

9. August 2007

Product Safety Advisory notice

Product: Code: CF0200 Flex One Suction Hard Canister (reusable)

Explanation:

A safety issue has been reported to us that suction with our suction reusable devices CF0200 assembled with a 2 liter disposable liner (F0200 (without filter) or F0201(with filter)) could not be performed due to the misalignment of the white bracket and the hard canister. Consequently vacuum can not go through and suction is not occurring. The root cause of the white bracket displacing was due to incorrect torque on the screws.

Our investigation also highlighted the following:

The problem of bracket displacing occurs when the screws, which hold the bracket in the correct position, are not fixed properly and when the canister is used in a basket instead of a rail clamp.

When the canister is used in combination with a rail clamp, the weight of the canister and the force to put the liner into the canister brings the canister down into the correct position to the white bracket. In this case the two holes are in line and the system functions correctly.

When the canister is used with the basket each movement on the bracket (e.g. to connect or disconnect the tubing) may cause the bracket to move down and may cause a misplacement of the two holes which provide the vacuum to the canister.

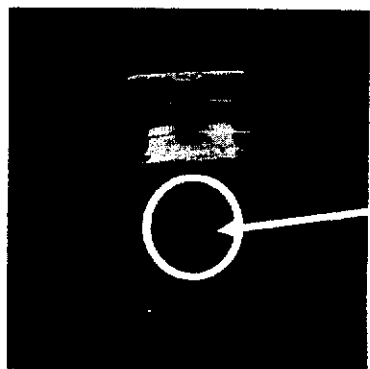
Corrective actions:

Corrective actions on the product design (assembly improvement of the canister to the bracket: modification of changing the screws and the fixation method) and revision of the Directions for Use are in progress.

We have blocked our inventory and only released products which have been checked 100 % and where the bracket is fixed correctly.

In the meantime, please ensure that the following instructions are correctly followed:

- The maximum recommended level of vacuum pressure is 600 mmHg.
- To clean the hard canister, rinse it with water, proceed with a chemical disinfection that cannot damage the polycarbonate, rinse again with water, dry with a clean, dry and non-fluffing cloth or with clean air.
- Do not sterilize the hard canister.
- Should you decide to use an automated means to clean the hard canister, use a chemical agent that cannot damage the polycarbonate and set the temperature to a maximum of 60°C.
- During the installation of the hard canister, ensure that no damage occurs: Check that the holes (which provides the vacuum) of the bracket and the canister are aligned -see photo below. Replace the canister if it is damaged.
- Do not temper, modify or dismantle the hard canister.



Holes are aligned

Exchange of products:

When the new product design has been validated and is available (estimated time frame: 3 months), we will replace the products you have in use.

Contact Information :

If you have any questions regarding this information, please contact your local sales representative or contact for

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