



## New Humanitarian Device Approval

### **AVANTA METACARPOPHALANGEAL (MCP) JOINT IMPLANT FINGER PROSTHESIS - H010001**



*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: Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis  
Manufacturer: Avanta Orthopaedics, Inc.  
Address: 9369 Carroll Park Drive, Suite A, San Diego, California 92121  
Approval Date: August 28, 2001  
Approval Letter: <http://www.fda.gov/cdrh/pdf/h010001a.pdf>

What is it? The Avanta MCP Joint Implant Finger Prosthesis is an artificial finger joint. It consists of two parts: (1) a metal "ball-shaped" end and stem and (2) a plastic "cup-shaped" receptacle and stem.

How does it work? The Avanta MCP Joint Implant Finger Prosthesis is used to replace the metacarpal phalangeal (MPC) joint of the hand (the knuckle). The stems of each component are implanted into the shafts of the finger bones using bone cement. The finger bones and surrounding soft tissues (e.g., muscles, tendons, and ligaments) make the joint stable.

When is it used? The Avanta MCP Joint Implant Finger Prosthesis is a device used in patients who need a replacement of a prior MCP implant; have osteoarthritis; or arthritis due to trauma.

What will it accomplish? The Avanta MCP Joint Implant Finger Prosthesis may relieve pain and allow for an increase in function of the MCP joint.

When should it not be used? The implant should not be used on patients who:

- Have an infection,
- Have bone or soft tissue affected by disease or a previous implant that will not provide adequate

support for the device,

- Are too young to have mature bones, or
- Will use the hand or joint under conditions that require strenuous lifting or excessive mobility.

Additional information: The Summary of Safety and Probable Benefit will be available at:

<http://www.fda.gov/cdrh/ode/H010001sum.html>

NIH: <http://www.niams.nih.gov/hi/topics/arthrit/oahandout.htm>

<http://www.niams.nih.gov/hi/topics/arthrit/arthexfs.htm>

<http://www.niams.nih.gov/hi/topics/arthrit/orwhseminar.htm>

*(Updated 9/24/2001)*