



## OsseoPulse AR300 Bone Regeneration System

### Clinical Guidelines

#### Therapeutic Mechanism of Action:

##### **Summary**

- Surgical wounded bone and blood clot between implant and bone has poor circulation due to lack of blood supply.
- Until in-growth of capillaries which can supply nutrients and oxygen, the wound is ischemic and cellular metabolism is decreased. ATP production is low.
- Wound healing is slow, bone regeneration is slow
- OsseoPulse therapy delivers energy via biologically available photons to the cells in the wound and surgical site.
- These photons are absorbed by **Cytochrome c oxididase (CCO)** an enzyme present in the mitochondria
- CCO absorption of photons causes protons (hydrogen ions) to be pumped into the **intramembrane space (IMS)** of the mitochondria, increasing their concentration
- The increase of the proton concentration and electrochemical gradient between the IM and mitochondrial cytoplasm causes protons to flow through **ATPase** enzyme which catalyzes formation of ATP from ADP
- Increased ATP in the mitochondria provides energy for the normal function of the cell
- Wound healing is increased through increased metabolism of fibroblasts, osteocytes, endothelial cells and other cell types.
- Bone healing and implant stability is accelerated.

##### **Summary**

- **Blood clot in interface between implant and bone is ischemic**
- **Cells in this wound have decreased ATP (energy) due to lack of blood supply.**
- **Early Healing is slow**
- **OsseoPulse photons are absorbed by mitochondria**
- **Mitochondria convert light energy to ATP**
- **Increased ATP -> increased metabolism -> faster healing**
- **Mitochondria act as “rechargeable ATP batteries”...they require frequent “recharging” to produce an ongoing acceleration of healing.**

References available at [bioluxresearch.com/science](http://bioluxresearch.com/science)



## **Evidence Based OsseoPulse Treatment Protocols:**

### **Regen 21 Protocol** *Accelerates implant stability and healing directly after surgery*

#### **Indications:**

- For single or multiple implant placements
- Immediate implant placement after extraction
- maximum 2 surgical / treatment sites (per OsseoPulse controller)

#### **Protocol**

- Start same day as implant placement
- 21 day treatment
- 20 minute treatment by the patient once per day.
- Protocol assumes patients will miss one or two days. Advise patient that they can make up the missed treatment on the following day. One treatment in the morning, and one treatment later in the day
- Patients should set up OsseoPulse near a comfortable chair where they can read, watch TV or do some other relaxing treatment while they have their treatment.
- best to ask patient to remove facial makeup prior to home treatment.

#### **Special Situations**

In situations where the clinician feels that the treatment area will have **decreased** exposure to OsseoPulse photons, treatment will need to be enhanced.

#### **Examples:**

- Thick heavyset jaws and cortical plate
- Thick cheeks and masseter muscles
- Very wide alveolar ridges which diminish exposure of the palatal tissues
- Posterior Maxilla (Molar areas)
- Situations where the position of the array is less than ideal and the clinician is feels that decreased exposure of the surgical site will result.
- The use of opaque membranes on the Buccal of the surgical site which may decreased transmission of photons.
- Use of titanium mesh
- Extensive grafting with non-autogenous bone (more opaque)

These situations will result in a decreased exposure to OsseoPulse photons. In order to achieve a positive clinical result, these patients will require increased treatment times.



### **Modify Protocol:**

**2 treatments daily of 20m each. For 21 days.**

**Recall patient at day 10 to evaluate progress and re-prescribe 21 day treatment in the OsseoPulse controller.**

### **Contraindications**

- Acute infection associated with alveolus and or tooth.
- Rare cases of photosensitivity
- Patients taking Tetracyclines, as they can develop photosensitivity

Treat patient with antibiotics and only proceed with OsseoPulse treatment once the acute phase of the infection has resolved.

As Photobiomodulation stimulates function of ALL cell types in the treatment area, if there is an infection that is producing pus, then the immune cells will be further stimulated to produce more pus and MAY exacerbate local response.

### **Recommendations:**

- Patients to be treated pre and post-operatively with appropriate antibiotics to reduce microorganisms in the surgical site, particularly in cases of pre-existing chronically infected

### **Clinical Notes and Tips:**

- Use the opportunity to perform the first 20m treatment for the patient in the dental chair postoperatively. This allows them to experience the treatment and have demonstration.
- If you have more than 3-4 adjacent teeth/implants width to be treated, you will need to use a second OsseoPulse Array. Instructions for placing the additional implants can be found in the ***OsseoPulse Dentist Guide***
- The greater the tissue contact of the OsseoPulse Array, the greater the exposure of the surgical site to photons.
- Clinical results will be dependent on correct positioning of the Array
- ALWAYS use the Alignment Tool to ensure correct positioning of the OsseoPulse array.
- Ensure Array window is in maximum tissue contact with the cheek.
- Ideally the Array will depress and slightly blanch the cheek over the surgical site. Patients will feel pressure but no discomfort.
- IF the Array is not creating this slight tissue depression...utilize the secondary adjustment slot in the array to position the Array closer to the face – this is particularly important in patients that have small faces and retrognathic jaws.



## Evaluating Treatment Progress

- Research has shown that there is variability in implant healing speeds... variables can be:
  - Implant design
  - Implant surface topography
  - Initial implant stability
  - Health status and age of patient
  - Bone quality
  - Medications that may interfere with healing and bone regeneration
- OsseoPulse acceleration of implant healing will affect different patients and implants with variability. Knowing the stability of the implant(s) is an important variable in using the OsseoPulse effectively in clinical practice.
- In order to know when to load your implants, you need to know their stability.
- The **Osstell Mentor** is a device which uses Resonance Frequency Analysis (RFA) to evaluate the stability of the implant from day of placement to prior to loading.
- It is a non-invasive, very quick method to measure stability of the implant and know when it is ready to load.
- Clinical research has shown that implants can be successfully loaded when their stability is greater than ISQ 65-70.

Visit [www.osstell.com](http://www.osstell.com) for more information on the Osstell Mentor and Clinical research and guidelines.