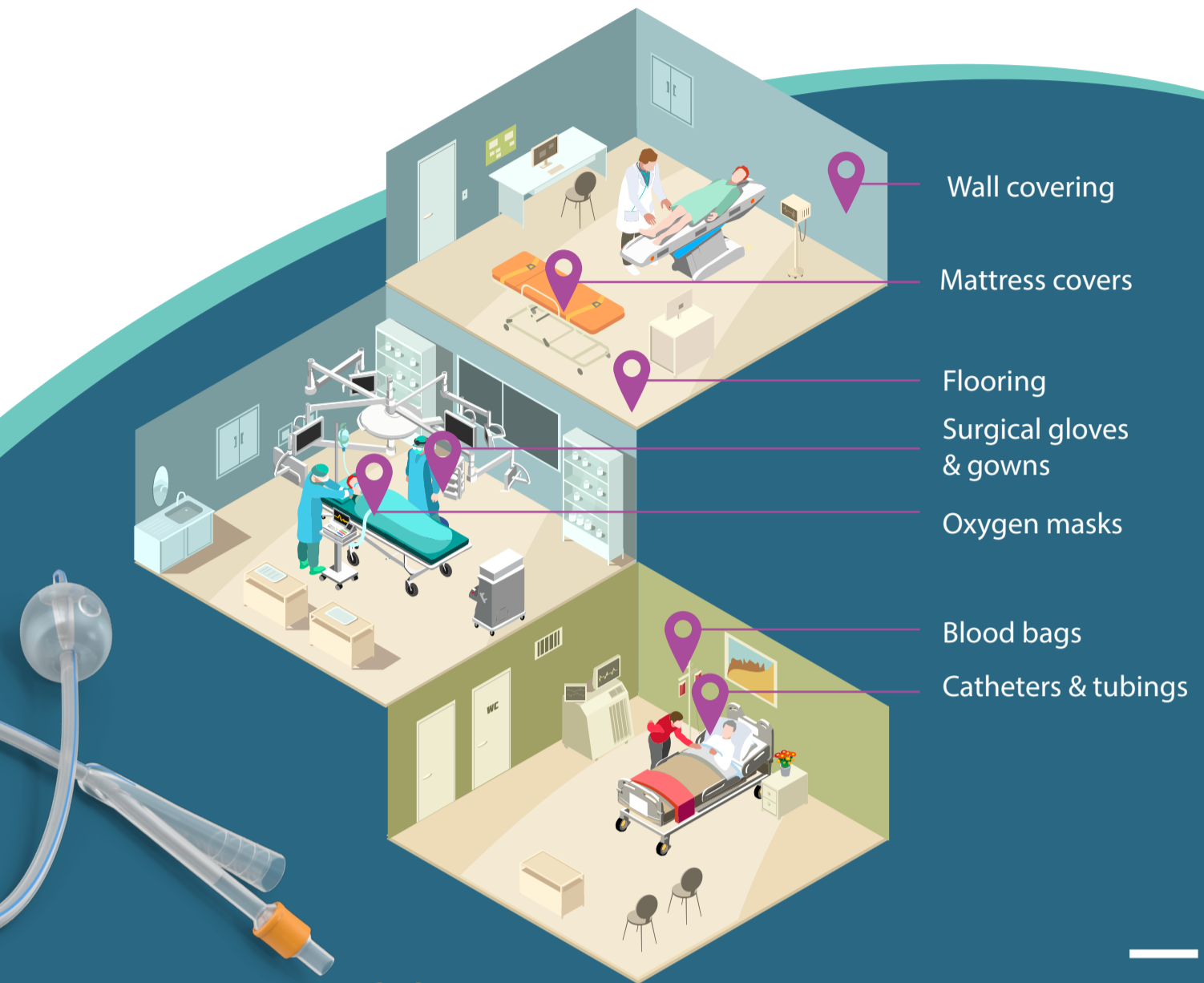


Medical applications

Plasticised PVC for outstanding & safe performance in modern healthcare

~40% of medical devices use flexible PVC.

The safety, high performance, low cost and versatility of PVC reduces the risks of life-threatening and healthcare-associated infections caused by traditional multiple-use medical devices. PVC also makes it possible to manufacture hospital-friendly environments through flooring, ceilings and more!



Safety

PVC fully complies with safety requirements for professionals and patients in the healthcare environment. Due to its versatility and cost efficiency, it enables the mass-production of medical devices and reduced cross-contamination between patients.



The advantages of flexible PVC in medical devices

Cost Efficiency

PVC combines very low manufacturing and maintenance costs with excellent durability and long-lasting performance.



Flexibility & Durability

Plasticised PVC can be moulded or formed into endless shapes and products (eg. blood bags, tubings, intravenous bags, respiratory masks). It can also be relied upon for its strength and durability under changing temperatures and conditions.

Chemical Stability

Plasticised PVC medical devices are capable of accepting or conveying a variety of liquids without undergoing any significant changes in composition or properties.



Easy Sterilisation & Maintenance

PVC medical devices can be easily sterilised using methods such as steam, radiation or ethylene oxide. Flexible vinyl wall and floor coverings are also easy to clean and can resist strong antibacterial agents that are involved in preventing the spread of diseases.

Clarity & Transparency

PVC can be formulated with excellent transparency to allow for continual monitoring of fluid flow.



Biocompatibility

PVC is characterised by high biocompatibility which can be further increased by appropriate surface modification.

Four additional plasticisers listed in European Pharmacopoeia

Four plasticisers were recently listed in the [European Pharmacopoeia](#), which sets quality guidelines for medicines, medical devices and the substances used to make them in Europe and beyond. It is referred to by the EU Medical Devices Regulation, the key legal instrument for regulating medical devices for the EU.



DINCH

(cyclohexane 1,2-dicarboxylic acid, diisononyl ester)



BTHC

(butyl tri-n-hexyl citrate)



TOTM

(tris(2-ethylhexyl) trimellitate)



DEHT

(bis(2-ethylhexyl) terephthalate)

The four plasticisers join DEHP which has been listed in the European Pharmacopoeia for many years. Other plasticisers such as DINP and DIDP are used safely in non-invasive medical applications in hospitals such as investigation gloves, but also flooring, wall covering or mattress covers.

The **low molecular weight phthalate Di-2-ethylhexyl phthalate (DEHP)** has been widely used in medical devices due to its high performance that is relevant to the needs of the healthcare sector. As of July 2021, the use of DEHP in medical applications will be further regulated but will remain possible provided that it is in compliance with the new [Medical Devices Regulation](#). A justification and a benefit-risk assessment for the presence of DEHP will be mandatory, taking into account possible available alternatives. DEHP is also subject to Authorisation and Restriction under the REACH regulation.

The **non-classified high molecular weight phthalates DINP, DIDP and DPHP** are used in wire and cables for electrical and electronic medical equipment (patient monitors, defibrillators, respiratory ventilators, CT scanners, dialysis systems, sterilisers, anaesthesia machines, etc.) thereby ensuring safe, secure and durable electricity supply for these life saving machines. Such use is in full compliance with the EU RoHS Directive (DEHP, DBP, BBP and DIBP are restricted in electrical and electronic equipment including medical devices since July 1, 2019).

Recycling non-contaminated PVC medical devices

Many initiatives have been taken around the world to develop new recycling technologies for flexible PVC medical devices.

In the UK the RecoMed project, a partnership between the British Plastics Federation and industry representatives, was launched to collect and recycle non-contaminated used PVC medical devices from UK hospitals, including face masks and tubings. The project currently involves 36 hospitals, and another 100 are ready to enroll. Over 9,000 kg of medical devices have already been collected for the purpose of recycling in 2019.

In Sweden, a waste management project has been launched by PVCMed and the Swedish Governmental Agency for Innovation Systems to investigate how PVC medical waste can best be recycled.

This recycling effort goes beyond Europe, with pioneers like Australia and New Zealand where more than 170 hospitals recycle non-infectious PVC-based IV bags, face masks and oxygen tubings. Every month +20 tonnes of PVC waste is thus collected and recycled.

More info: plasticisers.org