



The Decc Company

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POLICY STATEMENT ON THE COATINGS USED IN MEDICAL APPLICATIONS

There has been significant confusion regarding the use of fluoropolymer coatings for certain medical applications. The statement that follows should help eliminate the confusion and clarify Decc's position on the subject. Please read carefully.

The Decc Company ("Decc") is an applicator of various coatings. Some of our coating suppliers have received inquiries from manufacturers, applicators and others that wish to use these coatings in medical applications. Decc is issuing this policy statement in response to these inquiries and to provide guidance to companies that contemplate the use of coating in medical applications. This policy statement applies to all medical applications and medical devices that involve implantation in the human body or contact with internal human body fluids or tissues (whether permanent or temporary).

DISCLAIMER

The coatings applied by Decc are designed and manufactured by other companies, for various industries and applications. Decc does not choose the types of coatings that are to be applied; this is the responsibility of the companies who use Decc. Decc does not manufacture or supply any medical grades of coatings, and has not conducted any clinical tests or studies concerning the suitability or efficacy of the coatings that we apply which might be for medical uses or applications. Decc has not sought or received any approvals or other rulings from the U.S. Food and Drug Administration or any other governmental or regulatory agency (federal or state) concerning the use of the coatings that we apply for medical applications.

The companies who use Decc to apply coating on their products for medical applications must undertake their own clinical tests and other studies to determine the safety and efficacy of the coatings for medical applications. Such companies must make their own independent evaluation and judgment concerning the safety and efficacy of the coatings used in medical applications and must not rely on Decc on any information relating to medical applications that is supplied by Decc or otherwise obtained from Decc.

No person has been authorized to give any information or to make any representations concerning the coatings applied by Decc, which are used in medical applications (other than the information contained in or provided pursuant to this policy statement) and, if given or made, such information or representations must not be relied upon as having been authorized by Decc.

USE OF DECC APPLYING COATINGS USED IN MEDICAL APPLICATIONS

WARNING

The coatings applied by Decc (and the materials used in those coatings) are technical products that carry risks of coating failure and adverse medical consequences.

The risks of coating failure include, but are not limited to, physical failure (e.g., failure due to disbonding of the coating from its substrate), mechanical failure (e.g., failure due to premature wear of the coating), and chemical failure (e.g., failure due to incompatibility of chemicals with the coating).

The risks of adverse medical consequences have been published in articles appearing in newspapers, medical journals, and other publications concerning coatings used in medical applications and the materials used in the coatings (of the type applied by Decc). Persons who contemplate the use of coatings in medical applications are encouraged to read and review those articles.

EXCLUSION OF WARRANTIES

DECC MAKES NO WARRANTY OR REPRESENTATION OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND NO WARRANTY OR REPRESENTATION SHALL BE IMPLIED BY LAW OR OTHERWISE.

DECC SHALL NOT BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER OR NOT BASED UPON NEGLIGENCE OR BREACH OF WARRANTY OR STRICT LIABILITY IN TORT OR ANY OTHER CAUSE OF ACTION. THE EXCLUSIVE REMEDY AGAINST DECC FOR ANY CAUSE OF ACTION IN CONNECTION WITH THE APPLICATION OF COATINGS IS A CLAIM FOR DAMAGES AND IN NO EVENT WILL DAMAGES OR ANY OTHER RECOVERY OF ANY KIND AGAINST DECC EXCEED THE PRICE OF THE SPECIFIC COATINGS AS TO WHICH THE CLAIM IS MADE. DECC SHALL NOT BE LIABLE FOR ANY LOSS, DAMAGE, OR INJURY TO PERSONS OR PROPERTY RESULTING FROM THE APPLICATION OF COATINGS USED IN MANUFACTURING PROCESSES, OR IN COMBINATION WITH OTHER SUBSTANCES, OR OTHERWISE.

MISCELLANEOUS

Decc may in any event condition the sale of its application of coatings upon the receipt of appropriate assurances that : (i) the purchaser has conducted all clinical test and studies necessary or appropriate to determine the safety and efficacy of the coatings and products in medical applications, and has obtained all approvals required by federal and state laws and regulations; and (ii) the coatings and products will be used in strict accordance with all applicable federal and state laws and regulations (including, without limitation, laws and regulations that require manufacturers of medical devices to develop appropriate warnings and ensure that physicians and other users receive those warnings).

ACKNOWLEDGEMENT OF POLICY STATEMENT CONCERNING DECC'S APPLICATION OF COATINGS USED FOR MEDICAL APPLICATIONS

USE OF DECC APPLYING COATINGS USED IN MEDICAL APPLICATIONS

The undersigned understands and accepts the policy statement of The Decc Company concerning the application of coatings used in medical applications. The undersigned confirms that it has made, and will continue to make, its own independent evaluation and judgment concerning the safety and efficacy of coatings applied by Decc for use in medical applications, and that it will not rely on The Decc Company.

The undersigned represents and agrees that it will conduct all clinical tests and other studies that may be appropriate concerning the safety and efficacy of coatings applied by Decc for use in the medical applications contemplated by the undersigned. The undersigned further represents and agrees that it will comply with all legal requirements applicable to the medical applications contemplated by the undersigned, and that it will develop appropriate warnings and will ensure that physicians and other users of its products will receive those warnings.

The Decc Company shall have no responsibility or liability for any claims, demands, losses, injuries, damages, costs or expenses of any kind or nature arising out of or in connection with the production, sale, distribution, or marketing of any products applied for the undersigned, and the undersigned shall indemnify and hold harmless The Decc Company from and against any and all such claims, demands, losses, injuries, damages, costs and expenses (including, but not limited to counsel fees and court costs).

Print or type name

Signature

Title

Company

Date