

3.1.2 Properties of the Bone Graft Substitute

(Content from P060021 Executive Summary February 2009, page 1, paragraph 2)

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Stryker Biotech's OP-1[®] Putty device consists of osteogenic protein-1 (BMP-7) in a bioresorbable matrix of bovine collagen and carboxymethyl cellulose that is surgically implanted into the lumbar region of the spine. At the time of surgery, the product is reconstituted with normal saline, and mixed to produce a product with a putty-like consistency. The product does not harden with time and retains its moldable consistency. The product is radiolucent, which ensures that when bone is formed and detected during post-operative imaging, it is de-novo bone formation that is seen. This is in contrast to other spinal implants composed of radiopaque materials, which can be difficult to distinguish from de novo bone on plain film X-rays at later time points.