TRUFILL® n-BCA Liquid Embolic System

Proven and Effective AVM Treatment

In-Service Guide

Over 15,000 patients treated since 2000
Unique Variability and Range of TRUFILL n-BCA Liquid Embolic System Concentrations

**Recommended Mixtures**
(Listed volumes based on a total volume of 1.0 cc – actual total volumes may vary)

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>TRUFILL Ethiodized Oil: n-BCA Ratio</th>
<th>TRUFILL Ethiodized Oil: Volume (cc)</th>
<th>TRUFILL n-BCA: Volume (cc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intranidal injections without AV fistulae or high flow rates in order to more deeply penetrate the nidus</td>
<td>3:1</td>
<td>0.75</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>75% Eth. Oil / 25% n-BCA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2:1</td>
<td>0.67</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td>67% Eth. Oil / 33% n-BCA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feeding pedicle injections close to the nidus at high flow rates where venous opacification occurs on contrast injections within 1/2 second</td>
<td>1:1</td>
<td>0.50*</td>
<td>0.50*</td>
</tr>
<tr>
<td></td>
<td>50% Eth. Oil / 50% n-BCA</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>0.33</td>
<td>0.67*</td>
</tr>
<tr>
<td></td>
<td>33% Eth. Oil / 67% n-BCA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* TRUFILL Tantalum Powder may also be added to TRUFILL Ethiodized Oil to augment radiopacity. TRUFILL Tantalum Powder should not be used alone with TRUFILL n-BCA. At higher TRUFILL n-BCA concentrations (> 50%), addition of up to 0.5g TRUFILL Tantalum Powder is advised.

**Warning:** A 0:1 TRUFILL Ethiodized Oil to TRUFILL n-BCA ratio should never be used. Recommended mixtures based on the clinical study.
Convenient Preparation and Delivery

4 Convenient Steps to mix TRUFILL n-BCA Liquid Embolic System and Treat Cerebral AVMs

Important: Prior to use, refer to the “Instructions for Use” for full product information.

**STEP 1:**
- Gather accessories. Verify compatibility.
- Inject TRUFILL Ethiodized Oil into sterile glass beaker.
- Add TRUFILL Tantalum Powder.
- Mix by aspirating in and out of a syringe until mixture appears homogenous.

**STEP 2:**
- Attach self-piercing cap to a luer lock syringe.
- Attach the other end of the cap to the TRUFILL n-BCA vial.
- Extract TRUFILL n-BCA into syringe.

**STEP 3:**
- Inspect the TRUFILL n-BCA to verify that it is clear and free flowing.
- Add desired amount of TRUFILL n-BCA to sterile glass beaker with radiopaque mixture.
- Mix thoroughly.
- Compare radiopacity to contrast-filled syringe.

Important: Prior to use, refer to the “Instructions for Use” for recommended Mixture Ratios.

**STEP 4:**
- Rinse the outside of the catheter hub with D5W.
- Flush catheter with D5W.
- Aspirate mixture into appropriate syringe through a 21 or 23 gauge needle to verify no material is agglomerated.
- Inject mixture through catheter.
- After injection is completed, immediately aspirate with the injection syringe and rapidly withdraw the catheter.
TRUFILL n-BCA Liquid Embolic System

Proven and effective AVM treatment

- Convenient Preparation and Delivery
- Customized Radiopacity for Visualization
- Effective Penetration of AVM
- Results That Matter

Proven and effective AVM treatment

ORDERING INFORMATION:

<table>
<thead>
<tr>
<th>Product Code</th>
<th>TRUFILL n-BCA</th>
<th>TRUFILL Tantalum Powder</th>
<th>TRUFILL Ethiodized Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>631-400</td>
<td>two 1 g vials</td>
<td>one 1 g vial</td>
<td>one 10 cc vial</td>
</tr>
<tr>
<td>631-500</td>
<td>one 1 g vial</td>
<td>one 1 g vial</td>
<td>one 10 cc vial</td>
</tr>
</tbody>
</table>

COMPLEMENTARY SYSTEMS:

<table>
<thead>
<tr>
<th>Complementary System</th>
<th>Outer Diameter (prox/distal)</th>
<th>Inner Diameter (in.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROWLER® 10 Microcatheter</td>
<td>2.3F / 1.7F</td>
<td>0.015</td>
</tr>
<tr>
<td>PROWLER® 14 Microcatheter</td>
<td>2.3F / 1.9F</td>
<td>0.0165</td>
</tr>
<tr>
<td>PROWLER® Plus Microcatheter</td>
<td>2.8F / 2.3F</td>
<td>0.021</td>
</tr>
<tr>
<td>PROWLER® SELECT® LP ES Microcatheter</td>
<td>2.3F / 1.9F</td>
<td>0.0165</td>
</tr>
<tr>
<td>PROWLER® SELECT® Plus Microcatheter</td>
<td>2.8F / 2.3F</td>
<td>0.021</td>
</tr>
<tr>
<td>RAPIDTRANSIT® Microcatheter</td>
<td>2.8F / 2.3F</td>
<td>0.021</td>
</tr>
<tr>
<td>TRANSIT® Microcatheter</td>
<td>2.8F / 2.5F</td>
<td>0.021</td>
</tr>
</tbody>
</table>

AGILITY® Guidewires Available in 0.010, 0.014 and 0.016 inch diameters

ENVOY® and ENVOY® XB Guiding Catheters Available in 5F and 6F sizes in 90 cm and 100 cm lengths

TRUFILL n-BCA Liquid Embolic System Essential Prescribing Information (EPI)

Cautions: Federal (US) law restricts this product to sale by or on the order of a physician.

INDICATIONS: The TRUFILL n-BCA Liquid Embolic System is indicated for the embolization of cerebral arteriovenous malformations (AVMs) when pre-surgical devascularization is desired. CONTRAINDICATIONS: Separate use of the individual components of the TRUFILL n-BCA Liquid Embolic System is contraindicated. These components must be used as a system. TRUFILL Ethiodized Oil alone should not be injected intravascularly, intraarterially or intravenously. The use of the TRUFILL n-BCA Liquid Embolic System is contraindicated when any of the following conditions exist: Optimal catheter placement is not possible; A previous history of reactions to cyanoacrylates exists; A previous history of hypersensitivity to ethiodized oil exists; A previous history of reactions to iodine exists; Promotive testing indicates intolerance to the occlusion procedure; and/or Vasospasm stops blood flow. WARNINGS: The safety and effectiveness of the TRUFILL n-BCA Liquid Embolic System as a long-term implant has not been established. Performing therapeutic embolizations to occlude blood vessels is a high risk procedure. The procedure should be carried out under the direction of personnel with interventional training and thorough knowledge of angiographic techniques. Therapeutic embolization should not be performed when high blood flow precludes safe infusion of embolic agent. Fluoroscopic determination of the radiopacity of the TRUFILL n-BCA Liquid Embolic System by comparison with a similar syringe containing contrast prior to injection is essential. Inadequate visualization of the n-BCA mixture may cause inappropriate embolization. TRUFILL n-BCA is a fast-setting adhesive capable of adhering to most body tissues. It will polymerize in the presence of anionic media, such as any body fluids or tissues. Proper handling is required to avoid premature polymerization and occlusion of the delivery system or adherence of the catheter tip to the vessel wall. TRUFILL Ethiodized Oil should NEVER be used as a radio opaque contrast agent to assess hemodynamics and should be used ONLY to prepare the TRUFILL n-BCA Liquid Embolic System. AVM embolization may influence blood flow patterns, thereby subjecting arteries supplying the AVM or the brain proximal to the AVM to increased pressures. Increased arterial pressures could result in hemorrhagic complications. Laboratory studies have determined that TRUFILL Ethiodized Oil may elute from the device over time. Life threatening and fatal reactions may occur without warning. At all times a staff familiar with the “Recommended Procedure” section of the “Instructions for Use” should be readily available, and personnel competent in recognizing and treating reactions of all severity should be on hand.

PRECAUTIONS: Store in a cool, dark, dry place. Do not use if package is open or damaged. Use prior to “Use By” date. Angiography is necessary for pre-embolization evaluation, operative control and post-embolization follow-up. Verify that the TRUFILL n-BCA is a clear and free-flowing liquid prior to use. Material that is thickened or discolored should be discarded. It is recommended to use a 21 or 23 gauge needle to aspirate the TRUFILL n-BCA into an appropriate injection syringe. TRUFILL n-BCA will adhere to most surfaces. Avoid contact with non-disposable surfaces or surfaces that cannot be cleaned with acetone. Gloves and eye/face protection are recommended when handling TRUFILL n-BCA. Verify that the catheters and accessories used in direct contact with the TRUFILL n-BCA are clean and compatible with the material and do not trigger polymerization or degrade with contact. Refer to “Accessories” under the “Recommended Procedure” section of the “Instructions for Use”. Do not use with any device containing polycarbonate. Cyanoacrylates cause polymers containing polycarbonate to deteriorate. ADVERSE EVENTS: seizure; catheter glued inside vessel; late polymerization; occluded catheter; parenchymal hemorrhage; vasospasm; pulmonary embolism; allergic reaction; AVM rupture; early polymerization; inability to subselect vessel; CVA (stroke); death; hematomas; headache; hemorrhage; incorrect vessel(s) acculded; infection/inflammation; over-the-wire system could not be advanced; thromboembolism; vessel dissection; vessel perforation; neurological deficits; and/or passage of embolic material into normal vessels adjacent to the lesion.

Other Important Information: Prior to use, please read full “Instructions for Use” supplied with these devices for more detailed product and use information.

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For technical/product questions, call 1-800-225-0460.
For product availability, please contact your Codman Neurovascular representative.