

## **Fujifilm Starts a Clinical Investigation in Europe on FF-37101, a Bone Grafting Material Useful for Bone Regeneration**

**-Aiming to create a new bone grafting material in the field of dentistry and oral surgery-**

TOKYO, October 12, 2020—FUJIFILM Corporation (President: Kenji Sukeno) has announced the start of a clinical investigation in Europe (The Netherlands) on FF-37101, a bone grafting material useful for bone regeneration. This study targets the fields of dentistry and oral surgery.

A method generally being employed in today's dental implant treatments is to implant the bone grafting material in the indentation after tooth extraction or bone defect site to regenerate the alveolar bone<sup>\*1</sup> that is required as the base for implants. One of the bone grafting materials is the autogenous bone from a patient, however, because normal bone must be collected from a part of the body other than the treatment site, it causes a heavy physical burden on the patient. There is also a limit to the amount of bone that can be collected. In Europe and the United States, generally animal derived bone (xenograft) or human donor bone (allograft) is used to fill extraction sockets to allow for dental implant placement.

In general, bone grafting materials promote bone formation when placed into an extraction socket or other dental bone defect site. The aim of bone grafting materials is (a) to ensure space maintenance and (b) to stimulate bone regeneration. However, most bone grafting materials that are currently used do not meet both requirements sufficiently. Therefore, a new material that combines both functions has been developed by Fujifilm.

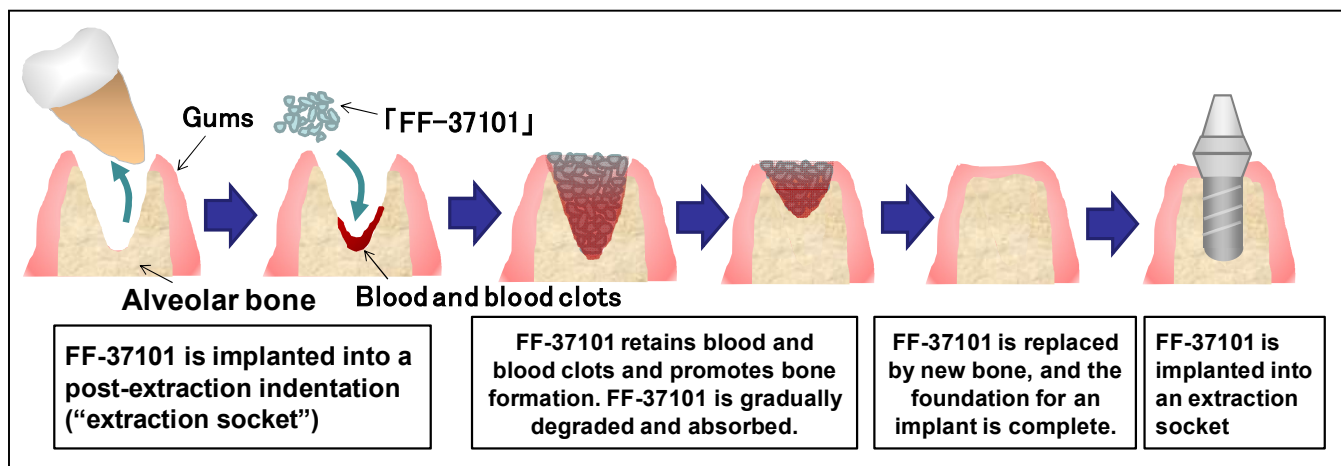
Fujifilm has made use of its extensive knowledge of collagen that it has acquired during research on photographic film, to develop a recombinant peptide (RCP) by genetic engineering. RCP is free from animal derived materials which ensures a high level of safety and reproducibility. RCP has strong interaction with the integrins<sup>\*2</sup> that are present on cell surfaces. This makes the material highly suitable for bone regeneration.

FF-37101 is a bone grafting material made by processing and thermally<sup>\*3</sup> crosslinking RCP into a porous granular form. FF-37101 achieves strong interaction with osteoblasts<sup>\*4</sup> and can retain blood and blood clots<sup>\*5</sup>, which contain nutrients required for bone formation. The *in vivo* degradation of FF-37101 has been optimized, resulting in both space maintenance and concomitant formation of new mature bone.

FF-37101 is intended to support new bone formation in the oral region, including bone formation in the tooth extraction socket and other indications.

Fujifilm has conducted non-clinical studies of FF-37101 with rat models for skull defects and dog models for tooth extraction. After confirming that FF-37101 was safe and has better bone forming properties compared to existing bone grafting materials, Fujifilm has started the clinical investigation of FF-37101 in Europe. In this study, FF-37101 is implanted into an extraction socket, and the safety and performance of the material in humans will be evaluated.

**【The mechanism of bone regeneration using FF-37101 (in the case of dental implant treatment)】**



Fujifilm has a strong desire to help solve issues that affect health by bringing together its proprietary technologies that the company has cultivated through the development of photographic films, as well as biotechnology and other advanced technologies. This clinical investigation for FF-37101 is another step forward to achieve Fujifilm's goal to contribute to new medical technologies to improve patient care worldwide.

\*1 A bone that plays the role of supporting a tooth.

\*2 A receptor present on the surface of cells for extracellular collagen, laminin, and other proteins, responsible for cellular adhesion and migration to substrates.

\*3 A reaction of protein and other substances by heat, and changing their physical and chemical properties.

\*4 Cells responsible for bone formation.

\*5 A clump of blood that is formed after bleeding.

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