Instructions for Use
Radial Head Replacement System

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Nov 10, 2020

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SE_791079 AB 10/2020

Instructions for Use

Radial Head Replacement System

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Introduction
The Synthes Radial Head Replacement System offers 30 one-piece smooth stem implant options. There are 3 head diameters, 3 head heights and 4 stem diameters. The implant offering is accompanied by a sterile single-use instrument kit to be utilized with the individually packed sterile Radial Head Replacements. The treating physician must compare their patient's anatomic and biomechanical requirements to the implants available when planning surgical intervention.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Device(s)	Material(s)	Standard(s)
Radial Head Implant	Cobalt Chromium Molybdenum Alloy	ASTM F-1537, ISO 5832-12
Planer	POLYARYLAMIDE – IXEF GS-1022 WH01	none
Handle	POLYCARBONATE – CALIBRE 2061-15-FC850122, COLOR: WHITE	none
Sounder	SS – 17-4PH, H900	ASTM F-899
Trials and Spacers	POLYCARBONATE – CALIBRE 2061-15-FC56 0048, COLOR ORANGE; 2061-15-FC330005, COLOR BLUE; 2061-15-FC780434, COLOR: LIGHT GREY	none

Intended Use
The Radial Head Replacement System is intended for partial replacement of the elbow joint. The system consists of uncemented fixation mono-block radial heads. Implants are available in a variety of sizes for primary and revision applications.

Indications
The Radial Head Replacement System is indicated for:
- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  - joint destruction and/or subluxation visible on x-ray; and/or
  - resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

Contraindications
- Growing children with open epiphyses
- Dislocations of radius on ulna that would not allow a radio-humeral articulation
- Rheumatoid arthritis

Patient Target Group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and /or the Synthes "Important Information" brochure as appropriate.

Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of the Radial Head Replacement System when used according to instructions for use and recommended technique are:
- Instruments to aide with in-situ height determination of the radial head and visualization of the proximal ulna and joint.
- Implants to support against longitudinal collapse of the radius allowing associated soft tissue injuries to heal with the radial head in an anatomic position.

Performance Characteristics of the Device
The Synthes Radial Head Replacement System allows for direct and radiographic visualization of the radio-capitellar, proximal radio-ulnar and ulno-humeral joints during trialing. Clear visualization with Radiolucent Trials ensures that the chosen implant allows for a degree of play within the radial neck helping the implant remain centered during elbow motion. In addition, efficiency and cost savings are realized with single-use instrumentation.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
- Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction
- Infection
- Dislocation
- Poor Joint Mechanics
- Damage to Surrounding Structures (including uninjured ligaments)
- Neuro-vascular Damage
- Pain or Discomfort
- Bone Damage including Intra-and Post-Operative Bone Fracture, Bone Resorption, or Bone Necrosis
- Soft Tissue Damage (including Compartment Syndrome and Heterotopic Ossification)
- Injury to User
- Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage

Sterile device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

 Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

 Do not resterilize

Single-use device

 Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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.

Warnings and Precautions
The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".

It is strongly advised that Radial Head Replacement System is implanted only by operating surgeons who are familiar with the general problems of elbow surgery and who are able to master the product-specific surgical procedures. 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.

Precautions
- Radial head subluxation can occur if the annular ligament is not repaired. To prevent subluxation or dislocation of the radial head, ensure ulno-humeral joint stability through anatomic reduction of any ulnar injury and restore global stability of the elbow using appropriate fixation tools.
- When resecting the radial head, minimize radial neck resection.
- Overstuffing results from over lengthening the radius relative to the ulna and/or increasing radial head diameter relative to the native radial head. Reduced motion and/or pain may ensue, necessitating revision.
- When sounding the radial canal:
  - Do not use impaction to advance or remove Sounder from radial canal.
  - Surgical access to the medullary canal must be sufficient to prevent damage to the radial neck while using the Sounder.
- When performing the optional radial neck planing, avoid excessive planing as this may increase the height of the implant head required.
- When inserting Radiolucent Trial, Radiolucent Spacers and implants:
  - Do not use excessive force when inserting or removing.
  - Do not implant the Radiolucent Trial and Radiolucent Spacers. They must be removed before implant insertion.
- Avoid soft tissue impingement when inserting the implant.
- Heterotopic ossification (HO) is a potential adverse event following elbow fracture. Factors associated with HO formation following elbow fracture are the extent and nature of the injury as well as the time to first surgery after fracture. Other contributing factors may include, but are not limited to, duration of elbow immobilization, infection, and number of post-trauma surgeries.

Magnetic Resonance Environment
MR Conditional
The induced heating, torque, displacement, and image artifacts are according to the standards and acceptance criteria listed in the table below.

Test	Standard	Acceptance Criteria
RF Heating	ASTM F2182-11a	Induced heat < 6°C increase after 15 minutes of exposure
Force	ASTM F2052-15	Induced force < weight of device
Torque	ASTM F2213-17	Induced torque < weight of device × longest dimension of device
Image Artifact	ASTM F2119-07	N/A: Result is characterization of artifact size

Non-clinical testing has demonstrated the Radial Head Replacement System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 3.0 T or less;
- Maximum spatial field gradient of 4,180 G/cm (41.8 T/m);
- Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg (First Level Control Mode).

Under the scan conditions defined above, the Radial Head Replacement System is expected to produce a maximum temperature rise of less than 1.8 °C after 15 minutes of continuous scanning at 1.5 T and less than 3.1 °C after 15 minutes of continuous scanning at 3 T.

In non-clinical testing, the image artifact caused by the device extends approximately 64 mm from the Radial Head Replacement System when imaged with a gradient echo pulse sequence and a 3 T MRI system.

Treatment before Device is used
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices 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.

Implant Removal
The Radial Head Replacement Implant is for permanent implantation and not intended for removal once implanted. However, the treating surgeon may decide to remove the implant based on a risk-benefit evaluation in the following situations:
- Breakage, migration or other clinical failure
- Pain
- Infection
- Clinical function is no longer needed

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Additional Device-Specific Information

 Do not use when packaging is damaged

 Do not re-use

 Reference Number

 Lot or batch number

 Legal Manufacturer

 Manufacturing date

 MR Conditional

 Expiration date

 Consult instructions for use

Disposal
Any 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.

All instruments are single use. Do not resterilize. Dispose of all used and unused instruments after surgery in accordance with hospital procedures.

Special Operating Instructions
Operative Planning and Surgical Technique

1. Planning and position the patient
Before undertaking replacement surgery, the surgeon must determine if the implant sizes offered will match their patient's anatomic and biomechanical needs. During the pre-operative exam and imaging, attempt to determine the extent of ligament and additional bone injury beyond the radial head. Position the patient on the table in the supine position. Prepare the elbow using sterile technique ensuring you have access to the hand, wrist and upper arm. You will need access to imaging throughout the procedure.

2. Approach
There are many acceptable surgical approaches for radial head replacement arthroplasty including the Kaplan and Kocher approaches.

3. Open sterile single-use instrument kit
Open outer box and remove inner tray. Peel back the lid and drop the tray onto the sterile field. Lift the open corner of the plastic lid to access the instruments.

4. Resect radial head
Remove any radial head bone fragments and select an appropriate sized micro sagittal saw. Determine the cut level. The shortest implant yields a head height of 9 mm with a 19 mm head diameter and the largest implant yields a head height of 17 mm with a 25 mm head diameter. Resect bone at the level head/neck junction, perpendicular to the axis of the radial neck. The cut should be just distal to the distal edge of the Proximal Radial Ulnar Joint (PRUj). Save the radial head and fractured pieces as they will be utilized to determine initial component sizing.

5. Determine radial head diameter and height
Use the three dishes in the Quick Connect Handle with Sizer (Handle) to determine the initial component diameter and height.

6. Assemble the Sounder
Align the D-shape of the Sounder shaft to the Handle slot and gently depress the "U" shaped button to enable to the connection on the Sounder to slide completely into the Handle slot. If properly seated, you will hear a click.

7. Sound radial canal
The Sounders are intended to be used by hand, to probe for depth and diameter of the radial canal. The intention of the Sounder is not to ream endosteal bone. Introduce the tip of the starting 4.5 mm Sounder into the center of the canal while maintaining axial alignment. Use sequentially larger diameter Sounders until the Sounder no longer passes easily into the canal.

8. Optional assembly of Planer
Dissemble the Sounder from the Handle. Slide the Planer onto the final Sounder size used until you hear the tabs click into place. Reassemble the Sounder to the Handle.

9. Optional radial neck planing
Introduce the Sounder into the center of the canal and advance the assembly until the Planer is resting on the bone. With your hand, gently rotate the Planer to create a smooth contact surface on the radial neck, perpendicular to the longitudinal axis of the radial neck.

10. Optional removal of Planer from Sounder
In certain cases, it may be desirable to remove the Planer from the Sounder. Removal features have been incorporated into the Handle to assist with disassembly.

11. Insert and evaluate Radiolucent Trial and Spacer
With the selected trial (and spacer) in place assess the ability to accurately close the ligament(s). Ensure that the annular ligament can be approximated without gap. Select the appropriate Radiolucent Trial diameter based on the previously determined head diameter, head height and the stem diameter corresponding with the appropriate Sounder size. If the height is unknown, begin with the base height as Radiolucent Spacers can be connected to the Radiolucent Trial to add additional head height. With the Radiolucent Trial and Spacer, if needed, in place, examine elbow stability, range of motion and radio-ulnar length at the elbow and wrist with fluoroscopy.

12. Remove the Radiolucent Trial and Spacer
Using Forceps or Needle Drivers grasp the Spacer. Pull the Spacer outwards to allow the Spacer to disengage from the Trial. Using Forceps or Needle Drivers, grab onto the flats located on the side of the Trial to aid in removal. Depending on the anatomy, the radius may be lifted or retracted to gain access to the medullary canal.

13. Open the implant
Open outer box and remove inner tray. Peel back the lid and drop the tray onto the sterile field. Remove the lid to access the implant.

14. Insert and evaluate implant
Insert the selected size Radial Head Replacement into the proximal radius. You may need to extend and pronate the arm to allow for the anterior portion of the implant to slide around the capitellum and into place. With the implant in place, examine elbow stability, range of motion and radioulnar length at the elbow and wrist under x-ray imaging. With the selected implant in place ascertain if the ligaments can be approximated at closure.

15. Implant removal
Access the radial head. Place the arm into extension. Using forceps, slowly lift the radius until the neck is no longer in line with the capitellum. Remove the implant and slowly lower the radius back into alignment with the capitellum.

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