

DAVID L. ROBERTS, DDS, PA

— General Dentist Providing Oral Surgery Services —

(office) 972/768-1911 (cell) 972/404-1911 (home) www.robertsdds.com

INFORMED CONSENT FOR DENTAL/SURGICAL TREATMENT FOR PATIENTS WHO HAVE RECEIVED BISPHOSPHONATE OR DENOSUMAB DRUGS

Important notice to patients taking medications for the treatment of: *osteoporosis, osteopenia, bone cancer, and/or postmenopausal bone loss.*

If you are currently or have been previously treated with an oral or IV bisphosphonate or with a denosumab, including, but not limited to: Fosamax[®] (alendronate); Aredia[®] (pamidronate disodium); Actonel[®] (risedronate sodium); Zometa[®] (zoledronic acid); Reclast[®] (zoledronic acid); Boniva[®] (ibandronate sodium); Xgeva[®] (denosumab); or, Prolia[®] (denosumab), you should know there might be a risk of future complications relating to poor bone healing with surgical dental treatment. This is especially true if you have received the drugs <u>directly/intravenously</u>.

Bisphosphonate or denosumab drugs appear to adversely affect the ability of bone to break down or to remodel itself, thereby reducing or eliminating its healing capacity. This risk is increased after extraction, implant placement, and other "invasive" procedures, including denture sore spots, and may result in osteonecrosis of the jaw (ONJ). ONJ is a rare but serious side effect of certain medications that target the bone. These medications are bisphosphonates and denosumab. You may be prescribed these medications if you have: multiple myeloma or other cancers; cancer that has spread to the bone; or, osteoporosis or osteopenia (a weakening of the bones that can lead to fractures/broken bones). ONJ is a smoldering, long-term, and destructive process in the jawbone that is often very difficult or impossible to eliminate. **Please initial each item below after reading:**

 1.	Despite precautions, there may be delayed healing; osteonecrosis; loss of bone and soft tissue; pathological fracture of the jaw; or, other significant complications.
 2.	If osteonecrosis should occur, treatment may be prolonged and difficult, involving ongoing, intensive therapy, including hospitalization, long-term antibiotics, and debridement to remove non-vital bone. Reconstructive surgery may be required, including bone grafting; metal plates and screws; and/or, skin flaps and grafts.
 3.	I have not had IV chemotherapy with a bisphosphonate.
 4.	I understand the importance of my health history and affirm that I have given any and all information that may impact my care. I understand that failure to give true health information may adversely affect my care and lead to unwanted complications.
 5.	I realize that, despite all precautions that may be taken to avoid complications, there can be no guarantee as to the result of the proposed treatment.
 6.	Before proceeding with the procedure, I was given the option to delay treatment in order to first consult with my medical doctor; and, I have chosen to proceed with the procedure.

SIGNATURE:

I certify that I speak, read, and write English and have read and fully understand the above notice and have had my questions answered.

Patient's (or Legal Guardian's) Signature

Date