

Information Bulletin

Return/Repair of potentially contaminated products

Dear Business Partner,

this information bulletin is based, among other things, on the legal requirements of the Ordinance of Biological Agents and of the occupational safety law and should help summarize measures and information important to us in order to ensure the efficient processing of products you intend to send back.

These products might have had contact with biological agents on your premises and may be contaminated by them. In order to best protect your employees who work with the processing of the products as well as ours, and to be able to carry out testing as well as possible, we ask you to take the following into consideration:

1. Please let us know in advance about every shipment in writing with an explanatory statement.
2. Products which are potentially contaminated with biological agents of risk groups 3 and 4 (Ordinance of Biological Agents) are excluded from return.
3. With only a few exceptions (e.g. hydrocephalus valves), the products should be cleaned after determining a deficiency or after use to minimize adhesion. As far as bodily fluids and tissues, secretions, contrast agents, etc. are not themselves the cause for the product deficiency, such deposits and adhesions should be carefully removed to prevent damage to the product as much as possible. If in doubt, discuss how to further proceed with the manufacturer.
4. If the products come into contact with biological agents (e.g. blood or other bodily fluids), disinfect or sterilize them in such a way that the product remains unchanged, in order to rule out a hazard to the employees. The type and execution of the disinfection/sterilization procedure are to be confirmed on the attached "Decontamination Certificate" form.
5. The product treated in this manner is packaged so that it is safe from contamination as follows:
 - Placement in sealable primary packaging (e.g. sterile bag or comparable bag).
Important: Be particularly careful with parts having sharp edges!
 - Enclose the primary packaging in water-tight secondary packaging (preferably hard packaging).
 - Enclose the secondary packaging in a neutral packaging.
 - Use the accompanying shipping papers of the respective service provider/shipping agent (they contain the corresponding current transportation requirements, e.g. Ordinance on Hazardous Substances for road haulage GGVS)
 - Shipment/transfer to a1 medical.
 - Attach the delivery note or other accompanying written material like the Decontamination Certificate inside the package separately from the products or outside on the package.

On request, we are naturally willing to support you with advice on how to implement these requirements. In this case, please contact the sales representative responsible for you.

Thank you very much for your cooperation.

a1 medical

Attachment: Decontamination Certificate

Decontamination Certificate

Please make sure that this form is being filled out with the utmost care and is enclosed with every product shipment sent to a1 medical.

Complaint no.: _____ Order no.: _____ Other no.: _____

Article sent for...

... repair return other _____

It is herewith confirmed that (please check the corresponding box)

all products which are being sent back under the complaint and order number given above have not been clinically used, and the instruments/endoscopes coming into contact with tissue or tissue fluids (blood/saliva) can be ruled out with certainty and are therefore hygienically harmless.

all products which are being sent back under the complaint and order number given above were cleaned and decontaminated according to a validated processing procedure.

The following methods have been used:

Cleaning and steam sterilization (at least 3 minutes at 134-138°C at >28 psi)

Other method (please describe): _____

Please enclose the processing log of the processing authority/clinic.

The products which are sent back could not be decontaminated. The reasons for this are as follows:

(Articles which could not be decontaminated must be packed and labelled separately. a1 medical reserves the right to refuse the receipt and repair of these articles.)

Date/Place

Signature and stamp of client/clinic

Please Note:

- Put this filled out document inside the package separately from the products or attach it outside on the package.
- When reprocessing the products, it is imperative that the instructions specified by a1 medical be followed. A1 medical takes no responsibility for incorrectly reprocessed products.