Instructions for Use
Radial Head Prosthesis

This instruction for use is not intended for distribution in the USA.

EC REP

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Instructions for Use

Radial Head Prosthesis
Please read these instructions for use, and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.
Radial Head Prosthesis Implants consist of uncemented fixation stems and radial heads connected by a connecting screw. Components are available in a variety of sizes, are single packed, and available sterile.

Important note for medical professionals and OR staff: These instructions for use do not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information (Instructions for Use, corresponding Surgical Technique Guide, and device-specific label).

Material(s)

Implant(s):	Material(s):	Standard(s):
Radial Heads	CoCrMo	ISO 5832-12
Radial Heads, Radial Stems	TAN	ISO 5832-11

Intended use
The Radial Head Prosthesis is intended for partial replacement of the elbow joint by primary or revision applications.

Indications
The Radial Head Prosthesis System is indicated for primary replacement of the radial head after:
1. Degenerative or posttraumatic disabilities presenting pain, crepitation, and decreased motion at the radiohumeral and/or proximal radio-ulnar joint with:
   a. Joint destruction and/or subluxation visible on x-ray
   b. Resistance to conservative treatment
2. Fracture of the radial head
3. Symptomatic sequelae after radial head resection

Revision following failed radial head arthroplasty.

Potential Risks
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), pain, thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, and potential risks associated with hardware prominence, malunion, non-union.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings
It is strongly advised that the Radial Head Prosthesis is implanted only by operating surgeons who are familiar with the general problems of prosthetic surgery and who are able to master the product-specific surgical techniques. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

A prosthesis that is too large will result in varus alignment with opening of the medial ulnohumeral joint space relative to the lateral ulnohumeral joint space. Overstuffing may have a detrimental effect on motion.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Important Information and Precautions
1. Selecting the implant. It is of paramount importance to select the proper implant. The potential for success is increased by selecting the proper implant size and shape.
   The characteristics of human bone and soft tissue pose restrictions on the size and strength of implants. No partial weight-bearing or non-weight-bearing product can be expected to withstand the full, unsupported weight of the body. If a strong bone union is to be achieved, the patient needs adequate external assistance. Likewise, the patient must restrict physical activities that would place stress upon the implant or allow movement at the fracture site and thus delay healing.

2. Patient-related factors. A series of patient-related factors have a strong influence on the success of surgery:
   a. Occupation or activity. Professional occupations pose a risk when external forces subject the body to substantial physical loads. This can cause the product to fail and even undo the achievements of surgery.
   b. Senility, mental illness, or alcoholism. These conditions may cause the patient to ignore certain necessary limitations and precautions, leading to the failure of the product or other complications.
   c. Certain degenerative diseases and smoking. In some cases, a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant. In such cases, the products serve only as a means to delay or temporarily relieve the disease.
   d. Sensitivity to foreign bodies. Where hypersensitivity to a material is suspected, appropriate tests should be undertaken prior to selecting or implanting the material.

3. Postoperative care is essential. Physicians should inform their patients about the implant's load restrictions and offer a plan for postoperative behavior and increasing physical loads. Failure to do this can generate malalignment, delayed bone healing, implant failure, impaired joint function, infections, thrombophlebitis, and/or wound hematomas.

4. Information and qualification. Surgeons should be fully aware of the intended use of the products and the applicable surgical techniques, and they should be qualified by appropriate training (for example, by the Association for the Study of Internal Fixation, AO).

Magnetic Resonance environment
When a device has been evaluated for use in the MR environment, MRI information will be found in the Surgical Technique Guide at www.depuysynthes.com/ifu

Interpretation of Symbols

Reference Number

Lot or batch number


Manufacturer


Manufacturing date


Expiration date


Do not use when packaging is damaged

European Conformity

Notified body


Caution, see instructions for use


Consult instructions for use

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