

FORMULAIRE DE RETOUR DE DISPOSITIFS / DEVICE RETURN FORM

DEVICE RETURN FORM FOR U.S. COMPLAINTS

Instructions

When to fill out this form
This form shall be completed when returning devices for complaint investigation by KeriMedical for U.S. complaints only.
Sensitive Personal Data Management
In accordance with applicable U.S. patient privacy laws, including HIPAA, we kindly ask that all patient identifiers (such as name, date of birth, or social security numbers, medical record number) be removed from the X-rays and from any related communications.
Please note that returned devices may be subject to destructive testing for investigation purposes. By returning a device you authorize Keri Medical to undertake these investigations.
Shipping Devices for Investigation
For safety reasons, all devices that have been in contact with a patient, blood, body fluids or other biological samples must be cleaned and free from pathogenic micro-organisms before shipping. The shipment must include proof of decontamination demonstrating the disinfection and cleanliness of the returned devices.
INSTRUCTIONS FOR RETURNING A CONTAMINATED DEVICE:
<ol style="list-style-type: none"> Clean and disinfect the device Place the device preferably in an airtight container; if this is not possible, place it in a double polyethylene (PE) bag. Identify the container or bag with a label bearing the complaint number "NCE-XXX." Place the packaged device in a shipping box together with a copy of the completed form. Attach proof of decontamination Ship the package to the following address: <p style="text-align: center;">Medartis, Inc. KeriMedical Post-Market Surveillance 1195 Polk Drive Warsaw, IN 46582</p>

TO BE COMPLETED AND ATTACHED TO THE RETURNED DEVICE

Complaint Number (NCE)	<Specify the NCE number given by Keri Medical >	
Source	Reporter Name:	
	Organization:	
	Address:	
	Phone number/email:	
Product Information	Product Name:	
	Product Reference:	
	Batch no. / Expiration date :	
	Quantity:	
Device Decontamination	<input type="checkbox"/> YES <input type="checkbox"/> NO Decontamination proof must be attached	
Comments :		