ADVANCED MATERIALS AND DESIGN FOR IMPROVED FILTER PERFORMANCE

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Introduction

Developing an effective new Ostomy pouch filter presents several challenges in materials selection and product design. An ideal filter will:

- Provide high air flow through the filter to prevent pouch ballooning
- Prevent escape of odors through the filter
- Prevent leakage of liquids through the filter
- Function without the need for user intervention

Currently, available filters meet some of these needs, but there is a continuing need for improvement in design and materials to enhance the performance for all these features. In particular, current filters may provide fast air flow to diminish pouch ballooning, while not providing sufficient liquid protection for the filter. Conversely, some filters have a high degree of liquid protection at the expense of air flow capability. In addition, all filters can benefit from increased deodorization capacity to prevent the escape of embarrassing odors from the pouch.

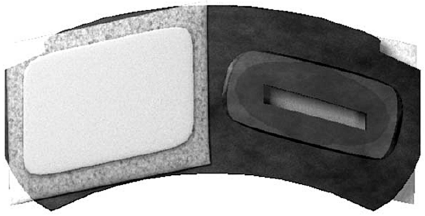
This report describes the design and development of the new Hollister AF300 pouch filter, showing how advanced materials and careful design work together to provide a higher level of performance for this important component of ostomy pouches. The performance advantages of the AF300 filter are demonstrated using laboratory testing with comparison to select competitors.

Materials

Control samples #1 are ConvaTec SUR-FIT Natura filters*. This filter has a protective membrane on the inlet side of the filter.

Control samples #2 are Coloplast SenSura filters*. This filter has a protective membrane on the inlet side of the filter.

Test samples are the Hollister AF300 filter* shown below. This filter has protective membranes on both the inlet and outlet sides of the filter.



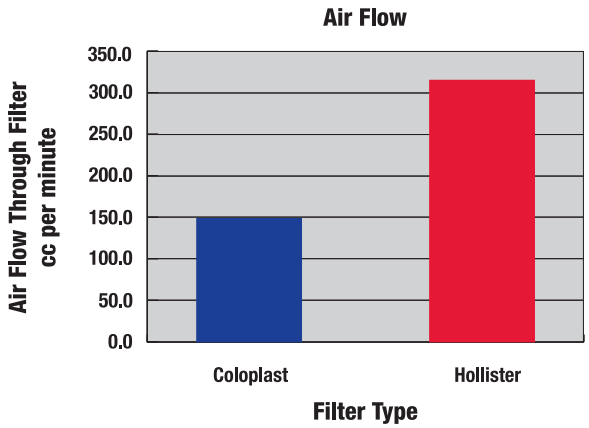
AF300 Filter

Methods

- Air flow Measurements were made using an industry standard Gurley Densometer instrument that measures the time required to pass a fixed volume of air (100 cc) through the filter.
- Liquid Protection was determined by measuring the amount of pressure required to force water to enter the filter.
- Deodorization Capacity was measured using a modification of the British Standard 7127, Part 101, Appendix H. In the current report, deodorization capacity was measured for two odor gases: Hydrogen Sulfide (HS) and Methyl Mercaptan (MM).

Results: Air flow

- Gurley Densometer results show the rate of air flow through each type of filter.
- The air flow rate through the new AF300 filter is greater than the flow through the Coloplast filter (Bonferroni confidence intervals, $\alpha = .05$).
- This air flow rate is designed to allow gas to escape the pouch more easily and to minimize the possibility of pouch 'ballooning.'



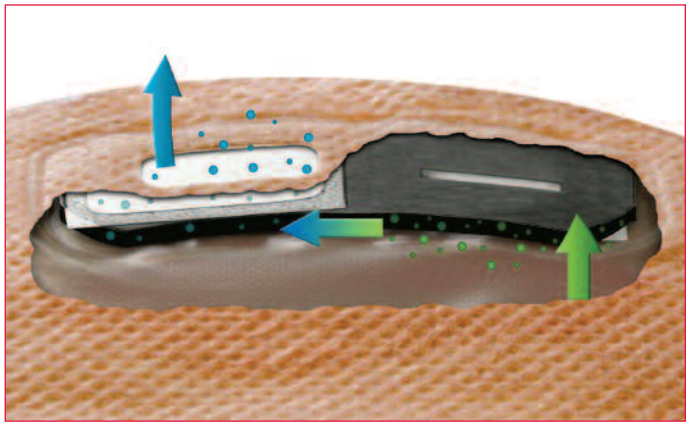
Results: Water Intrusion

- The semipermeable membrane of the AF300 filter protects the filter by preventing water from entering.
- The AF300 filter uses a special GORE™ Medical Membrane on both the internal and external sides of the filter.
  - The internal membrane protects against fluid leakage from the pouch contents.
- The AF300 filter using this GORE™ Medical Membrane has shown up to 10 PSI of water pressure resistance.
- The AF300 filter outer membrane, which is made from the same material as the internal one, eliminates the need for covering the filter outlet during bathing or other water activities.

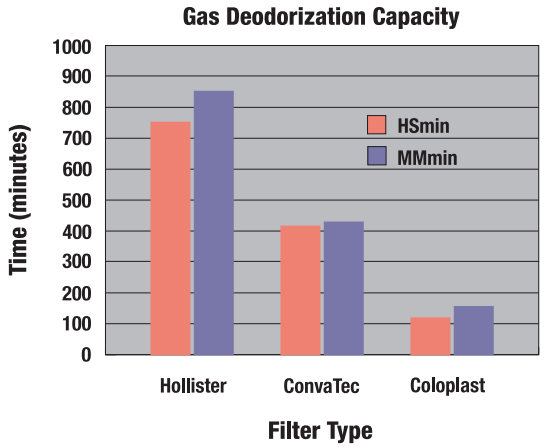
* Data on file.

Results: Deodorization Capacity

- Laboratory measurements show the capacity of each type of filter to deodorize both Hydrogen Sulfide and Methyl Mercaptan (two of the main elements of flatulence).
  - Hydrogen Sulfide smells like rotten eggs.
  - Methyl Mercaptan smells like rotten cabbage.
- The relative deodorizing capacity for each gas is shown in the graph to the right for ConvaTec SUR-FIT Natura filter, Coloplast SenSura filter and the Hollister AF300 filter.
- The AF300 filter has greater capacity for both of these important components (Bonferroni confidence intervals, $\alpha = .05$).
- As shown below, the specially designed flow path for gases passing through the AF300 filter helps ensure efficient use of the activated carbon deodorizer in the filter package.



AF300 Filter



Discussion

This report has shown how advanced materials and smart design work together in the development of improved products. We have used laboratory methods during development to test the new filter for several key performance attributes. These relationships between the identified needs of our customers and the material and design choices made in development are shown in the table below:

Customer Need	Materials and Design Choices to Meet This Need
Reduce pouch ballooning	• GORE™ Medical Membrane with high air flow properties • Effective surface area for more air flow
Prevent odors from escaping the pouch	• Activated carbon with special additive treatment • Controlled air flow path to make efficient use of activated carbon
Prevent leakage of fluids through the filter	• GORE™ Medical Membrane with hydrophobic/oleophobic surface repels fluids • The semipermeable membrane of the AF300 filter protects the filter by preventing water from entering
Function automatically without user intervention	• External membrane eliminates the need for filter cover during water activities

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