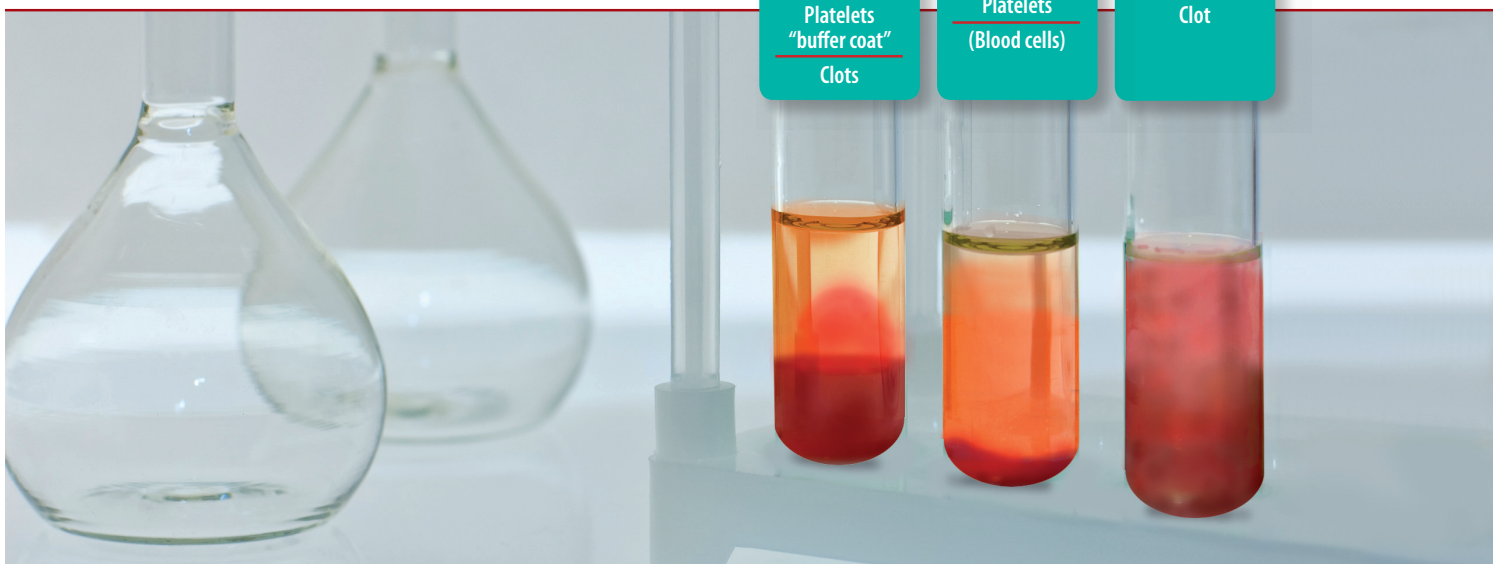


# AUDIOTIPS



## Preparation of Autologous "Fibrin Glue"

1. Draw 10 cc of blood from the patient.
2. Transfer 4 cc of blood to empty test tube (A) and leave it to coagulate.
3. Transfer 6 cc of blood to test tube (B) with anti-coagulant (sodium citrate).
4. Centrifuge test tube (B) at 800 rpm for 8 minutes.
5. Centrifugation gives a separation with red blood cells forming at the bottom and platelets on top: aspirate the "buffer coat" supernatant made up of platelets (pink) unavoidably mixed with plasma (yellow).
6. Transfer the "buffer coat" into the empty test tube (C) and centrifuge together with test tube (A) at 1200 rpm for 8 minutes to further concentrate the platelets.
7. Aspirate the blood platelets from the bottom of test tube (C), unavoidably intermingled with plasma.
8. Aspirate the plasma (containing the thrombin) to the surface of test tube (A) which contains the coagulated blood.
9. Mix blood platelets and thrombin on a concave microscope slide and add 3 - 4 drops of calcium gluconate or calcium citrate.



Revision 17/01/2008

## BONE TWO

**Bone Two** is produced by processing hydroxyapatite powder  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ . If not treated, the raw material - hydroxyapatite - is rapidly reabsorbed into the human body. The end product - porous grains - is obtained through a process of ceramisation which causes the formation of a crystal lattice at the molecular level. If the formation of the crystal lattice is complete, the result is a non reabsorbable product; if the formation is incomplete, then the result is a partially reabsorbable product.

The base hydroxyapatite powder (raw material) always contains a small quantity of tricalcium phosphate  $\text{Ca}_3(\text{PO}_4)_2$ , accounting for about 5% of the basic powder. Therefore, 5% of the ceramic mass can be reabsorbed with transfer of the equivalent quantity of  $\text{Ca}_3(\text{PO}_4)_2$  to the surrounding tissues.

**Bone Two** is prepared in a clean room environment with a controlled atmosphere by wet mixing at isostatic pressure: variations in the moisture level and the applied pressure can cause remarkable variations in the finished product. Other variations of the ceramic characteristics depend on the atmosphere and on the ceramisation thermal cycle. So, all these variables are monitored and controlled by strict Quality Control procedures in order to achieve optimal sintering of the hydroxyapatite. The link between **Bone Two** and bone takes from 2 to 6 months to develop and it has been observed even between the hydroxyapatite and soft tissues. The link developed by hydroxyapatite with bone is the strongest among those obtained with biomaterials. A block sized  $4 \times 4 \times 1.4$  mm of the same hydroxyapatite used to produce the grains has been put in contact with guinea pig bone for a period of 6 months: the strength necessary to separate it from the native bone was 30 N (Newtons) with regard to a bone / hydroxyapatite interface equal to  $6\text{mm}^2$ . Hence the implantation supports a pressure of  $5\text{N}/\text{mm}^2 = 5 \times 10^5 \text{Pa}/\text{mm}^2$ . That is the same safety pressure required for the surface of a hip prosthesis. To find higher adhesion values we have to leave the biomaterials / tissue interfaces and search among the strong physical chemical links: e.g. the ceramic vitreous coating on its metal substrate reaches a resistance up to  $30 \text{N}/\text{mm}^2 = 30 \times 10^5 \text{Pa}/\text{mm}^2$  (that is just 6 times higher than the hydroxyapatite / bone resistance). Other biomaterials show far weaker links: the biocarbons reach an adhesion resistance with bone equal to  $10 \text{Pa}/\text{mm}^2$ , 50 times lower than the hydroxyapatite / bone link.

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# BONE TWO

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 audio<sup>®</sup>  
TECHNOLOGIES

# Bone reconstruction porous grains

## BONE TWO®

**Bone Two** is made of a ceramic hydroxyapatite material (Porous Audiolite®) which is characterised by **biocompatibility** – no rejection phenomena – and **bioactivity** - the development of a chemical link with bone.

**Bone Two** is porous ceramised hydroxyapatite. Its pores have an average diameter of 200 microns and are intercommunicating, giving an open cell structure. It is characterized by its lightness and it can be infiltrated by osteoblasts and connective tissue, as well as new blood vessels. Host tissue will penetrate throughout the **Bone Two** graft. The penetration of new host bone into the pores of the implant (as already studied with reference to porous polyethylene) is generally referred to as osteoconduction.

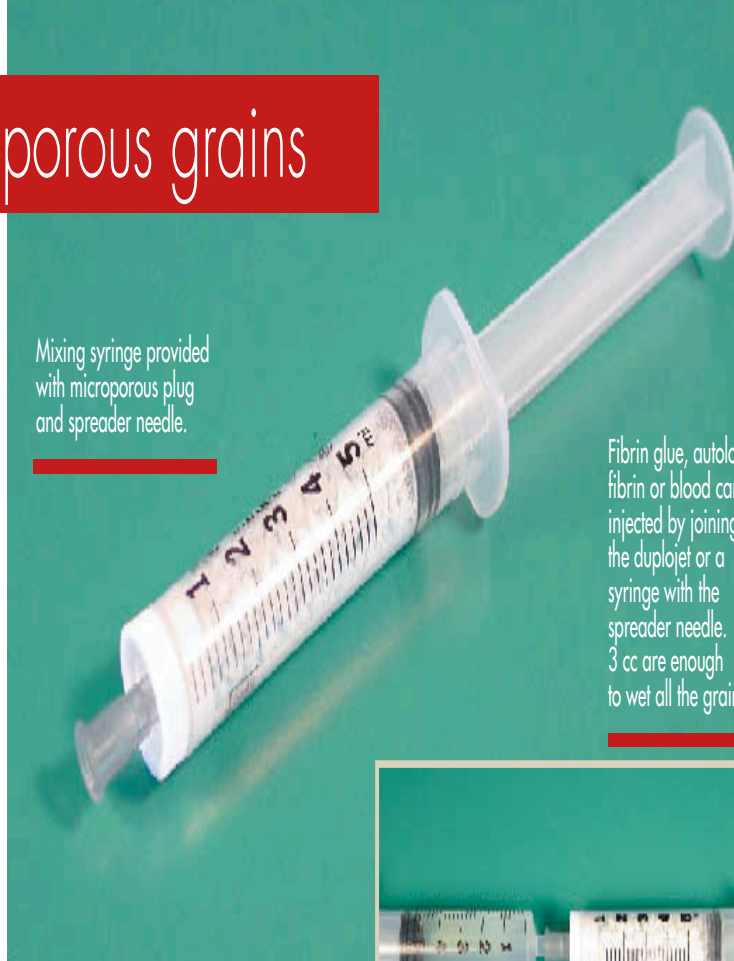
Osteoconduction is a physical link that develops within a few days, stabilising the prosthesis before the formation of the hard chemical link, which occurs in about two months as a result of the bioactive nature of hydroxyapatite.

**Bone Two** is indicated for the filling of bone voids and for onlay bone grafting. It acts as a scaffold and at the same time it stimulates the formation of new bone by osteoconduction.

**Bone Two**, when mixed with autologous fibrin or fibrin glue, forms a solid mass which can be shaped. Cohesion between the grains can also be improved by mixing them with blood.

**Bone Two** is used in ENT surgery, Neurosurgery, Spinal surgery, Dental surgery and Maxillofacial surgery.

Mixing syringe provided with microporous plug and spreader needle.



Fibrin glue, autologous fibrin or blood can be injected by joining up the duplojet or a syringe with the spreader needle. 3 cc are enough to wet all the grains.



**Bone Two** is sold in handy 5cc syringes ( with a spreader needle ) that enable quick and convenient mixing of the grains with the patient's own blood in the sterile environment.

### Packaging

Single sterile units 5 cc each  
Sterilization by ethylene oxide.

**Code TPL18.10**

Porous grains  $1 < \varnothing < 4$

**CE 0373**

Technique for the preparation of autogenous fibrin glue.

Draw from the patient 10 cc of blood for each pack of Bone Two to be used.

Transfer the blood to a test tube with sodium citrate anticoagulant (test tube for coagulation test).

Centrifuge at 1200 rpm for 4 minutes.

Aspirate the plasma and transfer it into a glass container (plate or capsule) adding a few drops of calcium chloride.

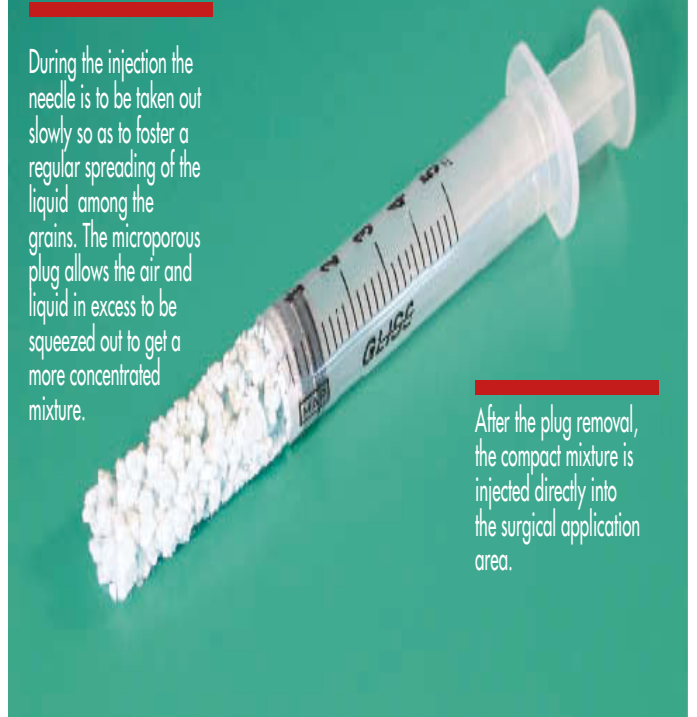
Stir with a glass rod till formation of the fibrin reticulum.

Draw with the syringe and inject into the Bone Two.

### Note

When using fibrin glue inject the grains immediately after the glue mixing so as not to run the risk of blocking the syringe.

During the injection the needle is to be taken out slowly so as to foster a regular spreading of the liquid among the grains. The microporous plug allows the air and liquid in excess to be squeezed out to get a more concentrated mixture.



After the plug removal, the compact mixture is injected directly into the surgical application area.

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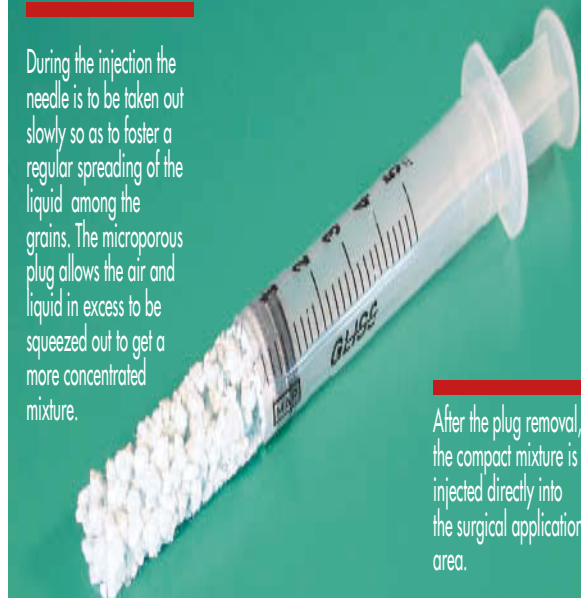
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