Informed Consent Form

Subject's Name:_____ **Date:**_____

Project Title: " 3D- PRINTABLE BIOPOLYMERS FOR SOCKET PRESERVATION TECHNIQUE "

1. Introduction

You are being (or have been) asked to participate in a research study. Please take your time to make your decision. If you feel it is necessary, you should discuss it with your family and friends before you make a decision. It is important that you read the following information and ask as many questions as necessary to be sure that you understand what your participation will involve. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you with to participate. You will be given a signed copy of the form to keep for your records.

2. Purpose of Study

You have been given a dental extraction treatment. The purpose of this study is to test if there is a faster and better healing of the soft tissues (gingiva) after the extraction by placing a disk of resorbable biopolymer to cover the site.

3. Descriptions of the Procedure to be Followed

With your consent and under local anesthesia the extraction will be performed and according to the allocation group you may receive :

1- nothing after the extraction
2- the coverage of the socket with a disk of poli-D-lactic acid with 10% of hydroxyapatite
3- the coverage of the socket with a disk of poli- **ε** caprolactone with 20% of β- tricalcium phosphate.

4. Descriptions of Any Reasonably Foreseeable Risks or Discomforts to the Subjects

We do not anticipate any additional risks or hazards by participating in this study. All procedures performed in this study are routine. The rationale for the surgical treatment options and other treatment options will be discussed and determined prior to the procedure and will be based entirely on your clinical needs.

5. Description of Any Benefits to the Subject or to Others Which May be Expected

All the participants will be treated free of charge for the extraction (regardless site and complexity) and will receive 10% discount on the implant-prosthetic treatment.

6. Description of Any Costs to the Subjects for Their Participation

We do not anticipate any additional costs to the participating subjects in this study.

7. Alternative Therapy

You can choose to undergo treatment with your dentist without participating in this study.

If you have any questions at this time, please feel free to ask them. If you decide to participate and have problems or questions at a later time, you should contact Dr. Nicola De Angelis (+390144320305). If you have an adverse reaction or injury as a result of this study, please contact Dr. Nicola De Angelis (+390144320305).

Every reasonable effort will be made to keep your dental/medical records confidential, and they will not be released without your consent. However, the sponsor will receive a Case Report giving the study results for each volunteer who will be assigned patient number, and the sponsor may also need to have access to your dental/medical records. Please note, however, that any research data kept, released or published will not identify you.

Participation in this study is voluntary. If you decide to participate, you may withdraw at any time. Neither refusal to participate nor withdrawal will result in your being denied conventional periodontal treatment by your dentist.

At the same time, your participation in this study may be terminated by the investigator without your consent. Your participation may be terminated because of a change in your medical condition, occurrence of serious side effects, or repeated failures to adhere to the study schedule.

You will receive a copy of this consent form.

I have explained to the subject _____, the nature and purpose of the procedures described above and such risks as are involved in its performance. I have asked if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

_____ _____

Investigator's Signature **Date**

I have been informed of the above noted procedure with its possible benefits, risks and consequences. I hereby agree to become a subject in this investigation. Furthermore, I recognize that I am free to withdraw this consent and to discontinue participation in this project at any time without prejudice to such matters as my dental care.

_____ _____

Subject's Signature **Date**

_____ _____

Subject's Legal Representative (If applicable) **Date**

I have witnessed the explanation made by the investigator and heard his/her response to questions. I have no conflicting interest in the activity proposed.

_____ _____

Signature of Witness **Date**