



# ComfortCoat®

## Hydrophilic lubricious coatings

Advanced coatings that can help to improve the performance of medical devices and patient comfort

ComfortCoat® hydrophilic lubricious coatings can help improve device performance in a wide range of applications and procedures, including cardiovascular and urology. Hydrophilic coatings are designed to enhance handling of medical devices such as catheters by clinicians during insertion by maintaining lubricity throughout the procedure. The hydrophilic coating also aides in patient comfort. Due to the coating's excellent durability, it also offers increased maneuverability of the device in various procedures such as use of guidewires for PTCA and stent placement. The low particulate lubricious coatings allow for use in procedures where superior coating integrity is essential.

All of our ComfortCoat® coating processes can be customized, making fine-tuning possible for your specific device requirements. The materials are UV-cured, a highly reliable process that results in consistent quality and coating uniformity. All of our coating reagents are ready-to-use and can be commercially applied on a large scale.

Many medical devices with ComfortCoat® coatings have received FDA approval and CE marking. Our UV-curable medical grade coating formulations are manufactured under strict ISO 13485 controls. Material Master Files can be made available to notified bodies and other regulatory agencies in support of your filings.

### Benefits to you and your customers

- Excellent lubricity, low friction and stiction
- Superior durability and resistance to wear
- Low particulate release for cardiovascular applications
- Extended maintenance of lubricity (dry-out time) for urology applications
- Biocompatible (ISO 10993 testing)
- Hemocompatible (extended beyond ISO 10993 testing)
- Proprietary coating technology
- Suitable for a wide variety of substrates
- Ready-to-use coating reagents: simplified use
- Robust and high-throughput process
- Application development expertise
- Technology transfer support to commercial scale
- Ongoing customer support
- Coating service available
- Commercialized on FDA and CE approved devices
- Material Master File available

## Used in a wide range of procedures

These highly adaptable, biocompatible coatings are widely developed for devices in interventional cardiology, vascular, urology and other clinical application areas.

Devices include:

- Introducer sheaths
- Guidewires
- Access systems
- Guiding catheters
- Diagnostic catheters
- Balloon catheters
- Thrombectomy devices
- Aspiration catheters
- Central venous catheters
- Neurovascular catheters
- Stent delivery systems
- Stent graft delivery systems
- Heart valve delivery systems
- Foley catheters
- Intermittent catheters

## Examples of markets served

- Cardiovascular
- Vascular
- Neurology
- Urology

## Coating service

DSM as a solution provider to the medical device industry can support you by coating your products. With state-of-the-art equipment for the application of ComfortCoat® coating, we can design the coating application process and provide high quality coating services. Coating service can include coating, testing, packaging, labeling and additional customized processes (e.g. cutting). Our coating service is operated in an ISO class 8 cleanroom, with a Quality Management System compliant with ISO 13485.

ComfortCoat® is a registered trademark of DSM.

## Product Disclaimer

The description by DSM Biomedical of the characteristics and properties of its products and services as contained in this brochure is for general information purposes only, and may not be relied upon in individual situations. All materials offered by DSM Biomedical are supplied under a contract containing detailed product specifications, and the user shall be exclusively responsible for, and shall bear full responsibility for the consequences of, (i) whether or not the product is suitable for use in the devices (or for any other (authorized) use that customer may wish to make of the product), and (ii) whether the product specifications are sufficient and sufficiently well defined in order for the product to be fit and suitable for use by user. User undertakes to keep itself actively informed as to developments in the relevant fields of its applications.

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## Regulatory and Clinical Support

DSM has a dedicated regulatory and clinical affairs team ready to assist you with world-wide strategic regulatory planning, submissions support including accessing our Material Master Files, addressing questions from regulatory agencies, and clinical trial planning.

## Partnering with DSM

By offering the broadest portfolio of biomaterials and process manufacturing in the industry, we help our partners increase the performance of each medical device. We continue to innovate in partnership with our customers to create solutions that improve people's lives. Together, we are at the leading edge of materials science, advancing healthcare by making medical devices longer lasting, more effective and less invasive.

## DSM's dipcoating with UV curing process

Scan the QR code to view our coating process video on DSM's website.



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