

# Bag-on-Valve – Optimal Solution for Pharma Products



**With the total separation of product and propellant, a bag with superior barrier properties, and complete oxygen protection, Bag-on-Valve is the optimal solution for pharmaceutical and health products. Many products can be made in a sterile presentation. Sterility is guaranteed – even when the can has been opened and used frequently over a long period of time.**

With tax-based healthcare services burdened by increasingly higher costs for pharmaceuticals and the ever-more stringent regulation governing the introduction of a new drug on the market, there is a growing trend moving from prescription (Rx) to non-prescription, over-the-counter (OTC) products. It has turned out that the Bag-on-Valve (BoV) may in several cases be a suitable technology for products to make this switch, as marketers are looking for modern, innovative packaging that can attract consumers.

Products for which the pharmacological claims are not the primary function can often be classified and registered as medical devices utilising the BoV technology. The physical or mechanical function of a medical device spray product is suitable for this modern aerosol system. Being classified as a medical device, rather than pharmaceutical, a product can reach the market much faster, and in the EU, an application for registration can be made once instead of the more complicated and costly drug application using the centralised, decentralised or mutual-recognition procedures. Registering an OTC-product as a medical device can provide a more cost-effective way of entering the European market.

There is therefore an increased interest in giving old products new, more convenient applications as well as finding niches for totally new



products using the BoV technology for administration.

Originating in the cosmetics industry, BoV technology has entered into the pharma industry where it is expanding, and now covers saline/seawater nasal sprays, wound cleansing/irrigation sprays, eyewash sprays, dermal drug delivery products, disinfectant sprays and veterinary products, among others.

## **Convenient and Environmentally-friendly**

The Bag-on-Valve consists of a rolled-up multi-layered flexible pouch attached to an aerosol valve. In the production of a BoV product, compressed air or nitrogen is charged into the can, and an aerosol valve with the bag attached is crimped onto the container. The formulation is forced through the aerosol valve stem to fill

the bag. When the spray button is pressed, the product is squeezed out of the bag by the compressed air/nitrogen, which creates the dispensing as a spray, cream or gel (see graphic for details).

As such, BoV is an ideal barrier pack for liquids, gels, creams and lotions, keeping high product integrity and protection against oxygen. Hence, for many formulations the amount of preservatives needed is very low and may in some cases be excluded altogether. For sterile products it is possible to arrange aseptic filling or use gamma irradiation to achieve sterility. The propellants eliminate the need for pumping out the content, which often is a great advantage compared to, for example, pump sprays or trigger sprays. Instead the content can be sprayed, smoothly and evenly, giving the user perfect control

## PACKAGING

over the administration of the product. Another major convenience connected with BoV is the fact that it is possible to spray from any angle without losing pace or force in the spray. The degree of emptying is very high, up to nearly 100 per cent for water-based solutions.

If desired, a Bag-on-Valve aerosol can produce a smooth and even layer of a film-forming product or a protective barrier cream to the skin – without any need for additional hand-spreading, thus resulting in advantages in hygiene and patient integrity. This means that the product can be applied without actually touching the skin, avoiding the spread of contamination from the hands, ideal for sensitive product applications. For healthcare professionals and patients alike it is less encumbering having someone to spray rather than rub the content onto the skin. Since a Bag-on-Valve aerosol functions equally well at all angles it is easy to use – even in emergency situations.

### A Wide Range of Applications

BoV can be used to upgrade the packaging of a product, increase the marketing opportunities, and/or to add new convenience to the formulation, for instance turning an emollient cream into an emollient spray. For an innovative pharmaceutical company it may be interesting how they can challenge established brands simply by using an alternative spraying technology. With its many dispensing possibilities, Bag-on-Valve is suitable for direct dispensing even in such sensitive areas as eyes or ears – even in children.

One of the most common formulations used in BoV medical devices is different saline solutions. They are used in several different applications, such as nasal sprays, wound cleansers, ear-cleansing sprays and also eyewashes. Market leading nasal spray brands like Simply Saline (US) and Stérimar (EU), both from Church & Dwight Co. Inc. are well-known examples. Nasal sprays in BoV are widely used based on saline or natural seawater solutions.

Wound care on the other hand is rather “virgin soil” when it comes to BoV, even if wound cleanser with saline



### Bag-on-Valve Technology

- 1. The Valve**  
Bag-on-Valve systems are available with both female and male valves.
- 2. The Bag**  
FDA-approved laminated bag (three or four layers depending on product requirements). Available in a large range of sizes.
- 3. The Product**  
Suitable for liquid as well as viscous products, such as gels, creams and ointments, in a number of application areas. Optimised for oxygen-sensitive and sterile products.
- 4. The Propellant**  
Because of the separation between product and propellant, Bag-on-Valve can be used with compressed air or nitrogen.
- 5. The Actuator**  
A large range of standard actuators depending on product demands.
- 6. The Can**  
Standard aerosol can, aluminium or tinplate. All sorts of shaped cans can be used. No limitation in marketing solutions.

The Cap – Can be used with many kinds of standard overcaps.



**STEP 1.**  
Placing of valve and bag inside the can



**STEP 2.**  
Gassing (air/nitrogen) followed by crimping of the valve onto the can



**STEP 3.**  
Pressure control



**STEP 4.**  
Product filling in the bag followed by weight control



**STEP 5.**  
Actuator and cap placement



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solutions for hospital and community care have been on the market for more than 10 years in the EU and the US. There is a lot of product development currently in process in this segment. One example of an innovative approach using BoV is the new product Granulox (SastoMed, Germany) for treatment of chronic wounds. The Granulox product uses haemoglobin in order to improve oxygen supply to chronic wounds. The haemoglobin-based formulation sprayed onto the wound area is able to penetrate the exudate and thereby increase the level of oxygen in the wound. The wound situation improves and wound healing is accelerated. Wounds stagnant due to hypoxia can also be activated.

Several companies are also recognising the benefits of BoV for the application of silicon-based products. An example of this is the growing market for medical adhesive remover sprays where sophisticated silicone formulations are sprayed to gently and painlessly remove adhesive products such as stoma pouches and wound dressings. Conventional adhesive dressing removal is often difficult for the healthcare professional and unpleasant for the patient.

Another upcoming area currently catching interest is throat spray, with the aim of soothing and preventing sore throat symptoms during colds and allergies. Maybe we will see a similar range of throat spray products on the market as is already available for nasal application. In the ENT segment there are also BoV-products on the market that help to prevent build-up of earwax.

Occupational safety is another area where BoV products are increasing their market shares. A BoV first aid eyewash, such as is available on the EU market, is a good complement to the water pipe or gravity-fed eyewashes that are usually found at industrial workplaces. Benefits include a lesser amount of liquid that lasts longer, portability and the ability to be either personal or available in a wall station.

In products such as first aid eyewashes, the effective flushing time has to be as long as possible. This can be achieved with very fine spray actuators and a controlled discharge flow rate. Thanks to the separation of



product and propellant, Bag-on-Valve offers a more constant pressure and flow rate until the last drop.

Let's not forget disinfection products used in critical environments like pharmaceutical industry cleanrooms. Double-bagged sterile disinfection sprays for this purpose with isopropanol alcohol or ethanol are now available using the BoV packaging. The greatest convenience of this is that they are easily sprayed on machinery and surfaces in the critical areas.

### Integrity of Brands

BoV products for the pharmaceutical market are often manufactured by contract manufacturing organisations (CMOs). For sterile products, some CMOs of BoV can offer aseptic production. A more common method to realise sterile products is the use of gamma irradiation of the final product. The manufacturers may be focusing on GMP production for products classified as drugs or on production of medical device classified products based on

### Fact box:

**Advantages of Bag-on-Valve (BoV)**  
The Bag-on-Valve system offers major advantages for a range of aerosol products where safe and contact-free dispensing is required. Bag-on-Valve gives new marketing opportunities through improved consumer conveniences, product protection, and controlled discharge of the product.

### Safety and environmental benefits

- No need for flammable propellants
- Hygienic and sterilisable
- Used with eco-friendly air or nitrogen
- Less need for preservatives

### Consumer benefits

- Up to 100% product emptying
- Longer shelf-life with less preservatives
- Even and controlled spraying pattern for optimal result
- No pumping motion needed
- Can be used at all angles
- Reduced spray noise
- Less-chilling product discharge

### Production and distribution benefits

- Longer shelf-life for oxygen-sensitive products
- Effective filling process
- Suitable for both liquid and viscous products
- Can be used with standard actuators and aerosol cans.

the ISO 13485:2003 standard.

Some CMOs in the EU, such as Aurena Laboratories, offer medical device products, developed in-house, for companies to sell and distribute under their own brands. In these cases the final products are already registered and CE-marked according to the European Medical Device Directive. The brand name and artwork design of the new private label will be added to the technical file (dossier) of the registered product and become a part of the registered product. The procedures will be different depending on the classification of the product.

Depending on the type of contractual arrangement between the CMO and the brand owner it can be either the



CMO or the brand owner that is stated as the legal manufacturer. This can ensure total integrity of the brand, as the production source is not disclosed on the packaging.

With BoV the cost per ml can often be decreased, particularly regarding nasal sprays with a filling volume of 50ml and upwards, compared to pump sprays that normally contain a lesser filling volume. Available standard BoV packaging covers a broad range from 30 to 500ml.

The components for BoV are made by other suppliers, of which Aptar Group, Lindal Group and Coster are among the leading companies.

Special aerosol filling machines are needed to fill BoV products.

Leading suppliers of filling machines are Pamasol (Switzerland) and MBC Aerosol (USA).

For transportation, the BoV products are classified as aerosols (UN 1950). For the pharmaceutical market the cans are most often made of aluminium, even if tinline BoV systems are also available. The cans are also light to carry and normally fit into the recycle programmes established in most countries.

The cans also offer interesting marketing opportunities, since they represent quite a large display area in the store and can be designed in a highly attractive way, giving the brand name a high degree of exposure.

**Magnus Hedman**

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Director, Business Development Manager of Aurena Laboratories AB. He is a seasoned entrepreneur and business development specialist who has been involved in the medical device and pharma industry for over 20 years. International Sales & Marketing Manager for Swedish respiratory care company Aiolos Medical, 1990 to 2000. He co-founded Aurena Laboratories in the year 2000 and has developed a range of medical devices in the Bag-on-Valve packaging for the Pharma industry. He has led the dedicated work to develop Aurena into a leading international company of medical device aerosols.

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