

Dear customer,

If you are returning products which have been opened, we must assume that these products are contaminated. Contaminated products represent a health hazard for everyone who comes into contact them.

In order to protect our employees and your employees, we ask you to take the following steps:

1. Returned products contaminated with blood, organic residues and body fluids must be cleaned, disinfected and sterilized prior to the return shipment.
2. The type of disinfection or sterilization has to be stipulated and confirmed in the 'proof of decontamination'.
3. In case of return shipments of **non-contaminated products**, the products have to be packed without any risk of contamination:
 - Product has to be packed in a sealable primary packaging
ATTENTION: sharp edges have to be protected carefully
 - Primary packaging has to be packed in waterproof secondary packaging; packaging has to be labelled with: **danger notice**
 - Secondary packaging has to be packed in a neutral packaging material (cardboard box)
 - 'Proof of decontamination' has to be filled in and confirmed with the reason why the product is not decontaminated
4. A signed 'proof of decontamination' statement and return delivery note must be included in the return shipment.

If you have any questions, please contact us:

Phone: +1.214.550.2879

Email: customercare@kiyoclear.us

Attached please find the 'proof of decontamination'.

Note: Should we not receive the 'proof of decontamination' or a comparable confirmation, we reserve the right to disinfect, clean, sterilize and return the goods to the sender at their own expense.

Thank you,

Your SheepMedical USA Customer Care Team

Proof of decontamination with regard to the safety of medical devices

In compliance with the applicable statutory provisions and, above all, for the protection of our employees, we require a signed "Proof of decontamination" for each return. Please ensure that this "Proof of decontamination" is filled in and enclosed with **each product return** (complaint / repair / other reason for return) and package the product such that no risk of injury or infection exists for our personnel in incoming goods inspection while unpacking.

Article no.: _____ Article name: _____

If possible, please provide information on

Delivery note no.: _____ of [date]: _____ Lot no.: _____

Reason for return:

We hereby confirm that

- the medical device(s) enclosed with the letter has/have **not** come into contact with blood, tissue or other bodily substances/fluids and hygienic safety can be confirmed by signing.
- the medical device(s) enclosed with the letter has/have come into contact with blood, tissue or other bodily substances/fluids and have been disinfected, cleaned and sterilized according to the applicable hygiene requirements for medical devices and the manufacturer's specifications, which we confirm by signing.

Specifications on disinfection, cleaning and sterilization:

- Disinfection and cleaning have been performed manually
 - Disinfection and cleaning have been performed mechanically
 - Steam sterilization (3 min. at 134°C / 15 min. at 121 °C)
 - Other method (please specify)
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- the medical device(s) enclosed with the letter could not be decontaminated! Reason:
-

Practice Name

Signature and full name

Date

Please send the return product with enclosed signed 'proof of decontamination' to:

SheepMedical USA
4514 Cole Ave, Suite 600
Dallas, TX 75205
U.S.A.