



**Change Notification  
to Users of  
Sartorius Standard  
Filter Capsules**

# Change Notification to Users of Sartorius Standard Filter Capsules



## Introduction

This notification is to inform users of Sartorius standard filter capsules of a design change affecting the polypropylene housing of Sartorius standard filter capsules for the existing filter units.

The use of disposable filter capsules in pharmaceutical and biopharmaceutical production has increased significantly in the last years. Meanwhile filter capsules are an integral part of many production processes. The extended use of filter capsules in biopharmaceutical manufacturing added new requirements onto these filter capsules. Therefore Sartorius AG has decided to introduce a new capsule design for its existing filter units into the market. This new capsule design focuses on design improvements of the capsule housing, offering multiple advantages for users in biopharmaceutical production:

- GMP compliant, easy to operate vent and drain valves with integral hose barb for fluid containment during the venting process
- Imprinted, easy to read labeling including flow direction indication, filter type, pore size, lot-no., piece-no. and operating parameters for optimal traceability
- Broad range of connector styles for flexible integration into any production process
- Optimized capsule design for reduced dead volume, maximized flow and enhanced mechanical stability

## Description of the change

The existing filter capsule design for the existing filter units will be replaced by an improved filter capsule design incorporating the unchanged existing filter units. All materials of construction and production methodologies used for the manufacture of the filter units for the existing and the new capsule design are completely identical. Thereby the filter units used for manufacture of filter capsules of the existing and the new capsule design are completely identical for each product line.

The polypropylene granulate used for the manufacture of the existing filter capsule housing remains identical for the manufacture of filter capsule housings of the new capsule design. Thereby filter capsule housings of the existing and the new capsule design are manufactured of the identical polypropylene granulate.

This change does not involve any filter membrane materials, filter active fleece materials, support fleeces, nor does the change affect the form, fit or function of the filter capsules.

## Comparability Study and Change Classification

Sartorius AG has performed a comprehensive comparability study in order to demonstrate comparability between the filter capsules of the existing and the new capsule design. The comparability study was performed using Sartopore 2 0.2 µm rated capsules of the new and the existing capsule design as model capsules to compare all application relevant data of both capsule designs. As a result of this study full comparability of the new and the existing filter capsule design could be demonstrated.

The results of the comparability study are summarized in a separate document which is distributed together with this change notification.

Consequently this change is classified by Sartorius AG as a **minor change**. (Annual Report)

## Affected Product Lines

The new capsule design will be implemented for all filter capsule product lines starting from 500 cm<sup>2</sup>/0.5 ft<sup>2</sup> (Size 7) up to 4.500 cm<sup>2</sup>/4.5 ft<sup>2</sup> (Size 0) filtration area of Sartorius AG, which includes the following product lines:

- Sartopore 2 (54413...)
- Sartopore 2 Gamma Capsules (54413 G...)
- Sartobran P (52313...)
- Sartolon (51013...)
- Sartofluor (51813...)
- Sartoclean CA/GF (56213.../56013...)
- Sartopure PP2/GF2 (55913.../55713...)

Filter capsules with 150 cm<sup>2</sup>/0.15 ft<sup>2</sup> (Size 4) and 300 cm<sup>2</sup>/0.3 ft<sup>2</sup> (Size 5) filtration area as well as the MaxiCaps product line are not affected by this change!



### Standardisation of package sizes

With the implementation of the new capsule design package sizes of the filter capsules will be standardized to improve logistic processes for our customers. Filter capsules of size 7, 8 and 9 (500 cm<sup>2</sup>/0.5 ft<sup>2</sup>, 1.000 cm<sup>2</sup>/1 ft<sup>2</sup> and 2.000 cm<sup>2</sup>/2 ft<sup>2</sup>) will be supplied in boxes of 4 pieces. Filter capsules of size 0 (4.500 cm<sup>2</sup>/4.5 ft<sup>2</sup>) will be supplied in boxes of two pieces.

### Change of Order Code

To allow for an easy differentiation between the existing and the new capsule design and to assure complete traceability of the change a modified order code will be implemented for the new capsule design. The modification of the order code for capsules of the new design will also reflect the standardisation of the package sizes of filter capsules.

The basic order code of the filter capsules identifying filter material, pore size or retention rate and filter size remains completely unchanged. For filter capsules of the new design at the 4th digit "1" is replaced by "5" to differentiate the existing from the new design.

At the 16th digit (final digit) for capsules of size 7 and 8 "B" (package of 5) is replaced by "A" (package of 4). For capsules of size 0 "V" (package size of 2) is added at the final digit.

### Schedule for Market Introduction and Conversion Period

The market introduction of the new capsule design starts in February 2005 with the Sartopore 2 standard capsule product line. The market introduction of the new capsule design for all other filter capsule product lines follows a defined time schedule. This time schedule for market introduction is as follows:

Product Line	Order Code	Market Introduction of New Design
Sartopore 2	54453...	March 2005
Sartofluor	51853...	May 2005
Sartolon	51053...	May 2005
Sartopore 2 Gamma	54453 G...	t.b.d.
Sartobran P	52353...	November 2005
Sartoclean CA	56253...	January 2006
Sartopure GF Plus	55553...	March 2006
Sartoclean GF	56053...	March 2006
Sartopure PP2	55953...	May 2006

For each product line we guarantee the availability of filter capsules of the existing capsule design for 2 years after market introduction of the new capsule design of the respective product line. We encourage our customers to contact their local Sartorius organisations in order to arrange the implementation of the new capsule design.

### Example of Order Code Change for Sartopore 2 Capsules\*

Order code existing design	Package Size [Pieces]	Order code new design	Package Size [Pieces]
544 13 07 H0--SS	1	544 53 07 H0--SS--V	2
544 13 07 H9--SS--A	4	544 53 07 H9--SS--A	4
544 13 07 H8--SS--B	5	544 53 07 H8--SS--A	4
544 13 07 H7--SS--B	5	544 53 07 H7--SS--A	4

\* with SS-connector at inlet and outlet

Goettingen, January 2005

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