The horizontal ridge augmentation using equine xenograft and a collagenated porcine cortical lamina membrane: A clinical, radiographic and histological prospective study

Informed Consent Form

Date: October 17, 2017

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Faculty of Dental Medicine

Department of Periodontology

INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

The horizontal ridge augmentation using the cortical lamina: a clinical, radiographic and histological study

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I, the undersigned Dr XXXXXX, resident in the department of Periodontology at the Faculty of Dental Medicine at XXXXXX, invite you to participate in this clinical study.

This study consists in treating the horizontal deficiencies of the bone crests by guided bone regeneration in order to allow the placement of dental implants in cases where implant placement without a regeneration procedure is not possible.

The membrane we are testing in this research is called Soft Lamina by Osteobiol®

The bone substitute material we are testing in this research is called Gen-Os by Osteobiol®

They have been tested before in clinical trials and we are looking to gather more data about these

products with this research.

If you participate in this study you should know that:

• This study is implemented after evaluation by the ethics committee of XXXXXX

Ref: USJ-2017-107

• Your participation is voluntary and remains free of any constraints. Even after signing this document, you can stop participating in this study at any time. Your decision will have no impact on the quality of your dental care or on your relationship with the investigating doctor.

• You will be asked to present yourself to the department of Periodontology at the Faculty of Dental Medicine at Saint XXXXXX for

- A cleaning and hygiene session
- A session where bone graft surgery will take place
- A suture removal and control session
- Approximately six months later, an implant placement session at the regenerated site.

• By participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your regeneration procedure will fail and your will require another surgery to solve this issues. It is also possible that you experience infection of the regenerated site. You will be given proper treatment to solve this issue (extended dose of antiobiotics).

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring as much as possible.

• The data collected on this occasion is confidential and your anonymity is guaranteed when the results are published.

• A small bone biopsy will be taken at the site of implant placement, during the same session as the implant placement, in order to study the quality of the grafted bone.

• The materials concerned by the graft will be offered by the study. You will only be billed the amount of 10 USD or 15,000LL.

This proposal has been reviewed and approved by the "Comité universitaire d'éthique", which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about this comity: contact cue@usj.edu.lb or +96101421229.

If you agree to participate in this research, please sign this form to confirm that the doctor has informed you orally and in writing of the aims of this study.

I remain at your disposal for any further information and thank you for your cooperation.

Tel : XXXXXX

Email: XXXXXX@gmail.com

Dr. XXXXXX

I, the undersigned……declare I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Beirut, on……