

OCHSNER

PATIENT CONSENT TO MEDICAL TREATMENT OR SURGICAL PROCEDURE AND ACKNOWLEDGEMENT OF RECEIPT OF MEDICAL INFORMATION

IMPORTANT INFORMATION ABOUT THIS DOCUMENT - READ COMPLETELY BEFORE SIGNING

We have told you that you should consider medical treatment/surgery. Louisiana law requires us to tell you (1) the nature of your condition, (2) the general nature of the proposed treatment/surgery, (3) the risks of the proposed treatment/surgery, (4) the probability of success, (5) the risks of refusing treatment/surgery, and (6) the risks of alternative methods of treatment.

In keeping with the Louisiana State Law, you are being asked to sign a confirmation that we have discussed all these matters. We also want to inform you that it is possible that a manufacturer's representative may be present during your procedure. The purpose of this representative is not to provide direct patient care but to provide verbal technical assistance, if necessary, to the physicians. We have already discussed with you the common problems and risks. We wish to inform you as completely as possible. Please read the form carefully. Ask about anything that you do not understand and we will be pleased to explain it.

1 TREATMENT / PROCEDURE

Description, nature of treatment/procedure:

Left knee Yes [] No []

Right knee Yes [] No []

The following will be performed:

Total knee arthroplasty

A total knee arthroplasty is the surgical removal of the diseased joint and replacement with a metal hinge joint (prosthesis) that is attached to the thighbone (femur) and the shinbone (tibia). In most cases, bone cement is used to fix the prosthesis to the thigh and shin bone.

Purpose/Benefit:

The pain should gradually improve making it possible to take up activities, which could not have been done prior to surgery because of pain and stiffness in the knee joint.

3 PATIENT CONDITION / INDICATION FOR PROCEDURE

Patient's diagnosis, description of the nature of the condition or ailment for which the medical treatment, surgical procedure or other therapy described in Part 1 is indicated and recommended:

Severe knee arthritis

The knee is a hinge joint, formed by the end of the thighbone (femur) and the end of the shin bone (tibia). The bones are coated in cartilage, which acts as a cushion between the two bones and allows the knee to move. In front of these bones is the kneecap (patella) which glides in a groove on the end of the thigh bone. Total knee replacements are usually performed for people who have arthritis that is getting worse and is no longer responding to other treatments. The most common type of arthritis is osteoarthritis, which happens with aging or previous injury to the knee joint.

2 SEDATION

[] Moderate Sedation [] Deep Sedation

Level of sedation will be determined by the complexity of the procedure and the status of the patient.

You may receive moderate or deep sedation during your procedure. See page 3 for explanation.



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4 MATERIAL RISKS OF TREATMENT/PROCEDURE

The material risks associated with the medical treatment, surgical procedure or other therapy described in Part 1 and of any anesthesia or blood transfusion administered in connection therewith are:

<i>Considered Material if Checked</i>	<i>Risk</i>
<input checked="" type="checkbox"/> Death	<input checked="" type="checkbox"/> Paralysis From the Waist Down (Paraplegia)
<input checked="" type="checkbox"/> Brain Damage	<input checked="" type="checkbox"/> Loss, or Loss of Function, of an Arm or Leg
<input checked="" type="checkbox"/> Paralysis From the Neck Down (Quadriplegia)	<input checked="" type="checkbox"/> Disfigurement (Including Scars)

Loss, or Loss of Function, of the Following Organs:

OTHER MATERIAL RISKS:

See page 3 for specific risks related to total knee replacement surgery

Use additional space provided on Page 3 if necessary and reference Section 4.

5 ALTERNATE TREATMENTS/PROCEDURES, MATERIAL RISKS

The possible alternate methods of treatment or surgery, and the material risks associated with such alternatives are:

<i>Alternatives</i>	<i>Risk</i>
Walking aids such as a walking stick. An exercise program can strengthen the muscles around the knee joint and sometimes improve positioning of the knee and relieve pain. Nonsteroidal anti-inflammatory drugs, or NSAIDs. Some common NSAIDs are aspirin, ibuprofen and cerebrex. Corticosteroids such as prednisone or cortisone reduce joint inflammation but can cause further weaken the bones in the joint. Side effects from corticosteroids are increased appetite, weight gain, and lower resistance to infections. Osteotomy. The surgeon cuts the bone away at a point from the damaged joint and restores the joint to its proper position, which helps to load weight evenly across the joint. For some people, an osteotomy relieves pain. Recovery from an osteotomy takes 6 to 12 months. The function of the knee joint may get worse and the patient may need more treatment.	

Use additional space provided on Page 3 if necessary and reference Section 5.

6 MATERIAL RISKS OF REFUSING ANY TREATMENT/PROCEDURE

The material risks associated with the Patient's failing or refusing to undergo any medical treatment or surgical procedure for the Patient's condition are:

<i>Risk</i>
The pain may become so severe that independence with every day activities such as showering, walking, shopping, gardening, climbing stairs, getting out of a chair, may be lost or difficult to do alone.

Use additional space provided on Page 3 if necessary and reference Section 6.

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Section 4 continued.....

There are risks and complications with this procedure. They include but are not limited to the following:

General risks:

- Infection can occur, requiring antibiotics and further treatment.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs such as Warfarin, Asprin, Clopidogrel (Plavix) or Dipyridamole (Persantin or Asasantin).
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs.
- Death as a result of this procedure is possible.

Specific risks:

See page 5 for risks specific to undergoing total knee replacement surgery.

Section 2 - Sedation

Definition:

Moderate Sedation consists of administering medications by mouth or intravenously to produce drowsiness and to relieve pain. Although sleepy, you will usually still be awake and able to respond to questions and tell us if you are comfortable.

Deep Sedation consists of administering medications by mouth or intravenously to produce depression of consciousness and to relieve pain. You will be asleep and unable to respond to questions.

General anesthesia consists of administering medications to produce deep depression of consciousness and relieve pain. You will be asleep and unable to respond. This generally requires assistance with breathing and circulation.

While you are sedated, your body's vital functions will be monitored. A patient's reaction to drugs is variable and not always predictable. You may become sleepier than intended. This means that a patient scheduled for moderate sedation may progress to deep sedation. A patient scheduled for deep sedation may progress to general anesthesia. This may require support of your breathing or blood pressure and may require a breathing tube.

Material Risks of Sedation:

1. Allergic reaction to drugs or equipment which may be fatal.
2. Brain damage.
3. Breathing difficulties.
4. Burns.
5. Chipped or broken teeth.
6. Dangerously high fever which may result in death (malignant hyperthermia).
7. Death.
8. Eye injuries, including blindness.
9. Heart attack (cardiac arrest) or other heart problems.
10. Inhalation (aspiration) into the airway (bronchi) or lungs of stomach contents, stomach acids and foreign objects with consequent lung injury.
11. Injury to lips, tongue and inside of mouth and airway.
12. Nerve damage ranging from loss of sensation to total paralysis.
13. Partial or total awareness during surgery.
14. Severe drop in blood pressure (shock) with vital organ damage.
15. Sore throat, injury to or swelling of the vocal cords (laryngeal and/or vocal cord trauma or edema), hoarseness or voice changes.
16. Throat (esophageal) injury.

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ACKNOWLEDGEMENT, AUTHORIZATION AND CONSENT

No Guarantee. All information given me, and in particular, all estimates made as to the likelihood of occurrence of risks of this or alternate procedures or as to the prospects of success, are made in the best professional judgment of my physician. The possibility and nature of complications cannot always be accurately anticipated and, therefore, there is and can be no guarantee, either express or implied, as to the success or other results of the medical treatment or surgical procedure.

Additional Information. Nothing has been said to me, no information has been given to me, and I have not relied upon any information that is inconsistent with the information set forth in this document.

Particular Concerns. I have had an opportunity to disclose to and discuss with the physician providing such information those risks or other potential consequences of the medical treatment or surgical procedure that are of particular concern to me.

Questions. I have had an opportunity to ask, and I have asked, any questions I may have about the information in this document and any other questions I have about the proposed treatment or procedure, and all such questions were answered in a satisfactory manner.

Tissue. Any human organ or other tissue provided by Ochsner for use in the course or in connection with the surgical procedure hereby authorized are furnished without any warranty or guarantee, express or implied, as to the merchantability or fitness of such organ/tissue for its intended use, or its freedom from latent or other defects. Ochsner disclaims any such warranty, guarantee or representation, and I hereby release and discharge Ochsner from all liability for damages, direct or consequential, which may occur without fault or negligence on the part of Ochsner, or its employees or agents.

7 AUTHORIZED PHYSICIAN	8 PHYSICIAN CERTIFICATION
<p>The physician who is authorized to and will administer or perform the medical treatment, surgical procedure or other therapy described in Part 1 hereof is:</p> <p>Michael W. Hartman, MD</p> <hr style="width: 80%; margin-left: 0;"/> <p style="text-align: center;">(Full Name of Authorized Physician)</p>	<p>I HEREBY CERTIFY that I have provided and explained the information set forth herein and answered all questions of the Patient, or the Patient's representative, concerning the Medical Treatment or Surgical Procedure, to the best of my knowledge and ability.</p> <hr style="width: 80%; margin-left: 0;"/> <p style="text-align: center;">(Signature of Physician)</p>

CONSENT

Consent. I hereby authorize and direct the Authorized Physician named and designated in Part 7, together with associates, assistants, and residents of his choice, to administer or perform the Medical Treatment or Surgical Procedure described in Part 1, including any additional procedures or services as they may deem necessary or reasonable, including the administration of any general or regional anesthetic agent, x-ray or other radiological services, laboratory services, and the disposal of any tissue removed during a diagnostic or surgical procedure, and I hereby consent thereto. I understand and agree that associates, assistants, and residents working with the primary surgeon may perform important parts of the procedure.

I have read and understand all information set forth in this document and all applicable blanks were filled in prior to my signing. This authorization for and consent to medical treatment or surgical procedure is and shall remain valid until revoked by me in writing.

<i>Signature of Patient</i>	<i>Signature of Patient Representative (where required)</i>
<i>Signature of Witness</i>	Patient Representative Print Name
Date	Relationship to Patient
Time	Patient Representative Address
	City, State, Zip Code

Section 4 continued

Specific risks associated with undergoing total knee replacement:

- Clots in the legs
Blood clots can form in the legs. If untreated, this can happen in 1 in 5 people.
The clots can break off and travel to the lungs in 1 in 100 people, and can cause death in 1 in 3,000 people.
- Wound infection
Wound infection in about 1 in 100 people.
Infection is a major complication and may require further surgery and possibly the new knee joint to be removed and possibly the leg amputated.
- Dislocation of the knee joint
The knee joint/patella can dislocate because muscles and ligaments have not yet repaired themselves to provide support to the joint.
Re-operation is required.
- The bones around the joint may break
The bones around the joint may break during or after surgery. This can occur in 1 in 40 to 1 in 300 cases depending on bone strength.
A cast may be required to repair the break or further surgery may be required.
- The kneecap may break
The kneecap may break in 1 in 650 people.
Further surgery may be required to repair the knee cap.
- The artificial joint will loosen or wear out
This can happen over a period time but 9 out of ten knee joint replacements are still working after 10 years.
Surgical revision of the knee joint replacement may be required.
- Numbness by the cut
Numbness at the side of the cut can happen
This may be temporary or permanent.
- Numbness/ paralysis of the foot.
Damage to the peroneal nerve around the knee during surgery in 1 in 300 people.
This may be temporary or permanent. Further surgery may be necessary.
- Loss of blood supply to the leg
Damage to the blood vessel behind the knee in 1 in 300 to 1 in 500 people.
Surgery on the blood vessel, and sometimes leg amputation may be required.
Temperature disturbance to the operated leg may be a long term consequence of loss of blood supply to the leg.
- Damage to the nerves may cause a burning pain and inability to straighten the leg in 1 in 125 people.
A nerve block to relieve the pain and manipulation of the leg may be required.
- Stiff knee joint
Stiffening of the knee causing difficulty in walking and sitting and pain on movement may occur in 1 in 60 people.
Manipulation and possibly further surgery may be required.
- Infection around the prosthesis years later
Infection can spread to the replaced joint via the bloodstream for years after replacement surgery (1 in 300 people).
The knee joint may have to be removed. To prevent this, you will need antibiotics before other procedures and dental work.
- Increased risk in smokers.
Smoking slows wound healing and affects the heart, lungs and circulation. Giving up smoking before operation will help reduce the risk.
An increased risk of wound infection, chest infection, heart and lung complications, and thrombosis has been associated with smoking.
- Death
Death is extremely rare due to knee replacement