Do Not Reuse - Single Use Only

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Product Insert

Distal Radioulnar Joint Prosthesis

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CAUTION

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The device is semi-constrained as it is fixed to both the radius and the ulna but allows migration and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. Although it has a captive articular surface it does not have an across-the-joint linkage. The components of the implant articulate on their mating surfaces. The radial component fixes to the ulnar side of the radius. The ulnar component is press fit into the intramedulary canal of the ulna. These components are intended to articulate with an interface which is an UHMWPe ball. The device allows for normal radial migration and full rotation during pronation and supination. The encased UHMWPe ball interface prevents both volar and dorsal subluxation. The implant is available in multiple sizes. An alphanumeric coding system will be used to distinguish sizes. An additional surgical instrument set is available for application of the device.

Materials:

- ASTM F-648 ultra-high molecular weight polyethylene (UHMWPe) distal component. Composition: 100% UHMWPe (polyethylene resin)
- ASTM F 1537 cobalt chromium proximal component. Composition: Cobalt (balance, typically ~60%), Chromium 26–30%, Molybdenum 5–7%, with ≤1% Nickel, ≤1% Manganese, ≤1% Silicon, ≤0.75% Iron, ≤0.35% Carbon, and ≤0.25% Nitrogen. Other elements ≤0.20% each.
- ASTM F 1580 commercially pure titanium. Composition: ≥99% titanium, ≤1% oxygen, iron, and trace elements.

INDICATIONS

Aptis Medical Distal Radio Ulnar Joint implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:
- Pain and weakness of the wrist joint not improved by non-operative treatment
- Instability of the ulnar head with radiographic evidence of dislocation or erosive changes of the distal radioulnar joint
- Failed ulnar head resection; eg. Darrach resection
- Primary replacement after fracture of the ulnar head or neck.
- Revision following failed ulnar head arthroplasty.

This prosthesis is intended for single use only.

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.
- Skeletal Immaturity.
- Active or suspected infection in or around the joint.
- Known sensitivity to materials used in the device.
- Possibility for conservative treatment.

PATIENT TARGET GROUP:

- The Aptis DRUJ is intended for skeletally mature Individuals presenting the indications for use described above at the distal radioulnar joint.

INTENDED USERS:

- Intended users of the Aptis DRUJ are medical professionals trained in the use of implants.

WARNINGS (See also the Patient Counseling Information Section)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contain a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.
- Patients should be cautioned not to lift loads of 9 kg (20 lbs) or greater, as doing so may result in device failure.
- Use only cobalt chromium parts and screws provided by Aptis. Using parts and screws other than those provided by Aptis may cause injury to the patient.
- MRI: See below for MRI safety information
- This device is manufactured from ASTM F1537 Cobalt-Chromium-Molybdenum alloy. This alloy contains cobalt, which is classified under Regulation (EC) 1272/2008 (CLP) as a Category 1B carcinogen, mutagen, and reproductive toxicant (CMR).

PRECAUTIONS

- Do not resterilize. 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.
- 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. Polished bearing and articulating surfaces must not come in contact with hard or abrasive surfaces.
- Do not re-use. If implant is re-used, potential adverse effects could lead to infection or death.

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 (e.g., numbness)
- stiffness
- night and weather related pain
- loss of motion
- implant fracture
- periprosthetic bone fracture
- bone resorption
- heterotopic bone formation
- rotation of implant
- accelerated wear of the device components
- loosening of the implant from the bones
- dislocation of the joint
- infection
- lengthening or shortening of the forearm
- 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

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)

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.
• This device is intended to provide the clinical benefit of restoring the patient to activities of daily living. Heavy lifting, repetitive motion, punching, sporting activities, or trauma to the treated extremity should be avoided.
• Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

STERILIZATION

- This component has been sterilized by ethylene oxide.
- Do not resterilize. 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.
- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

LIMITED WARRANTY

Aptis Medical LLC, 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. Aptis Medical, LLC does not warrant the outcome of the surgical procedure.

DISPOSAL

Implants may present a biological hazard due to contamination with blood or bodily fluids.
Dispose of devices in accordance with applicable local, national, and institutional regulations for biohazardous medical waste.

PRODUCT COMPLAINTS

Any medical professional or patient who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributor of Aptis Medical, LLC and, where applicable, the local competent authority. If any Aptis Medical, LLC product ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

Recommended MRI safety information for the DRUJ:

MRI Safety Information

A patient with the DRUJ implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/identification of device	Aptis Medical Distal Radio Ulnar Joint (DRUJ)
Nominal values of static magnetic field (T)	1.5 T or 3 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	19 T/m (1900 Gauss/cm)
RF excitation	Circularly Polarized (CP)
RF transmit coil type	Whole body transmit coil, Head RF transmit-receive coil
RF receive coil type	Any receive only coil may be used
Maximum Whole Body SAR (W/kg)	See details below
Maximum Head SAR (W/kg)	3.2 W/kg (Normal Operating Mode)
Limits on RF Conditions and Scan Duration	**1.5 T MRI Systems** B_1+RMS ≤ 3.25 µT for 60 minutes of continuous RF* or Whole body average SAR ≤ 1.0 W/kg for 60 minutes of continuous RF*
	3 T MRI Systems B_1+RMS ≤ 0.90 µT for 60 minutes of continuous RF* or Whole body average SAR ≤ 0.3 W/kg for 60 minutes of continuous RF*
MR image artifact	The presence of this implant may produce an image artifact of 60 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter	

*a sequence of back-to-back series/scan without breaks