

## 3.1 Device Components

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OP-1<sup>®</sup> Putty device consists of a therapeutic protein in a bioresorbable matrix that is surgically implanted into the lumbar region of the spine. The components of OP-1<sup>®</sup> Putty device are packaged in two vials, each in separate blister packages, and stored together in one shelf box. Each vial must be aseptically combined with the other and reconstituted with sterile saline just prior to use. The contents of the two vials include:

- OP-1 protein and bovine collagen matrix (also known as OP-1<sup>®</sup> Implant);
- sodium carboxymethylcellulose (putty additive).

OP-1<sup>®</sup> Implant consists of one gram of sterile powder containing 3.5 mg OP-1 protein and Type 1 bovine bone collagen in a 2 ounce vial for reconstitution. The carboxymethylcellulose (CMC or putty additive) consists of 230 mg of sterile CMC in a 10 mL vial for reconstitution. At the time of surgery, the contents of each vial are transferred to a sterile mixing bowl, reconstituted with normal saline, and mixed with a spatula to produce a product with a putty-like consistency. This process is repeated to prepare a second unit for implantation into the contralateral side of the spine. The Product Preparation Instructions and Surgical Technique booklet contain complete directions for use.