SINGLE USE DENTAL INSTRUMENTS
1/24 Hoopers Road, Kunda Park, QLD 4556 AUSTRALIA
+61 (0)7 5445 6486 | sales@sudinstruments.com

INCIDENT GUIDELINES

The following document will outline the necessary steps to report an adverse event to Single Use Dental Instruments to ensure we are able to adequately rectify the event. Where possible the document will provide guidelines on what to do and includes a form to fill in that is required for each adverse event.

What should be reported

We ask that you report any Single Use product which has been involved in an adverse event or could potentially lead to an adverse event.

Potential problems include but are not limited to:
- deficiencies in labelling, instructions or packaging
- defective components
- performance failures
- poor construction or design.

How to report the event

We ask that you contact Single Use to notify them of the adverse event within 24 hours of the incident occurring. This does not include supplying all the supporting and necessary information. Details of what Single Use require to complete a thorough investigation of the event can be found below.

You will be provided with the most up to date copy of the Incident Report Form when notifying Single Use of an adverse event.

What to do with the device

At the time of the incident take as many pictures of the device as possible. These pictures will need to be supplied to Single Use Dental Instruments with the Incident Report Form.

Please keep the device related to the incident and its associated packaging until you are contacted by Single Use Dental Instruments and advised what to do.

If the device has not been used on a patient and is not considered clinical waste, it can be stored using whatever safe means allow you to keep the device and packaging until further instructions are given.

If the device has been used and is considered clinical waste, the device should be double packaged in plastic bags designed for transporting bio-hazardous objects. If instructed to return the device to Single Use Dental Instruments you will be sent a sharps container to seal the device and plastic bags in for transport. The outer package must be clearly labelled with the contents and warnings if the device is contaminated.

Complete Incident Report Form

Complete the supplied Incident Report Form and return to Single Use within 3 days of initial contact regarding the adverse event. It may be necessary for Single Use to contact the person reporting the event in order to receive a verbal description of the event. It is not necessary for us to know specific details related to the patient or personnel involved in the incident.

What happens next

Single Use will endeavour to provide an appropriate response within 5 working days of receiving the completed incident report form. The Incident Report Form and associated images, the description of the event, and where possible the device, will be used to determine the severity of the incident.

Our manufacturing includes very high-quality management systems which are designed to minimise adverse events related to manufacturing. However as with any process there are unforeseen variables which cause isolated manufacturing defects. The information provided to Single Use in conjunction with the report will allow us to determine whether the adverse event may have occurred batch wide or is an isolated manufacturing event.

If action is considered necessary, it may involve any of the following:
Replacement – if goods were found to be faulty, they will be replaced free of charge or a refund may be offered.
Safety Alert – information relating to the correct use of the device to inform those affected by the problem.
Recall - removal of goods from sale or use for reasons relating to safety. In this case replacement of the remaining stock will be provided.

Post incident procedure

A representative from Single Use will contact the person who has reported the event to allow them to provide any feedback. This can be about how the event was handled and/or the outcome of the event.

Depending on the outcome of the event it may be necessary for a representative of Single Use Dental Instruments to meet with the involved parties to discuss the adverse event in more detail.

If at any point in the adverse event procedure you are unhappy with the process, please inform a member of our staff immediately.

SINGLE USE

SINGLE USE DENTAL INSTRUMENTS
1/24 Hoopers Road, Kunda Park, QLD 4556 AUSTRALIA
+61 (0)7 5445 6486 | sales@sudinstruments.com

INCIDENT REPORT FORM

(This form needs to be downloaded and saved before completing)

A Incident Reporter

Date of Report: _____ Date of Incident: _____

Name: _____ Position: _____

Phone: _____ Email: _____

Organisation Address: _____

B Product Identification

Product SKU: _____ Lot Number: _____ Expiry Number: _____

Please provide any additional product information relevant to the adverse event:

C Incident

1. Is the device issue related to:

- ☐ Packaging
- ☐ Damaged goods
- ☐ Broken in use
- ☐ Labelling
- ☐ Defective device
- ☐ Not fit for purpose

2. Has the device been retained and is able to be shipped to Single Use? ☐ Yes ☐ No

3. Were suitable pictures of the device taken at the time of the adverse event? ☐ Yes ☐ No
If YES please email to sales@sudinstruments.com with this Incident Report Form.

Provide a brief description of the adverse event: **Please do not provide any personal details of any patient or clinician involved*

4. To the best of your knowledge was the device being used for its intended function?
☐ Yes ☐ No ☐ Not Applicable

5. Was anyone (patient or clinician) harmed during the adverse event? ☐ Yes ☐ No
If **YES** please provide details of the injury:

SINGLE USE DENTAL INSTRUMENTS
1/24 Hoopers Road, Kunda Park, QLD 4556 AUSTRALIA
+61 (0)7 5445 6486 | sales@sudinstruments.com

OFFICE USE ONLY

D Receiver Information

Report Number: _____ Adverse Event Date: _____

Date Incident Report Form Received: _____ Receiver Name: _____

E Resolution

Resolved Date: _____ Resolver Contact Name: _____

Provide a brief description of the adverse event resolution:

Has the resolution and copy of the Incident Report Form been supplied to the Incident Reporter? ☐ Yes ☐ No

Contact details of person sent the resolved adverse event:

Name: _____

Position: _____

Email: _____