

## Ascension® PIP Patient Information

This brochure summarizes information about the use, risks, and benefits of the Ascension PIP finger implant. If you have any questions after reading this, or any problems after surgery, you should contact your doctor.

**Humanitarian Device:** The Ascension PIP is authorized by Federal law for use in arthroplasty of the proximal interphalangeal (PIP) joint when the patient:

- Has soft tissue and bone that can provide adequate stabilization and fixation under high-demand loading conditions after reconstruction; and
- Needs a revision of a failed PIP prosthesis, or has pain, limited motion, or joint subluxation/dislocation secondary to damage or destruction of the articular cartilage.

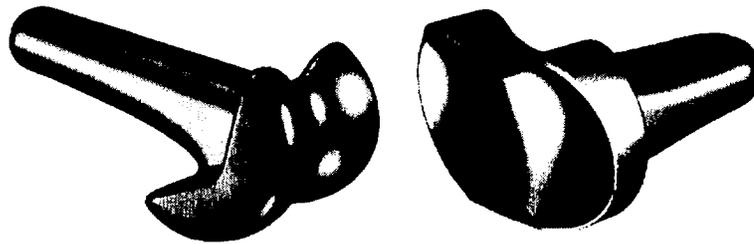
The effectiveness of this device for this use has not been demonstrated.

### 1. WHAT IS A HUMANITARIAN DEVICE?

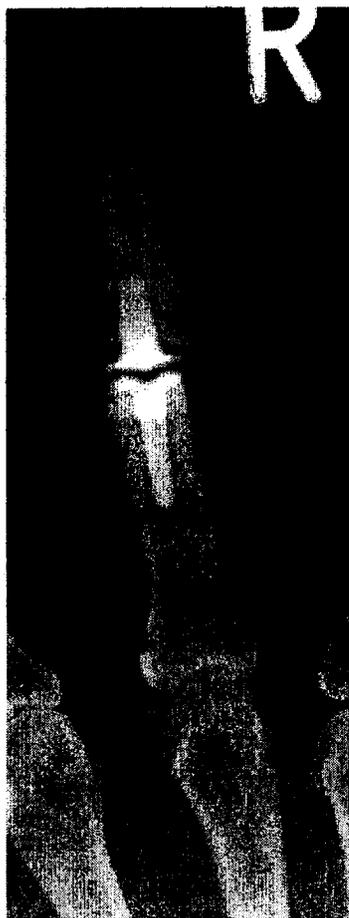
The Ascension PIP has been approved by the Food and Drug Administration (FDA) for use as a Humanitarian Use Device (HUD). A humanitarian use device is one which is used for conditions or diseases which typically affect fewer than 4,000 people in the United States per year, and when there is no comparable device marketed to treat/diagnose those conditions or diseases. **The ability of this implant to relieve your symptoms has not been proven, but it is probably safe and may improve your condition.**

### 2. WHAT IS THE ASCENSION® PIP?

The Ascension® PIP is a two-piece joint implant. Each piece is made of a special form of carbon called "pyrocarbon." It is used to replace the middle joint in your finger. Surgery is required to implant the device and physical therapy and exercises are needed after the procedure. The Ascension PIP should reduce your pain and help your finger move. It is easy to see the implant on x-rays.



The Ascension® PIP



**X-ray of the Ascension® PIP**

**3. WHEN IS THE ASCENSION® PIP USED?**

If you are reading this brochure, your doctor has probably said the Ascension PIP implant is the best treatment for you. It is used when your finger joint is painful, stiff, or cannot move because of arthritis or injury.

**4. WHEN SHOULD THE ASCENSION® PIP NOT BE USED?**

The Ascension PIP should not be used if you 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 finger implants that block insertion or motion of the Ascension PIP
- problems with cuts healing or other skin problems
- problems with numbness or tingling in your hands or fingers

## **5. WHAT ARE SOME ALTERNATIVE PRACTICES AND PROCEDURES?**

Besides the Ascension PIP, there may be other treatments for your finger joint. Your medical condition will determine if any of these treatments are good for you. You should discuss these with your doctor.

Non-surgical treatments include:

- joint injections (when a needle is placed in a joint space and medication is injected that may reduce inflammation and pain)
- medication (such as aspirin)
- avoiding heavy lifting or use of hand and fingers
- physical therapy exercises and splints

Surgery may be necessary to help your finger joint. It is used when non-surgical treatments do not work.

Alternative surgical options are:

- surgery on your tendons and ligaments
- joint fusion surgery
- surgery with a silicone rubber spacer

Tendon and ligament surgery may improve finger motion or bent and crooked fingers. Joint fusion may reduce pain but your joint will not move. Surgery with a silicone rubber spacer may reduce pain and improve motion. However, silicone rubber spacers may not work in people who are very active and use their hands a lot.

Please be sure to discuss your situation and all your options with your doctor.

## **6. WHAT ARE THE BENEFITS OF THE ASCENSION® PIP?**

There are many potential benefits with the Ascension PIP. It may:

- reduce finger joint pain
- help your finger move
- improve how your finger looks

Keep in mind that your medical condition may limit your improvements.

## 7. WHAT ARE THE RISKS OF THE ASCENSION® PIP?

### **Risks from the Implant**

The Ascension PIP should not cause you any harm or pain. But complications can occur and may reduce the success of the surgery. Heavy loads on your hand or fingers may cause problems with the implant such as:

- implant loosening
- implant fracture
- implant wear

### **Risks from the Surgery**

Finger surgery may also cause some problems. These problems do not usually happen, but it is best to know the risks. Finger surgery may result in:

- a longer or shorter finger
- pain when your finger moves or when it is still
- pain at night or when the weather changes
- finger joint stiffness
- less or no finger motion
- a dislocated joint
- a bent, crooked or twisted finger
- a useless finger or hand (permanent disability)
- a joint that is fused or a different implant because, due to a variety of factors, the Ascension PIP cannot be implanted
- more surgery to fix a bent or twisted finger or dislocated joint
- more surgery to remove the implant or fuse the joint
- bleeding, infection, or numbness (nerve damage)
- damage to blood vessels or tendons or tissue around the joint
- finger amputation
- death

## **8. WHAT SHOULD I DISCUSS WITH MY DOCTOR BEFORE SURGERY?**

Treatment with the Ascension PIP involves surgery followed by splints, physical therapy and exercises. Before surgery, your doctor should talk with you about your specific medical needs. You and your doctor should discuss:

- alternative treatment options
- treatment goals
- finger joint surgery
- length of surgery
- things you may need to do to prepare for surgery
- splints, physical therapy and exercises
- problems to look for
- any questions you have

## **9. HOW SHOULD I CARE FOR MY HAND AFTER SURGERY?**

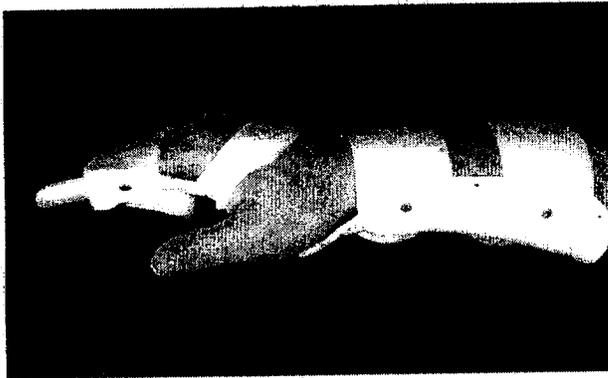
After surgery, it is important that you:

- keep your hand clean and dry
- keep your hand raised to lessen any pain and swelling
- do not use your hand for daily activities until your doctor approves
- attend all of your appointments after surgery

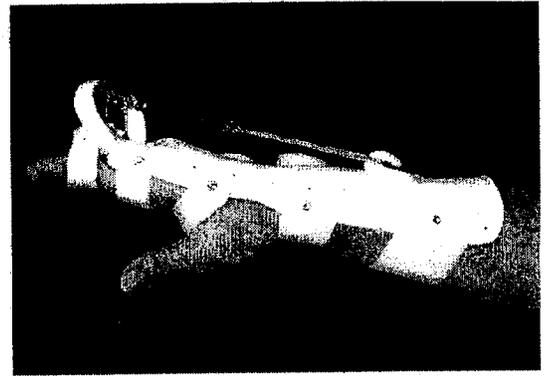
Some soreness after surgery is normal but it should go away slowly. You may be able to move the end of your finger, but you should not try to move your operated joint for 2 – 4 days until the bandages are removed, according to the instructions from your surgeon.

After your surgery you will probably have:

- a bandage or a cast
- a static splint for rest or night use (a static splint does not allow finger motion)
- a dynamic splint for day use (a dynamic splint allows limited finger motion)
- physical therapy and exercises



**Static splint**



**Dynamic splint**

Physical therapy and exercises may last up to 12 weeks (3 months) after surgery. You should wear the static and dynamic splints during this time. Your doctor or therapist will show you how to do the exercises. It is very important to follow their instructions carefully so you can recover from surgery with good hand function.

## **10. WHAT ARE SOME GENERAL WARNINGS AND PRECAUTIONS?**

- Do not use your hand for daily activities after surgery until your doctor or therapist approves. Your finger needs time to heal.
- When doing therapy exercises, move your fingers slowly and avoid pain.
- Make sure you do not twist your finger.

## **11. WHEN SHOULD I CALL MY DOCTOR?**

You should call the doctor if:

- you have questions
- you develop a fever
- your finger becomes:
  - red
  - hot
  - swollen
  - painful
  - bent, crooked, or twisted
- you experience:
  - sudden onset of pain
  - sudden change in joint function or motion

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