



Important safety information

Elsfleth, July, 25 2019

Please ensure in your organization that all users of the products mentioned here and other persons who need to be informed are made aware of this safety information. If you have handed over the mentioned products to third parties, please forward a copy of this safety information to them or inform our contact person specified below

Subject: Use of our products "Medilainer, MediBowl, MediDuo" (all item codes) as carrier shells for sterile instruments/utensils *for* the operating room area

Dear customer,

This letter is intended to inform you of a possible problem with the sterilisability of the above products when used as a carrier for sterile surgical kits used in the operating room area

Purpose:

According to the technical documentation, MediTainer, MediBowl, MediDuo are intended for the reception of body excretions and/or as a collection container for smaller waste in the medical field for short-term use.

The following has been found:

During an official review of the products in sterilised surgical kits using a standard method *for* determining the total germ count, non-sterile carrier shells were detected.

Our products are made of molded fibre material (paper) and therefore cannot be used as a part of a sterile treatment set in the surgical area/operating room area

Possible dangers:

This problem can lead to re-contamination of the surgical utensils and thus could create a possible infection of patients when using a non-sterile surgical kit in the operating room area.

Preventive action:

Please do not use MediTainer, MediBowl, MediDuo" as carrier shells for surgical instruments and surgical utensils or part of another sterile treatment unit for the surgical/operating room area.

Please confirm that we have received this "Important safety Information" and send a confirmation of receipt back to our contact person: b.luebsen@cdl-omnipac.com.

Yours sincerely

25, 2019

Datum: .10., Q21

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