

Ridgewood Orthopedic Group, P.A.
85 South Maple Ave., Ridgewood, N.J. 07450 (201) 445-2830

INFORMED CONSENT FORM FOR RESEARCH

A Retrospective and Continuing Prospective Study of Total Joint Replacement Prostheses

Principal Investigator: Joseph P. Pizzurro, M.D.

SUMMARY: By signing this form I grant Dr. Pizzurro permission to use routine information about my surgery for research purposes, so long as I am not identified.

The purpose of this Consent Form is to provide you with the information you need to consider in deciding whether to participate in a research study. Your decision to take part in this study is voluntary. If you decide not to participate in this study or if you choose to withdraw after beginning the study, you will not lose any benefits associated with your medical care. You are encouraged to ask questions before deciding whether you wish to participate and at any time during the course of the study. You will be told of any new findings that may influence your decision to continue to participate in this research study.

SPONSER: STRYKER ORTHOPAEDICS

PRINCIPAL INVESTIGATOR: Joseph P. Pizzurro M.D.
Co-investigators: None

COMPENSATION OF INVESTIGATOR: The Sponsor compensates your enrolling physician for his research and services in conducting studies associated with their products.

PURPOSE: The purpose of the study is to collect data on patients undergoing primary total knee, primary total hip, revision total knee and revision total hip surgery for research to evaluate the outcome and results of these surgeries.

INVITATION TO PARTICIPATE: I have been asked to participate in a research study because I am having, or have had, total knee or total hip replacement surgery done by Dr. Pizzurro.

VOLUNTARY PARTICIPATION:

My participation in this study is entirely voluntary. I may refuse to participate or may quit at any time during the study. All I have to do is tell my doctor. Withdrawal will occur without penalty or loss of benefits to which I am otherwise entitled. If I withdraw from the study, no prejudice will be shown toward me for medical care or participation in future research studies. However, it is important that I report any problems that might have occurred during my participation in the study.

Participant's Name: _____
Participant's Initial's: _____

PROCEDURES: This consent grants permission to Dr. Pizzurro, and associates he may appoint, to record and analyze information about the management and care of my condition before, during and after my knee or hip surgery. Data may be collected from hospital records, clinic records, x-rays or records from the treating agencies (i.e. home health agency) for this purpose. I also grant Dr. Pizzurro permission to disclose such data to the manufacturer of the prostheses used in my care provided that (a) the data is deidentified and (b) used solely for research and educational purposes. The results from this study may be presented at scientific meetings, used by the manufacturer of the prostheses for training and educational purposes, or published in scientific publications without identifying me.

RISKS: Participation in this study poses no additional risk to me because the data will be collected from information that is normally recorded as part of Dr. Pizzurro's routine care, regardless of my participation in the study. **Only FDA approved prostheses will be used.**

COSTS AND FINANCIAL RISKS: Participation in this study will not involve any extra costs or financial risk to me.

BENEFITS: This research will not provide any direct benefit to me, but may help future patients who need similar treatment.

COMPENSATION: There will be no financial compensation for participation.

CONFIDENTIALITY: Confidentiality of records will be maintained; however the Health Authorities, the Food and Drug Administration (FDA), the Principal Investigator, study personnel of (the study sponsor) or their designee, clinical research representatives, the Valley Hospital's Office of Clinical Trials, the Valley Hospital's Institutional Review Board, the Ethical Review Board, and regulatory authorities may need and will be granted direct access without expiration to view and copy my medical records to verify either the clinical trial procedures or the data they contain as part of the data management. Every effort will be made by the investigator and his associates to maintain all information used for this study as strictly confidential, except as may be required by court order or by law. If any publications or presentations result from this research, my identity would not be revealed. This acknowledgement complies with practice policies stated in the "Notice of Privacy Practices" adopted by Ridgewood Orthopedic Group effective April 15, 2003, as required by the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996.

DISCLAIMER/WITHDRAWAL: I understand I am not required to enter this research study, and that my agreement to participate is voluntary. I am free to withdraw from this study at any time without penalty or prejudice to present or future care. I may withdraw from the study by notifying Dr. Pizzurro. To revoke this Authorization, you must write to: *Dr. Joseph Pizzurro at 85 South Maple Ave., Ridgewood, N.J. 07450.* If I withdraw, the information already collected will remain as part of the research otherwise this authorization will be ongoing and does not expire.

SUBJECT RIGHTS: This study is overseen by the Valley Hospital Institutional Review Board (IRB), a committee charged with protecting the rights and welfare of human research subjects and ensuring that the studies are carried out in an ethical manner. I understand I may contact the the Patient Relations Department at The Valley Hospital (201) 447-8169 or the IRB at (201) 634-5368 if I wish further information about my rights as a research subject.

I understand I may contact Dr. Pizzurro at (201) 445-2830 if I have questions about the study.

CONCLUSION: I have read and understand the consent form. I have been given the opportunity to ask questions and have had them answered to my satisfaction. I agree to participate in this research study. I will receive a copy of this consent form.

Participant Full Name (print): _____

Participant Signature: _____ **Date:** _____

_____ Witness to signature of participant or representative or guardian	
_____ Witness Title (nurse, friend, receptionist, etc.)	_____ Date