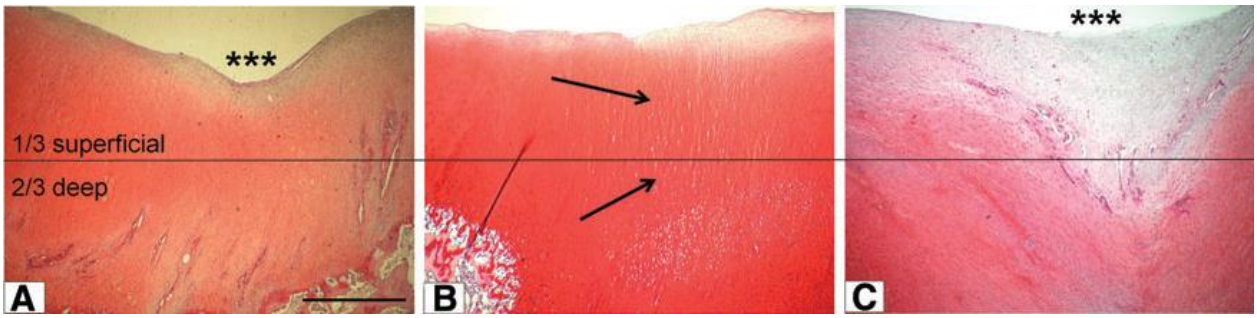
"Composite Scaffold for Tissue Repair"

Background and Description of Invention. Orthopaedic surgeons in collaboration with engineers have developed a biphasic scaffold for the regeneration of the osteochondral tissue, composed of collagen 1 and hydroxyapatite. This scaffold can be used as a cell-free implant or in combination with a source of cells, it has good press-fit properties facilitating the filling of the defect and it is stable throughout long term regenerative applications (*Sosio et al.; Osteochondral Repair by a Novel Interconnecting Collagen–Hydroxyapatite Substitute: A Large-Animal Study. Tissue Engineering 2015*).

Fig. 1



Untreated **Cell-free scaffold** **Cell-seeded scaffold**

Figure 1. Glycosaminoglycans staining of the repaired tissue after 3 months.
As indicated by arrows, the cell free scaffold of the present invention promoted a better regeneration of the chondral tissue. *** indicates the center of the defect

Fig. 2

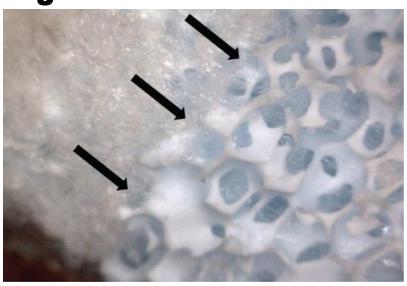


Figure 2. Arrows show a detail of the integration between the collagen and the hydroxyapatite layers (black arrows)

Patent information. The international patent application was published as WO2014184391. Patent applications pending in Europe and US.

Stage of Development. This biphasic scaffold is at a pre-clinical stage of development. It has been validated in the swine model, in osteochondral defects of the trochlea where the scaffold was implanted in the unseeded form and in association with autologous chondrocytes.
Inventors are now validating the scaffold by implanting it in the medial femoral condyle (MFC) of the sheep model, in order to evaluate its potentialities in defects subjected to higher load-bearing activity. Moreover, a growth factor releasing version of the scaffold will be produced and tested in vivo in order to potentiate the regenerative qualities. Additionally, a novel version of the scaffold will be tested in MFC of the sheep model, presenting columnar organization of the hydroxyapatite within the bony part of the osteochondral substitute, in order to allow a more efficient penetration of the bone marrow mesenchymal stem cells throughout the entire thickness of the scaffold, to the bony and chondral part. This new version presents also an important feature: the possibility to be cut and shaped before the implantation, based on the shape of the defect. A longer time point is planned in order to verify the long term efficacy of its reparative properties *in vivo*.

Potential Applications and Competitive Advantages. This biphasic scaffold was developed for the treatment and regeneration of osteochondral defects and presents competitive aspects with respect to the current commercial solutions, in particular:

- A interconnection zone between the upper collagen 1 layer (that represents the chondral phase) and the lower hydroxyapatite layer (that represents the bony phase), thus conferring a strong integration of the two materials and allowing for a better stability and integrity of the scaffold;
- An external thin layer made of collagen 1 that surrounds the whole biphasic scaffold, thus conferring good press-fit qualities to the composite and facilitating the insertion of the scaffold into the defect;
- A cell free application, as it can be efficiently repopulated by cells deriving from the bone marrow or the surrounding tissues, as demonstrated by the in vivo experiments in the swine model;
- An early regenerative potential of the chondral tissue, observed after three months in the swine model. Data are also confirmed in ovine models.

We seek a commercial partner focused on manufacture and distribution of orthopaedic medical devices intended for regenerative medicine.

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