

Use of IFU's in Connection with Four D Dental Dam Device

Affected Device

Latex Dental Dam

Many medical devices include instructions for use (IFU) or a safety sheet. Risk assessments have suggested that an IFU/safety sheet may mitigate some risks to the use of a Device. Four D have not considered inclusion of an IFU necessary with their Latex Dental Dam Device. This document provides a rationale why an IFU has not and will not be provided with the Device.

Rationale

The reasons for providing an IFU/safety sheet are:-

- To provide the user with information on the designated use of the and associated contraindications.
- To provide the user with safety information regarding setup and use of the Device.
- To provide the user with allergy information.
- To provide the user with storage information.

The reasons for not providing an IFU/safety sheet for the stated Four D Dental Dam Device are:-

- The Device is only to be used by qualified professionals which is clearly stated on the Device labelling.
- The qualified professional will adapt the specific use of the Device to the requirements of each patient and so it is not possible to detail this in an IFU.
- The Device is generally used with other equipment to form a system. The details of the equipment and system will vary according to the nature of the procedure and preference of the user. The user is trained in how to combine the elements of the system in an appropriate way.
- The Device cartons contain the required safety, storage, and allergy warnings.
- The Devices have been in widespread use for more than 40 years without incident and have never included an IFU or safety sheet. Therefore, they are deemed safe to use without these items.

Reflecting on above and taking into account the risk factors it has been decided not to provide an IFU or safety sheet with the Device detailed above.

A handwritten signature in black ink, appearing to read 'R. Gogerty'.

Richard Gogerty
01-MAY-2021