



Designation: F 619 – 023

Standard Practice for Extraction of Medical Plastics¹

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1. Scope

1.1 This practice covers methods of extraction of medical plastics and may be applicable to other materials. This practice identifies a method for obtaining “extract liquid” for use in determining the biological response in preclinical testing. Further testing of the “extract liquid” is specified in other ASTM standards. The extract may undergo chemical analysis as part of the preclinical evaluation of the biological response, and the material after extraction may also be examined.

1.2 This practice may be used for, but is not limited to the following areas: partial evaluation of raw materials, auditing materials within the manufacturing process, and testing final products. This practice may also be used as a referee method for the measurement of extractables in plastics used in medical devices.

1.3 The values stated in SI units are to be regarded as the standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

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