Joint Implant Surgeons, Inc.

7277 Smith's Mill Road, Suite 200
New Albany, Ohio 43054
(614) 221-6331
(614) 304-2100 - Fax

Dear Friends:

Our team of professionals at Joint Implant Surgeons, Inc. welcomes you to our family. JIS is an organization of surgical and medical professionals committed to the care of individuals with degenerative and traumatic disorders of the hip, knee and shoulder. We were the first orthopaedic surgical practice in Central Ohio dedicated exclusively to performing joint replacement surgery and associative reconstructive procedures of the hip and knee. Our practice has since expanded to include evaluation and treatment of knee and shoulder disorders, joint preservations techniques, ligament reconstruction and meniscal augmentation of the knee, development of rehabilitation programs, and care of the hip fracture patient.

Our organization has flourished over the span of three decades. We feel that our growth is related to our belief in the value of excellent patient care and commitment to each individual patient's welfare. Our success has been based more than anything else on patient referrals from satisfied individuals.

Growth has produced the need to increase the services of our organization. A single surgeon or nurse cannot adequately care for the number of patients that currently exists. Therefore, an organized and well-supervised team is essential. Our team consists of skilled orthopaedic surgeons and internal medicine physicians, supported by outstanding nurse professionals, physician assistants, and physical therapists. The surgical and medical staff are supported by a competent group of business and health-related personnel.

Throughout Joint Implant Surgeons' ever increasing realm of patient care, our philosophy will simply remain: "We Care."

Sincerely:

The Staff of
Joint Implant Surgeons, Inc.

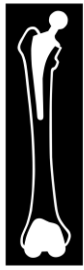
Our JIS Physicians

Adolph V. Lombardi, Jr., M.D., F.A.C.S. received his bachelor's degree from Saint Joseph's University, medical degree from Temple University, and postgraduate training at Temple University Hospital and Albert Einstein Medical Center in Philadelphia, Pennsylvania. He pursued two Fellowships in Reconstruction of the Hip and Knee. He is a Clinical Assistant Professor at The Ohio State University in both the Dept. of Orthopaedics and the Dept. of Biomedical Engineering. Dr. Lombardi lectures nationally and internationally. He is a volunteer surgeon for Operation Walk and the founder of Operation Joint Implant. He is board certified and a member of the American Academy of Orthopaedic Surgeons, The Hip Society, The Knee Society, the American Orthopaedic Association, the American Association of Hip and Knee Surgeons, the International Society of the Knee, and the International Hip Society. He is President of The Hip Society and an Oral Examiner for the American Board of Orthopaedic Surgeons.

Jason M. Hurst, M.D., received his bachelor's degree from Washington & Lee University and his medical degree from Georgetown University. He completed orthopaedic residency training at Duke University where he also worked in sports medicine research. Dr. Hurst completed a fellowship in joint preservation and sports medicine of the hip, knee, and shoulder at the Steadman-Hawkins Clinic in Vail, Colorado. He is a member of the American Orthopaedic Society for Sports Medicine, the Arthroscopy Association of North America, the International Society for Hip Arthroscopy, the Piedmont Society, and is board eligible for the American Board of Orthopaedic Surgeons. His clinical interests include hip, knee, and shoulder joint replacement and arthroscopy, femoroacetabular impingement, joint preservation, cartilage restoration, ACL reconstruction, rotator cuff repair, osteotomy and sports related injury. He is a team physician for the U.S. Ski and Snowboard Association. Dr. Hurst leads the Joint Preservation Institute at Joint Implant Surgeons, Inc. dedicated to the treatment of joint problems in the younger, active patient.

Keith R. Berend, M.D., received his bachelor's degree from Florida Southern College, and his medical degree and orthopaedic residency training from Duke University in North Carolina. Dr. Berend completed a Fellowship in Adult Reconstruction of the Hip and Knee, and was awarded the International College of Surgeons Research Scholarship in 1994. He is a Clinical Assistant Professor in the Department of Orthopaedics at The Ohio State University. He is board certified and a member of the American Academy of Orthopaedic Surgeons, The Knee Society, the American Association of Hip and Knee Surgeons, the Piedmont Orthopedic Society, and the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine. Dr. Berend was a Hip Society-British Hip Society Traveling Fellow in 2004 and a John N. Insall Knee Society Traveling Fellow in 2005. Dr. Berend is a volunteer surgeon for Operation Walk, a charitable organization which provides medical education and free surgical treatment for patients in developing countries.

Michael J. Morris, M.D., received a bachelor's degree in Economics and Business from Lafayette College in Easton, PA, and completed a baccalaureate program in health professions at the University of Pennsylvania. He earned his medical doctorate from Jefferson Medical College in Philadelphia. He completed orthopaedic residency training at Duke University, with training in pediatric orthopaedic surgery at Shriners Hospitals for Children in Greenville, SC. At Duke he earned the John M. Harrelson Chief Resident Teaching Award. Dr. Morris completed a fellowship in adult reconstruction of the hip and knee with Dr. Lombardi and Dr. Berend at Joint Implant Surgeons. He is a Resident/Fellow member of the American Academy of Orthopaedic Surgeons, and a member of the International Congress of Joint Replacement, the American Medical Association, the Piedmont Orthopedic Society, Alpha Omega Alpha National Medical Honor Society and the Hobart Amory Hare Honor Medical Society. Dr. Morris is Medical Director of Joint Implant Salvage Program at Mount Carmel Health Systems.



7277 Smith's Mill Road, Suite 200
New Albany, Ohio 43054
(614) 221-6331
(614) 304-2100 - Fax

Dear Patient,

As you prepare for your upcoming surgery, we want to provide you with information regarding the association between orthopaedic manufacturers and Joint Implant Surgeons, Inc., three of its principals, Dr. Lombardi, Dr. Berend and Dr. Hurst, and its emeritus principal Dr. Mallory.

Since its inception in the 1970's, Joint Implant Surgeons, Inc. and its physicians have been dedicated to reconstruction of the adult hip and knee. Our practice philosophy has always involved exemplary patient care combined with research and education. This has afforded us the opportunity to evaluate and treat thousands of patients on an annual basis. It is this type of practice pattern that has kept us at the forefront of technology. It has afforded us great insight into the implant requirements of our patients, as well as patients throughout the world. We have refined surgical technique and have designed instruments that facilitate the operative intervention. This intellectual property has been shared with and developed in conjunction with orthopaedic manufacturing. We have provided and continue to provide consulting services with orthopaedic manufacturing. We perform numerous instructional lectures on implants and surgical techniques for physicians and medical personnel. We are a host site to a number of national and international physicians who come to learn about our techniques.

Currently, Dr. Lombardi receives royalties, is a paid consultant and speaker, and receives research support from Biomet, and receives royalties from Innomed. Dr. Berend receives royalties, is a paid consultant, and receives research support from Biomet, and is a paid consultant and receives research support from Salient. Dr. Hurst is a paid consultant to Biomet. Dr. Mallory receives royalties from Biomet. Drs. Lombardi, Berend and Hurst use products from these companies in the care of their patients, but also use similar products from other implant manufacturers. Our selection of prosthetic requirements for patients is based on patient specific need and not on a specific implant in which we have a vested interest since we receive no financial remuneration on any implants we use personally or any implants used at facilities at which we operate.

We are members of the American Academy of Orthopaedic Surgeons (AAOS), which holds its members to extremely high ethical standards to ensure that even the appearance of a conflict of interest does not jeopardize the trust that the patients place in their physicians.

AAOS has adopted Standards of Professionalism that require orthopaedic surgeon members to identify and disclose potential conflicts of interest to their patients, the public, and colleagues. These Standards also clearly articulate how and under what circumstances AAOS members may work with and be compensated by industry, as well as the penalties for failure to comply.

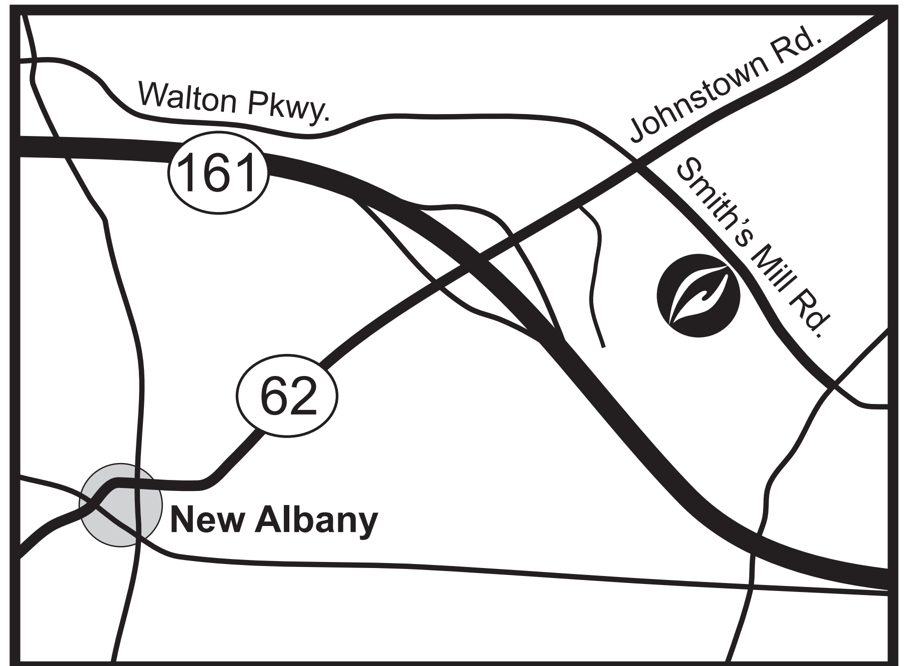
You can learn more about these Standards of Professionalism at the AAOS website:
http://www3.aaos.org/member/profcomp/sop.cfm

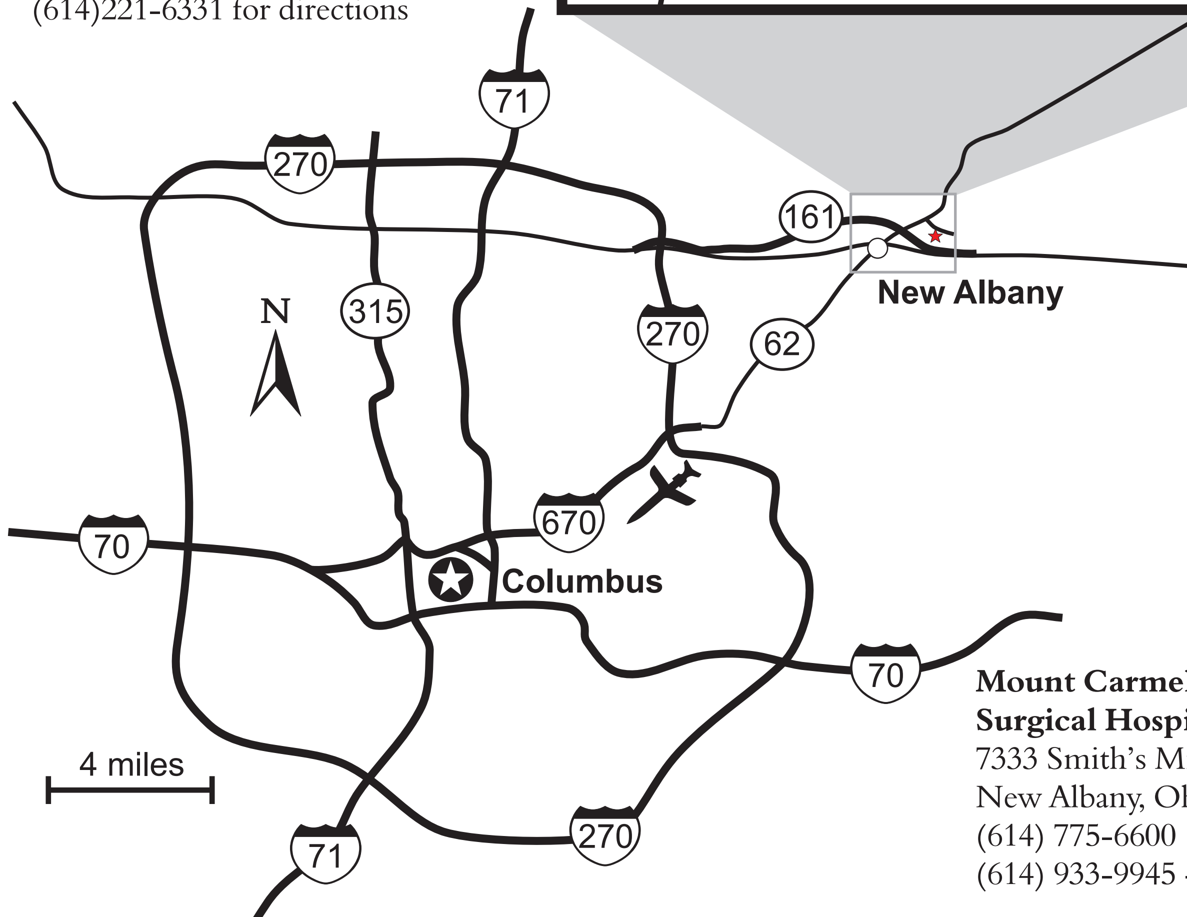
It is important to our office that you are aware of these relationships with implant manufacturers, that our office puts the interests of patients first, and that we are available to answer any questions that you may have.

7277 Smith's Mill Road, Suite 200
New Albany, Ohio 43054
(614) 221-6331
(614) 304-2100

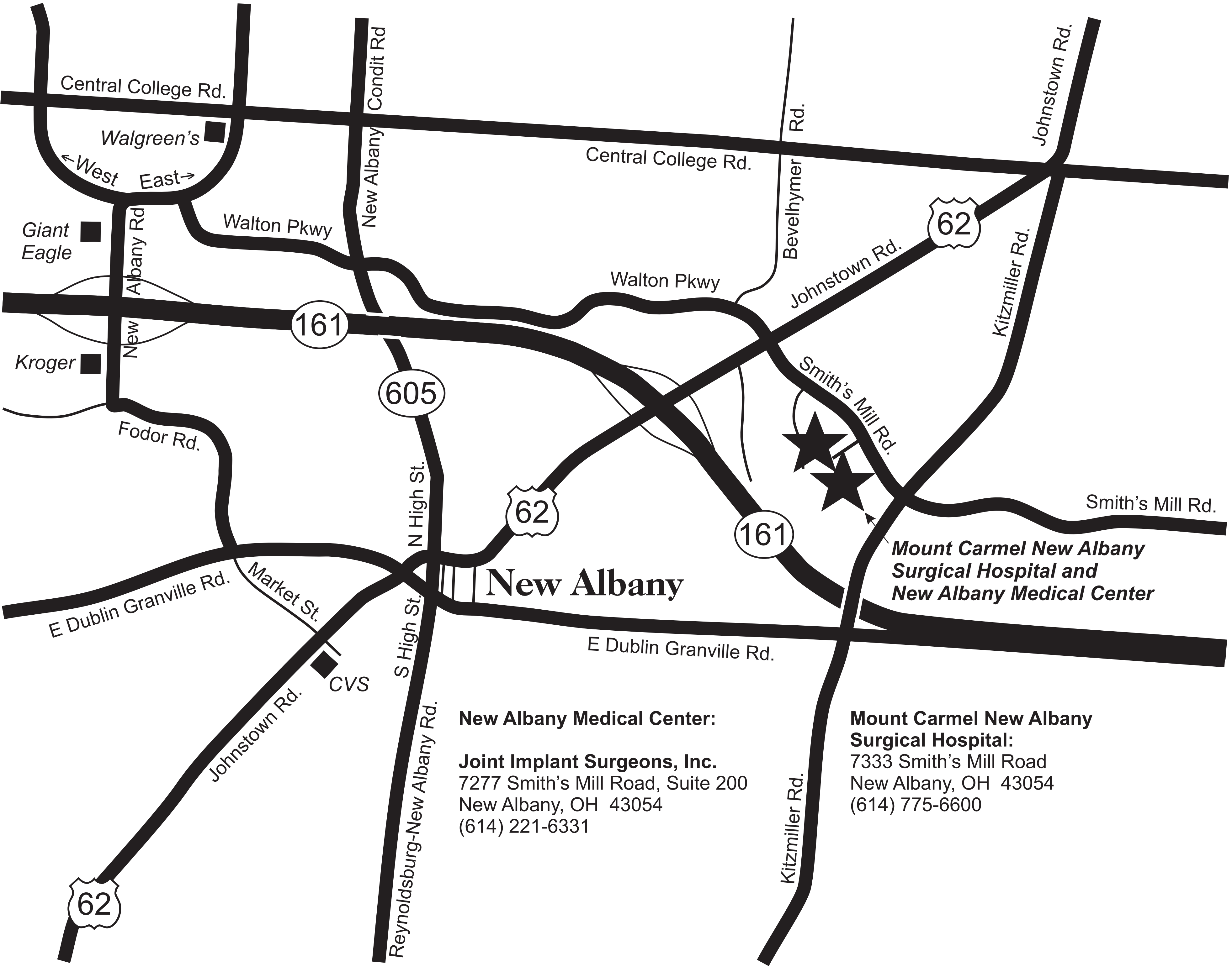
Directions:

- Take I-270 to the northeast side of Columbus
- Exit at 161 East toward New Albany, and travel for approximately 5 miles
- Exit at New Albany / Johnstown, which is the second exit for New Albany
- Turn left (northeast) onto Johnstown Road (Rt. 62), toward Johnstown
- Turn right at the second light onto Smith's Mill Road
- New Albany Surgical Hospital and the New Albany Medical Center will be on the right side of the street
- **If you get lost**, please call us at (614)221-6331 for directions





Mount Carmel New Albany Surgical Hospital
7333 Smith's Mill Road
New Albany, Ohio 43054
(614) 775-6600
(614) 933-9945 - fax



New Albany Medical Center:

Joint Implant Surgeons, Inc.
7277 Smith's Mill Road, Suite 200
New Albany, OH 43054
(614) 221-6331

Mount Carmel New Albany Surgical Hospital:
7333 Smith's Mill Road
New Albany, OH 43054
(614) 775-6600

Joint Implant Surgeons, Inc.
Demographic Information

Name (First):_________________________ (MI):_____________(Last):_________________________________

Address (Street):____

(City/State/Zip/Country): ____

Home Phone: (________) _______________________ Mobile Phone: (________) ______________________

Email: ____

Date of Birth:_______/_______/_______ **SSN:**_______–_______–_______ **Sex:** ❑ Male ❑ Female

Marital Status: ❑ Married ❑ Divorced ❑ Widowed ❑ Separated ❑ Single ❑ Unmarried Partner

Race: ❑ White ❑ Black or African American ❑ Hispanic ❑ American Indian, Alaska Native
❑ Asian ❑ Native Hawaiian or Other Pacific Islander ❑ Other (please specify): ______________________

Contact Person in Case of Emergency (Other Than Person With Whom You Reside)

Name (other than person you live with): ____

Relationship: ____ Telephone: (_____) _______________

Referring Physician

***Please Note*: We will be sending letters to both your referring and family physicians. Please provide complete information with respect to your physician's full name, degree (MD or DO), address, city, state and zip code. Thank you for your assistance.**

Name: ____Degree:________________

Address (Street): ____

City/State/Zip:____

Telephone: (______) _______________________ Date of your last visit: _______________________________

Current Family Physician

Name: ____Degree:________________

Address (Street): ____

City/State/Zip:____

Telephone: (______) _______________________ Date of your last visit: _______________________________

Referred by JIS Patient

Name: ____

Employment Information

❑ Employed ❑ Disabled ❑ Unemployed ❑ Retired
❑ Self-employed ❑ Student ❑ Leave of Absence Date:__________________________

Employer: ____

Address (Street): ____

City/State/Zip:____Telephone: (______) ______________

(Please continue to the other side)

Spouse Information

Name: ____

SSN: ______________________________ Date of Birth: ______________________________________

❑ Employed ❑ Disabled ❑ Unemployed ❑ Retired
❑ Self-employed ❑ Student ❑ Leave of Absence Date:_______________________

Employer: ____

Address (Street): ____

City/State/Zip:____Telephone: (______) ____________

Primary Insurance Carrier

Please bring your insurance cards to the appointment. Please complete all information as fully as possible.

Insurance Company: ____

Company's Address: ____

City/State/Zip: ____

Insured's Name: ___________________________________ Relationship to Patient: __________________

Insured's Address: _______________________________ Insured's SSN: _______________________

City/State/Zip: ______________________________________ Insured's Phone: (_______) _____________

Insured's Date of Birth: __________________ ID#: ___________________Group #: _________________

Secondary Insurance Carrier

Insurance Company: ____

Company's Address: ____

City/State/Zip: ____

Insured's Name: ___________________________________ Relationship to Patient: __________________

Insured's Address: _______________________________ Insured's SSN: _______________________

City/State/Zip: ______________________________________ Insured's Phone: (_______) _____________

Insured's Date of Birth: __________________ ID#: ___________________Group #: _________________

Industrial Claim, If Applicable

Industrial Claim Number: _________________________________ Date of Injury:____________________

Employer at Time of Injury: ____

Allowed Condition/Injury: ____

Signature of Patient or Authorized Party

I authorize the release of medical information necessary to process my claim.

X Signature: ____ Date:____________________

I authorize payment of medical benefits to Joint Implant Surgeons, Inc. for service rendered.

X Signature: ____ Date:____________________

I understand that Joint Implant Surgeons, Inc., and/or its physicians are involved in research, prosthetic design, education, and consultation services that result in reimbursement from implant manufacturers.

X Signature: ____ Date:____________________

Joint Implant Surgeons, Inc.

Patient Health History

This information is very important in your care. Please complete as carefully and accurately as possible.

Name: ___________________________________ Date: _______________

Height: ____________ inches Weight: __________ lbs

Symptoms:

1. Type of symptoms related to your visit: ☐ Pain ☐ Instability ☐ Infection
2. Other symptoms: ____
3. Location of symptoms: ☐ Right Hip ☐ Left Hip ☐ Right Knee ☐ Left Knee
   ☐ Right Shoulder ☐ Left Shoulder ☐ Back
   Other: ____
4. Severity of symptoms: ☐ Mild ☐ Moderate ☐ Severe
   ☐ Constant ☐ Intermittent ☐ With Activity
5. Duration of symptoms: Days: ________Weeks: _______ Months: _______ Years: ________

Please list all prior surgeries **OR** ☐ **No previous surgeries**

Type of surgery including side/area | Estimated Year

A. ____ ____________

B. ____ ____________

C. ____ ____________

D. ____ ____________

E. ____ ____________

F. ____ ____________

G. ____ ____________

6**. Prior Hospitalizations other than surgery** **OR** ☐ **No previous hospitalizations**

Reason for Hospitalization: Estimated Year

A. ______________________________ ____________

B. ______________________________ ____________

C. ______________________________ ____________

D. ______________________________ ____________

7. **Medical Illnesses** for which you are currently being treated for (i.e. high blood pressure, diabetes, heart disease, etc.) **Please list on the next page (9) the name of the medication that you take for this condition**.

☐ **NONE**

Condition: Estimated year at onset

A. ______________________________ ____________

B. ______________________________ ____________

C. ______________________________ ____________

D. ______________________________ ____________

E. ______________________________ ____________

F. ______________________________ ____________

G. ______________________________ ____________

H. ______________________________ ____________

8. **Medication Allergies** or Sensitivities (example: Penicillin causes rash) **OR** ☐ **NONE (NO KNOWN ALLERGIES)**

Name of Medication Reaction

A. ______________________________ ____________

B. ______________________________ ____________

C. ______________________________ ____________

D. ______________________________ ____________

9. List **all current medications** you are now taking or have taken in the last two weeks (including over the counter medications, herbal medications, inhalers, breathing machines, and/or oxygen).

Medication name	**Strength or dosage**	**Time of day taken (AM, PM, bedtime)**	**Number of pills taken each time**	**Reason for use**
Example: Lipitor	*20 mg*	*Bedtime*	*One*	*High cholesterol*

10. Have you ever received a blood transfusion in the past? Yes ☐ No ☐
    If yes, did you have an adverse reaction to the blood transfusion?

____

11. Do you have any religious beliefs against receiving blood? Yes ☐ No ☐

12. Have you ever had difficulty with anesthesia? Yes ☐ No ☐
    If yes, please explain

____

13. Do you have any bleeding tendencies? (Example: bloody urine, bloody stools) Yes ☐ No ☐
    If yes, please explain ____

14. Have any of your primary/direct **family** members (mother, father, brother, sister) had any of the following:
    NOT yourself --your family member
    ☐ **Unknown**

Blood clots in the legs or lungs	Yes ☐ No ☐
Surgical complications	Yes ☐ No ☐
Difficulty with anesthesia	Yes ☐ No ☐
Heart disease (heart attack, angina, or chest pain) — prior to age 60	Yes ☐ No ☐
Diabetes	Yes ☐ No ☐
Bleeding tendencies or disorders	Yes ☐ No ☐

If you answered yes to any of the questions about your family history in number 14 please explain:

____

____

____

15. Do you currently smoke or chew tobacco products? Yes ☐ No ☐
    If yes, year you started? __________ Number of packs per day at most were you smoking? ________
    Have you ever been a smoker in the past? Yes ☐ No ☐
    How many years did you smoke? __________ If you quit smoking, what year did you quit? ________
    Never used tobacco products ☐

16. Do you currently drink alcohol? Yes ☐ No ☐ Never ☐
    Number of drinks per day ________ Number of drinks per week ________
    Number of years of alcohol use _________
    Have you had any medical complications from alcohol Yes ☐ No ☐
    Have you had any withdrawal symptoms when not drinking? Yes ☐ No ☐

17. Do you have any history of substance abuse or drug addiction? Yes ☐ No ☐

Review of Systems: Do you have a personal history of the following?

18. **General**

Recent unexplained weight loss	Yes ☐ No ☐
Recent unexplained weight gain	Yes ☐ No ☐
Recent unexplained fevers or chills	Yes ☐ No ☐
Do you exercise?	Yes ☐ No ☐

If yes, how long and how often? ____

HEENT

Glasses	Yes ☐ No ☐
Cataracts	Yes ☐ No ☐
Glaucoma	Yes ☐ No ☐
Hearing loss or wear hearing aids	Yes ☐ No ☐
Dentures or partials Upper ☐ Lower ☐ Both ☐	Yes ☐ No ☐

Cardiac

High blood pressure	Yes ☐ No ☐
Heart attack	Yes ☐ No ☐
Congestive heart failure	Yes ☐ No ☐
Heart valve replacement	Yes ☐ No ☐
Open-heart surgery for bypass	Yes ☐ No ☐
Did your heart doctor balloon open any of your heart arteries?	Yes ☐ No ☐
Did your heart doctor stent any of your heart arteries?	Yes ☐ No ☐
Do you have chest pain with exertion?	Yes ☐ No ☐
Do you have swelling in your legs?	Yes ☐ No ☐
Have you ever been told that you have a heart murmur?	Yes ☐ No ☐
Do you have palpitations or rhythm disturbances?	Yes ☐ No ☐

Heart Tests

Have you ever had a cardiac stress test?	Yes ☐ No ☐
Heart catheterization/ angiogram	Yes ☐ No ☐
Echocardiogram (an ultrasound of your heart)	Yes ☐ No ☐

If you answered yes, please state what year and the name of where you had the test performed:
____

____

Name of Cardiologist (if applies) ____

Date of last visit ____

Pulmonary

Asthma, COPD, emphysema, or chronic bronchitis? Yes ☐ No ☐
Do you experience shortness of breath with exertion? Yes ☐ No ☐
Need to sleep propped up on 2 or more pillows due to breathing? Yes ☐ No ☐
Do you wake up at night with shortness of breath? Yes ☐ No ☐
Have you ever required treatment with oxygen at home? Yes ☐ No ☐
Do you have sleep apnea? Yes ☐ No ☐
If yes, do you use C-PAP ☐ or Bi-PAP ☐
Have you ever tested positive for tuberculosis (TB)? Yes ☐ No ☐
Do you have seasonal allergies or hayfever Yes ☐ No ☐

GI

Frequent diarrhea Yes ☐ No ☐
Frequent constipation Yes ☐ No ☐
Diverticulitis Yes ☐ No ☐
Irritable bowel syndrome Yes ☐ No ☐
Crohn's disease Yes ☐ No ☐
Ever had part of your colon removed or an intestinal surgery? Yes ☐ No ☐
Peptic ulcer disease/ Duodenal ulcer Yes ☐ No ☐
Intestinal bleeding Yes ☐ No ☐
Difficulty with swallowing Yes ☐ No ☐
Heartburn or gastro-esophageal reflux disease Yes ☐ No ☐
Abdominal pain Yes ☐ No ☐
History of severe post-operative constipation/ileus Yes ☐ No ☐
Liver disease or cirrhosis Yes ☐ No ☐

Genitourinary

Frequent urination Yes ☐ No ☐
Urinary incontinence Yes ☐ No ☐
Prostate enlargement (if you're a man) Yes ☐ No ☐
Have you ever donated a kidney or had one removed? Yes ☐ No ☐
Kidney stones Yes ☐ No ☐
Have you ever been told that your kidneys weren't working as well as they should or that you have Chronic Kidney Disease? Yes ☐ No ☐
Receiving dialysis? Yes ☐ No ☐
If so who is your kidney doctor? ____________________________

Where do you go for dialysis? ______________________________

What days do you receive dialysis? __________________________

Musculoskeletal

Have you ever been told that you have Rheumatoid Arthritis Yes ☐ No ☐
Have you ever been told that you have Osteoporosis Yes ☐ No ☐

Joint Implant Surgeons, Inc.

Neurologic

Stroke or TIA (mini stroke) Yes ☐ No ☐
Paralysis or temporary loss of strength, sensation, or vision Yes ☐ No ☐
Were you ever told that you are legally blind? Yes ☐ No ☐
Frequent fainting spells or dizziness Yes ☐ No ☐
Seizures Yes ☐ No ☐
Frequent headaches or migraine headaches Yes ☐ No ☐
Chronic neck or back pain Yes ☐ No ☐
Chronic pain syndrome Yes ☐ No ☐

Emotion/Mood

Confusion or disorientation Yes ☐ No ☐
Anxiety for which you are being treated or are taking medicines Yes ☐ No ☐
Depression for which you are being treated or are taking medicines Yes ☐ No ☐
Any other emotional problems Yes ☐ No ☐

Endocrine

High cholesterol Yes ☐ No ☐
Thyroid problems (underactive or overactive thyroid) Yes ☐ No ☐
Diabetes (this includes being borderline) Yes ☐ No ☐
Have you ever been in DKA (diabetic ketoacidosis)? Yes ☐ No ☐

If Diabetic HgBA1c (date/level) ______________________________

Typical AM fasting blood sugar ______________________________

Vascular

Blood clots in your legs/lungs (DVT, phlebitis, pulmonary embolism) Yes ☐ No ☐

If yes, what was your treatment and for how long? ______________________________________

Aneurysm, if yes where ____________________________________ Yes ☐ No ☐

Have you ever had surgery on any of your arteries? Yes ☐ No ☐
(This includes stent, balloon procedure, or bypass of the leg arteries)

If yes, where was your surgery? ____

Do you have pain in the legs, buttocks or calves with walking? Yes ☐ No ☐

Other

Unusual or frequent infections Yes ☐ No ☐
Poor wound healing Yes ☐ No ☐
Current open wound Yes ☐ No ☐
Pressure ulcers/ bed sores Yes ☐ No ☐
Currently pregnant or have been in the last 3 months Yes ☐ No ☐
If you’re a woman have you gone through menopause? Yes ☐ No ☐
Do you take hormone replacement therapy or birth control? Yes ☐ No ☐

Joint Implant Surgeons, Inc.

Have you ever had cancer of any kind? Yes ☐ No ☐

If you answered yes, where was/is the cancer? ______________________________________

What was/is your treatment? ____

Who was/is your cancer doctor? ____

Have you ever had an organ transplant? Yes ☐ No ☐

If yes, when and what organ? ____

Who is the doctor that follows your progress? _________________________________

If you have answered yes to any of the above mentioned questions please explain:

____

____

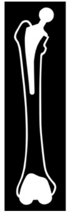
____

____

Form completed by: ______________________________________ Date: ______________

If other than the patient, please identify the relationship: ___________________________________

Reviewed by: ____ Date: ______________



7277 Smith's Mill Road, Suite 200
New Albany, OH 43054
(614) 221-6331 – Main
(614) 242-1068 – Billing Dept.

Billing Information

The Billing Department at Joint Implant Surgeons, Inc. will be happy to file all health insurance claims for you, to both your primary and secondary carriers. To accomplish this successfully, we need your help in the following ways:

Insurance Information: Our receptionist will need to copy your ***current*** insurance cards and your driver's license at your first appointment. Insurance cards will need to be copied any time there has been a change in coverage, or policy numbers. It is your responsibility to keep our office informed of your correct, current insurance information.

Referrals: If your insurance requires you to have a referral from your Primary Care Physician, it is ***your*** responsibility to make sure a current referral is on file in our office each time you are seen. Failure to have a current referral will result in a reduction in benefits paid by your carrier and more out of pocket cost for you.

BWC: If you are covered under an ***active*** Bureau of Workers' Compensation Claim, it is your responsibility to make sure you have authorization from your managed care organization (MCO) for each visit. Failure to have authorization may result in a denial of payment from your MCO, leaving ***you*** responsible for payment.

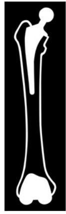
Co-pays: Co-pays are part of your signed contract with your insurance company and will be collected upon checking in at the front desk. A co-payment is required at each office visit. Failure to pay your co-payment will result in a $20.00 processing fee which will be applied to your account.

Medicare: We do not participate in Medicare HMO plans. Please call our Billing Department at (614) 242-1068 if you have questions regarding your coverage.

Medicaid: If you are a recipient of Medicaid from the State of Ohio, you must bring your ***current*** month's card with you to all office visits.

No Insurance / Motor Vehicle Accidents: If you have no billable health insurance, or if you have been involved in a motor vehicle accident, you will be required to pay in full at the time of service. Please call us if you have any questions.

Thank you for your cooperation.



JOINT
IMPLANT
SURGEONS,
INC.

7277 Smith's Mill Road, Suite 200
New Albany, OH 43054
(614) 221-6331 – Main
(614) 242-1068 – Billing Dept.

Medicare/Medigap Lifetime Authorization

______________________________ ______________________
Patient/Beneficiary HIC Number

I authorize any holder of medical information about me to release to the Health Care Financing Administration (HCFA) and its agents any information needed to determine those benefits payable for related services.

I request that payment of authorized medical benefits be made to:
Joint Implant Surgeons, Inc. on my behalf for any services furnished by that Physician/ Provider.

I understand my signature requests that payment be made and authorizes release of medical information necessary to pay the claim. If item 9 of the HCFA 1500 claim form is completed, my signature authorizes releasing of needed information to my Medigap carrier. In Medicare assigned cases, the physician agrees to accept the charge determination of the Medicare carrier as the full charge, and the patient is responsible only for the deductible, coinsurance, and non-covered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier.

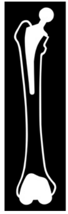
______________________________ ______________________
Beneficiary/Patient Signature Date

Release Form for Non-Covered Services

Insurance regulations now suggest that we inform you in advance if we believe certain services / supplies, such as durable medical equipment, may not be covered by your insurance carrier. Although this implies that such services and/or supplies may not be medically necessary, in our professional judgment these services/supplies are needed in order to render the highest quality of care to you.

By signing this statement, you are agreeing to pay for the services/supplies, even if your insurance carrier determines that, according to their guidelines, the services / supplies are not covered.

______________________________ ______________________
Patient's Signature Date



7277 Smith's Mill Road, Suite 200
New Albany, OH 43054
(614) 221-6331 – Main
(614) 242-1068 – Billing Dept.

Prior Records Release

If you have had previous joint replacement surgery performed by surgeons other than Joint Implant Surgeons, Inc., we would like to have that surgical operative report when you come to your new patient consultation. Please complete this form and take it to your previous surgeon's office. The surgical report can be released to you and brought to your appointment with us, or faxed directly to our office.

I authorize ____________________________________ to release my operative report records to:

Attention: New Patients
Joint Implant Surgeons, Inc.
7277 Smith's Mill Road, Suite 200
New Albany, OH 43054
Fax: (614) 221-6301

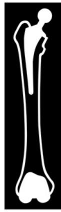
Patient's Name: ____

Patient's Date of Birth: ____

Patient's Social Security No.: ____

Patient's Signature: ____

Date: ____



Joint Implant Surgeons, Inc.

7277 Smith's Mill Road, Suite 200, New Albany, OH 43054
(614) 221-6331 • Fax: (614) 221-6301

Please review and sign Acknowledgment Page prior to your appointment

Privacy Notice

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

This Privacy Notice is being provided to you as a requirement of a federal law, the Health Insurance Portability and Accountability Act (HIPAA). This Privacy Notice describes how we may use and disclose your protected health information to carry out treatment, payment, or health care operations and for other purposes that are permitted or required by law. It also describes your right to access and control your protected health information. Your "protected health information" means any written or oral information about you, including demographic data that can be used to identify you, created or received by your health care provider, which relates to your past, present, or future physical or mental health or condition.

Uses and Disclosures of Protected Health Information for Treatment, Payment, and Health Care Operations

We may use your protected health information for the purposes of providing treatment, obtaining payment for treatment, and conduction health care operations. Your protected health information may be used or disclosed only for these purposes unless we have obtained your authorization or the use or disclosure is permitted or required by the HIPAA regulations or other law. Disclosures of your protected health information for the purposes described in this Privacy Notice may be made in writing, orally, or by electronic means.

1. **Treatment**. We will use and disclose your protected healthcare information to provide, coordinate, or manage your health care and related services, including coordination and management with third parties for treatment purposes. Here are some examples of how we may use or disclose your protected health information for treatment:
   a. We may disclose your protected health information to a laboratory to order tests.
   b. We may disclose your protected health information to other physicians who may be treating you or consulting with us regarding your care.
   c. We may disclose your protected health information to those who may be involved in your care after you leave here, such as family members or your personal representative, extended care or rehabilitation facilities, home care and physical therapy providers.
2. **Payment**. We will use your protected health information to obtain payment for the services we provide to you. We may also disclose your protected health information to another provider involved in your care for their payment activities. Here are some examples of how we may use or disclose your protected health information for payment:
   a. We may communicate with your health insurance company to get approval for the services we render, to verify your health insurance coverage, to verify that particular services are covered under your insurance plan, and to demonstrate medical necessity.
   b. We may disclose your protected health information to anesthesia care providers involved in your care so they can obtain payment for their services.
3. **Health Care Operations**. We may use and disclose your protected health information to facilitate our own health care operations and to provide quality care to all of our patients. Health care operations include such activities as: quality assessment and improvement; employee review activities; conduction or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance reviews; business planning and development; and business management and general administrative activities. In certain situations, we may also disclose your protected health information to another provider or health plan for their health care operations. Here are some examples of how we may use or disclose your protected health information for health care operations:
   a. We may use your protected health information to review our treatment and services and to evaluate the performance of our staff in caring for you.
   b. We may combine protected health information about many patients to decide what additional services we should offer, what services are not needed, and whether certain new treatments are effective.
   c. We may also disclose information to doctors, nurses, technicians, medical students, and other personnel for review and learning purposes.

d. We may also use or disclose your protected health information in the course of maintenance and management of our electronic health information systems.

4. **Other Uses and Disclosures**. As part of the functions above, we may use or disclose your protected health information to provide you with appointment reminders, to inform you of treatment alternatives, or to provide you with information about other health-related benefits and services which may be of interest to you.

Uses and Disclosures of Protected Health Information Permitted without Authorization Required or Opportunity for the Individual to Object

The Federal privacy rules allow us to use or disclose your protected health information without your authorization and without your having the opportunity to object to such use or disclosure in certain circumstances, including:

1. **When Required By Law**. We will disclose your protected health information when we are required to do so by federal, state, or local law.
2. **For Public Health Reasons**. We may disclose your protected health information as permitted or required by law for the following public health reasons:
   a. For the prevention, control, or reporting of disease, injury or disability;
   b. For the reporting of vital events such as birth or death;
   c. For public health surveillance, investigations, or interventions;
   d. For purposes related to the quality, safety, or effectiveness of FDA-regulated products or activities, including:
      - Collection and reporting of adverse events, product defects or problems, or biological product deviations
      - Tracking of FDA-regulated products
      - Product recalls, repairs, or lookback,
      - Post-marketing surveillance

   e. To notify a person who has been exposed to a communicable disease or who may be at risk of contracting or spreading a disease or condition;
   f. Under certain limited circumstances, to report to an employer information about an individual who is a member of the employer's workforce.
3. **To Report Abuse, Neglect, or Domestic Violence**. We may notify government authorities if we believe a patient is a victim of abuse, neglect, or domestic violence. We will make this disclosure only when specifically authorized or required by law, or when the patient agrees to the disclosure.
4. **For Health Oversight Activities**. We may disclose your protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight.
5. **For Judicial or Administrative Proceedings**. We may disclose your protected health information in the course of any judicial or administrative proceeding in response to an order of a court or administrative tribunal as expressly authorized by such order. We may disclose your protected health information in response to a subpoena, discovery request, or other lawful process that is not accompanied by an order of a court of administrative tribunal if we have received satisfactory assurances that you have been notified of the request or that an effort has been made to secure a protective order.
6. **For Law Enforcement Purposes**. We may disclose your protected health information to a law enforcement official for law enforcement purposes, including:
   a. Wound or physical injury reporting, as required by law.
   b. In compliance with, and as limited by the relevant requirements of a court order or court-ordered warrant, a subpoena, summons, or similar process.
   c. Identification or location of a suspect, fugitive, material witness, or missing person.
   d. Under certain limited circumstances when you are the victim of a crime.
   e. Alerting law enforcement of the death of an individual where there is suspicion that the death may have resulted from criminal conduct.
   f. Reporting criminal conduct that occurred on the premises of the provider.
   g. In an emergency to report a crime.
7. **To Coroners, Medical Examiners, and Funeral Directors**. We may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. We may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. In some cases such disclosures may occur prior to, and in reasonable anticipation of, the individual's death.
8. **For Organ or Tissue Donation**. We may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating donation and transplant.
9. **For Research Purposes**. We may use or disclose your protected health information for research

purposes when an institutional review board that has reviewed the research proposal and protocols to safeguard the privacy of your protected health information has approved such use or disclosure.

10. **To Avert a Serious Threat to Health or Safety**. We may, consistent with applicable law and standards of ethical conduct, use or disclose your protected health information if we believe, in good faith, that such use or disclosure is necessary to prevent or lessen a serious and imminent threat to your health and safety or that of the public.
11. **For Specialized Government Functions**. We may use or disclose your protected health information, as authorized or required by law, to facilitate specified government functions related to military and veterans activities; national security and intelligence activities; protective services for the President and others; medical suitability determinations; correctional institutions and other law enforcement custodial situations.
12. **For Workers' Compensation**. We may use and disclose your protected heath information, as necessary, to comply with workers' compensation laws or similar programs.

Uses and Disclosures of Protected Health Information Permitted without Authorization Required but with an Opportunity for the Individual to Object

We may use your protected health information to maintain a directory of patients in our facility. The information included in the directory will be limited to your name, your location in our facility, and your condition described in general terms.

We may disclose your protected health information to a friend or family member who is involved in your medical care or payment for care. In addition, if applicable, we may disclose medical information about you to an entity assisting in a disaster relief effort so that your family can be notified about your condition, status and location.

You may object to these disclosures. If you do not object to these disclosures, or we determine in the exercise of our professional judgment that it is in your best interest for us to disclose information that is directly relevant to the person's involvement with your care, we may disclose your protected health information.

Uses and Disclosures of Protected Health Information which You Authorize

Other than the uses and disclosures described above, we will not use or disclose your protected health information without your written authorization. Authorizations are for specific uses of your protected health information, and once you give us authorization, any disclosures we make will be limited to those consistent with the terms of the authorization. You may revoke your authorization, by submitting a revocation in writing, at any time, except to the extent that we have already taken action in reliance upon your authorization.

Your Rights Regarding Your Protected Health Information

You have the following rights regarding your protected health information:

1. **The Right to Request Restriction of Uses and Disclosures**. You have the right to request that we not use or disclose certain parts of your protected health information for the purposes of treatment, payment, or healthcare operations. You also have the right to request that we do not disclose your protected health information to friends or family members who may be involved in your care, or for notification purposes as described earlier in this notice. Your request must be made in writing and must state the specific restriction requested and the individuals to whom the restriction applies.

   We are not required to agree to a restriction you may request. We will notify you if we do not agree to your restriction request. If we do agree to the restriction request, we will not use or disclose your protected health information in violation of the agreed upon restriction, unless necessary for the provision of emergency treatment.

   We may terminate our agreement to a restriction if you agree to the termination in writing; if you agree to the termination orally and the oral agreement is documented, or if we notify you of termination of the agreement and the termination applies only to protected health information created or received by us after you receive the notice of termination of the restriction.

   Request for restrictions must be made in writing to the Privacy Officer.
2. **The Right to Request Confidential Communications**. You have the right to request that you receive communications of protected health information from us by alternative means or at alternative locations. We must accommodate reasonable request of this nature. We may condition the provision of accommodation by requesting information from you describing how payment will be handled, or by requesting specification of an alternative address or alternative form of contact. Requests for confidential communications must be made in writing to the Privacy Officer.
3. **The Right to Inspect and Copy Protected Health Information**. You have the right to inspect and obtain a copy of your protected health information that is maintained in a designated record set for as long as we maintain the protected health information. The designated record set is a collection of records maintained by us, which contains medical and billing

information used in the course of your care, and any other information used to make decisions about you.

By law, you do not have a right to access psychotherapy notes; information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative proceeding; and protected health information which is subject to a law which prohibits access to protected health information. Depending on the circumstance of your request, you may have the right to have a decision to deny access reviewed.

We may deny your request to inspect or copy your protected health information if, in our professional judgment, we determine that the access requested is likely to endanger you or another person, or is likely to cause substantial harm to another person referenced within the protected health information. You have a right to request a review of a denial of access.

If you request a copy of your information, we may charge you a fee for the costs of copying, mailing, or other costs incurred by us as a result of complying with your request. Requests for access to your protected health information must be made in writing to the Privacy Officer.

4. **The Right to Amend Protected Health Information**. You have the right to request that we amend your protected health information in a designated record set for as long as we maintain that information. In certain cases we may deny your request. If we deny your request you will be notified in writing, and you will have the right to file a statement of disagreement with us. We may prepare a rebuttal to your statement of disagreement and if we do so we will provide a copy of our rebuttal to you. Requests for amendment of protected health information must be made in writing to the Privacy Officer, and must include a reason to support the requested amendments.
5. **The Right to Receive an Accounting of Disclosures of Protected Health Information**. You have the right to request an accounting of disclosures of your protected health information made by us. This right applies to disclosures made by us except for disclosures: to carry out treatment, payment, or health care operations as described in this Notice or incidental to such use; to you or your personal representatives; pursuant to your authorization; for our directory, or other notification purposes, or to persons involved in your care; or for certain other disclosures we are permitted to make without your authorization.

   Requests for disclosure of accounting must specify a time period sought for the accounting, with the maximum time period being six years prior to the date of the request. We are not required to provide accounting for disclosures made before April 14, 2003. We will provide the first disclosure accounting you request during any 12-month period without charge. Subsequent disclosure accounting request will be subject to a reasonable cost-based fee.
6. **The Right to Obtain a Paper Copy of this Notice**. Upon request, we will provide a paper copy of this notice.

Your Rights Regarding Your Protected Health Information

We are required by law to maintain the privacy of your health information and to provide you with this Privacy Notice of our legal duties and privacy practices with respect to protected health information. We are required to abide by the terms of the Notice currently in effect. We reserve the right to change the terms of this Notice and to make any new provisions effective for all protected health information that we maintain. If we change the Notice, we will provide a copy of the revised notice through in-person contact.

Your Rights Regarding Your Protected Health Information

You have the right to express complaints to us and to the Secretary of the Department of Health and Human Services if you believe that your privacy rights have been violated.
If you wish to complain to us, please do so in writing, and direct your complaint to the Privacy Officer.
You will not be penalized for filing a complaint.

Contact Information

If you have privacy issues, if you believe that your privacy rights have been violated, or for further information about this Notice, please contact:

Privacy Officer and Contact
Joint Implant Surgeons, Inc.
7277 Smith's Mill Road, Suite 200
New Albany, Ohio 43054

The Privacy Officer and Contact can be contacted by telephone at (614) 221-6331

Effective Date

This Notice is effective April 14, 2003.

JOINT IMPLANT SURGEONS, INC.
7277 Smith's Mill Road, Suite 200, New Albany, OH 43054
(614) 221-6331 • Fax: (614) 221-6301

Privacy Notice Acknowledgement

I acknowledge that I have received a copy of the Privacy Notice for Joint Implant Surgeons, Inc.

Privacy Notice Revision Date: April 14, 2003

____ __________________________

Patient or Personal Representative Signature **Date**

____

Personal Representative's Relation to Patient

ABOVE - Patient or Personal Representative Use Only

BELOW - Provider Use Only

Documentation of Good Faith Effort

The patient identified above was provided with a copy of the Provider's Privacy Notice on this date. A good faith effort has been made to obtain a written acknowledgement of the patient's receipt of the Privacy Notice. However, acknowledgement has not been obtained because:

❑ Patient refused to sign the Privacy Notice Acknowledgement

❑ Patient was unable to sign because:

____

____

There was a medical emergency. Provider will attempt to obtain acknowledgement as soon as practical.

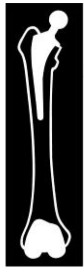
❑ Other reason, described below:

____

____

____ __________________________

Employee Signature **Date**



JOINT IMPLANT SURGEONS, INC.

7277 Smith's Mill Road, Suite 200
New Albany, Ohio 43054
(614) 221-6331
(614) 221-6301 - Fax

We at Joint Implant Surgeons are actively involved in studying Outcomes Research on how our patients have done with their joint replacement surgery. Outcomes Research results are then used for evaluation and improvement of clinical and surgical processes, and for publication, presentation or both. For example, we may write an article to be published in a medical journal or textbook, or give a lecture at a meeting. We respect your right to privacy, and all information is de-identified when presented.

In order to do this type of research we need your consent. This general research consent has been reviewed and approved by the Western Institutional Review Board. The information we collect is obtained from our routine records. You will not be expected to come in for extra office visits as a result of signing this consent. There is no extra cost to you; there is also no reimbursement for participating.

It is through ongoing efforts such as these that we continually are able to bring improvements to the care and treatment of patients.

Thank you for your consideration of this consent. If you are agreeable, please provide your signature and date, as well as a witness signature where indicated. The witness can be a friend or family member, or one of our office staff. Please then return the consent to our office staff. You only need to return the last page of the consent after you have signed it.

Should you have any questions, please do not hesitate to contact our office at 614-221-6331 and request to speak with a member of our research staff.

Sincerely yours,

Adolph V. Lombardi Jr., M.D., F.A.C.S.

Keith R. Berend, M.D.

Jason M. Hurst, M.D.

Michael J. Morris, M.D.

APPROVED
AS MODIFIED
Dec 27, 2005
WIRB®
Olympia, WA

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	General Research - Joint Implant Surgeons Inc.
PROTOCOL NO.:	2004-03 WIRB® Protocol #20041825
SPONSOR:	Joint Implant Surgeons, Inc. Columbus, Ohio United States
INVESTIGATOR:	Keith R. Berend, M.D. Suite 200 7277 Smith's Mill Road New Albany, Ohio 43054 United States
SITE(S):	Joint Implant Surgeons, Inc. Suite 200 7277 Smith's Mill Road New Albany, Ohio 43054 United States
STUDY-RELATED PHONE NUMBER(S):	Keith R. Berend, M.D. 614-221-6331
SUB-INVESTIGATOR:	Adolph V. Lombardi, Jr., M.D.

We at Joint Implant Surgeons are actively involved in research study to learn about the causes, prevention and treatment of your joint condition.

This form serves two purposes. First, it provides information about the research study so that you can decide if you want to take part in the study. And secondly this consent form will ask for your authorization (permission) to use and disclose the medical information that will be obtained from you. Please take your time to make your decision. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with your friends and family before making your decision.

You are being asked to take part in this research study because you have been diagnosed with degenerative arthritis of your knee or hip joint and have been found to be a candidate for surgery.

WHY IS THIS RESEARCH BEING DONE?
The purpose of the research study is to report outcome results. Outcome results help to point out areas of excellence and/or areas in need of improvement or process change with respect to orthopaedic devices, and your orthopaedic care. Specifically, the research study involves the review of your medical and surgical record for purposes of reporting outcome results and may include information that may identify you. This outcome results review and reporting may include information from your office visits, surgery, hospitalizations specifically in areas such as pain, wound appearance, function ability (such as walking, ability to perform daily activities), and surgery information.

HOW MANY SUBJECTS WILL TAKE PART IN THIS RESEARCH?
All surgery patients at Joint Implant Surgeons are asked for permission and consent for the use of their medical record in the research study.

WHAT IS INVOLVED IN THIS RESEARCH?
Once your study doctor determines that you are candidate for joint surgery (this includes first time surgery and revision surgeries) you will be presented with this consent form. Beyond this consent form there are no special requirements on your part. We will simply use the clinical information obtained at your regularly scheduled follow up visits for our research study and reporting outcome results.

<u>THE FOLLOW UP SCHEDULE RECOMMENDED FOR ALL SURGERY PATIENTS, IN OTHER WORDS, THERE ARE NO EXTRA" OFFICE VISITS IF YOU PARTICIPATE</u>

The follow up schedule recommended for ALL surgery patients is shown below.

- Six weeks following your surgery
- Six months following your surgery - *In some cases*
- One year following your surgery
- Once a year for as long as you have your joint replacement

At the time of each return visit your evaluation will include:

- Questions about your pain level and where is your pain located
- Evaluation of how your incision looks
- Listing of any medications you are taking for pain or inflammation
- Activities such as stair climbing, walking distance, use of a cane or walker
- Examination of your joint regarding swelling, tenderness, bending, straightness, strength
- X-ray's of your joint, which are considered standard procedure following such surgery, will be taken at the time of the visit.

HOW LONG WILL I BE PART OF THIS RESEARCH?
You and your medical record will be part of our research and reporting as long as you are a patient with Joint Implant Surgeons.

You have the right to stop participation in the research study at any time. However, if you decide at any time that you do not wish for your medical record to be part of the research study we encourage you to discuss this decision with your surgeon. You will still receive all necessary medical care, however, your medical record and surgical record will no longer be reviewed for purpose of reporting outcome results.

Your study doctor recommends yearly visits and yearly x-rays for all joint surgery patients for purposes of evaluation of pain and x-ray changes.

WHAT ARE THE RISKS OF PARTICIPATION IN THIS RESEARCH?

THE RISKS AND/OR DISCOMFORT THAT YOU MAY EXPERIENCE FROM JOINT SURGERY AND PARTICIPATION IN THIS RESEARCH STUDY ARE NO DIFFERENT THAN IF YOU WERE NOT PARTICIPATING IN THIS RESEARCH.

If you decide to participate in this research study, you risk a loss of privacy associated with participation in the research study (see discussion below for further information about the use and disclosure of your medical information for research purposes).

ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH?

Should you agree to take part in our research, there may or may not be of any direct benefit to you. It is our hope that the information learned from our research study will directly benefit you and other patients with arthritis in the future, and will advance the understanding of joint replacement surgery.

WHAT ARE THE COSTS?

There is no additional cost beyond the routine cost of care associated with joint surgery to you or your insurance company for participation in our research study and outcomes reporting. Contact is made by office staff with your insurance company to arrange for any pre-certification required for joint surgery.

In the case of injury or illness associated with your joint surgery, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury or illness. You or your insurance company will be charged for continuing medical care and/or hospitalization.

IS THERE PAYMENT FOR PARTICIPATION?

You will receive no payment for participating in this research study.

WHAT OTHER OPTIONS ARE THERE?

This is not a treatment study. Your alternative is not to participate in this study.

You may elect to decline permission for your medical information to be part of our research study. If you do decline to participate in our research study, your medical care will be unaffected.

WILL INFORMATION ABOUT ME BE KEPT CONFIDENTIAL?
Efforts will be made to keep your personal information confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The following sections will describe to you how your information will be used and released if you take part in this research study. If you decide to take part, you will be asked to give your authorization (permission) to use and release your information by signing this consent form. If you choose not to give your authorization (permission) for the use or release of your information, you will not be able to take part in this study.

WHAT PROTECTED (PERSONAL) HEALTH INFORMATION DOES THE STUDY DOCTOR WANT TO USE?

- The history and diagnosis of your joint problem
- Information created or collected from you while you are in the study including your over-all medical condition, information about your hospital stay, doctor visits, any complications
- Information in your medical records about your medical history and treatment you received before taking part in this study
- Information related to the surgery event, such as: the replacement parts used, and any surgical complications
- Long-term information and your general health status and the status of your joint problem

WHO WILL MY PROTECTED HEALTH INFORMATION BE DISCLOSED TO?
Organizations that may inspect or copy your research records for quality assurance and information analyses include:

- Food and Drug Administration (FDA)
- Biomet, Inc.
- Western Institutional Review Board

The information released to the above sources may identify you by name, health plan number, study number, date of birth, and/or dates that you had medical tests or procedures done. The results of the research may eventually be reported in medical journals or at meetings, however, your identity and any of your protected health information that could identify you specifically, will not be reported in journals or at meetings.

HOW MY PROTECTED (PERSONAL) HEALTH INFORMATION WILL BE USED AND RELEASED?
If you sign this consent form and take part in this study, you are giving the study staff at Joint Implant Surgeons permission to use your protected health information to carry out the goals of

this research study. You are also giving the study staff your permission to disclose your personal information to any or all of the following groups involved in this study that need to review the information:

- Food and Drug Administration (FDA)
- Western Institutional Review Board
- Biomet, Inc.

These groups may also look at or copy your research records for quality or information review. Once your protected health information is disclosed, the information may be subject to re-disclosure and may no longer be protected by the federal patient privacy laws.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?
Your study doctor will keep all subject information private to the extent possible. Only researchers working with your study doctor will have access to your information. Your study doctor will not release protected (personal) health information about you to others except as authorized by you pursuant to this consent form or as authorized or required by law.

WILL I HAVE ACCESS TO THE INFORMATION IN MY STUDY RECORD?
You will have the right to see and copy the medical information collected from you during this study, for as long as that information is kept by the study staff and other groups subject to federal privacy regulations.

WHAT HAPPENS IF I REFUSE TO SIGN THIS AUTHORIZATION TO RELEASE MY PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES?
You have the right to refuse to sign this consent form to use/disclose your protected health information. If you refuse to sign this consent form, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

WHAT HAPPENS IF I WANT TO WITHDRAW MY AUTHORIZATION (PERMISSION)?
You can change your mind at any time and withdraw your authorization. If you decide to do this, you must withdraw your authorization in writing. Beginning on the date you withdraw your authorization, no new protected (personal) health information will be used for research. However, your study doctor and other individuals and/or organizations may continue to use the health information that was provided before you withdrew your authorization, but only to the extent the continued use and disclosure of your protected health information is necessary to protect the integrity of the research.

If you sign this consent form and enter the research study but later change your mind and withdraw your authorization, you will be removed from the research study at that time.

You may revoke take back your authorization at any time by sending written notice to Joint Implant Surgeons Inc., Suite 200, 7277 Smith's Mill Road, New Albany, Ohio 43054. If you take back your authorization:

- Your participation in the study will end
- The study staff will stop collecting your medical information
- The study staff will stop using and releasing your information to the FDA, the Western IRB, and Biomet Inc., except to the extent necessary to protect the integrity of the research
- Your study doctor will continue to treat your joint replacement with the best means available. Your study doctor will discuss any further treatment with you.

HOW LONG WILL MY AUTHORIZATION (PERMISSION) REMAIN IN EFFECT?
If you agree by signing this consent form that your study doctor and other researchers can use your protected (personal) health information, this authorization (permission) has no expiration date. However, as stated above, you can change your mind and withdraw your authorization at any time.

WHO WILL PROVIDE THE SOURCE OF FUNDING?
Funding for this research study will be provided by Biomet, Inc.

WHAT ARE MY RIGHTS AS A SUBJECT?
Taking part in our research is voluntary. You may choose not to take part at any time. Ending participation in our research will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

You have the right to review and/or copy records of your protected (personal) health information kept by your study doctor. You do not have the right to review and/or copy records kept by the Food and Drug Administration (FDA), Biomet, Inc., or other researchers associated with this study.

WHAT IF THERE ARE NEW FINDINGS?
We will tell you about new information that may affect your health, welfare, or might change your decision to be in this study.

QUESTIONS
If you have any questions concerning your participation in this study, or if at any time you feel you have experienced a research-related injury, contact:

Dr. Keith R. Berend at 614-221-6331.

For any questions about your rights as a research subject, contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will be given a signed and dated copy of this consent form. Upon request, a copy of the results of research may be obtained from your surgeon.

CONSENT

I have read the information in this consent form (or it has been read to me). I hereby freely and voluntarily consent to take part in the research study described above. I have discussed the above with the study doctor and have been given the opportunity to ask questions, which have been answered to my satisfaction. I am also free to ask additional questions at any time.

I am able to refuse to take part or to withdraw from the study at any time without facing any penalty or loss of benefits otherwise available, including medical care from Joint Implant Surgeons.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

______________________________	____________________
Subject signature	Date
______________________________	____________________
Printed Name of Subject	Date
______________________________	____________________
Person Conducting Informed Consent Discussion	Date
______________________________	____________________
Witness’ signature (different from investigator)	Date

-----------------------------------Use the following only if applicable --------------------------------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

____ _________________________
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.