



INTRODUCTION TO THE SAN FRANCISCO SHOULDER, ELBOW & HAND CLINIC SHOULDER REPLACEMENT STUDY

The San Francisco Shoulder, Elbow, and Hand Clinic invites you to participate in a clinical research study focused on shoulder replacement surgery

The purpose of this study is to determine the outcome of shoulder replacement surgery. Data is collected from over a dozen sites in the United States. Data is also collected internationally, although through a separate entity. This study begins by evaluating your shoulder prior to surgery and continues for the rest of your life. While these shoulder replacements have already been FDA approved, the long term outcomes are not precisely known. Information from this study helps doctors and manufacturers to continue the improvement of joint replacements and surgical techniques.

This particular study analyzes implants manufactured by Tornier, Inc., one of the major upper extremity implant manufacturers worldwide. Tornier, Inc., supports the study.

Your participation in this study will include the completion of a patient survey that asks questions about how your shoulder functions, how your shoulder feels, how you feel, and types of activities you can or cannot do. You will also be asked to complete the questionnaire prior to surgery, and then periodically thereafter. As a patient, this questionnaire is helpful to you in targeting direct areas of concern before your visit, so that during your visit and also during surgical planning, our doctors can more accurately understand your specific needs and conditions.

Your doctor will perform an examination of your shoulder before surgery, and record the results as part of her/his standard clinical care. This same information will also be recorded at every annual visit. The doctor will record the implant information during the. This information will be entered into a database. The data entered does not include your name, rather you are assigned a number so that your identity is confidential to anyone outside of our practice.

Please understand that your treatment and standard care at our clinic is NOT dependent on whether or not you choose to participate in our study. All patients receive equivalent treatment regardless of their decision to participate.

When you partake in our study, you are helping us to understand how to best treat patients like you, and helping us to improve the outcomes of future patients. We greatly appreciate your participation.

