

Proposed Patient Labeling



Ascension[®] MCP

Metacarpophalangeal Joint Implant

Patient Information

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1. WHAT IS THE ASCENSION[®] MCP?

The Ascension[®] MCP is a two-piece joint prosthesis. Each piece is made of a special form of carbon called "pyrocarbon." It is meant to replace the actual bone joint in your finger. It is also meant to help give you better use of your hand, reduce your pain, and improve how your hand looks.

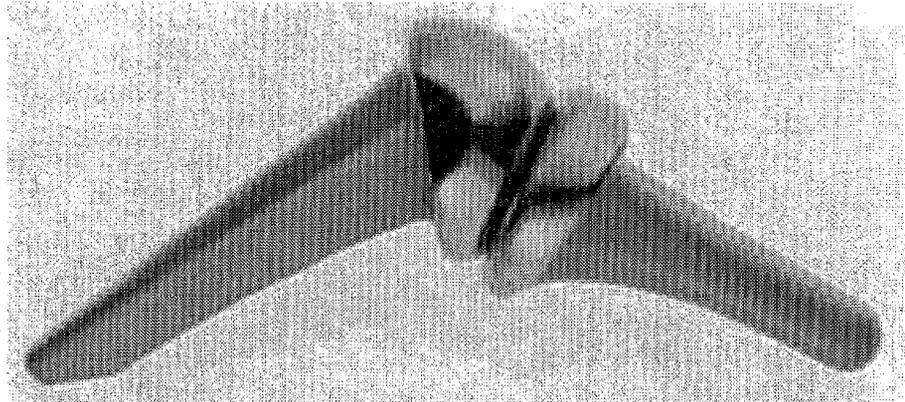


Figure 1: The Ascension[®] MCP

2. PURPOSE OF THE DEVICE (INDICATIONS FOR USE)

If you are reading this brochure, your doctor or surgeon has probably said that the Ascension[®] MCP may be the best course of action for you. This device is meant to replace the metacarpophalangeal (MCP) joint for people with certain conditions. These include:

- osteoarthritis
- post-traumatic arthritis
- rheumatoid arthritis
- destroyed articular surface(s)
- ankylosed joints, or those with limited range of motion which have not responded to conservative treatment
- nonfunctional joints due to inadequate bony alignment and joint space which can not be restored by soft tissue reconstruction

3. WHEN THIS DEVICE SHOULD NOT BE USED (CONTRAINDICATIONS)

In general, this device should not be used in patients with the following conditions:

- skin, bone, circulatory and/or neurological deficiency
- muscles and tendons that do not work and cannot be repaired
- indications that sepsis or infection are already present
- not enough bone stock
- a physiologically unsuitable patient

4. WHAT ARE THE RISKS AND BENEFITS?

There are no known harmful effects on your health due to the use of this device. General risks with any surgery include:

- bleeding
- infection
- loss of use of the hand
- permanent disability
- death

Potential risks with any finger joint device may include:

- pain
- stiffness
- infection
- injury to your nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- night and weather-related pain
- loss of motion
- smaller range of motion
- dislocated joint
- loosening of the implant from the bone
- implant rotation
- implant fracture
- accelerated wear of the device components
- lengthening or shortening of the finger
- more surgery may be required for reoperation, revision, or fusion of the joint
- surgery may be started but a joint replacement cannot be done, resulting in fusion of the joint

Heavy loads on the implant, overuse, or misuse of your finger joints can increase the potential for complications, including fracture of your implant.

The intended benefits of the Ascension® MCP include:

- better range of motion of your finger
- better grip and pinch strength
- less pain
- better appearance of your hand
- better joint stability

The Ascension® MCP is designed to help restore your finger to near normal motion. This range of motion may, however, be limited by your medical condition. The following drawing shows the normal range of motion of this device.

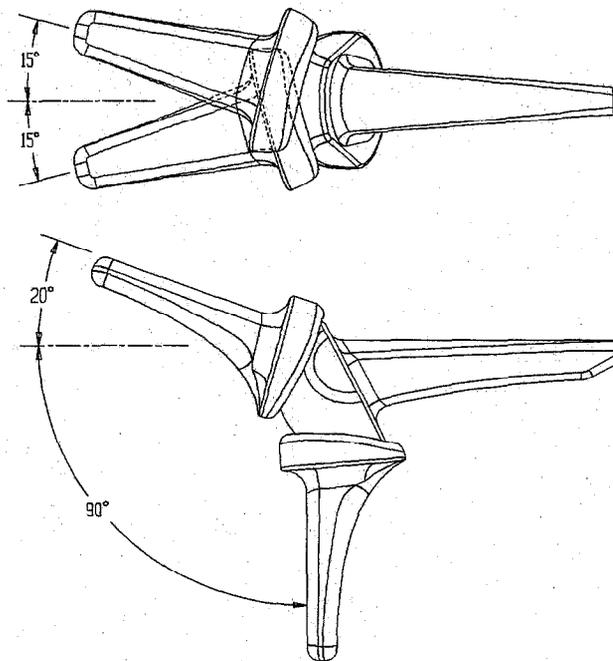


Figure 2: The Ascension® MCP Range of Motion

5. EXPECTATIONS OF THE DEVICE

Before the surgery, your doctor will talk with you about your medical situation and the surgery. You should ask any questions you have.

After your surgery, you will be fitted with bandages, and you will be asked to do physical therapy exercises. It is very important that you work on your exercises with your doctor and your hand therapist so that you can recover from surgery with good hand function. This provides the best chance for a success.

Your hand therapist will put your hand in a splint for several weeks after the surgery. You will learn how to care for your hand while it heals. It is important that you keep your hand clean and dry. Do not put unnecessary stress on it. Keep it raised to lessen any pain and swelling. After a successful surgery, you should notice less pain after your hand heals. Normally, you can expect good long-term use from this device. It is possible, however, that you could need more surgery if your finger becomes infected, dislocated, or if you and your doctor decide that the implant is not helping.

As with any surgical implant, it is possible that you could see unusual symptoms appear after the surgery. These may include redness and swelling, unusual pain, unusual sounds or sensations, and crooked fingers. Such symptoms may mean that your implant is infected, loose, or dislocated. Call your doctor or hand therapist right away if you notice any of these symptoms.

6. GENERAL WARNINGS AND PRECAUTIONS

- Do not put unnecessary stress on your hand for several weeks after surgery. Your finger needs time to heal.
- When doing your exercises during the first six weeks, move your fingers in a slow, pain-free manner. Make sure you do not twist your finger.
- If you notice any unusual redness, swelling, pain, crooked fingers, or anything else unusual, call your doctor.

7. PROCEDURE ASSOCIATED WITH THE DEVICE

The implant surgery will likely take a few hours. The surgeon will fit your finger with the correct size of device, and then implant it into the natural cavities of your finger bones. When you wake up after the surgery, your hand will be bandaged in a bulky dressing. For several days, you should not try to move your finger while it heals. Some soreness is normal after surgery.

8. ALTERNATIVE PRACTICES AND PROCEDURES

The alternatives to this implant include a silicone rubber spacer, joint fusion, surgery on your tendons and ligaments, physical therapy without surgery, and medication. The status of your medical condition may determine whether any of these alternatives is a good choice.

Conservative early stage treatment includes joint injections, drug therapy (e.g. aspirin, etc.) and avoiding heavy stress through the joints. (Regular, gentle, active exercises are needed to maintain joint range of motion). Wrapping the joints at night may also help control swelling and morning stiffness. Sometimes wrapping may be combined with splinting.

Surgery may restore some range of motion. It is typically used when conservative treatments no longer help. Surgical options include fusion of the bones, which may help with the pain but will eliminate joint motion. Another option is to replace the joint with a silicone rubber spacer, which may also help with the pain. People who are very active and use their hands a lot may not be good candidates for silicone rubber implants. You should discuss your situation with your doctor.

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