ODEP Assure

An ODEP service to monitor the impact of design changes on an implant's ODEP rating

Service Description

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Document Control

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ODEP
Orthopaedic Data Evaluation Panel

NEC

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Introduction

The Orthopaedic Data Evaluation Panel (ODEP) provides ratings for implants and plays an important role in providing an independent assessment of the performance of an implant; providing assurance to patients, clinicians, procurement managers of its safety and expected benefits.

This document describes the ODEP Assure process for handling changes to an existing ODEP-rated implant which do not merit a re-set of its rating i.e., where ODEP does not see a significant risk of a "minor modification" leading to an unexpected and poor outcome.

Background

Implant technology continues to develop to meet evolving requirements and to exploit new and emerging knowledge and techniques in medical science. In addition to product innovations, implants are also subject to ongoing incremental changes and adaptations. These can range from small changes to radical product redesigns, as well as the introduction of line extensions to existing products (such as new product sizes within a brand), or a change in the manufacturing process of a particular aspect of the implant. All such changes, whether large or small, are assessed through a regulatory framework with oversight by an independent Notified Body to assure safety and effectiveness of the changes.

On occasion, ODEP is asked by a manufacturer to retain the ODEP rating for their implant following such a modification. Historically there have been cases where seemingly "minor" modifications to an existing implant have resulted in major changes in its performance and consequent poor patient outcomes. Major design changes are therefore unlikely to be accepted into the ODEP Assure service. ODEP sees these as essentially constituting the introduction of a new implant and will require it to re-start its ODEP journey, through "Pre-Entry" or, preferably, through Beyond Compliance with a Pre-entry A* rating.

The main challenge for ODEP, therefore, is to consider the extent to which changes to an implant should result in the removal or retention of its ODEP rating.

It is ODEP's policy to be cautious, whilst at the same time not wishing to deny patients access to a well-established, effective implant by removing an ODEP rating where patient safety does not seem likely to be compromised.

ODEP Assure

ODEP Assure is a process for modified implants that have been assessed by ODEP, and ODEP have agreed that it can keep its present rating.

It provides assurance that the implant design change, which has been carefully assessed by the Panel, is being independently monitored on an ongoing basis in sufficient detail as to be able to distinguish the performance of the modified

implant and track this performance against that of its original ODEP-rated parent.

Under ODEP Assure, the manufacturer must provide independently collated and analysed evidence of the observed outcomes for the modified implant in comparison to both the "parent" implant as well as relevant ODEP benchmarks. A primary source of the evidence needed will be from registries. Registries, such as the National Joint Registry (NJR) and other national registries, enable a manufacturer to request a bespoke report to compare a product variant against its wider product group. The manufacturer will be required to provide ODEP with such evidence on a regular basis (quarterly unless otherwise specified), which will be assessed through ODEP's regular review meetings.

The duration of ODEP Assure monitoring required for any one implant may vary based upon the consideration of the Panel on a case-by-case basis. It is likely to be a three-year monitoring arrangement in most cases but clearly the performance of the modified implant will be the deciding factor.

The implant's details on the ODEP website will be edited with a statement indicating that it has been subject to a modification and that it is in the ODEP Assure process, with associated dates.

N.B.: For implants in use within the jurisdiction of the NJR, should the outcome performance of the modified implant reach the threshold for it to be an outlier, the Medicines and Healthcare products Regulatory Agency (MHRA) and the NJR Implant scrutiny committee will be notified. This is in line with ODEP's standard code of conduct.

ODEP Assure is complimentary to existing implant surveillance processes. Figure 1 below illustrates how the ODEP Assure process fits within the wider implant surveillance lifecycle.

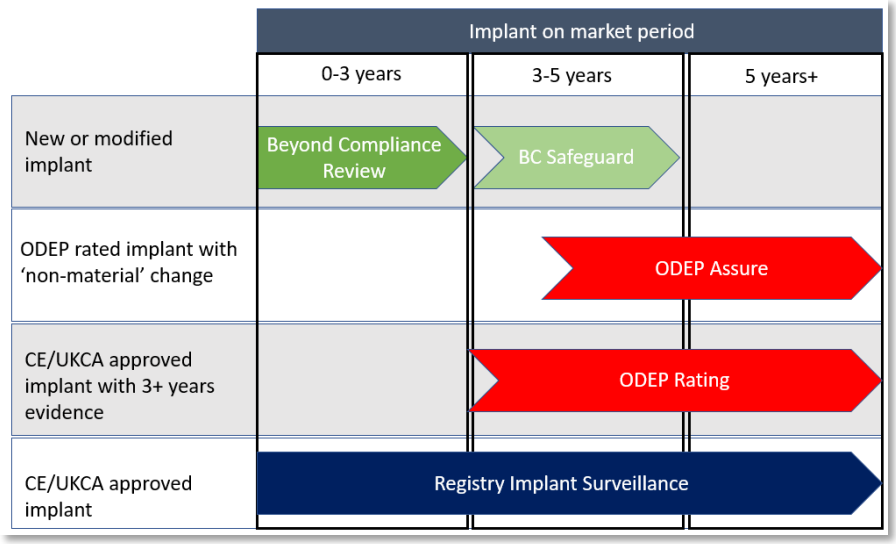

Figure 1: ODEP Assure within the wider Implant Surveillance Lifecycle

ODEP Assure Process

If a manufacturer changes, in any way, an implant or its method of production, whilst wishing to keep its ODEP rating, they must declare it to ODEP. In these circumstances the manufacturer will contact ODEP and request a meeting where details of the proposed change are presented to the Panel. The Panel will apply their expert knowledge of the type of implant and may invite the views of external experts, such as Bioengineers.

Close attention is paid to the view of the Notified Body dealing with the proposed change, taking note of any restrictions they have placed on it, such as the necessity for a full clinical investigation, its rate of introduction to the market and any other conditions.

ODEP will take a considered view as to the extent of the changes and whether they are likely to have a 'material' effect on the implant's performance in comparison to its "parent" and other relevant ODEP benchmarks. When it agrees that it is unlikely that the changes will have a deleterious effect on the performance of the implant, the manufacturer will be offered the opportunity of having the "new" implant monitored by ODEP Assure.

Service Description

Following ODEP's acceptance of a modified implant into ODEP Assure manufacturers must adopt the following process to submit their evidence on a frequency agreed by ODEP (a flow diagram of the acceptance process is included as an appendix to this document).

1. Go to the ODEP website (https://www.odep.org.uk/) and under the "Events" menu at the top of the page check the ODEP calendar to find the next suitable ODEP meeting which aligns to the implant's agreed monitoring frequency. ODEP Assure submissions must be submitted via the ODEP website at least 2 weeks in advance of the meeting's date.
2. Under "For Manufacturers", select the menu option "Submit a product" and download the ODEP Assure version of the ratings assessment form for the relevant joint type.
3. The evidence entered into the form must be obtained from an independent and reliable source, e.g. a recognised registry, and output by the source in a way that populates the ODEP Assure form in the prescribed format. The implant variant must be clearly identified by means of its catalogue numbers and (if necessary) batch or lot numbers.
4. Complete the submission form and upload it using the "Submit a Product" facility on the same web page.
5. You will receive an email receipt from ODEP Admin confirming that your submission has been received and has passed summary inspection.

   N.B.: ODEP is not responsible for ensuring accurate completion of an ODEP submission form, that lies with the manufacturer. ODEP has the right to

reject a submission form at its assessment meeting if it is concerned that important evidence has been omitted or misrepresented. Any resulting delays may put the implant's ODEP Assure process timetable at risk.

6. Within 2 weeks of the meeting ODEP will expect to communicate to the manufacturer by email the findings of its review of the submitted evidence. The result will either be "Accepted", "Rejected" or either of these with conditions attached. These conditions may be a request for clarification or for further evidence. Where a submission has been rejected, the manufacturer will be provided with the reasons for rejection and offered the opportunity to discuss the best way forward.

7. Where the decision is "Accepted" the implant's entry on the main ODEP site remains unchanged. This also applies even where the initial decision is "Rejected" but while it remains under active discussion between ODEP and the manufacture.

8. Where the decision is "Rejected" and ODEP has decided the implant must exit the ODEP Assure process, the manufacturer will be formally notified by email and the reference to ODEP Assure on the website will be removed.

Appendix 1: Process Flow Chart