

Uncovering advantages with digital printing on healthcare packaging

While helping to meet UDI requirements, digital printing has many benefits such as improving production efficiencies, increasing flexibility, reducing waste and improving patient outcomes.

With the full adoption of UDI requirements in the US FDA and the EU MDR, traceability of medical devices will be significantly enhanced. Better traceability leads to improved incident reporting, targeted field safety corrective actions and better monitoring by components authorities, as described in the regulation. Ultimately, increased transparency and access to information will protect public health and enable informed decisions to be made by the healthcare professionals to the benefit of patients.



Enabling better barcodes

Barcodes provide a practical way to store all of the required data into a small space and enable quick access to regulatory databases for reliable identification and traceability. To help support patient safety, it is crucial that the printed barcodes work well within their intended use environment, consisting of manufacturing, possible sterilization, distribution and storage until the point where the product is used. Please see also the white paper “Printing variable data on DuPont™ Tyvek® for healthcare packaging” in the online [DuPont Resource Center](#).

Brand and non-variable product information is traditionally printed on the top-web of packaging by flexographic technology. As the barcodes contain variable information such as production date and lot number, it is more and more essential to use printing technologies that enable effective variable printing. The variable printing is usually printed online on a form-fill-seal machine or applied via an adhesive label. Digital printing technologies have gained ground because of their flexibility to changing print information and layouts without the need to have physical print plates. Automated quality control and inspection lines can help reduce and prevent manual work and errors at the end of the packaging process.

Vygon evaluates printing options

Procedure packs, or medical device kits, contain a combination of products packaged together for a specific medical purpose. Kits can contain several medical devices or components nested in a package such as a blister tray for easy and safe access during a medical treatment. Vygon designs, manufactures and markets high-tech single-use medical devices for healthcare professionals. This article focuses on peripherally inserted central catheters from Vygon that are supplied in a kit tray consisting of four or more components: catheter, sheath, needle and guidewire. The PETG tray is thermoformed on a form-fill-seal line followed by the manual placement of devices into the formed tray and the sealing with a lid made of coated Tyvek® 2FS™. For components contained inside the hard blister tray, Tyvek® 2FS™ provides trusted performance against punctures and other threats that could compromise sterile integrity.

Contrary to previously used flexographic printing, digital technology is now used for printing the non-variable data on Tyvek®. Digital thermal transfer is used for the variable information on an adhesive label which is intended to be removed from the packaging at the point of use for recording patient files.

Because of their versatile use, procedure packs come in multiple SKUs, keeping the production volumes rather low per unit while information and layout changes are rather frequent. In this case, the use of traditional flexographic printing technology was resulting in frequent changes of printing plates and thus time-consuming production line stops, manual readjustments and maintenance procedures.

With manual adjustments there is an increased risk of human errors. This may lead to increasing costs across the product life cycle starting from material losses and repackaging to customer complaints and even recalls compromising patient safety.



Vygon switches to digital printing

“Due to its specialty products, Vygon has a very wide range of different sets which require a different print image; however, the lot sizes are comparatively small,” Volker Ganser, Technical Manager at Vygon, explained. “It is therefore important to reduce setup times and avoid downtime and rework. With the switch to digital printing, manual printing plate changes by employees are replaced by an automated digital process acting when there is an order change on the packaging machine.”

Recognized by their strategy in implementing the latest technology at all levels in operations, Vygon has invested in a digital printing capability at their facility in Aachen, Germany. Typically, inkjet printing requires higher capital investment compared to traditional flexographic printing but is balanced with the reduction of operational expenses in the long term.

The new piezo drop-on-demand (DOD) inkjet printing line using oil-based ink coupled with in-line inspection system was installed by AMACO, an Austria-based full-service printing solution provider servicing the medical packaging industry. In addition, a fully automated inspection system has been implemented for 100% print quality control, product arrangement and seal integrity control, allowing for early detection of non-conformity of products packaged.

AMACO provides printing solutions

“In the past 20 years, printing information requirements for medical device manufacturers have changed dramatically with the implementation of barcodes containing variable production-related data, usually applied at the last stage of the packaging process. First, thermal transfer printing systems were added to our flexographic printer portfolio, but in the past eight years DOD inkjet systems have increasingly been state of the art to comply with the latest EU MDR. UDI-compliant printing can only be done using digital printing solutions. Also, in the case of frequent lot

and thus print layout changes, inkjet printing is a highly efficient solution which provides excellent results on DuPont™ Tyvek®. The ink adapts very well to the structure of the material.

Single source of truth in data supply, online connection with printing systems, visual print quality and product perfection control, as well as traceability of quality in all production and packaging steps, are all key to patient safety and the success of medical device manufacturers such as Vygon,” stated Christoph Lajda, Area Sales Director at AMACO.

Digital printing improves results

Volker Ganser emphasized, “The automatic print control, which was only made possible by the high and consistent print quality, has contributed to the fact that there have been no complaints from hospitals due to poor or incorrect printing since the introduction of the systems. Internal claims have already been avoided because failures were identified immediately.”

DuPont Application Development Leader EMEA Nicole Kaller concluded, “This is a great example of a robust and high-quality solution which Vygon selected for packing, printing and controlling their catheter kit. They now have a smooth printing and packing process in place, resulting in a reduced error rate. This helps ensure correct product use at the healthcare facility, which will contribute to patient safety—and this positive outcome is the main objective for all of us.”

Major benefits with digital printing and visual control systems



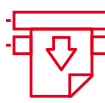
Time gain and productivity

Quicker changeover time, enhancing production capacity



Quick market response

Flexibility for layout and SKU changes



Sustainability, cost and logistics

Less waste from printing plates and decreased storage space needed due to elimination of printing plates (and no ink cartridges with DOD inkjet)



Resourcing

Lower maintenance requirements



Safety

Ink composition change from solvent flexo to oil-based inkjet; less risk of human errors through digital solutions and visual control systems



Quality and usability

Excellent print results on Tyvek® for good readability and reduction of user errors

Learn more about digital printing on Tyvek®



Please see the white paper “Printing variable data on DuPont™ Tyvek® for healthcare packaging” in the online [DuPont Resource Center](#).



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