

Irish ASR Hip
Alternative Dispute
Resolution Process

Claims Handbook

The Alternative Dispute Resolution (“ADR”) Process provides a voluntary, neutral and without prejudice Evaluation of claims made by eligible ASR Hip patients in Ireland who had revision surgery to replace either their ASR Hip Resurfacing System or ASR XL Hip Acetabular Hip System.

Please see the ‘Eligibility’ section on page 4, to determine which claims may be resolved by the ADR Process.

This brochure contains information about the ADR Process document, approved by the High Court on 16 December 2015. If there is any conflict between this brochure and the ADR Process document, the ADR Process document prevails.

Solicitors and their clients do not have to use the ADR Process and may discuss possible settlement of any eligible claim on a without prejudice basis with McCann FitzGerald, as solicitors for DePuy.

As of 29 April 2016, 246 claims have been resolved by negotiation.

Information contained in this handbook is also set out on the website <http://hipadr.ie/>

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Overview of the ADR Process

What is the ADR Process?

The ADR Process is an independent Evaluation of an eligible claim. The Evaluators are retired Judges of the Supreme and High Courts or senior counsel who have prior experience of personal injuries cases. The ADR Process is not a judicial or arbitral process.

How does it work?

Details of the procedure are set out in the ADR Process agreement, approved by the Court on 16 December 2015. In brief, the Claimant's solicitor must complete and submit Form B with the prescribed accompanying documents to McCann FitzGerald as solicitors for DePuy. If the claim qualifies for the Process and if the prescribed documents accompany Form B, McCann FitzGerald will endorse Form B and return it to the Claimant's solicitor. The Claimant's solicitor may then submit the endorsed Form B to the relevant Evaluator, copying McCann FitzGerald, with the other documents as required by the Process. Please refer to the 'Making a Claim' tab for a list of these documents. Claimants' solicitors can easily identify which Evaluator to send the documents to by reference to the last digit of the High Court Record number of their client's proceedings. The process agreement prescribes further steps that may be taken before the Evaluation occurs.

The Evaluator will evaluate the claim. This non-binding monetary Evaluation will be set out in Form C. A copy of Form C will be sent to both the Claimant's solicitor and McCann FitzGerald.

Both DePuy and the Claimant may accept the Evaluation within 45 days of the date of Form C. Acceptance will be without admission as to liability and must be communicated in writing either by emails or letters between the parties' solicitors.

If both parties accept the Evaluation, McCann FitzGerald will send a Settlement Agreement ("Form D") to the Claimant's solicitor for execution by the Claimant. DePuy will pay the Evaluation amount within 28 days of receipt of a signed Form D. The Claimant's party and party costs in respect of the Claimant's legal proceedings and in respect of the Evaluation are payable by DePuy within 28 days after they are agreed or taxed in default of agreement.

What happens if the Claimant or DePuy does not accept the Evaluation?

If either DePuy or the Claimant rejects, or does not accept the Evaluation in writing within 45 days of the Evaluation date of Form C, the Evaluation shall be deemed lapsed and the Claimant may continue with the existing proceedings.

Eligibility

A claim may enter the ADR Process if:

- The index surgery of the ASR product took place in Ireland; AND
- The Claimant had revision surgery in Ireland within 10 years of the index surgery but not earlier than 180 days after the index surgery.

Index surgery in Ireland

180 days post index surgery

Revision Surgery

10 years post index surgery



A claim cannot enter the ADR Process if:

- The Claimant has not undergone revision surgery; OR
- The claim is statute barred pursuant to the Statue of Limitations 1957 (as amended); OR
- The Claimant has not obtained Injuries Board authorisation pursuant to the Personal Injuries Assessment Board Act 2003; OR
- The claim relates exclusively to a revision surgery necessitated by:
 - Dislocation;
 - Trauma;
 - Infection;
 - Fracture of the femoral head; or
 - Any issue related to the femoral system; OR
- The claim is not sufficiently particularised OR sufficient medical records are not supplied OR other essential details have not been given to McCann FitzGerald.

Making a Claim

Steps to Make a Claim

Step 1

Review eligibility criteria



Step 2

Complete Form B



Step 3

Submit Form B and prescribed documents to McCann FitzGerald



Step 4

Provide any additional medical records as requested to have Form B endorsed



Step 5

On receipt of endorsed Form B from McCann FitzGerald send prescribed documents to the Evaluator



Step 6

Send McCann FitzGerald a copy of **all** documents submitted to the Evaluator



Step 7

See Process agreement for details of any further submissions that may be made



Step 8

Accept or reject Evaluation within 45 days

1. Review eligibility criteria.
2. Complete Form B (included in this package).
3. Claimant's solicitor submits Form B, a schedule of special damages and relevant medical records to:

McCann FitzGerald

Riverside One

Sir John Rogerson's Quay

Dublin 2

D02 X576

Reference: Hip ADR Process

4. McCann FitzGerald reviews the documents submitted and determines whether further information and medical records are required for the Evaluation to proceed. If the claim meets the eligibility criteria and sufficient information has been provided, **including all relevant medical records, and full details of special damages sought with vouchers (if any)**, McCann FitzGerald will endorse Form B.
5. Claimant's solicitor receives endorsed Form B.
6. The Claimant's solicitor must then send to the Evaluator:
 - Endorsed Form B;
 - A complete set of pleadings;
 - A complete set of relevant medical records; and
 - A schedule of special damages with supporting documentation.

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Making a Claim cont.

6. *cont.*

The Claimant **may** also include in support of the Evaluation:

- A condition and prognosis report;
- A witness statement from the Claimant;
- Concise written submissions.

7. A copy of **all** documents submitted to the Evaluator must also be sent to McCann FitzGerald.

The Evaluators

(with appropriate number for allocation of claims)

0. Mr Justice Iarfhlaith O'Neill

1. Mr Justice Joseph Finnegan

2. Mr Justice Barry White

3. Mr Justice John Quirke

4. Sara Moorhead SC

5. Hugh Mohan SC

6. Vincent Foley SC

7. Michael Byrne SC

8. Pdraig McCartan SC

9. Marjorie Farrelly SC

Note: Mr Justice O'Neill is evaluator for all claims with High Court record number ending with the digit 0. Mr Justice Finnegan is is evaluator for all claims with High Court record number ending with the digit 1 and so forth for each evaluator in accordance with the digit listed with his or her name above.

Costs

- There is no fee to submit a claim to the ADR Process
- The cost of the Evaluator will be borne by DePuy
- Claimant's costs are paid by DePuy subject to the conditions below.

If the Evaluation is accepted by the Claimant and DePuy, the Claimant shall be entitled to High Court party and party costs in respect of the Claimant's legal proceedings and in respect of the Evaluation, to be taxed by the High Court Taxing Master in accordance with the Rules of the Superior Courts, in default of agreement.

Where the Evaluation is not accepted by a Claimant or by DePuy and

where the Claimant is subsequently awarded party and party costs in the litigation, or if as part of a subsequent settlement DePuy agrees that the Claimant shall recover High Court party and party costs, those costs shall include the Claimant's party and party costs in respect of the Evaluation, to be taxed by the High Court Taxing master in accordance with the Rules of the Superior Courts, in default of agreement.

FAQs

Can I settle the claim outside the ADR Process?

Yes. You do not have to use the ADR Process. You may discuss possible settlement of an eligible claim with McCann FitzGerald, as solicitors for DePuy, on a without prejudice basis.

I have reviewed the eligibility criteria but I am still unsure whether the claim can enter the ADR Process. What should I do?

Please consult your solicitor to discuss your options.

I am a resident in Ireland but my index surgery did not take place in Ireland. Is the claim eligible?

The claim is not eligible for the ADR Process.

The revision surgery was within 180 days of index surgery of the ASR device. Is the claim eligible?

The claim is not eligible for the ADR Process.

The revision surgery was 10 years or more after the index surgery. Is the claim eligible?

The claim is not eligible for the ADR Process.

I do not have Injuries Board authorisation under the Personal Injuries Assessment Board Act 2003. Can I make a claim in the ADR Process?

No, the claim is not eligible. You must have Injuries Board authorisation to submit a claim to the ADR Process.

What does statute barred mean?

The Statute of Limitations 1957 (as amended) sets out the time limits by which a civil action must be commenced. If an action is commenced after the date proscribed by the statute, it may be subject to the defence of being 'statute barred'. If you are uncertain in respect of this, please consult a solicitor.

Was the revision surgery necessitated exclusively by dislocation/ trauma/ infection/ fracture of the femoral head/ any issue relating to the femoral stem?

If yes, the claim is not eligible for the ADR Process.

Do I need a solicitor to make a claim?

You are not required to have a solicitor to submit a claim to the ADR Process. However, for the purpose of being independently advised it is recommended you seek legal advice.

Does it cost to submit a claim to the ADR Process?

No. There is no fee to submit a claim to the ADR Process.

FAQs cont.

How are the claims allocated?

Claims are automatically allocated to Evaluators based on the last digit of the High Court Record number in the Claimant's litigation.

Who are the Evaluators?

The Evaluators are a mix of retired Judges of the Supreme and High Courts or senior counsel who have prior experience of personal injuries issues.

Will I have an opportunity to meet the Evaluator?

In most cases the Evaluation will be a paper-only process. However, in exceptional cases the Evaluator has discretion to hear from Claimant's, representatives of DePuy or an expert. The Evaluator has discretion whether and in what manner to hear from such persons. It is envisaged that this discretion shall be exercised very sparingly as the Process is intended to avoid any unnecessary cost and delay.

How long will it take to complete an Evaluation?

The aim of the ADR Process is to process claims as efficiently and quickly as possible. To achieve this aim parties should endeavour to submit the necessary documents to the Evaluator without delay and in a form which allows for quick review. It is essential that the documents submitted to the Evaluator are properly copied and collated.

Is it possible to 'fast-track' a claim in the ADR Process?

It is possible to 'fast-track' a claim. When completing Form B, highlight whether an early Evaluation is sought for ill health or other stated reason.

What happens after the Evaluator has made an Evaluation?

DePuy and the Claimant may accept the Evaluation in writing by way of an exchange of emails or letters between the parties' solicitors. Acceptance will be without admission as to liability. If either DePuy or the Claimant rejects or does not accept in writing within 45 days of the date marked on Form C, the Evaluation will lapse.

What are 'party and party' costs?

Party and party costs are defined in the Rules of Superior Courts as were necessary or proper for the attainment of justice or for enforcing or defending the rights of the party whose costs are being taxed.

Why must I submit my client's medical records?

A Claimant is required to submit all relevant medical records so the Evaluator has all necessary information before making an assessment.

How will I know when the Evaluator will deal with a claim?

The Evaluator will send notice to the Claimant's solicitor stating that he or she will commence the Evaluation within 14 days unless the Claimant intends to submit further documents.

FAQs cont.

Once a claim has been submitted to the ADR Process, what happens to the litigation relating to that claim?

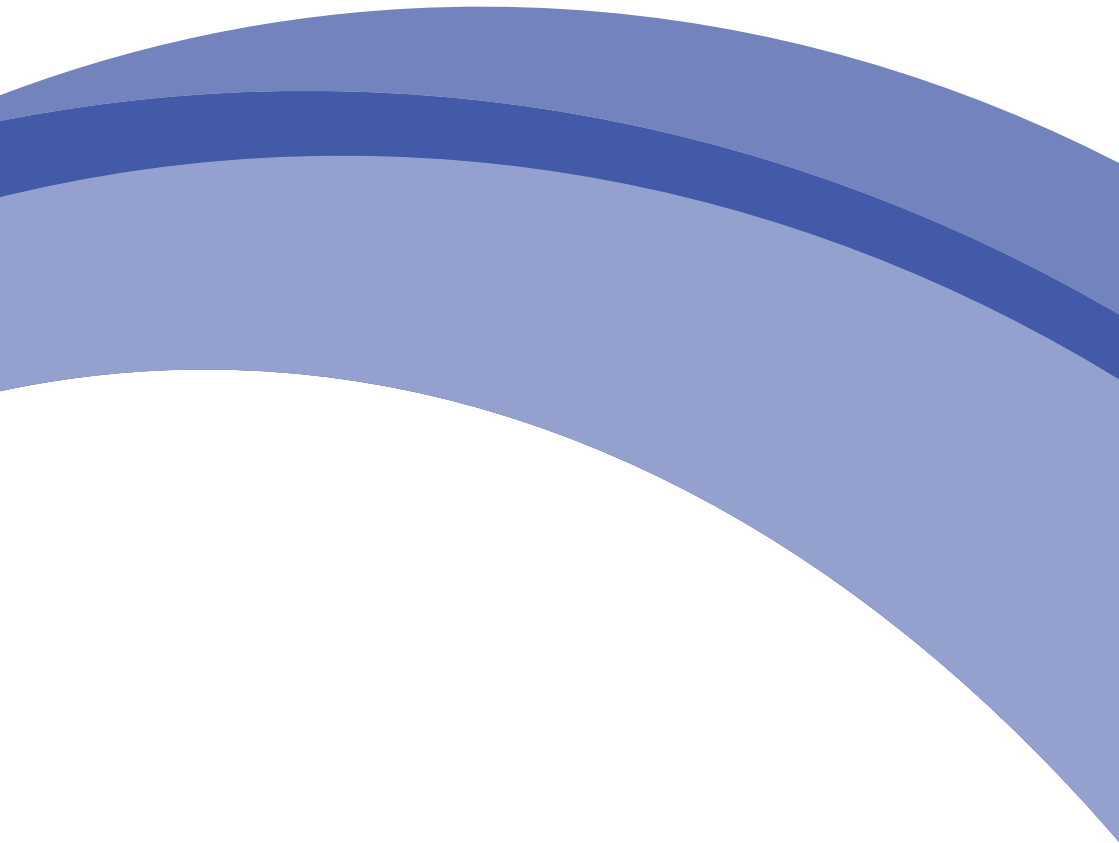
Pursuant to clause 9.1 of the Process, following the submission of a completed Form B by the Claimant's solicitors to McCann FitzGerald, the Claimant and DePuy shall not take any active steps in existing proceedings concerning the claim, or shall not issue new proceedings regarding an ASR Product, before an Evaluation has been issued by the Evaluator and the Evaluation has lapsed due to the passing of 45 days of the date marked on Form C without acceptance or rejection.

My case is listed for trial before October 2016. May I lodge the claim for Evaluation while I continue to take steps in the litigation?

No. Unless the case is taken out of the list and no further steps are taken in the litigation, the case will not be eligible for Evaluation.



Hip ADR



Medical Records

Reference Sheet

Relevant medical records comprise legible, unredacted (as regards to the Claimant) and up-to-date copies of:

1. A complete set of GP records, to include the period three years prior to the index surgery to date
2. Hospital records:
 - (a) Relating to the primary ASR surgery, to include operation notes and ASR product labels
 - (b) Orthopaedic clinic attendances and procedures subsequent to (a)
 - (c) Relating to the revision of the ASR components, to include operation notes and product labels
 - (d) Orthopaedic clinic attendances and procedures subsequent to (c)
 - (e) X-rays, MRI / CT / ultrasound scans, together with reports and reports of blood metal ion testing, histology/histopathology and microbiology
3. Any other notes or records relating to medical conditions and treatment relating to mobility, function and life expectancy that are relevant to the claim

Where records are missing, please provide written confirmation from the medical service provider(s) that they do not hold such records.