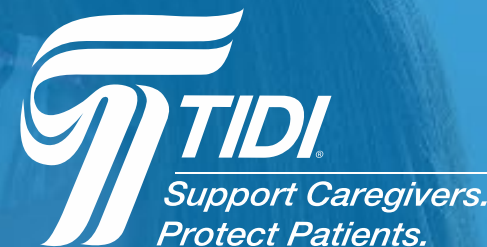


# Complaint Handling Training for Distributors & Sales



# What is a Complaint?

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A Complaint is any written, electronic, or oral communication that alleges deficiencies related to the:

- Identity
- Durability
- Quality
- Safety
- Reliability
- Effectiveness
- Performance

of a device (including its labeling and packaging) AFTER it is released for distribution. **Did the device function as intended?**

# Why do we take complaints?

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- To identify and correct potential problems related to product in the field. If there is potentially bad product out there, TIDI NEEDS To Know so we can address the issue ASAP.
- It's good customer service. Responsive complaint handling helps all of us KEEP our CUSTOMERS.
- It closes the loop between design and the post market experience. Complaints are an input to design iterations and feedback.
- It's the law! US law and most other countries require medical device manufacturers to have documented systems for receiving and investigating complaints (21 CFR 820.198 for example).

# What is Your Role in Complaint Handling as a distributor or Sales Rep?

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- Report all complaints to TIDI's Customer Service and/or Technical Service Dept immediately – as soon as contact is made with you.
  - If you are aware, you are responsible to ensure the complaint is reported.
- Your job is not done until Customer Services / Technical Services has the information for the complaint.
  - Calling someone outside of Customer Service / Technical Service is NOT fulfilling your obligation.
- We may need additional details to support the investigation, and in that case, we may reach out to you for assistance in collecting the product or additional information.

# Vigilance Reporting of Adverse Events

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- You may be responsible for reporting a vigilance report for an adverse event to a regulatory body depending on the country requirement.
- The reporting decision, investigation and report will be completed in partnership with TIDI.
- Communication of an adverse event and reporting requirements necessitates timely collaboration with TIDI. Some countries have short reporting timelines, and so we will need to start the complaint process ASAP.



# TIDI Customer Service / Technical Service Contact



## Customer Support

TIDI

Toll Free: +1 800.521.1314  
Toll Free Fax: +1 800.837.7770

POSEY

Toll Free: +1 800.447.6739



## Email TIDI Products

TIDI

[excellence@tidiproducts.com](mailto:excellence@tidiproducts.com)

POSEY

[Technicalservices@tidiproducts.com](mailto:Technicalservices@tidiproducts.com)

# What complaint information to report

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1. **Contact Information** (customer's name, phone #, email, etc.)
2. **Date** you learned of the information
3. Any **patient involvement** AND the patient condition (injury/no injury)
4. Description of the **Issue** (when, what, how)
5. **Product information** as available
  - Product Model/Name
  - Serial or lot number
  - Either an example of the defective product or a picture which demonstrates the product defect or malfunction

\*Note – if you do not have all the above information, immediately report what information you do have. Do not wait to report while collecting additional missing information



# Return of Product Related to Complaint

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- As a distributor or sales rep for TIDI, TIDI may need your help in collecting product from your customers related to a complaint.
- Collecting samples of the actual product in question help TIDI determine root cause.
- This allows for appropriate corrective action and reduction in repeat complaints.
  - When a complaint is reported to you from one of your customers, please ask for a sample of the product as well.
  - If that is not possible, please ask for pictures of a video of the failure.
    - Thank you for your cooperation in assisting TIDI in complaint investigations!

