

Product Insert:

Avanta MCP Finger Prosthesis

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HUMANITARIAN DEVICE. The Avanta MCP Finger Prosthesis is authorized by Federal law for use in arthroplasty of the MCP joint when either the:

- patient is in need of a revision of failed MCP prosthesis(es); or
- patient expects to place his/her hands under loading situations, which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic MCP joint.

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

CAUTION

Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION

The Avanta MCP Finger Prosthesis consists of a distal component which is made of an ultra-high molecular weight polyethylene (UHMWPe) articulating surface and stem, and a proximal component consisting of a cobalt-chromium-molybdenum articulating surface. The joint prosthesis is intended for use with bone cement. The device is semi-constrained because it limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage. The two components of the implant articulate on their mating surfaces.

The proximal component is designed for implantation onto the distal end of the metacarpal. The distal component is designed for implantation into the proximal end of the proximal phalanx. Both components are intended to articulate on each other allowing for 90 degrees of flexion/extension. The articular surfaces prevent dislocation of the joint through simulation of the natural joint implant articular surface. Both the proximal and distal components are designed to be used with cement.

The implant is available in five sizes. An alpha-numeric coding system is used to distinguish sizes. A full surgical instrument set with appropriately sized trials and broaches is available.

Materials:

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component
- ASTM F75 cobalt chromium proximal component

INDICATIONS

The Avanta MCP Finger Prosthesis is indicated for use in arthroplasty of the MCP joint when either the:

- patient is in need of a revision of failed MCP prosthesis(es); or
- patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritic and post traumatic arthritic MCP joint.

CONTRAINDICATIONS

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Infection.
- Skeletal Immaturity.

WARNINGS (See also the Patient Counseling Information Section)

- Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure when excessive demands are made upon it.

PRECAUTIONS

- **Do not resterilize.** The implant is provided sterile. If either the implant or the package appears damaged, the expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

ADVERSE EVENTS

REPORTED ADVERSE EVENTS

There has been some clinical experience with this device. In the US, 20 patients have been implanted with the device with a maximum length of follow-up of 24 months. In the US patients, the most commonly reported adverse events were:

- post operative pain
- subluxation
- dislocation

For more details see **Table 5: Complications for US Patients** in the Clinical Experience Section for reported adverse events associated with the device.

POTENTIAL ADVERSE EFFECTS

General Surgery Related Risks

- bleeding
- infection
- loss of use of the hand

- permanent disability
- death

Joint Replacement Related Risks

- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- instability of the joint
- dislocation of the joint
- cement extrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional 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
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

CLINICAL EXPERIENCE

There has been some clinical experience with this device. In the US, 20 patients have been implanted with the Avanta MCP Finger Prostheses with a maximum length of follow-up of 24 months in a prospective randomized clinical study. Patients are randomized into either the experimental group, which received the Avanta MCP Finger Prosthesis, or into the control group, which received a silicone elastomer implant. Thirty-four patients have been randomized into the study to date. However only 29 of these patients, 20 experimental and 9 control, have had surgery performed to implant either the control device or the Avanta MCP Finger Prosthesis. Table 3 describes the patients randomized into the study, patients implanted with a device and the patient dropouts from the study. Twenty nine of these patients have follow-up data, which is summarized in Tables 4-6. Tables 4-6 describe the patient demographics, reported complications and length of follow-up for this clinical study to date.

Table 3. US Patients MCP

<i>Patient Category</i>	<i>Patients with Avanta MCP implant (patients)</i>	<i>Patients with Silicone Implant (patients/hands)</i>	<i>Total (patients/hands)</i>
Total Randomized into Study	20	14/15	34/35
Total Who Have Had Surgery	20	9/10	29/30
Withdrew Prior to Surgery	0	5	5
Withdrew After Surgery	5	2	7
With follow-up Data*	20	9/10	29/30

* Data report forms have been returned on 29 patients. Tables 4-6 describe the clinical results for these 29 patients.

Table 4. Demographics for 29 US Patients* with Follow-up

<i>Category</i>	<i>Patients with Avanta MCP Implant</i>	<i>Patients with Silicone Implant</i>	<i>Total</i>
Male	3	1	4
Female	16	8	24
Unknown	0	1	1
Mean Age, SD	56.3±11.3 (n=19)	61.9±8.1(n=6)	58.2±10.3
Age Range (years)	32-77	52-74	32-77
Osteo-arthritis	1	1	2
Polymyositis	0	1	1
Rheumatoid Arthritis	18	7	25
Silicone Implant Revision	1	0	1

*Description of number of patients with more than one implant. There are 29 patients with 99 implants: twenty patients with 4 implants; three patients with 3 implants; three patients with 2 implants; four patients with 1 implant.

Table 5. Complications for US Patients

<i>Complication</i>	<i>Avanta MCP Device (n=8 Patients)</i>	<i>Silicone Device (n=0 Patients)</i>
Skin Necrosis	1	0
Wound Dehiscence	1	0
Implant Failure	1	0
Joint Dislocation	3	0
Joint Subluxation	4	0
pain (6 months post-op)	4	0

Table 6. Number of US Patients (Implants) at Each follow-up Time Point

<i>Length of follow-up</i>	<i>Avanta MCP Implant Patients (# implants)</i>	<i>Silicone Implant Patients (# implants)</i>
Post-op (1-4 weeks)	20 (68)	9 (31)
3 months	18 (61)	8 (29)
6 months	16 (53)	6 (21)
12 months	9 (32)	2 (12)
24 months	4 (14)	2 (5)
Post-op withdrawal	5(20)	2 (5)

Linscheid¹ reported on sixty-one fingers in 25 patients treated with this device. Eight implants were implanted in eight patients with traumatic or degenerative arthritis. Fifty-three implants were implanted in 17 patients with rheumatoid arthritis. There were 23 women and 2 men, with an average age of 63 years (range = 45-78 years). The average preoperative MCP arc of motion was 45 degrees, with an extension lag averaging 45 degrees. Preoperatively, there was an average of 20 degrees of ulnar deviation. Swan-neck deformities were common in those patients with rheumatoid arthritis.

The follow-up averaged 30 months (range = 4-60 months). The results in single joints with traumatic or degenerative arthritis were better than in the multiple fingers with rheumatoid arthritis. The average arc of motion was 50 degrees (range 25-90 degrees). Extension lag was improved in the rheumatoid patients. The author stated, "Grip and pinch strength showed little change, but discomfort was noticeably better subjectively." The author only reported "Subluxation or dislocation recurred despite repair of the collateral ligaments and recentering of the extensor tendon." The report did not provide the rate of these adverse events. The author states that this complication was addressed through postoperative splinting, or casting, and careful monitoring of joint reduction through the use of x-ray.

SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

PATIENT COUNSELING INFORMATION (See also Warnings)

A patient brochure is available for use in counseling the patient.

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

- While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.
- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION

- This component has been sterilized by ethylene oxide or gamma radiation.
- **Do not resterilize.** The implant is provided sterile. If either the implant or the package appears damaged, the expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY

Avanta Orthopaedics Inc., warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Avanta Orthopaedics does not warrant the outcome of the surgical procedure.

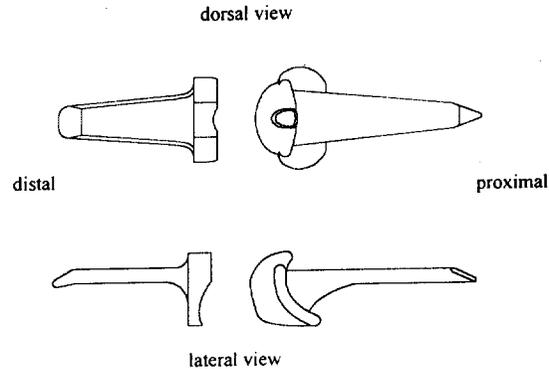
EU Representative:

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Patient Labeling Brochure



Photograph or drawing of the implant

What is the purpose of the (MCP) joint prosthesis?

HUMANITARIAN DEVICE. The Avanta Metacarpophalangeal (MCP) Finger Prosthesis is authorized by Federal law for use in arthroplasty (surgery) of the MCP joint when either the:

- patient needs the surgery again because a previous joint surgery failed.
- patient expects to use his/her hand under heavy loading (doing heavy lifting) and other types of devices are not useful for this purpose.

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

When should the device not be used?-- Contraindications

- When your bone, musculature, tendons, or adjacent soft tissue is damaged by disease, infections or by prior implantation.
- Infection
- When you do not have adequate skeletal support for the implant.
- When you are young and your bones are still growing.

What is my doctor thinking about using for my implant?

- Avanta Orthopaedics has developed an implant for the Metacarpophalangeal (MCP) finger joint. The (MCP) joint is the joint that is also referred to as your knuckle.

- This implant is available for sale in the United States as a humanitarian use device. A humanitarian use device is one, which is used for conditions or diseases which typically affect fewer than 4000 people in the United States per year, and when there is no comparable device marketed to treat/diagnose those conditions or diseases.
- Your physician has determined that you may benefit from implantation of this finger joint implant.
- **You should be aware that the effectiveness of this device for this use has not been demonstrated.**

What will occur during the surgery?

- This surgery involves the use of a finger joint replacement device for treatment of patients with certain kinds of arthritis (osteo-arthritis or post traumatic arthritis) and who expect to place their hands in heavy loading situations, or patients needing revision of a failed implant placed in the MCP joint.
- A joint replacement surgery is an operation where the arthritic joint is removed and a metal and plastic joint is inserted to replace the natural joint. The surgery is expected to last about 2 hours.
- The procedure is done in the operating room and requires general anesthesia or an axillary block. (General anesthesia effects the entire body and is accompanied by a loss of consciousness. An axillary block results in anesthesia of the hand and forearm only. A tourniquet is applied to the arm to prevent bleeding during the surgery.)
- In joint replacement surgery, your hand is opened at the finger joint, and the bones are trimmed. The metal and plastic joint replacement parts are fixed to the bones using bone cement.

Will there be special care after the surgery?

- Antibiotics are usually given during and after the operation to prevent infection, as is normal in these cases, with current surgical treatment.
- Your doctor may give you medicine for pain after surgery.
- After the operation, your hand will be in a bandage. This will be removed two to five days following the operation. You may need to wear a splint or a cast for up to 4 weeks.
- When the bandage or splint is removed, you will start physical therapy.
- Your doctor and therapist will tell you how to take care of your hand. It is very important to follow their instructions and attend all of your appointments.

Are there Warnings I should be aware of?

- It is unlikely that your finger joint will be restored to the condition it was before your injury, arthritis or previous surgery. You should discuss your expectations of having surgery with your doctor before having surgery, as this procedure may not meet your expectations.

- You should be aware that strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. There is an increased potential for device failure when excessive demands are made upon it.

Does this surgery have risks that I should be aware of?

Note: It is important that you discuss all of these risks with your doctor.

General Surgery Related Risks – These are problems you may have because you are having surgery.

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

Joint Replacement Related Risks – These are problems you may have because you are having this implant placed in your hand.

- pain
- injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- cement protrusion injury
- infection
- lengthening or shortening of the finger
- amputation
- bone weakening around the implant
- decrease in range of motion
- allergic or other reactions to the metal or plastic materials
- additional surgery may be required for reoperation, revision or fusion of the joint
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What Benefits may I hope to receive?

- improved range of motion
- relief of pain
- improved grip and pinch strength.

Are there other treatments that I could receive for my condition?

You should thoroughly discuss the options for treating your finger joint with your doctor before selecting surgery as an alternative. Arthritis of the Metacarpophalangeal Joint can be treated non surgically or with surgery. The non surgical options include the use of splints, joint injections and medications (including the use of aspirin type drugs).

Current surgical treatments include fusion of the bones together, surgery on the joint with tendon or joint replacement with silicone implants. Joint replacement, with silicone implants has been available for a number of years and has the advantages of relieving pain and allowing motion at the joint. Some of the risks of silicone implants include the possibility for breakage, deformation, and side to side instability. If you are very active and use your hands heavily, you may not be good candidates for silicone implants.

What can I expect after surgery?

You should be aware, all implants will wear over time with use. It is important that you ask you surgeon what range of motion you may hope to have after the surgery and what strength you may hope to regain These factors will vary from one patient to another Therefore some degree of wear particle formation is inevitable with all implants including those made of silicone. The patient's biological response to these particles is variable. There are also reports in the medical literature suggesting a possible link between silicone implants and immunological abnormalities and autoimmune rheumatic disorders.

Glossary

Amputation – The removal of your entire finger or limb.

Antibiotics – Medication used to treat infection caused by bacteria and other microorganisms.

Axillary Block – A type of anesthetic, which numbs only the hand and forearm. You stay awake during the surgery with this type of anesthesia.

Immunological abnormalities – A condition which results in inadequate or ineffective functioning of your bodies immune system.

Instability – The joint doesn't provide enough support to resist your activities and may slide off to the side.

Metacarpophalangeal (MCP) finger joint – Commonly referred to as your knuckle.

Revision Surgery – A joint or implant may need more than one surgery if the first surgery doesn't work as well as expected.

Therapist – A person who will help you care for your hand after surgery to give you the best result possible. This person works with your doctor to treat your hand.

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