



New Humanitarian Device Approval

OP - 1™ Implant - H010002

FDA approved this device under the Humanitarian Device Exemption (HDE) program <http://www.fda.gov/cdrh/ode/hdeinfo.html>. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: OP-1™ Implant
Manufacturer: Stryker Biotech
Address: 35 South Street, Hopkinton, MA 01748
Approval Date: October 17, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/h010002a.pdf>

What is it? The OP-1 Implant is used to treat fractured bones that do not heal after a normal period of time. It is made of a manufactured human protein powder and bovine (cow) bone collagen that is mixed with sterile saline solution (salt water) to form a paste. The paste is then placed between the broken ends of the bone during surgery.

How does it work? The OP-1 Implant may help to form new bone by imitating the body's own method of bone healing and growth. The OP-1 also gives a physical platform to support any bone that forms.

When is it used? The OP-1 Implant is selected when using the patient's own bone (autograft) is not a good choice and when other treatments have failed.

What will it accomplish? It may promote healing in fractures that have not healed normally.

When should it not be used? This device should not be implanted if the patient:

- is allergic to OP-1 or collagen,
- has had a tumor removed at or near the fracture,
- has had a previous history of cancer,
- is under 18 years of age or still growing, or
- is pregnant.

Women of childbearing age should practice birth control for one year following treatment with the OP-1 Implant. It is not yet known if use of this implant may affect a developing fetus.

Additional information:

· SSPB and Labeling: <http://www.fda.gov/cdrh/ode/h010002sum.html>

Other

- National Institutes of Health (NIH) MedLine Plus: Information on standard of care for fractures

<http://medlineplus.nlm.nih.gov/medlineplus/ency/article/002966.htm>

- NIH Comprehensive information of fractures
<http://www.nlm.nih.gov/medlineplus/fractures.html>
- NIH General information with picture of bones of skeleton
<http://www.nlm.nih.gov/medlineplus/bonediseases.html>

(updated 11/30/01)