

CELANEX® MT® PBT – EASI-FILL VALVE BK361 SUCCESS STORY BESPAK'S INNOVATIVE EASI-FILL VALVE: KEY COMPONENTS MADE FROM CELANEX PBT

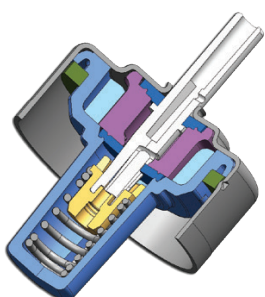
Pressurised metered dose inhalers (pMDI's) are used by patients suffering from asthma and COPD to deliver drugs directly to the lungs for effective relief of symptoms. The drug is dissolved or suspended in a solvent, which is delivered at high pressure via a valve assembly. PMDI's are frequently used as an emergency rescue remedy in the case of a severe breathing issue, and they are critical in relieving symptoms so the patient can breathe easily again. The standard way to use a pMDI is to first shake and then prime the device by releasing a dose into the air before the patient uses it to deliver the medicine to the lungs. This procedure costs time and is wasteful.

To solve this problem, Bespak, a Recipharm company based in the United Kingdom and dedicated to the world class supply of advanced medical devices, has developed a new pMDI valve. The Easi-fill BK361 valve has a very innovative design, which requires no priming. The valve fully drains and refills each time it is used. The patient can use it immediately, which is very important in emergency situations, where time and simplicity is critical. Furthermore, there is no wasted drug due to the priming procedure, so the devices last longer. Design for pMDI's is very difficult; the components are small and the tolerances are very tight.

The selection of materials must also take into account that the components are permanently in contact with the dissolved drug, which presents a challenge in terms of drug stability and extractables — chemicals from the valve materials which are affected by the solvent. Bespak has achieved this new design supported by Celanese experts, who advised Bespak during the material selection process. The material of choice, CELANEX® MT® PBT 2402MT, combines good tolerance and flowability with chemical resistance, and an extractable profile which is suitable for drug/solvent contact over the lifetime of the device. Therefore, precision and moldability are assured, leading to faultless operation during the life of the device.

Celanex® MT® PBT Advantages:

- Dimensional stability
- Dimensional tolerance
- Accuracy of the components
- Change Control
- Regulatory compliance
- Medical Technology Service Package



BK361 Easi-fill





CELANEX® MT® PBT 2402MT - FOR COMPLEX MEDICAL DEVICES WITH LONG TERM STABILITY AND EXCELLENT WEAR

Physical properties	Value	Unit	Test Standard
Density	1310	kg/m ³	ISO 1183
Melt Volume rate (MVR)	40	cm ³ /10min	ISO 1133
MVR test temperature	250	°C	ISO 1133
MVR test load	2.16	kg	ISO 1133
Mold shrinkage-parallel	1.8-2.0	%	ISO 294-4

ADVANTAGE: MEDICAL SERVICE PACKAGE

- Biocompatibility tests (USP 23 Class VI, ISO-10993)
- Change Control
- Enhanced production, quality control and testing processes
- FDA Drug & Device Master File listing
- Material compliance to FDA and BGWV regulations

CELANEX® MT® PBT 2402MT IS AN UNFILLED, EASY FLOW THERMOPLASTIC POLYESTER

PROPERTIES

- Good wear and slip characteristics
- Good chemical resistance to polar and non-polar solvents
- Modified impact strength
- Excellent gamma ray resistance up to 50kGy

APPLICATIONS

- Drug delivery systems
- Metal gear replacement
- Functional parts with high dimensional precision and stability requirements
- Tribological systems
- Sliding mechanisms
- Snap fittings
- Clips and clamps

PROCESSING

- Injection molding

This publication was printed based on Celanese's present state of knowledge, and Celanese undertakes no obligation to update it. Because conditions of product use are outside Celanese's control, Celanese makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Nothing herein is intended as a license to operate under or a recommendation to infringe any patents.

Celanese®, registered C-ball design and all other trademarks identified herein with ©, TM, SM, unless otherwise noted, are trademarks of Celanese or its affiliates.

Copyright © 2015 Celanese or its affiliates. All rights reserved.

Brochure Publication Number: PBT-024-BespakEasi-FillValve-CS-EN-1015

Contact Information: healthcare.celanese.com healthcare@celanese.com

Americas

8040 Dixie Highway, Florence, KY 41042 USA
Product Information Service
t: +1-800-833-4882 t: +1-859-372-3244

Customer Service
t: +1-800-526-4960 t: +1-859-372-3214

Europe

Am Unisys-Park 1, 65843 Sulzbach, Germany
Product Information Service
t: +(00)-800-86427-531 t: +49-(0)-69-45009-1011

Asia

4560 Jinke Road, Zhang Jiang Hi Tech Park
Shanghai 201203 PRC
Customer Service
t: +86-21-3861-9266 f: +86-21-3861-9599