Casey v DePuy International Limited and Johnson & Johnson Medical Pty Ltd
Federal Court of Australia, Proceeding ACD 10 of 2010

LIABILITY PROTOCOL

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1. OVERVIEW

1.1 This **Liability Protocol** provides a regime for assessing whether Group Members are eligible to receive compensation pursuant to the settlement of the proceeding. A separate **Compensation Protocol** provides a regime for assessing the compensation entitlements of such eligible Group Members.

1.2 This Liability Protocol provides for the identification of the failure of Affected Implants that are caused by wear of the Articulating Surfaces from alumina particles, leading to inflammation, swelling and/or pain of the joint and revision surgery.

2. INTERPRETATION

Abnormal Wear means striations, scratches or deep grooves in the direction of articulation on any of the Articulating Surfaces that is greater than the wear that would generally be expected in a total knee replacement prosthesis that had been implanted for a comparable period of time.

Affected Implant has the meaning given in the statement of claim filed by the applicant on 7 September 2010 and for the purpose of this protocol includes, where appropriate, the tibial component and the ultrahigh molecular weight polyethylene (**Polyethylene**) component used in conjunction with the femoral component.

Articulating Surfaces means, as appropriate, the following:

(a) the distal surface of the femoral component of the Affected Implant;

(b) the proximal surface of the tibial component of the Affected Implant;

(c) the distal surface of the Polyethylene component of the Affected Implant;

(d) the proximal surface of the Polyethylene component of the Affected Implant.

Explant means those of the following components of the Affected Implant as may be available, including:

(a) the femoral component:

(b) the Polyethylene component:

(c) the tibial component , if it has been explanted; and

(d) the patellar component, if it has been explanted.

Group Member means a group member in proceeding ACD 10 of 2010 in the Federal Court of Australia, as defined in the further amended originating application to be filed in the proceeding.

Group Member's lawyer means any legal representative of a Group Member who is assessed pursuant to the Liability Protocol, or where the Group Member has not appointed a lawyer, the Group Member.

Joint includes the synovium of the knee joint, the synovial lining, the capsule of the knee joint, any soft tissue surrounding or within the knee joint, the Articulating Surfaces, the patellar bone (including any artificial patella), the joint space between the Articulating Surfaces and any fluid within the joint space.

Maurice Blackburn means Maurice Blackburn Pty Ltd, the solicitor for the Applicant and some Group Members.

NRA means Norton Rose Australia, the solicitor for the Respondents.

3. NOTIFICATION OF INTENTION TO MAKE A CLAIM

3.1 A Group Member who wishes to make a claim must submit a Claim Form in the form of **Schedule A** (a copy of which is to be annexed to the opt out/settlement notice) to Maurice Blackburn or NRA.

3.2 The Claim Form must be provided to Maurice Blackburn or NRA:

(a) if the Group Member's Affected Implant was revised on or before 31 August 2012: no later than 31 May 2013; or

(b) if the Group Member's Affected Implant was revised after 31 August 2012: no later than:

(i) 31 May 2013; or

(ii) six months after the date on which the Group Member's Affected Implant was revised,

(whichever is later); or

(c) if the Group Member's Affected Implant is not able to be revised for medical reasons: no later than:

(i) 31 May 2013; or

(ii) six months after the Group Member became aware that their Affected Implant requires revision due to Abnormal Wear and is not able to be revised,

(whichever is later).

3.3 A Group Member is precluded from making a claim pursuant to this Liability Protocol if:

(a) the Group Member's Affected Implant was revised more than eight years after it was implanted; or

(b) the Group Member became aware more than eight years after implantation of the Affected Implant that it requires revision due to Abnormal Wear and is not able to be revised.

3.4 On the first and third Monday of each month, Maurice Blackburn and NRA will exchange:

(a) copies of Claim Forms received during the preceding period; and

(b) a list in the form of **Schedule B** with the following details relating to Group Members from whom Claim Forms were received during the preceding period:

(i) the name and date of birth of the Group Member;

(ii) the date that the Claim Form was received;

(iii) whether Maurice Blackburn, the Group Member's lawyer or NRA, as the case may be, retains the Group Member's Explant; and, if so, what components are retained; and

(iv) details of the legal representative (if any) who acts for the Group Member.

4. CONSTITUTION OF THE PANEL

4.1 Maurice Blackburn and NRA will each nominate three orthopaedic surgeons, having experience in removing knee implants (**Assessors**) for the purpose of constituting a "**Panel**" of surgeons. The Assessors, and in the case of any orthopaedic surgeon appointed as a Special Assessor pursuant to paragraph 7.1(a) , must be appropriately licensed or qualified to handle biohazardous material, given that the explants may be biohazardous.

4.2 An Assessor will not be appointed to the Panel without the agreement of both Maurice Blackburn and NRA.

4.3 The names of the Assessors on the Panel will be arranged in alphabetical order by surname.

4.4 Where this Liability Protocol requires a step to be carried out by an Assessor:

(a) NRA will appoint an Assessor from the Panel by selecting the next Assessor in the alphabetical list of Assessors;

(b) Assessors will be appointed on a strictly rotational basis;

(c) if an Assessor is unable to accept the appointment for whatever reason, the Assessor who next appears in the alphabetical list of Assessors will then be appointed.

4.5 Where an Assessor is asked pursuant to this Liability Protocol to provide an opinion, the Assessor will be requested to provide to the Group Member's lawyer, copied to NRA, a written report within 28 days of the Assessor receiving the Group Member's Assessment Materials.

4.6 If an Assessor contacts the Group Member's lawyer or NRA with a query concerning the assessment of a Group Member, the Group Member's lawyer or NRA, as the case may be, that is contacted by the Assessor will notify the other firm and will provide to it a copy of any correspondence from the Assessor. The Group Member's lawyer and NRA will then use their best endeavours to agree on an appropriate response to the Assessor's query.

5. ASSESSMENT PROCESS

5.1 Within 90 days of the receipt by Maurice Blackburn or NRA of the Group Member's Claim Form, the Group Member's lawyer will notify NRA when the Group Member is ready to be assessed and at the same time will provide evidence of the Group Member having been surgically implanted with an Affected Implant, confirmation as to whether or not the Group Member retains the Group Member's Explant and the product lot and product code (if known) (the **Notification**). The Group Member's lawyer will take no further steps following the Notification for a period of 7 days, during which time NRA will advise the Group Member's lawyer if the Respondents accept that a Group Member's Affected Implant manifested the Characteristic and, accordingly, the Group Member is eligible for compensation and will have his or her compensation assessed in accordance with the Compensation Protocol. Where NRA does not so notify the Group Member's lawyer, the provisions of paragraphs 5.2 to 5.5 will apply, as appropriate.

5.2 If, pursuant to paragraph 5.1, the Group Member's lawyer advises NRA that the Group Member retains the Group Member's Explant, the following provisions will apply:

(a) within 14 days of receipt of notice from the Group Member's lawyer that the Group Member retains the Group Member's Explant, NRA and the Group Member's lawyer will arrange for receipt by NRA of the Group Member's Explant to enable the inspection and analysis of the Group Member's Explant;

(b) within 28 days of receipt of notice from the Group Member's lawyer that the Group Member retains the Explant, the Group Member's lawyer will provide NRA with copies of the following materials (**Assessment Materials**) relating to the Group Member:

(i) any relevant macroscopic images, including images of the Explant (if available);

(ii) copies of all pathology (including any histopathology, cytology and chemical pathology) reports relating to the Group Member's revision surgery, arthroscopy and/or Joint aspirate;

(iii) copies of all operation reports, surgical notes or other documents in which intra-operative observations are recorded;

(iv) copies of any other medical records, materials or specimens that are relevant to the assessment of the Group Member;

(c) if, within 60 days of NRA receiving the Group Member's Explant and the Assessment Materials as provided in paragraphs 5.2(a) and (b), the Group Member's lawyer and NRA are unable to agree whether the Group Member is entitled to compensation in accordance with paragraph 6, NRA will advise the Group Member's lawyer accordingly, and the following provisions will then apply:

(i) within 14 days of the receipt by the Group Member's lawyer of NRA's advice that the Group Member is not entitled to compensation:

(A) the Group Member's lawyer and NRA will arrange for receipt by the Group Member's lawyer of the Group Member's Explant to enable the inspection and analysis of the Group Member's Explant, if not already undertaken on behalf of the Group Member, or the Group Member's lawyer will advise NRA to that effect;

(B) NRA will provide to the Group Member's lawyer any medical records it holds of the Group Member, not included in the Assessment Materials, together with the Respondents' Explant analysis (**Respondents' Assessment Materials**);

(ii) within 30 days of receipt by the Group Member's lawyer of the Respondent's Assessment materials, the Group Member's lawyer will provide the Group Member's Explant analysis if it proposes to do so and any submission to NRA;

(iii) if, within 21 days of receipt of the material referred to in paragraph 5.2(c)(ii), the Group Member's lawyer and NRA are unable to agree whether a Group Member is entitled to compensation in accordance with paragraph 6, NRA will advise the Group Member's lawyer accordingly, and will proceed to appoint an Assessor.

5.3 If, pursuant to paragraph 5.1, the Group Member's lawyer advises NRA that the Group Member does not retain the Group Member's Explant, NRA will advise the Group Member's lawyer within 14 days if the Group Member's Explant is available to NRA, and if available to NRA, the following provisions will apply:

(a) within 14 days of receipt by the Group Member's lawyer of notice from NRA that the Group Member's Explant is available to NRA, the Group Member's lawyer will provide to NRA copies of the Assessment Materials relating to the Group Member;

(b) if, within 60 days of NRA receiving the Assessment Materials, the Group Member's lawyer and NRA are unable to agree whether a Group Member is entitled to compensation in accordance with paragraph 6, NRA will advise the Group Member's lawyer accordingly, and the following provisions will apply:

(i) within 14 days of receipt by NRA of the advice referred to in paragraph 5.3(b):

(A) the Group Member's lawyer and NRA will arrange for receipt by the Group Member's lawyer of the Group Member's Explant to enable the inspection and analysis of the Group Member's Explant;

(B) NRA will provide to the Group Member's lawyer copies of the Respondents' Assessment Materials;

(ii) within 60 days of receipt by the Group Member's lawyer of the Respondents' Assessment Materials, the Group Member's lawyer will provide the Group Member's Explant analysis and any submission to NRA;

(iii) if, within 21 days of receipt of the materials referred to in paragraph 5.3(b)(ii), the Group Member's lawyer and NRA are unable to agree whether the Group Member is entitled to compensation in accordance with paragraph 6, NRA will advise the Group Member's lawyer accordingly and will proceed to appoint an Assessor.

5.4 If, pursuant to paragraph 5.1, the Group Member's lawyer advises NRA that the Group Member does not retain the Group Member's Explant, NRA will advise the Group Member's lawyer within 14 days if the Group Member's Explant is available to NRA, and if not available to NRA, the following provisions will apply:

(a) within 14 days of receipt of notice from NRA that the Group Member's Explant is not available to NRA, the Group Member's lawyer will provide to NRA copies of the Assessment Materials relating to the Group Member;

(b) within 14 days of receipt by NRA of the Assessment Materials, NRA will either provide to the Group Member's lawyer copies of the Respondents' Assessment Materials or will notify the Group Member's lawyer that it does not have any such documents that are not already included among the Assessment Materials;

(c) if, within 60 days of NRA receiving the Assessment Materials, the Group Member's lawyer and NRA are unable to agree whether a Group Member is entitled to compensation in accordance with paragraph 6, NRA will advise the Group Member's lawyer accordingly and will proceed to appoint an Assessor.

5.5 NRA may at any time notify a Group Member's lawyer that the Respondents accept that a Group Member's Affected Implant manifested the Characteristic and, accordingly, the Group Member is eligible for compensation and will have his or her compensation assessed in accordance with the Compensation Protocol.

6. ASSESSMENT CRITERIA FOR ASSESSMENT BY THE PARTIES

6.1 (*Overarching criterion*) Subject to paragraphs 6.2 to 6.5, a Group Member is eligible for compensation and will have his or her compensation assessed in accordance with the Compensation Protocol if it is more likely than not that alumina particles from an Affected Implant caused Abnormal Wear (the **Characteristic**).

6.2 (*Presumptive evidentiary criteria*) The Characteristic will be presumed if the Group Member's lawyer and NRA agree that:

(a) if the Group Member's Explant is available: Abnormal Wear is observable;

(b) if the Group Member's Explant is not available or if only one of the metal components of the Explant is available: one of the following is observable:

(i) metal wear particles together with discernable soft tissue staining or discolouration of the synovial fluid, the synovial lining or the capsular soft tissue; or

(ii) Abnormal Wear; or

(iii) synovitis, capsular thickening or metallosis:

(A) unless the synovitis, capsular thickening or metallosis was caused by something else; or

(B) if the synovitis, capsular thickening or metallosis had multiple causes, it is more likely than not that wear of an Articulating Surface caused by alumina particles made a

material contribution to the synovitis, capsular thickening or metallosis.

6.3 (*Other evidence*) The Group Member's lawyer and NRA may agree, based on the evidence that is available, that it is more likely than not that alumina particles from an Affected Implant caused Abnormal Wear in the Group Member's Affected Implant. The provisions of this paragraph do not apply to Group Members who are unable to undergo revision surgery for medical reasons.

6.4 (*Unable to undergo revision surgery*) Where a Group Member is unable to undergo revision surgery for medical reasons, the Group Member will be eligible for compensation (also subject to the Exclusionary criteria) and will have his or her compensation assessed in accordance with the Compensation Protocol if the Group Member supplies acceptable medical evidence of their inability to undergo revision surgery and:

(a) where the Group Member has had an arthroscopy, Abnormal Wear is observable on the Articulating Surfaces for which images are available; or

(b) where the Group Member has not had an arthroscopy, the Group Member's lawyers and NRA agree, based on the medical evidence that is available, that it is more likely than not that the alumina particles from an Affected Implant caused Abnormal Wear in the Group Member's Affected Implant.[1]

6.5 (*Exclusionary criteria*) A Group Member is not eligible for compensation if it is more likely than not that the failure of the Group Member's Affected Implant occurred because:

(a) there was metal/metal contact of the Articulating Surfaces of the Affected Implant; or

(b) there was metal/metal contact between a piece of metal not constituting part of the Affected Implant and a piece of metal which is part of the Affected implant; or

(c) the components of the Affected Implant were mis-sized or not compatible; or

(d) the Group Member had an infection that arose during or as a result of the implantation of the Affected Implant and the infection was confirmed by positive culture; or

[1] If liability in respect of a Group Member is to be determined under paragraph 6.4(b), the period during which the Group Member may opt out of the proceeding has been extended by an order made by the Federal Court of Australia. If applicable, the extended opt out date is the thirtieth day after the date on which the Group Member receives final written notification that the Respondents do not accept liability in respect of the Group Member pursuant to paragraph 6.4(b).

(e) the Group Member had an allergic reaction to his or her Affected Implant, where the allergy was likely to have pre-dated the onset of symptoms such as pain, swelling and decreased range of motion; or

(f) of trauma; or

(g) a substance other than alumina particles was the cause of Abnormal Wear,

and Abnormal Wear caused by alumina particles did not make a material contribution to the failure of the Group Member's Affected Implant.

7. PROCESS AND CRITERIA FOR ASSESSMENT BY AN ASSESSOR OR SPECIAL ASSESSORS, IF NECESSARY

7.1 Within 7 days of the Group Member's lawyer and NRA being unable to agree whether a Group Member is entitled to compensation pursuant to paragraphs 5.2(c)(iii), 5.3 (b)(iii) or 5.4(c) NRA will:

(a) if a Group Member has sought to rely upon paragraph 6.3, appoint Independent Counsel (as defined in the Compensation Protocol) and an orthopaedic surgeon, whose appointment is agreed upon by the Group Member's lawyer and NRA (together, the **Special Assessors**); or

(b) in all other circumstances, appoint an Assessor.

7.2 NRA will send a letter in the form of **Schedule C** to the Assessor or a letter in the form of **Schedule D** to the Special Assessors confirming the appointment and will provide a copy of the letter to the Group Member's lawyer.[2] At the same time as sending the letter of appointment to the Assessor, NRA will provide the following materials to the Assessor or Special Assessors:

(a) the Assessment Materials;

(b) the Respondents' Assessment Materials;

(c) the Group Member's Explant, if it is in the possession of the Respondents; and

(d) any analysis and/or submissions exchanged by the parties pursuant to paragraphs 5.2(c)(ii) and 5.3(b)(ii).

7.3 If either the Group Member or the Group Member's lawyer is in possession of the Explant, the Group Member's lawyer will forward the Group Member's

[2] The letters in Schedule C and Schedule D may be modified to suit the circumstances of an individual case by omitting any paragraphs that are not relevant to an individual Group Member; for example, if a Group Member has undergone revision surgery, the letter may omit paragraph 4 in Schedule C, or if a Group Member's Explant is not available the letter may omit paragraph 2(a) in Schedule C.

Explant to the Assessor or Special Assessors within seven days of receiving notice from NRA as provided in paragraph 7.2.

7.4 For the avoidance of doubt, the following provisions apply to assessments by Assessors or Special Assessors, as the case may be:

(a) Assessors: 7.5, 7.6, 7.8, 7.9 and 7.10;

(b) Special Assessors: 7.5, 7.7, 7.9 and 7.10.

7.5 (*Overarching criterion*) Subject to paragraphs 7.6 to 7.11, a Group Member is eligible for compensation and will have his or her compensation assessed in accordance with the Compensation Protocol if in the opinion of the Assessor or Special Assessors, following consideration of the Assessment Materials, the Respondents' Assessment Materials and the Group Member's Explant, it is more likely than not that alumina particles from an Affected Implant caused Abnormal Wear (the **Characteristic**).

7.6 (*Presumptive evidentiary criteria*) The Characteristic will be presumed if the Assessor, following consideration of the Assessment Materials, the Respondents' Assessment Materials and the Group Member's Explant, is of the opinion that it is more likely than not that:

(a) if the Group Member's Explant is available: Abnormal Wear is observable;

(b) if the Group Member's Explant is not available or if only one of the metal components of the Explant is available: one of the following is observable:

(i) metal wear particles together with discernable soft tissue staining or discolouration of the synovial fluid, the synovial lining or the capsular soft tissue; or

(ii) Abnormal Wear; or

(iii) synovitis, capsular thickening or metallosis:

(A) unless the synovitis, capsular thickening or metallosis was caused by something else; or

(B) if the synovitis, capsular thickening or metallosis had multiple causes, it is more likely than not that wear of an Articulating Surface caused by alumina particles made a material contribution to the synovitis, capsular thickening or metallosis.

7.7 (*Other evidence*) If a Group Member has sought to rely upon paragraph 6.3, a Special Assessor is to consider the evidence that is available in forming their opinion about whether, for the purpose of paragraph 7.5 it is more likely than

not that alumina particles from an Affected Implant caused Abnormal Wear in the Group Member's Affected Implant.

7.8 (*Unable to undergo revision surgery*) Where a Group Member is unable to undergo revision surgery for medical reasons, the Group Member will be eligible for compensation (also subject to the Exclusionary criteria) and will have his or her compensation assessed in accordance with the Compensation Protocol if, in the opinion of the Assessor, following consideration of the Assessment Materials and the Respondents' Assessment Materials, the Group Member supplies acceptable medical evidence of their inability to undergo revision surgery and Abnormal Wear is observable on the Articulating Surfaces for which arthroscopic images are available.

7.9 (*Exclusionary criteria*) A Group Member is not eligible for compensation if it is more likely than not that the failure of the Group Member's Affected Implant occurred because:

(a) there was metal/metal contact of the Articulating Surfaces of the Affected Implant; or

(b) there was metal/metal contact between a piece of metal not constituting part of the Affected Implant and a piece of metal which is part of the Affected implant; or

(c) the components of the Affected Implant were mis-sized or not compatible; or

(d) the Group Member had an infection that arose during or as a result of the implantation of the Affected Implant and the infection was confirmed by positive culture; or

(e) the Group Member had an allergic reaction to his or her Affected Implant, where the allergy was likely to have pre-dated the onset of symptoms such as pain, swelling and decreased range of motion; or

(f) of trauma; or

(g) a substance other than alumina particles was the cause of Abnormal Wear,

and Abnormal Wear caused by alumina particles did not make a material contribution to the failure of the Group Member's Affected Implant.

7.10 (*Additional material sciences evidence*) Where the assessment raises an issue of material science or implant analysis arising from the application of, for example, paragraphs 7.6(a), 7.6(b)(i), 7.6(b)(ii), 7.7 or 7.9(g):

(a) if the orthopaedic surgeon does not have expertise in material science or implant analysis, they must contact NRA in order to request advice or evidence on that issue;

(b) NRA and the Group Member's lawyer will seek to agree on the scope and source of the additional advice or evidence to be provided to the Assessor or Special Assessors; and

(c) the Assessor or Special Assessors must take into account the additional advice or evidence that is provided.

7.11 (*Disputes among the Special Assessors*) Where the Special Assessors disagree with each other on the assessment of a Group Member, the assessment will be referred for final resolution to Senior Counsel whose appointment is agreed upon by the Group Member's lawyer and NRA.

8. COSTS

8.1 If a Group Member is assessed as being eligible for compensation, the costs of carrying out the assessment pursuant to this Liability Protocol will be paid in accordance with the costs provisions in the Compensation Protocol.

8.2 If a Group Member is assessed as being ineligible for compensation:

(a) the Group Member will pay the costs of the Assessor or Special Assessors; and

(b) all other costs will be borne by the respective parties.

9. MISCELLANEOUS

9.1 A Group Member's lawyer and NRA will use their best endeavours to adhere to the timeframes stipulated in paragraph 5 of this Liability Protocol.

9.2 If necessary, a Group Member's lawyer and NRA may at any time agree to extend the timeframes contemplated in paragraph 5 in this Liability Protocol and neither the Group Member nor the Respondents will unreasonably refuse to extend a timeframe if requested by a Group Member or the Respondents.

9.3 Where a Group Member or Group Member's lawyer is in breach by more than 60 days of a timeframe stipulated in paragraph 5 of this Liability Protocol as extended by any agreement pursuant to paragraph 9.2 and there is no reasonable explanation for the breach, the Respondents may apply to the Federal Court for orders seeking to strike out the Group Member's claim, alternatively seek directions from the Federal Court, including an order for costs.

9.4 Where notification of a claim is not made within the time limits stipulated in clause 3.2 of this Liability Protocol, a late claim may be made no later than 18 months after the date on which notification of the claim ought to have been made, where the Group Member has reasonable grounds for providing late notification such as prolonged illness or legal disability. Any dispute as to whether the grounds provided by the Group Member for the delay in

notification of the claim are reasonable may be referred by any of the parties to the Court for determination.

9.5 If a party (Party A) is in possession of documents relating to a Group Member, another party (Party B) may request copies of documents, in which case Party A must provide copies of the documents to Party B.

9.6 Any written correspondence between a party and an Assessor will be copied to the other party or parties.

9.7 The applicant, a Group Member or the Respondents may apply to the Federal Court of Australia in respect of any legal issue arising from the implementation of this Liability Protocol.

9.8 In the event of any disagreement or dispute between the parties (including any Group Member) as to the implementation, interpretation or application of this Liability Protocol, the parties will use their best endeavours to seek to resolve the dispute. If the parties are unable to resolve the dispute, a party may apply to the Federal Court of Australia for orders.

SCHEDULE A

Casey v DePuy International Limited and Johnson & Johnson Medical Pty Ltd
DePuy LCS ® Duofix ™ knee implants class action
Federal Court of Australia, Proceeding ACD 10 of 2010
CLAIM FORM

I confirm that I have been surgically implanted with a DePuy LCS Duofix femoral component (**LCS Duofix knee implant**). I now give notice that I wish to make a claim for compensation under the proposed settlement scheme.

I acknowledge that my claim will involve a two step process: first, determining whether I am eligible to receive compensation and, secondly, if so, determining the amount of compensation.

I acknowledge that personal information, medical records and other documents, including my explant (and any tissue), if available, will need to be shared with DePuy International Ltd and Johnson & Johnson Medical Pty Ltd, their lawyers and organisations acting on their behalf for the purposes of this Liability Protocol and, if appropriate, the Compensation Protocol, and I provide my consent to same.

Note: If you were implanted with an LCS Duofix knee implant in each knee, please use a separate Claim Form for each LCS Duofix knee implant.

Name: _____

Date of birth: _____

Address: _____

Date that my LSC Duofix knee implant was inserted: _____

Knee (left or right): _____

Surgeon: _____

Hospital: _____

Product (if known) Lot: Code: _____

Date that my LSC Duofix knee implant was removed: _____

Surgeon: _____

Hospital: _____

Location of my removed LSC Duofix knee implant: _____

Name and address of my lawyer (if applicable): _____

Signed: _____

Date: _____

Note: the Claim Form must be provided to Maurice Blackburn (PO Box A266, Sydney South NSW 1235) or Norton Rose Australia (GPO Box 3872, Sydney NSW 2001):

(1) if the LCS Duofix knee implant was revised on or before 31 August 2012: no later than 31 May 2013; or

(2) if the LCS Duofix knee implant was revised after 31 August 2012: no later than (a) 31 May 2013 or (b) six months after the date on which Group Member's LCS Duofix knee implant was revised (whichever is later); or

(3) if the LCS Duofix knee implant is not able to be revised for medical reasons: no later than (a) 31 May 2013 or (b) six months after the Group Member became aware that their LCS Duofix knee implant requires revision due to Abnormal Wear and is not able to be revised (whichever is later).

SCHEDULE B

Casey v DePuy International Limited and Johnson & Johnson Medical Pty Ltd
Federal Court of Australia, Proceeding ACD 10 of 2010

LIST OF GROUP MEMBERS FOR WHOM CLAIM FORMS HAVE BEEN RECEIVED

Name of Group Member **Surname, first name)**	**Date of birth** **/ /19**	**Date claim form received** **/ / 20**	**Is Explant available for examination** **Yes / No**	**If Yes, what components are retained**	**If retained,** **in whose possession**	**Solicitor acting for the Group Member (if applicable)**

Date of list:

Period covered by list:

Prepared by: [Norton Rose / Maurice Blackburn]

SCHEDULE C

[Letter from NRA to the Assessor confirming the appointment and providing instructions for the assessment]

[Omitting formal parts]

[Date]

[Assessor's name and address]

Dear [Salutation and Assessor's surname],

DePuy LCS Duofix femoral components Liability Protocol (Protocol)
Claimant: [Group Member's name]

We hereby request your appointment pursuant to the Protocol to undertake an assessment of the following Claimant:

[Name of Group Member and date of birth]

If for any reason you are unable to undertake the assessment, please let us known as soon as possible so that another Assessor can be appointed to assess the Claimant, and return the enclosed materials to us.

For the purpose of the assessment we **enclose** the following materials:

(a) [identify materials];

(b) [etc].

Assessment

1. Based on the enclosed materials, please provide your opinion as to whether it is more likely than not that alumina particles from an Affected Implant caused Abnormal Wear (**the Characteristic**). In considering your opinion, please have regard to the following principles:

A. *Abnormal Wear* means striations, scratches or deep grooves in the direction of articulation of any of the Articulating Surfaces that is greater than the wear that would generally be expected in a total knee replacement prosthesis that had been implanted for a comparable period of time.

B. *Articulating Surfaces* means, as appropriate, the following:

(a) the distal surface of the femoral component of the Affected Implant;

(b) the proximal surface of the tibial component of the Affected Implant;

(c) the distal surface of the Polyethylene component of the Affected Implant;

(d) the proximal surface of the Polyethylene component of the Affected Implant.

C. *Explant* means those of the following components of the Affected Implant as may be available, including:

(a) the femoral component;

(b) the Polyethylene component;

(c) the tibial component, if it has been explanted; and

(d) the patellar component, if it has been explanted.

D. *Joint* includes the synovium of the knee joint, the synovial lining, the capsule of the knee joint, any soft tissue surrounding or within the knee joint, the Articulating Surfaces, the patellar bone (including any artificial patella), the joint space between the Articulating Surfaces and any fluid within the joint space.

2. The Characteristic will be presumed if you are of the opinion that it is more likely than not that:

(a) if the Claimant's Explant is available: Abnormal Wear is observable;

(b) if the Claimant's Explant is not available or if only one of the metal components of the Explant is available: one of the following is observable:

(i) metal wear particles together with discernable soft tissue staining or discolouration of the synovial fluid, the synovial lining or the capsular soft tissue; or

(ii) Abnormal Wear; or

(iii) synovitis, capsular thickening or metallosis:

(A) unless the synovitis, capsular thickening or metallosis was caused by something else; or

(B) if the synovitis, capsular thickening or metallosis had multiple causes, it is more likely than not that wear of an Articulating Surface caused by alumina particles made a material contribution to the synovitis, capsular thickening or metallosis.

3. Please also provide your opinion as to whether it is more likely than not that the failure of the Explant occurred because:

(a) there was metal/metal contact of the Articulating Surfaces of the Affected Implant; or

(b) there was metal/metal contact between a piece of metal not constituting part of the Affected Implant and a piece of metal which is part of the Affected implant; or

(c) the components of the Affected Implant were mis-sized or not compatible; or

(d) the Claimant had an infection that arose during or as a result of the implantation of the Affected Implant and the infection was confirmed by positive culture; or

(e) the Claimant had an allergic reaction to his or her Affected Implant, where the allergy was likely to have pre-dated the onset of symptoms such as pain, swelling and decreased range of motion; or

(f) of trauma; or

(g) a substance other than alumina particles was the cause of the Abnormal Wear,

and Abnormal Wear caused by alumina particles did not make a material contribution to the failure of the Claimant's Affected Implant.

4. Where a Claimant is unable to undergo revision surgery for medical reasons, please provide your opinion as to whether there is acceptable medical evidence of the Claimant's inability to undergo revision surgery and Abnormal Wear is observable on the Articulating Surfaces for which arthroscopic images are available.

5. Where the assessment raises an issue of material science or implant analysis arising from the application of, for example, paragraphs 1, 2(a), 2(b)(i), 2(b)(ii) or 3(g) and you do not have expertise in material science or implant analysis, you must contact Norton Rose Australia in order to request advice or evidence on that issue. Such additional advice or evidence that is then provided must be taken into account when providing your opinion.

Please provide a written report of your opinion to us within 28 days of receiving this letter and at the same time please also return the enclosed materials to us.

Yours faithfully

[Signature]

cc [Claimant's lawyer]

SCHEDULE D

[Letter from NRA to the Special Assessors confirming the appointment and providing instructions for the assessment]

[Omitting formal parts]

[Date]

[Assessor's name and address] [Assessor's name and address]

Dear [Salutation and Assessor's surname] and [Salutation and Assessor's surname]

DePuy LCS Duofix femoral components Liability Protocol (Protocol)
Claimant: [Group Member's name]

We hereby request your appointment pursuant to the Protocol as Special Assessors to undertake an assessment of the following Claimant:

[Name of Group Member and date of birth]

If for any reason you are unable to undertake the assessment, please let us known as soon as possible so that another Assessor can be appointed to assess the Claimant, and return the enclosed materials to us.

For the purpose of the assessment we **enclose** the following materials:

(a) [identify materials];

(b) [etc].

Assessment

1. Based on the enclosed materials, please provide your opinion as to whether it is more likely than not that alumina particles from an Affected Implant caused Abnormal Wear (**the Characteristic**). In considering your opinion, please have regard to the following principles:

A. *Abnormal Wear* means striations, scratches or deep grooves in the direction of articulation of any of the Articulating Surfaces that is greater than the wear that would generally be expected in a total knee replacement prosthesis that had been implanted for a comparable period of time.

B. *Articulating Surfaces* means, as appropriate, the following:

(a) the distal surface of the femoral component of the Affected Implant;

(b) the proximal surface of the tibial component of the Affected Implant;

(c) the distal surface of the Polyethylene component of the Affected Implant;

(d) the proximal surface of the Polyethylene component of the Affected Implant.

C. *Explant* means those of the following components of the Affected Implant as may be available, including:

(a) the femoral component;

(b) the Polyethylene component;

(c) the tibial component, if it has been explanted; and

(d) the patellar component, if it has been explanted.

D. *Joint* includes the synovium of the knee joint, the synovial lining, the capsule of the knee joint, any soft tissue surrounding or within the knee joint, the Articulating Surfaces, the patellar bone (including any artificial patella), the joint space between the Articulating Surfaces and any fluid within the joint space.

2. The Characteristic will be presumed if you are of the opinion that it is more likely than not that:

(a) if the Claimant's Explant is available: Abnormal Wear is observable;

(b) if the Claimant's Explant is not available or if only one of the metal components of the Explant is available: one of the following is observable:

(i) metal wear particles together with discernable soft tissue staining or discolouration of the synovial fluid, the synovial lining or the capsular soft tissue; or

(ii) Abnormal Wear; or

(iii) synovitis, capsular thickening or metallosis:

(A) unless the synovitis, capsular thickening or metallosis was caused by something else; or

(B) if the synovitis, capsular thickening or metallosis had multiple causes, it is more likely than not that wear of an Articulating Surface caused by alumina particles made a material contribution to the synovitis, capsular thickening or metallosis.

3. Please also provide your opinion as to whether it is more likely than not that the failure of the Explant occurred because:

(a) there was metal/metal contact of the Articulating Surfaces of the Affected Implant; or

(b) there was metal/metal contact between a piece of metal not constituting part of the Affected Implant and a piece of metal which is part of the Affected implant; or

(c) the components of the Affected Implant were mis-sized or not compatible; or

(d) the Claimant had an infection that arose during or as a result of the implantation of the Affected Implant and the infection was confirmed by positive culture; or

(e) the Claimant had an allergic reaction to his or her Affected Implant, where the allergy was likely to have pre-dated the onset of symptoms such as pain, swelling and decreased range of motion; or

(f) of trauma; or

(g) a substance other than alumina particles was the cause of the Abnormal Wear,

and Abnormal Wear caused by alumina particles did not make a material contribution to the failure of the Claimant's Affected Implant.

4. Where the assessment raises an issue of material science or implant analysis arising from the application of, for example, paragraphs 1, 2(a), 2(b)(i), 2(b)(ii) or 3(g) and you do not have expertise in material science or implant analysis, you must contact Norton Rose Australia in order to request advice or evidence on that issue. Such additional evidence that is then provided must be taken into account when providing your opinion.

Please provide a written report of your opinion to us within 28 days of receiving this letter and at the same time please also return the enclosed materials to us.

Yours faithfully

[Signature]

cc [Claimant's lawyer]