Hydrogels are water imbibing polymeric networks that have an enormous capacity to attract and hold water. Composed of homopolymer and copolymer chains, hydrogels are not water soluble yet have the capacity to soak up large quantities of the solvent; sequestering it in polymer domains that have high affinity for polar molecules. Commonly, synthetic hydrogels are produced through cross-linkage and polymerisation of low-molecular-weight hydrophilic polymers or through chemical cross-linkage of high-molecular-weight hydrophilic polymer chains. In both instances, a 3D network of polymer molecules is formed with large regions of highly polar and oftentimes ionically charged chemical moieties that both attract and retain water in their pore structure. In addition to chemical synthesis, hydrogels abound in nature and constitute much of the structure of joint spaces providing for viscoelasticity and shock absorption. Naturally derived hydrogels, such as hyaluronic acid, can be extracted from tissues or obtained from bacterial fermentation processes. Hyaluronic acid-based biopolymers can hold up to 99% of their weight in water and have molecular weights in the hundreds of thousands in the MDalton range. They are very complex chemical structures that are often incompletely characterised. By virtue of the fact that much of their weight is in the form of water, some hydrogels offer little in the way of mechanical behaviour; however, an interesting class of hydrogels exhibiting enormous capacity to attract and hold water; these unique mechanical and physical properties are exploited in the development of a novel, viscoelastic implant for treatment of a degenerative condition of the spine, known as spinal stenosis.

The chemical structure of PAN, the high-molecular-weight precursor polymer used in the preparation of HPAN, is depicted in Figure 1. The molecular weight of the starting material is approximately 220,000 Daltons. The starting polymer PAN consists of both crystalline and amorphous domains.

The nitrile or CN side chain groups attached to the aliphatic (C–C) polymer backbone are the sites at which the polymer undergoes hydrolysis during the production of HPAN. Hydrolysis of the CN side chains does not affect the molecular weight of the polymer backbone, which is important to its mechanical strength. The resultant HPAN polymer can be shaped into a wide array of forms and then dried into nearly any desired configuration. Once rehydrated, the HPAN implant resumes the original hydrated shape and retains ‘memory’.

**Functional Application of Hydrolysed Polyacrylonitrile Hydrogel for Use in Degenerative Conditions of the Spine**

There are a number of medical applications of hydrogels where mechanical strength and durability are necessary requirements for...
function. Orthopaedic and spinal implants that seek to replace a joint- or weight-bearing function must bear considerable load. Not surprisingly, implants dedicated to these activities are largely composed of metal.

Spinal Stenosis and Interspinous Spacer Devices

Interspinous spacer devices (ISDs) are a class of lumbar spinal devices gaining acceptance as an alternative to fusion for the treatment of lumbar spinal stenosis (LSS), which is a common degenerative disease that causes a narrowing of the spinal canal and neural foramen. Stenosis leads to the painful condition, neurogenic intermittent claudication (NIC). The degree of stenosis is exacerbated in extension of the spine. In extension, painful symptoms worsen due to increased neurologic compression. Flexion in the spine relieves these symptoms. An interspinous device distracts (flexes) the two adjacent spinous processes at the afflicted level and prevents the pathological extension. Degenerative spinal changes can be observed in 95% of people by 50 years of age, and stenosis is the most common cause of serious back pain in adults ≥60 years of age.

GelFix™ Interspinous Spacer Device – ‘The Soft Solution’

Treatments for spinal stenosis vary from non-surgical pain management, such as simple physical therapy or steroid injections, to serious surgical intervention. Decompression laminectomy and fusions are the most common surgical solutions to LSS but both involve inherent risks. ISDs are becoming a more popular solution to manage this compression. However, ISD surgery has recently been associated with a higher rate of early post-operative spinous process fracture. These fractures, often concealed by the metallic wings of certain commercial devices, can go unnoticed and are mostly responsible for an unacceptable outcome following surgery. Although interspinous devices have been previously composed of metal or hard plastics such as polyetheretherketone (PEEK), hydrogel is an attractive material for this application because of its elastic response to loading and its ability to conform to the bony anatomy of the interspinous space. The viscoelastic HPAN hydrogel, Gelfix™, allows normal motion while selectively restricting painful extension (see Figure 2). Gelfix provides a soft distraction, in contrast with more rigid conventional materials such as titanium and PEEK. Gelfix is surgically implanted in the dehydrated, collapsed state facilitating minimally invasive surgery. The implant begins to hydrate immediately after implantation by absorbing bodily fluids. Within four hours it is substantially hydrated and within eight hours close to full hydration (see Figure 3).

Clinical Case Study

A 59-year-old patient experiencing significant back and leg pain preoperatively was diagnosed with stenosis at L4/S and L5/S1 and

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**Figure 1:** Acrylonitrile – Polyacrylonitrile

**Figure 2:** Fully Hydrated Gelfix™ Implant

**Figure 3:** Gelfix™ Hydration as a Function of Time

**Figure 4:** Reduction in Pain Score After Treatment of Spinal Stenosis with Gelfix™ Interspinous Spacer

VAS = visual analogue scale.
degenerative disc disease at L5/S1. Using a posterior approach, a GelFix was implanted at L4/5 without incident or complications. During the three-week follow-up, a marked decrease in back and leg pain was documented with a Visual Analogue Scale (VAS) and Oswestry Disability questionnaires (see Figure 4). Prior to the six-week follow-up, the patient re-injured his back while performing heavy manual activities. While this incident led to a temporary increase in both the VAS and Oswestry scores, the patient subsequently improved at all later time points. The GelFix is visible during the surgery through radio opaque platinum-iridium wires embedded in the device. Post-operatively, the hydrated implant is easily visualised with a T2-weighted MRI (see Figures 5 and 6).

Summary
Hydrogel GelFix Interspinous Spacers, manufactured by Replication Medical inc., provide a simpler, softer approach to the treatment of back pain associated with spinal stenosis. Using a minimally invasive surgical approach, the GelFix implant is introduced into the body in a collapsed dehydrated state and then expands and swells by absorbing the body’s own fluids. After expansion, the GelFix distracts the interspinous space reducing nerve encroachment. The GelFix is flexible, providing viscoelastic resistance to painful extension. Main design features of the implant include, a single piece construct that serves as an elastic structure between the spinous processes, no moving parts, minimally invasive surgical procedure and instrumentation. The GelFix is intended to prevent or reduce nerve root impingement associated with spinal stenosis by increasing the space between the spinous processes in order to maintain flexion and reduce painful motion in extension.