# Clinical trial shows implantable device reduces knee pain, increases functionality for 90% of osteoarthritis patients

The shock absorber device aims to prevent or delay a knee replacement and is now under consideration by the FDA

\*Note: Embargoed until Thursday Sept. 22, 2022 at 11:30 a.m. eastern

The Ohio State University Wexner Medical Center

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Package Length: 1:38	Content provided by: The Ohio State University Wexner Medical Center

NEWS PACKAGE	
SUGGESTED TEASE	LIVING WITH KNEE PAIN, BUT NOT READY FOR JOINT REPLACEMENT SURGERY? THERE MAY SOON BE A NEW SOLUTION TO HELP THOSE WITH KNEE OSTEOARTHRITIS GET BACK ON THEIR FEET. THE DETAILS ON THE MINIMALLY-INVASIVE DEVICE BEING CONSIDERED FOR F-D-A APPROVAL, COMING UP.
ANCHOR LEAD	OF THE FOURTEEN MILLION AMERICANS SUFFERING WITH THE PAIN OF OSTEOARTHRITIS IN THEIR KNEES, MORE THAN HALF ARE UNDER THE AGE OF SIXTY-FIVE <sup>1</sup> , THAT MAKES A KNEE REPLACEMENT RISKY— WITH THE LIKELIHOOD THAT A PROSTHETIC WOULD NEED TO BE REPLACED AGAIN IN THEIR LIFETIME. FEW OPTIONS EXIST TO GET THESE PATIENTS BACK ON THEIR FEET WITHOUT MAJOR SURGERY. NOW, A CLINICAL TRIAL INVESTIGATING AN IMPLANTABLE SOLUTION TO SLOW ARTHRITIS AND REDUCE KNEE PAIN IS COMPLETE, WITH LIFE-CHANGING RESULTS FOR PATIENTS. BARB CONSIGLIO HAS THE DETAILS.
(PACKAGE START)	AL 1 0 N 00
CG: Courtesy: The Ohio State University Wexner Medical Center	(Nats - Sound) :02
Shots of Chuck going into surgery	IN TWO-THOUSAND-EIGHTEEN, CHUCK STENGER WAS THE FIRST PERSON IN THE U-S TO HAVE A NEW DEVICE IMPLANTED THAT'S DESIGNED TO
Shots of surgery	TAKE SOME OF THE PRESSURE OFF THE KNEE FOR THOSE WITH PROGRESSING OSTEOARTHRITIS. :09
CG: Chuck Stenger First patient to receive knee implant	"It looked like a miniature shock absorber that would go on a tiny model car." :04

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Shot of Dr. Flanigan showing AND THAT'S SIMILAR TO HOW THE IMPLANT model WORKS TOO.:03 CG: Dr. David Flanigan (Dr. Flanigan demonstrating on model) "It actually has **Ohio State Wexner Medical Center** this shock absorber with a piston that's anchored into the (cut to close-up of model) bone through this little plate on the femur and on the tibia." BEFORE THE FIRST-OF-ITS-KIND PROCEDURE AT Shots of Chuck going down THE OHIO STATE UNIVERSITY WEXNER MEDICAL stairs in 2019 CENTER, CHUCK'S OSTEOARTHRITIS WAS PROGRESSING TOWARD MAJOR SURGERY. :04 "Well my original orthopedic doc was wanting to give Chuck Stenger (CG'd earlier) me injections and said I was probably a candidate for knee replacement and I didn't think I was guite ready for that yet.":14 THE MEDIAL IMPLANTABLE SHOCK ABSORBER. Graphic showing how implant KNOWN AS THE "MISHA" (MEE-shuh) SYSTEM works DELAYS THE NEED FOR A KNEE REPLACEMENT BY REDUCING THE DAMAGE TO THE JOINT WITH EACH STEP.:07 "When you're walking, doing activities, it's going to take Dr. Flanigan (CG'd earlier) about 30% of that shock or that stress on that knee every time you actually put weight on your leg.":09 THREE YEARS LATER. CHUCK IS STILL ON THE Shot of Chuck walking up stairs MOVE. AS ARE OTHERS WHO PARTICIPATED IN THE CLINICAL TRIAL — RESULTS THAT HAS NOW BEEN Shots of Dr. Flanigan examining SUBMITTED THE F-D-A.:10 patient "Over 90% of our patients have gotten back towards a Dr. Flanigan (CG'd earlier) lot of further activities that they've never been able to for quite some time and had significant improvement in that pain and function.":09 CHUCK HOPES HIS EXPERIENCE WILL PAVE THE Shots of Chuck being active WAY TO HELP OTHERS WITH KNEE PAIN GET BACK TO THE ACTIVE LIFE THEY LOVE. :05 "The device has, I think, stemmed off a knee Chuck Stenger (CG'd earlier) replacement, so I definitely don't need one of those for hopefully quite a while.":07 AT THE OHIO STATE WEXNER MEDICAL CENTER, Shots of Chuck walking dogs THIS IS BARB CONSIGLIO REPORTING. :03 (PACKAGE END) ---AFTER TWO-YEARS OF PATIENT FOLLOW UPS, **ANCHOR TAG** THE RESULTS OF THE CLINICAL TRIAL WERE RECENTLY PRESENTED AND THE DATA IS BEING REVIEWED BY THE F-D-A.

#### SOCIAL MEDIA

Share it! Suggested tweet:

A clinical trial conducted at <u>@OSUWexMed</u> may soon offer a new solution for the millions living with the pain and stiffness of knee osteoarthritis, but who are not yet ready for a total joint replacement. <a href="https://bit.ly/3UuTy40">https://bit.ly/3UuTy40</a>

Suggested post:

There may soon be a new solution to slow damage to the knee and reduce pain without the immediate need for a total knee replacement. Three years after surgeons at <a href="The Ohio State University Wexner Medical Center">The Ohio State University Wexner Medical Center</a> implanted the first knee shock absorber, the clinical trial is complete, with life-changing results for patients. <a href="https://bit.ly/3UuTy4o">https://bit.ly/3UuTy4o</a>

### **EXTRA BITES**

Flanigan says the procedure allows the full knee joint to remain intact:

"Devices such as the ISA allow you to keep all your normal anatomy, all that normal bone contour, and it's just, again, just removing some of that stress allowing some of that shock absorption when you're weight-bearing on that inside compartment. We haven't changed the anatomy and that's what I think is really beautiful about this device." :18

CG: Dr. David Flanigan
Ohio State Wexner Medical Center

Flanigan says recovery from the implant procedure is quick: "We allow weight-bearing right away and most of our patients were fully weight-bearing within a couple days and off the crutches within a couple weeks, which I think is truly the benefit of a procedure like this and they can allow getting back towards their activities and daily living pretty quickly.":13

Flanigan describes the dramatic improvement in patients who receive the implanted device:

"You see patients who are truly struggling just to walk and have pain on a daily basis. They have this device, and they're going through the rehabilitation and they're all of a sudden walking and getting back towards their activities that are really important to them.":13

Flanigan says the implant bridges the gap in treatment, so a knee replacement isn't the only choice:

"How do we go from these more, I would say, basic options of different types of medications, therapy and injections, all the way to a knee replacement? Well, what's in between? And that's where, again, MISHA really has looked to fill in that gap." :15

Chuck explains why he wanted to be the first patient to receive the implant:

"He explained how it worked and I thought that was pretty cool. It would basically hold the bones apart and it just acts as a cushion as the cartilage used to. So I said, 'Let's give it a go. If I meet all the parameters, let's go for it." :16

CG: Chuck Stenger
First patient to receive knee implant

Chuck explains his recovery process after the procedure: "Three days later the crutches and the pain medicine went away. I was able to walk with a little bit of pain and stiffness, but 08:07:00 after that everything was great. Went through a lot of therapy, reconditioning on the leg and it all worked.":16

Chuck says a lot of people asked him if the implant could help them too:

"It was kind of like being a pioneer that I was the first one to do it. And when the news came out about that, I was receiving phone calls from all over the country, people asking me questions because, I think, they were interested in signing up, but they actually wanted to talk and find out what it was all about." :19

Chuck says the implant intervened in time to preserve the functionality he still had:

"If you wait too long and you wear out the cartilage in your knee, you're looking at knee replacement. Luckily, I still had a little bit of cartilage left and with the device, it's actually holding the bones apart, which helps out a bunch." :16

## References

<sup>1</sup>Number of Persons With Symptomatic Knee Osteoarthritis in the US: Impact of Race and Ethnicity, Age, Sex, and Obesity, **Arthritis Care & Research, March 25, 2016**. Online: https://doi.org/10.1002/acr.22897

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