

A clear choice for effective and safe
intravesical instillations



Uro-Tainer[®] M PVC-free

IMPROVING PATIENT QUALITY OF LIFE

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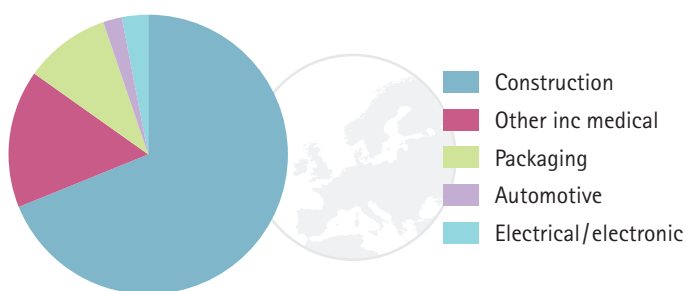
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What is PVC and what kind of products is it used for?

PVC (polyvinyl chloride) is the third most widely used plastic worldwide after polyethylene each year¹. PVC is used across a wide range of industrial sectorsylene and polypropylene, with 4.9 million tonnes produced in Eur including construction, transport, packaging, electronics and healthcare (Fig 1). It is a popular material due to its relatively low cost, biological and chemical resistance, longevity and versatility¹.

The rigid form of PVC is used in construction for pipes, windows and doors¹. It is also used for bottles, non-food packaging, children's toys, home furnishings, car parts and bankcards¹. It can be made softer and more flexible by the addition of plasticizers, the most widely used being phthalates¹. In this form, it is also used in plumbing, electrical cable insulation, signage, inflatable products and medical devices¹.

Figure 1: PVC use areas in Europe¹



Why are there concerns about the use of PVC?

Health issues

There has been growing concern about the health impact of PVC products due to the release of potentially toxic chemicals into the environment during their manufacture, use and disposal^{2,3}. In particular the safety of phthalate plasticizers such as DEHP (di-2-ethylhexyl phthalate) has been the focus of consumer groups and the scientific community as

- Phthalates are very susceptible to leaching into the environment from the PVC as they are not tightly bound to the polymer^{2,4}
- Some types of phthalates such as DEHP are thought to have the potential to be 'endocrine disruptors' and have been shown to adversely affect the reproductive system of laboratory animals^{5,6}
- Certain groups such as young children seem to be at higher risk of exposure to phthalates due to their hand to mouth behaviours⁷. Neonates treated in intensive care are particularly susceptible to phthalate exposure due to invasive use of PVC products⁴
- Critically ill or injured patients may be at increased risk of developing adverse health effects from DEHP⁸

Despite the high level of consumer concern investigations by government authorities in the US and Europe have found no convincing evidence of the adverse effects of phthalates in the general population⁸. In order to reduce the risk of exposure to phthalates in high-risk groups the European Union (EU) banned the use of DEHP in all children's toy products in 1999⁷. In 2008 the US government followed suit and banned the manufacture or import of children's toys containing more than 0.1% DEHP⁹. In 2010 the EU also introduced specific labeling requirements for all devices containing phthalates such as DEHP to enable healthcare professionals to use this type of equipment safely in patients at risk of over-exposure¹⁰.

Individual healthcare providers have responded to the concerns about PVC in medical devices. The Glanzing Clinic in Austria became the world's first paediatric healthcare provider to eliminate all invasive use of PVC in 2003¹¹.

In January, 2012 a major US healthcare provider, Kaiser Permanente, announced that it would no longer buy intravenous (IV) medical equipment made with PVC and DEHP type plasticizers¹¹. Many hospitals in Europe have now begun taking steps to eliminate PVC¹¹. These include countries well known for their environmental programmes such as Sweden as well as the Czech Republic and Slovakia¹¹.

Environmental issues

There are also concerns about the environmental effects of the production and disposal of PVC products. PVC products do not biodegrade easily and given the large volumes involved this means that landfill is not a sustainable option for disposal¹². Moreover additives such phthalates and heavy metals can leach out of landfilled PVC and have the potential to contaminate ground water¹². Burning PVC adds to the environmental burden of carcinogenic chemicals such as dioxin and hydrochloric acid¹². Recycling is theoretically possible, however, the process of recycling is also associated with increased emission of toxic chemicals; it is relatively expensive and the market for recycled PVC is relatively small¹².

Why PVC-free?

In response to these health and environmental concerns PVC products softened with plasticizers other than DEHP (e.g. citrates and adipates) are also available on the market¹³. However, many of these chemicals are like DEHP, in that they all have the potential to leach out of devices and into patients¹³. The potential health risks of DEHP alternatives are largely unknown, due to the lack of toxicological data publicly available on these softeners¹³. Furthermore the use of alternative softeners does not eliminate the environmental problems associated with the manufacture and disposal of PVC¹³.

There are now many PVC-free materials available, suitable for a wide variety of medical applications, which do not require phthalates or other softeners¹³. The potential hazards posed by phthalates leaching from equipment and being carried into the patient can therefore be avoided¹³. Furthermore, since the alternatives are not made from PVC, they can be more easily recycled, eliminating the problems associated with disposal of PVC medical equipment¹³. As well as being PVC-free these products can also have additional benefits¹³. For example PVC-free IV bags do not stiffen with use, as softeners are not removed from the plastic by the bag contents¹³.



B. Braun – product sustainability and innovation

B. Braun is constantly working to improve the environmental credentials of their products and packaging¹⁴.

B. Braun is also continuously expanding the product range to offer more choice, to meet new consumer requirements as well as optimising the usability and safety of existing products¹⁴.

“
Beginning at the product development stage, environmentally compatible design, technical safety and health protection are fixed as targets”

*B. Braun Infection Control –
Responsibility & Sustainability Strategy 2013*



B. Braun

- Selects environmentally friendly raw materials for new products¹⁴
- Is constantly improving formulations in order to provide an environmentally friendly product portfolio¹⁴
- Utilizes PVC-free packaging materials
- Minimizes the weight of packaging materials in order to increase environmental sustainability¹⁴
- Utilises a state of the art safety management system which guarantees a uniformly high level of quality, from product conception to dispatch¹⁴
- Helps to improve treatments and working procedures in hospitals and medical practices and to increase the safety of patients, doctors and nursing staff by
 - Being a reliable partner by implementing the EU Directive 2010 / 32 / EU¹⁴
 - Supporting customers through the built in safety of our innovative product systems¹⁴
 - Delivering safety data sheets for all products¹⁴

In November, 2005 one of the largest hospital networks in the US Catholic Healthcare West, signed a contract with B. Braun Melsungen to supply PVC-free IV bags and tubing¹⁵.

Uro-Tainer® M PVC-free

B. Braun have set a new standard by being the first company in the field to introduce PVC-free bags for the Uro-Tainer® M catheter maintenance system¹⁶. Uro-Tainer® M is the only product of its kind to be manufactured without

- Polyvinyl chloride (PVC)
- The phthalate plasticizers – di-[2-ethylhexyl]phthalate (DEHP) and Bisphenol A (BPA)
- Latex

The new Uro-Tainer® M PVC-free

- Bags are manufactured from Nexcel® M312A¹⁶
- Flexible tube and urologic closure are manufactured from polypropylene (PP)¹⁶

Nexcel® M312A (Figure 2) is a polyolefin film which is sterilizable at 120 °C and has excellent clarity, flexibility and durability. Nexcel® M312A is designed to be chemically inert and to have low levels of extractables with a wide range of solutions even when sterilized at 120 °C¹⁷ Nexcel M312A (non PVC primary film) has a much better water barrier property than PVC and leads to less drug adsorption than PVC¹⁹. These properties make it ideal for use in medical applications such as the Uro-Tainer® M^{16,17}.

Polyolefins including polypropylene are more sustainable manufacturing materials compared to PVC. They are 100% recyclable and due to the wide number of applications for polyolefins there is also a high demand for recycled product¹⁸

The performance of the new Uro-Tainer® M PVC-free was perfected¹⁶.

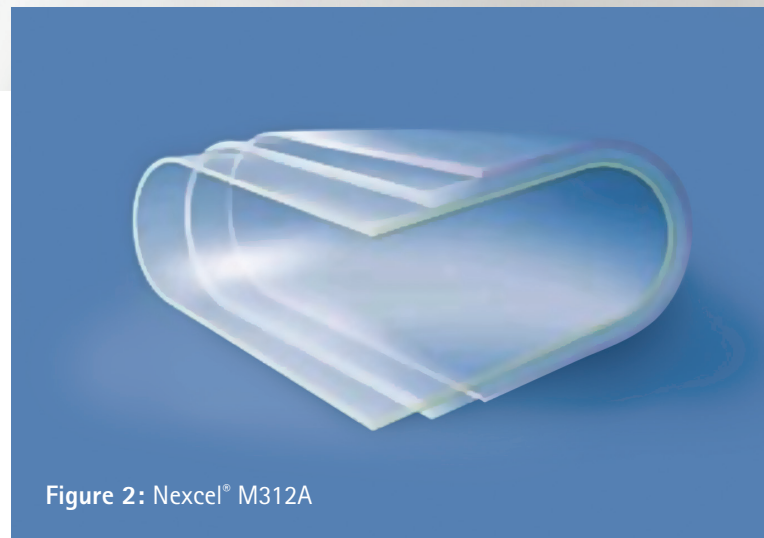


Figure 2: Nexcel® M312A



Design features

The design features of the new Uro-Tainer® M PVC-free bags help improve handling and safety¹⁶

Improved handling & feel



Insertion of hanger

Enables easier administration of drugs



Softer plastic

Improves the feel of the product for the patient and nursing staff



Colour-coded conus and clamp

Improves identification in a busy working environment



New clamp design

Enables one-handed operation and makes safe instillations possible by preventing that the liquid catches up before connecting.



Improved administration & safety



Improved sealing technology

The port has a new resealing rubber closure technology that hermetically recloses after needle insertion. The port is situated newly on the same side as the conus.



Flow rate

No change in technique required



Drugs database

Enables healthcare professionals to assess compatibility of drugs used in combination with Uro-Tainer® M



Overwrap

Uro-Tainer® M with injection port is safely enveloped in a solid overwrap to grant its sterility.

Uro-Tainer® M PVC-free bags have improved shelf-life to help reduce wastage¹⁶

With Uro-Tainer® M PVC-free straight to the target

The Uro-Tainer® concept was developed to replace the standard bladder washes with syringe and to reduce the ongoing risks of high pressure and suction on the bladder wall.

Uro-Tainer® M has a drug additive port and can be used to specifically administer prescribed drugs directly into the bladder through the urinary catheter.

Uro-Tainer® M is a sterile, endotoxine-free, ready to use, closed and disposable system that opens the way straight to the target. The advantages of Uro-Tainer® M are as follows:

- It increases the hygienic conditions
- It decreases the number of manipulations and accessories
- Reduces time for the drug preparation and instillation
- Avoids side effects of systemic drugs
- Avoids costs of systemic treatments



single use catheters



Foley catheters

Uro-Tainer® M – perfected injection port

The port of the Uro-Tainer® M has a resealing rubber closure technology that hermetically recloses after needle insertion. The rigid walls of the port are designed to be as short as possible and just long enough to guide the needle during puncture. Therefore the threats of perforation of the container as well as needle injuries of the nursing personnel while piercing the needle into the port are minimized.

The new injection-port tube has a residual volume < 1 ml, along with correct handling (see instructions) this is a guarantee for a perfect dosage.

The resealability was tested according to ISO 15747. Internal tests showed a 100% resealability when using a semi-blunt needle Sterican® Mix (art 4550400-01) 18G x 1½ – 1.20 x 40 mm, puncturing once as well as a 2nd time into the port.



Uro-Tainer® M Injection Port

Uro-Tainer® M – Drug admixture

The solution NaCl 0.9% contained in the Uro-Tainer® M serves as carrier for diagnostics, antibiotics, mucolytics, cytostatics and so on. The Saline solution is sterile, isotonic, pH 7 and does itself not contain any preservatives.

The new Uro-Tainer® M PVC-free has been tested on a number of drugs. Its absorption and stability features are more similar to glass bottles than to PVC bags. In general the results are exceptionally good and indicate that the new foil is compatible with even more drugs¹⁹.

The dosage shall be made according to the medical prescription of the drug. The duration of the contact with the bladder depends on the individual therapeutic goal. The maximum quantity of liquid remaining in the bag after emptying is less than 1 ml.

Maximum additional injection volume:

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|--------|---|-------|
| 50 ml | = | 87 ml |
| 100 ml | = | 37 ml |



The Uro-Tainer® M is sterilized in the outer packaging, which increases the safety of the product. So you can place the Uro-Tainer® M in the laminar air flow cabin without danger of contamination.



It is possible to prepare one or multiple Uro-Tainer® M at once.



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