



New Device Approvals

TRUFILL® n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System

This is a brief overview of information related to FDA's approval to market this product. See Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: TRUFILL® n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System
Manufacturer: Cordis Neurovascular, Inc
Address: 14000 NW 57th Court, Miami Lakes, Florida 33014
Approval Date: September 25, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990040a.pdf>

What is it? The TRUFILL® n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System is an artificial material used to block blood flow in the treatment of malformed (abnormally formed) blood vessels in the brain. This material is used to block the flow of blood before surgical treatment of the malformed vessels.

How does it work? The TRUFILL® n-Butyl Cyanoacrylate, or n-BCA, is a kind of 'glue' that is injected through a thin hollow tube (a catheter) into the blood vessels of the brain at the location of the abnormal vessels. Upon contact with blood, the material solidifies so that the flow of blood to the malformed vessels is blocked.

When is it used? Malformed blood vessels in the brain may rupture and cause bleeding into the surrounding brain tissue. In order to prevent such bleeding, it may be necessary to surgically remove the malformed vessels. The surgeon may decide that blocking the blood flow to these malformed vessels before removing them can make the surgical procedure easier.

What will it accomplish? The clinical study of this material (TRUFILL® n-Butyl Cyanoacrylate or n-BCA, Liquid Embolic System) demonstrated that its use performed the same as another blocking agent (Poly Vinyl Alcohol PARTICLES) in its ability to block blood flow in the malformed brain vessels, as well as in a number of blood vessels supplying the malformed vessels. This material is an additional tool for surgeons to use during brain surgery.

When should it not be used? It should not be used by surgeons who have not had adequate training. Physicians should contact a Cordis Neurovascular, Inc. sales representative for information on training courses.

Additional information: Labeling Information can be found at:
<http://www.fda.gov/cdrh/pdf/p990040.html>