Instructions for Use
Radial Head Prosthesis

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

DePuy Synthes
TRAUMA
COMPANIES OF Johnson&Johnson

CE
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Instructions for Use

Radial Head Prosthesis
Please read these instructions for use, the Synthes brochure "Important Information" 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. Components are available in a variety of sizes and 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 (corresponding Surgical Technique Guide, Important Information and device-specific label).

Material(s)

Material(s):	Standard(s):
CoCrMo alloy	ISO 5832-12
Titanium Alloy	ISO 5832-11

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

Indications
For specific indications of Radial Head Prosthesis it is mandatory to consult the corresponding Surgical Technique Guide (www.synthes.com/lit) of the product system being used.

Contraindications
For specific contraindications for Radial Head Prosthesis it is mandatory to consult the corresponding Surgical Technique Guide (www.synthes.com/lit) of the product system being used.

Side effects
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.), 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 side effects 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.

Precautions
For general precautions consult "Important Information".
For application specific precautions related to Radial Head Prosthesis it is mandatory to consult the corresponding Surgical Technique Guide (www.synthes.com/lit) of the product system being used.

Warnings
For general warnings consult "Important Information".
For application specific warnings related to Radial Head Prosthesis it is mandatory to consult the corresponding Surgical Technique Guide (www.synthes.com/lit) of the product system being used.

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

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

Additional device-specific information

REF Reference Number

LOT Lot or batch number

Manufacturer

Manufacturing date

Expiration date

0123 Notified body

Caution, see instructions for use

Consult instructions for use

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