

Informed Consent Bone / Soft Tissue Graft(s)

1. I have been informed and afforded the time to fully understand the purpose and the nature of the bone and/or soft tissue graft surgery procedure. I understand what is necessary to accomplish the placement of the bone graft under the gum on/or in bone.
2. My doctor has carefully examined my mouth. Alternatives to this treatment have been explained. I have tried or considered these methods, but I desire a bone graft to help secure the replaced missing teeth and/or soft tissue graft to improve my gum.
3. I have further been informed of the possible risks and complications involved with surgery, drugs and anesthesia. Such complications include pain, swelling, prolonged swelling, infection, bleeding, discoloration, restricted mouth opening, gum recession (shrinkage), fainting, dizziness, interference with phonetics (speech sounds), eating, breathing, sensitivity to hot and cold. Numbness of the lip, tongue, chin, cheek, gums or teeth may occur. The exact duration may not be determinable and may be irreversible. Also possible are thrombophlebitis (inflammation of the vein), injury to teeth present, bone fractures, sinus penetration, sinusitis, wound dehiscence, delayed healing, scarring, anaphylaxis, headaches, allergic reaction to drugs or medications used, etc.
4. I understand that if no treatment is done any of the following could occur: bone disease, loss of bone, gum tissue inflammation, infection, sensitivity, looseness of teeth followed by necessity of extraction. Also possible are temporomandibular joint (jaw) problems, headaches, referred pains to back of the neck and facial muscles and tired muscles when chewing. In addition, I am aware that if no treatment is done an inability to place a bone graft, soft tissue graft or implants at a later date due to changes in oral or medical condition could exist.
5. My doctor has explained that there is no method to predict accurately the gum and bone graft healing capabilities in each patient following the placement of a bone and/or soft tissue graft. It has been explained that bone and/or soft tissue graft in its healing process remodels and there is no method to predict the final volume of bone and/or soft tissue graft, thus additional grafting may be necessary.
6. It has been explained that in some instances bone and/or soft tissue grafts fail (mal-union, delayed union or non-union of the donor bone and/or soft tissue graft to the recipient bone and/or soft tissue graft site) and must be removed. It also has been explained to me lack of adequate bone growth into the bone graft replacement material could result in failure. I have been informed and understand that the practice of dentistry is not an exact science; no guarantees or assurances as to the outcome of the results of treatment or surgery can be made. I am aware that there is a risk that the bone graft and/or soft tissue graft surgery may fail, which might require further corrective surgery or the removal of the bone and/or soft tissue graft with possible corrective surgery associated with the removal. If the bone and/or soft tissue graft surgery fails I understand that alternative prosthetic measures may have to be considered.
7. I understand that smoking, alcohol, blood sugar, high stress or poor nutrition will effect gum healing and will limit the success of the bone graft. I agree to follow my doctor's home care instructions. I agree to report to my doctor for regular examinations as instructed.
8. I agree to the type of anesthesia, depending on the choice of the doctor. I agree not to operate a motor vehicle or hazardous device for at least 24 hours or more or until fully recovered from the effects of the anesthesia or drugs given for my care.
9. To my knowledge, I have given an accurate report of my physical and mental health history. I have also reported any prior allergic or unusual reaction to drugs, food, insect bites, anesthetics, pollens, dust, blood or body diseases, gum or skin reaction, abnormal bleeding or any other conditions related to my health.
10. I consent to photography, video recording, x-rays and additional professional staff observing the procedure to be performed for the advancement of implant dentistry, provided my identity is not revealed.
11. I agree to notify the doctor's office of any and all changes to my address and/or telephone number within a reasonable time frame (two to four weeks).
12. With clear knowledge of all of these possible complications, I have requested that the procedure be performed in the:

 Office environment Hospital environment

13. I agree to the following procedures:

Autograft, Autologous, (or Autogenous) graft – Which transplant bone from one region to another.

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|------------|---|----------------|--|
| Donor Site | <input type="checkbox"/> Edentulous area
<input type="checkbox"/> Maxillary tuberosity
<input type="checkbox"/> Ascending ramus
<input type="checkbox"/> Chin (mental symphysis)
<input type="checkbox"/> Iliac crest (hip)
<input type="checkbox"/> Tibia (lower leg)
<input type="checkbox"/> Skull (cranium) | Recipient Site | <input type="checkbox"/> Upper arch
<input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus |
|------------|---|----------------|--|

Allograft – Which transplants bone from one individual to a genetically non-identical individual of the same species (cadaver bone). All allograft procedures are processed from donors found to be negative, by FDA approved tests, for HBsAg, anti-HBc, anti-HCV, STS, anti-HIV ½ and anti-HTLV-I. Although efforts are made to ensure quality, most tissue banks make no claims concerning the biological or biomechanical properties of provided allograft. All allografts have been collected, processed and distributed for use in compliance with US Food and Drug Administration (FDA) regulations and American Association of Tissue Banks (AATB) standards.

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| Donor Site | <input type="checkbox"/> Mineralized Cortical/Cancellous _____
<input type="checkbox"/> Mineralized Cancellous _____
<input type="checkbox"/> Other _____ | Recipient Site | <input type="checkbox"/> Extraction socket(s) _____
<input type="checkbox"/> Upper arch <input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus |
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Xenograft – Implantation of bone substitutes which has origins from species other than human. Similar to Allografts

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| Donor Site | <input type="checkbox"/> BioOss (bovine) _____
<input type="checkbox"/> NuOss (bovine) _____
<input type="checkbox"/> OsteoBiol (porcine) _____
<input type="checkbox"/> Equimatrix (equine) _____
<input type="checkbox"/> Other _____ | Recipient Site | <input type="checkbox"/> Extraction socket(s) _____
<input type="checkbox"/> Upper arch <input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus
<input type="checkbox"/> Bony defect |
|------------|---|----------------|--|

Alloplast (Synthetic) – Implantation of synthetic/chemically derived bone substitutes or membranes.

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| Donor Site | <input type="checkbox"/> Non-resorbable – PTFE _____
<input type="checkbox"/> Resorbable Collagen membrane _____
<input type="checkbox"/> Resorbable HA <input type="checkbox"/> Non-Resorbable HA
<input type="checkbox"/> Other _____ | Recipient Site | <input type="checkbox"/> Extraction socket(s) _____
<input type="checkbox"/> Upper arch <input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus
<input type="checkbox"/> Bony defect |
|------------|--|----------------|--|

Bioactive Modifiers – contains BMP which cause the chemotactic migration of bone forming cells to the site of local concentration.

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| Donor Site | <input type="checkbox"/> Patient's blood : PRF, L-PRF, PRP, PRGF _____
<input type="checkbox"/> Gem 21S® (rhPDGF-BB) _____
<input type="checkbox"/> Infuse® (rhBMP-2/ACS) _____
<input type="checkbox"/> Other _____ | Recipient Site | <input type="checkbox"/> Extraction socket(s) _____
<input type="checkbox"/> Upper arch <input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus
<input type="checkbox"/> Bony Defect |
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Space Maintenance/Fixation – bone graft containment and protection

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|------------|---|----------------|--|
| Donor Site | <input type="checkbox"/> Titanium Mesh _____
<input type="checkbox"/> Screws _____ <input type="checkbox"/> Tenting screws _____
<input type="checkbox"/> SonicWeld Rx® _____
<input type="checkbox"/> Other _____ | Recipient Site | <input type="checkbox"/> Extraction socket(s) _____
<input type="checkbox"/> Upper arch <input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus
<input type="checkbox"/> Bony defect |
|------------|---|----------------|--|

Soft Tissue Grafts – Soft Tissue bioengineering and enhancement.

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| Donor Site | <input type="checkbox"/> CTG <input type="checkbox"/> VCTG Subepithelial Connective Tissue Graft
<input type="checkbox"/> FGG Epithelialized Palatal Free Graft
<input type="checkbox"/> Alloderm (GBR) <input type="checkbox"/> Alloderm (RTM) Acellular Dermal Matrix
<input type="checkbox"/> Lateral Pedicle Graft (LPG) <input type="checkbox"/> Semi-Lunar Graft (SLG) <input type="checkbox"/> Papilla Grafting
<input type="checkbox"/> Inlay/Onlay ST Grafting for Pontic site
<input type="checkbox"/> 1 st <input type="checkbox"/> 2 nd Stage Implant ST Procedures <input type="checkbox"/> Pre Bone Graft ST Augmentation | Recipient Site | <input type="checkbox"/> Extraction socket(s) _____
<input type="checkbox"/> Upper arch <input type="checkbox"/> Lower arch
<input type="checkbox"/> Edentulous area
<input type="checkbox"/> Sinus
<input type="checkbox"/> Bony defect area
<input type="checkbox"/> Implant area(s) _____ |
|------------|--|----------------|---|

PRF, L-PRF, PRP, PRGF: Growth factors derived from fractionating a small sample of your drawn blood into its components via different centrifugation processes. These growth factors offer improved quality and speed of healing for both hard and soft tissue. Derived from your blood, the risk is very minimal. Not indicated for sites with infection, bleeding disorders and hematologic disease.

- Gem 21S® (rhPDGF-BB)** exerts its effects through the recruitment and stimulation of cells within the surrounding matrix for regeneration of bone, cementum and periodontal ligament. It is a powerful stimulant of angiogenesis (formation of blood vessels) that also stabilizes newly formed blood vessels. Blood vessels are needed to grow bone. Gem 21S® consists of two parts: a protein that is found in everybody’s blood, plus a scaffold matrix for space maintenance. The protein ingredient in GEM21s is rhPDGF-BB (recombinant (engineered) human platelet-derived growth factor), a synthetic version of a protein everybody’s blood produces naturally in small amounts to stimulate wound healing and bone regeneration. The osteoconductive matrix provides a scaffold (framework) for new bone to grow into, and is absorbed and replaced by your bone.
- Infuse® (rhBMP-2/ACS) Bone Graft** (FDA 2007) regenerates vital, vascular *de novo* bone for dental implant placement. INFUSE® Bone Graft consists of two parts: a protein that is found in everybody’s body, plus a natural carrier for delivery. The protein ingredient in INFUSE® Bone Graft is rhBMP-2 (recombinant (engineered) human bone morphogenetic protein-2), a synthetic version of a protein everybody’s body produces naturally in small amounts to regulate bone growth and healing. The absorbable collagen sponge (ACS) is composed of a purified Type I collagen, and undergoes an extensive purification process following harvesting from bovine (cow) tendons. ACS releases the protein over time where it is placed, provides a scaffold (framework) in combination with an osteoconductive graft material, for new bone to grow into, and is absorbed and replaced by your bone.
- “Off label”** use for biologics means any use other than their intended labeling approved by the U.S. Food and Drug Administration (FDA)- is legal and common, and done with your best interest, strong clinical emerging evidence and adequate supporting data. Good dental practice and your best interests require that we use legally available biologics to the best of our knowledge. It is not uncommon for some uses of dental/medical products to become standard of care in the practice of dentistry before there is approval or clearance of the labeled indications for use for a particular product.

14. I request and authorize medical/dental services for myself, including bone and/or soft tissue graft(s) and other surgery. I fully understand the contemplated procedure, surgery or treatment conditions that may become apparent which warrant, in the judgment of the doctor, additional or alternative treatment pertinent to the success of comprehensive treatment. I also approve any modifications in design, materials or care, if it is felt this is for my best interest. If any unforeseen condition arises in the course of treatment which calls for the performance of procedures in addition to or different from that now contemplated I further authorize and direct my doctor, associate or assistant, to do whatever they deem necessary and advisable under the circumstances, including the decision not to proceed with the bone and/or soft tissue graft(s) procedure.

_____	_____	_____	_____	_____
Signature of Patient or Guardian	Date	Initial/ Date	Initial/ Date	Initial/ Date
_____	_____	_____	_____	_____
Signature of Witness	Date	Initial/ Date	Initial/ Date	Initial/ Date
_____	_____	_____	_____	_____
Signature of Doctor	Date	Initial/ Date	Initial/ Date	Initial/ Date