

Complaint Handling

AtriCure

WHAT IS A COMPLAINT

Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

REPORTING A COMPLAINT

WHEN

Report a complaint immediately after you become aware of a potential deficiency.

- **All** locations must report the complaint within **24 hours** of awareness.

Any delay could lead to serious regulatory and compliance consequences for AtriCure. **You are AtriCure.**

CONTACT INFORMATION

Complete required information email to:

PComplaints@AtriCure.com. Do not send duplicate emails to Complaint Coordinators.

For any questions or concerns, worldwide, phone the Product Safety and Surveillance Department at **1-866-349-2342, option 6**, Mondays through Fridays, 8AM-5PM EST. Messages can be left after hours.

WHAT

The following minimum information is required:

- Complainant contact information
- Information about the product involved
- Involvement of other equipment
- Information regarding potential user or patient impact, such as injuries, reactions and other adverse events
- Details of the event and the circumstances surrounding the event (Who, What, Where, When, How and Why)
- Location of any failed device(s) and availability for return or inspection

HOW

Supply these details and additional information to support internal investigations and information that the Regulatory Authorities may request using the forms listed below, as applicable.

Requests copies of forms through PComplaints@AtriCure.com.

Location of Complainant	Form
US	Form 381 Complaint Information Form
Outside the US	Form 433 Customer Observation Form

REQUESTING A RETURNED GOODS AUTHORIZATION (RGA) NUMBER FOR COMPLAINT PRODUCT RETURNS

RGAs are initiated through the **PComplaints@AtriCure.com** system.

- Upon request, a RGA number will be provided to you via an email confirmation from the complaint coordinator.
- **IMPORTANT:** An RGA number will not be provided until all required complaint information is provided to the complaint coordinator.
- Ensure that the RGA number is clearly written on all packages being shipped back to AtriCure, LLC.
- Ship the product to the designated
 - AtriCure location
 - FedEx account number
 - Name of the recipient
- Package product for returns as directed in the product specific Instructions for Use to meet regulated mandated shipping requirements.

RETURN THE MATERIAL As Soon As You Receive the RGA Number

Contact AtriCure's Toll Free Customer Service Number **1-866-349-2342, option 6** if you have any further questions regarding product returns for complaint investigation.

Exception: For EU capital only returns, contact AtriCure Europe BV at **+31 20 7005560** to obtain an RGA number.