INCIDENT INVESTIGATION PROCESS

Quarantine Device
CUSTOMER

- Retain accessories and consumables used during the mission

Request Device Uplift
CUSTOMER

You can find the device uplift form here:

https://knowledge.theortusgroup.com/id-like-to-return-my-device-for-service

Or, contact medsupport@ortus.co.uk for assistance

The Ortus Group Begins Investigation
ORTUS GROUP

Technical Review
MedServ

SBARDR*
***if required**
Clinical Application Specialist
*if required

Device Repaired*
***if necessary**
MedServe/ MANUFACTURER

Your organisation will be contacted by the Ortus Group before any repair work is carried out on the device

Device Returned to Customer
ORTUS GROUP

Request Investigation
CUSTOMER

Contact MD-Vigilance@ortus.co.uk

Include the following details in your email:

- Date and time of incident
- Incident reference number
- Brief description of events
- If the event was declared a Serious Incident

Complete & Return Incident Investigation Form
CUSTOMER

You will be sent a form by MD-Vigilance@ortus.co.uk

- Include as much information as possible
- The starred sections are mandatory - **the investigation cannot be completed without this information**
- Return to MD-Vigilance@ortus.co.uk

Device Returned to Manufacturer*
***if necessary**
ORTUS GROUP

In certain circumstances The Ortus Group will request that the manufacturer investigates the incident

Incident Report Shared
ORTUS GROUP

The Ortus Group will share the incident report with you, and ensure you are happy for the device to be returned to you

FOR FURTHER INFORMATION SEE THE QUICK GUIDE "**INCIDENT INVESTIGATION REPORTING**" OR CONTACT MD-VIGILANCE@ORTUS.CO.UK