to manage inflammatory bowel disease in children, lupus and other conditions. Trials for patients with multiple sclerosis and Crohn’s disease are also planned.

In a yearlong randomized controlled trial of 242 patients that included a sham-treatment arm, over half of the participants using the SetPoint implant alone achieved remission or saw their disease recede. Measures of joint pain and swelling fell by 60 percent and 63 percent, respectively.

The most common serious complication was hoarseness associated with the implantation surgery, which just under 2 percent of participants experienced.

The device’s long-term effectiveness and safety outside a clinical trial are not yet known. The F.D.A. required post-marketing monitoring of patients and adverse events as part of the approval.

Surgery involving implants can lead to serious infections that may be resistant to antibiotics, experts noted.

For Dawn Steiner, 58, a speech pathologist in Massapequa, N.Y., who participated in the clinical trial, the implant has been a game changer.

She was diagnosed with rheumatoid arthritis 15 years ago and has tried eight different biologic agents since then. Some of them worked for a time, but their efficacy eventually waned and they carried serious side effects.

Ms. Steiner received the implant in July 2023. In an interview, she said the change was dramatic. She is much more mobile than she used to be, and though she is not completely pain-free, she can go for walks and experiences much less swelling in her joints.

Importantly, she is not immunocompromised, a side effect of the medications she had taken.

"Before the implant, the doctor would ask where I was in terms of pain on a scale of one to 10, and I would say I was living a six or seven," Ms. Steiner said. "Now I'm about a two."

Best of all, she added, she can go to rock concerts and ball games, which she often had to miss in the past because it was so hard to get in and out of large arenas and stadiums.

"I literally feel like I got my life back," Ms. Steiner said.

The SetPoint device is the product of decades of research spearheaded by Dr. Kevin J. Tracey, a neurosurgeon who is president and chief executive of the Feinstein Institutes for Medical Research at [Northwell Health](#).

Dr. Tracey co-founded [SetPoint Medical](#), but now serves as an adviser.

He describes the vagus nerve, which originates in the brain and travels to virtually all the organs of the body, as an "on-off switch" for an overactive immune system.

"The brain can turn off inflammation as long as the vagus nerve is intact," he said. "It's like a brake system in your car."

Dr. David Chernoff, chief medical officer of [SetPoint Medical](#), said, "Drugs find a pathway that contributes to damaging joints in R.A. patients and try to block it."

"What we're doing is completely different," he added. "We're re-educating the immune system through the brain to behave differently." As a result, he said, "we're not blocking the ability to fight off infection."

The body needs some level of inflammation, Dr. Tracey said, to help with healing wounds, fighting infections and promoting tissue repair.

The price of the implant has not been disclosed, but a spokeswoman said that the implant was designed to last for 10 years and would be less expensive than a year's worth of some rheumatoid arthritis drugs, which can cost thousands of dollars a month.

Dr. Aaron Kesselheim, a professor of medicine at [Harvard Medical School](#) who said he was not familiar with the SetPoint device specifically, noted that drugs that go through expedited F.D.A. approval are more likely to need updated safety labels after wider use.

"Those sorts of risks are potentially reasonable if it means providing earlier access to an effective product for patients who need it," he said.

One key question is whether the implant's effectiveness will wane over time, said Dr. Lou Bridges, chief of the division of rheumatology at the [Hospital for Special Surgery](#) and NewYork-Presbyterian/Weill Cornell Medical Center.

"It's still early days. The proof will be in the pudding," he said. "I'm hoping they are correct, and this is a revolutionary new way to treat R.A. without drugs and without side effects. But I've heard this story before."

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