

# Tissue Bulking with Injectable Hydrogels

## Hydrogel Medical Devices

### Summary

CPG scientists have developed a formulation of injectable hydrogel that can be used to reinforce human tissue, acting as a bulking agent. CPG hydrogels use a wellrecognized biocompatible synthetic polymer, polyvinyl alcohol (PVA) that can be physically crosslinked after injection. Alternate tissue bulking materials are particlebased or are chemically crosslinked. These techniques pose potential health risks as chemical by-products can cause cell necrosis and particles can migrate. CPG hydrogels offer a safe tissue bulking agent that can be formulated for specific tissue applications.

#### Description

CPG developed permanent, non-migrating, а biocompatible material suitable for percutaneous injection. In collaboration with the Massachusetts General Hospital <sup>1,2,3</sup>, this hydrogel has been used to treat mitral valve regurgitation in an ovine model. Additionally, CPG has investigated the use of this formulation for urinary incontinence and gastroesophageal reflux disease (GERD). The formulation was injected through a long, narrowgauge catheter, and gelled in vivo without a chemical reaction. Different requirements for a specific application, including delivery systems, stiffness, and gelation time, can be met by formulation adjustment.

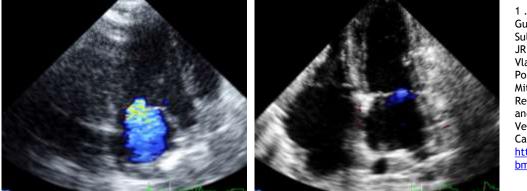


#### **Discussion**

Injection of hydrogel into the infarcted heart muscle allows stiffening of the dead muscle and restoration of the geometry of the valve tethers. Chronic regurgitation is therefore reduced or removed with a simple, minimal access treatment. Long-term animal studies are currently ongoing but data at 6 months is highly encouraging.

#### Applications

Injectable hydrogels can be utilized in support and augmentation of a variety of human tissues including urinary, cardiovascular, esophageal, and cosmetic.



Moderate MR resulting from an infarction (left ultrasound) is reduced by injection of hydrogel into the myocardial wall (arrows)

1 .Zeng X, Zou L, Levine RA, Guerrero JL, Handschumacher MD, Sullivan SM, Braithwaite GJ, Stone JR, Solis J, Muratoglu OK, Vlahakes GJ, Hung J.; "Efficacy of Polymer Injection for Ischemic Mitral Regurgitation: Persistent Reduction of Mitral Regurgitation and Attenuation of Left Ventricular Remodeling," JACC: Cardiovascular Interventions 2015 http://www.ncbi.nlm.nih.gov/pu bmed/25596792 ANALYTICAL TESTING BIOMEDICAL MATERIALS MATERIALS CONSULTATION RESEARCH & DEVELOPMENT



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