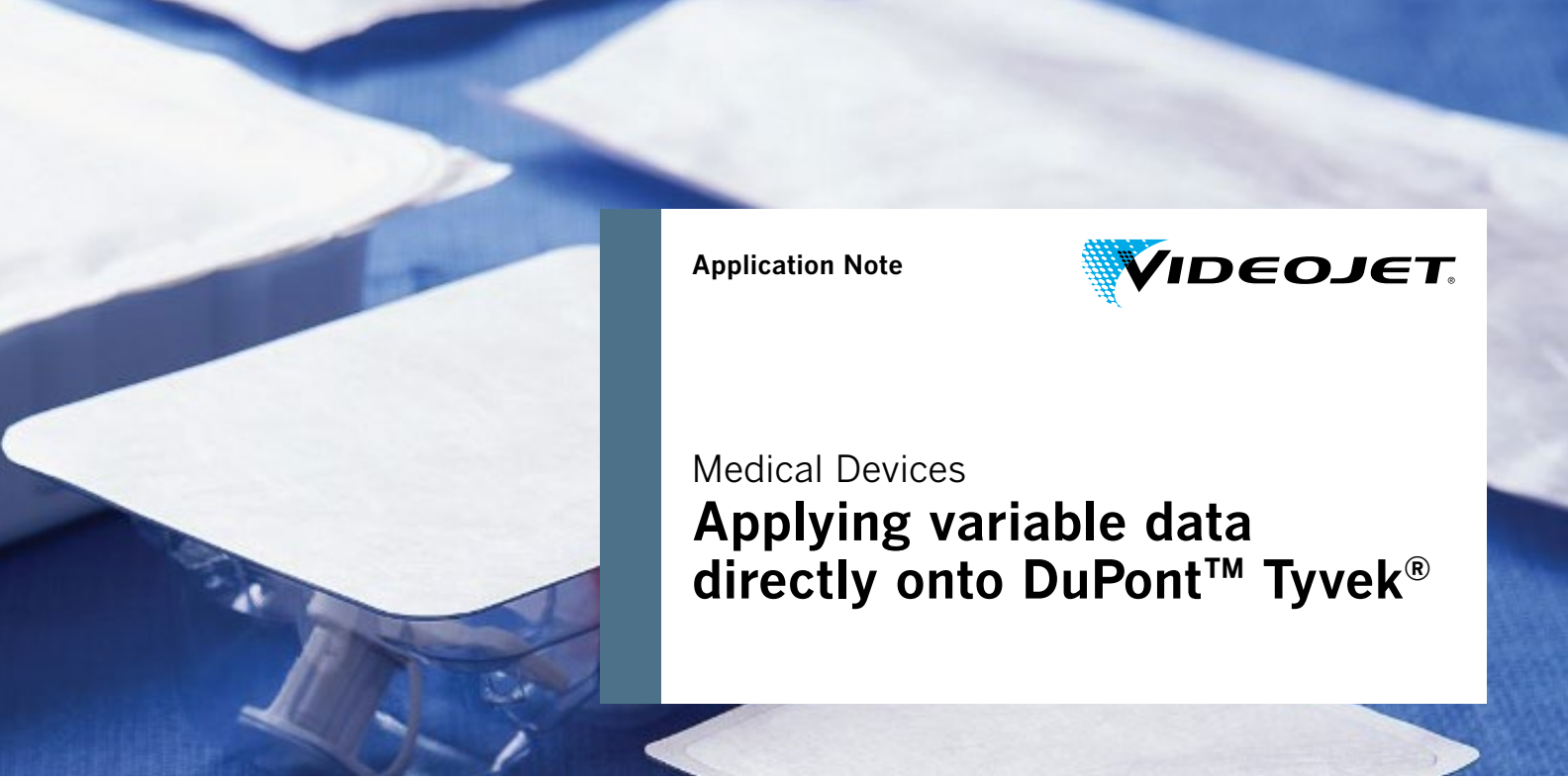


Application Note

Medical Devices

Applying variable data directly onto DuPont™ Tyvek®

The challenge

Due to the induction of the Unique Device Identification (UDI) system, medical devices can now be identified throughout the supply chain, from manufacturing to patient use.

In order to comply with the UDI standards, medical devices must be labelled with both product and production-specific data. This information is usually printed on the packaging of the device in human and machine readable forms using a GS1 DataMatrix code or GS1 128.

For sterile packaging DuPont™ Tyvek® is a trusted choice for all medical devices because of its tear resistance, durability, breathability and superior microbial barrier properties.

To ensure high-quality UDI codes on DuPont™ Tyvek® and other substrates, adapted printing equipment and consumables need to be chosen. This Application Note gives an overview of the different Tyvek® styles used in medical packaging and the corresponding Videojet coding technologies, inks and ribbons.

The Videojet advantage

Videojet offers three coding technologies that can be considered for direct printing on the medical packaging styles of Tyvek®.

- Thermal Transfer Overprinter (TTO)
- Thermal Inkjet (TIJ)
- UV Laser Marking

In order to help ensure coding quality, the Videojet sample laboratory has conducted extensive test to determine the best application equipment for the various Tyvek® styles.

Testing approach

GS1 DataMatrix ECC 200 codes were printed on DuPont™ Tyvek® sheet samples using different coding technologies, inks, or ribbons. Once the testing determined the most promising combinations, a set of 10 codes were printed and graded with a barcode verifier in accordance with ISO/IEC 15415.

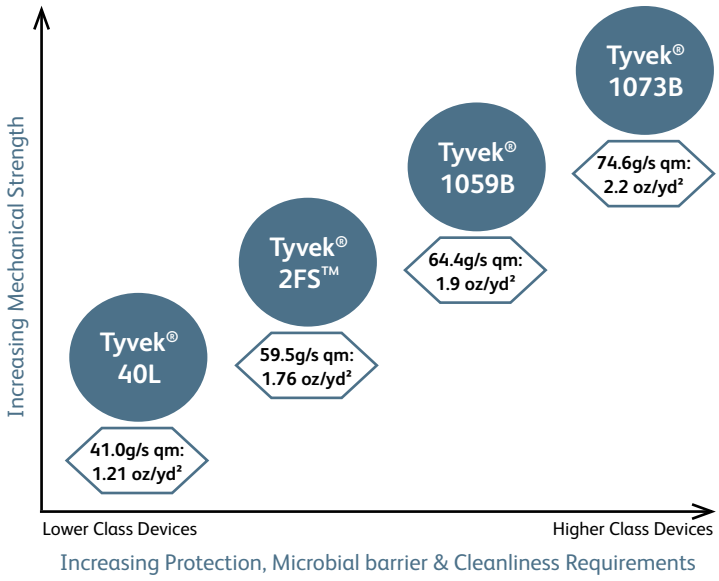
ISO/IEC 15415 recommends verifying the code in its final configuration wherever possible (e.g. package containing the product). In this study, printed Tyvek® sheet samples were used without final configuration. For verifying codes printed on Tyvek® 40L, which has a linen-like appearance, a white cover was used to support the sheet from the backside of the sample which resulted in good grading quality.

The coding technologies and consumables presented in this application note have consistently achieved a grading of 2.5 (B) or better in these tests under laboratory conditions.

Four unique styles for Tyvek® medical packaging needs

Tyvek® is a porous packaging material made of very fine and continuous filaments of virgin high-density polyethylene (HDPE). The unique structure of Tyvek® creates a tortuous path with substantial lateral movement, making it harder for bacterial spores and other contaminating microbes to get through. This tough filament web makes Tyvek® also highly durable yet breathable reducing the risk of package failure. Tyvek® packaging material is a trusted choice for all medical devices ranging from catheters to implantable devices.

Four Tyvek® styles are available for the market to serve unique packaging needs in medical industry. These Tyvek® styles cover all medical packaging performance requirements. If you have questions or need information regarding Tyvek®, contact your local DuPont™ representative or visit medicalpackaging.dupont.com.



Printing application	Thermal Inkjet (TIJ)	Thermal Transfer Overprinter (TTO)	UV Laser Marking System
Tyvek® 1073B	✔	✔	
Tyvek® 1059B	✔	✔	
Tyvek® 2FS™	✔	✔	✔
Tyvek® 40L	✔	✔	

Videojet coding solutions for Tyvek®

Thermal Inkjet (TIJ)

A non-contact printing technology that enables high-speed, high-resolution printing on flat and slightly uneven surfaces. Ink drops are propelled out of the cartridge's multiple nozzles by air bubbles formed by thermal initiation. For printing onto Tyvek®, Videojet recommends using Wolke Global Solvent Ink. It is manufactured in-house by industry-leading ink experts and offers proven performance that rivals other solvent inks.

Recommended ink: **Global Solvent**

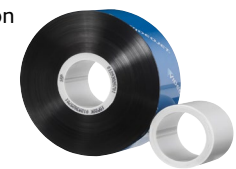
- Average dry time <3 seconds on non-porous materials with 2D codes
- Best-in-class decap (cap open) time while in printing pocket helps ensure worry-free production

Thermal Transfer Overprinter (TTO)

A digitally controlled printhead precisely melts ink from a ribbon directly onto flexible substrates such as Tyvek® to provide high resolution, real-time prints. For printing onto Tyvek®, Videojet recommends using the Videojet Rough Texture black ribbon. It is coated with a blend of wax and resin and features excellent adhesion and contrast when printing on rough, uneven surfaces.

Recommended ribbon: **Rough Texture black ribbon**

- Very good print quality at high speeds; sharp bar codes at 90°
- Very good resistance to smudging and abrasion
- Excellent light resistance



UV Laser Marking System

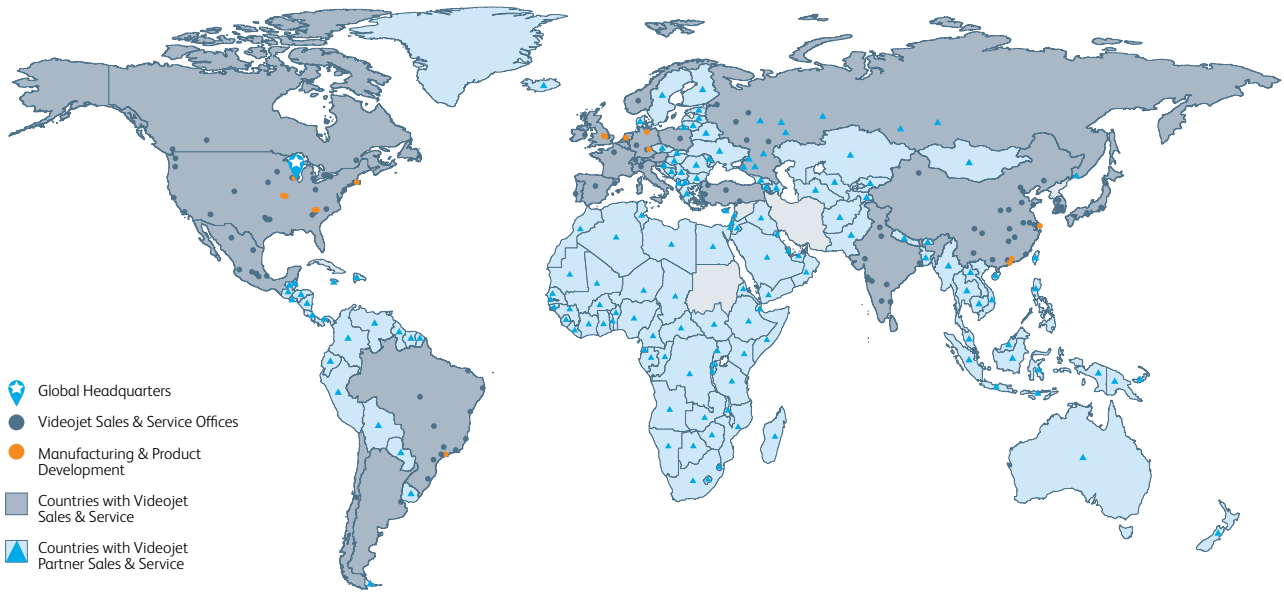
A beam of infrared light focused and steered with a series of carefully controlled small mirrors to generate permanent, high-contrast marks on Tyvek® 2FS™. The UV wavelength creates a color change on Tyvek® 2FS™ through a chemical reaction without damaging the material. This eliminates the need for additives and substrate revalidation.

Peace of mind comes as standard

Videojet Technologies is a world leader in industrial coding and marking solutions with a dedicated global healthcare team supporting organizations and supply chain partners with solutions, certifications and fast, reliable service.

A product portfolio including thermal inkjet, laser marking, continuous inkjet and labeling provides consistent, high-quality serialization and traceability codes, helping the pharmaceutical and medical device industries safeguard their products against counterfeiting and protect consumer safety. With a wide range of technologies addressing virtually any application, Videojet is the expert in realizing the specific requirements of a wide range of healthcare applications.

With decades of knowledge, Videojet Technologies' expertise in industry standards and global regulations makes them the right partner for understanding complex coding needs. Videojet solutions code 10 billion products a day worldwide, playing a vital and responsible role in the world. With over 4,000 associates serving 135 countries, Videojet has the capability to provide local service through global resources.



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