



Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application¹

This standard is issued under the fixed designation F647; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

A hydrocephalus shunt assembly is a one-way pressure-activated or flow-controlling device or combination of devices intended to be surgically implanted in the body of a patient with hydrocephalus and designed to divert cerebrospinal fluid (CSF) from fluid compartments in the central nervous system (CNS) (the cerebral ventricles or other site within the cerebrospinal fluid system) to an internal delivery site (internal shunt) in another part of the body or an external collection site (external shunt), for the purpose of relieving elevated intracranial pressure or CSF volume.

A hydrocephalus shunt system typically consists of three basic elements: (1) an inflow (proximal) catheter, which drains CSF from the ventricular system, lumbar subarachnoid space or extraventricular structure and transmits it to (2) an arrangement of one or more valves which regulate(s) the differential pressure or controls flow through the system, and (3) an outflow (distal) catheter which drains CSF into the cardiovascular system via the peritoneal cavity, heart or other suitable drainage site. In addition, specialized accessory devices such as reservoirs, antisiphon devices and on-off valves and filters are added at the discretion of the physician to modify performance or adapt the basic system to the specialized needs of the patient.

Because of the considerable length of time over which a shunt or component may be required to function after implantation, it is felt that it should be type-tested to ensure its durability. It has not yet been found feasible to specify a test method of durability testing, but a test method is proposed in [Appendix X1](#).

1. Scope

1.1 This practice covers requirements for the evaluation and specification of implantable shunts as related to resistance to flow, direction of flow, materials, radiopacity, mechanical properties, finish, sterility, and labeling of shunt assemblies.

1.2 Devices to which this practice is applicable include, but are not limited to, those that are temporarily implanted to effect external drainage; or permanently implanted to effect shunting of fluid from a cerebral ventricle, a cyst, the subarachnoid space to the peritoneal cavity, the venous circulation, or some other suitable internal delivery site, and intracranial bypass.

1.3 *Limitations*—Although this practice includes a standard test method for the evaluation of pressure/flow characteristics

of shunts or shunt components, it does not include specific pressure/flow requirements.

1.4 The following components, that individually or in combination comprise shunt assemblies, are considered to be within the scope of this practice: catheters (such as atrial, peritoneal, ventricular), connectors, implantable accessory devices (such as antisiphon devices and reservoirs), valved catheters and valves.

1.5 *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 F04.31 on Neurosurgical Standards.

Current edition approved Nov. 15, 2014. Published November 2014. Originally approved in 1979. Last previous edition approved in 2006 as F647 – 94 (2006). DOI: 10.1520/F0647-94R14.

NOTE 1—The following standards contain provisions that, through reference in this text, constitute provisions of this practice. At the time of publication, the editions indicated are valid. All standards are subject to revision, and parties to agreements based on this practice are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Devices or components, or both, whose