

# The Future of Shoulder Replacement Surgery is Happening in Fremont

## Exciting Shoulder Arthroplasty FDA Clinical Trial Now Underway

Many people suffer from shoulder pain and diminishing range of motion that can occur naturally in aging adults or from an injury. Arthritis in the joint or a damaged rotator cuff can make everyday actions challenging, such as reaching up into a cabinet, sleeping comfortably, or enjoying sports like tennis or golf. Now there's good news in the form of a local clinical trial for the growing number of people who find themselves in need of a shoulder replacement (arthroplasty).

John Costouros, MD, FAAOS, FACS, chief of shoulder surgery of the Institute for Joint Restoration and Research (IJRR) at Washington Hospital, is one of six principal investigative surgeons across the country participating in the Stemless Reverse Total Shoulder Replacement Food and Drug Administration (FDA) Clinical Trial, and the only one conducting the trial in the western United States.

"This groundbreaking stemless implant is the first of its kind, minimally invasive reverse total shoulder replacement in the U.S.," said Dr. Costouros. "For patients who qualify for this operation (which is generally an outpatient procedure), it translates to a less-invasive, blood- and bone-preserving surgery with less postoperative pain, reduced surgical time, a faster recovery and overall better outcome."

### What is a Clinical Trial and Who Can Participate?

Clinical trials are research studies with strict oversight by the FDA that aim to evaluate a new drug or medical device to determine if it is safe, effective, and better than the current treatment. Once the trial goes through a series of phases, the data is reviewed by the FDA to determine whether it is approved for clinical use. By participating in clinical trials, people can help others while receiving the newest treatment available. In some cases—like with this particular stemless implant—the device has already been studied, reviewed, and has been in clinical use outside of the U.S. for many years.



Dr. John Costouros prepares patient for a clinical trial shoulder replacement surgery.

Qualifications for participation in this clinical trial require the shoulder replacement candidate to have degenerative arthritis of the shoulder, a massive and irreparable rotator cuff tear, a functioning deltoid muscle, and good bone quality – specifically of the upper humerus bone where the stemless implant is attached. If patients are not candidates for the trial based on screening prior to surgery or intraoperative findings by Dr. Costouros, a standard "stemmed" device is used. The reverse total shoulder replacement was FDA approved for clinical use in the U.S. in 2004, after being available outside the country for nearly 25 years prior.

This study calls for a total of 90 candidates to receive the Easytech® Stemless Reversed new-generation shoulder implant in the U.S. over the next few months. Meanwhile, overseas it is already proving to be safe, effective and an improvement over stemmed implants. The device has received approval in Europe and more than 1,500 people have had it implanted over the past few years with excellent results.

Dr. Costouros is a foremost shoulder expert who moved his practice to the IJRR 14 months ago after serving for a decade on the orthopedic surgery faculty at Stanford University. He trained at UCSF, Harvard Medical School, and the University of Zurich and has run several FDA clinical trials on shoulder replacements as well as helped to design numerous surgical implants. He was one of the first surgeons to bring reverse total shoulder replacement to the U.S. after it was approved by the FDA in 2004.

Reverse total shoulder replacement changes the geometry of the shoulder to give a biomechanical advantage to the deltoid muscle for raising and lowering the arm. It is ideal for those with rotator cuff-deficient shoulders who have arthritis, irreparable rotator cuffs and some complex fractures. This new stemless prosthesis features an anchor base that is attached to the bone at the top of the humerus instead of a traditional stemmed device which is inserted into the shaft of the humerus after some of the bone has been removed.

"This is a tremendous opportunity for certain people in need of a reverse shoulder replacement to have access to a state-of-the-art implant here in their own backyard," said Dr. Costouros. "Patients who receive the stemless reverse shoulder replacement are able to go home the day of surgery instead of staying in the hospital for two or three days, and they can get back to a pain-free, active life sooner. We saw the same evolution with stemless anatomic shoulder replacements which are in widespread use today."

If you think you may be a candidate for this stemless reverse total shoulder replacement clinical trial, call 510.818.2185 to schedule an appointment with Dr. Costouros. You can learn more about Washington Hospital's Institute for Joint Restoration and Research at [www.whhs.com/IJRR](http://www.whhs.com/IJRR) and Dr. Costouros' background and research at [www.californiashoulder.com](http://www.californiashoulder.com).