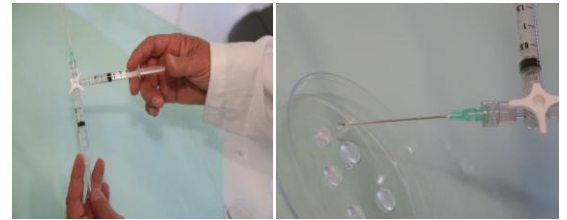
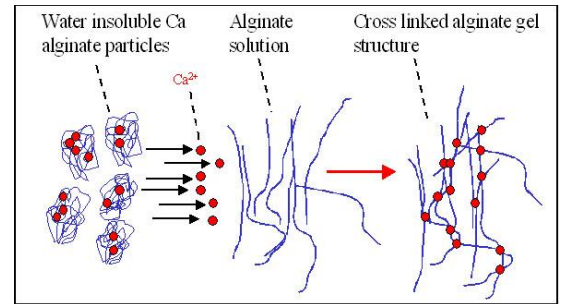


## Injectable Alginate Self-Gelling Technology

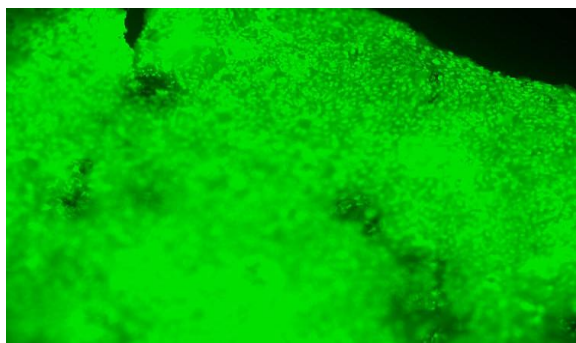
Hydrogel structures are useful across a wide range of biomedical applications. Alginate hydrogels, in particular, are of interest because of their unique properties and high degree of biocompatibility. As alginate gels are formed very rapidly in the presence of free gelling ions like  $\text{Ca}^{2+}$ , alternative formulations are necessary to allow for increased set time and control of gelation. NovaMatrix has accomplished this by using internal gelling systems that allow the gelling ion source to be mixed with the alginate solution before the gel sets. Other currently available gelling systems have limitations because of their low biocompatibility (due to pH changes), the involvement of other undesirable constituents, and/or suboptimal gelling properties.



Injectable Alginate Self-Gelling principle and handling

Self-gelling alginate formulations developed by NovaMatrix are made by mixing a dispersion containing insoluble calcium (or other gelling ion) alginate particles, with sodium alginate solutions (see figure). Mixing can be easily performed, for example by repeatedly passing the solutions between two connected syringes. This initiates a rearrangement of gelling ions between insoluble and soluble alginate molecules resulting in gel formation. The setting of the gel is highly accelerated by physiologic sodium levels, and gel formation may therefore be initiated or accelerated in contact with physiologic fluid. The gelling process may be modulated through the variation of several parameters such as the alginate quality, particle size, concentration of alginates and gelling and non-gelling ions, and the use of sequestering agents. Cells, API's, or other components may also easily be entrapped into the gel system, ready for injection *in-situ*. The gelling process may be delayed appropriately (up to several minutes) so that the formulation may be molded or injected as desired before the gel is set. Gel formation kinetics can easily be characterized by rheological methods.

The high degree of formulation flexibility of alginate self-gels can be utilized to meet your specific requirements. For example gelling time, gel strength, stability, and degradation rate can all be modified. The alginate self-gelling-systems may find use in numerous biomedical applications: Implantation as a space filling material, coating of medical devices, delivery of active substances, cell entrapment, wound healing and a range of other tissue engineering uses.



Human chondrocytes entrapped in self-gelling alginate (vibratome section). After six months the cells were stained for viability before the picture was taken.

Biocompatibility and toxicity testing has shown a high degree of biocompatibility.

NovaMatrix is capable of adapting the gel-system for specific application requirements. This technology is available for license from NovaMatrix.

## Patents

NovaMatrix/FMC Corporation does not warrant against infringements of patents of third parties by reason of any uses made of the product in combination with other material or in the operation of any process, and purchasers assume all risks of patent infringement by reason of any such use, combination, or operation.

## Warranty

Because of the numerous factors affecting results, NovaMatrix/FMC products are sold under the understanding that purchasers will make their own tests to determine the suitability of these products for their particular purpose. The several uses suggested by NovaMatrix/FMC Corporation are presented only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by NovaMatrix/FMC Corporation.

## Technical Service

The information contained in this bulletin is intended to be general in nature. Techniques and data pertaining to specific uses for NovaMatrix/FMC products and new developments will be published periodically in the form of supplemental application bulletins. Our technical staff is ready to offer assistance in the use of NovaMatrix/FMC products.

## Regulatory Status

PRONOVA™ sodium alginate meets the standards set forth in the current editions of the United States Pharmacopeia/National Formulary and European Pharmacopoeia. PRONOVA™ sodium alginate satisfies ASTM F 2064 for use in tissue engineered medical products (TEMPs). PRONOVA™ sodium alginate and PRONOVA™ calcium alginate are manufactured in compliance with GMP and described in a DMF submitted to the US FDA.

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