

Optimized Product Safety through Cleanroom Packaging and Laser Marking



Packaging technologies that meet the most stringent standards

Background



As a provider of integrated supply chain solutions, DOT specializes in cleanroom packaging services for orthopedic and dental implants as well as instruments. Our in-house capabilities include contract packaging and labeling.

We are dedicated to meeting the requirements of our customers flexibly and timely.

Our highly qualified staff operate two internationally classified and qualified ISO 14644 (class 7) cleanrooms with a total of 200 m² floor space. (DIN EN ISO

14644, Class 7 or C in accordance with GMP Annex 1).

Before the implants and instruments are packaged in the cleanroom, they are washed and disinfected by using mechanical/automated methods in accordance with Robert Koch Institute standards.

A transfer step into the cleanroom via pass-through/transfer hatch is performed and the product is then packaged.

All of these processes are conducted using validated procedures.

Sterile packaging

Blister packaging

Sterile packaging is performed with validated blister-sealing machines in a cleanroom environment. Our packaging equipment is fitted with customizable sealing dies and heat plates for different blister pack sizes. Your products can be packaged and labeled in accordance with individual customer needs.

Pouch packaging

Our validated vacuum-sealing equipment is custom built for sterile, healthcare packaging in cleanroom environments.

We have PA and PE pouch solutions for products that are vacuum-packed. Our packaging capabilities include gas flushing, box packaging and labeling. All our sealing processes are subjected to a regular monitoring process.

Non-sterile packaging

Serial packaging

Our comprehensive offering includes: packaging non-sterile PE pouches with customized graphic designs as well as high-volume packaging of bags-on-a-roll featuring optional perforation for easy opening (ideal for packaging sets).

Shrink-wrapping

Boxed products can be shrink-wrapped with optional tear-open Strips.

Laminar flow packaging

DOT offers packaging with laminar air flow systems for viable particle reduction.

Cleanroom packaging media

Benefit from DOT's expansive range of packaging material that is leveraged from a close relationship reputable suppliers.

We have a large selection of materials that ranges from transparent pouches to blister packaging for your cleanroom packaging needs. Our other packaging capabilities include providing you with

materials such as roll bags and PS tubes with stoppers (for packaging dental implants).

DOT offers special packaging that is customized to your product or manufacturing needs enabling blister development and production, labelling different label sizes and barcode generation.

Monitoring procedures

Our processes are controlled in accordance with strict hygiene standards on a regular basis. Testing capabilities include monitoring environmental conditions for production, process water and airborne particles in the cleanroom.

In addition, our measuring portfolio comprises regular chemical and biological testing to consistently deliver accuracy,

repeatability and high quality of all supplied products packaged in the DOT cleanroom.

Cleanroom surfaces and ambient air are subjected to microbiological tests every seven days. In order to ensure compliance with the most stringent standards, our measurements are verified by accredited laboratories.



Sterilization

Cooperating with prominent German sterilization vendors is one of the key elements of our supply chain concept.

On request, we offer our customers consolidated sterilization services and validation expertise.

Laser Marking that ensures Label Integrity

Background



Safety regulations today require a medical device to be correctly marked and its label to be legible. Guaranteeing consistent traceability and adequate identification are mandatory. For this reason, integrating numbers, text and/or ID codes onto

implants and instruments is a significant part of DOT services.

Labeling a device with laser marking systems requires specialized expertise and experience, as well as modern equipment.

Laser marking technology

Our laser marking process fully complies with statutory requirements and other labeling regulations for medical devices and instruments.

The benefits offered by its non-contact technology are; virtually no wear on system components, wear resistant labels and minimal thermal load. When compared to other traditional systems, laser marking solutions have proven to be faster and more versatile and have yielded

excellent marking quality. Our specialists can configure the required designs quickly, reducing processing time and costs.

Thanks to the diode-pumped technology of the lasers, precise, consistent and high quality marking results can be ensured. Customized surfaces and deep engravings are configured on the basis of customer's specifications and/or drawings.

We have extensive experience with laser marking techniques and technologies.

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DOT
medical implant solutions

DOT is one of Europe's leading providers of medical coating solutions for orthopedic and dental implants and instruments and also their cleanroom packaging.

Our comprehensive supply chain concept makes us an ideal medical technology partner. Our activities help restore the health of patients worldwide and thus make a major contribution to the improvement of their quality of life.