



# New Device Approvals

## STAARVISC™ Sodium Hyaluronate - P000046

*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

Product Name: STAARVISC™ Sodium Hyaluronate  
Manufacturer: Anika Therapeutics, Inc  
Address: 236 West Cummings Park, Woburn, MA 01801  
Approval Date: April 18, 2001  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000046a.pdf>

**What is it?** Sodium hyaluronate is a thick liquid similar to the natural fluid found in the eye.

**How does it work?** It acts as a tissue lubricant, and also maintains the volume of eye fluid during surgery on the inside of the eye.

**When is it used?** During surgery in the eye, such as:

- cataract removal
- implanting intraocular lenses (IOL)
- corneal transplantation
- glaucoma-filtering surgery
- retinal reattachment

**What will it accomplish?** It helps keep the eye's shape and protects different tissues within the eye during surgery.

**When should it not be used?** There are no known reasons that would cause this product to be dangerous if used as the company recommends. For more information on precautions, please refer to the link to the labeling below.

**Additional information:** The SSED and Labeling is available at:  
<http://www.fda.gov/cdrh/pdf/p000046.html>

*(Updated 6/4/2001)*