



Memorandum

Date • JUN 19 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Avanta Orthopaedics Braun-Cutter Trapezo-
metacarpal Prosthesis - ACTION

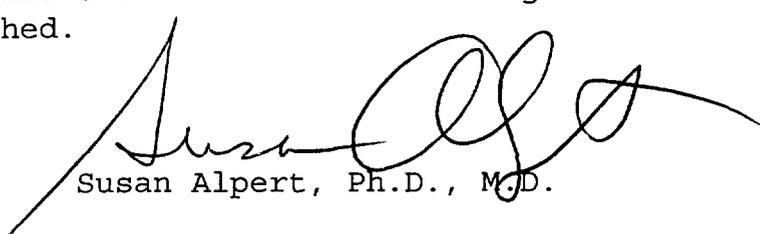
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the
subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above
referenced medical device (Tab B); and
- (2) the availability of a summary of safety and
effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and
published.


Susan Alpert, Ph.D., M.D.

Attachments

Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by T. Stevens, CDRH, HFZ-410, 10 June 1997, 594-2036
M. Melkerson, CDRH, HFZ-410, 10 June 1997, 594-2036

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. _____]

Avanta Orthopaedics Corp.; Premarket Approval of Braun-Cutter
Trapezo-metacarpal prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Avanta Orthopaedics Corp., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Braun-Cutter Trapezo-metacarpal prosthesis. After reviewing the recommendation of the Orthopedics and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of June 19, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Theodore R. Stevens,
Center for Devices and Radiological Health (HFZ-410),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-2036.

SUPPLEMENTARY INFORMATION: On December 24, 1996 Avanta Orthopaedics Corp., San Diego, CA 92121 submitted to CDRH an application for premarket approval of the Braun-Cutter Trapezo-metacarpal prosthesis. The device is a finger joint metal/polymer cemented prosthesis and is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

On June 9, 1997 the Orthopedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On June 19, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written

request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 1997

Ms. Louise M. Focht
Vice President, Research and Development
Avanta Orthopaedics
9396A Carroll Park Drive
San Diego, California 92121

Re: PMA Number P960053
Avanta Orthopaedics Braun-Cutter
Trapezo-metacarpal Prosthesis
Filed: December 24, 1996
Amended: January 10, 13 and 24; March 25 and 26;
April 4, 7 and 14; May 6 and June 20, 1997

Dear Ms. Focht:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Avanta Braun-Cutter Trapezo-metacarpal Prosthesis. This device is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may continue commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL

Page 2 - Ms. Louise M. Focht

REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

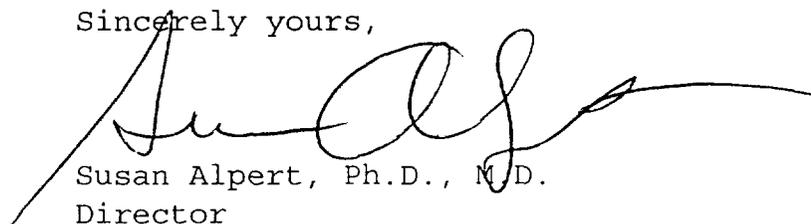
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Theodore R. Stevens at (301) 594-2036, extension 166.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effectuated" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effectuated" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effectuated." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
 - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
 - (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies

of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
 - (a) has not been addressed by the device's labeling or
 - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name: Finger joint polymer/constrained cemented prosthesis

Device Trade Name: Braun-Cutter Trapezo-metacarpal Prosthesis

Applicant's Name and Address:

Avanta Orthopaedics
9369-A Carroll Park Drive
San Diego, CA 92121

Premarket Approval (PMA) Number: P960053

Date of Panel Recommendation: June 9, 1997

Date of Notice of Approval to Applicant: June 19, 1997

II. INDICATION FOR USE

The Braun-Cutter Trapezo-metacarpal prosthesis is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

III. DEVICE DESCRIPTION

The Braun-Cutter Trapezo-metacarpal prosthesis is a device which replaces the joint between the thumb and the wrist. The device has two components: an ultrahigh molecular weight polyethylene socket which attaches to the trapezium, and a titanium ball attached to a titanium stem. The titanium stem is inserted into the long axis of the first metacarpal. The ball at the end of the stem snaps into the polyethylene socket attached to the trapezium. Both components of the device are intended for use with bone cement.

The device can be used in either the left or the right hand. Once the ball is snapped inside the socket, the stem can rotate 360° around its long axis and up to 45° from its long axis. The device is classified as a constrained device because it provides linkage across an anatomic joint: the ball-and-stem component does not pull out along its long axis from the snap-locking socket under normal *in vivo* conditions.

The ball and stem, subsequently described as the metacarpal component, is made of Titanium Alloy Ti-6Al-4V, ASTM F 136. The socket, subsequently described as the trapezium component, is made from ultra-high weight polyethylene ASTM F648, medical grade 415.

The trapezium component comes in two sizes, with a maximum diameter at the base of 1.992 and 11.43 mm respectively. The base has a short stem, 3.848 mm long and either 5.842 or 6.35 mm in diameter, which fits into the trapezium. The metacarpal component comes in three sizes, with shaft lengths of 17.17, 17.55, and 24.892 mm, respectively. Two sides of the shafts of both components are slightly concave to prevent them from rotating after they have been implanted. Both components are intended to be cemented into place, and there are grooves in the stems of both components to accommodate bone cement.

IV. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE EFFECTS

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.

- a) Any active or suspected infection in or around the thumb joint.
- b) Skeletal immaturity.

WARNINGS

This device is for cemented use only.

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 if excessive demands are made upon it.

PRECAUTIONS

The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome. A complete range of trial sizes for each type of implant is available to aid in bone preparation.

The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

Implants should only be handled with blunt instruments to avoid scratching, cutting, or nicking the device.

ADVERSE EVENTS

Adverse events in a published series of 50 patients included loosening, transient radial neuritis, cement extrusion injury to the palmar digital nerves and de Quervains tendinitis.²

Event	Number of events (50 cases)
Loosening	5 (10.0%)
transient radial neuritis	2 (4.0%)
cement extrusion injury	1 (2.0%)
de Quervan's tendinitis	6 (12%)

In addition to the adverse events from this publication, adverse events with other finger joint prostheses include loosening, fracture, dislocation, or infection of the implant. All of these complications would ordinarily require reoperation for successful treatment. Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device. Metal sensitivity reactions have been reported following joint replacement.

No Medical Device Reports related to the Braun-Cutter Trapezo-metacarpal prosthesis have been filed.

V. ALTERNATE PRACTICES AND PROCEDURES

Alternative therapies include conservative treatment of the hand with immobilization or physical therapy; arthrodesis; excisional arthroplasty; implantation with other metal/polymer, metal/metal or all-polymer finger joint prostheses; and ligament reconstruction.

VI. MARKETING HISTORY

This application was submitted in response to the final rule published in the Federal Register of September 27, 1997 (61 FR 50704) requiring the submission of PMA applications for finger joint constrained cemented prostheses. The device was cleared via premarket notification in January 1979 as the Braun-Cutter Trapezo-Metacarpal Prosthesis (K781937). The device was introduced into the European Union market in 1996. The device has not been withdrawn from any market for any reason.

VII. SUMMARY OF PRECLINICAL STUDIES

Biomechanical analysis of the device provided by the applicant was used to show that the mechanical strength of the device components exceeds stresses expected to be applied to the device *in vivo*. No other preclinical studies were reported for this device.

VIII. SUMMARY OF CLINICAL INVESTIGATIONS

The Braun-Cutter Trapezo-metacarpal prosthesis was designed and developed by Richard M. Braun, MD, in 1974².

Twelve of the original 29 patients implanted with this device had osteoarthritis, 8 had rheumatoid arthritis, and 3 had a failed arthrodesis. Diagnoses in the remaining 6 patients were post-traumatic arthritis, failed Silastic implant arthroplasty, failed total joint replacement of this type and of another design, and ankylosis of the joint secondary to long-standing paralytic imbalance. The patients had pain and instability of the trapezio-metacarpal joint. Minimum followup was 1 year; maximum followup was 7 years.

Twenty-two of the 29 patients achieved full, painless range of motion postoperatively. The remaining 7 failed to achieve full range of motion because of significant preoperative muscle imbalance of soft tissue scarring and contracture.

Three of the 29 patients experienced postoperative loosening of their prosthesis. Two of these cases occurred after direct trauma (one from a fall, the other when the thumb became stuck in a bowling ball). The third was attributed to poor surgical technique. No other major complications were reported.

Braun published a second paper on this device in 1985¹. This paper describes 50 patients and appears to include the 29 patients described in Braun's prior publication. Followup of the 50 patients was from 6 months to 10 years. Unfortunately, baseline data including diagnosis is not specified for each patient, nor is the patient sex ratio given.

Full range of motion was achieved in 26 patients with osteoarthritis, although the total number of patients in this series with osteoarthritis is not given. Twelve patients with rheumatoid arthritis are mentioned as having associated problems such as soft-tissue contracture, thenar muscle loss, metacarpophalangeal joint destruction, and spontaneous tendon ruptures. Despite these additional problems range of motion was improved over preoperative measurements.

The author describes 5 cases of implant loosening in this series of 50 patients. Two cases were attributed to trauma, one to faulty operative technique; a cause for the other two cases is not specified. Subsidence of the trapezoidal component was not observed.

Other adverse events in these patients were as follows. Two patients had transient radial neuritis which cleared within 6 months, as did one case of cement extrusion injury to the palmar digital nerves of the thumb.

Six patients had significant de Quervain's tendinitis, three of which obtained full symptomatic relief from operative release under nerve-block anesthesia as outpatients. The other three cases required splinting and occasional anti-inflammatory medication.

The following Table compares Braun's outcome data to published outcome data in patients treated with a similar device, the de la Caffiniere trapezo-metacarpal prosthesis (success as defined in each publication):

	#	FOLLOW-UP	SUCCESS	CAUSE OF FAILURES
Braun ¹⁻²	50	6 m-10y.	90%	loosening
Nicholas ³	20	10 y	90%	operative technique; trauma
Nonnenmacher ⁴	20	12 y	70%	loosening; ossification
Ehall ⁵	-	-	-	loosening
Wyss ⁶	-	4 y	70%	loosening
Boeckstyns ⁷	28	4 y	75%	4 replacements; 3 loosening
Sondergaard ⁸	20	9 y	85%	loosening
August ⁹	21	15m	38%	loosening
Sennwald ¹⁰	13	3 y	62%	loosening

The overall success rate for the de la Caffiniere prosthesis appears to be about 70%, and the principal cause of failure appears to be loosening of the prosthesis.

Treatment, very briefly, has evolved from resection of the trapezium to joint replacement to reconstruction of the lost anterior oblique ligament. The operative procedures for painful basal joint arthritis of the thumb are as follows:

OPERATION	ADVANTAGES	DISADVANTAGES
EXCISIONAL ARTHROPLASTY	Technically easy No prolonged postop immobilization Consistent pain relief	Predictable subsidence of thumb Weakened grip and pinch Does not stabilize first metacarpal joint
FUSION	Consistent pain relief Durable Can withstand heavy use in manual labor Maintains thumb length	May lead to problems in metacarpophalangeal joint Prolonged immobilization Nonunion Decreased motion
TOTAL JOINT ARTHROPLASTY	Attempts to restore lost anatomy Maintains thumb length	Problems with implant loosening No widespread acceptance Must have adequate bone stock Technically demanding
SILICONE IMPLANT ARTHROPLASTY	Consistent pain relief	Silicone synovitis Instability
LIGAMENT RECONSTRUCTION AND EXCISIONAL ARTHROPLASTY	Maintain thumb length Durable Consistent pain relief Reproducible Biologic Motion sparing	Technically demanding Few long-term followup reports No single method shown to be superior

The early use of excisional arthroplasty was replaced by arthrodesis in hopes of providing a more stable joint. The enthusiasm generated by the successes of total hip and total knee replacement in the 1970s initially extended to total thumb replacements, but this enthusiasm was tempered by the relatively high rate of joint loosening. The alternative, silicone implants, became more popular in the 1980s but are no longer the treatment of choice because of long-term implant wear, joint instability, and silicone synovitis. The ligament reconstruction procedures, initially developed for patients with failed arthroplasties, now appear to be the favored approach.

The review by Wolock et al.¹⁸ discusses the relationship between stage of arthritis and preferred treatment in more detail. Wolock et al. feel that ligament reconstruction is most useful in patients with stage I or II disease. For patients with stage III disease, excisional arthroplasty (with/without tendon interposition) and arthrodesis both relieve pain, but excisional arthroplasty leads to an unstable joint and arthrodesis to an excessively stable one. Patients with pantrapezial arthritis are better candidates for trapezial replacement; patients with adequate bone stock are better candidates for total joint arthroplasty.

The results of this literature review indicate that total joint arthroplasty remains a valuable therapeutic option for some patients with basal joint arthritis of the thumb. For these patients, results with the Braun-Cutter and de la Caffiniere prostheses are roughly equivalent. In both, loosening of the prosthesis is the major cause of failure, which occurs in roughly 30% of cases. (Cement is required to achieve even these results; without cement, results are substantially worse¹⁹). While this rate is less than ideal, it is not sufficient to deny eligible patients access to a therapy for which there may as yet be no preferable option.

IX. PANEL RECOMMENDATION

At a June 9, 1997 meeting of the Orthopedic Devices Advisory Committee (Panel), the Panel recommended the Avanta Orthopaedics PMA for the Braun-Cutter Trapezo-metacarpal Prosthesis was approvable subject to labeling modifications and the approval by the Center for Devices and Radiological Health (CDRH), and recommended that a patient registry be established.

X. CDRH DECISION

Reports of significant human experience with the marketed device is valid scientific evidence as defined under 21 CFR 860.7 for the purposes of determining safety and effectiveness. Based on review of the submitted information, FDA concludes that the benefits of the use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use. CDRH concurred with the Panel recommendation, with the exception of the establishment of a patient registry. CDRH believes that because of the low incidence and transient nature of most of the complications reported in the literature, that established means such as the Medical Device Reporting and User Facility Reporting systems should be sufficient to capture any unforeseen types or incidence of adverse events. The applicant amended the PMA to address the labeling issues raised by the Panel.

The most recent FDA inspections determined the manufacturing facilities to be in compliance with Good Manufacturing Practices (GMP) regulations.

CDRH issued an approval order on June 19, 1997.

XI. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.

XII. REFERENCES

- 1) Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985;195:161-7.
- 2) Braun RM. Total joint replacement at the base of the thumb - preliminary report. J Hand Surg 1982;7(3):245-51.
- 3) Nicholas RM, Calderwood JW. de la Caffiniere arthroplasty for basal thumb joint osteoarthritis. J Bone Joint Surg [Br] 1992;74:309-12.
- 4) Nonnenmacher J Graftiaux AG. [The de la Caffiniere trapezo-metacarpal prosthesis in rhizarthrosis of the thumb. A propos of 20 cases surgically treated between 1978 and 1990]. Ann Chir Main Memb Super 1994;13:26-35 [Fr].
- 5) Ehall R Neubauer W Stampel O Aigner C. [Carpometacarpal joint arthrosis and its surgical therapy with the de la Caffiniere endoprosthesis.] Beitr Ortho Traumatol 1990;37:644-53 [Ger].
- 6) Wyss A Saegmuller G. [Several years' experience with thumb saddle joint prosthesis by the de la Caffiniere method]. Handchirurgie 1980;12:65-8 [Ger].
- 7) Boeckstyns ME Sinding A Elholm KT Rechnagel K. Replacement of the trapeziometacarpal joint with a cemented (Caffiniere) prosthesis. J Hand Surg [Am] 1989;14:83-9.
- 8) Sondergaard L Konradsen L Rechnagel K. Long-term followup of the cemented Caffiniere prosthesis for trapezio-metacarpal arthroplasty. J Hand Surg [Br] 1991;16:428-30.
- 9) August AC Coupland RM Sandifer JP. Short term review of the de la Caffiniere trapezio-metacarpal arthroplasty. J Hand Surg 1984;9:185-8.
- 10) Sennwald GR Segmuller G. The value of scapho-trapezio-trapezoid arthrodesis combined with de la Caffiniere arthroplasty for the treatment of pan-trapezial osteoarthritis. J Hand Surg [Br] 1993;18:527-32.
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PRODUCT INSERT

Braun-Cutter Trapezo-Metacarpal Prosthesis

CAUTION

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

DESCRIPTION

The Braun-Cutter Trapezo-metacarpal joint prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) component which is cemented to the prepared trapezium, and a titanium alloy stem component with integral head which is inserted into the shaft of the first metacarpal. The titanium head articulates with the UHMWPe component to form a snap-fit constrained prosthetic replacement for the basal thumb joint. The implant is available in three sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

Materials:

- ASTM F-136 Titanium 6Al-4V ELI alloy metacarpal stem/head
- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) trapezium component
- ASTM F-75 cobalt chromium radiographic marker wire

INDICATIONS

The Braun-Cutter Trapezo-metacarpal prosthesis is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

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.
- Any active or suspected infection in or around the thumb joint.
- Skeletal immaturity.

WARNINGS (See also the Patient Counseling Information Section)

- This device is for cemented use only.
- 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 if excessive demands are made upon it.

PRECAUTIONS

- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.**
- 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 only be handled with blunt instruments to avoid scratching, cutting, or nicking the device.

ADVERSE EVENTS

- Adverse events in a published series of 50 patients included loosening, transient radial neuritis, cement extrusion injury to the palmar digital nerves and de Quervains tendinitis¹.

Event	Number of events (N=50)
Loosening	5 (10.0%)
transient radial neuritis	2 (4.0%)
cement extrusion injury	1 (2.0%)
de Quervan's tendinitis	6 (12%)

Potential adverse events reported with other finger joint prostheses include loosening, fracture, dislocation, or infection of the implant. No additional significant adverse events have been reported to date during the marketing period of this device.

Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

Metal sensitivity reactions have been reported following joint replacement.

CLINICAL DATA

Results of twenty-nine patients implanted with the device were reported². Replacement was performed for arthritis, failure of attempted arthrodesis, previous Silastic or total joint arthroplasty failure, or postparalytic fibrous ankylosis of the joint. Twenty-two patients had achieved a good range of painless motion at the time of publication (up to 7 years follow-up). Seven cases failed to achieve normal ROM due to significant muscle imbalance or soft tissue scarring and contracture. There were no reported cases of implant fracture or infection, but three cases demonstrated loosening at the cement--bone interface.

In a subsequent expanded publication including an additional 21 cases in the series¹, most of the 50 patients showed a full range of motion within four weeks of suture removal and continued to demonstrate good long-term results. Full range of asymptomatic motion was achieved in 26 osteoarthritic patients with articular derangement. Five patients showed clinical or radiographic evidence of loosening. No cases of implant fracture, surface wear, fragmentation or infection were seen.

SURGICAL PROCEDURES

A manual is available describing detailed surgical procedure 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 procedure before use.

PATIENT COUNSELING INFORMATION (See also Warnings)

In addition to the patient related information contained in the Warnings and Adverse Effects 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 physicochemical 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. The reported rate of loosening in a clinical study of this device was 10% at up to 10 years followup. (Braun RM. Total joint arthroplasty at the carpometacarpal joint of the thumb. Clin Orthop 1985;195:161-7.)
- Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION

- This component has been sterilized by ethylene oxide or gamma radiation.
- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.**
- 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 Corporation 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.

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¹ Braun RM, Total joint arthroplasty at the carpometacarpal joint of the thumb. In: Clin Orthop (1985 May)(195):161-7

² Braun RM, Total joint replacement at the base of the thumb--preliminary report. In: J Hand Surg [Am] (1982 May) 7(3):245-51

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A V A N T A
ORTHOPAEDICS

**Guide to Surgical Technique
for the Avanta Trapezio-Metacarpal Prosthesis**

DESCRIPTION

The Braun-Cutter Trapezo-metacarpal joint prosthesis consists of an ultra-high molecular weight polyethylene (UHMWPe) component which is cemented to the prepared trapezium, and a titanium alloy stem component with integral head which is inserted into the shaft of the first metacarpal. The titanium head articulates with the UHMWPe component to form a snap-fit constrained prosthetic replacement for the basal thumb joint. The implant is available in three sizes, each of which can be used in right or left hands. A range of trial sizers for each type of implant is available to aid in bone preparation.

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INDICATIONS

The Braun-Cutter Trapezo-metacarpal prosthesis is indicated for total joint replacement in skeletally mature patients with pain or instability of the trapezo-metacarpal joint due to trauma, inflammatory or degenerative disease or revision of previous procedures, as an alternative to arthrodesis or reconstructive surgery.

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.
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- This device is for cemented use only.
- 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 if excessive demands are made upon it.
- See also the Patient Counseling Information Section.

PRECAUTIONS

- The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. **Do not resterilize.**
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ADVERSE EVENTS

- Adverse events in a published series of 50 patients included loosening, transient radial neuritis, cement extrusion injury to the palmar digital nerves and de Quervains tendinitis¹.

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

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- 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.

Potential for Complications

As with the use of all implant devices, the potential for intraoperative and postoperative complications is possible. It is the responsibility of the surgeon using the implant(s) to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of the implant(s) surgical procedure and all potential complications associated with each specific case.

The implants have been designed to offer appropriate strength for each size and configuration, however, due to anatomical size constraints it is possible that high demand patients will be able to overload their implant(s). To insure the best possible function and longevity of the implant(s), proper implant selection and sizing on the part of the surgeon is critical.

Joint implants utilize mechanical attachments and articulating bearing surfaces. These interfaces may see micro and/or macro motion between parts, as well as, between the patients anatomy with normal use. This motion is known to cause wearing of the parts, which in turn, over time, may lead to failure of the device or of the device/patient interface. Symptoms of failure, or impending failure, may include: pain, swelling, inflammation, tenderness and infection. Strenuous implant loading, excessive mobility, the presence of articular instability, improper sizing, improper patient selection and misuse all may lead to accelerated wear and early failure of the device. Patients should be made aware of these limitations and the potential for complications arising from them.

Risk/Benefit Decision by Surgeon

The judgment by a surgeon to use an implant is a risk/benefit decision which must take into account the patient's needs, desires and expectations in addition to the surgeon's knowledge of expected results and complications as well the alternative treatments. Therefore, surgeons must balance many considerations to achieve the best result in individual patients. Providing each patient scheduled for implant surgery with documented counseling of potential complications and alternatives, which may include non-implant procedures such as soft tissue reconstruction or arthrodesis, prior to surgery is necessary.

INSTRUCTIONS FOR USE

The following procedure is furnished as an example of an appropriate technique for informational purposes only. Each surgeon must evaluate the appropriateness of the procedure based on the current state of the art and personal medical training and experience.

Eaton Type Surgical Exposure

The MP joint is examined. If there is a fixed extension deformity, this is addressed with soft tissue releases of the surgeon's choice. If the joint is to be pinned in flexion, this should be left until the end of the case.

Accurate alignment and placement of the implant requires a good exposure of the dorsal and volar trapezoid joint surface and the base of the metacarpal. An Eaton type incision is used to get a broad exposure of the trapezoid and the metacarpal, including the volar joint surface. Eaton's incision is through the origin or insertions of the Intrinsic and gives excellent TMC exposure for replacement arthroplasty. The planes are relatively avascular and the incision does not compromise major neurovascular structures.

The carpometacarpal joint is palpated. A curved incision is made along the volar crease which lies at the level of the TMC joint. The incision is carried over to the lateral margin and is extended distally for two cm along the metacarpal at the edge of the intrinsic muscle insertions. Spreading dissection is carried out to the fascia overlying the muscles and tendons. Care is taken to identify and spare the branches of the radial sensory nerve and small vessels on the dorsal radial aspect. These should be freed up and retracted dorsally. The intrinsic and the first compartment tendons are clearly identified. The volar branch of the radial artery is identified, freed up from the palmar fascia and protected. In most hands, a slip of the APL inserts on the origin of the APB. This is identified, sectioned and tagged for later repair. The first compartment is opened from the volar side and the strands of the APL are inspected.

A strand of the APL which inserts on the base of the metacarpal in the bone area which will be resected should be freed from its insertion and tagged for later repair. A 64 Beaver blade is then used to free the intrinsic from their insertion on the scaphoid, trapezium, and metacarpal base. The dissection should be subperiosteal and the muscle flap should be lifted intact without transection of the fibers. Dissection is then carried dorsally subperiosteally under the extensor tendons. The gliding tissues under the EPB and EPL should not be violated. Care is taken to free the ulnar edge of the TMC joint, remembering the course of the dorsal branch of the radial artery between the first and second rays.

The capsule of the TMC joint is then excised and the joint exposed. Pre-drill with standard size drill or resect metacarpal head first then open canal. Any slips of the APL which insert on the resected bone should be dissected free and tagged for later reattachment to the metacarpal. The metacarpal canal can be reamed and prepared for prosthetic insertion either at this time or following preparation of the trapezium. The alignment of the metacarpal component is parallel to the axis of the metacarpal shaft with slight volar inclination.

The trapezial joint surface is evaluated. If the surface is fairly intact, blocking volar, ulnar and radial osteophytes are removed and the hole is burred for the trapezium component.

The appropriate trials are inserted and a trial reduction is performed. The components are evaluated for, alignment, tissue tension and joint stability. If these are satisfactory, the size of the implants are selected based on the trial reduction.

The components are then cemented into place with the trapezium first and the metacarpal second. Compression should be maintained until the bone cement has completely set.

The joint is reduced and alignment and stability are again evaluated. The tourniquet is deflated, hemostasis is secured and the APL is reattached to the metacarpal. The intrinsic origin on the trapezium and the APL slip is reattached with an absorbable suture. The MP joint is pinned if this is the desire of the surgeon. If the MP joint is pinned in flexion, the pins should be left under the skin to reduce the chance of a pin tract infection which could infect the TMC prosthesis. Intraoperative films are obtained. The skin is closed in routine fashion.

A postoperative splint is fashioned which fits over the dorsum of the TMC and MP joints and the volar ulnar surface of the palm. The plaster should not extend over the thenar eminence, and free flexion of the MP and TMC joints should be possible. The IP joint should be out of the splint entirely. This splint prevents the metacarpal from moving into extension and dislocating the TMC joint. It also prevents the metacarpal from levering on a volar plaster and pushing the arthroplasty out of joint.

Postoperative care

The TMC should be splinted in this fashion for three weeks. Active IP motion is encouraged to minimized adhesions of the EPL. Active motion is started at three weeks with a removable protective resting splint used for another month.

X-rays may be obtained intraoperatively, and at two and eight weeks, six and twelve months postoperatively. These should be checked for alignment, subsidence, bone resorption or formation.

Any post operative inflammation should be treated by a physician. The decision to salvage or remove the implant should be made by the surgeon. The salvage procedure following excision can be fusion or arthroplasty, the decision to be made by the surgeon.

Dislocations should be treated by closed reduction under anesthesia. X-rays should be obtained to evaluate the reduction, and if it is correct, the TMC joint should be splinted in flexion with the post op splint for three weeks. If a satisfactory closed reduction cannot be obtained, the joint should be reduced open through the original approach and splinted for three weeks postoperatively. Perioperative antibiotics should be used with open reductions.

Patient complaints of pain, numbness, stiffness, night and weather related pain and passive and active range of motion of all finger joints should be recorded at each visit.

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LIMITED WARRANTY

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