



# New Device Approvals

## **Ascension® MCP - P000057**

*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: **Ascension® MCP**  
Manufacturer: **Ascension Orthopedics, Inc.**  
Address: **8200 Cameron Road, Suite C-140, Austin, Texas 78754**  
Approval Date: **November 19, 2001**  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000057a.pdf>

What is it? The Ascension® MCP is a two-piece artificial finger joint. One piece has a ball-shaped end and a stem, and the other piece has a cup-shaped receptacle and stem. Each piece is made of a special form of carbon called "pyrocarbon."

How does it work? The Ascension® MCP is used to replace the metacarpal phalangeal (MCP) joint of the hand (the knuckle). The ball-shaped and cup-shaped ends of the two pieces form the joint and move against each other. The stems of each piece are implanted into the shafts of the finger bones without bone cement. The finger bones and surrounding soft tissues (e.g., muscles, tendons, and ligaments) make the joint stable.

When is it used? The Ascension® MCP is used in patients who need replacement of a finger MCP joint that is painful, stiff, or cannot move because of arthritis or injury. The Ascension® MCP should be used only when reconstruction of surrounding soft tissues (e.g., muscles, tendons, and ligaments) is able to make the joint stable.

What will it accomplish? The Ascension® MCP may relieve pain and allow for an increase in function of the MCP joint.

When should it not be used? The Ascension® MCP should not be used in patients who have:

- thin or weak bones or other bone problems;
- an infection in the joint;

- finger or hand muscles or tendons that do not work and cannot be repaired;
- other hand or wrist implants that block insertion or motion of the Ascension MCP;
- bones that have not fully developed;
- poor healing of cuts or other skin problems; or
- problems with numbness or tingling in the hands or fingers.

Additional information:

- Summary of Safety and Effectiveness and labeling are available at: <http://www.fda.gov/cdrh/pdf/p000057html>
- National Institutes of Health (NIH):
  - Injuries & disorders of hand with links to other organizations: <http://www.nlm.nih.gov/medlineplus/handwristarminjuriesanddisorders.html>
  - Arthritis Seminar: <http://www.niams.nih.gov/hi/topics/arthritis/orwhseminar.htm>
  - Handout on arthritis: <http://www.niams.nih.gov/hi/topics/arthritis/oahandout.htm>
  - Information on arthritis: <http://www.niams.nih.gov/hi/topics/arthritis/arthexfs.htm>

(Updated 04/17/2002)