



Medical Device Alert

MDA/2017/016

Issued: 12 June 2017 at 14:30

DePuy Synthes Radial Head elbow prosthesis system: risk of post-operative loosening of the radial stem

Summary

Manufactured by Synthes GmbH - Recall of Radial Head Prosthesis System.

Associated Radial Head Prosthesis system parts also need to be returned to DePuy Synthes but will be available for revision surgeries of the radial head component.

Action

- Do not implant these devices (see details below).
- Locate and return all affected products to DePuy Synthes as detailed in their [Field Safety Notice](#).
- Identify and advise all patients implanted with affected devices to contact their orthopaedic surgeon if they develop symptoms such as pain, loss of function or instability.
- Consider monitoring patients at 6 monthly intervals for up to 2 years post-implantation, with both clinical and radiographic assessments (i.e. X-rays*) to identify possible loosening of the radial stem.
- Any asymptomatic patients identified with loosening of their implants should continue to be monitored at 6-monthly intervals for progressive osteolysis (including potential risk of fracture), or the development of symptoms needing revision surgery.
- Report all adverse events involving this device to DePuy Synthes and to MHRA or the appropriate Devolved Administration.

*In all cases, the benefit of ionising radiation screening should be weighed against the risks from radiation exposure on an individual basis, in line with the requirements of The Ionising Radiation (Medical Exposure) Regulations 2000.

Action by

- Medical directors
- Orthopaedic departments
- Orthopaedic surgeons
- Staff involved in the management of patients with joint replacement implants

Deadlines for actions

Actions underway: 19 June 2017

Actions complete: 03 July 2017

NOTE: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and imaging.

Device details

Examples of affected devices:



All lots of the DePuy-Synthes Radial Head prosthesis system are affected.

For part number and description information for the device and associated parts refer to **Attachment 1** of the manufacturer's [Field Safety Notice](#) and the spreadsheet attached to this alert, which includes both catalogue numbers and relevant UDI Device Identifier codes (GS1 GTINs).

Problem / background

In December 2016, DePuy-Synthes issued a [Field Safety Notice](#) informing clinicians of the recall of the Radial Head prosthesis due to the possibility of post-operative loosening of the stem at the stem-bone interface. Implant loosening may lead to osteolysis, poor joint mechanics, bone fracture or soft tissue damage.

The radial stem was introduced into the UK market in 2015 and up to the publication date of this medical device alert, MHRA has received no reports of stem loosening.

Manufacturer contacts

Martyn Kedia
Johnson & Johnson Medical Ltd
DePuy Synthes
Leeds One
St Anthony's Road
Leeds, LS11 8DT
Tel: 0113 387 6261
Email: MDFieldActionsUKIrl@its.jnj.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Fracture clinics
- Orthopaedic surgeons
- Outpatient clinics
- Physiotherapists
- Purchasing managers
- Radiology departments
- Radiology directors

- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Public Health England

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practice managers
- General practice nurses
- General practitioners

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/016** or **2017/001/005/299/001**

Technical aspects

Salman Ghani or Bayode Adisa, MHRA

Tel: 020 3080 6920 and 020 3080 7223

Email: salman.ghani@mhra.gov.uk or bayode.adisa@mhra.gov.uk

Clinical aspects

Mark Grumbridge, MHRA

Tel: 020 3080 7128

Email: DCT@mhra.gov.uk

Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

Northern Ireland

Alerts in Northern Ireland are distributed via the [NI SABS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

<https://www.health-ni.gov.uk/niaic>

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – [report to Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – [report to Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

| Device Identifier | Catalogue number (Manufacturer product code) | Product Description | Batch/Lot number |
|--------------------------|---|--|-----------------------------|
| 10886982079862 | 03.402.006 | 6MM STRAIGHT TRIAL RADIAL STEM 24MM | All |
| 10886982079879 | 03.402.007 | 7MM STRAIGHT TRIAL RADIAL STEM 26MM | All |
| 10886982079886 | 03.402.008 | 8MM STRAIGHT TRIAL RADIAL STEM 28MM | All |
| 10886982079893 | 03.402.009 | 9MM STRAIGHT TRIAL RADIAL STEM 30MM | All |
| 10886982079909 | 03.402.010 | 10MM STRAIGHT TRIAL RADIAL STEM/32MM | All |
| 10886982079916 | 03.402.018 | 18MM TRIAL RADIAL HEAD STANDARD HEIGHT/11.5MM | All |
| 10886982079923 | 03.402.020 | 20MM TRIAL RADIAL HEAD STANDARD HEIGHT/12.0MM | All |
| 10886982079930 | 03.402.022 | 22MM TRIAL RADIAL HEAD STANDARD HEIGHT/12.5MM | All |
| 10886982079947 | 03.402.024 | 24MM TRIAL RADIAL HEAD STANDARD HEIGHT/13.0MM | All |
| 10886982079954 | 03.402.026 | 26MM TRIAL RADIAL HEAD STANDARD HEIGHT/13.5MM | All |
| 10886982079961 | 03.402.028 | 28MM TRIAL RADIAL HEAD STANDARD HEIGHT/14.0MM | All |
| 10886982079978 | 03.402.106 | 6MM CURVED TRIAL RADIAL STEM 40MM | All |
| 10886982079985 | 03.402.107 | 7MM CURVED TRIAL RADIAL STEM 42MM | All |
| 10886982079992 | 03.402.108 | 8MM CURVED TRIAL RADIAL STEM 44MM | All |
| 10886982080004 | 03.402.109 | 9MM CURVED TRIAL RADIAL STEM 46MM | All |
| 10886982080011 | 03.402.110 | 10MM CURVED TRIAL RADIAL STEM 48MM | All |
| 10886982080028 | 03.402.218 | 18MM TRIAL RADIAL HEAD 2MM HT EXTENSION/13.5MM | All |
| 10886982080035 | 03.402.220 | 20MM TRIAL RADIAL HEAD 2MM HT EXTENSION/14.0MM | All |
| 10886982080042 | 03.402.222 | 22MM TRIAL RADIAL HEAD 2MM HT EXTENSION/14.5MM | All |
| 10886982080059 | 03.402.224 | 24MM TRIAL RADIAL HEAD 2MM HT EXTENSION/15.0MM | All |
| 10886982080066 | 03.402.226 | 26MM TRIAL RADIAL HEAD 2MM HT EXTENSION/15.5MM | All |
| 10886982080073 | 03.402.228 | 28MM TRIAL RADIAL HEAD 2MM HT EXTENSION/16.0MM | All |
| 10886982080080 | 03.402.418 | 18MM TRIAL RADIAL HEAD 4MM HT EXTENSION/15.5MM | All |
| 10886982080097 | 03.402.420 | 20MM TRIAL RADIAL HEAD 4MM HT EXTENSION/16.0MM | All |
| 10886982080103 | 03.402.422 | 22MM TRIAL RADIAL HEAD 4MM HT EXTENSION/16.5MM | All |
| 10886982080110 | 03.402.424 | 24MM TRIAL RADIAL HEAD 4MM HT EXTENSION/17.0MM | All |
| 10886982080127 | 03.402.426 | 26MM TRIAL RADIAL HEAD 4MM HT EXTENSION/17.5MM | All |
| 10886982080134 | 03.402.428 | 28MM TRIAL RADIAL HEAD 4MM HT EXTENSION/18.0MM | All |
| 10886982080141 | 03.402.618 | 18MM TRIAL RADIAL HEAD 6MM HT EXTENSION/17.5MM | All |
| 10886982080158 | 03.402.620 | 20MM TRIAL RADIAL HEAD 6MM HT EXTENSION/18.0MM | All |
| 10886982080165 | 03.402.622 | 22MM TRIAL RADIAL HEAD 6MM HT EXTENSION/18.5MM | All |
| 10886982080172 | 03.402.624 | 24MM TRIAL RADIAL HEAD 6MM HT EXTENSION/19.0MM | All |
| 10886982080189 | 03.402.626 | 26MM TRIAL RADIAL HEAD 6MM HT EXTENSION/19.5MM | All |

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| 10886982080196 | 03.402.628 | 28MM TRIAL RADIAL HEAD 6MM HT EXTENSION/20.0MM | All |
| 10886982080202 | 03.402.701 | Sizing Dish for Radial Head Prosthesis | All |
| 10886982080219 | 03.402.710 | Canal Finder for Radial Head Prosthesis | All |
| 10886982080226 | 03.402.711 | Planer for Radial Head Prosthesis | All |
| 10886982080233 | 03.402.712 | Offset Planer for Radial Head Prosthesis | All |
| 10886982080240 | 03.402.716 | 6MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080257 | 03.402.717 | 7MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080264 | 03.402.718 | 8MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080271 | 03.402.719 | 9MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080288 | 03.402.720 | 10MM BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080295 | 03.402.721 | 6MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080301 | 03.402.722 | 7MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080318 | 03.402.723 | 8MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080325 | 03.402.724 | 9MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080332 | 03.402.725 | 10MM BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080349 | 03.402.726 | 6MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080356 | 03.402.727 | 7MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080363 | 03.402.728 | 8MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080370 | 03.402.729 | 9MM OFFSET BROACH/STRAIGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080387 | 03.402.730 | 10MM OFFSET BROACH/STRGHT TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080394 | 03.402.731 | 6MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080400 | 03.402.732 | 7MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080417 | 03.402.733 | 8MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080424 | 03.402.734 | 9MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080431 | 03.402.735 | 10MM OFFSET BROACH/CURVED TIP FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080448 | 03.402.740 | STEM INSERTER/EXTRACTOR FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080455 | 03.402.741 | OFFSET STEM INSERTER/EXTRACTOR FOR RADIAL HEAD PROSTHESIS | All |
| 10886982080479 | 03.402.744 | Impactor, convex, for Radial Head Prosthesis | All |
| 10886982128034 | 04.402.006S | 6MM TI STRAIGHT RADIAL STEM 24MM-STERILE | All |
| 10886982128041 | 04.402.007S | 7MM TI STRAIGHT RADIAL STEM 26MM-STERILE | All |
| 10886982128058 | 04.402.008S | 8MM TI STRAIGHT RADIAL STEM 28MM-STERILE | All |
| 10886982128065 | 04.402.009S | 9MM TI STRAIGHT RADIAL STEM 30MM-STERILE | All |
| 10886982128072 | 04.402.010S | 10MM TI STRAIGHT RADIAL STEM 32MM-STERILE | All |
| 10886982128089 | 04.402.026S | 6MM TI CURVED RADIAL STEM 40MM-STERILE | All |
| 10886982128096 | 04.402.027S | 7MM TI CURVED RADIAL STEM 42MM-STERILE | All |

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| 10886982128102 | 04.402.028S | 8MM TI CURVED RADIAL STEM 44MM-STERILE | All |
| 10886982128119 | 04.402.029S | 9MM TI CURVED RADIAL STEM 46MM-STERILE | All |
| 10886982128126 | 04.402.030S | 10MM TI CURVED RADIAL STEM 48MM-STERILE | All |
| 10886982132574 | 09.402.018S | 18MM COCR RADIAL HEAD STANDARD HEIGHT/11.5MM-STERILE | All |
| 10886982132581 | 09.402.020S | 20MM COCR RADIAL HEAD STANDARD HEIGHT/12.0MM-STERILE | All |
| 10886982132598 | 09.402.022S | 22MM COCR RADIAL HEAD STANDARD HEIGHT/12.5MM-STERILE | All |
| 10886982132604 | 09.402.024S | 24MM COCR RADIAL HEAD STANDARD HEIGHT/13.0MM-STERILE | All |
| 10886982132611 | 09.402.026S | 26MM COCR RADIAL HEAD STANDARD HEIGHT/13.5MM-STERILE | All |
| 10886982132628 | 09.402.028S | 28MM COCR RADIAL HEAD STANDARD HEIGHT/14.0MM-STERILE | All |
| 10886982132635 | 09.402.218S | 18MM COCR RADIAL HEAD 2MM HT EXTENSION/13.5MM-STER | All |
| 10886982132642 | 09.402.220S | 20MM COCR RADIAL HEAD 2MM HT EXTENSION/14.0MM-STER | All |
| 10886982132659 | 09.402.222S | 22MM COCR RADIAL HEAD 2MM HT EXTENSION/14.5MM-STER | All |
| 10886982132666 | 09.402.224S | 24MM COCR RADIAL HEAD 2MM HT EXTENSION/15.0MM-STER | All |
| 10886982132673 | 09.402.226S | 26MM COCR RADIAL HEAD 2MM HT EXTENSION/15.5MM-STER | All |
| 10886982132680 | 09.402.228S | 28MM COCR RADIAL HEAD 2MM HT EXTENSION/16.0MM-STER | All |
| 10886982132697 | 09.402.418S | 18MM COCR RADIAL HEAD 4MM HT EXTENSION/15.5MM-STER | All |
| 10886982132703 | 09.402.420S | 20MM COCR RADIAL HEAD 4MM HT EXTENSION/16.0MM-STER | All |
| 10886982132710 | 09.402.422S | 22MM COCR RADIAL HEAD 4MM HT EXTENSION/16.5MM-STER | All |
| 10886982132727 | 09.402.424S | 24MM COCR RADIAL HEAD 4MM HT EXTENSION/17.0MM-STER | All |
| 10886982132734 | 09.402.426S | 26MM COCR RADIAL HEAD 4MM HT EXTENSION/17.5MM-STER | All |
| 10886982132741 | 09.402.428S | 28MM COCR RADIAL HEAD 4MM HT EXTENSION/18.0MM-STER | All |
| 10886982132758 | 09.402.618S | 18MM COCR RADIAL HEAD 6MM HT EXTENSION/17.5MM-STER | All |
| 10886982132765 | 09.402.620S | 20MM COCR RADIAL HEAD 6MM HT EXTENSION/18.0MM-STER | All |
| 10886982132772 | 09.402.622S | 22MM COCR RADIAL HEAD 6MM HT EXTENSION/18.5MM-STER | All |
| 10886982132789 | 09.402.624S | 24MM COCR RADIAL HEAD 6MM HT EXTENSION/19.0MM-STER | All |
| 10886982132796 | 09.402.626S | 26MM COCR RADIAL HEAD 6MM HT EXTENSION/19.5MM-STER | All |
| 10886982132802 | 09.402.628S | 28MM COCR RADIAL HEAD 6MM HT EXTENSION/20.0MM-STER | All |
| NA | 68.402.001 | Modular Tray 1, for Instruments, for Radial Head Prosthesis, size 1/1, without Contents, Vario Case " | All |
| NA | 68.402.002 | Modular Tray 2, for Instruments, for Radial Head Prosthesis, size 1/2, without Contents, Vario Case " | All |
| NA | 68.402.003 | Modular Tray 3, for Broaches, for Radial Head Prosthesis, size 1/1, without Contents, Vario Case " | All |
| NA | 68.402.004 | Modular Tray 4, for Trial Implants, for Radial Head Prosthesis, size 1/2, without Contents, Vario Case " | All |