User Name
User Address Line 1
User Address Line 2
User Address Line 3

**URGENT FIELD SAFETY NOTICE**

| | |
|---|---|
| Product Name: | ADEPT® |
| Reference: | FSN-21-005 |
| Action Type: | Field Safety Notice on Medical Device – Read updated IFU |
| Date: | 18 October 2021 |
| Device Type: | Metal on Metal Hip Resurfacing |

Reason for this Field Safety Notice:

This FSN is to inform you that the indications and contraindications in the current instructions for use for these devices have been updated to reflect the post market surveillance (PMS) data presented at the last product approval which was completed in May 2021.

Root Cause:

The previous indications and contraindications were too general and were not specific to each product family. Whilst they were acceptable when they were originally used, clinical practise has evolved and the PMS data now available can be used to make them more specific and reflective of current clinical practice.

Revised indications for use:

The ADEPT® Hip Resurfacing System is intended for use in resurfacing hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients having Osteoarthritis.

The ADEPT® Hip Resurfacing System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip replacements. Patient selection factors which should be considered include:

1. Ability and willingness of the patient to follow instructions.
2. Ability to commit to rehabilitation programme and attend regular follow-up as advised by health guidelines.
3. A good nutritional state of the patient and full skeletal maturity.
4. Patient bone density, osteopenia or family history of osteopenia including avascular necrosis (AVN) or osteonecrosis.
5. Patient age including need to regain mobility.



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6. Patient femoral head size and specifically the slight increased risk of revision for the 46 mm diameter head.

7. Female patients who may have an increased risk of revision compared to males.

Revised contraindications for use:

1. Patients with active or suspected infection or sepsis in or around the hip joint.

2. Distant foci of infections (which may cause hematogenous spread to the implant site).

3. Osteoporosis, metabolic disorder, or a condition of marked bone loss which could impair bone formation.

4. Cases where there is inadequate neuromuscular status, vascular insufficiency, muscular atrophy, incompetent or deficient soft tissue surrounding the joint, neuromuscular disease, poor skin coverage around hip joint or prior implantation that cannot provide adequate support or fixation for the prosthesis which would compromise implant stability or post-operative recovery, making the procedure unjustifiable.

5. Skeletally immature patients.

6. Severe dysplasia.

7. Significant acetabular or femoral deformity that may preclude safe placement of components.

8. Bone stock which in the surgeons opinion is inadequate to support the device or where absorption is apparent on roentgenogram, this includes patients with severe osteopenia and a family history of severe osteoporosis or severe osteopenia, osteonecrosis or avascular necrosis (AVN) with >30% involvement of the femoral head (regardless of FICAT grade).

Note – In cases of questionable bone density, a Dual Energy X-Ray Absorptiometry (DEXA) scan may be necessary to assess inadequate bone stock.

9. Patients with multiple cysts of the femoral head (>1cm).

10. Patients with known moderate to severe renal insufficiency.

11. Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids.

12. Patients with known or suspected metal sensitivity (e.g., jewellery).

13. Females of child bearing age or planning on becoming pregnant in the near term due to unknown effects on the foetus of metal ion release.



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14. Metal sensitivity.

Additional information:

Additional information is provided in the IFU including:

The probability of revision at 10 years is:

| ADEPT® size range | Group | At risk at time point | Mean % cumulative revision rate at 10 year | 95% confidence intervals | |
|---|---|---|---|---|---|
| 46mm to 58mm | Whole dataset (46 to 58mm heads, male and female) | 584 | 4.5 | 3.5 | 5.8 |
| | Males | 518 | 4.0 | 3.0 | 5.3 |
| | OA | 545 | 4.4 | 3.4 | 5.8 |
| ***Higher risk groups:*** | | | | | |
| 46mm to 58mm | Females | 64 | 8.6 | 4.5 | 15.5 |
| 46mm head only | | 63 | 9.2 | 4.7 | 17.0 |

Please read to current instructions for use which can be found at the following:
https://info.matortho.com/reg/400-482.pdf

The legal manufacturer for these devices is:

MatOrtho Limited
19/20 Mole Business Park
Randalls Road
Leatherhead
England
KT22 7BA
SRN: GB-MF-000007614

The EU Authorised Representative for these devices is:

MatOrtho Ireland
The Black Church
Saint Mary's Place
Dublin
Ireland
D07 P4AX
SRN: IE-AR-000006856

AR@matortho.eu

The EU Importer for these devices is:

MatOrtho Europe BV
Tour & Taxis
Havenlaan 86C
Box 204
1000 Brussels
Belgium
SRN: BE-IM-000007870

Dissemination of this FSN:

This FSN has been sent to all current users of the device.

Please pass this Field Safety Notice to all those who need to be aware of it and, if relevant, pass the FSN on to any another organization where the device may have been transferred

The relevant National Competent Authorities have been advised of the FSN.

All lots of the following devices:

| Catalogue Number | Description | GMDN Code | EMDN Code | UDI-DI | Basic-UDI-DI |
|---|---|---|---|---|---|
| 172-525 | ADEPT® Metal On Metal Cup 52mm with 46mm bore | 64684 | P09080302 | 05055455507883 | 0505545550000015Z |
| 172-541 | ADEPT® Metal On Metal Cup 54mm with 46mm bore | 64684 | P09080302 | 05055455507890 | 0505545550000015Z |
| 172-545 | ADEPT® Metal On Metal Cup 54mm with 48mm bore | 64684 | P09080302 | 05055455507906 | 0505545550000015Z |
| 172-561 | ADEPT® Metal On Metal Cup 56mm with 48mm bore | 64684 | P09080302 | 05055455507913 | 0505545550000015Z |
| 172-565 | ADEPT® Metal On Metal Cup 56mm with 50mm bore | 64684 | P09080302 | 05055455507920 | 0505545550000015Z |
| 172-581 | ADEPT® Metal On Metal Cup 58mm with 50mm bore | 64684 | P09080302 | 05055455507937 | 0505545550000015Z |
| 172-585 | ADEPT® Metal On Metal Cup 58mm with 52mm bore | 64684 | P09080302 | 05055455507944 | 0505545550000015Z |

| Catalogue Number | Description | GMDN Code | EMDN Code | UDI-DI | Basic-UDI-DI |
|---|---|---|---|---|---|
| 172-601 | ADEPT® Metal On Metal Cup 60mm with 52mm bore | 64684 | P09080302 | 05055455507951 | 0505545550000015Z |
| 172-605 | ADEPT® Metal On Metal Cup 60mm with 54mm bore | 64684 | P09080302 | 05055455507968 | 0505545550000015Z |
| 172-621 | ADEPT® Metal On Metal Cup 62mm with 54mm bore | 64684 | P09080302 | 05055455507975 | 0505545550000015Z |
| 172-625 | ADEPT® Metal On Metal Cup 62mm with 56mm bore | 64684 | P09080302 | 05055455507982 | 0505545550000015Z |
| 172-641 | ADEPT® Metal On Metal Cup 64mm with 56mm bore | 64684 | P09080302 | 05055455507999 | 0505545550000015Z |
| 172-645 | ADEPT® Metal On Metal Cup 64mm with 58mm bore | 64684 | P09080302 | 05055455508002 | 0505545550000015Z |
| 172-661 | ADEPT® Metal On Metal Cup 66mm with 58mm bore | 64684 | P09080302 | 05055455508019 | 0505545550000015Z |
| 181-146 | ADEPT® Metal on Metal Resurfacing Head 46mm | 64683 | P09080402 | 05055455508064 | 0505545550000263 |
| 181-148 | ADEPT® Metal on Metal Resurfacing Head 48mm | 64683 | P09080402 | 05055455508071 | 0505545550000263 |
| 181-150 | ADEPT® Metal on Metal Resurfacing Head 50mm | 64683 | P09080402 | 05055455508088 | 0505545550000263 |
| 181-152 | ADEPT® Metal on Metal Resurfacing Head 52mm | 64683 | P09080402 | 05055455508095 | 0505545550000263 |
| 181-154 | ADEPT® Metal on Metal Resurfacing Head 54mm | 64683 | P09080402 | 05055455508101 | 0505545550000263 |
| 181-156 | ADEPT® Metal on Metal Resurfacing Head 56mm | 64683 | P09080402 | 05055455508118 | 0505545550000263 |
| 181-158 | ADEPT® Metal on Metal Resurfacing Head 58mm | 64683 | P09080402 | 05055455508125 | 0505545550000263 |



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If you require further information, please contact your usual representative in the first place or customer services on customer.services@matortho.com +44 (0)1372 366300.

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# Field Safety Notice Distributor/Importer Reply Form

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | FSN-21-005 |
| FSN Date* | Pre-filled by manufacturer |
| Product/ Device name* | ADEPT® Metal on Metal Hip Resurfacing |
| Product Code(s) | See Attached FSN |

| 2. Distributor/Importer Details | |
|---|---|
| Company Name* | |
| Account Number | |
| Address* | |
| Shipping address if different to above | |
| Contact Name* | |
| Title or Function | |
| Telephone number* | |
| Email* | |

| 3. Return acknowledgement to Sender | |
|---|---|
| Email | customer.services@matortho.com |
| Distributor/Importer Helpline | +44 (0)1372 366300 |
| Postal Address | 19/20 Mole Business Park<br>Randalls Road<br>Leatherhead, Surrey, KT22 7BA |
| Deadline for returning the Distributor/Importer reply form* | Pre-filled by manufacturer/sender/requester |

| 4. Distributors/Importers (Tick all that apply) | | |
|---|---|---|
| ☐ | *I confirm the receipt, the reading and understanding of the Field Safety Notice. | Distributor/Importer to complete or enter N/A |
| ☐ | I have identified customers that received or may have received this device | |

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| 4. Distributors/Importers (Tick all that apply) | | |
|---|---|---|
| ☐ | I have attached customer list | |
| ☐ | I have informed the identified customers of this FSN | Date of communication: |
| ☐ | I have received confirmation of reply from all identified customers | |
| Print Name* | | Distributor/Importer print name here |
| Signature* | | Distributor/Importer sign Here |
| Date * | | |

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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