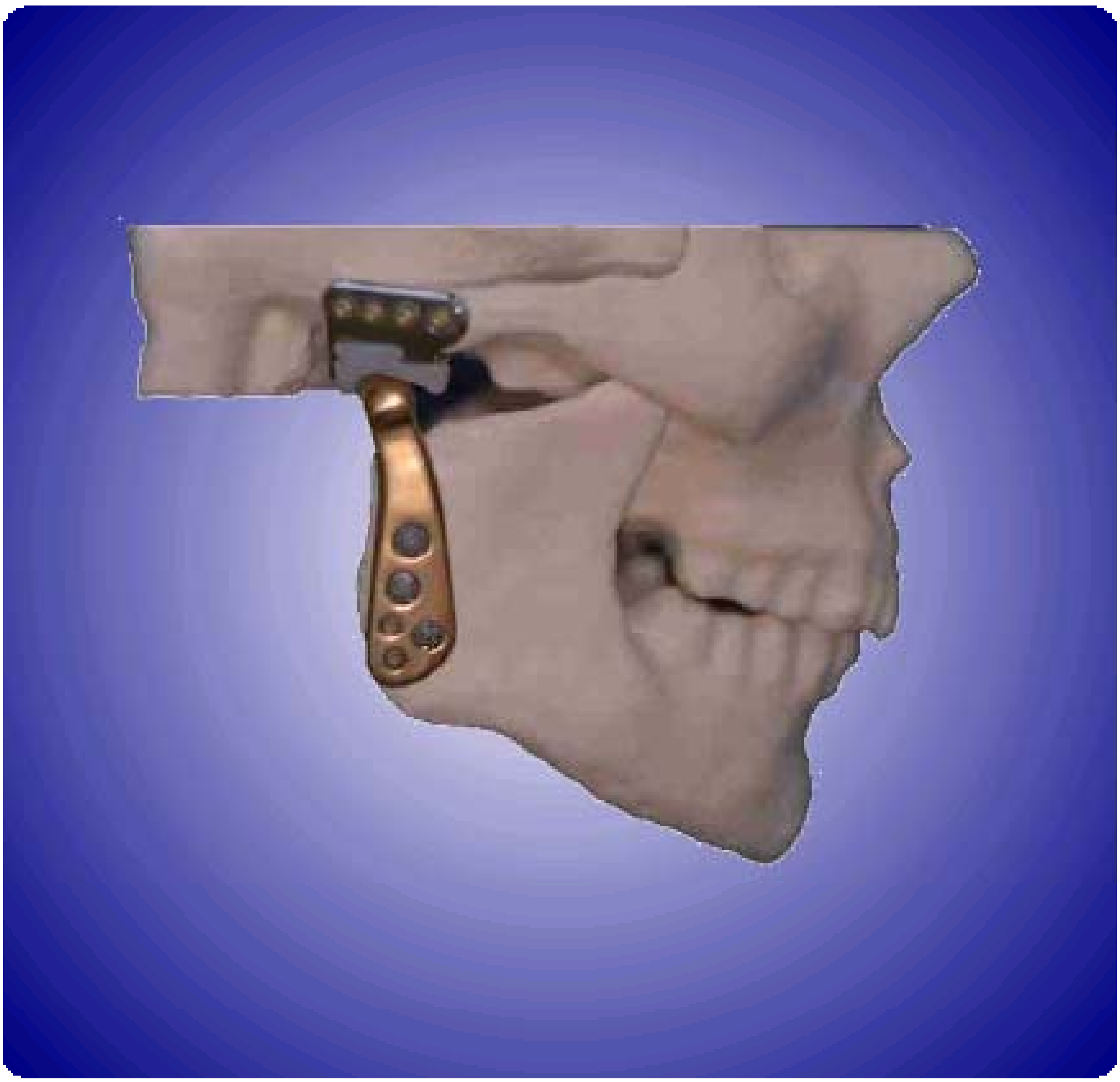
The Hoffman-Pappas™ Temporomandibular Joint Replacement System

Developed by D.C. Hoffman, DDS, PC and M.J. Pappas Ph.D.,P.E.



ENDOTEC

Improving Clinical Performance Through Advanced Technology

Summary of Design Features

Custom CAD-CAM design allows precise fit for each patient

Locking screw fixation for ramus allows maximum fixation with no micromovement

Condylar head design increases contact, while allowing for various motions

Custom ramus component allows for use in irregularly shaped or deformed mandibular anatomy

Custom fit fossa adds stability

Bearing materials (TiN on UHMWPe) provide similar wear characteristics to current joint prosthesis

UltraCoat® TiN on Ramus reduces Wear and Friction

Titanium Alloy with UltraCoat Provides
Superior Mechanical and Biological Compatibility

Two piece fossa allows for bearing exchange without removing well fixed component

One piece condylar component reduces cost, corrosion, micromovement, and part failure

CAD-CAM DESIGN PROCESS FOR EACH PATIENT

Computer Aided Design and Computer Aided Manufacturing has opened new dimensions for custom made joint prostheses.

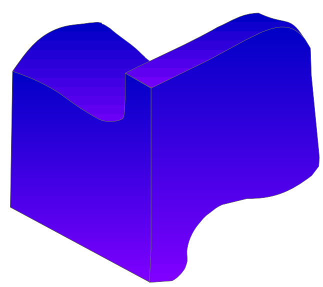
Once the facial skeleton has been obtained from a CT scan the biomedical engineers and surgeons can team together to create the optimal design for any given patient. This allows for exact surface fits, changes in angles and unique designs for altered skeletal anatomy.

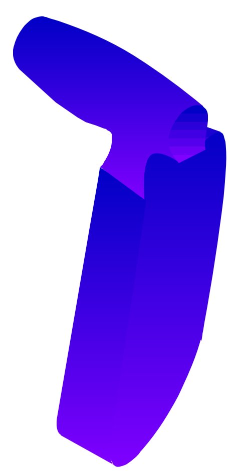
In addition, because the base material is titanium, it can be machined in a relatively inexpensive manner, allowing for custom made prostheses at a reduced cost compared to other methods. The application of the thin film ceramic surface coating, UltraCoat, provides an ideal articulating surface.

Custom Design Verification

Since manufacture is performed using CAD-CAM technology, before any metallic components are constructed, wax or plastic replicas are fabricated and used with a 3D skull model.

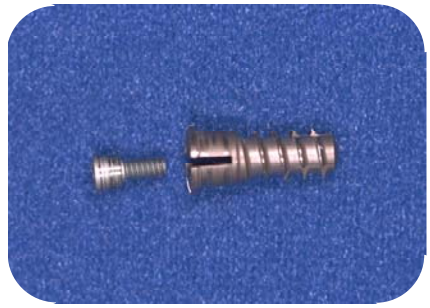
If necessary, the surgeon can alter the shape and design to correct potential problems prior to going to the operating theater.



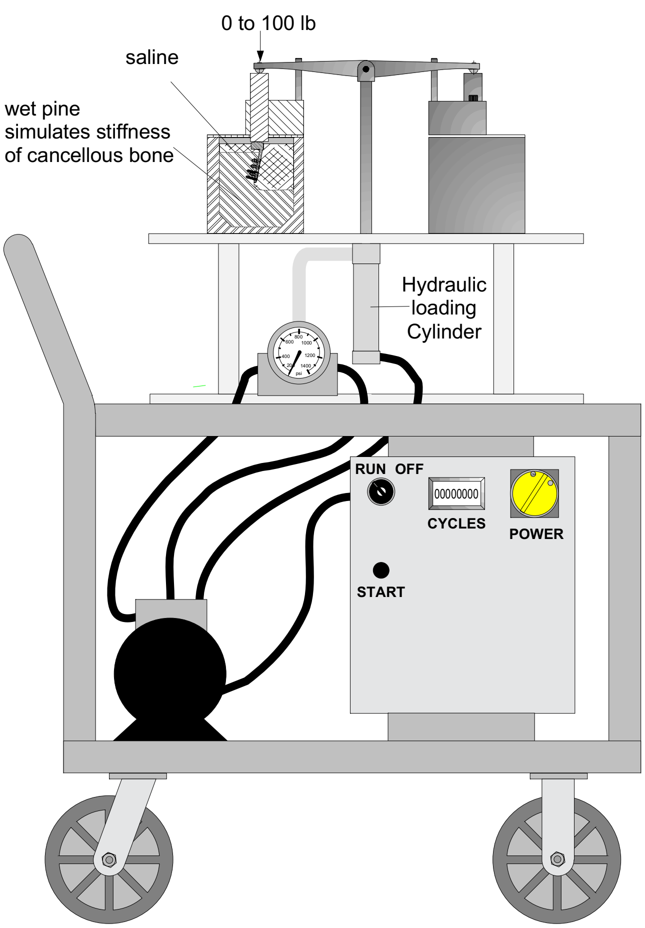


LOCKING SCREW FIXATION FOR RAMUS COMPONENT

A combination of screws are used with the condylar component for fixation to the ramus. Initially two standard 2mm screws are used for quick fixation to allow placement of the joint after the occlusion is set. Once the permanent position of the ramus is determined, a second set of locking screws that have a double screw system locks into the ramus and makes the entire ramus 1 unit with no micromotion along the screw.



Ramus and Screw Fatigue Testing



To evaluate experimentally the fixation screw system six samples of the ramus component were tested. The test was run in normal saline for 10 million cycles at five hertz under a 0 to 100 pound fluctuating load.

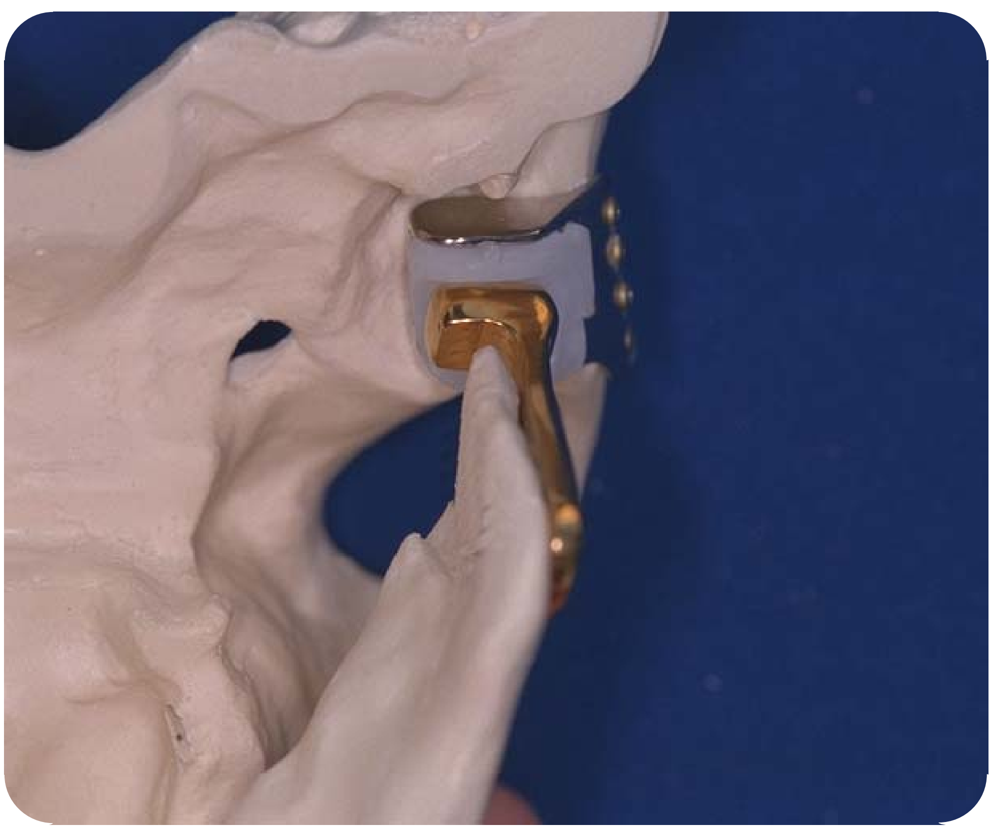
Examination of the samples after testing found that there was no loosening of the screws and no evidence of cracking or component failure. Also, fatigue or fretting corrosion around the screw surfaces was not seen.

This unique screw fixation system should safeguard against screw failure in long-term use of the prosthesis. Because of the screw design, there should be no micromovement or metal debris produced.

CONDYLAR HEAD DESIGN INCREASES CONTACT AND IMPROVES WEAR OF SURFACES

The standard condylar design for the Hoffman-Pappas prosthesis is a modified barrel shape. This allows for line contact between the condylar head and polyethylene bearing surface. The advantages of this contact as opposed to point contact which occurs from a ball on flat type design, is the increase in contact area and disbursement of load. This decreases the wear of the polyethylene bearing. Beveling is present on either side of the barrel to allow for a greater range of motion and adapting a superior fit to the condylar surface.

Mathematical analysis of this type of design shows that there is an approximate ten fold decrease in load disbursement offering a significant amount of biomechanical advantage over ball on flat designs. Additionally, this design along with the titanium alloy and UltraCoat ceramic coating provides a superior biocompatible condylar component.



CUSTOM RAMUS COMPONENT ALLOWS FOR USE IN IRREGULARLY SHAPED MANDIBLE

FLAT INTERFACE

CUSTOM INTERFACE

In patients who have irregularly shaped or mutilated skeletal anatomy, a standard flat surface may not be adequate. The advantage of custom ramus components allows for modification of the shape of the condylar component, the position of the screw holes and the adaptation of the internal surfaces.

If the mandibular ramus is irregular in shape or size, a specific design can be incorporated to allow for either increased fixation or positioning of the screw holes. The mandibular nerve may be in the way of the standard screw holes and the holes can be changed to either accommodate the best bone stock or thickness, as well as the position of the mandibular nerve. If the position of the mandible needs to be changed to improve the occlusion, then this can be incorporated in the design of the components prior to surgery. Examples are a mandibular advancement or lengthening of the posterior vertical height.

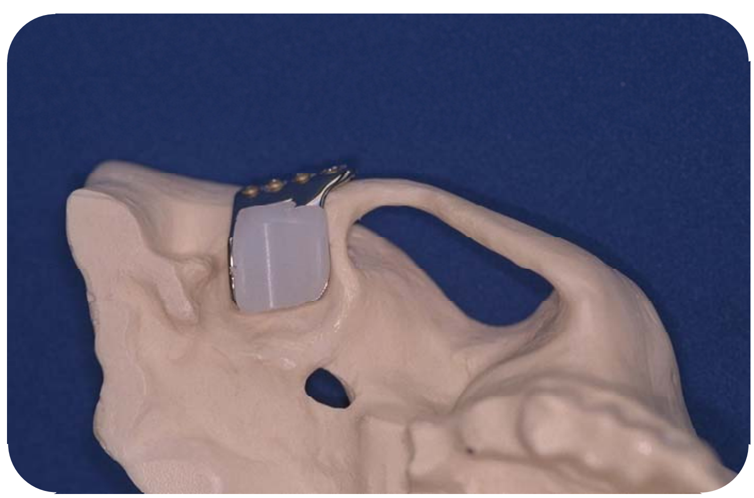
CUSTOM FIT TITANIUM BACKED FOSSA ADDS STABILITY

The use of a custom fit titanium backed fossa allows for maximum adaptation of the fossa component to the bony skeletal fossa. The technique utilized in the construction of this component is based on the patient's CT-scan in a similar fashion to the ramus component. The data is constructed in a computer for CAD-CAM fabrication of a custom fit fossa. Using titanium alloy allows for a rapid and inexpensive means of milling an exact surface fit. Because there is a close surface adaptation, there is no rocking or sliding of the fossa components.

The fossa is additionally secured with three or four lateral screw holes using a standard titanium 2 mm screw. The purpose of this screw is to hold the fossa in place and avoid downward movement, however stability is obtained by the close surface adaptation.

Forces directed by the condyle against the fossa are counteracted by the exacting fit. When the fossa is placed in the surgical site, there should be no rocking movement or horizontal displacement.

The shape of the fossa is designed to encapsulate the polyethylene bearing surface. This metal-plastic interface minimizes any distortion, creeping or changes in the polyethylene which can occur in unsupported poly.



BEARING MATERIALS (TiN on UHMWPe) PROVIDE SIMILAR WEAR CHARACTERISTICS TO CURRENT HIP AND KNEE PROSTHESES

The use of Ultra-High Molecular Weight Polyethylene (UHMWPe) is the current standard in orthopedic joint replacement designs. Traditionally a highly polished metal against a polyethylene surface provides the best wear characteristics.

The Hoffman-Pappas prosthesis employs the use of the latest technology with the minimal bearing thickness to provide durability and long term wear. The polyethylene is backed by titanium which decreases the chance of fracture of biomechanical break downs.

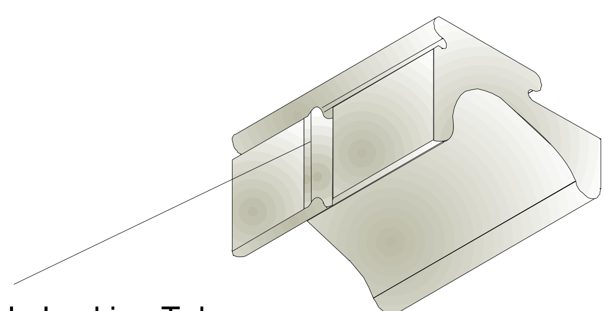
Replaceable polyehtylene surfaces

The design of the polyethylene inserts allows for them to slide into position and can be changed if there is excessive wear over along term period of time without removing a well fixed fossa component. This provides the ability to use these joints in a younger patient and know that the articulating surface may be replaced with minimal surgery.

In addition, changes in height or thickness of the polyehtylenecan be made increasing the vertical height of the mandible without replacing the metal prosthesis.

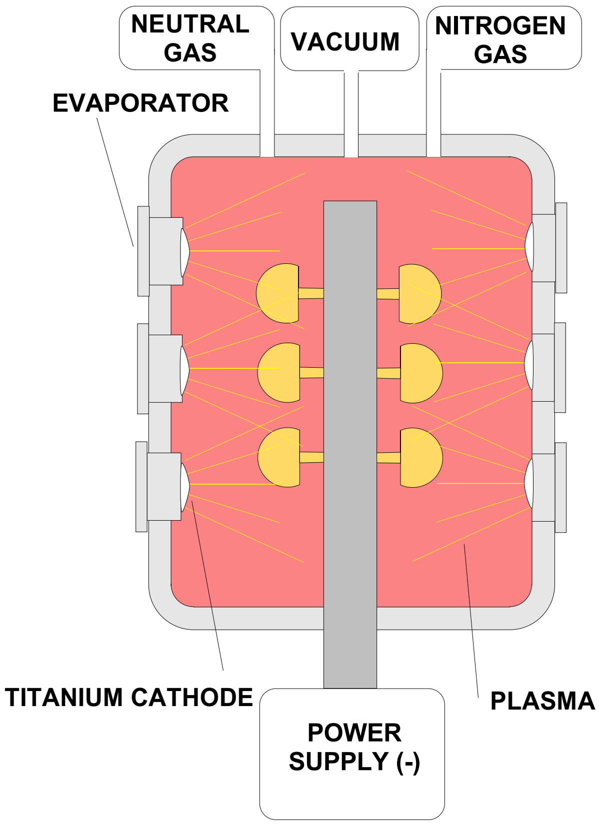
Bearing dissociation from the metal backed fossa is prevented laterally by the addition of a flexible locking tab which engages a groove in the fossa component to lock the component into place.

Anterior/posterior stability is provided by the dovetail connection.



Flexible Locking Tab
Engages slot in Fossa

ULTRACOAT TiN CERAMIC ON RAMUS REDUCES WEAR AND FRICTION

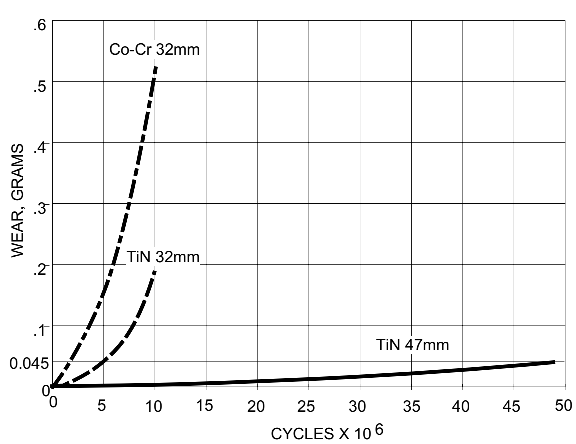


UltraCoat is a highly adherent, near diamond hard, titanium nitride (TiN) ceramic coating about 10 microns thick. This coating reduces wear by about two thirds and friction by about one-half [1,2] compared to Co-Cr alloy heads when articulated against an UHMWPe bearing surface.

The extreme hardness of TiN ceramic coating is attested to by its wide use on tools for cutting steel and other metals.[3] The use of TiN coatings is now also becoming widespread to protect the cutting edges of hardened steel surgical instruments.

The coatings are extremely adherent on a properly prepared, contaminant free, substrate. Such adherence results from an ionic (atomic) bond between the film and the substrate [4]. When a TiN ceramic film is applied to titanium alloy, the film to substrate interface is not susceptible to corrosion, and thus to corrosion delamination. In fact, a titanium coating is applied to steel parts to be coated with TiN for applications requiring corrosion resistance.

The substantial reductions in wear and friction against UHMWPe result from the extreme hardness of the TiN ceramic film. This film is substantially harder than the alumina ceramic used for femoral heads [5]. To obtain these improvements, however, theTiN film must be polished. Coating a polished femoral head with a TiN film will produce a slightly roughened surface and can increase polyethylene wear [6]. Endotec polishes its ceramic coated heads to a much smoother finish than typical in current Co-Cr femoral heads. This smoothness is an important factor in reducing wear. Further, the extreme hardness of TiN ceramic results in a decrease in the rate of degradation of the polished articular surface, thus decreasing the rate of increase in wear with time observed in testing.[2] The durability of this ceramic coating has been documented in a 48 million cycle hip simulator test.[7]



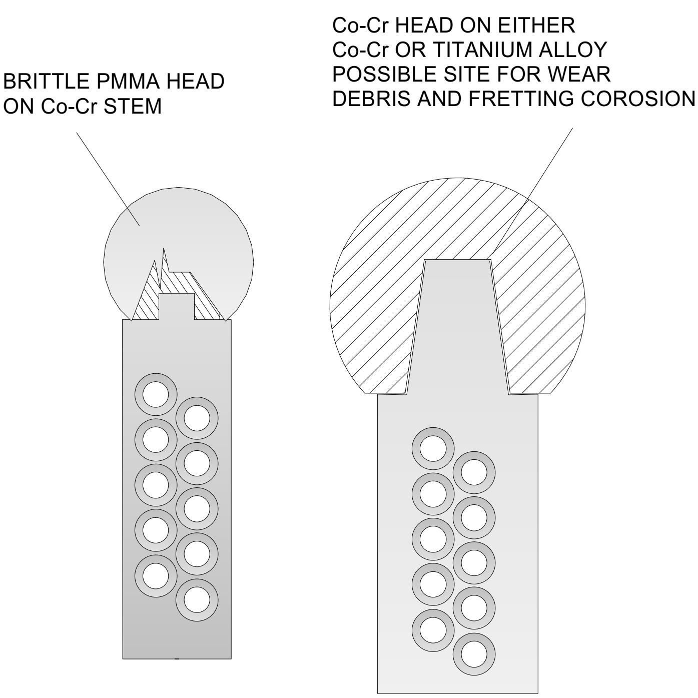
TiN ceramic films are currently in use in Europe on articulating surfaces [8], and are approved by the FDA for use in the United States. Endotec recommends this coating in applications where long service life is needed. This is particularly true for heavy, active patients where analysis based on the manufacturer's recommendations for UHMWPe Hip bearings indicates that 32 mm heads should be used. Unfortunately, a 32mm head generates higher frictional torque on the acetabular component than smaller heads. This disadvantage can be overcome by use of UltraCoat. With the use of this coating, the friction produced by a coated 32mm head can be less than that of an uncoated 22 mm head [9].

UltraCoat is an ultra-high quality TiN ceramic coating produced by a series of proprietary processes that carefully monitor and control precoating surface preparation, the coating processes and the post coating polishing. These procedures guarantee the film adherence and the reductions in wear and friction observed in our extensive testing program.

ONE PIECE TITANIUM ALLOY WITH ULTRACOAT PROVIDES SUPERIOR MECHANICAL AND BIOLOGICAL COMPATABILITY

The greater flexibility of titanium alloy allows a greater share of the load to be carried by the bone than by the stiffer Co-Cr alloy. Thus, titanium alloy provides superior mechanical compatibility by reducing stress protection of bone. Further, titanium alloy is more biocompatible than Co-Cr alloy whose major components can be carcinogenic.[14] Finally, titanium alloy is stronger than Co-Cr alloy in both fatigue and yielding resistance.[15] Thus, except for the inferior abrasion resistance of titanium alloy, it is superior to Co-Cr alloys for use in implants.

UltraCoat finished stems provide enhanced biocompatibility. TiN is inert invivo.[16] It shields the surface of the implant, particularly the porous coated region with its high surface area, against metallic ion release. The extreme hardness, and abrasion resistance, of TiN ceramic coatings should eliminate the metallosis observed in both titanium and Co-Cr alloy prostheses [17, 18] since much less abrasion debris is generated, the debris is inert and the debris consists of nontoxic Ti and N ions. As a result, UltraCoat finished titanium stems represent the most mechanically and biologically compatible implants available.



The condylar component is fabricated from one solid piece of titanium, utilizing CAD CAM manufacturing. With the use of Ultracoat there is no need for a additional Co-Cr metal head, thus eliminating the metal-metal interface or connection. Retrieved orthopedic specimens of stems with modular heads have shown a disturbing degree of corrosion at the taper connection interface. This corrosion is the result of micromotion in the interface (fretting corrosion) and is present in both mixed and similar metal combinations.[19]

The one piece condylar design functionally eliminates this problem. Because there are no additional steps in joining metal components, the prosthesis cost is reduced, and the overall strenght enhanced.

Additional benefits from this design are the elimination of micromovement between the parts, and the decreased potential for device failure.

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