

Complaints (& Feedback)

Why is the Complaint Process Important?

- FDA requirement for medical device manufacturers
- Part of good manufacturing practice (GMP)
- Possible time-sensitive FDA reporting

Complaint = Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a Tenex Health device.

What is the Complaint Process?

- Customer reports complaint (verbally, electronically or in writing) to **Sales Rep.**
- Complete Complaint Form QR-85-03-1.
- Submit to Tenex Health within 2 business days at: returns@tenexhealth.com. (949) 238-8124.
- *Note: please notify Tenex Health of any complaints (deficiencies / issues) you find reported in literature, social media or conferences, also.*

Complaint Process (cont'd)

- Tenex must report some complaints to FDA:
 - Involving death or serious injury (or malfunctions that could lead to this): within 30 days of the Aware Date.
 - Requiring remedial action: within 5 days.
- Aware Date = when **Sales Rep** or Tenex employee first receives a report from the Customer.

Complaint Process (cont'd)

- Tenex issues RMA. Please retain and return all MicroTips involved (even with Console complaints).
- Note: MicroTips with patient contact are shipped first to LSO, a facility for decontamination.
- Tenex sends Acknowledgment Letter to Customer/Reporter.
- Tenex completes Complaint Investigation.
- Tenex sends Response Letter to Customer/Reporter, and replacement / returned product, as applicable.

Complaint Process (cont'd)

- Loaner / Replacement Consoles
 - Contact Customer Service: orders@tenexhealth.com, (949) 454-7500
 - Provide: no-charge PO (if necc.), Console S/N, Ship to name and address, next case date
- Replacement MicroTips
 - Provide no-charge PO (if necc.), MicroTip L/N
 - After product decontamination + evaluation
 - Typ. < 30d

What is Feedback?

- Comments / opinions on our product (that do not allege any deficiency).
- Comments / opinions on product aesthetics.
- Suggestions for product changes or improvements (not based on failure to perform as intended).
- Send to: returns@tenexhealth.com,
(949) 238-8124.