Periodontics and Dental Implants

During a discussion you have been informed of the possible risk of complications of undergoing your proposed surgery seeing that you have in the past used or are now receiving Bisphosphonate medications. P*lease read this document which restates issues we discussed and provide the appropriate signature on the last page. Please ask for clarification of anything you do not understand.*

Consent for the performance of surgery on _____ related to the

past or current use of Bisphosphonate medications.

USAGE OF BISPHOSPHONATES AND THEIR RELATIONSHIP TO OSTEONECROSIS OF THE JAW (ONJ)
Bisphosphonates, also known as bone-sparing drugs, are commonly used in the treatment of osteoporosis and cancer that has spread to the bone. Doctors prescribe intravenous bisphosphonate therapy, which was the subject of the FDA published precautions, for patients with cancer that has spread to the bone to help decrease associated pain and fractures. In addition, emerging research is exploring the ability of intravenous bisphosphonate therapy to inhibit the spread of some cancers to the bone.

Doctors also prescribe an oral dose of bisphosphonates for patients at risk for osteoporosis to help delay the onset of disease by slowing the natural progression of bone tissue destruction, or to reduce its complications. Orally administered bisphosphonates have not been the subject of the drug precautions. However, the FDA noted that there have been anecdotal reports of ONJ in association with oral bisphosphonates administered for osteoporosis.

DESCRIPTION OF THE POSSIBLE RELATIONSHIPS BETWEEN BISPHOSPHONATE USAGE AND OSTEONECROSIS OF THE JAWS RELATED TO ORAL-DENTAL-PERIODONTAL SURGERY: I have been informed that certain risks exist related to my undergoing dental-oral-periodontal surgery that is specifically related to my past or current use of bisphosphonate medications. Bisphosphonate drugs appear to adversely affect the ability of bone to remodel (repair, grow and heal) itself thereby reducing or eliminating its normal healing capacity. This risk is increased after surgery, especially from extraction; implant placement, bone tumor removal or other “invasive” procedures that might cause even mild trauma to bone. Osteonecrosis of the Jaw (ONJ) may result. This is a smoldering, long-term, destructive process in the jawbone that is often very difficult or impossible to eliminate. This condition has been observed in cancer patients who undergo invasive dental procedures such as dental implants or tooth extractions during or after receiving treatment with intravenous bisphosphonates. ONJ can cause severe, irreversible and often debilitating damage to the jaw. The two intravenous bisphosphonates reported in the 2005 FDA bulletin are marketed under the trade names Aredia and Zometa. Other bisphosphonates may also be of concern.

PRE-EXISITING FACTORS THAT MAY INCREASE THE RISK FOR OSTEONECROSIS OF THE JAW
I have been informed of the following co-incidental factors that if they are a part of my personal history, could increase my possibilities for development of ONJ after my proposed surgery: (1) Definite risk factors include major trauma, fractures, dislocations, Caisson Disease, Sickle Cell Disease, post-irradiation, chemotherapy, Arterial Disease and Gaucher’s Disease. (2) Probable risk factors include corticosteroids, blood clotting, alcohol, lipid disturbances, connective tissue disease, pancreatitis, kidney disease, liver disease, lupus, and smoking. (3) The FDA recognizes additional risk factors associated with the development of osteonecrosis (not limited to the jaw) in cancer patients, such as being of the female gender, advanced age, areas of my jaws in which I am missing teeth, combination cancer therapy, blood dyscrasias, metastatic disease, anemia problems related to coagulation, surgical dental procedures, history of high dose corticosteroid therapy such as for lupus, significant use of alcohol or of smoking and prior infection.

POTENTIAL PREVENTIVE MEASURES PRIOR TO THE INITIATION OF IV BISPHOSPHONATE THERAPY
As suggested by my treating physician and dental surgeon, I agree to any of the following which they recommend:

- Receive a dental examination prior to initiating therapy with intravenous bisphosphonates (Aredia and Zometa); and
- Avoid invasive dental procedures while receiving bisphosphonate treatment.
- Avoid any elective jaw procedure that will require bone to heal
- Receive a routine clinical dental exam that may include a panoramic jaw radiograph to detect potential dental and periodontal infections.
- If bisphosphonate therapy can be briefly delayed without the risk of a skeletal-related complication, teeth with a poor prognosis or in need of extraction should be extracted and other dental surgeries should be completed prior to the initiation of bisphosphonate therapy. The benefit or risk of withholding bisphosphonate therapy has not been evaluated

to date. Therefore, the decision to withhold bisphosphonate treatment must be made by the treating oncologist in consultation with a dental surgeon or another dental specialist

- Suggested preventive dentistry before initiation of chemotherapy, immunotherapy, and/or bisphosphonate therapy may include:
    1. Remove abscessed and non-restorable teeth and involved periodontal tissues.
    2. Functional rehabilitation of salvageable dentition, including endodontic therapy.
    3. Dental prophylaxis, caries control, and stabilizing restorative dental care. 4. Examine dentures to ensure proper fit (remove dentures at night)
    5. Oral self-care hygiene education.
    6. Prophylactic antibiotics are not indicated before routine dentistry unless otherwise required for prophylaxis of bacteremia in those patients at risk (e.g., those with an indwelling catheter).
- Educate patients regarding the importance of good dental hygiene and symptom reporting • Suggest regularly scheduled hard-tissue and soft-tissue oral assessments, possibly every 3 to 4 months, depending on risk
- Oncologists should perform a brief visual inspection of the oral cavity at baseline and at every follow-up visit.

DENTAL TREATMENT FOR PATIENTS CURRENTLY RECEIVING BISPHOSPHONATE THERAPY

- I agree to maintain excellent oral hygiene to reduce the risk of dental and periodontal infections
- I agree to have check-ups and adjustments of my removable dentures, particularly if I become aware of discomfort of tissues under or around the denture.
- I agree to have routine dental cleanings at intervals recommended by my dentist or my treating dental surgeon
- I agree to receive non-surgical root canal treatment if possible, rather than undergo extraction of the problem tooth or teeth.
- I understand that Endodontic (root canal) therapy is preferable to extractions when possible. It may be necessary to carry out removal of the crown (exposed portion of my tooth) with subsequent root canal therapy on retained roots to avoid the need for tooth extraction and, therefore, the potential development of osteonecrosis.

I understand that if I develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. Clinical judgment by my treating physician and dentist should guide my management plan based on individual benefit/risk assessment. I understand that each patient is unique. Differences in the amount of bone involvement, other diseases that I may have, my level of activity, and other factors are extremely important in determining the appropriate treatment for me.

NO WARRANTY OR GUARANTEE: I hereby acknowledge that no guarantee, warranty or assurance has been given to me that the proposed surgery will be completely successful. It is anticipated that the surgery will provide benefit in reducing my problems, but that bisphosphonate administration may reduce the effectiveness. Due to individual patient differences, however, one cannot predict the absolute certainty of success. Therefore, there exists the risk of failure, the need for selective retreatment, or worsening of my present condition, despite the best of care.

CONSENT TO UNFORESEEN CONDITIONS: During surgery, unforeseen conditions could be discovered which would call for a modification or change from the anticipated surgical plan. These may include but are not limited to, extraction of hopeless teeth, the removal of a root or root fragment or foreign body associated with the bony abnormalities, or termination of the procedure prior to completion of all of the surgery originally scheduled. I therefore consent to the performance of such additional or alternative procedures as may be deemed necessary in the best judgment of the treating doctor.

COMPLIANCE WITH SELF-CARE INSTRUCTIONS: I understand that excessive smoking and/or alcohol intake may affect healing and may limit the successful outcome of my surgery. I agree to follow instructions related to the daily care of my mouth and to the use of prescribed medications. I agree to report for appointments as needed following my surgery so that healing may be monitored, and the doctor can evaluate and report on the success of surgery.

SUPPLIMENTAL RECORDS AND THEIR USE: I consent to photography, video recording and x-rays of my oral structures as related to these procedures, and for their educational use in lectures or publications, provided my identity is not revealed.

PATIENT'S ENDORSEMENT: My endorsement (signature) to this form indicates that I have read and fully understand the terms used within this document and the explanations referred to or implied. After thorough consideration, I give my consent for the performance of any and all surgical procedures as presented to me during my consultation and treatment

plan presentation by the doctor or as described in this document and as authorized by me in other specific informed consent documents which I have also signed.

_____	_____	_____
Patient's Signature	Date	Patient's Name (please print)
_____	_____	_____
Signature of Patient's Guardian	Date	Relationship to Patient (please print)
_____	_____	
Signature of Witness	Date	