INFORMATION LEAFLET

Title: **HISTOLOGICAL INVESTIGATION OF THE DENTAL RESTORATIVE CEMENT BIODENTINE AS A VITAL PULP TREATMENT MATERIAL**

Name of principal researcher: Mr Hal Duncan, Consultant in Endodontics, Dublin Dental University Hospital (DDUH), Trinity College Dublin (TCD)

Co-investigator: Mr Roberto Careddu, PhD student, TCD; Dental Surgeon, Smile Design, Dental Surgery, 16 Main Street, Baldoyle, Dublin 13

Introduction: The purpose of this study is to investigate a potential therapeutic role for a new group of dental filling materials – Biodentine and MTA – in stimulating repair of the dental pulp or 'nerve' of the tooth. This material has recently demonstrated benefits over traditionally used filling materials and has been now been marketed specifically for its role in treating deep decay and exposed pulp tissue. The tooth which you are to have extracted can be used to investigate this potential. Your involvement would be to consent to the placement of a filling in a tooth scheduled for later extraction. We would examine the response of the tooth after extraction; however your treatment would not be affected.

Description of the study: The aim is to investigate the benefits of a new biologically-based dental filling in teeth with an exposed pulp. The use of a human tooth is important as it allows the results to be as realistic as possible. The investigations may allow this material to be used to repair teeth rather than lead to more invasive procedures such as root canal treatment or extraction. All previous experimentation indicates that there is no risk to you or any after effects of material placement. After the tooth is extracted it will be examined using a microscope to assess the regenerative response to treatment. The filling placement will be carried out in dental practice and DDDUH, while the microscope analysis will be carried out in the DDUH. Although, it is proposed to publish the results of this study your identity will remain anonymous.

Procedures: The decision to extract the tooth for clinical reasons will be made by your dentist prior to possible inclusion in the study. Any benefits, risks and alternatives will have been explained to you and a separate consent form signed. An evaluation of the tooth's suitability for the study will be carried out by a dentist. There are no adverse risks. The nature of your dental treatment will not be affected by your participation in the study. Equally should you choose not to participate in the study your proposed treatment will not be affected.

Benefits: There are general benefits in that you will be contributing to original research in an area with a potential therapeutic benefit for patient care.

Inclusion for participation: Male or female aged 10-60 years (patients under 18 years with consent of parent/guardian).

Exclusion from participation: Although there is no contraindication to pregnant women participating in the study we elected to exclude them form potential participation

Confidentiality: Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group. The information will be stored in coded form, the code being kept under 'lock and key' by the principal investigator. Only the named researcher will have access to this information. The data will be kept under 'lock and key' for 5 years. Confidentiality will be ensured by use of only the code in written reports or on computer format.

Compensation: This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation: You are in no way obliged to take part in this study; if you do not participate your treatment will not be affected in any way. If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.

Stopping the study: It is understood that the investigators may withdraw your participation in the study at any time, without your consent.

Permission: The trial has Research Ethics Committee approval from the St James's Hospital, Research Ethics Committee

Space for questions:

Further information: You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr. Hal Duncan who can be telephoned at 016127356. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.